REVIEW

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Telemedicine and Orthopedic Surgery: A Narrative Review

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SUMMARY

Purpose of review. The purpose of this paper is to review the current concepts regarding a new form of medicine which, especially in recent years, is enjoying more and more success. Especially how telemedicine can be beneficial in many areas of orthopedic clinical practice.
Recent findings. In the past, telemedicine for orthopedics was the prerogative of rural areas, where the distance from the hospital could be as much as 150 miles, to assure patients equal access to the care. In the last few years telemedicine has undergone an important boost so much that it has now routinely entered the approach to the patient. Multiple appropriate telemedicine applications are suggested for orthopedic practice, such as teleconsultation for diagnosis, treatment, and patient follow-up with a pivotal role in virtual rehabilitation.
Discussion. The fields of application of telemedicine in orthopedics range from teleconsultation to fracture management, to postoperative follow-up and above all to telerehabilitation.
Telerehabilitation is one of the fields of greatest interest in tele-orthopedics due to the possibility of providing remote rehabilitation services using digital technology, regardless their location and reducing the geographical and access barriers to the care.
Technology is evolving more and more and tele-orthopedics is also benefiting from it, thanks above all to the advent of AI which improve the accuracy of or reduce the time associated with critical diagnostic steps.
Conclusions. This trend will be confirmed, and the adoption of telemedicine practices will continue to expand because due to the necessary digital evolution that is characterizing the medical practice.

KEY WORDS

Telemedicine; orthopedics; telehealth; tele-rehabilitation; video-consultation.

INTRODUCTION

Telemedicine is a branch of telehealth defined as a digital intervention that could bring patients and practitioners closer together, allowing information exchange despite being geographically separated, using smartphones, computers or other electronic devices. WHO (World Health Organization) defined telemedicine as "healing from a distance", providing patients with healthcare consultation, monitor-

ing, and treatment services at a distance. Orthopedics, being provided both in the hospital and in the community setting, is a specialty that can benefit greatly from telemedicine. It is considered an opportunity with potential to be explored given its cost-effectiveness, for positive patient-reported outcomes (1) and for the reduction of geographical and accessibility barriers. In the past, telemedicine for orthopedics was the prerogative of rural areas, where the distance from the hospital could be as much as 150 miles (2), to assure patients equal access to the care. In 2019 the whole world is hit by the Coronavirus pandemic, closing all non-life-saving businesses (the so-called lockdown). To prevent the circulation of the virus, a travel ban is imposed, and it is precisely at this moment that telemedicine comes to the aid of practitioners. Because of COVID-19 pandemic, to address the new needs and challenges, telemedicine has undergone an important boost so much that it has now routinely entered the approach to the patient. Multiple appropriate telemedicine applications are suggested for orthopedic practice, such as teleconsultation for diagnosis, treatment, and patient follow-up with a pivotal role in virtual rehabilitation (3).

MATERIALS AND METHODS

Search strategy

The literature search of the present narrative review was conducted according to this protocol:
1) Telemedicine.
2) Linkage about telemedicine and orthopedics.
3) Telehealth, tele-rehabilitation, video-consultations.

Literature search

In March 2023 the following databases were accessed: PubMed, Embase, Scopus, Web of Science, Google Scholar. The following keywords were used in combination: telemedicine, orthopedics, telehealth, mhealth, videoconsultations, follow-up, post-operative, cost-effectiveness. If title and abstract matched the topic, the full text was accessed. The bibliographies of the full-text articles were also screened for inclusion. Disagreements were solved by a third author (FO). All the articles that investigate possible association between gut microbiota and musculoskeletal pathologies were considered. According to the authors language capabilities, articles in English, French, German, Italian, and Spanish were considered.

DISCUSSION

Based on the published literature, a review has been carried out on telemedicine and its fields of application in orthopedics. Starting from the history of telemedicine, its role in video consultation, tele-rehabilitation and post-operative management was addressed. With a view to the economic impact, a review of the actual costs was carried out.

History of telemedicine

The first historical trace of the use of telemedicine dates back to 1959, University of Nebraska established a two-way television setup to transmit information to medical students across campus, and five years later linked it with a state hospital to perform video consultations (4). In the early 1960's, due to advent of radio system, telemedicine appeared in urban communities, especially in emergency situations (5, 6). An example is given by the University of Miami School of Medicine partnered with the local fire department that in 1967 transmitted electrocardiographic rhythms over radio to Jackson Memorial Hospital in rescue situations (7). Telehealth became popular in rural areas, where populations with limited access to health care had the ability to reach specialists without leaving home. In the 1960's and 70's, the Public Health Department, NASA, the Department of Defense and the U.S. Health and Human Services Department all invested time and money for research in telemedicine. One of the most successful of these government projects was the partnership between the Indian Health Services and NASA. The project was called Space Technology Applied to Rural Papago Advanced Health Care (STARPAHC) and provided both Native Americans on the Papago Reservation in Arizona and astronauts in orbit with access to medical care. Microwave technology transmitted X-ray photographs, electrocardiographs, and other medical information to and from the Public Health Service hospital. Innovative projects like STARPAHC spurred research in the field of medical engineering, leading to quick growth for telemedicine. Over the following decades, the number of projects, researches and investments carried on by universities and companies increased, following the lead of STARPAHC (8).

Telemedicine and orthopedics

Telehealth is a way to provide healthcare services from another location. The most common methods include a live interactive visit with the patient, collecting and analyzing data and imaging, and monitoring patient progress, measuring patient-reported outcomes (3, 9) and the ones provided through data measured by the implemented digital technology (**table I**).

Potential uses of this digital system in healthcare are huge, but what attracts the most is the possibility of using this application in daily clinical practice. Two necessary premises are that telemedicine is feasible as non-inferior with regard to regular healthcare practices and not all patients are eligible for remote treatments.

Table I. Main types of telemedicine.

Three main types of telemedicine	
Interactive medicine	Patients and doctors communicate with each other in real-time
Store and forward	Providers are permitted to share patient health information with physicians elsewhere
Remote patient monitoring	Mobile medical devices are used to collect data which is then used by remote caregivers to monitor patients and health outcomes

The fields of application of telemedicine in orthopedics range from teleconsultation to fracture management, to postoperative follow-up and above all to tele-rehabilitation (3, 10). These medical practices, when provided in the hospital setting, burden the NHS both on the financial side and on the involved resources one (*i.e.*, medical staff), highlighting a huge potential and relevant benefits when the same practices are provided through telemedicine (11).
Published data regarding specifically tele-orthopedics date back to the late 1990's, with the pioneering works of Lamminen *et al.* (2), reporting the experience of independent services. Authors reported their experience with a service of videoconferencing for consultation and communication with good clinical results and patient high satisfaction.
On the same wavelength, there are work of McGill and Caffery. McGill *et al.* (12) remotely followed non-surgical fractures successfully from a technical point of view, in a rural area. Caffery *et al.* (13) explored Australian-based tele-orthopedic services and also reported technology use mainly for fractures and peri-operative consultations. Both studies highlight the importance of telemedicine service in rural and remote areas, due to mobility difficulties and convenience of avoiding long-distance transportation.
In 1997 Lambrecht *et al.* (14) reported an analysis of 410 orthopedic teleconsultations done during a 2-year period by three orthopedic surgeons, they observed no adverse outcomes (**table II**).
Final suggestion of different authors was that telemedicine can be an option where orthopedic physicians are not available for in person treatment.

Table II. Distribution of teleconsultations.

Teleconsultation	% patients
Fractures	43 = 176 p
Ligaments injury, joint swelling, infections	35 = 144 p
Post operative evaluation	18 = 74 p
Evaluation and treatment of dislocations	4 = 16 p

In 1999, Aarnio *et al.* (15) published a prospective study analyzing teleconsultation in orthopedics. In this work, teleconsultations took place by videoconference between two 150 miles distant cities in Finland. This was one of the first studies that reported data about patient satisfaction, where 87% percent of patients considered the remote visit a good or very good method and the rest found it satisfactory.
In 2019, the whole world has been hit by the COVID-19 pandemic which led to a limitation in the movement of people to avoid the widespread of the virus; it is in this period that telemedicine revived great enthusiasm due to the possibility of treating patients directly at home.
Telemedicine for orthopedics has been reported in several scenarios as video-consultations, post-operative follow-up, management of fracture, tele-rehabilitation and also in pediatric cases.

Video consultations

The Orthopedic Video-consultation (OVC) is a special form of digital interaction, where the clinician and the patient carry out the medical examination through dedicated devices. Patients in rural regions may benefit more from video consultations in terms of cost and time. However, even patients in densely populated urban regions with a full-time job could still benefit from a quickly available consultation (16). The possibility of having a better involvement of patients in their treatment thanks to a digital affinity and the corresponding motivation, as well as the possibility of attracting new patients through digital offers, makes the OVC an increasingly used solution by physicians (17). On the other hand, clinicians suspect a lengthening of the telemedicine visit time compared to regular visits and some of them express concerns about the security of the data exchange (18).
In orthopedic trauma, video consultations can be utilized for initial assessment of minor injuries, post-surgical rehabilitation and follow-up, as well as pre-surgical assessment (19). Scientific evidence has shown that especially in orthopedic trauma, there is no difference in terms of satisfaction between in-person and online consultation between patients and doctors and that the efficacy is comparable (20).
One of the questions that spontaneously arises regarding the telemedicine visit is how to carry out a clinical examination of the patient.

Russell's work (21) highlighted how the use of the goniometer web-based practice was statistically comparable to the use of the goniometer in person and Tanaka *et al.* (22) designed protocols and methods to standardize the virtual orthopedic examination for common musculoskeletal conditions.
Obviously, this type of physical exam cannot be compared to the in-person exam, but it can help the practitioner to better address the specific patient condition. and the subsequent healthcare need.

Tele-rehabilitation

Tele-rehabilitation is a way to provide remote rehabilitation services using digital technology, through which is possible to collect and share data between the different medical and non-medical staff involved in the care path, regardless their location and reducing the geographical and access barriers to the care (23, 24).
Tele-rehabilitation and virtual physical therapy are innovative and cost-effective ways to provide the best rehabilitation services to patients without having to move from where they live (25, 26).
Tele-rehabilitation may include assessment, education, monitoring and exercise interventions.
Tele-rehabilitation interventions have been successfully used in the management of chronic diseases. Reduced travel barriers, flexible operating hours and the ability to better integrate skills into daily life are just some of the positive points that emerged from patients' opinion (27).
Tele-rehabilitation interventions decrease travelling costs, are significantly less time consuming and are generally more convenient (28, 29); moreover, tele-rehabilitation allows patients to perform their exercises more frequently without extra face-to-face visits (23, 29).
Moffet *et al.* (30) reported that patients undergoing tele-rehabilitation could benefit from a lightening of the burden of care and greater efficiency leading to a higher perception of quality of life.
Kairy *et al.* (31) stated that tele-rehabilitation in patients with physical disabilities could lead to similar clinical outcomes compared with usual care, with possible positive effects on areas of healthcare utilization (32).

Post-operative follow-up

Telemedicine has been reported useful not only in preoperative and postoperative surgical consultations, but also for intraoperative mentoring with successful outcomes for patients (33, 34).
The use of mHealth in orthopedic surgery has been shown to be very important in increasing patient involvement in the therapeutic process through better control and management of postoperative pain (35).
Survey systems to collect patient-reported pain levels, opioid consumption, and adverse effects in the acute postoperative period after total knee arthroplasty (TKA), total hip arthroplasty (THA), and surgery of the lumbar spine, according to many studies, are considered important in the post-operative management of the patient (36-39).
Acute and chronic pain is influenced by psychological factors that could result in interference with patients' activities of daily living and decreased quality of life. Communication via smartphone or other device, therefore not in person, has proven useful and effective in reducing the use of opioids and in the treatment of various psychological conditions and cognitive problems (38, 40).
In addition, with regards to post-operative pain management, telemedicine has also proved to be of great importance in all those patients who had been prescribed anticoagulant therapy (ASA) for the prophylaxis of venous thrombosis. Through the use of a real telephone alarm clinicians have found an improvement in therapeutic adherence (41).

Cost-effectiveness of telemedicine in orthopedic

Telemedicine consultations using real-time videoconferencing has the potential of reducing health care costs, indeed in the recent years various studies have faced the cost effectiveness of telemedicine (42-45).
Buvik *et al.* (42) reported a reduction of costs using videoconferencing for orthopedic consultations in the remote clinic compared to standard outpatient consultations at the specialist hospital, if the total number of patient consultations exceeds 151 per year. If costs were calculated from a health sector perspective, rather than a societal perspective, the number of consultations needed to break even was 183.
Tousignant *et al.* (46) documented costs for in-home tele-treatment *versus* conventional home-visit rehabilitation following TKA based on an RCT, demonstrating the cost savings of tele-treatment compared to home visits for patients post-TKA.
Patients revealed particularly high satisfaction with telemedicine for reasons of convenience, reduced appointment delays, travelling times, travel costs and time off work, findings which support existing literature on high patient satisfaction with telemedicine (47).
EBM (Evidence Based Medicine) suggests that once patients were exposed to telehealth, a majority preferred further follow-up using digital technology (48). High patient satisfaction is associated with an increased patient compliance and consequently with a reduction in missed appointments. Missed appointments cost the UK NHS £1 billion a year (49); patient compliance consequently translates into cost savings for the healthcare system.

AI in orthopedics

Computer-navigation, robot-assistance and three-dimensional digital planning have become commonplace in many parts of the world. With advances in computer processing power and the development of new softwares, orthopedic medicine and surgery have begun to delve into artificial intelligence (AI) systems (50).

There are conceivably diagnostic, decision-making and technique execution, and administrative considerations, automating the interpretation of radiologic imaging.

AI applications have already been employed to either improve the accuracy of or reduce the time associated with critical diagnostic steps. This may involve recognition and classification of pathology, or the correct determination of in situ implant types/models (51).

Large volumes of patient data, ever-increasing patient expectations of positive post-surgical outcomes, and a profession-driven push to improve the quality and precision of care we offer have opened many avenues for AI use. Orthopedic applications include image recognition (diagnostics/implant identification) (52), risk prediction, cost-outcome determinations, clinical decision making seem popular early targets of AI technologies. Applications in primary TKA (53), primary total hip arthroplasty (THA) and resurfacing (54), and primary total shoulder arthroplasty (TSA) (55, 56) have all been reported with positive value.

Zhao *et al.* (57) demonstrated that with AI, classification of osteoarthritis from plain radiographs was as accurate as that of trained arthroplasty surgeons, but faster.

As medicine and surgery push onward towards a seemingly inevitable uptake of technology-assisted data management (including potentially AI applications), a unique opportunity for a more universal commitment to "standardization" of prospective patient data capture and storage arises.

CONCLUSIONS

The application of telemedicine in orthopedics has expanded the fields of application with positive outcomes in terms of effectiveness, efficiency, and patients' satisfaction. It can be used in different scenarios such as postoperative follow-up of selected cases, video-consultations, and even orthopedic trauma. Remote care had dramatically increase in 2020 due to COVID-19 pandemic. This trend will be confirmed, and the adoption of telemedicine practices will continue to expand because due to the necessary digital evolution that is characterizing the medical practice. Over the last few years, different tools and technologies to provide rehabilitative care at a distance have been developed, studied, and validated. However, the implemented technologies and the validated practices could not be used for all the pathologies and further investments in research are necessary to implement effective telemedicine protocols for as many pathologies/healthcare needs as possible.

Data security and privacy are two important aspects for the successful use of mHealth systems, both for patients and professionals. Special attention must be paid to sharing sensitive patients' data, that must always be done in compliance with European regulations or current privacy regulations.

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DATA AVAILABILITY

N/A.

CONTRIBUTIONS

FO, AB: writing – original draft, writing – review & editing, study selection, data collection and extraction, risk of study bias assessment. FO: methods. GS: writing – original draft, study selection, data collection. MC: writing – original draft, writing – review & editing. GO: writing – original draft, writing – review & editing. NM: writing – original draft, writing – review & editing, final approval. All authors: final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Changes in Proprioceptive Control in the Menstrual Cycle: a Risk Factor for Injuries? A Proof-of-Concept Study

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SUMMARY

Introduction. Over the past three decades, there has been an increase in female sport participation attributable to the growing development and investment in professional women's sports. For an effective preventive strategy, it is necessary to analyze all risk factors that expose women to a higher probability of incurring injuries. The aim of our study is to evaluate the hormonal influence on proprioception and neuromuscular control, to identify whether a particular phase of the menstrual cycle may be related to a higher probability of injuries.

Materials and methods. A group of female participants was objectively evaluated through baropodometric platform test, postural assessment (Tecnobody, Bergamo, Italy), and functional tests at different phases of the menstrual cycle.

Results. Eleven participants (age = 29 ± 3.41) were enrolled in the study. The results showed slight fluctuation ($p > 0.05$) of postural and proprioceptive control related to hormonal variations of the ovarian cycle.

Discussion and conclusions. Despite no significant differences, it is conceivable that, during an athletic gesture with a high functional demand, the different performances shown in relation to the different hormonal concentrations could influence the risk of sustaining an injury. These assumptions assume significance in the context of the development of neuromuscular strategies to prevent lower limb injuries during sports activities.

KEY WORDS

Rehabilitation; menstrual cycle; proprioception; injuries; hormonal variations.

INTRODUCTION

Over the past three decades, there has been an increase in female participation in sport attributed to the growing development and investment in professional and recreational women's sport (1). In general, female sport participation has skyrocketed in the past 25 year, with approximately 53% of female students reported participating on one or more sports teams in school and/or non-school setting. Moreover, the number of female athletes participating in the Olympic Games has increased significantly from 34%

in Atlanta 1996 to 48% at the last Olympic Games in Tokyo 2020, with a high probability of achieving full gender parity for the Paris 2024 Olympic Games (2).

There is great interest in preventing ACL injuries to protect the athletes' health, reduce out of competition time, and save on health care costs. At this regard, it is estimated that the short-term cost associated with an ACL incident is $11,500 per injury, with approximately $2 billion per year being spent in the United States (3).

For an effective preventive strategy, it is necessary to analyze all risk factors that expose women to a higher probability of incurring this type of injury.

Several studies have shown that women are at particularly high risk for ACL injuries, with 3 to 6 times greater rates than men. This higher odd may be related to intrinsic factors related to knee joint (intercondylar notch, "loose jointendness", anatominc alignment, Q-angle, or hormones), and extrinsic factors (playing surface, muscle imbalance, hamstrings-to-quadriceps strength ratio, neuromuscular control) (4, 5). Recently, the effects of hormones on ligamentous tissues have gained more attention in ACL injuries. Wojtys *et al.* highlighted a higher probability of ligamentous lesions during ovulation within the menstrual cycle, due to increased laxity of these structures under the influence of estradiol (6). However, results in the literature are discordant, according to Slauterbeck *et al.* (7) the risk of ACL injury would increase at the beginning of the follicular phase (7), on the other hand, the results of Fridén *et al.* indicates a higher risk at the end of the luteal phase (8).

Moreover, the influence of endocrine system on postural control has gained attention. Estrogen and progesterone have direct and indirect influence on $GABA_A$ and several neurotransmitter receptors; in addition, direct link of the menstrual cycle on visual-vestibular function has been shown with menopausal women presenting a lower postural stability and, consequently, higher risk of fall, that improves with hormone replacement therapy (9). Another study, on female athletes taking oral contraceptives showed a higher stability than the group without the oral therapy (10). The physiology under the correlation between postural control has not been fully explored. However, it could be related to a change in proprioception, associated with a negative effect on sensory feedback from peripheric afferences (11). The cyclic hormone oscillation has a plausible influence the dynamic neuromuscular control of the knee joint suggesting a hormonal effect in altering the balance and/or proprioception of young women within a menstrual cycle (10).

In this context, the advancement in rehabilitative technologies has provided new tools for the functional evaluation of athletes. In particular, baropodometric and balance platforms include an assessment procedure of the patients' proprioception, monitoring through a force platform, the displacement of the patient's center of pressure (COP), with a high grade of accuracy (12).

Thus, the aim of our study is to evaluate the hormonal influence on proprioception and neuromuscular control in an objective and detailed way, trying to identify whether a particular phase of the menstrual cycle may be related to a higher probability of injuries.

MATERIALS AND METHODS

This study was conducted at the Department of Physical Medicine and Rehabilitation of the University of Padua. The study was conducted in accordance with the Declaration of Helsinki and all participants signed a written consent to participate in the study.

A group of female voluntary participants, resident in Physical and Rehabilitation Medicine at the University Hospital of Padua were enrolled. Inclusion criteria were: 1) age between 18 and 45 years old (fertile age), and 2) regular menses. Exclusion criteria were: 1) previous pregnancies, 2) vestibular problems, 3) previous lower limb injuries in the last 2 years, 4) central and/or peripheral neurological problems, 5) taking contraceptives, 6) endocrine pathologies, 7) muscle skeletal pathologies that could affect testing (*e.g.*, scoliosis > 20°), 8) muscle injuries in the last 6 months. The sample size was determined based on previous analogous studies (11).

During the entire trial period, the female participants performed their usual daily activities.

Each subject was assessed during the 3 phases of the menstrual cycle: follicular phase, ovulation, and luteal phase. The days on which the tests were carried out were chosen on the basis of the model adopted by Ellen Casey (13).

In women with a total cycle length of 27 to 29 days, measurements were taken in the different phases according to the following time intervals:

- Follicular phase: days 1-3.
- Ovulatory phase: days 12-14.
- Luteal phase: days 21-25.

In those with a total cycle length between 24 and 26 days as follows:

- Follicular phase: day 1-3.
- Ovulatory phase: days 10-12.
- Luteal phase: days 19-23.

In those with a total cycle length between 30 and 35 days as follows:

- Follicular phase: day 1-3.
- Ovulatory phase: days 14-16.
- Luteal phase: day 23-27.

Day 1 coincided with the onset of menstruation. The tests were performed in each phase of the menstrual cycle.

Procedure

The participants were evaluated in each phase of the menstrual cycle through a series of objective and detailed instrumental and functional tests. The participants were asked to keep a menstrual diary. Test day included a first phase of familiarization with the instruments utilized, in which the physiotherapist explained the procedure, and a light warm-up.

Bipodal balance with open eyes

This test was performed with the subject placed on a MF - STABILITY system (Tecnobody, Bergamo, Italy). The system evaluates postural control, the oscillation of the Pressure Center (COP) in anterior-posterior and right-left direction, as well as the area and perimeter of the latter. The patients were in orthostatic position, with tibial extrarotation of 30°, a distance of 2 cm between the tibial malleoli, the intermalleolar line placed on the fulcrum of the platform and the arms along the sides.

The subject was then asked to stand upright for 30" while looking at a visual stimulus on a screen.

The sway area was then measured, *i.e.*, 95% of the area of the COP excursions, the perimeter of the COP excursions, the antero-posterior and mid-lateral standard deviations from the COP, the mean COP and the trunk standard deviation, which is the vector sum of the antero-posterior and mid-lateral standard deviations of the trunk inclinations.

Bipodal balance with eyes closed

The procedure was the same as the previous test but was performed with eyes closed.

Dynamic bipodal balance with eyes open

This test was performed on the ProKin 252 (Tecnobody, Bergamo, Italy) for a proprioceptive-stabilometric assessment of the dynamic balance (14); an electro-pneumatic baropodometric platform able to provide a an starting assessment analysis, and a series of exercises biofeedback guided. Patient is positioned with the tibiae in neutral position, tibial malleolar distance of 2 cm and intermalleolar line placed 3 cm posterior to the fulcrum of the platform. The subject was asked to maintain balance and equilibrium with the aid of visual feedback. A tracing of the movements of the footplate expressed in degrees of inclination was then obtained, which made it possible to identify any imbalances of the subject, the motor strategies of response and counter-balance, and the dynamic balance midpoint.

Star excursion balance test

The Star Excursion Balance Test is a dynamic test requiring strength, mobility and proprioception, to assess dynamic postural-control deficits in lower extremity injury, used to identify individuals at increased risk of lower-limb injuries (15, 16).

The original test involves 8 directions of movement, but Plisky *et al.* (17) showed that even just 3 particular directions (anterior, posteromedial and posterolateral) can identify the risk of lower limb injury.

The test therefore involves holding the weight-bearing on one of the lower limbs and reaching with the contralateral limb to the furthest point along a line drawn on the floor (anterior, posteromedial and posterolateral) and then returning to the starting position.

Before collecting the data, six simulation tests were performed, as indicated by the results of the study by Hertel *et al.* (18) in order to standardize the results.

The distance achieved in each of the 3 directions was also normalized according to the following formula:

Distance standardized by limb length = (distance achived / lower limb length) × 100.

The Total Performance Value for the entire test was obtained according to the following formula:

Total Performance Value = (sum of distances achieved in the 3 directions / lower limb length × 3) × 100.

A Total Performance Value of less than 94% of the lower limb length correlates with a 6 times higher probability of a lower limb injury (17).

The lower limb length was measured as the distance between the antero-upper iliac spine and the tibial malleolus.

Single hop leg test

This test identifies global knee dynamic stability and is useful tools for a bilateral comparison of knee strength and function (19). Each participant was asked to perform a monopodalic jump trying to reach the maximum distance forward, keeping their hands on their hips. After falling back to the ground, the subject had to maintain single-podal balance for no less than three seconds.

The test was performed by alternating both limbs so that the limb symmetry index (LSI) could be calculated:

LSI = (worst performing limb / best performing limb) × 100.

An LSI value < 85% correlates with an increased risk of injury (20).

Postural analysis

Postural analysis was performed through an automatic Postural Bench (Tecnobody, Bergamo, Italy) to perform an accurate postural analysis without load on the limbs;

a two inclinable tops system with several electronic inclinometers that detects the inclinations of the multiple planes to analyze difference in the symmetry of 3 body segments, namely, scapular, lumbar and hip plane. The tool allows to evaluate the state of the muscular structure, kinetic chain, and posture.

Statistical analysis

The data were analyzed with SAS 9.4 (SAS Institute, Inc., Cary, NC, USA) for Windows. Descriptive statistics were expressed as means and standard deviations for each of the three phases considered (follicular, ovulatory, luteal). Shapiro-Wilk test was utilized to determine if the continuous variables were normally distributed. We performed generalized repeated measures model (ANOVA) to assess the variation between the three phases. We reported P-value for the variation and as an estimate of the difference between the phase averages, and the corresponding 95% confidence interval. The correlation between the results obtained for each phase was assessed with Spearman's correlation coefficient. Statistical significance was considered for $p \leq 0.05$.

RESULTS

Out of fifteen volunteers, 11 female participants with a mean age of 29 ± 3.41 years and a mean BMI of 21.24 ± 1.84 kg/m² were included. All results are shown in **table I**.

In the functional tests a worse performance was observed during menstruating period. In the Star Excursion Balance Test, a worse performance was recorded in the follicular phase, while in the Single Hop Leg Test a greater asymmetry (LSI) was recorded in the follicular and luteal phases (**figure 1**).

In addition, in the ProKin balance test, a greater fluctuation of COP was observed in the luteal phase, while in closed and open eyes stability tests (**figure 2**), a greater fluctuation of COP was recorded in the ovulatory and luteal phases, respectively (**figure 3**).

Moreover, even if there are not significant differences, the postural analysis showed a higher pelvis load during ovulatory phase, with a more asymmetric load distribution between scapular, lumbar e pelvis segment, compared with follicular and luteal phase (**table II** and **figure 4**).

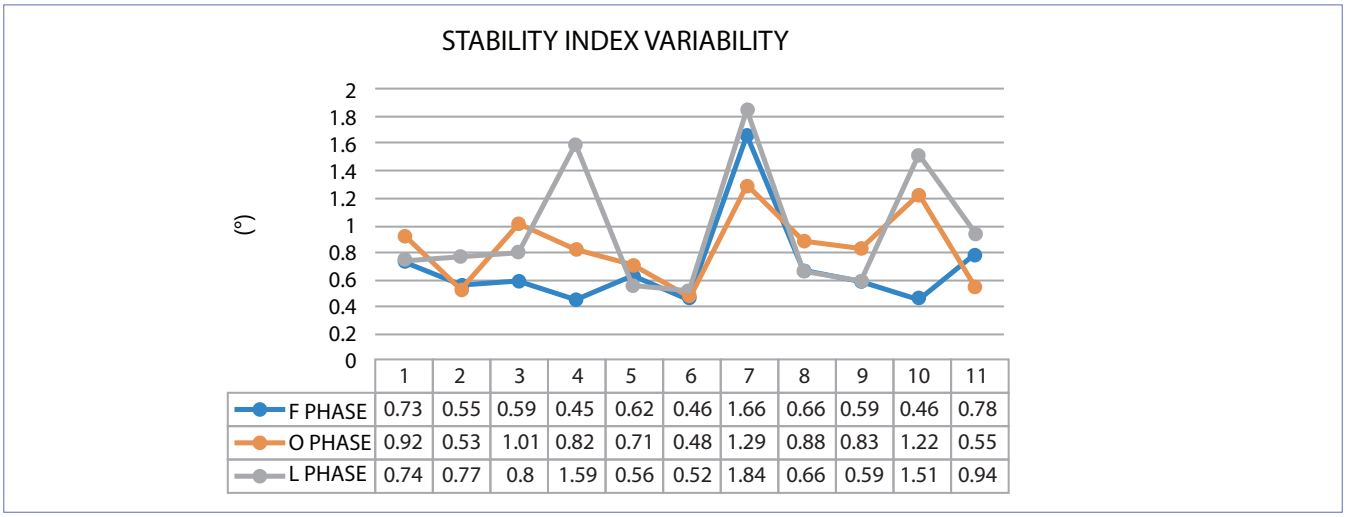
DISCUSSION

The assessment of balance and neuromuscular control represent an indirect measure of the risk of injury. In literature, the link between hormonal fluctuations and changes in neuromuscular control has been extensively evaluated. In particular, several theories have been proposed to define the

Table I. Differences in proprioceptive tests during follicular, ovulatory and luteal phase comparing the same study population (n = 11).

	F phase	O phase	L phase	P-value	Difference F-O phase (95%CI)	Difference F-L phase (95%CI)	Difference F-L phase (95%CI)
Star excursion balance test dominant leg	0.83 (0.06)	0.84 (0.06)	0.84 (0.04)	0.741	-0.01 (-0.05-0.02)	-0.01 (-0.04-0.02)	0.00 (-0.03-0.03)
Star excursion balance test non-dominant leg	0.83 (0.07)	0.84 (0.07)	0.84 (0.06)	0.353	-0.01 (-0.05-0.03)	-0.02 (-0.05-0.01)	0.00 (-0.01-0.03)
Single hop leg test	0.92 (0.05)	0.93 (0.10)	0.92 (0.07)	0.978	-0.01 (-0.08-0.06)	0.00 (-0.08-0.08)	0.01 (-0.10-0.09)
Dynamic bipodal balance test	0.85 (0.59)	0.60 (0.31)	0.64 (0.24)	0.497	-0.24 (-0.17-0.66)	0.20 (-0.17-0.59)	0.04 (-0.11-0.18)
Closed-eye bipodal stability test (mm^2)	233.76 (166.47)	226.26 (172.17)	291.39 (274.53)	0.688	7.49 (-67.66-82.86)	-57.62 (-286.26- 171.00)	-65.12 (-125.71-255.96)
Open-eye bipodal stability test (mm^2)	85.62 (38.32)	146.05 (114.75)	111.20 (64.78)	0.687	-60.43 (-130.41-9.55)	-25.29 (-11.59- 26.02)	-34.84 (-39.45-109.13)

Means (SD) for continuous variables; balance test and single hop test are expressed as ratio; stability tests are expressed as mm2 of the area described by COP; Statistical analysis performed to assess the inter-group differences was ANOVA; CI: confidence Interval 95%.



	1	2	3	4	5	6	7	8	9	10	11
F PHASE	0.73	0.55	0.59	0.45	0.62	0.46	1.66	0.66	0.59	0.46	0.78
O PHASE	0.92	0.53	1.01	0.82	0.71	0.48	1.29	0.88	0.83	1.22	0.55
L PHASE	0.74	0.77	0.8	1.59	0.56	0.52	1.84	0.66	0.59	1.51	0.94

Figure 1. Stability Index Variability. SD of the trunk stability index at balance platform test (Prokin-Tecnobody, Bergamo, Italy).
F: follicular; O: ovulatory; L: luteal.

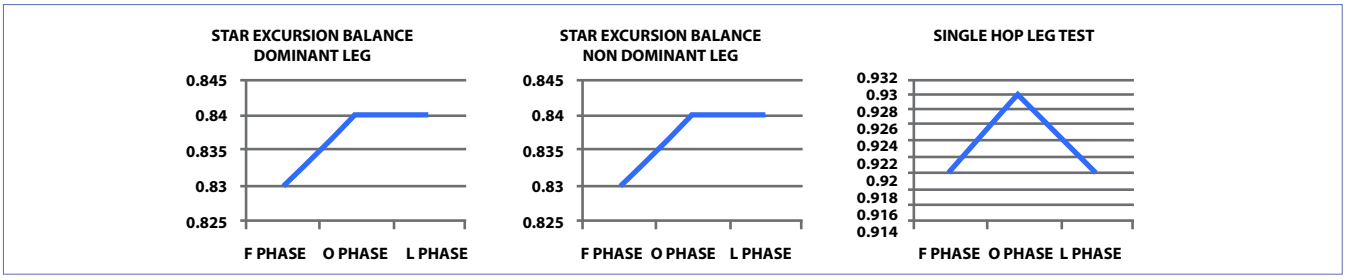


Figure 2. Star Excursion Balance Test (Total Performance Value) and Single Hop Leg Test (Limb Symmetry Index).
F: follicular; O: ovulatory; L: luteal.

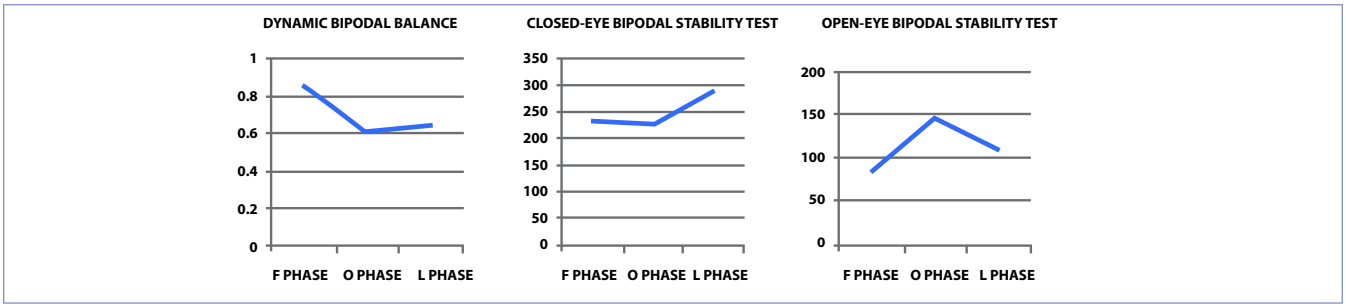


Figure 3. Centre of Pressure displacement (blue line) during dynamic bipodal balance with eyes open (ProKin baropodometric platform), closed and open-eye bipodal stability test.
F: follicular; O: ovulatory; L: luteal

Table II. Postural test. Percentage of segmental scapular, lumbar, and pelvis load during follicular, ovulatory, and luteal phase comparing the same study population (n = 11).

	F phase	O phase	L phase	P-value
Scapular	28.9 (3.88)	25.1 (6.97)	29.3 (5.32)	0.161
Lumbar	31.9 (6.22)	32.3 (12.2)	36.9 (10.54)	0.433
Pelvis	37.6 (4.45)	42.7 (15.23)	33 (9.84)	0.123

Means (SD) for continuous variables. Statistical analysis performed to assess the inter-group differences ANOVA; C.I. Confidence Interval 95%.

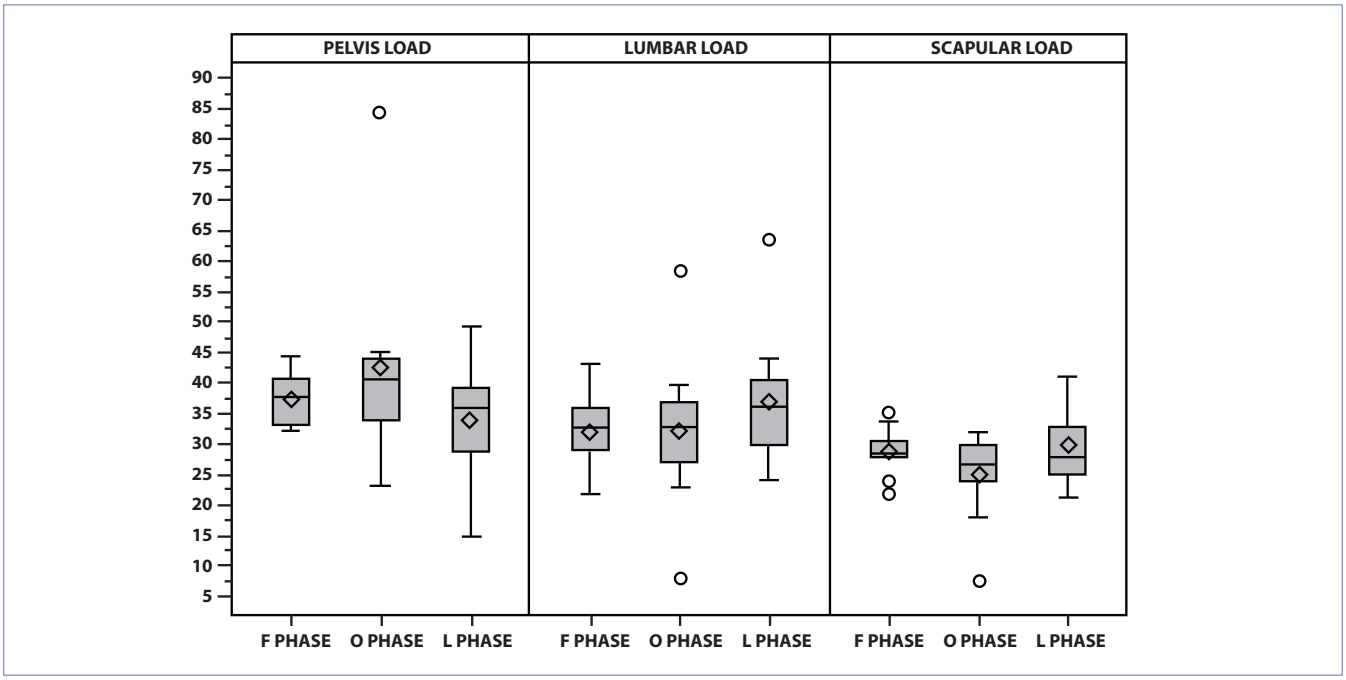


Figure 4. Box and Whisker Plot of the postural load distribution during follicular, ovulatory and luteal phase.

mechanisms that explain gender differences in injury rates. These theories include gender differences in both anatomical and motor patterns, hormonal differences and neuromuscular imbalances (4, 5).

In our study, we aimed to identify possible postural and balance alterations in a homogeneous sample of female participants, objectively evaluating the oscillation of the COP using baropodometric platforms; dynamic gestures, such as those required in daily life or during a sporting activity through functional tests, and finally, postural symmetry load of the participants using postural bench.

Taken together, these results reveal slight fluctuations in the trend of analyzed outcome, even if not statistically significant, that could be correlated with in estrogen blood concentration within the menstrual cycle.

Estrogen peaks during the ovulatory phase, with a gradual decline during the luteal phase, until reaching minimum levels during the follicular phase, which corresponds to the beginning of a new cycle. The role played by hormonal fluctuation during the menstrual cycle in increasing the probability of anterior cruciate ligament (ACL) rupture and lower limb injuries has long been debated (21). In particular, ACL injury has been hypothesized to be influenced by hormones with a direct effect on ligament laxity or stiffness throughout due to estrogen, progesterone, testosterone, and relaxin receptors on the ACL that modify collagen synthesis and tensile properties, or throughout neuromuscular modifications affecting knee alignment (21). However, the overall strength of evidence on this topic in literature is low, influenced by both the difficulties in measuring the exact hormone concentration of the participants during the experimental trials, and from the multiplicity of factors inherent in the injury mechanism. Moreover, the reason of no consensus could be attributable to the high heterogeneity of age, and sociodemographic data (21).

Wojtys *et al.* (6) were the first authors who addressed the correlation between hormone concentrations and the risk of ACL, suggesting that the risk of ligament injuries increases during the ovulation phase due to the increased laxity of these structures following the estrogen peak, which influences the collagen production of the fibroblasts and, consequently, the tensile strength of the ACL. On the other hand, the risk would be reduced in the follicular phase (6) or during the luteal phase (22).

These findings have been confirmed more recently by other authors, who reported increased plantar fascia elasticity, reduced balance, and increased tremor during the ovulatory phase with an increased potential risk of falling (23-25).

In contrast, other authors have shown that the risk of ACL injury increases and neuro-muscular control worsens at the beginning of the follicular phase (7, 26) or in the luteal phase in women with Premenstrual Symptoms (8, 27, 28). In fact, premenstrual syndrome may reduce concentration causing an alteration in the correct execution of a complex

motor movement. Darlington *et al.* (9) confirmed these results by showing worst test performance under unstable conditions during the follicular and luteal phase. Several studies have also evaluated the effect of oral contraception on the risk of injury in women. In particular, Wojits *et al.* and Nielsen *et al.* (22, 27) have demonstrated the protective role of oral contraception in the risk of injury, probably due to the reduction of hormonal fluctuation during a menstrual cycle.

On the other hand, Naessen *et al.* (29) confirmed the protective effect of oral contraception demonstrating that postural balance function is better preserved in long-term estrogen users' menopausal women than in nonusers (29).

The proprioceptive system and neuromuscular control are fundamental in determining joint stability. Their disruption therefore leads to an increased joint injuries risk.

Analyzing the results of our study, it is plausible that an alteration of this system, although very slight, can be identified during the follicular and luteal phases, in which there is a lower estrogen blood concentration. The parameters investigated in this study should be, also, interpreted in consideration of the characteristics of the sample considered; indeed, the fluctuations of balance and proprioception are negligible during the activity of daily life in a young and healthy population.

In addition, we found an asymmetrical distribution between lumbar and pelvis load in ovulatory phase, corresponding to a higher lordosis angle. According to Kim *et al.* (30), there is a link between menstrual cycle and pelvis imbalance, due to body fluid and uterus contraction, more evident in women with menstrual pain. Our study confirms the results of Legerlotz *et al.* (11), namely, premenstrual symptoms are responsible of a postural sway, that can be improved with aerobic training. This is particularly relevant in the management of female athletes, that should include aerobic trainer to relieve fluid retention and menstrual symptoms. This could be particularly relevant in athletes, because an higher lordosis and a retraction of the posterior kinetic chain could be a predisposing factor for overuse injuries at lower limbs (31). To the best of our knowledge, this is the first study based on an objective, and comprehensive approach for the change in proprioceptive control across the menstrual cycle.

This proof-of-principle study had some limitations: the small sample size and the indirect method of hormone assay based on Casey's model (13) could affect the generalizability of the results.

CONCLUSIONS

The results of this study show no statistically significant relationships between proprioceptive control and hormonal variations due to the ovarian cycle. However, it is conceivable that, during an athletic gesture with a high functional demand, the different performances in relation to the different hormonal concentrations become decisive in predisposing to the genesis of an injury. Thus, we confirm the results of previous study, on the likely influence of the ovarian cycle on the neuromuscular control and the importance to consider the ovarian cycle of an athlete during the sport season to plan a tailored program of exercises based on the athlete's needs.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

AF: conceptualization, writing – original draft. AF, DB: methodology. FP, SF: formal analysis, investigation, data curation. AF, FO, AD: writing – review & editing. DB, SP: visualization. CC: supervision. AF: project administration. All authors: final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Relationship between Functional and Laboratory Balance Assessment in Females with Patellofemoral Pain Syndrome

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SUMMARY

Background. Patellofemoral pain syndrome (PFPS) is one of the most common musculoskeletal problems, especially in young females. Dynamic standing balance impairment is a risk factor for PFPS. Objective of this study is to investigate the relationship between functional and laboratory dynamic standing balance assessment in women with PFPS to determine the role of each test in PFPS balance assessment and achieve a comprehensive approach to balance deficit detection in these patients.

Methods. Forty-nine females participated (26 with PFPS and 23 without). The Y balance test (YBT) as a functional balance test, consisted of anterior, posteromedial, posterolateral, and composite balance scales, and the Biodex balance system (BBS) as a laboratory stability test, consisted of total, anteroposterior, mediolateral stability indices, have been used in both groups. Pearson correlation coefficient test was used to compute the relationship between laboratory and functional balance tests. Independent t-test was used for between-group balanced comparisons.

Results. In control group, two balance tests had moderate to good correlation (r^2 = -0.44 to -0.80, $p \leq 0.01$), but in experimental group, there was limited balance scales correlation (r^2 = -0.45 to -0.50, $p \leq 0.02$). Statistically significant difference was found between the study and control group in all balance scales ($p \leq 0.000$).

Conclusions. Females with PFPS had dynamic standing balance impairment. Low Correlation between YBT and BBS in the PFPS group indicated that these two tests might assess a different aspect of balance. Therefore, it is appropriate to use other tests to better identify the relationship.

KEY WORDS

Patellofemoral pain syndrome; postural balance; proprioception; postural control; equilibrium.

INTRODUCTION

Patellofemoral pain syndrome (PFPS) is one of the common knee musculoskeletal disorders characterized by the presence of idiopathic retro patellar and/or prepatellar pain aggravated by the activity-increased patellofemoral joint stress such as stair climbing, squatting, running, jumping, and kneeling (1-4). PFPS is commonly observed in adolescents and young physically active populations and prevalence in the general population was reported as 22.7 annually and the chance of affection in females is 2.23 times more in males (5). This syndrome can limit functional performance and intensively affect the quality of life (6). Also, some studies showed balance impairments in PFPS (7-13), but the recent systematic review study indicated that there is a controversy between studies about balance deficits in these patients (14).

Dynamic balance is defined as the ability to do a task while maintaining a stable position (15) and is a basic need for

independent activities of daily living (16-18). It was one of the three most important gait-related intrinsic risk factors for PFPS development (19). Standing balance deficits often lead to an increase in the risk of falling and this can limit the activity of daily living (ADL) (20). The results of Yelvar *et al.* (20) research indicated that the risk of falling increases in people with PFPS. This can affect their ADL and limit their functions. So, the dynamic standing balance assessment is a necessity for good rehabilitation of this group of patients.

Gender is one of the factors that can affect postural stability (21, 22). Males and females with PFPS have differences in kinematics, strength, and neuromuscular activation during functional activities (23), so it is expected that the balance control of females and males with PFPS has differed. There is controversy in studies that evaluated dynamic balance in females with this syndrome. Some studies showed no balance deficit (24, 25), but others showed impairment in overall, sagittal, frontal, or both of this movement plan (7, 8, 10, 11, 13, 26). With this in mind, there are some functional and laboratory dynamic standing balance assessment tests for these patients. The Y Balance Test (YBT) is a functional tool for lower limb balance evaluation derived from the star excursion balance test (SEBT) (27). It is a cost-effective and portable test to evaluate lower extremity dynamic balance and neuromuscular control and its reliability is very good (28). The Biodex Balance System (Biodex, Inc., Shirley, NY) (BBS) is one of the laboratory balance measure tools. It is a multiaxial device with a circular platform that can simultaneously move in the anterior-posterior and medial-lateral directions and calculate 3 stability indexes including anterior-posterior stability index (APSI), mediolateral stability index (MLSI), and overall stability index (OSI) (29, 30). It has moderate to good reliability in PFPS subjects (31). The BBS provides quick, objective balance assessment, but the device is costly so its use in clinical practice is limited (27). Nakagawa *et al.* evaluated the relationship between static, dynamic, and functional balance tests in people with a recurrent ankle sprain and found a very weak relationship between these tests in these patients (32). On the other hand, Akbari *et al.* examine the correlation between BBS and SEBT in athletes with an ankle sprain and found a good correlation (33).

Balance problems affect ADL and can decrease quality of life, so assessment of balance is very important. When both the YBT as a functional test and BBS as a laboratory test are used to evaluate dynamic balance in females with PFPS but no study investigated their relationship and their advantage as means for obtaining reliable feedback on this group dynamic balance and evaluating the effects of rehabilitation for them. So, this study aimed to investigate the relationship between functional and laboratory dynamic standing balance assessment in women with PFPS to determine the role of each test in PFPS balance assessment to achieve a comprehensive approach to balance deficit detection in these patients.

MATERIALS AND METHODS

The protocol of this study was approved by the ethics committee on research of Tabriz University of Medical Science (IRTBZMED.REC.1397.302 – Date of approval: July 21, 2018). All participants provided written informed consent before participation in this study.

Participants

The case-control study consisted of forty-nine females who were divided into two groups: the PFPS (either unilateral or bilateral) group (n = 26) and a matched control group (n = 23). Subjects with PFPS were diagnosed by an orthopedist and referred to a biomechanics laboratory according to inclusion and exclusion criteria. All tests were performed in the biomechanics laboratory of the Iran University of Medical Science. The subjects of the control group were recruited from Iran University of Medical Science students and personnel. The inclusion criteria for the PFPS group were non-athletic females aged 18-35 years with a history of unilateral or bilateral anterior knee pain of more than 3 months (10), the intensity of knee pain at least 3 of 10 according to visual analog scale (VAS) (11), pain in palpating medial or lateral facet of the patella (10), having pain during at least 3 of following activities: squatting, jumping, running, kneeling, standing when squatting, stair climbing, prolonged sitting, doing resistance exercises (10). The inclusion criteria for the control group were non-athletic females aged 18-35 years with no history of knee pain in any of the activities described for the PFPS group. The exclusion criteria for both groups were body mass index (BMI) more than 28 kg/m^2 (10), history of knee surgery, ligamentous and/or meniscus injuries (10, 13), patellar tendinopathy (10, 13), traumatic patellar dislocation (10, 13), ankle, hip, or lumbar joint injuries (10, 13), a neurological disorder (10, 13), use of anti-inflammatory medication (10, 13), pregnancy (10), increase subjects pain and conditions that effect on balance such as positional vertigo, hypertension, internal ear problems (13), not corrected eyesight problems (13), and if subjects did not want to continue participation in the investigation. The required sample size was calculated with a pilot.

Procedures

The control group was assessed by a physical therapist with 4 years of clinical experience to verify inclusion and exclusion criteria. The dominant limb was characterized by the kick-a-ball method (34). Then the lower limb length for each subject was measured in a supine position from the vertex of the anterior superior iliac spine to the center of the ipsilateral medial malleolus with a standard meter (35).

Balance tests

YBT

YBT is a version of SEBT that utilizes only three directions of eight directions of SEBT. This test consists of 3 tapes set in anterior (ant), posteromedial (post-med), and postero-lateral (post-lat) directions that form a "Y" shape together (36). Before this test, each person was educated by examiner instructions and with pictures about performing the test. Each participant stood in the center of the modified SEBT grid while her hands were on the hips barefoot and the most distal aspect of the greater toe of her test limbs was in the center (36). She wanted to reach as far as possible with her other limb in ant, post-med, and post-lat directions respectively while not weight bearing on reaching limb (36, 37). Participants did 6 practical trials (38) and 3 testing trials for each of the 3 reach directions. For each testing trial, the examiner visually recorded the location of the most distal part of the reaching foot as it contacts the grid in centimeters. The most recorded reach distance was used in future analyses. The test was repeated if (28, 36) the participant could not maintain a single leg stance throughout the test, the hands separated from hips during the test, the heel of the stance foot separated from the floor during the test, through reaching in any direction, the weight of the subject migrated from stance limb to reaching limb (the reaching limb contacted with the floor), if the subject was unable to return reaching limb to start position.

Biodex balance system

BBS (Biodex Medical Systems, Shirley, NY, USA) measures three stability indices: APSI, MLSI, and OSI (29, 34). The stability of the platform can be adjusted between 1 to 12 where level 1 is the most unstable and level 12 is the most stable level. In this study, we used level 6 for balance assessment. Before testing, the examiner instructed the participant about performing the test and each subject used the device for 1 minute to justify it (39). The participants were asked to single leg stance on the platform barefoot while the tested limb was on the platform and the other limb was in slight abduction and flexion of the hip and 90-degree flexion of knee position, they looked ahead, and their hand crossed the chest then were asked to adjust their foot and try to keep the platform in a horizontal position (9). The subjects preferred foot position was saved and was maintained for each one during the testing trial (18, 40). For testing, participants wanted to keep the platform as motionless as possible for 20 seconds without a change in head, hands, and lower limb position (41). Balance testing consisted of 2 practical and 2 testing trials (29). With 2-minute rest between practical and testing trials and 20 seconds rest between 2 testing trials. The average of 2 testing trials was recorded and used for future analysis. The test was repeated if the position of the head, hands, and lower limbs changed during the test, the subject was unable to maintain a single leg stance or complete the determined time for balance test (20 s) throughout the test.

Statistical analysis

Spss 16 software was used for data analysis. The level for statistical significance value was set to $p < 0.05$. The normality of the data distribution was determined with the Kolmogorov-Smirnov test. Comparison between PFPS and control group balance indices was performed by independent t-test. All data had normal distribution, so the Pearson correlation coefficient was used to distinguish the strength of correlation between YBT and BBS balance scales with a coefficient value set as follows: 0-0.19 = none to slight; 0.20-0.39 = low; 0.40-0.69 = moderate; 0.70-0.89 = high, and 0.90-1 = very high (42).

RESULTS

There was no significant difference in demographic characteristics between the PFPS and control groups ($p < 0.05$, **table I**).

Balance assessment

Table II shows the means and standard deviation (SD) of the BBS and YBT balance scales. Analysis by independent t-test showed significant differences between PFPS and control groups for all balance indices of YBT and BBS ($p < 0.01$, **table II**).

Correlation analysis

In the correlation analysis of the PFPS group, we found only some low to moderate indirect correlations come in follow: BBS OSI and YBT anterior $r = -0.45$, $p < 0.05$; right BBS APSI and right YBT anterior $r = -0.50$, $p < 0.05$, **table III**). In the control group, we found moderate to strong indirect correlation in all balance scales of two tests ($r = -0.44$ to -0.80 and $p < 0.01$, **table IV**).

Table I. Demographic features of study participants.

Demographic data	PFPS group (n = 26) Mean (SD)	Control group (n = 23) Mean (SD)	P-value (mean difference)
Age (year)	23.27 ± 4.10	23.22 ± 3.71	0.96
Height (m)	1.65 ± 0.05	1.65 ± 0.04	0.06
Mass (kg)	59.85 ± 8.03	61.91 ± 5.31	0.30
BMI (kg/m^2)	22.83 ± 2.40	22.70 ± 1.58	0.82
Lower limb length (cm)	83.25 ± 5.23	85.63 ± 4.04	0.08

PFPS: patellofemoral pain syndrome; SD: standard deviation; BMI: body mass index.

Table II. Comparison between YBT and BBS balance indices (mean ± SD).

Balance indices	PFPS group	Control group	P-value
YBT overall (%)	72.75 ± 4.70	85.09 ± 2.92	0.000
YBT anterior (%)	64.76 ± 3.32	76.42 ± 3.18	0.000
YBT posteromedial (%)	80.03 ± 6.35	91.80 ± 4.70	0.000
YBT posterolateral (%)	73.49 ± 6.64	87.08 ± 4.19	0.000
BBS OSI (Degree)	1.73 ± 0.52	0.54 ± 0.16	0.000
BBS APSI (Degree)	1.48 ± 0.54	0.35 ± 0.12	0.000
BBS MLSI (Degree)	0.56 ± 0.28	0.32 ± 0.14	0.000

Table III. Correlation between YBT and BBS balance indices in the PFPS group.

Test	BBS OSI		BBS APSI		BBS MLSI	
	R^2	P-value	R^2	P-value	R^2	P-value
YBT overall	-0.17	0.38	-0.18	0.35	0.02	0.90
YBT anterior	-0.45*	0.02	-0.50**	0.009	-0.01	0.90
YBT posteromedial	0.06	0.70	0.07	0.73	0.003	0.98
YBT posterolateral	-0.22	0.27	-0.22	0.27	0.04	0.81

R^2 values and P-values for the correlation analysis between the Y balance test (YBT) and biodex balance system (BBS) balance scales in the patellofemoral pain syndrome (PFPS) group; a significant correlation is indicated with the asterisk ($p < 0.05$).

Table IV. Correlation between YBT and BBS balance indices in the control group.

Test	BBS OSI		BBS APSI		BBS MLSI	
	R2	P-value	R2	P-value	R2	P-value
YBT overall	-0.73**	0.000	-0.73**	0.000	-0.52**	0.003
YBT anterior	-0.80**	0.000	-0.80**	0.000	-0.53**	0.002
YBT posteromedial	-0.66**	0.000	-0.66**	0.000	-0.44*	0.01
YBT posterolateral	-0.59**	0.001	-0.59**	0.001	-0.47**	0.008

R^2 values and P-values for the correlation analysis between the Y balance test (YBT) and biodex balance system (BBS) balance scales in the control group; a significant correlation is indicated with the asterisk ($p < 0.05$).

DISCUSSION

Our result showed also the females with PFPS had standing balance deficits in all balance scales of both laboratory and functional tests but the relationship between these two tests was weak in these groups of patients.

BBS balance evaluation

The result showed all BBS balance scales are significantly greater in PFPS. Since a greater balance scale in BBS indicates poor balance (9), dynamic standing balance control was impaired in females with PFPS. Several parameters can

affect standing balance control in PFPS including proprioception deficits (43-46), impairment in ankle, knee, and hip joints kinematic and muscle performance (7-11, 47, 48), pain (12, 20, 49), and deficit in core stability (20, 50). These findings are consistence with previous studies that examine the PFPS group dynamic standing balance with BBS (13, 51). But on the other hand, there was some controversy between this study's results and previous ones (9, 12). Negahban *et al*. (9) evaluated the dynamic standing balance in people with PFPS and found only an anterior-posterior (sagittal plane) balance deficit and there was no significant difference in overall and medial-lateral balance scales between this group of patients and the control. This inconsistency can be because of the difference in demographic features of participants of these two studies. Negahban *et al*.'s research was on both males and females, but gender effect on kinematic and balance control (21, 44), so in the present study just females joined. The other reason can be the different methodologies of the two studies. Negahban *et al*. used level 4 of BBS and we used level 6. Balance control in level 4 is more difficult than 6, so it can challenge the control group's balance and their overall and medial-lateral balance scales may be decreased so they couldn't find differences in these balance scales. Rezazadeh *et al*. (12) measured the dynamic standing balance of athletes men with PFPS and in open eyes conditions, just the overall balance scale was different compared to the control group. This controversy in our study can be because of differences in the demographic features of participants. Being male and an athlete can increase the balance of these patients so the researchers couldn't find differences in other balance scales.

YBT balance evaluation

Our findings showed all YBT balance scales of females with PFPS are lower than control ones. A lower balance scale in YBT means poor balance control, so the females with PFPS had poor balance control in all directions of YBT. These results are in agreement with previous studies (26, 44, 52, 53). But there was some dissimilarity between Song and Zamboti's research (24, 25). Song *et al.* (24) measured the balance of females with PFPS by anterior direction of YBT and didn't find any difference compared to controls. This disagreement can be because of the methodological difference between the two studies. Song *et al*. used only 4 practical tests before the main test which could be not enough to control the learning effect. On the other hand, in contrast to our study, in their study, the distal point of the mover limb had touched the ground. The other reason can be the participants' number that was 16 in Song *et al*. which was lower than ours. Zamboti *et al*. (25) in another study evaluated the balance of 10 women with PFPS by three directions of YBT and found no difference compared to controls. The controversy of this research to ours can be because the participant's number was very lower than in our study.

Correlation of BBS and YBT

The result of this investigation showed only some low to the moderate indirect correlation between BBS and YBT balance scales in the PFPS group, but this relationship was moderate to high in almost all balance scales of the two tests in the control group. The lack of correlation between BBS and YBT in females with PFPS can indicate that each test has different balance aspects in this group. Balance controlling is a complex performance including three basic aspects: 1) maintaining the body position, 2) controlling the stability in conscious movement, 3) appropriate response to external perturbation (54), and needs the integration of sensory information, central processing, and motor response (39). In the present study, YBT can maintain stability in a conscious movement, but BBS has the ability of postural control toward an external perturbation that is the movable platform. So, each of these tests may have different aspects of balance that can be complemented or one be weaker in balance evaluation than another (32, 54-56) that needs further investigation. On the other hand, YBT is a functional test that needs lower limb coordination, flexibility, muscle strength, and balance (52). It seems that this test has the overall joint performance more than a specific balance test (32). The exact balance properties described by functional balance evaluation can't be defined easily because other factors than balance affect this test performance (56). These results are consistent with previous studies (32, 56). Nakagawa *et al*. (32) investigated the relationship between functional and laboratory balance tests in people with a recurrent ankle sprain and found a very weak association. Sawacha *et al*. (56) have the correlation between functional balance tests and posturography in chronic hemiplegic post-stroke persons and found only some relationships. In contrast to our study, Zamboti *et al*. (25) found a moderate correlation between YBT overall balance scale and static unimodal COP oscillation measured by force plate in females with PFPS. This disagreement can be because of methodological differences between the two studies. They investigated the correlation between static COP and YBT, but we determined the association between two dynamic balance tests. The good correlation in the control group indicated the fact that all aspects of balance controlling are appropriate in this group, so the acceptable association was expectative. This good correlation in the control group wasn't consistent with previous ones (27, 57). The previous study didn't separate the males and females. It seems that gender has a significant effect on balance control as demonstrated in other studies (21, 58, 59).

This study had some limitations: we didn't determine the pain level and functional capacity. Perhaps the person with different levels of pain and functional capacity had a different balance controlling. We didn't determine the factors that could affect each test such as proprioception and muscle strength, etc. Further investigations are needed to research these factors. The same study in the male group with PFPS should be performed.

Limitation and future perspectives

This study had some limitations. Only the females with PFPS were included in the study so due to the influence of gender in maintaining balance and kinematic differences and muscle strength between women and men, it is suggested to measure the relationship between functional and laboratory dynamic standing balance in the males with PFPS. In this study the patients with the history of knee pain during the last 3 months has been participated. It seems that the results of function and balance tests are different in patients with chronic anterior knee pain and maybe this issue could influence the relationship between functional and laboratory balance tests. Therefore, it is suggested to investigate this relationship in patients with chronic PFPS.

CONCLUSIONS

Females with PFPS had a dynamic standing balance deficit. Both YBT as a functional test and BBS as a laboratory test showed this deficit but the correlation between the two tests in this group of patients was weak. So, it needs to perform a similar study with different functional and laboratory balance tests to better identify the relationships.

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None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

SN, TG, ZS: design. SN, MA: data collection. ZS, TG: data analysis. SN, ZS, NKE: writing - original draft. TG, MA: writing - review & editing.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Long-Term Whole-Body Vibration on Knee Extensor Function: A Randomized Clinical Trial

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SUMMARY

Introduction. The whole-body vibration platform (WBV) has shown positive effects on muscle aspects of strength and power due to the tonic vibration reflex. However, there is still disagreement about the parameters to be used.

Objective. To investigate the effect of two WBV frequencies (30 and 45 Hz) on maximum isometric and resistance torques of the knee extensors, and power in two jumping modalities, Squat Jump (SJ) and Counter-Movement Jump (CMJ).

Methods. Randomized clinical trial, composed of 40 healthy young adults of both sexes, aged between 18 and 30 years, not practicing systematic physical activities and randomized into three interventions according to the frequency of WBV: 30 Hz (F30), 45 Hz (F45) and sham (SG). The outcomes evaluated were the maximum isometric torque and quadriceps resistance measured by a traction dynamometer, and the quadriceps power obtained in two jumping modalities: squat and countermovement jump. The WBV intervention lasted 12 weeks, 2x weekly. After a familiarization session the outcomes were measured before and after the interventions. For statistical analysis the percentage of change between pre and post measures was used (Delta percentage).

Results. No statistical differences were observed in the percentage deltas for any of the outcomes evaluated.

Conclusions. WBV, regardless of the frequency adopted, did not influence the aspects of muscle function.

Study registration. Registro Brasileiro de Ensaios Clínicos (ReBEC) with the number RBR-4rrn7cf.

KEY WORDS

Vibration; muscle strength; skeletal muscle; knee joint; quadriceps muscle.

INTRODUCTION

Optimizing aspects of muscle function is widely recognized as an effective way to prevent diseases and improve quality of life through physiological adaptations. High-intensity strength training aims to increase muscle strength, while low-intensity strength training promotes endurance (1, 2).

Neuromuscular adaptations and an increase in muscle cross-sectional area are the main outcomes of strength training, achieved by improving motor unit synchronization and increasing the number of sarcomeres in parallel, respectively. To recruit high-threshold muscle fibers, strength training typically involves a volume of 4 to 12 repetitions at 60% to 80% of the maximum load, determined by a one-repetition maximum test (3-5).

Endurance is defined as the ability of muscles to contract over a given time. Low-intensity strength training involves continuous repetitions of submaximal loads to improve endurance, with minimal homeostatic variation. Strength endurance training increases motor unit firing at the neural level and promotes mitochondrial biogenesis and capillary density, leading to improved oxygen consumption and delayed fatigue during prolonged exercise (4, 6).

Muscle power is defined as the product of force and velocity, representing the amount of work performed per unit of time.

Vertical jump performance is a key indicator of lower limb muscle power, and it is optimized by the Stretch-Shortening Cycle since it involves eccentric contraction followed by concentric contraction, leading to an increase in power (7, 8). Various training methods are available to improve strength, endurance, and power. Studies suggest that whole-body vibration (WBV) can increase strength and power by activating muscle spindles through the tonic vibration reflex and promoting the synchronized recruitment of high-threshold motor units (9-11). However, the neuromuscular effects and practical applications of WBV in strength and power training are still under investigation, with controversial effects and potential risks of injury (12-16).

The present study aims to investigate the effect of two WBV frequencies (30 and 45 Hz) on maximum isometric and resistance torques of the knee extensors, and power in two jumping modalities, Squat Jump (SJ) and Counter-Movement Jump (CMJ).

MATERIALS AND METHODS

Ethics of the study and volunteer recruitment

This study was a blind (participant), parallel, randomized, placebo-controlled clinical trial, following the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) and approved by the Ethics Committee on Research Involving Human Beings of a Higher Learning Institution under number 5.269.114 – Date of approval: March 02, 2022. All participants were informed about the objectives and procedures of the research and signed the informed consent form in duplicate, one copy for themselves and the other for the researcher.

Volunteers were recruited in a non-probabilistic and consecutive manner from young adults aged between 18 and 30 years, who did not engage in systematic physical activities, of both genders. The study was promoted through digital media and personal approaches in the proximity of the University where the research was conducted. Volunteers with neurological and cognitive problems, cardiorespiratory diseases, and a history of joint or muscle injuries in the last six months were excluded from the study. The exclusion criterion for data analysis was the withdrawal of the volunteer's authorization to participate in the study.

Randomization and blinding

The volunteers were assigned to one of three intervention conditions based on the frequency imposed by the WBV as follows: sham (SG), frequency 30 Hz (F30), frequency 45 Hz (F45) (explained in detail in the next item). The distribution between intervention frequencies was matched by sex. The randomization process was carried out by a researcher not involved in any other stage of the study, and a list was generated electronically using GraphPad QuickCalcs software. The recruitment process is shown in **figure 1**.

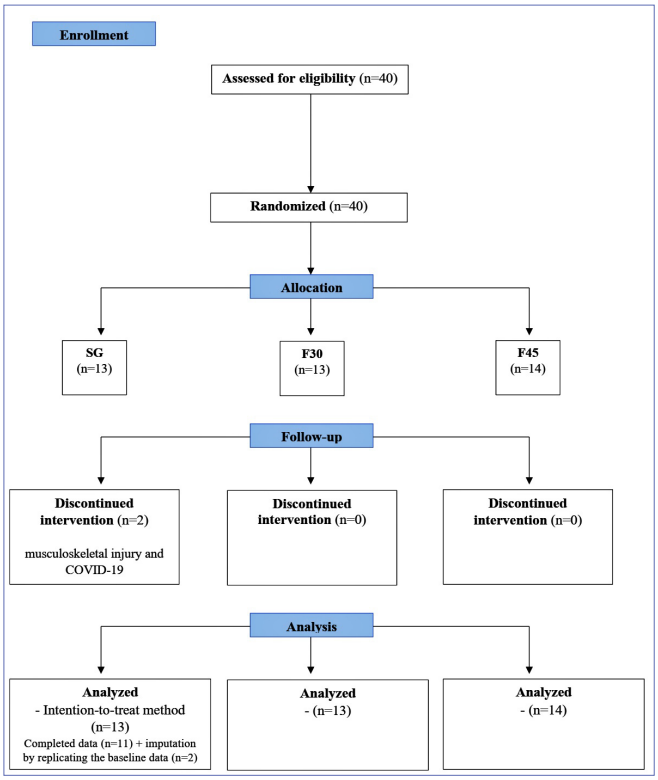

Figure 1. Study flowchart for distribution of volunteers into interventions according to vibration platform frequency.
SG: Sham; F30: frequency 30 Hz; F45: frequency 45 Hz.

Interventions

Determination of maximal squat volume - Exhaustion Squat Test (EST)

The EST was conducted during the familiarization visit to measure the volume of squats during the interventions. For this test, participants were instructed to perform squats until exhaustion within an amplitude range of 180° to 120° of hip flexion, as delimited by fixed bars. The pace of execution was standardized using a metronome for all participants, and the test intensity was targeted to correspond to the Borg 6 to 20 scale rating of "Slightly Tiring", which is equivalent to numerical ratings of 13 and 14 scale rating (17). The time until test interruption and the number of repetitions performed were recorded.

If participants failed to reach the bars that delimited the test amplitude or executed squats outside the rhythm deter-

mined by the metronome for three consecutive times, the test was interrupted, and only the data that followed the test protocol correctly were used for analysis.

Whole-Body Vibration (WBV)

The intervention comprised 12 sessions over a 6-week period, with 2 sessions per week. Participants performed a series of squats identical to the baseline evaluation. The WBV parameters for the intervention were an amplitude of 1.5 mm at a frequency of 30 Hz and an amplitude of 2.0 mm at a frequency of 45 Hz. The SG performed the same squatting protocol on the platform, but with the vibration function turned off.

The percentage volume was calculated for each of the 12 sessions based on the maximum number of squats performed by each participant, and the volume was progressively increased weekly. **Figure 2** shows the distribution of the volume over the sessions, expressed as a percentage of the maximum number of squats.

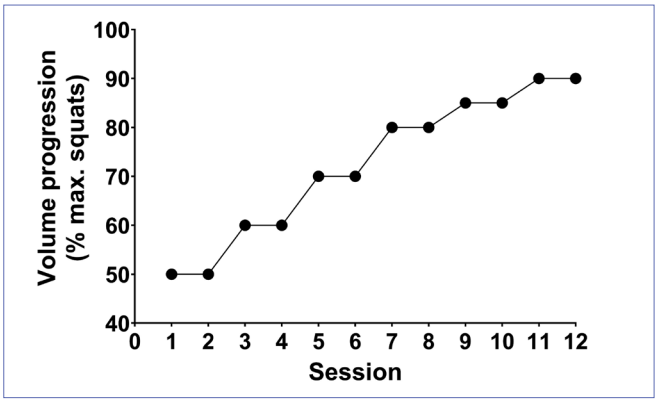

Figure 2. Distribution of squat volume, in each of the sessions, over the intervention period.

To ensure external load control, if volunteers failed to reach the amplitude limits set for squats or perform them out of rhythm with the metronome three times consecutively, the prescribed volume of squats for the following week would remain the same as the current week.

Outcomes

The study assessed the quadriceps maximum isometric torque, quadriceps resistance torque, and quadriceps power.

Maximal isometric quadriceps strength test

The volunteer sat in a chair, with the trunk inclined backwards by 10° and the upper limbs resting at the edges of the chair, so that the hip flexion angle was kept around 100°. The volunteer was instructed not to make compensatory movements during the execution. He was instructed to apply as much force as possible to extend the knee for 5 s at a fixed 45° angle.

Evaluation of the maximum isometric force was done using an inextensible chain connected to a load cell (E-lastic model 200 kg, W-sporte SE, Brazil) that was fixed to the frame of the chair. The other end of the chain was hooked to an anklet worn by the volunteer. The test was performed twice and there was a 60 s interval between repetitions. Considering that the length of the volunteer's leg was always invariable, the lever arm was always determined by the center of the distance between the knee joint to the point where the load cell chain attaches to the ankle support.

Quadriceps strength endurance test

The volunteer remained in the seated position in the chair, as previously described. In the endurance test, each volunteer performed four series of knee flexion-extension movements, starting at 90° of knee flexion, moving to 40° and returning to 90°, performing as many repetitions as possible until muscle fatigue. The rest interval between each series was 45 s, and there were beacon lines to delimit the range of motion between 90° and 40°. The fatigue point was considered by the volunteer's own perception or when he did not reach the mark corresponding to the 40° angle for three consecutive repetitions. At the end of each series, the perceived exertion level (PSE) was collected using the Borg scale from 6 to 20 (17). The number of repetitions and the duration of each series were recorded.

The load imposed during the strength endurance test was determined using a latex tube exerciser present in the elastic kit, which could be red (weak intensity) or blue (strong intensity). One end of the elastic tube was hooked to the load cell, which in turn was attached to the chair frame, and the other end was hooked to an anklet worn by the volunteer. In the familiarization test, all participants started wearing the red rubber band. If the participant, with the red rubber band, reached 250 repetitions or more in the first series along with a PSE lower than 13 (a bit tiring), the load was switched to the blue rubber band and with it the participant would perform the remaining evaluations. The muscle strength needed to overcome the elastic resistance of the exerciser was quantified by the load cell in each extension movement. The values of mean and maximum force, recorded in kgf, and the number of repetitions of the extension moment were obtained by a smartphone application of the elastic system.

The strength data from both the maximal isometric test and the strength endurance test were converted to torque. Once the force was obtained and the distance between the volunteer's knee and the ankle support was measured, the torque was obtained by the following equation:

$T = F \times D$

where T = torque; F = force; D = distance.

Jumping parameters

The jumping parameter evaluated was the power of the lower extremities. In the SJ there is no countermovement, which is the acceleration of the center of mass in a downward direction prior to the act of jumping and, therefore, the concentric action of the agonists is predominant. On the contrary, in the CMJ there is the presence of countermovement that lengthens the agonist muscle, activates the stretching and shortening cycle, and mobilizes elastic energy from the stretching of the musculotendinous unit that, added to the concentric agonist work, enhances the jump performance of the jump (18).

To determine the power, jump height and flight time, for both types of jumps, the volunteers jumped over the JumpTest® contact mat (Hidrofit LTDA, Belo Horizonte, Brazil) with dimensions of 50 × 66 cm. The contact mat was connected to a laptop computer (Itautec Infoway, Intel® Core i3 370M 2.40 GHz, 8.00 GB RAM) in which Multisprintfull® (Hidrofit, Belo Horizonte, Brazil) software was installed, which processed the data in real time. This mat is made up of two conductive surfaces that respond to small pressures by closing the system. After the subject's feet lose contact with the mat during the jump, the system is opened, and a chronometer in the software is started and kept timing until the subject regains contact with the mat, closes the system again, and stops timing. Considering the flight time, obtained by the stopwatch, the jump height is calculated as (19, 20):

$h = g \times t^2 \times 8^{-1}$

where: h = jump height; g = acceleration of gravity (9.81 m × s^{-2}); t = flight time (s).

In the SJ, the volunteer, already on the contact mat, performed a maximum jump from a static semi-lying position in which the knee was bent at approximately 90°, with the trunk as straight as possible and the hands positioned at the waist where they should remain for the entire excursion of the jump (18). Two maximum jumps were requested with a two-minute interval between them, and the highest value was considered for analysis. Subsequently, in the JMC, the evaluated began the jump from the standing position with the knees extended and the hands at the waist. When starting the jump they should first flex the knee to about 90° and then jump as high as possible without taking the hands off the waist (18). They were also asked to perform two maximal jumps with a two-minute interval between them and the highest value was considered for the analysis. The Multisprintfull® software calculated the power of each jump, expressed in watts (W), using the following equation:

$power = m \times g \times (h/t)$

where: power = muscle mechanical power, obtained by the contact mat for each jump; m = body mass in kilograms; g = acceleration of gravity (9.81 m × s^{-2}); h = jump height (m); t = flight time in seconds.

The power was normalized by the mass of the volunteer and then expressed by the unit W× kg^{-1}.

Methodological procedures

Initially, volunteers were informed about the research objectives and procedures and subsequently gave their consent to participate in the research.

The evaluations occurred on three occasions in time: 1) familiarization, 2) pre-intervention; 3) post-intervention. A schematic description of the methodological procedures can be seen in **figure 3**.

Familiarization

After the registration of the sample characterization variables such as age (years), body mass (kg), and height (m), the volunteers were familiarized with the evaluative procedures of isometric maximum strength and quadriceps strength resistance and jumps in SJ and CMJ modalities, to minimize the learning effect. The volunteers also performed the EST, as previously described. The familiarization data was not computed for the statistical analyses.

Pre-intervention

The volunteers were re-evaluated, in relation to the measures corresponding to the study's endpoints, in the same way as practiced at familiarization, between 72 h and 168 h.

Post-intervention

The volunteers were re-evaluated, in relation to the measures corresponding to the study outcomes, between 24 h and 168 h after the end of the intervention.

Figure 3. Schematic representation of methodological procedures over time.

Data processing

The data were treated by calculating the percentage change between the pre- and post-intervention occasions by the equation:

Delta percentage = (post-intervention value / pre-intervention value) -1 × 100

Statistical analysis

SPSS 20 software was used for statistical analysis. The significance level adopted was 5% ($\alpha = 0.05$).

The factor used in the analyses exploring the effects of the vibration platform on the study results was frequency (sham; 30 Hz; 45 Hz). The outcome variables in the comparisons were percentage deltas of torque measurements (resistance torque, maximum isometric torque) and of the power in the two jumping modalities (SJ and CMJ). Comparisons were made using the Generalized Linear Model Test (GzLM), which is based on maximum likelihood and uses Wald's chi-square test (Wald χ^2) to identify the effect of the variable in the generalized linear model. Sidak's test was used as a *post-hoc* test.

RESULTS

Sample characterization data can be viewed in **table I**. No significant differences were observed for any of the characterization variables between the interventions (age / χ^2 [1,2] = 2.214 and p = 0.331; body mass / χ^2 [1,2] = 0.520 and p = 0.771; height / χ^2 [1,2] = 0.810 and p = 0.667).

No statistical differences were observed in the percentage deltas for any of the outcomes evaluated (resistance torque / χ^2 [1,2] = 1.115 and p = 0.572; maximal isometric torque / χ^2 [1,2] = 2.191 and p = 0.334; power in SJ / χ^2 [1,2] = 0.424 and p = 0.809; power in CMJ / χ^2 [1,2] = 0.284 and p = 0.0.867). The descriptive statistics for each outcome before and post-intervention, and the percentage delta values according to the intervention can be seen in **table II**.

DISCUSSION

The current study emphasized the effect of two different WBV frequencies on maximal isometric and resistance torque, and muscle power. The results pointed out that the WBV intervention for 6 weeks did not present a significant difference in the outcomes.

Previous studies have shown that the tonic vibration reflex caused by WBV can lead to an increase in recruited muscle fibers. Lai *et al.* (21) concluded that training with WBV associated with squat training for 8 weeks showed muscle strength gains in patients with knee osteoarthritis using 20 Hz frequency and 2 mm displacement amplitude. Delecluse *et al.* (22) report a significant increase in the isometric and dynamic strength of the quadriceps femoris, since the study was conducted in 12 weeks of intervention, with frequencies of 35 Hz to 40 Hz with wave amplitude of 2.5 to 5 mm. However, the present study is consistent with Kvorning and colleagues (9) who reported that WBV alone or associated with weighted squatting showed no significant effect on

Table I. Characterization data of the sample (mean and standard deviation values).

	F45	F30	SG
Age (years)	20.7 ± 0.7	75.9 ± 20.6	1.67 ± 0.11
Body mass (kg)	21.7 ± 2.8	72.1 ± 17.0	1.71 ± 0.11
Height (m)	21.5 ± 1.2	71.6 ± 15.3	1.70 ± 0.08

F45: 45 Hz group; F30: 30 Hz group; SG: sham group - 0 Hz.

Table II. Average values for resistance torque, maximum isometric torque, power in SJ and CMJ for each group during the 2 evaluation moments (PRE- and POST-intervention) and the percentage delta values.

	PRE			POST			Delta (%)		
	F45	F30	SG	F45	F30	SG	F45	F30	SG
Resistance torque (Nm × kg^{-1})	1.10	1.18	1.19	1.12	1.14	1.24	1.18	-4.24	3.52
Maximum isometric torque (Nm × kg^{-1})	2.13	1.87	1.64	2.31	2.19	1.89	13.6	19.9	7.57
Power in SJ (W)	372.3	342.8	332.4	374.1	352.4	343.8	1.73	5.22	5.61
Power in CMJ (W)	378.7	352.2	340.3	386.4	367.3	354.2	2.89	5.73	5.66

F45: 45 Hz group; F30: 30 Hz group; SG: sham group - 0 Hz; PRE: period before the intervention protocol; POST: period after the intervention protocol; SJ: Squat Jump; CMJ: Counter-Movement Jump.

maximal isometric voluntary contraction with a training over 9 weeks with progressive volume of squats, with a frequency variation of 20 and 25 Hz and amplitude of 4 mm being used. The present study evaluated muscle power from SJ and CMJ, a topic indicated as important for research (23), there was no significant difference between the pre and post-intervention tests, despite showing minimal superiority in the values of low frequency (30 Hz) compared to high frequency (45 Hz) in both jumps. On the other hand, Oliveira and colleagues (24) state that long-term WBV training (3 times a week for 4 weeks) contributes to the improvement of muscular capacity in lower limbs of soccer athletes; however, this study used the frequency of 35 Hz and the wave amplitude of 4 mm. Furthermore, the intervention occurred in five series of static squatting with knee joint amplitude at 90° on the vibration platform for 60 seconds. They also evaluated jump height after 4 weeks of follow-up with loss of muscle performance. In agreement, Torvinen and others (25) analyzing the acute effect of vibration (15-30 Hz and 10 mm), 2 and 60 minutes after intervention, observed an increase in performance of maximum knee extension strength and vertical jump height 2 minutes after intervention, and in the post-test at 60 minutes there were no changes in the proposed variables. In contrast, Charlton and colleagues (26), observed an inhibitory effect in the hamstrings in knee flexion in subjects undergoing WBV and squatting. Meanwhile, in the current study, volunteers were reassessed, with respect to the corresponding measures, between 24 h and 168 h after the end of the intervention, as it was not of interest to analyses the effects of the platform on transient physical and muscular performance, but rather analysis of long-term training.

According to a study (27) the ideal relation between load and movement execution speed during muscle power training is a difficult aspect to control. Training should be performed with average loads and maximum execution speed of a given movement. Taking this into account, it is assumed that the current study did not show significant differences between the groups due to the low volume and load of training used, since the squats performed on the platform were performed in a controlled manner, and the intervention time for each participant varied according to the EST.

CONCLUSIONS

We conclude that there WBV, regardless of the frequency adopted, did not influence the aspects of muscle function.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

EKS, JR, KAH, RAB: research project, data collection, writing - original draft, final approval. ARdC, GRFB: research project, data analysis, writing - critical review & editing, final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Cross-Cultural Adaptation and Validation of the Italian Version of the Spine Functional Index

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SUMMARY

Purpose. The Spine Functional Index (SFI) was developed to assess spinal function based on the idea of a single kinetic chain concept for the entire spine. The SFI has been translated into Spanish, Turkish, Simplified Chinese, Korean, Persian and Polish with accepted psychometric properties. The aim of this study is to translate and culturally adapt the SFI into Italian language and to verify the construct validity and reliability of this version.

Methods. The English version of the SFI has been translated according to international guidelines. The measurement properties (construct validity and reliability) have been tested according to COSMIN checklists. A total of 230 patients were included in this study. Exploratory Factor Analysis (EFA) was used to analyze structural validity. Cronbach's α was calculated to assess the internal consistency and the Intraclass Correlation Coefficient (ICC) was calculated to estimate the reliability. The Functional Rating Index (FRI), the Oswestry Disability Index (ODI), the Neck Disability Index (NDI), the EuroQol Health Questionnaire 5 Dimensions (EQ-5D) and a Visual Analogue Scale (VAS) were used to assess the validity of the construct.

Results. All the items were similar in meaning to the originals. EFA showed a mono-factorial structure. Cronbach's α was 0.743 and the ICC was 0.914 (95%CI 0.864-0.945). The Pearson's Correlation Coefficient showed significant correlations ($p < 0.01$) between SFI and FRI, ODI, NDI, EQ-5D and VAS items.

Conclusions. The study provided an Italian version of the SFI with good reliability and construct validity. The results of current study suggest that the Italian version of the SFI can be applied by physicians and researchers to measure the spine functional status in Italian population.

KEY WORDS

Spine Functional Index; cross-cultural adaptation; internal consistency; reliability; validity.

INTRODUCTION

Musculoskeletal disorders affect various structures including muscles, tendons, ligaments, joints and spinal discs. Those located at the level of the spine are the most frequent musculoskeletal disorders. Musculoskeletal disorders of the spine (low back pain and neck pain) are a major global concern due to their high morbidity and the resulting economic loss. Low back pain and neck pain have the highest prevalence in the adult population and affect almost 10% of the world's population. They are also the most common causes of long-term pain and physical disabilities, which prevent patients from going to work and worsen their quality of life (1, 2).

Rehabilitation treatment is based on careful clinical evaluation, which assumes a role of equal importance to the therapy itself. Therefore, it becomes necessary to have objective measuring instruments available that can provide indications on the patient's health status: this role is played by patient-reported outcome measures.

In recent years, the use of patient-reported outcome measures (PRO measures) in clinical practice has been increasingly recommended. These measures are able to detect statistically significant information on individual body districts, their functions and the patient's quality of life; thus, allowing the formulation of a diagnosis, a classification of the severity of the disease, an estimation of the prognosis, patient monitoring and treatment regulation. In addition to the elaboration of the therapeutic plan, these tools are also extremely useful to monitor their effectiveness in a completely objective manner. PRO measures provide objective answers that help physicians, health care professionals and researchers to monitor patients' progress and to understand if their health status has changed (3, 4).

In this way physicians, health care professionals and researchers can assess and understand much more quickly how the patient's health, functional status and symptoms have changed over time or in response to an intervention. This is applicable to a wide range of conditions, diseases and injuries and helps progressive management through recognition of effects on the patient's abilities (5).

Patients with pain or symptoms arising at the spinal column level can be assessed through PRO measures by determining their functional status and level of health (3, 6). These PRO measures may be regional, designed to assess a region of the body, or they may be specific to a single joint, condition or pathology.

Most of the PRO measures related to the spine are divided into sub-regions of the neck and back, which prevents their use in the assessment of the entire spine (6-8). In contrast, there are fewer PRO measures that assess the spine from cervical to lumbar as a single kinetic chain (6). Unfortunately, many of the outcome measures reported by patients for the entire spine have been criticized for clinical and practical limitations.

The PRO measures that do not evaluate the spinal column as a whole unit and that are commonly used in Italy are: the Oswestry Disability Index (ODI), the Roland Morris Disability Questionnaire (RMDQ), the Bournemouth Questionnaire (BQ) for low back pain, the Neck Disability Index (NDI), the Neck Bournemouth Questionnaire (NBQ) and the Neck Pain and Disability Scale for neck pain (9-14).

While the PRO measures that evaluate the spine as a single kinetic chain that are usually used in Italy are: the Functional Rating Index (FRI) and the Core Outcomes Measures Index (COMI) (15, 16).

The Spine Functional Index (SFI) is a PRO measure proposed to evaluate the spine as a whole unit. Published in 2013, the SFI has proven to have good clinical properties for both psychometric and practical characteristics (17). These include reliability, validity and internal consistency, specificity regarding spinal problems, sensitivity, easy understanding, speed of compilation, quick and easy scoring (17, 18). The results also showed clinimetric properties preferable to FRI for the evaluation of the entire spine (17, 19).

SFI has been culturally adapted in Spanish, Turkish, Simplified Chinese, Korean, Persian and Polish, with good psychometric properties (20-25). Currently no validated Italian version of the SFI has been published. It is therefore important to adapt the SFI in an Italian version.

The aims of this study were: 1) to translate and culturally adapt the English version of SFI into Italian and 2) to test the measurement properties of the Italian version of SFI according to the COSMIN checklist.

METHODS

The research group of this study is composed of rehabilitation professionals from the Sapienza University of Rome and Department of Rome Aerospace Medicine.

Authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study. Institutional Review Board approval was not required because the administration of these tool was part of the usual process of assessment of these individuals in clinical practice, the research involved the analysis of data collected such that individual subjects cannot be identified in any way (26).

Translation and cultural adaptation

The translation and cultural adaptation of the original version of the SFI into the Italian version was done using a forward and backward method as summarized in **figure 1**. Two independent Italian-language translators with good knowledge of English and external to the work have translated the original version of SFI, producing two different independent versions in Italian. In the next step, an Italian native speaker and out-of-work translator, who had not been involved in any of the previous translations, optimized the two translations and produced a single one in Italian. In the third phase, the version obtained from the optimization process was then independently translated into the original language by two bilingual translators who were not aware of the original version of the questionnaire. In the last phase, the two backward trans-

lated versions of the questionnaire were compared with the original by a focus group composed of three physiotherapists who corrected some spelling, grammar or other errors to minimize the differences from the original version by creating a single version, in order to reach a consensus on the semantic, idiomatic, experiential and conceptual equivalence between the Italian version and the original version of the SFI (27, 28).

Figure 1. Flowchart of the Spine Functional Index (SFI) translation from English to Italian.

Participants

A total of 230 patients diagnosed with musculoskeletal disorders of the spine participated in our study.
All participants were recruited between April and July 2020 and, before joining the study group, signed informed consent and were made aware of the study's objective.
The criteria for inclusion were musculoskeletal pain or symptoms at the level of the spine.
The exclusion criteria were age under 18 years, poor understanding of the Italian language, pregnancy, presence of infections, tumors, fractures, osteoporosis, structural deformity, inflammatory or neurological diseases and cauda equina syndrome.
77 patients performed the re-test after one week. This means that after seven days, 77 individuals have re-tested only and exclusively the SFI, so that its reliability can be known.

Questionnaire administration

All 230 study participants have compiled the SFI and the five comparison scales that we will see later. Since the study was conducted between April and July 2020, due to the impossibility of administering the assessment scales in person, all questionnaires were administered remotely using the Google Forms platform.
A single link was sent to all participants that included informed consent, four mandatory assessment scales (SFI, FRI, EQ-5D and VAS) and two optional ones (NDI and ODI) administered depending on whether the participant had received a diagnosis of neck pain or low back pain, respectively.

Spine Functional Index (SFI)

The SFI is a regional PRO measure consisting of 25 items. Each item has an answer option on a three-point Likert scale: "Yes", "Partially" and "No". These three response options are equivalent to 1, ½ and 0, respectively. It is the same patient who, by completing the scale, will indicate the most appropriate value that best represents his or her situation. It takes about one minute to complete. The score is calculated by adding the 25 items, then multiplied by four and subtracted by 100 to provide a percentage scale that indicates a score related to the functional status of the patients. Therefore, the scale has a total score range from 0% (maximum disability) to 100% (no disability). Up to two missing answers are allowed (17).

Functional Rating Index (FRI)

FRI is a regional PRO measure containing 10 items each rated on a five-point Likert scale. The score for each item varies from 0 to 4 points, where 0 indicates no pain or full ability in functions, and 4 indicates the worst possible pain or inability to perform a certain function, for a maximum total score of 40. The final score is calculated by adding the scores of the 10 items, is then divided by the maximum total score achievable and multiplied by 100% to obtain a percentage scale. The score varies from 0% (no pain or disability) to 100% (worst pain or disability). Only one missing answer is allowed (15).

Oswestry Disability Index (ODI)

The ODI is a PRO measure containing 10 six-point items that assess low back pain. Each item has a score ranging from 0 (no pain/problem) to 5 (maximum pain/problem). The total score is obtained from the sum of the scores of the 10 items, is then divided by the maximum total score achievable and multiplied by 100% to obtain a percentage scale, whose value can vary from 0% (no disability) to 100% (maximum disability). Only one missing answer is allowed. The questionnaire is completed in about 5 minutes and the score is assigned in less than 1 minute (9).

Neck Disability Index (NDI)

The NDI is a PRO measure containing 10 six-point items that evaluate neck pain. Each item can assume a score ranging from 0 (no pain or disability) to 5 (maximum pain or disability), for a total score between 0 and 50 which is interpreted as follows: 0 to 4 - no disability; 5 to 14 - mild disability; 15 to 24 - moderate disability; 25 to 34 - severe disability; greater than 34 - full disability. You can also provide a percentage result by dividing the total score obtained by the maximum total score achievable and then multiplying by 100% to obtain a percentage scale. It is allowed until a missing answer (12).

EuroQol Health Questionnaire 5 Dimensions (EQ-5D)

The EQ-5D is a widely used 6-item questionnaire, not disease-specific, which has proven to be valid and reliable in the Italian population (29). It consists of 5 items with a three-point answer option, representing various aspects of health: mobility, personal care, habitual activities, pain/discomfort/malaise and anxiety/depression. Respondents can independently assess their health in each area by reporting if they have no problems (score 1), some problems (score 2) or extreme problems (score 3). At the end of the questionnaire there is also a visual analogical scale of 100 mm, through which the respondent indicates the self-perceived state of health classifying it between the "worst imaginable state of health" (score 0) and the "best imaginable state of health" (score 100).

Visual Analogue Scale (VAS)

The VAS is represented by a horizontal line, 100 mm long, delimited at its extremities. Patients make a mark along this line, at the point that most accurately expresses the perceived pain. At the point where the sign is located, a score from 0 to 100 is assigned that corresponds exactly to the millimeters that make up the scale. The maximum score is therefore 100 and corresponds to the maximum degree of pain and disability.

Statistical analysis

Statistical analysis was performed by Statistical Package for the Social Sciences (SPSS) 25.00, following the checklist "Consensus-Based Standards for the Selection of Health Status Measurement Instrument" (COSMIN), the reliability and construct validity of the culturally adapted scale were evaluated (30, 31).
The descriptive analysis was used to analyze the data obtained from the sample and the administration of the scales: the average and the standard deviation (DS) of the variables were calculated, as shown in **table I**.

Internal consistency

To verify the internal consistency, Cronbach's α was calculated, the values of α should be in a range of 0.70-0.90 as an indicator of satisfactory homogeneity of the elements within the total scale, otherwise high redundancy is expected for values above 0.90.

Reliability

To assess the reliability of the test-retest, the SFI was administered twice (after seven days to 77 patients) so that the Intraclass Correlation Coefficient (ICC) could be calculated, which should be higher than 0.70 (32). Reliability was good when ICC = 0.70 or more.

Measurement error

To evaluate error, the standard error of measurement (SEM) and minimal detectable change (MDC_{90}) were used. The SEM was calculated as an element from the mean square error (MSE) from the analysis of variance, ANOVA. The MDC is the minimum change in a patient's score that ensures the change is not the result of measurement error. The MDC90 was calculated using the formula: $MDC = SEM \times 1.65 \times \sqrt{2}$, where 1.65 is the z-value that reflects the 90% CI of no change and √2 indicates two measurements assessing change (34).

Validity

Structural validity was determined from maximum likelihood extraction (MLE) with the a-priori extraction requirements being satisfaction of three criteria: Scree Plot inflection, Eigenvalue > 1.0 and variance > 10%. The recommended minimum ratio of five participants-per-item was satisfied (32). Exploratory Factor Analysis (EFA) indicated a single factor structure was likely, therefore more 100 participants were required (35).

Construct validity

In order to evaluate the validity of the SFI construct, participants also compiled a copy of the FRI, ODI, NDI, EQ-5D and VAS (ODI and NDI were compiled according to whether the patient suffered from low back pain or neck pain respectively) to calculate the Pearson Correlation Coefficient (r). This value is necessary to establish the correlation between the SFI score and other instruments to demonstrate the validity of the construct. The correlation values were classified as follows: low: r = 0.00-0.30; moderate: r = 0.30-0.60; high: r ≥ 0.60. The level of significance was set for a P-value less than or equal to 0.05 (36).

Content validity

Floor and ceiling effect are considered to be present if more than 15% of the participants are measured in the maximum or minimum limit score of any PROM. Floor and ceiling effects were calculated in the group of 230 patients for the SFI test-retest and for other tools.

RESULTS

Translation and cross-cultural adaptation

The translation and cultural adaptation were done following the guidelines, and all items corresponded consistently to the original version (**appendix 1**).

Characteristics of the participants

A total of 230 patients diagnosed with musculoskeletal disorders of the spine participated in our study. All participants were recruited between April and July 2020 and, before joining the study group, signed the informed consent and were made aware of the study's objective.

There were 44 patients with neck disorders, 109 patients with back disorders and 77 patients with both regional disorders. Analyzing qualitatively the participants, it can be noted that of the 230 subjects considered, 137 were female (59.6%) and 93 were male (40.4%). In addition, the participants had an average age of 39.06 years (± 15.68), an average height of 170.40 cm (± 8.97) and an average weight of 69.46 kg (± 13.38).

Exploratory factor analysis

For factor analysis the correlation matrix for the Italian version of the SFI was determined as suitable from the Kaiser-Meyer-Oklin values (0.890) and Barlett's Test of Sphericity, as reported in **table II**. This indicated that the correlation matrix was unlikely to be an identity matrix and was therefore suitable for MLE. The Scree Plot (**figure 2**) indicated a one-factor solution as determined by satisfaction of all three *a-priori* factors of the Scree Plot inflection point, Eigenvalue > 1.0 and variance > 10%. EFA revealed a satisfactory percentage of total variance explained by the one factor at 30.2%. The items loading for the one-factor solution for the MLE method are shown in **table III**.

Table I. Descriptive analysis: demographic characteristics.

	n	Minimum	Maximum	Mean	Standard deviation
Age	230	18	88	39.06	15.68
Height (cm)	230	148	196	170.40	8.97
Weight	230	42.0	113.0	69.46	13.38
		Frequency	**Percentage**	**Percentage Validity**	**Cumulative percentage**
Female		137	59.6	59.6	59.6
Male		93	40.4	40.4	100.0
Total		**230**	**100.0**	**100.0**	

Mean and standard deviation of SFI.

Table II. Kaiser-Meyer-Oklin values and Barlett's Test of Sphericity of the Italian version of the Spine Functional Index (SFI).

Kaiser-Meyer-Olkin Measure of Sampling Adequacy	Bartlett's Test of Sphericity
0.890	
Approx. Chi^2	1965.605
df	300
Sig.	.000

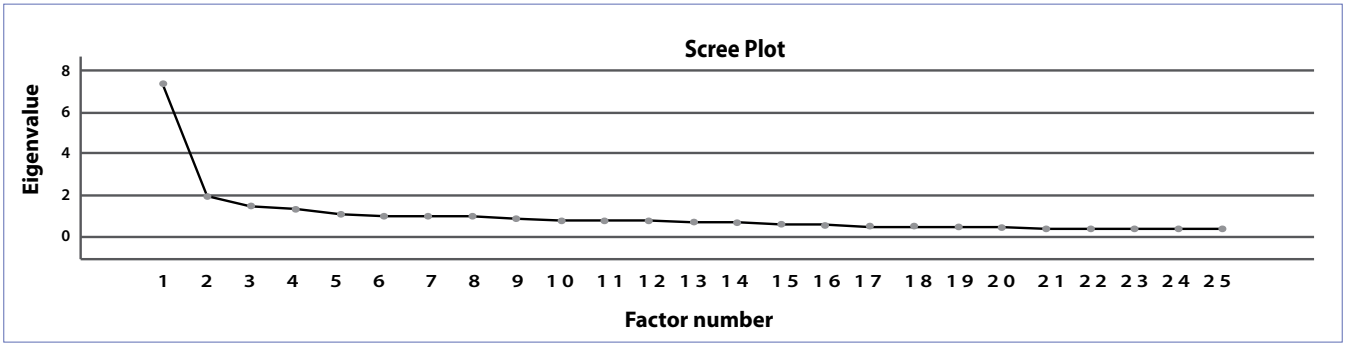

Figure 2. Scree plot of the Italian spinal functional index (SFI).

Table III. Factor loading items for the one-factor solution of the Italian version of the Spine Functional Index (SFI).

Factor	Initial Eigenvalues			Extraction sums of squared loadings			Rotation sums of squared loadings		
	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %	Total	% of variance	Cumulative %
1	7.568	30.274	30.274	6.977	27.907	27.907	2.818	11.272	11.272
2	1.913	7.651	37.925	1.326	5.306	33.213	2.358	9.433	20.705
3	1.458	5.831	43.756	.863	3.452	36.665	2.108	8.434	29.139
4	1.313	5.252	49.008	.839	3.355	40.020	1.781	7.124	36.263
5	1.071	4.282	53.290	.568	2.271	42.291	1.507	6.028	42.291
6	.997	3.987	57.278						
7	.955	3.821	61.099						
8	.922	3.686	64.786						
9	.842	3.369	68.154						
10	.780	3.121	71.275						
11	.714	2.857	74.132						
12	.701	2.805	76.938						
13	.656	2.625	79.562						
14	.623	2.492	82.055						
15	.602	2.407	84.461						
16	.517	2.069	86.531						
17	.481	1.923	88.454						
18	.475	1.901	90.355						
19	.443	1.772	92.127						
20	.385	1.540	93.667						
21	.366	1.462	95.129						
22	.346	1.385	96.514						
23	.315	1.260	97.774						
24	.292	1.169	98.943						
25	.264	1.057	100.000						

Extraction method: maximum likelihood.

Internal consistency

The internal consistency of the SFI was examined through Cronbach's α to verify the homogeneity between the items. The SFI was found to have a good internal consistency, with a Cronbach α of 0.893. This value is between 0.70 and 0.90, showing that the questionnaire has a good internal consistency, which means a good interrelation between the items on the scale. In addition, as can be seen in **table IV**, all items are actually relevant to the scale: if one of them were to be eliminated, the value of Cronbach's α would tend to decrease, thus reducing the internal consistency of the scale.

Reliability and measurement error

SFI was administered to patients twice after 7 days, the Intraclass Correlation Coefficient (ICC) was used to assess the reliability between test and retest. The test-retest reliability, covering only 77 patients of the 230 considered, was good with an Intraclass Correlation Coefficient (ICC) of 0.914 with SEM = 3.51 and MDC 90% CI = 8.17%, as reported in **table V**. The value is above 0.70, demonstrating good instrument stability. This means that following repeated administrations to the same patient after 7 days, the two versions obtained from administrations to the subject are almost identical.

Construct validity

To the participants were also administered the Italian versions of the FRI, ODI, NDI, EQ-5D and VAS so that the construct validity of the SFI could be calculated. The correlation between the SFI scores and the other scales considered was evaluated through the calculation of the Pearson Correlation Coefficient, as reported in **table VI**. Through this statistical test the correlation of the SFI with the FRI is 0.666, with the ODI 0.681, with the NDI 0.574, with the EQ-5D -0.541, and with the VAS 0.438. All correlations are statistically significant ($p < 0.01$). Therefore, the SFI has a good construct validity.

Table IV. Internal consistency: Cronbach's α.

	Scale mean if item deleted	Scale variance if item deleted	Corrected item-total correlation	Cronbach's alpha if item deleted
Item 1	7.507	17.145	.166	.897
Item 2	7.263	16.665	.419	.890
Item 3	7.457	16.249	.459	.890
Item 4	7.480	16.782	.304	.893
Item 5	7.615	16.540	.467	.889
Item 6	7.417	16.493	.455	.890
Item 7	7.452	15.991	.579	.886
Item 8	7.674	16.767	.402	.891
Item 9	7.422	16.107	.560	.887
Item 10	7.530	15.868	.703	.884
Item 11	7.326	16.435	.405	.891
Item 12	7.813	17.393	.322	.892
Item 13	7.541	16.154	.590	.886
Item 14	7.459	16.567	.401	.891
Item 15	7.276	16.398	.520	.888
Item 16	7.709	16.415	.601	.887
Item 17	7.746	16.665	.575	.888
Item 18	7.602	16.253	.572	.887
Item 19	7.611	16.886	.326	.892
Item 20	7.315	16.714	.336	.893
Item 21	7.589	16.264	.520	.888
Item 22	7.537	16.170	.534	.888
Item 23	7.448	15.882	.611	.886
Item 24	7.643	16.418	.492	.889
Item 25	7.654	16.054	.656	.885

Mean and variance if the item is deleted and for each individual item.

Table V. Reliability: Intraclass Correlation Coefficient (ICC) between the test and the retest of 77 participants.

	Intraclass Correlationb	95%CI		F Test with True Value 0			
		Lower bound	Upper bound	Value	df1	df2	Sig.
Average measures	.914[c]	.864	.945	11.780	76	76	.000

Two-way mixed effects model where people effects are random and measures effects are fixed; [a]the estimator is the same whether the interaction effect is present or not, but no result obtained corresponds to the description; [b]Type A intraclass correlation coefficients using an absolute agreement definition; [c]this estimate is computed assuming the interaction effect is absent because it is not estimable otherwise; CI: confident interval.

Table VI. Validity: Pearson Correlation Coefficient between SFI, FRI, ODI, NDI, EQ-5D and VAS.

		SFI	FRI	ODI	NDI	EQ-5D	VAS
SFI	Pearson Correlation	1	.666**	.681**	.574**	-.541**	.438**
	Sig. (2-tailed)		.000	.000	.000	.000	.000
FRI	Pearson Correlation	.666**	1	.850**	.667**	-.716**	.593**
	Sig. (2-tailed)	.000		.000	.000	.000	.000
ODI	Pearson Correlation	.681**	.850**	1	.701**	-.666**	.587**
	Sig. (2-tailed)	.000	.000		.000	.000	.000
NDI	Pearson Correlation	.574**	.667**	.701**	1	-.500**	.379**
	Sig. (2-tailed)	.000	.000	.000		.000	.000
EQ-5D	Pearson Correlation	-.541**	-.716**	-.666**	-.500**	1	-.511**
	Sig. (2-tailed)	.000	.000	.000	.000		.000
VAS	Pearson Correlation	.438**	.593**	.587**	.379**	-.511**	1
	Sig. (2-tailed)	.000	.000	.000	.000	.000	

**Correlation is significant at the 0.01 level (2-tailed).

Content validity

In any PROM weren't found the floor and ceiling effects. Only one patient had the maximum score in the SFI test, no one in the retest and no one in the other tools.

DISCUSSIONS

The purpose of this study is to produce an Italian version of The Spine Functional Index (SFI) that has good validity and reliability.

Translation and cultural adaptation have produced a version which is coherent with the original.

As demonstrated by the results, the SFI is an excellent tool for the evaluation of the spine as a whole unit, in order to be able to simultaneously highlight the presence of neck and back problems.

Gabel *et al.* found that it took 2 minutes to complete the questionnaire, which was acceptable during clinical practice (17). In our study, it was not practical to record the time to complete the SFI because all participants were asked to complete several questionnaires at a time.

As a result of the Exploratory Factor Analysis (EFA), it was shown that the questionnaire had a mono-factorial structure. The internal consistency was evaluated by calculating Cronbach's α, which was equal to 0.893. Moreover, as shown in **table IV**, all the items are actually relevant to the scale: if one of them was eliminated, the value of Cronbach's α would tend to decrease, thus reducing the internal consistency of the scale. Anyway, the Italian version of the SFI has good levels of internal consistency. The values are slightly lower than the previous validations, but it is still possible to compare them; in previous studies, the Cronbach α of SFI was found respectively 0.911 in the original version (17), 0.91 in the Chinese validation (22), 0.88 in the Korean validation (23), 0.80 (between 0.78 and 0.82) in the Persian validation (24), 0.90 (between 0.89 and 0.90) in the Polish validation (25), 0.85 (between 0.80 and 0.88) in the Spanish version (20), 0.85 (between 0.80 and 0.88) in the Turkish version (21).

For the test-retest analysis, as in the other validations, a time interval of one week was used. This means that after seven days, 77 individuals compiled only and exclusively the SFI again, so that their reliability could be known. In this validation, as shown in **table V**, the Intraclass Correlation Coefficient (ICC) is 0.914 (0.864-0.945). The value is higher than 0.70, demonstrating a good stability of the instrument. Also in this case, it is possible to compare the results with those of previous studies, where the ICC was 0.972 in the original version (17), 0.96 in the Chinese validation (22), 0.94 in Korean validation (23), 0.96 (0.83-0.98) in Persian validation (24), 0.97 (0.96-0.98) in Polish validation (25), 0.96 (0.93-0.98) in Spanish validation (20), 0.93 (0.75-0.95) in Turkish validation (21). Considering the ICC values, it is possible to say that the Italian version of the SFI has a very

good stability: this indicates that after repeated measurements, the instrument offers comparable results.
To verify the validity of the SFI construct, to all participants was also administered a copy of the Italian version of the FRI, ODI, NDI, EQ-5D and VAS (ODI and NDI were compiled according to whether the patient suffered from low back pain or neck pain respectively). The agreement between the answers given by the subjects was measured by the Pearson Correlation Coefficient, showing all statistically significant correlations with a value of p less than 0.01. As can be seen in **table VI**, the Italian validation has good correlations with the scales used as comparison, as well as the previous validations. As far as the association with FRI is concerned, the Italian version has shown to have a strong correlation, as well as the Chinese validation (22), where the Pearson r is 0.66. The Korean (23) and Turkish (21) versions have shown, instead, a moderate correlation (0.57, 0.52). Also, with the ODI, the Italian validation shows a strong correlation. In this case the previous versions, Chinese (22) and Turkish (21), show a strong correlation, with a Pearson r of 0.75 and 0.71 respectively. Regarding the correlation with the NDI, this is moderate, according to the Chinese (22), Korean (23), Persian (24), Spanish (20) and Turkish (21) validations, with a Pearson r of 0.61, 0.53, 0.57, 0.46 and 0.58 respectively. The Italian validation and the EQ-5D have a moderate inverse correlation, as well as the Spanish version (20), whose Pearson r is -0.42. Finally, in the Italian validation the correlation with the VAS was found to be moderate, according to the Chinese version (22), where the Pearson r is 0.48.
The comparability of the results obtained indicates that the SFI remained stable within the different cultures.

CONCLUSIONS

This study consists of translation, cultural adaptation and validation of the Spine Functional Index (SFI). The Italian version of the SFI has good psychometric properties: it has a good internal consistency, a good test-retest analysis and a very good construct validity, so it is proven that the SFI is a valid and reliable tool to evaluate the spine as a whole unit, in order to be able to highlight the presence of neck and back problems at the same time.
In conclusion, the questionnaire is short, intuitive, easy to understand and to administer.
This scale is a useful tool for clinicians, and especially for physiotherapists to assess the grade of pathological condition and then to set up a good rehabilitation program also allowing to evaluate the progress achieved after rehabilitation.

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None.

DATA AVAILABILITY

Data are available under reasonable request the corresponding author.

CONTRIBUTIONS

All authors contributed equally to the manuscript and read and approved the final version of the manuscript.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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Appendix 1. Italian version SFI.

SPINE FUNCTIONAL INDEX (SFI)

NOME_____TIPO DI LESIONE_____DATA_____
☐ Collo ☐ Dorso ☐ Lombare

Cortesemente, completare il seguente schema: la colonna vertebrale può rendere difficile svolgere alcune attività di vita quotidiana che normalmente eseguivi. Questo elenco contiene delle frasi che le persone solitamente utilizzano per descrivere la loro condizione. Rispondi al questionario in base ai sintomi avvertiti alla colonna negli ultimi giorni. Se una voce descrive la tua condizione, spunta la casella. Se non la descrive per niente, lasciala vuota. Se la descrive solo in parte, inserisci il segno "1/2".

A causa della mia schiena:

1_____ Sto a casa la maggior parte del tempo.
2_____ Cambio continuamente posizione per trovare sollievo.
3_____ Evito i lavori pesanti (es. pulire, sollevare oltre 5 kg, giardinaggio, etc).
4_____ Riposo più spesso.
5_____ Chiedo ad altre persone di svolgere compiti al mio posto.
6_____ Ho dolori/problemi quasi tutto il tempo.
7_____ Ho difficoltà a sollevare e trasportare oggetti (es. borse, spesa oltre 5 kg).
8_____ Il mio appetito adesso è diverso.
9_____ Le passeggiate, lo svago abituale e le attività sportive sono state influenzate.
10____ Ho difficoltà nello svolgimento dei normali lavori domestici o familiari.
11____ Dormo peggio.
12____ Ho bisogno di assistenza nella cura del mio corpo (es. lavarmi ed igiene personale).
13____ Ne risente lo svolgimento delle abituali attività giornaliere (lavoro, contatti sociali).
14____ Sono più irritabile e di cattivo umore.
15____ Mi sento più debole e/o indolenzito.
16____ È compromessa la mia indipendenza negli spostamenti (guidare, mezzi pubblici).
17____ Ho bisogno di aiuto o sono più lento nel vestirmi.
18____ Ho difficoltà a muovermi nel letto.
19____ Faccio fatica a concentrarmi e/o leggere.
20____ Ho problemi nella posizione seduta.
21____ Ho difficoltà a sedermi ed alzarmi dalla sedia.
22____ Riesco a stare in piedi solo per brevi periodi di tempo.
23____ Ho difficoltà ad accovacciarmi e/o inginocchiarmi.
24____ Ho problemi a tendere il braccio verso il basso (es. prendere oggetti, mettere i calzini).
25____ Salgo le scale più lentamente o uso il corrimano.

PUNTEGGIO SFI: Per dare un punteggio alla parte superiore - somma le caselle spuntate:

_____ **TOTALE (PUNTI SFI)** Scala 100: 100 - (Totale × 4) = ___ %

MDC (90% CI) = Collo: 6.9% o 1.7 punti; Dorso e lombare: 5.9% o 1.5 punti; Tutta la colonna: 6.5% o 1.6 punti

Variazioni in difetto possono essere dovute ad errori.

ORIGINAL ARTICLE

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Toe-In during Sit-To-Stand Reduces Knee Adduction Moment in People with Moderate Knee Osteoarthritis

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SUMMARY

Purpose. Sit-to-stand (STS) is functionally more critical for the independency of people with osteoarthritis (OA). During STS, OA people experience a lot of pain from high sagittal torque. This study investigated the effect of toe-out (T-O) and toe-in (T-I) on knee adduction moment (KAM) and knee flexion moment (KFM) during STS in moderate knee osteoarthritis (KOA) and healthy age-matched people.

Methods. In this cross-sectional study, 19 volunteers with moderate KOA (KOA group) and 15 age-matched healthy individuals (control group) participated. KAM, KFM, peak times, and terminal knee flexion angle were measured using a motion analysis system during STS in normal foot progression angle (FPA), 10° of T-O, and 10° of T-I. The repeated-measures ANOVA was used to determine the effects of group and FPA condition and their interactions on the knee kinetic and kinematic parameters.

Results. T-I reduced the peak KAM significantly in both groups ($p = 0.025$ and $p = 0.05$, respectively). Irrespective of the group, T-O and T-I significantly reduced the peak time of KAM and KFM ($p = 0.003$ and $p = 0.035$, respectively). People with KOA had significantly higher terminal knee flexion than healthy subjects in all FPA conditions.

Conclusions. Ten degrees of toe-in reduced KAM in healthy and KOA people during STS; it may effectively diminish the medial knee contact force in people with KOA.

KEY WORDS

Osteoarthritis; knee joint; foot progression angle; adduction moment; flexion moment; sit to stand.

INTRODUCTION

Osteoarthritis is a chronic degenerative and multifactorial joint disease (1). Knee osteoarthritis (KOA) is the commonest cause of disability in the elderly (2). Worldwide, KOA has a prevalence rate of 7.9%. Prevalence in Iran is 15.3% for urban areas and 19.3% for rural areas, much higher than in other communities. For instance, the prevalence of KOA in India is 5% and 4% in urban and rural areas, respectively. The overall figure for Pakistan is 1.8%. Lastly, 3.1% of Australian aborigines suffer from KOA(3).

People with KOA often complain of pain, decreased range of motion (ROM), muscle weakness, joint stiffness, and instability, which limit their daily physical activities (4): this deprives them of their independence, leading to decreased quality of life (5). The abnormal distribution of force plays an essential role in the degeneration of the medial compartment of the knee joint (6). Given that it is not possible to directly measure knee contact force (KCF), knee adduction moment (KAM) has been introduced as a surrogate measure of KCF (7). Maximum external knee flexion moment (KFM) has garnered the attention of researchers because it is consistent with the onset of KOA (8). Using a musculoskeletal model revealed that the simultaneous application of KAM and KFM provides a more accurate estimate of the internal loading of the knee joint (9).

KAM reduction has been considered in some conservative therapeutic methods, such as gait retraining strategies (10). Gait retraining, either toe-out (T-O) or toe-in (T-I), has been

shown to reduce KAM. Even one T-O gait retraining session permanently reduced the KAM's second peak (11). In addition, a significant relationship has been reported between foot progression angle (FPA) and KAM reduction at the end of the stance phase in healthy individuals and people with varying degrees of KOA.

A study has shown that T-I (an average of 5°) reduces the first peak of KAM by 13% without increasing KFM (10). Another study found that one month after T-I gait retraining, the participants continued to walk with reduced FPA and KAM compared to the initial measurements, indicating that they got used to the new gait pattern due to pain reduction (12). These findings suggest that T-I gait retraining may be helpful as a nonsurgical treatment for individuals with KOA. Although gait retraining has been extensively researched, its effect on daily functional activities such as sit-to-stand (STS) has not been explored precisely. The maximum knee excursion, where the maximum KFM occurs during the stance phase of gait, is 20° (8), much smaller than the knee angle used in STS. Therefore, it is necessary to identify biomechanical differences in the sagittal plane by selecting a more appropriate function with high mechanical demand and a more comprehensive ROM. Since the STS task takes place mainly on the sagittal plane, it can more effectively demonstrate the kinetic and kinematic discrepancies between healthy individuals and people with KOA (2). STS is functionally more significant than walking, or stair climbing due to the knee joint's greater sagittal torque and ROM. The good ROM of the joint and the proper strength of the muscles involved in the torque play a vital role in completing an STS task at the right pace (13). STS is frequently entailed in daily activities and induces high-impact force and pain in KOA people. FPA modification as a conservative therapeutic method may affect this contact force which can be surrogated by the knee joint adduction moment. So, this study aimed to investigate the effect of 10 degrees of T-O and T-I on KAM, KFM, and the peak time during STS. The present study's objective was to explore the effect of FPA condition on KAM and KFM in KOA and healthy age-matched people.

METHODS

Subjects

This cross-sectional study was conducted at the motion analysis laboratory of the Physical Therapy Department of the Tarbiat Modares University. The Medical Ethics Committee of Tarbiat Modares University approved the study (IR.MODARES.REC.1398.057 – Date of approval: May 20, 2019).

The participants were recruited using advertising literature from the Health Center of the authors' affiliated institutions. Forty volunteers, 20 KOA, and 20 healthy people announced their willingness to participate in the study. The inclusion criteria were 25 ≤ BMI ≤ 35, 45-65 years old, not participating in regular or musculoskeletal strengthening programs, and no intra-articular injection in the last six months. The KOA group had grade II or III unilateral KOA, as evidenced by radiographically assessment based on the Kallgren and Lawrence criteria. The exclusion criteria were obvious deformity (especially knee valgus of exceeding 15 degrees, knee varus of more than five degrees, calcaneal eversion, calcaneal inversion, and flat foot), a history of central nervous system disease, lower extremity trauma or surgery, lower extremity joint replacement, and rheumatoid arthritis. In addition, participants who were unable to perform STS without assistive devices were left out. One KOA volunteer was excluded from the study due to severe varus, and five healthy subjects were also excluded due to flat feet (two persons), patellofemoral pain (one person), and lumbar pain (two persons). Finally, 34 volunteers, 19 with KOA (KOA group, ten women and nine men), and 15 healthy age-matched people (control group, five women and ten men), were eligible to enter the study. After being informed about the study, all subjects gave their written consent to the experimental procedure.

Procedure

All assessments were performed in the motion analysis lab from 9 a.m. to 1 p.m. A Vicon motion analysis system (Vicon, Oxford, UK) captured the kinematics parameters using eight cameras (Vero, 2.2 MP, UK) with a sampling frequency of 120 Hz. A standard Plug-In-Gait lower body marker set was used, containing 16 retro-reflective markers. The markers adhered bilaterally on the 2nd metatarsal head, calcanei, malleoli, tibia, femur, femoral epicondyle, and anterior and posterior superior iliac spines. After a static calibration trial, the participants were asked to walk at a comfortable preferred speed along the 5.3 m laboratory walkway. During ordinary walking, the subject's normal FPA was calculated as an angle between the connecting line of the second metatarsal head marker and calcaneus marker and the forward progression line of the body during foot flat. After that, STS was performed at three angles (normal or original FPA, 10-degree T-O, and 10-degree T-I). STS task was performed three times for each FPA, and the KAM (peak and peak time) and KFM (peak and peak time) were measured.

The maximum isometric force of the lower limb muscle groups was measured using a digital handheld dynamometer (Lafayette Instrument Co., Lafayette, IN, USA). The isometric strength of the hip's abductors, adductors, exten-

sors and flexors, knee extensors and flexors, and dorsi and plantar flexors of the ankle were measured bilaterally. Each of the muscular groups was tested three times bilaterally with one minute of rest between repeated tests. The maximum isometric force was recorded for five seconds. The mean of the three repeated tests was considered the muscle strength value. The procedure, which included test positions, stabilized regions, and dynamometer placements, was based on Bohannon *et al.*'s study (14).

STS test

The participants were asked to sit on a height-adjustable stool without back support and armrest to perform the STS. The stool was placed next to the force plate (9286B; Kistler Co., Winterthur, Switzerland) and not on it. The stool height was adjusted in 90/90 flexion of each participant's knee/hip joints while the feet were apart on the force plate. The subjects put their hands on the waist and performed a vertical upward movement into a standing position without moving their feet from the situation.

The participants were asked to perform STS at a comfortable, ordinary speed in three FPA conditions: Normal FPA (original FPA), T-O FPA (10 degrees of T-O related to normal FPA), and T-I FPA (10 degrees of T-I from normal FPA). A sheet of squared paper was used on the force plate to plot FPA individually (**figure 1**). The sampling frequency of the force plate was 1,000 Hz. The affected feet in the KOA group and the nondominant foot in the control group were adjusted on the scaled paper. Thus, the STS test was carried out three times in each FPA condition. A sample of KAM and KFM in the KOA and control groups are shown in **figure 2**. The terminal knee flexion angle (TKFA) at the end of STS, the peak KAM and KFM, and their peak times were measured during STS. The assessor was blinded to grouping.

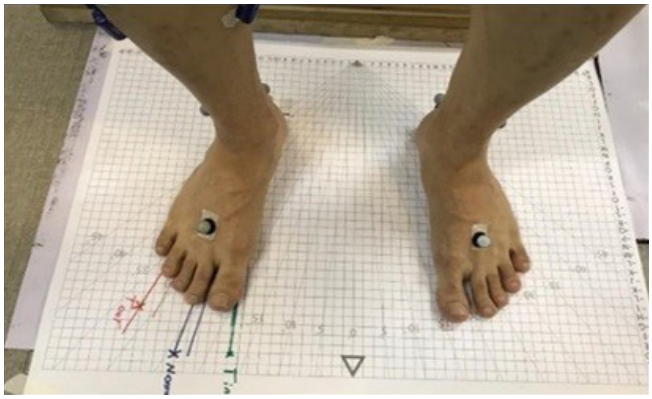

Figure 1. A squared paper on the force plate to set the foot progression angle (FPA).

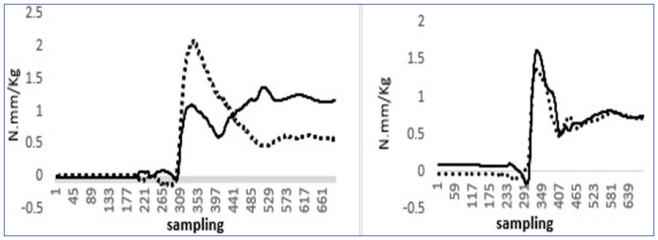

Figure 2. A sample of knee adduction moment (dashed line) and knee flexion moment (solid line) in the normal FPA during sit-to-stand in the KOA group (left) and the control group (right).

FPA: foot progression angle; KOA: knee osteoarthritis.

Data analysis

The normal data distribution was confirmed using the Shapiro-Wilk test ($p > 0.05$). Anthropometric parameters and muscle strength calculated in the KOA and control groups were analyzed using a regular t-test. The repeated-measures ANOVA and Bonferroni *post-hoc* test were used to determine the effects of group and FPA condition and their interactions on the knee kinetic and kinematic parameters during STS. Statistical significance was set at $p \leq 0.05$. SPSS 22 (IBM, NY, USA, 2013) was used for the statistical analysis.

RESULTS

Anthropometric data included age, height, weight, BMI, lower limb length, and normal FPA, and are shown in **table I**. In this regard, there was no significant difference between the two groups ($p > 0.05$).

The values of the MVIC are reported in **table II**. There was a significant decrease in the strength of the hip flexors and extensors, hip abductors and adductors, knee extensors, and ankle plantar flexors in the KOA group compared to the control group. However, ankle dorsiflexion's difference was insignificant ($p = 0.059$).

As **table III** shows, T-I decreased KAM in both groups. Reduction of KAM was significant in both control ($p = 0.050$) and KOA ($p = 0.025$) groups. In the KOA group, peak KAM decreased significantly with T-I compared to normal FPA ($p = 0.042$) and T-O ($p = 0.02$). In the control group, peak KAM showed a significant decrease in T-I compared to T-O ($p = 0.006$). Moreover, the peak time of KAM showed a significant change in the control group ($p < 0.001$), and KOA group ($p = 0.025$). In the KOA group PTKAM in T-O showed a significant decrease compared to normal FPA ($p = 0.034$). In the control group, the peak time of KAM decreased significantly in both T-I ($p = 0.013$) and T-O ($p = 0.003$) compared to normal FPA. Furthermore, the maximum KFM and the peak

Table I. Anthropometric data in the two study groups (mean ± SD).

Variable	Control n = 15	KOA n = 19	P-value
Male/Female	5/10	10/9	NA
Age (year)	51.7 ± 5.23	50.05 ± 6.73	0.63
Height (cm)	167.33 ± 9.44	164.68 ± 7.48	0.36
Weight (kg)	76.67 ± 11.67	76.84 ± 11.3	0.96
BMI (kg/m²)	27.10 ± 2.67	28.13 ± 3.31	0.33
Leg Length (cm)	88.47 ± 6.85	85.37 ± 4.33	0.11
Original (normal) FPA (°)	-8.40 ± 5.95	-8.50 ± 6.45	0.96

SD: standard deviation; KOA: the knee osteoarthritis group; NA: not applicable.

Table II. The maximum isometric voluntary contraction (MVIC) of the lower limb muscles in the two groups (mean ± SD).

MVIC (kg)	KOA group n = 19	Control group n = 15	P-value
Hip flexion	10.75 ± 3.03	13.57 ± 3.30	**0.001**
Hip extension	9.17 ± 2.08	13.01 ± 3.25	**< 0.001**
Hip abduction	9.76 ± 1.65	13.57 ± 3.39	**0.001**
Hip adduction	8.41 ± 2.16	10.92 ± 2.89	**0.007**
Knee extension	8.33 ± 2.10	11.08 ± 3.56	**0.008**
Knee flexion	6.92 ± 1.89	10.01 ± 3.41	**0.006**
Ankle dorsiflexion	7.52 ± 2.28	9.20 ± 2.70	**0.059**
Ankle plantar flexion	9.30 ± 1.57	12.02 ± 2.71	**0.001**

KOA: the knee osteoarthritis group.

Table III. The knee kinetic and kinematic parameters in the STS test in the control and KOA group (mean ± SD).

Variable	Control group n = 15	P-value	KOA group n = 19	P-value
peak KFM N (Nm/kg)	0.99 ± 0.72	0.1	0.51 ± 0.77	0.060
peak KFM T-I (Nm/kg)	0.83 ± 0.58		0.48 ± 0.77	
peak KFM T-O (Nm/kg)	0.90 ± 0.68		0.64 ± 0.87	
PT KFM N (s)	2.60 ± 0.45	0.132	2.57 ± 0.55	0.072
PT KFM T-I (s)	2.09 ± 0.39		2.34 ± 0.56	
PT KFM T-O (s)	2.33 ± 1.04		2.29 ± 0.46	
peak KAM N (Nm/kg)	1.77 ± 0.34	0.050	1.89 ± 0.73	0.025
peak KAM T-I (Nm/kg)	1.65 ± 0.39		1.75 ± 0.62*	
peak KAM T-O (Nm/kg)	1.90 ± 0.49€		1.92 ± 0.74	
PT KAM N (s)	2.48 ± 0.43	< 0.001	2.41 ± 0.54	0.025
PT KAM T-I (s)	2.01 ± 0.39§		2.27 ± 0.53	
PT KAM T-O (s)	1.96 ± 0.36¥		2.15 ± 0.47¥	

KFM: knee flexion moment; N: normal FPA; T-I: toe-in; T-O: toe-out; PT: peak time; KAM: knee adduction moment; KOA: the knee osteoarthritis group; *significant between N and T-I (p = 0.042) and also T-O and T-I (p = 0.02); €significant between T-O and T-I (p = 0.006); §significant between N and T-I (p = 0.013); ¥significant between N and T-O (p = 0.003).

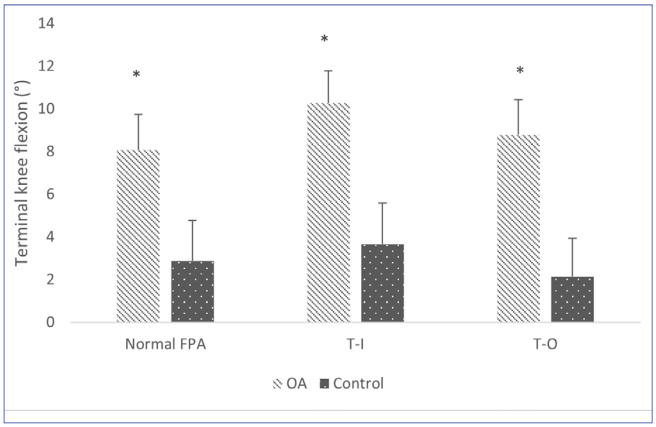

Figure 3. Comparison of the terminal knee flexion angle during sit-to-stand.

N: normal FPA; T-O: toe-out; T-I: toe-in; FPA: foot progression angle; KOA: knee osteoarthritis; *significant change compared to the control group at the same FPA.

time of KFM showed no significant changes in both group. In all FPA conditions, the TKFA was significantly higher in the KOA group than the control group; on the other hand, the TKFA was higher in all FPA conditions compared to the same in the control group (**figure 3**).

The univariate analysis revealed that the main effect of the group was significant for the maximum KFM ($p = 0.017$). Thus, regardless of the FPA condition, the maximum KFM was significantly lower in the KOA group (**figure 4A**). The maximum KAM was higher in the KOA group in all FPA conditions, although this difference did not reach significance ($p = 0.520$, **figure 5A**). T-I decreased the maximum KAM during STS, and T-O increased it compared to STS in normal FPA; the main effect of the group and FPA were insignificant. Moreover, irrespective of whether the knee joint is healthy or osteoarthritic, the peak times of KFM ($p = 0.035$, **figure 4B**) and KAM ($p = 0.003$, **figure 5B**) occurred significantly sooner in the T-O and T-I than in normal FPA.

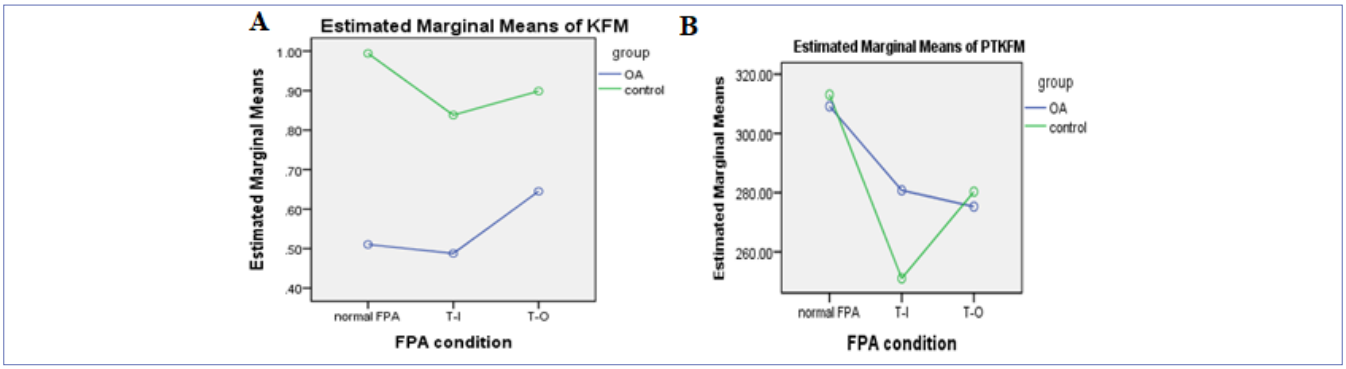

Figure 4. (A) The peak KFM in the three FPA conditions during the STS in the KOA and control group; the main effect of the group being significant ($p = 0.017$); **(B)** The peak time of KFM in the three FPA conditions during the STS in the KOA and control group; the effect of FPA being significant ($p = 0.035$).

KFM: knee flexion moment; FPA: foot progression angle; KOA: knee osteoarthritis.

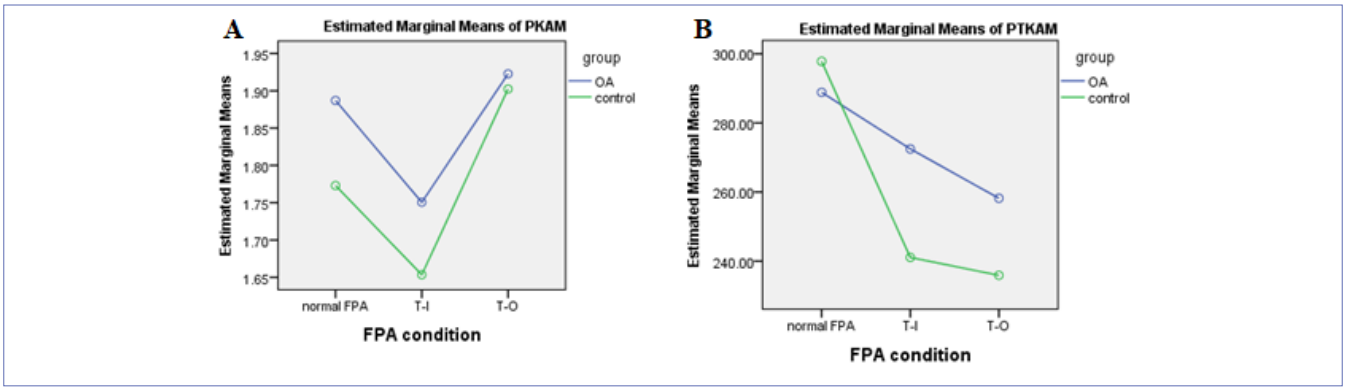

Figure 5. (A) The peak KAM in the three FPA conditions during the STS in the KOA and control group; no significant difference ($p > 0.05$); **(B)** The peak time of KAM in the three FPA conditions during the STS in the KOA and control groups, the effect of FPA being significant ($p = 0.003$).

KAM: knee adduction moment; FPA: foot progression angle; KOA: knee osteoarthritis.

DISCUSSION

This study aimed to investigate the effect of 10 degrees of T-O and T-I on KAM and KFM and their peak times during STS in the KOA and healthy age-matched people. Overall, the results showed an increase in the KAM and a decrease of KFM during STS in the KOA people compared to the age-matched healthy group; however, the rise in KAM was insignificant. A key finding of the present study was that T-I decreased the peak KAM during STS in both KOA and healthy age-matched groups. In addition, T-O and T-I decreased the peak time of the KAM and KFM when compared with STS in the normal FPA. Furthermore, people with KOA had a significantly higher TKFA in all FPA conditions than healthy control subjects. The higher TKFA may be due to an attempt to decrease the load on the knee articular surface and, consequently, pain during the loading phase of STS because Thomas *et al.* showed a condition-related variation in the knee kinematics for changing the joint loading. They concluded this behavior can have a profound influence on the initiation and progression of osteoarthritis of the knee (15). In the current study, the peak KAM in the KOA group was higher than in healthy individuals in all three FPA conditions, but this difference was insignificant. This finding accords with Sonoo *et al.*, where no significant differences were reported between the KOA and healthy individuals in terms of KAM (2). Of course, it should also be noted that the role of KAM is less through STS than walking (12).

Furthermore, increasing the lateral lean of the trunk to the healthy side may prevent KAM changing (16). Finally, we excluded the participants with varus and valgus deformities; these deformities in the knee joint significantly affect KAM. The knee varus is one of the best predictors of increasing the KAM (17). The lower KFM in people with KOA may be a cautious behavior to decrease knee contact force and knee pain during STS. Electromyography for recording trunk and lower limb muscle activities during STS might help clarify detailed strategies. Of course, in the present study, we showed a significant reduction of MVIC in the KOA people, so they probably have to co-contract muscles around the knee joint that will increase the knee contact forces (18).

During STS with T-I, a significant decrease in KAM was observed in both groups. Khan *et al.* showed that T-I reduced the adduction moment impulse at all walking speeds and that the T-I gait pattern at the highest walking speed reduced the peak of KAM (19). Also, Booij *et al.* showed that the T-I gait causes the most significant instantaneous reduction in KAM (20). Unlike some studies that have shown a decrease in KAM with T-O during walking, in the present study, KAM increased with T-O during STS, which was more significant than T-I in both groups. Turkot *et al.* examined FPA conditions during STS in healthy young people and explored the effect of T-O (10°, 20°, and 30°) in one foot or both feet on the reduction of KFM. They attributed the decrease in KFM to shifting weight to the contralateral leg due to the unusualness of the task (21).

Theoretically, T-I reduces KAM by displacing the center of pressure laterally and the center of the knee joint medially in the early stance (22). Further, T-I causes the external shift of the center of pressure with external heel rotation around a relatively fixed position of the forefoot (10). This outward shift can also be observed in T-O but with the external displacement of the forefoot. It is important to note that the current study explored the immediate effect of FPA conditions. So, long-term retraining should be considered to determine the impact of gait retraining on essential daily activities such as STS by forming adaptive patterns (23); STS is vital to the indecency of older adults with KOA. Given that T-I during the STS activity reduced KAM in the present study, and this parameter reflects increased internal loading in the tibiofemoral joint, it may be advisable for KOA patients with severe pain during STS to adopt the T-I condition during this activity.

We found that the main effect of the FPA condition was significant in decreasing the peak time of the KAM and KFM. Regardless of the knee joint condition (healthy or OA), the peak time of the KAM and KFM in T-O and T-I decreased compared to normal FPA. This reduction might be related to performing an unusual task that needs more caution to control balance. It may be associated with the early recruiting of fast motor units to maintain balance and perform an unusual sit-to-stand task. Unfortunately, we could not compare this result with other studies because the peak time of KAM and KFM during STS has not been subjected to scientific research, a fact mentioned by Sonoo *et al.* (2). Athletes and people undertaking intense physical activity are at high risk to develop early KOA (24), we suggest the investigation of gait retraining, especially with 10 degrees of toe-in in these target groups with KOA. Pain decrease and improvement of quality of life in these highly active people are very important. They are younger and more cooperative in the exercise program, and they may report better results.

A limitation of the present study was the small sample size. Also, it is better to consider trunk changes during STS; unfortunately, we used the Plug-In-Gait lower body marker set and neglected the flexion of the trunk during STS. Another limitation was the lack of simultaneous recording of electromyography, which will be very important in determining the muscle strategy of KOA and healthy people

during STS in different FPA conditions. In the present study, we investigated the immediate effect of FPA modification on knee moments. In future studies, the effect of adaptations made in FPA following long-term gait retraining should be considered on the knee moments and contact forces in functional activities such as STS and stair climbing in KOA people.

CONCLUSIONS

The results revealed that people with KOA had significantly higher terminal knee flexion during STS in all FPA conditions. This may be due to an attempt to decrease the load on the knee articular surface and, consequently, the pain during STS. In addition, the immediate effect of FPA modification at 10 degrees of T-I in both healthy and KOA groups reduced KAM during STS, which may effectively diminish knee joint loading. Therefore, adopting a T-I condition during STS can be recommended in KOA patients with severe pain. The shorter peak time of KAM and KFM in healthy and KOA people during STS at 10° T-I and T-O may indicate early recruitment of faster motor units to control balance while performing an unusual task.

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DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

GT: conceptualization, design. FF, SG: data acquisition. FF, SG, GT: data analysis and interpretation, writing – original draft. GT: writing – review & editing. All authors: manuscript approval.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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REVIEW

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The Role of Monitoring of the Board of Statutory Auditors in the Management of the Italian Hospitals

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SUMMARY
Italian public hospitals are healthcare companies whose actions must be informed by the principles of effectiveness and their management follows the principles of efficiency and economy. The Italian Council of Chartered Accountants and Accounting Experts defines the range of actions of the Board of Statutory Auditors to prevent inadequacies. The Board of Statutory Auditors has privileged relationships with stakeholders in the management activities of the Hospitals. The Board of Statutory Auditors is a corporate body and reports to the General Manager in a hierarchical system. The function of the Board of Statutory Auditors is to control legality. The Board of Statutory Auditors verifies compliance with Italian Statute and the public hospital statute. The BSA also verifies the adequacy of the administrative and accounting organization, and the correct administration of the company, reporting any relevant facts to the region. In the event of mistakes or improper management of the hospital, they are deemed responsible, together with the hospital directors, if the damage could have been avoided if they had supervised as required by law. The purpose of this article is to report the activity and the duties of the Board of Statutory Auditors as an inspector in the management of Hospitals in Italy.

KEY WORDS
Board of statutory auditors; health care; statutory auditors; public health; Italian hospital; hospital management.

INTRODUCTION

According to Italian civil Statute, an internal control organism for public or private entities of any nature which conduct economic activities is mandatory. Most of the specific legislation which regulates the duties, functioning, and responsibilities of the internal control organism in public entities originates from the civil legislation envisaged for capital companies. Indeed, according to the company law reform, any capital company must adopt one control system. These internal control organisms could be represented by the Board of Statutory Auditors (BSA) or other less commonly used organisms, such as the dualistic or the unitary board systems (1, 2). Italian public hospitals are healthcare companies whose actions must be informed by the principles of effectiveness and their management follows the principles of efficiency and economy. Therefore, the statutory legislation of the BSA for capital companies applies in full to the BSA of public hospitals and constitutes their primary regulatory source. The specific regulation of the BSA of public hospitals is regulated at the national level, and the regional regulations integrate the national legislation.

Election of the statutory auditors

The BSA is composed of 3 or 5 members called "Statutory Auditors" (3). The first members are elected by the deed of incorporation by the General Director of the hospital through a specific provision (4). The BSA nominate new members until the necessary number is restored, normally five. The State or Public institutions can in exceptional circumstances provide additional members. In the event of

revocation or resignation of a member of the BSA, a substitute will succeed, most of the time in order of seniority. The General Manager is responsible for re-establishing the BSA in the absence of members following death, resignation, forfeiture, or re-establishment. If General Manager does not reconstitute the BSA within thirty days, the region itself will provide the extraordinary reconstitution through two officials designated by the Italian Minister of Economy and Finance and an official designated by the region. The extraordinary BSA interrupts its functions when the ordinary BSA is appointed. The BSA remains in office for three years and is made up of three designated officials: one from the Region, one by the Italian Minister of Health, and one by the Minister of Economy and Finance.

Important professional skills are also required for the members to perform the functions of statutory auditors in public hospitals in Italy. The members of the BSA are chosen from those listed in the register of auditors of the Ministry of Economy and Finance or in the professional registers of chartered accountants and accounting experts, lawyers and labor consultants, or must be tenured university professors in economics or law. At least one statutory auditor and one alternate auditor must be entered in the register of auditors kept at the Ministry of Economy and Finance. Cancellation from these registers causes forfeiture of the office.

Incompatibility

Director, spouse, relative, and/or in-laws within the fourth degree of the directors of the hospital or other individuals who have a direct relationship with the hospital or controlling agencies are incompatible to become a member of the BSA (5). Cancellation or suspension from the register of statutory auditors or loss of the professional requirements required also represent a cause of incompatibility (6). Civilian employees of the State, parliamentarians in companies which manage services on behalf of the State (7), and members of the Superior Council of the Judiciary (if elected by Parliament) are not allowed to become statutory auditors (8). Other less common causes of incompatibility are envisaged by Italian civil Statute (9).

Term of office

The statutory auditors remain in charge until the end of their mandate which is typically established at three financial years. Once the assignment of a statutory advisor has been accepted, this should be registered in the Italian Companies Register by the administrative organism within 30 days. The BSA must assemble at least every 90 days. Minutes of the meetings are recorded in the register of meetings and resolutions of the BSA. The statutory auditors who do not participate without reason in two meetings in a financial year are forfeited (10). The BSA can deliberate if the majority of the members are present and the resolutions are approved by the absolute majority (11). The statutory auditors must attend the meetings of the Board of Directors of the hospital (3). In case of need, if they have to report on particular facts, the statutory auditors can convene extraordinary assemblies.

The function of the BSA

The function of the BSA is to control legality. The BSA verifies compliance with Italian law and the public hospital statute. The BSA also verifies the adequacy of the administrative and accounting organization, and the correct administration of the company, reporting any relevant facts to the region (12).

In the event of mistakes or improper management of the hospital, they are deemed responsible, together with the hospital directors, if the damage could have been avoided if they had supervised as required by law. In these cases, the hospital may also initiate liability action against the statutory auditors (13). The Italian Supreme Court has established that the violation of the duties of supervision, diligence, correctness, and good faith also exists in omissive conduct, such as the failure to detect macroscopic violations by the hospital directors, or in the failure to react to the conduct of dubious legitimacy, for example by informing the BSA.

Inspection power of the BSA

The statutory auditors may conduct inspections and controls at any time during the company life. The BSA can demand anytime the information or explanation to the hospital directors on the progress of corporate operations or specific business covenants. The BSA exchange information with the corresponding figures of the subsidiaries regarding the administration and control systems and the general trend of the public hospital business. The Board collaborates, within the scope of its professional mandate, with any other internal and external control structure following national and regional legislation or by provisions of administrative practice. During their inspection and control operations, the statutory auditors, under their responsibility and at their own expense, may make use of their employees and auxiliaries (9). However, the administrative body may refuse access to confidential information to the auxiliaries and employees of the statutory auditors (14, 15).

The BSA in public hospitals

The duties of the BSA in Italian public hospitals are regulated by civil law (4, 16). In Italian public hospitals, the BSA verifies the administration of the company from an economic point of view, monitoring compliance with the law, ascertain-

ing the regular keeping of the accounts and the compliance of the financial statements with the results of the accounting books and records, and conducting periodic cash audits. In this respect, the BSA reports to the region at least quarterly or on request the results of the verifications, or exceptionally in case of founded suspicion of irregularities.

To accomplish its function, the BSA of public hospitals in Italy verifies the acts of the administrative procedure, evaluates the control environment (management and internal control) and inventory management, analyses the tax, financial and treasury management, accounting and budget system, and controls the personnel, social security and welfare management.

In this respect, the BSA reunites periodically, sending their reports of each meeting to the General Manager and the other directors of the hospital, to the region, and the mayor of the city. All meetings are documented and saved into an online software (Progetto Informatico Sindaci ASL, P.I.S.A) since 2012 (17-20). In this software is also possible to verify the personal data of the Statutory Auditors, the report of each meeting and related minutes. This online software allows also access to the regions.

The BSA, with the support of the competent company structures, participates in the collaborative control of the Court of Auditors by filling in and sending to the regional Control Sections questionnaires which must show, in particular, the acknowledgement of observance of the restriction outlined in debt matters under article 119, last paragraph, of the Italian Constitution, and the evidence of any serious accounting and filing irregularity (21).

THE REFERENCE PRINCIPLES

Principles of conduct of the BSA recommended by the CNDCEC

In October 2016, the Italian National Council of Chartered Accountants and Accounting Experts issued the document (CNDCEC) entitled "The verification activity of the BSA in Local Health Agencies and Hospital Health Agencies (L'attività di verifica del Collegio sindacale nelle Aziende Sanitarie Locali e nelle Aziende Sanitarie Ospedaliere)". With this document, the National Council, in support of all subjects who approach these types of companies, has mainly pursued the aim of outlining the activity of the BSA in the Italian public hospital. This document, addressed to operators in general, provides indications relating exclusively to the national legislation on the management of Italian public hospitals. The provisions contained therein are divided into seven chapters (**table I**). This document provided to the category an operational and interpretative contribution aimed at strengthening the efficiency and effectiveness of the supervisory activity of the Statutory Auditors.

National accounting standards

To understand the importance of the national accounting standards issued by the Italian Accounting Organisation, it is essential to know the accounting excursus conducted by the Italian public hospitals to move from the financial accounting system, introduced with the creation of the National Health Service in 1978, to an economic-patrimonial accounting system. The necessary to verify whether the

Table I. Summary of the document "The verification activity of the BSA in Local Health Authorities and Hospital Health Authorities".

Chapter	Title	Description
I	Purpose	The purposes of the document are identified as a tool to support professionals called to assume the role of auditors in Local Health Trusts and Hospital Health Trusts, delimiting their duties and responsibilities
II	Scope of application	The territorial scope of application of the document in question is the superordinate one at national level. In fact, at the same time, the need to decline its application in accordance with regional legislation is highlighted
III	Institutional stakeholders	According to UNI ISO 26000, those who are the institutional stakeholders with whom the BSA has privileged relations are defined. All those who have any interest in the decisions or activities of an organization are defined as such
IV	Regulatory framework	The current national legislation on the subject of the BSA in the ASL and ASO is listed
V	General aspects	Outlines the fundamental aspects that regulate and qualify the activity of the BSA in the ASL and ASO from the appointment to the most salient aspects of their activity
VI	Control of administrative and accounting regularity	Indicates the sphere of control and activity of the BSA, as well as the indications for the meetings and the methods for taking minutes of the same
VII	Opinions and reports	Indicates which opinions and reports the panel must produce by outlining the salient contents

company is achieving its objective of existing economically, *i.e.*, of remunerating the costs of the production factors through revenues and not only the objective of financial balance, has led the healthcare companies to draw up a budget for the year that was no longer just a cash flow statement. In the initial phase, both accounting systems were maintained due to the delay in approving the national guidelines for the introduction of economic and equity accounting. This financial accounting was then abolished (22) and since 2002, all healthcare companies have adopted exclusively economic-patrimonial accounting. This phase was characterized by an increasing differentiation of regional accounting rules for the health sector, which contributed to creating inter-regional heterogeneity. Before the 2011 budget reform, this heterogeneity was accentuated by the choice of the national legislator not to extend the provisions of the Civil Code on the budget to public hospitals, leaving the decision to the regions. The only elements of national uniformity were limited to consolidation purposes. The lack of homogeneity in the budgets and accounting principles of Italian regions had as a consequence the difficulty of making comparisons between the different Italian regional health organizations. Furthermore, it was also difficult to compare the regimes over time due to the continuing instability of the regional accounting regulatory framework. The accounting autonomy of the regions led to the adoption of accounting principles of limited objectivity. The need to have reliable and comparable budgets became a priority in 2004 (23). It provided that regions with significant management deficits in their health service could receive coverage only if they signed up for a recovery plan with the State with a maximum duration of three years. The reliability of the data in the balance sheets of the health authorities thus became very important since the regions were now responsible for settling the operating deficits produced by their health systems. In June 2011 the definition of homogeneous accounting principles and structured budget schemes entered uniform for all Italian regions, definitively overcoming the condition of "accounting federalism" which had characterized the Italian health sector for a long time (24). This reform, which falls within the European context of creating comparable and verifiable reporting mechanisms of public expenditure, constitutes the reference framework for the accounting system of public healthcare companies. The most relevant architrave that emerges is the new accounting model, which conveys the reference model of the financial statements of the entities of the national health service closer to those envisaged by civil law on financial enterprises.

THE REPORT OF THE BOARD OF STATUTORY AUDITORS ON THE FINANCIAL MANAGEMENT

Documents

The financial statements (25), once adopted by the General Manager with a specific provision, are sent to the BSA which must express, through a specific report, its opinion on whether or not to approve this document. The report of the BSA on the financial statements constitutes one of the most important acts of its activity, as this document will provide assessments and judgments on the administrative-accounting regularity of the management, and assessments regarding the results achieved by the hospital management in the year. In particular, in its report, the BSA must first give evidence that the financial statements are composed and accompanied by all the documents required (26): income statement, balance sheet, cash flow statement, explanatory note, and the management Report of General Manager for the closing year and the previous year (27).

Essential contents of the opinion on the financial statements

Management from an economic-financial point of view

The report of the BSA must provide a detailed analysis of compliance with the requirement of stability of budget balances. In particular, if the financial statements being examined were to close with a loss for the year, the BSA will have to ascertain that the same has been contained within the limit authorized, with a specific resolution, by the region. Otherwise, if the loss should be greater than that authorized by the region, the BSA must ensure that the hospital has adopted the appropriate measures to bring corporate management back into balance. Safeguarding the financial balance requires, however, that the analysis of the BSA is not limited to the economic results of the reference year, but also extends to past losses, ascertaining that the same, although formally authorized, have been covered with a specific regional measure.

Regularity and correctness of the accounting system

The verification of the regular administration and the compliance of the financial statements with the economic and patrimonial outcomes falls in the report of the supervision of administrative and account regularity. In its report, the BSA summarize the results of the administrative and accounting activities conducted during the year, highlighting whether, during the controls, irregularities were found in the management and/or in the keeping of the records and accountants. In this regard, the BSA reports if particular critical issues have emerged within the administrative controls. The BSA verifies

the correspondence between the finances resulting from the accounting records of the hospital and those resulting from the accounts of the Treasurer Institute and the Treasury of the Bank of Italy (28, 29). Through controls on collection and payment orders, attesting or not the correct management of the cash desks, the ticket cash desks, the pharmacy warehouse, the unified warehouse (financial and technical), the correct and timely fulfilment of withholding payments and other sums due to the tax authorities and contributions due to social security institutions, and the successful presentation of all tax returns.

Correspondence between accounting records and balance sheet data

The BSA ascertains the correspondence of the financial reports in the statements with the accounting records. More specifically, the findings of the BSA on the financial balance records aim mainly at verifying the correspondence between the amount indicated in the financial statements for each financial asset and the corresponding balance from the inventory and warehouse entries, the correspondence between the balance of the treasurer institution and that of the liquid assets resulting from the accounting records. Moreover, the BSA controls if the credits from the Region have been subject to specific reconciliation with the competent regional offices if the main credits and debits have been duly circulated, and if the credits for capital grants from the State, the Region, and/ or other public bodies are supported by a specific allocation provision. Concerning the income statement, the BSA verify the correspondence of the account balances contained therein with those resulting from the closure of the related accounts.

Observance of the accounting principles and specific valuation principles for the Italian public hospitals

In compliance with current general and hospital-specific legislation, the BSA verify that the valuation of the items was made according to prudence and to continue the business and that the recognition and presentation of the items have been conducted considering the transactions or contracts (30). Moreover, the BSA verify if fixed assets (tangible and intangible) and those purchased with operating grants have been depreciated (31), and the costs of inventories of non-fungible assets have been calculated according to the weighted average method (31). In this instance, the BSA also should control that the contributions to cover losses correspond to the regional resolutions, that the doubtful debt provisions have been quantified taking into account the risks of bad debts, and that the registration of the provisions for risks and charges and their relative use have taken place in compliance with current legislation and accounting principles, relieving any critical issues due to any title. The BSA attest also that the unused portions of tied current contributions have been set aside in the appropriate expense funds.

Table II. The eight financial postulates.

Postulate	Title	Description
I	Continuity	Each evaluation must take place "in the perspective of the continuation of the activity"
II	Prudence	It is not possible to enter profits not yet realized in the financial statements while, on the other hand, it is necessary to enter all losses, even if presumed, and all foreseeable risks
III	Prevalence of substance over form	The principle of making the substance of corporate operations prevail over the form assumed
IV	Jurisdiction	The entry "of the income and expenses pertaining to the year, regardless of the date of collection or payment"
V	Separate valuation of the heterogeneous elements included in the individual items	Individual operations or cycles of operations in progress at the reporting date must be considered separately on the basis of their expected future outcome. Separate valuation, by imposing separate estimates and conjectures, prevents the compensation between positive and negative gross margins accrued on heterogeneous elements
VI	Constancy of valuation criteria	Valuation criteria cannot be changed from one year to another. The provision serves to guarantee the comparability of the financial statement values from one financial year to another.
VII	Comparability	The amount of the corresponding item from the previous year must be indicated for each item in the balance sheet and income statement
VIII	Relevance	It is not necessary to comply with the recognition, measurement, presentation and disclosure obligations when compliance with them has irrelevant effects in order to give a true and fair view of the financial statements.

Observance of drafting regulatory precepts

Once the preliminary controls have been conducted, the BSA analyses that the contents of the financial statements have been managed in compliance with the general principles of preparation of the financial statements envisaged by Italian law (32, 33). In addition, the BSA must approve that the administration of public hospitals has followed the following eight financial postulates (**table II**).

Presence of financial accounting regularity

The annual report of the BSA on financial management certifies the presence of general financial accounting regularity on the following points:

1. the correspondence of data reported in the annual financial statement of the general financial accounting with the predictions and estimations of the BSA conducted during the management;
2. the existence of assets and liabilities and their correct exposure in the balance sheet and the reliability of the valuations in the financial statements;
3. the correctness of the financial, economic, and equity results of management;
4. the accuracy and clarity of the data presented in the accounting schedules and related attachments;
5. the compliance with the public finance constraints, as envisaged by the regional and national legislation on the matter.

Concluding, the report of the BSA must be concluded with an explicit opinion according to their annual evaluation: positive without findings, positive with findings, or negative. In case of "positive with findings" or "negative" judgments, the BSA must analytically explain in the report the reasons supporting this decision. Moreover, in case of a "negative" judgment, the BSA must immediately inform the Region as supervising administration.

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None.

DATA AVAILABILITY

All data are presented in the current review.

CONTRIBUTIONS

MF: writing - original draft, writing review & editing. MA: writing - original draft, writing review & editing, project management.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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27. Legislative 118 of 2011, Ministerial Decree March 20 2013.
28. Article 2403, Italian Civil Code.
29. Article 20, Paragraph 2, Legislative 123 of 2011.
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REVIEW

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Targeted Injection can Improve Groin Pain Management in Osteitis Pubis: A Narrative Review

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SUMMARY

Introduction. The strategy of choice for the treatment of groin osteitis pubis is conservative treatment, and the treatment effectiveness increases when it relies on an individualized multimodal rehabilitative management. Osteitis pubis is a very common occurrence among athletes: it makes up 5-13% of injuries in male soccer players and 4-5% in female athletes, and it is frequently hard to locate and diagnose.

Methods. A literature review using online databases was carried out regarding the use of steroid injections for groin pain and sport related pubalgia. Articles were extracted from PubMed, Google Scholar, Medline, UpToDate, Embase and Web of Science, combining the terms "groin pain", "pubalgia", "injection in groin pain", "adductor pain", "adductor rectus syndrome" and "injections in pubalgia" as keywords for the research.

Results. The search yielded numerous papers, and 21 full-text articles were considered useful and screened. The review included trials and systemic or narrative reviews, recent guidelines and any report thought of with good methodological quality.

Discussion. The use of corticosteroid injections in the treatment of athletes with other myo-aponeurotic injuries has been reported to reduce pain and return an athlete to preinjury activity. Guided peritendinous infiltrations was already proposed as a valid minimally invasive option for fastening recovering from GPS during the conservative treatment of osteitis pubis and should be considered before approaching the area surgically.

Conclusions. Given the elevate occurrence of osteitis on groin pain imaging of chronic painful pubis, patients who present this inflammatory condition may benefit from the creation of tailored protocols of muscle strengthening exercises and early mini-invasive procedures, as per common clinical practice evidence and US guided injections performed in early stages could faster recovery and rehabilitation outcomes.

KEY WORDS

Groin pain; US guided steroid injections; pubalgia management; rectus adductor syndrome; osteitis pubis.

INTRODUCTION

According to literature "*Osteitis pubis is a common cause of chronic groin pain, especially in athletes*" (1). The strategy of choice for the treatment of groin osteitis pubis is conservative treatment, and the treatment effectiveness increases when it relies on an individualized multimodal rehabilitative management (2). Osteitis pubis is a very common occurrence among athletes: it makes up 5-13% of injuries in male soccer players and 4-5% in female athletes, and it is frequently hard to locate and diagnose (2).

Falvey *et al*. explain that the underdiagnosis of osteitis pubis is due to its non-specific symptoms and the complex anatomy of the groin, gluteal and greater trochanter triangles region; they propose a systemic patho-anatomical approach based on the accurate knowledge of the groin region, on anamnesis and diagnostic maneuvers (3).

To limit the differential diagnosis, the "Doha agreement meeting on terminology and definitions in groin pain in athletes" agreed that the heterogenous taxonomy of groin injuries hindered the diagnostical process, and it developed

a clinically-based taxonomy to standardize the terminology (4). Along with Doha's conference, the "Italian Consensus Conference on terminology, clinical evaluation and imaging assessment in groin pain in athlete" attempted to normalize groin pain syndrome (GRPS) terminology and defined it as "*Any clinical symptom reported by the patient, localized in the inguinal pubic adductor, which affects sporting activity and/or interferes with Activities of Daily Life (ADL), and which requires medical treatment*" (5). In addition to specific taxonomy, the usage of particular clinical examinations may ameliorate the GRPS diagnostical process; in fact, an MRI study will precisely evaluate the presence of muscle tears or complete/partial tendon lesions (3). The most urgent goal of the therapy is to reduce pain and recover the joint range of motion and strength through specific physical exercises (2). The return to sports practice is usually expected within two months for acute clinical pictures, six months for the chronic ones. If chronic groin pain persists, then surgical tenotomy is opted for, which guarantees a return to sport in 50-55% of cases (1, 6). However, physical therapy and rest may not be resolutory in some patients (5, 7).

A targeted groin injection is a common and minimally invasive procedure, performed to successfully treat groin pain, which has also proved its effectiveness in the treatment of osteitis pubis and different enthesopathies. The injections are used to deliver steroids, and sometimes local anesthetics or glucose for prolotherapy, to the peritendinous or periosteous space, directly to the site that causes the pain, with the patient positioned in a "frog-leg" orientation, supine with the hip flexed at 45° (8). This kind of injection is a well-founded anesthetic and analgesic technique; moreover, nowadays, new technological devices can help physician to learn and to administer it (8). Even though it is still not clear which type of conservative intervention is superior, several studies have proved that a single injection is able to increase patients' satisfaction, relieve groin pain and reduce time or recovery or delay more invasive interventions. Although injections should represent a treatment of choice in the case of different acute tendinopathies or joints pain, in our research we focused on the efficacy of targeted different injections in the treatment of groin pain in sportsmen.

The aim of this narrative review is to analyze the mini-invasive treatments of acute, sub-acute and chronic groin pain patients and to understand their current use, application and success in treating this significant widespread pathology in sportsmen.

METHODS

A literature review using online databases was carried out regarding the use of steroid injections for groin pain and sport related pubalgia. Articles were extracted from PubMed, Google Scholar, Medline, UpToDate, Embase and Web of Science, combining the terms "groin pain", "pubalgia", "injection in groin pain", "adductor pain", "adductor rectus syndrome" and "injections in pubalgia" as keywords for the research. Only papers in the English language and regarding human studies were taken into consideration. Non-English language studies were excluded. Scientific publications up to March 2023 were included. Only papers contributing to focus on steroid injections for groin pain or pubalgia were included. All reference lists of the relevant studies were then screened to identify any missing publications. The search and the study selection were performed by all investigators working independently. At the first level, the titles and abstracts of identified studies were screened. At the second level, the full texts were retrieved and assessed. Ethical approval and patient informed consent were not required because this was a review of previously published studies and did not involve direct contact with patients or alterations to patient care. Any discrepancies were resolved by the first author (LDL) through consensus. The following data were extracted from each eligible study: first author's name, publication year, study design, intervention protocol type, and any other relevant data.

RESULTS

The search yielded numerous papers, and 21 full-text articles were considered useful and screened. The review included trials and systemic or narrative reviews, recent guidelines and any report thought of with good methodological quality (**table I**).

Table I. Trials systemic or narrative reviews, recent guidelines and report thought of with good methodological quality.

Article	Study design	Study protocol	Summary of findings
Jacobs MLYE, Scheltinga MRM, Roumen RMH. Persistent pain relief following a single injection of a local anesthetic for neuropathic abdominal wall and groin pain. Scand J Pain. 2021;21(3):628-632. doi: 10.1515/sjpain-2021-0034	This report is an overview based on earlier studies from a center of expertise for neuropathic abdominal wall and groin pain syndromes	A total of 10 studies including 834 patients fulfilled study criteria	When a patient is suspected of having a neuropathic abdominal wall or groin pain syndrome, a single TPI using a local anesthetic agent should be administered as long-term pain relief may occur

Article	Study design	Study protocol	Summary of findings
Jose J, Buller LT, Fokin A, Wodicka R, Subhawong T, Lesniak B. Ultrasound-guided Corticosteroid Injection for the Treatment of Athletic Pubalgia. J Med Ultrasound. 2015;23(2):71-5. doi: 10.1016/j.jmu.2014.11.003	A series of 12 cases	Retrospective analysis	Ultrasound guided actions in pubalgia
Topol GA, Reeves KD. Regenerative injection of elite athletes with career-altering chronic groin pain who fail conservative treatment: a consecutive case series. Am J Phys Med Rehabil. 2008;87(11):890-902. doi: 10.1097/PHM.0b013e31818377b6	Consecutive enrollment of elite performance-limited athletes with chronic groin/abdominal pain who failed a conservative treatment trial	The treatment consisted of monthly injections of 12.5% dextrose in 0.5% lidocaine in abdominal and adductor attachments on the pubis	Athletes returned to full elite-level performance in a timely and sustainable manner after regenerative injection therapy using dextrose
Kim DS, Jeong TY, Kim YK, Chang WH, Yoon JG, Lee SC. Usefulness of a myofascial trigger point injection for groin pain in patients with chronic prostatitis/chronic pelvic pain syndrome: a pilot study. Arch Phys Med Rehabil. 2013;94(5):930-6. doi: 10.1016/j.apmr.2012.12.011	Prospective, unicenter trial	Myofascial trigger point injection for groin pain in patients with chronic prostatitis/chronic pelvic pain syndrome	US-guided trigger point injections are safe and effective for both diagnosis and treatment when the cause of groin pain is suspected to originate from muscles
Schilders E, Bismil Q, Robinson P, O'Connor PJ, Gibbon WW, Talbot JC. Adductor-related groin pain in competitive athletes. Role of adductor enthesis, magnetic resonance imaging, and entheseal pubic cleft injections. J Bone Joint Surg Am. 2007;89(10):2173-8. doi: 10.2106/JBJS.F.00567	Retrospective review analysis	Consecutive series of twenty-four competitive athletes with groin pain secondary to adductor longus dysfunction	A single entheseal pubic cleft injection can be expected to afford at least one year of relief of adductor-related groin pain in a competitive athlete with normal findings on a magnetic resonance imaging scan
Byrne CA, Bowden DJ, Alkhayat A, Kavanagh EC, Eustace SJ. Sports-Related Groin Pain Secondary to Symphysis Pubis Disorders: Correlation Between MRI Findings and Outcome After Fluoroscopy-Guided Injection of Steroid and Local Anesthetic. AJR Am J Roentgenol. 2017;209(2):380-8. doi: 10.2214/AJR.16.17578	Cohort study	Correlation between MRI findings and outcome after fluoroscopy-guided injection of steroid and local anesthetic	Fluoroscopy-guided corticosteroid symphyseal injection is a safe and effective treatment of sports-related groin pain. It is more frequently associated with a complete recovery in patients who display an isolated superior cleft sign on MRI
Schilders E, Talbot JC, Robinson P, Dimitrakopoulou A, Gibbon WW, Bismil Q. Adductor-related groin pain in recreational athletes: role of the adductor enthesis, magnetic resonance imaging, and entheseal pubic cleft injections. J Bone Joint Surg Am. 2009;91(10):2455-60. doi: 10.2106/JBJS.H.01675	Review of a consecutive case series of twenty-eight recreational athletes	Clinical reassessment five minutes after clef injection	Most recreational athletes with adductor enthesopathy have pain relief at one year after entheseal pubic cleft injection
Topol GA, Reeves KD, Hassanein KM. Efficacy of dextrose prolotherapy in elite male kicking-sport athletes with chronic groin pain. Arch Phys Med Rehabil. 2005;86(4):697-702. doi: 10.1016/j.apmr.2004.10.007	Consecutive case series	Twenty-two rugby and 2 soccer players with chronic groin pain	Dextrose prolotherapy showed marked efficacy for chronic groin pain in this group of elite rugby and soccer athletes

Article	Study design	Study protocol	Summary of findings
Brennan D, O'Connell MJ, Ryan M, Cunningham P, Taylor D, Cronin C, *et al*. Secondary cleft sign as a marker of injury in athletes with groin pain: MR image appearance and interpretation. Radiology. 2005;235(1):162-7. doi: 10.1148/radiol.2351040045.	Retrospective image or case record review	Patients study on the basis of radiography and/or MR imaging, also confirmed in each patient during contrast material injection into the central physiologic symphyseal cleft	The secondary cleft sign demonstrated at MR imaging is a marker of groin injury in athletes presenting with groin pain
Drager J, Rasio J, Newhouse A. Athletic Pubalgia (Sports Hernia): Presentation and Treatment. Arthroscopy. 2020;36(12):2952-3. doi: 10.1016/j.arthro.2020.09.022	Cohort open study	MRI can aid in ruling out other pathologies and identify specific findings including tears or strains. Lidocaine injections can be used to localize the source of the pain	If conservative therapy fails to allow an athlete to return to activity, a variety of open or laparoscopic surgical techniques can be used. Numerous studies report a high rate of return to play after surgical management
Bisciotti GN, Chamari K, Cena E, Garcia GR, Vuckovic Z, Bisciotti A, *et al*. The conservative treatment of longstanding adductor-related groin pain syndrome: a critical and systematic review. Biol Sport. 2021;38(1):45-63. doi: 10.5114/biolsport.2020.97669	Systematic review regarding conservative treatment for longstanding adductor-related groin pain syndrome	Screening 234 articles, 19 studies following the inclusion criteria were included and summarized in this current systematic review and seven different types of therapeutic interventions were described	Conservative treatment for longstanding adductor-related groin pain syndrome is limited and characterized by a low level of evidence. Therefore, our recommendation is to refer only to the few studies with higher level of evidence and at to encourage further research in this area
Matsuda DK. Editorial Commentary: Managing Hip Pain, Athletic Pubalgia, Sports Hernia, Core Muscle Injury, and Inguinal Disruption Requires Diagnostic and Therapeutic Expertise. Arthroscopy. 2021;37(7):2391-2. doi: 10.1016/j.arthro.2021.04.027.	Editorial comment	/	In select cases of pubalgia, patients might respond favorably, albeit temporarily, to an intra-articular injection
Scholten PM, Massimi S, Dahmen N, Diamond J, Wyss J. Successful treatment of athletic pubalgia in a lacrosse player with ultrasound-guided needle tenotomy and platelet-rich plasma injection: a case report. PM R. 2015;7(1):79-83. doi: 10.1016/j.pmrj.2014.08.943	Case Report	/	Athletic pubalgia is a syndrome of persistent groin pain due to chronic repetitive trauma or stress involving the pelvic joints structures
McCarthy E, Hegazi TM, Zoga AC, Morrison WB, Meyers WC, Poor AE, *et al*. Ultrasound-guided Interventions for Core and Hip Injuries in Athletes. Radiol Clin North Am. 2016;54(5):875-92. doi: 10.1016/j.rcl.2016.04.008	Review	Literature analysis and narrative summary	Article reviews ultrasonography-guided interventions for injuries at the core, including the pelvis and hips
Julian Ashberg L. Editorial Commentary: The Cause of Groin Pain Is Difficult to Determine: The Elusive "Nether-Nether Region". Arthroscopy. 2021;37(4):1179-81. doi: 10.1016/j.arthro.2021.01.017	Editorial comment	Literature analysis	Combining a clear history, detailed physical, basic and advanced imaging, as well as diagnostic injection is essential

Article	Study design	Study protocol	Summary of findings
Byrne CA, Bowden DJ, Alkhayat A, Kavanagh EC, Eustace SJ. Sports-Related Groin Pain Secondary to Symphysis Pubis Disorders: Correlation Between MRI Findings and Outcome After Fluoroscopy-Guided Injection of Steroid and Local Anesthetic. AJR Am J Roentgenol. 2017;209(2):380-8. doi: 10.2214/AJR.16.17578	Cohort study	104 patients study in open controlled study	Fluoroscopy-guided corticosteroid symphyseal injection is a safe and effective treatment of sports-related groin pain
Branci S. Robinson D, Robinson P. Imaging in long lasting groin pain in athlets. Aspetar Sport Med J. 2014;3. Available at: https://www.aspetar.com/Journal/viewarticle.aspx?id=155	Review	Narrative based on recent literature	Symptoms in this condition appear to be correlated to marked oedema of the pubic bone marrow and parasymphyseal soft tissues or partial disruption of the soft tissues involving the anterior joint capsular, adductor and rectus abdominis tendons (cleft)
Olafsen NP, Herring SA, Orchard JW. Injectable Corticosteroids in Sport. Clin J Sport Med. 2018;28(5):451-6. doi: 10.1097/JSM.0000000000000603	Narrative review	An extensive search of the literature was completed including search terms of corticosteroid, steroid, athlete, and injection, among others. Additional articles were used after being identified from previously reviewed articles	Corticosteroid injections should be used cautiously in athletes and only after a full consideration of the pharmacology, pathogenesis of disease, potential benefits, complications, factors specific to the athlete, and rules of athletic governing bodies. Corticosteroid injections are just one component of a comprehensive rehabilitation plan available to the physician providing care to athletes

DISCUSSION

As with most causes of groin pain, the treatment of groin pain and/or athletic pubalgia begins with a trial of physical therapy (1, 2). Physical therapy and rehabilitation protocols focus on core strengthening exercises that aim to balance the opposing forces of the abdominal musculature and the hip adductors. In general, 6-8 weeks of physical therapy is employed with anti-inflammatory medications, rest, and deep-tissue massage (1, 2). Unfortunately, groin pain rarely responds promptly to such conservative treatment and often requires more invasive management (9, 10). Surgical repair has consequently historically been advocated when conservative measures fail to alleviate pain. Treatment can be open surgery or laparoscopic surgery and patients can expect to return to play within 6 weeks to 6 months (9). The use of corticosteroid injections in the treatment of athletes with other myo-aponeurotic injuries has been reported to reduce pain and return an athlete to preinjury activity (8, 11), hypothesizing that ultrasound US-guided procedures could better alleviate pain and improve function in patients with athletic pubalgia. Because of the potential morbidity and prolonged return to sports-related activity associated with surgical treatment of athletic pubalgia, corticosteroid injections may definitely present a minimally invasive and effective alternative treatment option. Guided peritendinous infiltrations was already proposed as a valid minimally invasive option for fastening recovering from GPS during the conservative treatment of osteitis pubis and should be considered before approaching the area surgically (12). However, the administration of peritendinous infiltrations requires compliance with anti-doping legislation, as peritendinous injections are severely prohibited in-competition. The symphysis pubis is a real hub for muscles such as the rectus abdominis and the adductor muscle complex, and when groin pain occurs, the imbalance between these pelvic muscles, with following microtraumas and injuries, are thought to be the starting mechanism of osteitis. The deficit that interrupts the distribution of

force through the symphysis pubis seems to alter the biomechanics of the articulation, favoring stress injuries and cartilage degeneration. The pain is induced by repetitive exercises and occurs mainly in the lower abdomen and medial thigh. To date, MR allows a more detailed view of this region and it therefore represents the first-line examination. The typical sign of the chronic phase is the presence of a hyperintense subchondral T2 signal at the level of the symphysis (13) (**figures 1, 2**). Sometimes the radiograph demonstrates bone resorption, osteophytes or subchondral cysts (acute phase) where standard treatment will not be suitable (13), and other options will be considered, such as physical therapy for pain control, rest, improvement of lumbopelvic stability, exercises to strengthen

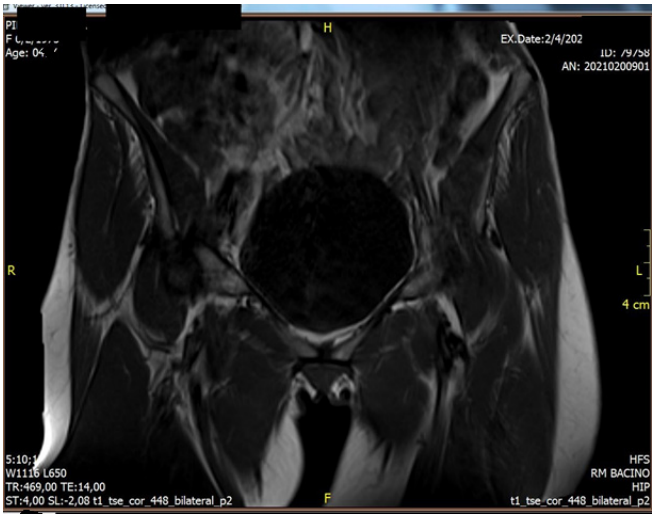

Figure 1. The typical sign of the chronic phase is the presence of a hyperintense subchondral T1 signal at the level of the symphysis.

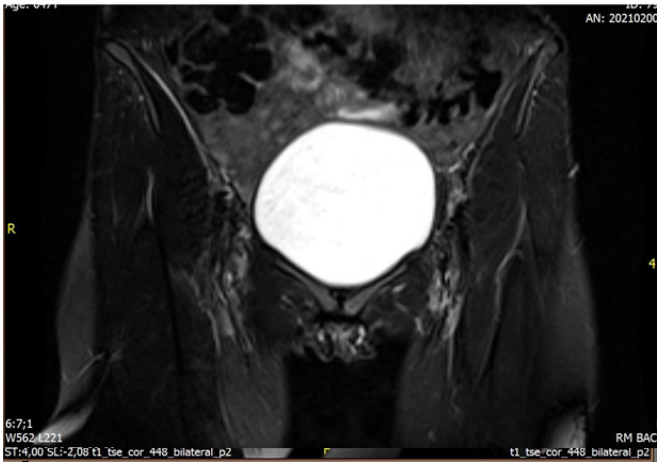

Figure 2. Same patient with hyperintense subchondral at the level of the symphysis.

the pelvic, abdominal, gluteal, adductor, flexor and extensor muscles of the hip (5, 12). The use of physical therapy with shock waves is particularly important in the rehabilitation process, reducing recovery times (1). In our anecdotal experience, according to common clinical practice for groin pathologies, MR has been the first-choice diagnostic exam thanks to the high spatial resolution it allows and its multiplanarity. This is because it enables the accurate evaluation of the alterations at the level of the pubis and of the myo-structures that originate from it. For diagnostic purposes, T1 and T2-weighted images are to be preferred: the former allows the identification of the anatomical structures, the latter allows the detection of any signal anomalies in tendon and bone structures (8-13).

Research on the usage of MRI for GPS diagnosis confirms the utility of MRI for differentiating the clinical phases of GPS, these being the acute phase (occurring within six months since the pain onset) and the chronic phase (after six months since the pain onset) (9). For instance, bone edema, fluid accumulation in the symphysis, and periarticular edema are all signs of a history prior to six months. Edema is the consequence of the action of impact forces which can cause subarticular microtrabecular trauma in the long run. On the contrary, sclerosis and subchondral resorption (cysts), bone irregularities and the presence of osteophytes are the confirmation of a history longer than six months (13-15). Conservative treatment in acute phases can be accompanied by injection therapy with drugs such as dexamethasone, betamethasone and methylprednisolone, and anesthetics such as bupivacaine and lidocaine. More specifically, ultrasound guided injections are an easy procedure and are proved to fasten any tendon pain recovery (8, 10).

CONCLUSIONS

Osteitis pubis is an overload disease that frequently tends to become chronic. Therefore, the achievement of a correct diagnosis and the identification of the most suitable therapy are crucial for the treatment of the condition (1, 4, 5, 14, 15).

All authors initially opted for an early conservative treatment combining physical and manual therapy. Then, mostly performed infiltrations and physical therapy such as ultrasound, laser or shock waves sessions to reduce the extent of the inflammation and fasten the pain relief. Given the elevate occurrence of osteitis on groin pain imaging of chronic painful pubis (14), patients who present this inflammatory condition may benefit from the creation of tailored protocols of muscle strengthening exercises and early mini-invasive procedures, as per common clinical practice evidence. Individualized programs would help patients self-manage recurrent myalgia due to overloading training and prevent further tears and inflammations and seems to

be evidence that guided injections performed in early stages could faster recovery and rehabilitation outcomes.

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DATA AVAILABILITY
N/A.

CONTRIBUTIONS
All authors gave its own contributions refining searching, reading abstract and full text, discussing about them and providing help for the final proof. Any controversial issue was solved by LDL as main author.

CONFLICT OF INTERESTS
The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Effects of Sliding Cupping Therapy on Pain Intensity, Fatigue Perception and Muscle Performance After a 10 Km Run: Protocol for a Sham-Controlled Randomized Clinical Trial

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SUMMARY

Background. Running induces adaptive responses, such as muscle fatigue that alter muscle strength and power. Button cupping therapy has been applied in clinical practice, under the theories that its application influences the microcirculation and the nervous system, however, there is a scarcity of studies that investigate its effects in athletes. In this context, this protocol aims to evaluate the effects of sliding cupping therapy on pain, perception of fatigue and muscle performance after a 10 km run, with the hypothesis that cupping will produce expected changes when it occurs to the other group.

Methods. This is a sham-controlled, randomized, double-blind clinical trial, in which 64 volunteers will be randomly allocated into two groups of 32 participants: intervention group (sliding suction cup with gentle suction on the quadriceps) and sham group (sliding suction cup without compression on the quadriceps). The participants will be evaluated before the race, after the race, immediately, 24 h and 48 h after the intervention, through isokinetic dynamometry, vertical jump test, algometry, and scales of perception of pain and fatigue and perception of recovery. Statistical significance will be set at 5% and a 95% confidence interval (95%CI).

Conclusions. This sham-controlled, randomized and blinded clinical trial protocol may serve as a basis for further research, contributing with a scientific direction for the application of sliding cupping therapy after physical activity.

Study registration. Brazilian Clinical Trials Registry (identifier RBR-10fg77vk).

KEY WORDS

Athletes; fatigue; physical functional performance; recovery of physiological function; running; sliding cupping.

INTRODUCTION

In addition to the various benefits that regular running practice provides (1), we observed the presence of adaptive responses, such as muscle fatigue, which is related to the adaptation mechanism of the neuromuscular system in response to prolonged or intense exercise (2), which it alters the homeostasis of the local musculature and the neural inputs for the motoneurons (3), reducing the strength and speed of muscle contraction, consequently, reducing the power (4), in addition to decreasing the proprioceptive feedback (5).

When the training dosage is not performed properly, the fatigue caused by running can impair performance (6), influence the risk of musculoskeletal injuries in amateur runners (7) and cause acute pain that, when not treated, can worsen or become chronic (8). To help with recovery, some therapeutic resources can be used, such as cryo-immersion (9), massage (10) and cupping therapy (11).

Cupping therapy is widespread as an auxiliary resource in muscle recovery, pain relief and treatment of various alterations (11). Cupping therapy was classified as dry, when a vacuum was used, or wet, when bleeding occurred (12). Currently these classifications have been updated, adding the sliding cup (12). The application of the suction cup mobilizes cutaneous, subcutaneous and muscular tissue, depending on the suction exerted (13), being slid for 5 to 10 minutes. Local vasodilation is observed with the presence of edema that can progress to erythema that disappears in a few days (14).

Although widespread in clinical practice, cupping therapy lacks studies with methodological rigor to substantiate its effectiveness, especially in relation to recovery after physical exertion (11). A study carried out a review addressing some theories about the effects of cupping therapy on microcirculation, but there are few clinical trials that actually prove its effectiveness in recovery (15).

Because of this, the present study aims to describe a clinical study protocol to evaluate the effect of sliding cupping therapy on pain, perception of fatigue and muscle performance in runners after a 10 km run. The hypothesis is that its application will provide better recovery of the evaluated outcomes compared to sham.

METHODS

Study design

This is a protocol for conducting a randomized, double-blind, sham-controlled clinical trial. The study was registered on the Brazilian Clinical Trials Registry (ReBEC) platform, identifier: RBR-10fg77vk and was approved by the Ethics Committee of the Federal University of Rio Grande do Norte (Number: 5.411.218 – Date of approval: May 16, 2022). The study follows the principles described in the Declaration of Helsinki and the privacy of participants is respected in accordance with Resolution 466/12 of the National Health Council. Research reports will be in accordance with the recommendation of the TIDieR (Template for Intervention Description and Replication) (16) and the SPIRIT (Standard Protocol Items: Recommendations for International Trials) checklist (17). The flowchart is shown in **figure 1**.

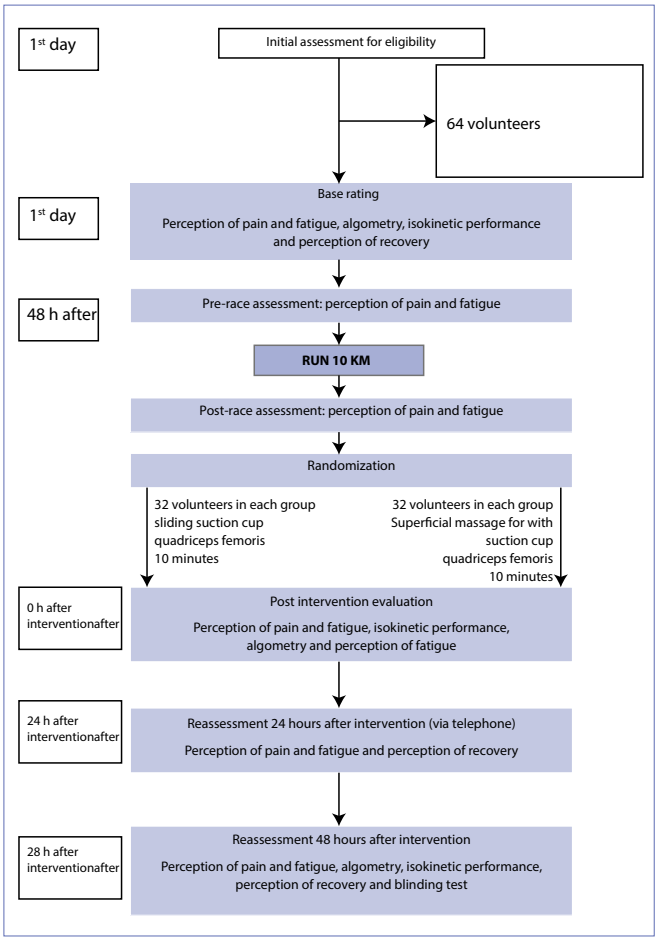

Figure 1. Study flow diagram.

Participants

Participants will be recruited through disclosure on social media and through direct contact with running advisors in the metropolitan region of Natal/RN. The first contact will take place via telephone to schedule the screening, which will

be carried out by a single evaluator. If eligible, participants will be informed about the objectives and procedures of the study and must sign the Informed Consent Form (TCLE).

Inclusion criteria

- Showing disorders in the quadriceps femoris, such as, for example, hematoma and cramps, during the study procedures.
- Failing to complete the 10 km run.
- Failure to correctly perform assessment procedures.
- Make use of anti-inflammatory drugs, corticoids, analgesics or muscle relaxants during the collection period.
- Carry out another type of intervention for muscle recovery during the development of the research.

Research team

This study will involve six researchers. Researcher A: screening and assessments; B: randomization of participants and intervention; C: scheduling of volunteers; D: monitoring of races; E: data tabulation; F: statistical analysis.

Randomization

The randomization table will be generated by researcher B, on the website www.randomization.com. The participants selected in the screening, carried out by researcher A, will be randomly allocated through an individual, opaque and sealed envelope, into two groups: intervention group that will receive the sliding cup, and sham group that will receive cup without negative pressure.

Blinding

All evaluations will be carried out by researcher A, who will not be involved with the interventions and will remain blind to the identification of groups.

Each participant will remain identified by numbers. Participants will be informed about the objective of the study to evaluate the effect of two different cupping techniques: the classic and the sham cupping. During the application of the technique, participants will be positioned in dorsal decubitus with a physical barrier above the hip to prevent visualization of the lower limb. The intervention times will be different so that there is no contact between the groups and possible exchanges of information. The data collected during the evaluations will not be revealed to other researchers.

At the end of the last assessment, each participant will be asked which intervention they believe they have received, in order to verify the effectiveness of the blinding strategy. After the last evaluation, researcher E will tabulate the data that will be delivered to researcher F, responsible for the statistical analysis and who did not participate in the previous stages of the research.

Procedures and interventions

Participants will be informed about the procedures adopted in the research, which will take place at the Neuromuscular Performance Analysis Laboratory (LAPERN), of the Department of Physiotherapy at UFRN. The baseline assessment will take place 48 hours before the race. After the race, there will be a new evaluation. Then, participants will be randomized and receive the intervention and reassessment. 24 h after the intervention, researcher A will contact the participant via telephone to carry out the subjective evaluation, and 48 h after the intervention, the final reassessment will be carried out.

Intervention group

There is no established protocol in the literature, however, one study suggests that, for sliding, humectant should be used, and negative pressure should be gentle, equivalent to suction performed with a pistol (13).

In the protocol adopted in this study, an acrylic cup with a diameter of 4.5 centimeters and sunflower oil will be used. The application will take place in the entire length of the quadriceps femoris, in the longitudinal direction, respecting the path of the muscle bundles, starting 5 cm below the anterior superior iliac spine up to 5 cm above the base of the patella, for 10 minutes and, at the end, the excess of the oil with wet wipes.

Sham group

The same cupping patterns of the intervention group will be used, but the cupping will be perforated superiorly, so that the vacuum escapes slowly, guaranteeing the blinding of the participants.

Sunflower oil will be applied and the suction cup on the quadriceps. A suction will be carried out producing a vacuum that will be gradually eliminated. The slide will be smooth, simulating the execution of the technique for 10 minutes. After the simulation, excess oil will be removed with wet wipes.

Assessments

After screening (T0), the volunteers will undergo the evaluation (T1), as well as after the race (T2), after the intervention (T4), remotely 24 hours after the intervention (T5) and 48 hours after the intervention (T6).

Primary outcome

Perception of pain and fatigue

The subjective perception of pain and fatigue will be evaluated from the numeric analogue scale that has a graduation from 0 to 10, where 0 would be no pain and fatigue

and 10 would be an extreme level of pain and fatigue. This scale has adequate reliability and applicability for subjective pain measurement and is responsive to changes in fatigue (18). The volunteer will be asked to perform a squat and soon after report the feeling of pain and fatigue based on the scale.

Secondary outcomes

Isokinetic performance of the quadriceps femoris

The evaluation of the isokinetic performance of the quadriceps femoris will be performed using an isokinetic dynamometer (Biodex Joint Multi-System 4, Biodex Biomedical System Inc, New York, USA). The participant will be positioned sitting on the dynamometer chair with the thigh, chest and pelvic region fixed by belts. The axis of rotation of the dynamometer will be aligned with the lateral epicondyle of the femur and the lever arm will be adjusted in the distal portion of the leg, fixed 5 cm above the medial malleolus of the ankle. The gravity correction factor will be calculated using the dynamometer with the lower limb relaxed at 30° of knee flexion (19). Five concentric knee contractions will be performed at an angular velocity of 60°/s and 30 contractions at 240°/s. The movements will start in 90° of flexion until the complete extension of the knee. Participants will be familiarized with the equipment before each evaluation through 3 contractions at each speed, with 1 minute of rest between series. During the test, the participant will be encouraged to perform with maximum strength and at their highest contraction speed. In addition to verbal commands, the participant will receive visual feedback via the computer monitor (19). Peak torque normalized by weight, power, total work and dynamometric fatigue index will be evaluated.

Power

The power will be calculated using the jump mat linked to the Jump System software (Cefise, São Paulo, BR) which calculates the flight time in milliseconds after the loss of contact with the ground and estimates the vertical displacement in centimeters (20), based on the equation $h = t^2 \times g \times 8\text{-}1$, where "h" refers to the height of the jump, "t" to the flight time measured in seconds and "g" to the acceleration of gravity, with a value of 9.81 m/s^2 (21). The individuals will be instructed to perform three jumps with their hands resting on their waists, with an interval of 30 seconds between tests. The highest projection will be considered for future analysis (22). The jumps must follow an execution pattern so that there is no discrepant alteration in the results obtained (20), thus, the individual must position himself for the test with the knees in extension and trunk erect and will perform a knee flexion at an angle of approximately 120°, followed by knee extension in order to propel the body upwards, in a vertical movement (23). During the flight and landing phase, the trunk must remain stable and the knees extended, with upper limb movements not being allowed (23).

Pain

Pain will be measured using a pressure algometer model Wagner Pain Teste – Model FPX Digital Algometer. Pressure will be applied on the skin with a perpendicular incidence, in the center of the rectus femoris muscle belly, with a constant speed of 1 kg/s, until the volunteer reports the onset of pain. Three measurements will be performed with an interval of 20 seconds between pressures and the highest value will be considered for analysis (24).

Perception of recovery

The total quality of recovery (TQR) scale was created based on the subjective perception of exertion scale and has validity, according to previous studies, to assess the athlete's recovery after activity. The scale evaluates the individual's perception of this variable through a score. The final score ranges from 6 to 20 points, where 20 points indicates a complete recovery of the individual and the lower the score, the less recovered he is (25).

Blinding test

A questionnaire with 5 questions will be applied, at the end of the procedures, to assess the volunteer's perception in relation to the group in which he was allocated and his belief about the proposed treatment (26). The questions are: 1) What treatment do you think you received? With the answer options for suction cup real, false or don't know; 2) Did you feel any sensation during the application of the suction cup? With yes or no answer; 3) What sensations did you experience? With the following alternatives: pressing, inflating, painful, squeezing, relaxing, cooling, burning, pulling or hot tingling sensations; 4) Where was the sensation located? With the responses being the cupping area, a large area around the cupping application, or the entire anterior thigh area; 5) How much sensation did you feel? Being answered through the visual analogue scale, in which 0 represents nothing and 10 represents a very strong sensation.

Involvement of participants and the public

Participants will not be involved in designing this study, establishing the research question, or developing recruitment procedures. At the end of the study, the results can be reported to the participants in the form of a lecture, presenting the effects found in the studied variables.

Researcher training

For the evaluation and treatment, a series of training steps will be implemented before the start of the study, aimed at registering the actions taken. In these training stages, treatment techniques and measures will be used to reach a consensus among the researchers involved.

Sample calculation

The sample size was calculated based on the numeric pain scale of a previous study (18). A statistical power of 80% was used to detect a minimum difference between means of 1 point, with an estimated SD of 1.7 points and equivalence limit of 2.4, 5% significance level, and possible sample loss of up to 10%. For that, 32 individuals per group will be needed. The calculation was performed using the G-power software.

Statistical analysis

Statistical analysis will be performed by researcher E, who will be blind. Data will be analyzed using the software SPSS 22.0. The Kolmogorov-Smirnov test will be applied to verify the data distribution and the Levene test will be used to analyze the homogeneity of variance. If the data are normally distributed, the mean differences (difference between the two groups) for all variables will be estimated using the ANOVA mixed model, which incorporates the two intervention groups, time and group × time interaction. When a significant F-value is found, the Bonferroni *post-hoc* test will be applied to identify the differences. If the data are not normally distributed, the Friedman test is used.

An intention-to-treat analysis will be applied to ensure randomization effects, so that prognostic factors are evenly distributed in both groups. A significance level of 5% and 95%CI will be adopted for all statistical analyses.

DISCUSSION

Cupping has become part of recovery protocols for athletes, both amateur and professional (13). Recently, a study by Hou *et al.* and Liao *et al.* investigated the effects of fixed cupping therapy on biceps brachii fatigue after exercise (27, 28). However, until now, no well-defined protocols have been reported on the use of cupping therapy in the sliding modality for pain outcomes, perception of fatigue and muscle performance after physical activity.

This protocol presents all the procedures to favor a study of high methodological quality. Procedures and outcome measures were well defined, there is adequate randomization, previously calculated sample size and adequate blinding. Despite this, the heterogeneity of the sample can be a limiting factor.

CONCLUSIONS

Even so, this sham-controlled, randomized and blinded clinical trial protocol may serve as a basis for further research, contributing with a scientific direction for the application of sliding cupping therapy after physical activity as a way to improve pain, fatigue and muscle performance, contributing for better muscle recovery.

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DATA AVAILABILITY

N/A.

CONTRIBUTIONS

MMXF: writing – original draft, assistance in the study protocol development. YTP: writing – original draft, final approval. ELDAF, JOA, EBC: assistance in the study protocol development. IFO, LON: conceptualization. CAAL: conceptualization, final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Rehabilitation after Anterior Cruciate Ligament Reconstruction: Dry Land *vs* Aquatic Rehabilitation

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SUMMARY

Purpose. Anterior cruciate ligament (ACL) rupture is a common injury in athletes and active patients. Aquatic therapy seems to be effective for the rehabilitation after ACL reconstruction, good outcomes and shorter rehabilitation time have been reported compared to dry land rehabilitation. The purpose of this study is to compare the results of dry land and aquatic rehabilitation. The hypothesis is that aquatic rehabilitation is effective and could reduce the rehabilitation time after ACL reconstruction.

Methods. After ACL reconstruction, 24 patients were randomly divided into 2 groups, group A who received standard dry land physiotherapy, and group B who received an aquatic rehabilitation protocol. Both groups received 12 rehabilitation sessions. The outcomes of the two groups have been evaluated according to the improvement of their knee ROM, the International Knee Documentation Kommittee (IKDC), the Lysholm scales, and the Visual Analogue Scale (VAS) score. We designed a prospective randomized controlled trial (RCT).

Results. The knee flexion improved in both groups during the rehabilitation period. The functional scores, according to IKDC and Lysholm scale, improved in both groups at the final follow up.

The mean score significantly improved at all time point, respectively 17.9 at T0, 33.2 at T1 and 40 at T2 (S.D. 2.07) for group A, and 20.5 at T0, 36 at T1, 41.8 at T2 (S.D. 2.06) for group B. The mean VAS score improved from 6.6 at T0 to 3.9 at final follow-up in group A, and form 5,9 at T0, to 3 at T2. When comparing the results of the two groups, no statistically significant differences have been reported.

Conclusions. Both dry land and aquatic therapy are effective for the rehabilitation of patients after ACL reconstruction, but there is not one therapy superior to the other.

KEY WORDS

Anterior cruciate injury; ACL reconstruction; aquatic rehabilitation; pool therapy; return to play.

INTRODUCTION

Anterior cruciate ligament (ACL) injury is a common injury in patients who practice sports. The incidence appears to be greatest in athletes between 15 and 40 years old which participate in pivoting sports like soccer, rugby, handball, volleyball and alpine skiing (1-3). As the rate of ACL rupture is higher in female than male population, anatomical differences as greater knee valgus, greater tibial external rotation during functional activity and laxity, and the influence of sexual hormones and menstrual cycle have been also proposed as potential pathogenetic factors (4).

The ACL does not heal spontaneously due to its poor vascularity. It provides 85% of the stability avoiding anterior-posterior translation of the tibia relative to the femur and acts as a

secondary restraint to tibial rotation and varus/valgus rotation. In addition to its mechanical function in maintaining knee stability, the ACL also contains mechanoreceptors that directly influence the neuro-muscular control of the knee (5, 6). As the ACL contributes to both the sagittal and the rotational stability of the knee, ACL deficiency may cause instability in pivoting, jumping, and landing activities, leading to meniscal and cartilage injuries, and early osteoarthritis at long term follow-up (7, 8). However, the natural history of the ACL-deficient knee as compared with the surgically reconstructed knee is not well understood (9, 10). Furthermore, there remains controversy as to the appropriate patient selection criteria for nonoperative management, as has been reported that one third of patients recover well and return to pre-injury activity level with conservative management (11, 12).

The gold standard treatment for young and active patients is ACL reconstruction (13). It can restore joint stability with low surgical risk. Some studies also demonstrated the restoration of postural stability, which can be explained by regeneration of sensory neurons after ACL reconstruction (14, 15). Over the years, numerous rehabilitation techniques and protocols have been proposed, but a rehabilitation protocol well accepted is still under investigation. Some authors hypothesized that early rehabilitation in water can improve recovery times. In literature some authors compared the effects of rehabilitation in water with more traditional dry land rehabilitation, but there is no agreement amongst authors if water rehabilitation may be superior. Peultier-Celli *et al*. compared 67 patients divided in two groups, one treated with an aquatic rehabilitation protocol *versus* a conventional rehabilitation group. The aquatic group showed faster recovery (16). Tovin *et al*. showed that pool exercises may not be as effective as dry land therapy for regaining maximum muscle strength, while aquatic rehabilitation can reduce joint effusion, edema and pain (17).

The aim of this study is to compare the outcomes of dry land and aquatic rehabilitation for patients who underwent ACL reconstruction. The hypothesis is that aquatic rehabilitation is effective and could reduce the rehabilitation time compared to dry land exercises.

MATERIALS AND METHODS

Twenty-eight consecutive patients affected by ACL injury were enrolled at a single institution. All patients were informed about the experimental study and declared that they understood the purpose of the study, signing an informed consent.

Ethics

All procedures were in accordance with the 1964 Helsinki declaration and its later amendments. The study protocol was approved by the Local Committee for Medical and Health Research Ethics, Villa Erbosa Hospital, Gruppo San Donato, Bologna, Italy (number of protocol 223/2020 – Date of approval: May 20, 2020). All patients gave informed consent prior to being included into the study. All methods were carried out in accordance with relevant guidelines and regulations.

Inclusion and exclusion criteria

Twenty-eight consecutive patients affected by ACL injury were enrolled at a single institution. Patients were eligible for enrollment according to the following inclusion criteria: body mass index (BMI) ≤ 30 kg/m^2, candidates for an arthroscopic procedure based on a previous magnetic resonance imaging (MRI) positive for isolated ACL injury, age of the patients at the time of surgery between 18 and 40 years, positive pivot-shift and Lachman pre-operative tests.

The exclusion criteria were associated injuries such as meniscal tears, posterior cruciate or collateral ligaments injury, cartilage defects. Patients with a varus or valgus malalignment greater than 5°, previous intra-articular fractures or joint infections, cardiac and/or respiratory comorbidities were not included. Patients who were not able to follow the post postoperatory instructions and rehabilitation were excluded from the study.

Patient assessment

A detailed physical examination was conducted in all patients, who were examined by fully trained orthopedic surgeons with a special interest in knee surgery. All patients underwent standard weight-bearing anterior-posterior (AP) and lateral plain radiographs of the knee, and an MRI was indicated to confirm the ACL rupture and exclude associated injuries.

The rehabilitation protocol consisted in 12 sessions, three sessions a week over four weeks, and all patients have been examined after the first rehabilitation session (T0), after the 6th session (T1), and at the end of the treatment (T2-12th session). The range of motion (ROM) was recorded at each control. The progress of physiotherapy was evaluated through the International Knee Documentation Committee (IKDC) and Lysholm scale, which assess the presence of symptoms, the degree of sporting activity and the functionality of the joint itself (18, 19). The Visual Analogue Scale (VAS) score was also recorded at each time point. Safety was assessed by recording all adverse events during treatment.

Surgery and rehabilitation protocol

All surgeries were performed by the senior surgeon (GP). Hamstring autograft have been used to reconstruct the injured ALC. Gracilis and semitendinosus tendons, once removed, were folded in half to obtain a new ligament with four strands. All patients received intravenous controlled

analgesia for 12 h, and they were discharged the day after surgery. Standard thromboembolic prophylaxis with low molecular weight heparin (LMWE) for 30 days.

All patients underwent rehabilitation at the same physiotherapy facility, equipped with a therapeutic pool and gym. All the patients began passive mobilization of the operated knee with kinetec from the first day after surgery. After 2 weeks, after the complete closure of surgical wounds, they were randomly divided into two groups, the control group (A) that followed the standard dry land treatment protocol, and the experimental group (B) that followed an aquatic treatment protocol. Both groups received 3 sessions of therapy a week. Patients who belonged to group B received one session a week on dry land, and 2 sessions in swimming pool under the direct supervision of an expert and trained physiotherapist. During the treatment, the number of repetitions and intensity of the exercises have been improved according to the clinical condition of the patient (**table I**).

Statistical analysis

The average and standard deviation values were calculated and subsequently compared with each other. To verify the

Table I. Rehabilitation protocols of control **(A)** and experimental **(B)** group.

Group A	Group A
3rd postoperative week	
Static bicycle	Water temperature 32 °C
Lymphatic drainage	Warm-up in water
Passive mobilization of the knee by a physiotherapist	Active mobilization of the hip and knee
Isometric strengthening exercises of the quadriceps muscle	Walking
Stretching exercises	Muscle strengthening exercises
	Swim
4th postoperative week	
Static bicycle	Warm-up in water
Closed chain exercises	Active mobilization of the hip and knee
Quadriceps and hamstrings strengthening exercise	Walking
	Muscle strengthening exercises
	Swim
5th postoperative week	
Static bicycle	Warm-up in water
Quadriceps, hamstrings and adductor muscle strengthening exercises	Active mobilization of the hip and knee
Monopodalic exercises	Walking on tiptoe and heel
Core stability exercises	Muscle strengthening exercises adding a 2 kg weight
	Proprioception
	Swim
6th postoperative week	
Static bicycle	Warm-up in water
Muscle strengthening exercises	Active mobilization of the hip and knee
Monopodalic exercises	Walking on tiptoe and heel
Core stability exercises	Muscle strengthening exercises adding a 2 kg weight
Proprioception	Proprioception
	Swim

The treatment protocols of group A and B are shown in this table. The intensity and number of repetitions of exercises proposed to experimental patients' group increased according to their clinical conditions and responsiveness to the physiotherapy.

effectiveness of the present study, the Student's statistical t-test was used, by means of which it was possible to compare the two groups A and B and evaluate the differences in the starting and ending treatment values within the same group. The purpose of this test is to verify if the average value of a data distribution deviates significantly from the reference value P. The P-value was set at a value equal to 0.05 which is equivalent to 95% of the actual significance of the test.

RESULTS

Four subjects were excluded from the study, two for each group. One changed rehabilitation protocol before the end of the study and was lost at follow-up, and 3 subjects were excluded because associated injuries were detected during surgery. Twenty-four patients met the inclusion criteria, 12 for group (13 males, 11 females; mean age 28 for group A, 26.3 for group B; range 19-35). No statistically significant differences were observed for variables such as age, sex, height, weight, BMI.

The knee flexion improved in both groups during the rehabilitation period, and a statistically significant improvement have been reported at the T1 and T2 compared to the baseline (**table II**). The mean knee flexion of group B was slightly better compared to control (**figure 1**), without any statistically significant difference (p = 0.74). All patients achieved full knee extension.

The mean IKDC score significantly improved at all time point for both groups, respectively 17.9 at T0, 33.2 at T1 and 40 at T2 (S.D. 2.07) for group A, and 20.5 at T0, 36 at T1, 41.8 at T2 (S.D. 2.06) (**table III**), but there was not a statistically significant difference between groups (p = 0.24). In particular, the IKDC score was slightly better for patients who received the hydrokinetic therapy in water (**figure 2**), but not significant.

Table II. Mean ROM and standard deviation of group A and B.

	Flexion (°)			Odds		
			Group A			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Knee flexion	83.8	101.8	118.7	18	16.9	34.9
SD	3.5633	4.7065	3.5194	3.2193	4.2525	4.3580
P-value				0.0	0.0	0.0
			Group B			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Knee flexion	84.9	101.7	120.5	16.8	18.7	35.5
SD	3.7285	3.5961	4.7958	3.8337	4.9749	5.5507
P-value				0.0	0.0	0.0

This tables shows the mean and standard deviation regarding the knee flexion of group A and B in the three-time point. Subsequently, the differences (D), means and standard deviations of the times T0-T1, T1-T2, T0-T2 have been calculated for each group.

Table III. Mean IKDC scale and SD.

	IKDC			Odds		
			Group A			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Mean ICDK	17.9	33.2	40	15.6	6.7	22.4
SD	2.2712	2.6568	2.0776	1.7824	1.9195	2.4680
P-value				0.0	0.0	0.0
			Group B			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Mean ICDK	20.5	36	41.8	15.4	5.8	21.2
SD	2.4391	4.4493	2.0664	2.3812	1.8656	2.2832
P-value				0.0	0.0	0.0

A significant improvement of the IKDC scale during the rehabilitation have been shown in both groups. A slightly higher improvement of scores have been reported in group B, but not statistically significant.

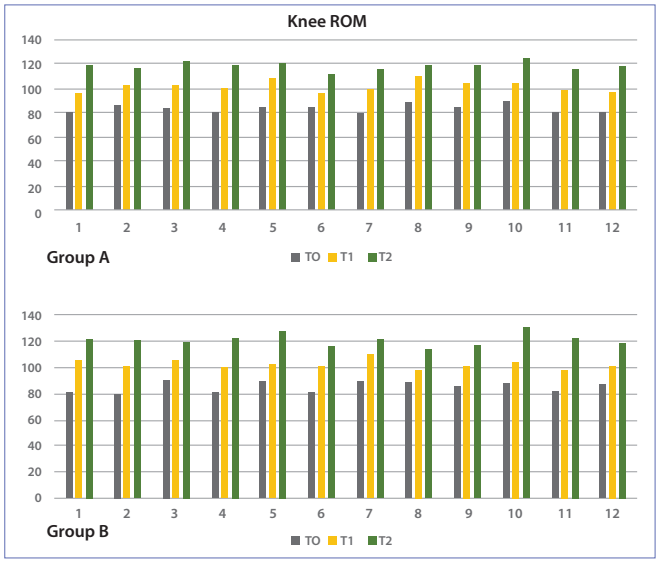

Figure 1. Knee ROM of group A and B.

For both groups, the graph shows the improvement in knee flexion of all patients at the end of treatment in both groups, but no statistically significant differences have been detected between intervention and control group.

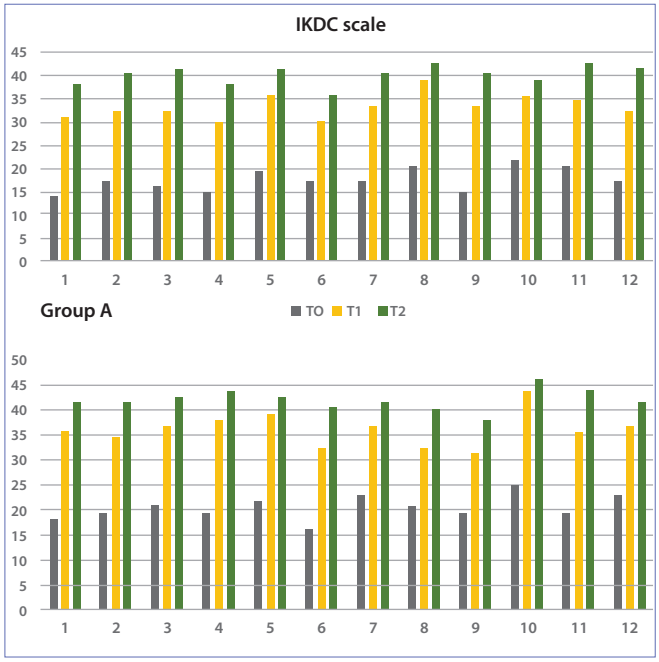

Figure 2. ICDK scale.

The ICDK scale showed better scores in group B than group A at all time points, but the difference is not statistically significant.

The Lysholm scale also improved during the rehabilitation in both groups. At T0 the mean Lysholm scale of group A and B was respectively 20.5 (SD 5.7912) and 22.5 (SD 6.12), and at the end of the treatment protocol it improved to 50.1 (SD 5.42) and 52 (SD 5.32) (**table IV**). When comparing intervention and control group, the results were better for patients of group B (**figure 3**), but not statistically significant (p = 0.95).
The VAS score showed an improvement during the rehabilitation period in both groups (**table V**). The median preoperatory VAS score improved from 6.6 at T0 to 3.9 at T2 in group A. The mean VAS score in group B was 5.9 at T0, 4.3 at T1 and 3 at T2. The improvement was statistically significant in both groups, but when comparing, no significant differences have been found (p = 0.71).
No adverse events have been recorded during the treatment period in both groups.

Table IV. Lysholm scale

	Lysholm			Odds		
			Group A			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Mean score	20.5	40.2	50.1	19.6	9.9	29.5
SD	5.7912	4.6147	5.4244	2.6013	5.5179	7.3294
P-value				0.0	0.0	0.0
			Group B			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Mean score	22.5	39.6	52	17	12.3	29.4
SD	6.1268	4.8866	5.3258	3.7040	4.2711	7.1282
P-value				0.0	0.0	0.0

The mean value and standard deviation of the Lysholm scale of A and B are shown in this table. The Student's test showed a significant improvement of the Lysholm scale during the rehabilitation in both groups. The patients of Group B showed a little higher improvement from T1 to T2, compared to group A, but not statistically significant.

Table V. VAS score.

	VAS score			Odds		
			Group A			
	T0	T1	T2	Δ T1-T0	Δ T2-T1	Δ T2-T0
Mean VAS	6.6	5	3.9	1.7	1	2.7
SD	1.2309	1.1645	0.9962	0.7538	0.7930	1.1382
P-value				0.01	0.12	0.0
			Group B			
Mean VAS	5.9	4.3	3	1.5	1.3	2.9
SD	1.0836	1.1547	0.8528	0.7930	0.8876	1.0836
P-value				0.002	0.004	0.0

This table shows the mean and standard deviation of VAS scale in group A and B in the three time points.

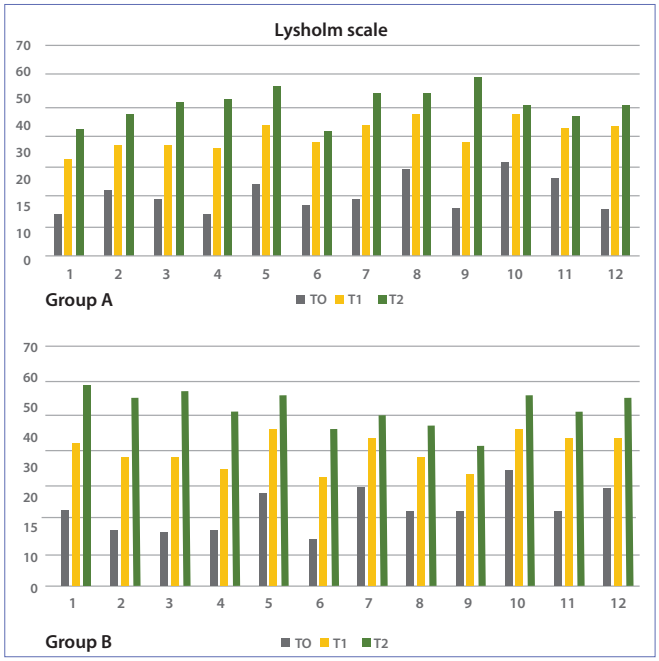

Figure 3. Lysholm scale.

The Lysholm scale showed better scores in group B than group A at all time points, but not significant.

DISCUSSION

The aim of this study was to compare the results of two different rehabilitation protocols for patients who underwent ACL reconstruction, dry land and aquatic therapy.

The aquatic environment has broad rehabilitative potential, extending from the treatment and rehabilitation of acute injuries to chronic diseases, in particular for patients affected by musculoskeletal problems. The effects of aquatic therapies have been studied since they were described for the first time by Charles L. Lowman in 1911 (20), who was the first to introduce therapeutic tubs to treat patients with cerebral palsy and spasticity. Aquatic immersion has many biological effects, extending across all homeostatic systems. The blood flow is increased during therapeutic exercise in water compared to dry land, determining a greater oxygen availability to muscles and catabolites drainage (21). Aquatic environment showed many beneficial effects on pain perception. Skin sensory nerve endings are stimulated, and different studies suggest that sensory overflow may act as pain modulator, increasing the pain threshold, improving pain and function (22). The hydrostatic effects of immersion significantly reduce soft tissue edema (23). The human body immersed in water to a depth of 120 cm is subjected to a hydrostatic pressure which is slightly greater than normal diastolic blood pressure. This hydrostatic pressure is effective to reduce the edema. Weight bearing can be easily controlled by water immersion. A person immersed to the symphysis pubis has effectively offloaded 40% of the body weight, approximately 50% when further immersed to the umbilicus, while xiphoid immersion offloads 60%-75% of body weight (24)

Gravitational forces can be controlled so that only muscle torque forces act on the injured site, allowing active assisted range-of-motion activities, and strength exercises (25). Another important propriety of water is viscosity, which is the resistance of a fluid to movement of neighboring portions relative to one another, and indicates the opposition to flow. A limb moving into the water is subjected to the resistive effects of the fluid. Viscous resistance increases as more force is exerted against it, and as the velocity of the movement increases, but that resistance drops immediately on cessation of force. Thus, viscosity is useful to control the strength apply to the injured limb, while when the patient feels pain and stops movement, the force drops precipitously as water viscosity stop the movement. This allows

enhanced control of strengthening activities within the pain threshold.

Many aquatic post-operative rehabilitative programs have been designed according to the idea that they could be more effective compared to normal dry land exercises. Peultier-Celli *et al*. (16) compared 67 patients divided in two groups, one treated with an aquatic rehabilitation protocol, *versus* a dry land rehabilitation group. The aquatic group had faster recovery according to the authors, but only 2 of the 7 parameters analyzed showed a statistically significant improvement. Zamarioli *et al.* (26) reported a faster recovery after 9 weeks in patients treated with aquatic rehabilitation after ACL reconstruction, according to pain, ROM, muscle strength, swelling, and muscle mass circumference. However, the differences were not statistically significant, in accordance with the present study. Biscarini *et al*. (27) developed a biomechanical and hydrodynamic theoretical model to calculate the knee joint load during underwater knee extension exercises. This biomechanical work highlights that aquatic exercises can theoretically be usefully and safely implemented in the rehabilitation program following ACL surgery. Exercises performed in the aquatic and dry land environment were also compared by Becker, reporting better knee function and muscle strength in patients who received pool therapy (28). Conversely when the exercise is static or involves a vertical movement, the cardiovascular and neuromuscular activity is reduced in water. This is a product of the effect of buoyancy (29). However, results are still controversial, as some authors agree that exercise in water may not be as effective as exercise on land for regaining maximum muscle strength (17). Therefore, although good outcomes have been reported after aquatic exercise for rehabilitation of patients after ACL reconstruction, therapeutic pool exercises are not included in many standard protocols and guidelines (30).

According to our study, both dry and aquatic therapy showed a significant improvement of all the parameters analyzed, as knee ROM, functional score and pain. This data supports the hypothesis that rehabilitation in water is effective for rehabilitation after ACL reconstruction. Both the ROM and the VAS score showed a slightly better improvement in patient who received aquatic rehabilitation program, but, according to many studies available in literature, the differences were not statistically significant.

Aquatic therapy after ACL reconstruction seems to be effective to improve knee function, because statistical significant improvement of functional scores have been reported evaluated according IKDC and Lysholm scale. Slightly better outcomes have been reported for patients after aquatic therapy compared to dry land after 12 sessions. This could support the assumption that rehabilitation in water can reduce the time of rehabilitation. However, successful return to sports after ACLR is influenced by multiple physical and psychological factors. Neuromuscular, balance, proprioception impairments and kinesiophobia may negatively influence perceived knee function and the pre-injury activity level (31, 32).

We are aware of the limitations of our study. The first is the small size of our cohort, 24 patients. The lack of statistical power due to the small sample size is another limitation of our study, but we do not claim which our conclusions can be extended to the general population. Furthermore, the short-term follow-up did not allow us to draw final conclusions on longer-term outcomes and differences between these two rehabilitation protocols.

CONCLUSIONS

Aquatic rehabilitation seems to be as effective as dry land therapy for rehabilitation of patients who underwent ACL reconstruction. When compared, aquatic protocol showed a slight better outcome according to pain and function after 12 sessions of rehabilitation therapy, but the difference was not statistically significant. Further studies are required to confirm these results and to identify the most appropriate rehabilitation protocol for patients who suffered an ACL injury.

FUNDINGS

None.

DATA AVAILABILITY

All the relevant outcome and results are included into the table of this manuscript. Data are also available from the corresponding author on reasonable request.

CONTRIBUTIONS

GP: surgeries. ET, DCV: patients' treatment. GP, ET, AT: patients' examination. ET, AGV, RM literature review. ET, AGV: writing – original draft. GP, DCV, RB: writing – review & editing. GP, RM, RB: supervision, writing – review & editing. All authors: final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Epidemiological Study of Foot and Ankle Injuries in Athletes: A Multivariate Logistic Regression Analysis

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SUMMARY

Introduction. Understanding the epidemiological profile of foot and ankle's injuries in athletes is relevant for the prevention and treatment its occurrence.

Objective. To describe the epidemiology and risk factors of foot and ankle injuries in athletes treated at an outpatient sports medicine clinic. The primary hypothesis is that ankle instability is the most frequent injury in athletes in the foot and ankle specialty outpatient clinic.

Methods. Observational, retrospective, descriptive study with patients treated at an outpatient sports medicine clinic, between 2015 and 2020. We performed a multivariate logistic regression analysis to verify the association of gender, age and laterality with the main injuries documented.

Results. 763 patients (387 men/376 women) met the inclusion criteria. The mean age was 35 years, the most prevalent diseases were chronic lateral ankle instability (n = 134, 17.6%), acute lateral ankle sprain (n = 120, 15.7%) and plantar fasciitis (n = 69, 9%). The multivariable analysis by logistic regression identified female gender and age group young adults as a risk factor for lateral ankle instability. In acute lateral ankle sprain, age was identified as a risk factor with statistical significance. In overuse injuries, only the female gender was evidenced as a risk factor.

Conclusions. Our work correlated several factors such as age, gender and laterality with specific sports through multivariate analysis, adding epidemiological data to the literature.

Study registration. The study was registered in Plataforma Brasil under the number 5.037.010.

KEY WORDS

Epidemiology; athletes; foot; ankle; injury.

INTRODUCTION

All recreational and competitive sports activities carry an inherent risk of injuries (1, 2). However, one of the goals of sports medicine is to reduce health risks associated with athletic participation by recognizing and controlling risk factors. Through epidemiological studies, it is possible to identify and quantify risks, along with the incidence and prevalence of injuries in a specific set of conditions (1-8). The classification into intrinsic and extrinsic risk factors can be approached based on the stress/capacity model, which has been used in its classical form in the field of social and preventive medicine to describe the interaction between humans and their environment (3, 9). It can also be applied in sports medicine, especially in injury prevention. In this

model, stress is determined by the athlete's environment (external factors), such as training techniques and playing environment (10, 11), and the athlete's capacity is determined by internal and personal factors, such as skill level, age, and gender (12-15). Preventive measures should therefore be designed to achieve or maintain this balance, either by increasing capacity or reducing stress, or both (16-19). To the best of our knowledge, there is a lack of studies reporting the epidemiological profile of athletes with foot and ankle disorders considering different sports. The aim of this study is to describe the epidemiology of foot and ankle injuries in athletes treated at a specialized outpatient clinic for sports-related injuries. The main hypothesis is that chronic ankle instability (CAI) is the most common injury among athletes in the specialized foot and ankle clinic.

METHODS

Protocol

This is an observational, retrospective, and descriptive level IV evidence study authorized and approved by the Research Ethics Committee of UNIFESP (Protocol number: 5.037.010 - Date of approval: October 14, 2021). The aim of the study was to describe the epidemiology of foot and ankle injuries in athletes treated at a specialized clinic for sports injuries, located in São Paulo, Brazil, between January 1, 2015, and December 31, 2020. The manuscript is organized according to the STROBE guidelines (20).

Eligibility criteria

The study sample consisted of patients treated at a specialized clinic for foot and ankle injuries in sports over a five-year period. This clinic, located in São Paulo, offers multidisciplinary care including physiotherapy, physiology, sports medicine, and orthopedics. Three certified orthopedists reviewed the medical records and documented patients' demographic information, sport, diagnosis, and injury side. The inclusion criteria were patients engaged in amateur or professional sports of all age groups. Only the first consultations and the patient's main sport and diagnosis were counted. The exclusion criteria were insufficient documented data in the medical records, injuries not occurring as a result of sports participation, and patients with conditions unrelated to the foot and ankle. Age was analyzed according to the following age groups: children (< 12 years), adolescents (≥ 12 and < 20 years), young adults (≥ 20 and < 40 years), adults (≥ 40 and < 60 years), and elderly (≥ 60 years). The diagnosed injuries were categorized as follows: chronic ankle instability (CAI), ankle sprain (AS), fractures, plantar fasciitis (PF), insertional or non-insertional Achilles tendonitis, and those due to overuse were defined as injuries without acute trauma, secondary to repetitive loading, such as stress fractures or posteromedial tibial syndrome.

Outcome evaluation

We evaluated patients' demographic information, sport practiced (soccer, amateur runner, fighters, dancers, basketball, volleyball, and athletics, being the most prevalent), diagnosis, and injury side. Injuries were classified according to the sports modality and patients' age group. Overuse injuries were identified and analyzed separately as explained in the eligibility criteria.

Statistical analysis

The data were analyzed using SPSS V20, Minitab 16, and Excel Office 2010 software. A multivariate logistic regression analysis was performed to assess the association of gender, age, and laterality with the main documented injuries. The quality and fit of the multivariate logistic regression analysis were tested using the Nagelkerke R2 test and the Hosmer-Lemeshow test. The statistical analyses were conducted with the aim of identifying risk factors for foot and ankle injuries in athletes treated at the specialized sports injury clinic.

RESULTS

Patient recruitment

A total of 872 medical records were analyzed, and 763 patients (387 males and 376 females) met the inclusion criteria. These patients were treated at this specific outpatient clinic, which serves patients from across the national territory, regardless of the region, although the majority of these athletes come from the city of São Paulo.

Summary of results

The mean age was 35 years (SD ± 14.1; minimum 8.9; maximum 77). The most prevalent age group was young adults, accounting for 51.7%, while the least prevalent group was children, at 1.4%. The most prevalent conditions were CAI (n = 134, 17.6%), acute lateral ankle sprain (AS) (n = 120, 15.7%), and plantar fasciitis (PF) (n = 69, 9%) (**table I**). The pattern of injuries in soccer players was, in order of frequency, AS, CAI, and traumatic injuries such as ankle or metatarsal fractures. On the other hand, the pattern of injuries in amateur runners was PF, overuse injuries, and non-insertional Achilles tendon tendinopathy (**table I**). **Table I** is divided according to sports practice and indexed injuries, presenting data on the most prevalent sports modalities in our setting.

Table I. Distribution of main diseases by sport.

Sport	n	%	CLAI	AS	PF	Overuse injuries	Fractures	Noninsercional tendinopathy	Insertional tendinopathy
Football	174	22.8	44	38	5	6	14	7	6
Amateur running	168	22.0	14	14	32	22	-	-	16
Fights	72	9.4	9	9	8	-	8	5	6
Dance	57	7.5	16	4	-	4	5	-	-
Basketball	48	6.3	10	17	3	3	2	-	-
Voleyball	45	5.9	9	6	3	8	-	-	2
Atletism	34	4.5	7	3	2	7	-	-	3

Multivariate logistic regression analysis

The multivariate analysis by logistic regression identified the young adult age group as a risk factor for CAI (OR 0.96, 95%CI 0.95-0.98, p < 0.05), as well as female gender (OR male/female 0.58, 95%CI 0.39-0.86, p < 0.05). In the case of AS, the young adult age group was identified as a risk factor (OR 0.97, 95%CI

Table II. Multivariate logistic regression analysis with the main injuries documented.

	Odds Ratio			P-value
	OR	Inferior limit	Superior limit	
CAI				
Age	0.96	0.95	0.98	< 0.001
Gender male/female	0.58	0.39	0.86	0.007
Laterality: Right/Left	1.13	0.75	1.72	0.556
AS				
Age	0.97	0.95	0.98	< 0.001
Gender Male/Female	1.49	0.99	2.25	0.058
Lateralidade: D/E	1.20	0.80	1.81	0.381
Overuse Injury				
Age	1.00	1.00	1.00	0.866
Gender Male/Female	0.43	0.25	0.73	0.002
Laterality: Right/Left	0.88	0.50	1.54	0.655
Non-insertional Achilles Tendinopathy				
Age	1.00	1.00	1.00	0.872
Gender Male/Female	1.85	0.98	3.49	0.059
Laterality: Right/Left	1.17	0.55	2.48	0.678
Laterality: Bilateral/Left	3.28	1.46	7.35	0.004
Insertional Achilles Tendinopathy				
Age	1.00	1.00	1.00	0.887
Gender Male/Female	4.86	2.22	10.63	< 0.001
Laterality: Right/Left	0.59	0.29	1.20	0.144
Acute Achilles Tendon Rupture				
Age	1.00	1.00	1.00	0.842
Gender Male/Female	2.60	1.13	5.96	0.024
Laterality: Right/Left	1.29	0.60	2.78	0.518

0.95-0.98, $p < 0.05$). In overuse injuries, only female gender was identified as a risk factor (OR male/female 0.43, 95%CI 0.25-0.73, $p < 0.05$). In non-insertional Achilles tendon tendinopathy, bilaterality was commonly found as a factor (OR bilateral/left 3.28, 95%CI 1.46-7.35, $p < 0.05$), while in insertional Achilles tendon tendinopathy, only male gender was identified as a risk factor (OR male/female 4.95, 95%CI 2.22-10.63, $p < 0.05$), as well as in Achilles tendon rupture (OR male/female 2.60, 95%CI 1.13-5.96, $p < 0.05$) (**table II**).

DISCUSSION

Presentation of results

In this study, we described the epidemiology of foot and ankle injuries in athletes treated at a specialized outpatient clinic for sports-related injuries. Each injury was correlated with intrinsic factors using multivariate logistic regression to identify the associated factors. The most prevalent age group with foot and ankle injuries related to sports was young adults (51.7%).

Discussion of results

A significant portion of the literature focuses on research by age groups, such as children, adolescents, and adults (21-24), as well as by sports disciplines. The most prevalent conditions in young adults were chronic ankle instability (CAI) and ankle sprain (AS), while plantar fasciitis (PF) was the most prevalent condition in adult males and females. AS and bruises around the foot and ankle are related as the most common injury in athletes (22-26), and CAI secondary to AS is often reported (27). In the case of AS, only the young adult age group was identified as a risk factor. The disparity in the prevalence of ankle sprains between genders appears to be small in the current literature (28), which is consistent with our data. Regarding limb dominance, the results were contrasting, with some studies showing no difference in the incidence of ankle sprains between dominant and non-dominant ankles, while others observed that the dominant leg suffered significantly more ankle injuries in male soccer players. In patients with CAI, the young adult age group and female sex were identified as risk factors.

Discussion of results from similar studies in the literature

Hosea *et al.* (29) conducted a comprehensive prospective study in high school and college basketball players, and female athletes had a 25% increased risk of suffering a grade I ankle sprain compared to male athletes; however, the relative risk between genders for more severe grade II and III sprains, ankle fractures, and syndesmotic sprains was not significantly different. Regarding limb dominance, Surve *et al.* (30) found that soccer athletes reported no difference in the incidence of ankle sprains between dominant and non-dominant ankles. In contrast, Ekstrand and Gillquist (31) observed that the dominant leg suffered significantly more ankle injuries in male soccer players, with 92% of ankle injuries affecting the dominant leg. These contrasting findings may have resulted from different study designs or methods used for data analysis. In patients with CAI, the young adult age group and female sex were identified as risk factors. Lin *et al.* (32) found that female athletes had a higher prevalence of CAI than men at the university level. This is consistent with previous work by Tanen *et al.* (33). The factors causing differences in ankle instability rates between genders may include different anatomical structures, joint laxity, and menstrual cycles (34, 35). Female sex has been most frequently associated with an increased incidence of overuse injuries (36). In particular, female long-distance runners appear to have the highest risk for sustaining stress fractures (37, 38) Although long-distance running itself can predispose runners to stress fractures, it appears that the associated nutritional and menstrual irregularities seen with increased frequency (39).

Limitations

This is a retrospective and descriptive study where the collected data were recorded prior to analysis, without interventions or prospective follow-up, limiting the ability to establish causal relationships between the analyzed facts and injuries. Additionally, foot and ankle injuries related to sports, age, and sex were listed without considering other factors that could be related to the described injuries, such as athlete biomechanics or other musculoskeletal injuries. The data were obtained from patient records, which may be subject to typing errors or lack of detailed information, affecting the precision and reliability of the results.

Future perspectives

We can identify other risk factors beyond those mentioned in this study, such as athlete biomechanics and previous injury history. These new studies could contribute to a more comprehensive understanding of foot and ankle injuries in athletes. Furthermore, the evaluation of specific preventive measures for each identified type of injury is highlighted as an important perspective. Based on the collected data, targeted preventive interventions could be developed and tested, such as specific training programs and strengthening measures. Future studies could assess the effectiveness of these interventions in reducing the incidence of foot and ankle injuries in athletes. Another relevant perspective is the analysis of other types of injuries in different body regions. Although the study focused on foot and ankle-related injuries, future research can investigate other regions and their

respective injuries in athletes, providing a broader view of the epidemiology of sports injuries.

Contributions to current practice

The study provides valuable information about the most common foot and ankle injuries in athletes, as well as the associated risk factors. This enables healthcare professionals to develop targeted prevention strategies, such as specific training programs and strengthening measures, with the aim of reducing the incidence of these injuries. The importance of a multidisciplinary approach to the treatment and prevention of foot and ankle injuries in athletes is also emphasized. The collaboration between physiotherapists, physiologists, and sports physicians, as seen in the mentioned specialized clinic, allows for comprehensive and holistic treatment, aiming to prevent future injuries and promote proper athlete recovery. Furthermore, the study provides a solid foundation of epidemiological data that can be used to support clinical practice. Healthcare professionals can utilize this information when evaluating athletes, identifying risk factors, and making informed decisions regarding the treatment and prevention of foot and ankle injuries. Although the data were obtained from a specific outpatient clinic, the results can be generalized to other sports and clinical contexts. The epidemiological data obtained in this study can be extrapolated and applied in different services, contributing to the improvement of sports practice as a whole. This means that other clinics and healthcare professionals can benefit from these results when developing prevention and treatment strategies for foot and ankle injuries.

CONCLUSIONS

The literature specifically describing foot and ankle injuries during sport is limited, despite being highly prevalent injuries. Our work correlated several factors such as age, gender and laterality with specific injuries in sports through multivariate analysis, adding epidemiological data to the literature that help in the prevention and treatment of foot and ankle injuries in sports.

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DATA AVAILABILITY

Our data are based on information acquired from the medical records of patients who were treated at the Foot and Ankle Ambulatory of the Sports Traumatology Center of the Paulista School of Medicine

CONTRIBUTIONS

LPBC: data collection, writing – original draft. FGC: data collection. HCMC: data collection and corrections. ESM, AVKCL, CASN: writing – review & editing. NSBM: conceptualization, design.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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POSITION PAPER

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Human Response to Plague: a Literary and Sociologic Perspective

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SUMMARY
As COVID-19 pandemic, other plagues struck people in the past, provoking potentially dangerous social reactions in mankind. Luckily, these reactions are quite constant, even in different eras and cultures, and famous novelists accurately reported them in their books. Starting from the meticulous description of people reactions reported in Manzoni's novel "The Betrothed", this article analyzes what we could learn about human response to plagues reading the great classical books, to plan a correct disaster response to infectious diseases.

KEY WORDS
COVID-19; human response to plague; disaster psychiatry; disaster preparedness; psychosocial reaction; humanities.

INTRODUCTION

The Italian outbreak of SARS-CoV-2 pandemic started on February 21st 2020 with the first case of ascertained local transmission in northern Italy (1). Up to April 2023, there have been more than 762,000,000 total confirmed cases worldwide, with approximately 6,900,000 deaths attributable to COVID-19 (2). Every "wave end" opens the way to a new disaster preparedness phase, to prevent further waves (3). To this end, a study of human reactions to pandemics could be useful. Luckily, some famous novelists from all over Europe, during the past centuries, gave an unexpected contribution to disaster preparedness through their descriptions of human responses to plagues. This perspective aims to identify possible constant reactions, analyzing their descriptions from Italian and classical literature and comparing them with recent events reported on newspapers during COVID-19 emergency.

THE "DENIAL" PHASE

Alessandro Manzoni, a XIX century Italian writer, described in detail the reactions, both of crowd and governors, to the arrival of the plague into the Duchy of Milan in 1630, in his novel, The Betrothed (4). An interesting analysis, especially considering that the first Italian focus of SARS-CoV-2 occurred in the same Italian region (Lombardy) were "The Betrothed" is set. Up to March 20th 2020, Lombardy reported 10% of worldwide cases of COVID-

19 (5, 6). People who read also the first chronicles about COVID-19 pandemic, could find a lot of similar recurrent behaviors of people towards a potentially lethal contagion. We read in the 31st chapter of this novel: «*Ludovico Settala, a famous physician […], announced to the Tribunal of Health, on October the 20th, that the contagion had undoubtedly appeared at Lecco; but no measures were taken after this report. Further similar news induced them to send a commissioner […] who […], based on the report of an old barber of Bellano, announced that the emerging disease just arose from the autumnal marsh exhalation, worsened by the sufferings caused by the passage of the German soldiers [...]. The governor […] replied […] the famine of the previous year, the army exactions, and the anxiety of mind which had suffered so much, were enough to explain the mortality of the surrounding country […]. The same incredulity, blindness, stubborness, prevailed in the senate […].*» (4). These few lines report the first common reactions, that we may rename the "denial" or "refusal" phase. Even on February 2020 lots of people, including some researchers and governors, attributed COVID-19 symptoms to "common flu", contributing to a general underestimation of the problem and to a delayed disaster response phase, notwithstanding others had advised to prepare containing measures since the beginning of January 2020. The lack of unity by the scientific community has probably contributed to the initial general underestimation. Noteworthy, the "refusal phase" tends to recur, as soon as the fear of the disease decreases. During 2021, worldwide newspapers reported more and more frequently the opinions of people believing that COVID-19 was only a politically-exploited invention, underestimating the risk of contagion and refusing to get vaccinated or to wear face masks.

The unpreparedness and contagion spreading due to the refusal phase, unluckily have their fatal consequences on first-line people assisting the infirms, as we can read still in Chapter 31: «*In the lazaretto there was confusion, disorganization, and anarchy. In this difficult situation, the Tribunal had recourse to the capuchins […]. As the crowd in the lazaretto increased, other capuchins joined them […]. Most of these brethren joyfully sacrificed their lives […].*» (4). In 2020, first-line physicians from every medical specialty and healthcare workers, who, as the Manzonian Capuchines, were deputed to patients' assistance and could not refuse their fundamental role in the national emergency, even in absence of correct Personal Protective Equipment, got sick and died with tremendously increasing numbers (~12% of first-wave COVID-19 cases in Italy) (7). With regards to the Lazaret of Milan, it was built during a previous plague in the XV century; similarly, in 2020, new hospitals were built specifically for the COVID-19 patients in Italy (8).

THE "UNWISE PHASE"

As soon as the "containment" laws are approved, the "unwise phase" starts, accompanied by a kind of skepticism towards institutional measures, and characterized by a general escape from the disease and from quarantine measures as well. Not only Manzoni, but also Giovanni Boccaccio, in his collection of novellas, entitled "The Decameron", referring to the XIV century "Black Death", anticipated our newspaper accounts about the "flights" from Milan and Paris just before the approval of quarantine laws: «*Some […] claimed that there was no medicine for the disease more or equally effective than flight; following which prescription, a multitude of men and women […] abandoned their city, their houses, their estates, their relatives, their goods, and went into voluntary exile, or migrated to the countryside […].*» (9). The fear of the disease may lapse into foolish behaviors, as verbal assaults towards healthcare workers or people underlying the severity of the spreading contagion: «*Even the eminent Settala […] was forced to seek refuge into a friend's house from the popular fury, because he had constantly urged the need of precautionary measures*» (4).

At the same time, looting and robberies and antisocial behaviours were unfortunately recurrent too (10). News about robbed couriers and supermarkets were reported not only during the first lockdown, but also in Manzoni's novel: «*In seasons of public calamity […] we often observe[…] an increase of vice and crime. […]. Spared by the plague, found in the common confusion, and in the slackening of the restraints of law, new occasions for mischief, and new assurances of impunity […]. [The monatti] entered houses as masters and enemies; and, not to mention their robberies […].*» (4). Similarly reported Thucydides in his "History of the Peloponnesian War", reporting that: «*With the plague, several law infringements occurred*» (11). Other people were reported to abandon their own relatives, suspecting they could be ill, as Boccaccio told: «*This sore affliction entered so deeply into the minds of men and women, that […] brother was forsaken by brother, nephew by uncle, brother by sister, and frequently husband by wife[…]*» (9).

THE "SCAPEGOATING" PHASE

When plague denial is not possible anymore, the "accuse" or "scapegoating" phase arrives. As Manzoni wrote: «*Human mind […] prefers attributing evil to human perversity, towards which revenge is possible, than accepting it could take origin from what men may only resign to […].*» (4).

Human beings in fact seem to have a profound need to find the guilty party of each tragedy, the "scapegoat" whom terrible illnesses, famines, economic crises should be attributed to, even without any clear logical link. The scapegoats of

Manzonian plague were the so-called "anointers": «*Three young Frenchmen […] had approached the cathedral, and were contemplating it very accurately. Some persons passing by stopped; a circle formed around them; they were not lost sight of for a second, having been recognized as strangers, and, above all, Frenchmen [...]. In a moment they were surrounded, and, with curses and blows, arrested […]. Frenzy propagated together with the contagion. The traveller met off the high road, the stranger with singular habits or appearance, were judged to be poisoners […]. The physicians agreed with the popular belief, and attributed to poison and diabolical conjurations the classical symptoms of the disease* (4)».
In the "History of the Peloponnesian War", also Thucydides referred some conspiracy theories about the Plague of Athens during the V century B.C.: "*The plague suddenly struck Athens, firstly infecting the citizens living around the harbour, so that the Athenians accused the Spartans to have polluted their wells.*» (11).
Nowadays, after Thucydides and the Manzonian "anointers", conspiracy theories about the spread of a man-made recombinant Coronavirus, diffused by China, US or other countries, according to different theories spread all over the world. Noteworthy, the role of crowd rumors, as amplifiers and modifiers of the "anointers' conspiracy", has nowadays been substituted by common fake news on social networks.

CONCLUSIONS

In 1963, Dr. Morgan Martin analyzed Daniel Defoe's "A Journal of the Plague Year", reporting Londoners' reactions to the 1665 Great Plague and summarizing them in "similarities" and "possible differences" compared to reactions to modern disasters (12). A similar analysis has been recently published by Wigand *et al.*, referring to Thucydides', Boccaccio's and Camus' plague descriptions (13).
Detractors to this "unproper" medical use of literature may object that human reactions could change across centuries, basing upon the higher cultural level of contemporary people. Nevertheless, after our combined analysis, we found many points in common with both Martin's and Wigand's analyses. Many centuries have passed, but the human behavioral response to plagues seems quite recurrent, maybe because the fear of massive deathly events is as constant in modern times as in the past. Especially the initial denial, the "unwise" reactions, scapegoating and antisocial behaviors are maybe the most recurrent across cultures and centuries, because they are based on instinct rather than reason or logic.
A correct disaster preparedness phase to infectious diseases should face and prevent all these harmful reactions. We may only hope that our descendants will treasure the COVID-19 chronicles and take prompter measures than we made with our ancestors' advice, wishing not to forget the take-home message: "Don't refuse, don't get unwise, don't accuse, prepare measures and put them into use".

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DATA AVAILABILITY

The data are contained into the article.

CONTRIBUTIONS

IM, NM, GMP: conceptualization. IM: writing - original draft. IM, NM, GMP: writing - review & editing, final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Treatment for Symptomatic Calcific Tendinopathy of the Shoulder: Ultrasound-Guided Needling Lavage and Extracorporeal Shock Wave Therapy *vs* Extracorporeal Shock Wave Therapy. A prospective observational study

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SUMMARY

Objective. To compare combined treatment ultrasound guided needling (UGL) and extracorporeal shockwave therapy (ESWT) *versus* ESWT alone in symptomatic calcific tendinopathy of supraspinatus.

Methods. It is a prospective observational study. The participants were 50 consecutive patients with painful (NRS > 5) calcific tendinitis of the shoulder. Clinical and radiological data were collected before treatment (T0) at one (T1) and three months (T2) follow-up.

Eligible patients were assigned to the Intervention Group (IG) with combined treatment and 3 sessions of focused ESWT (23 patients). Patients not willing to undergo UGL were considered as the Control Group (CG) and treated with 3 sessions of ESWT alone (27 patients). 36 patients reached T2.

Results. Combined treatment was more effective in NRS reduction at one (T1) month follow up ($p < 0.001$). Moreover, in IG, it was observed a statistically significant difference in NRS ($p < 0.001$) and in the CMS ($p < 0.001$) at three months follow-up (T2). Calcific deposit was eradicated more effectively by combined treatment, with total resorption in 79 % at T2 ($p < 0.001$).

Conclusions. Combined treatment ultrasound-guided needling lavage and shockwave therapy is a rapid, safe and effective treatment in patients with painful calcific tendinopathy, in pain reduction at one month follow-up.

KEY WORDS

Barbotage; calcific deposit; calcific tendinopathy; eccentric exercise therapy ESWT; rotator cuff; shock wave therapy; shoulder pain; ultrasound-guided needling lavage; ultrasound-guided percutaneous irrigation.

INTRODUCTION

Rotator cuff calcific tendinopathy (RCCT) is one of the most frequent causes of pain in the shoulder and is characterized by the presence of calcific deposits in the rotator cuff; it usually occurs during the fifth and sixth decades of life, with a prevalence varying from 2.7% to 22%, and it is more common in females (60%)(1). In almost 50% of cases, it involves the supraspinatus tendon at 1.5-2 cm from its insertion site on the greater tuberosity (2).

Clinical symptoms occur in 34% to 45% of patients with RCCT, mostly shoulder pain, variably associated with acute or gradual reduction of the articular range of motion (3). However, calcific deposits have also been described in asymptomatic individuals (4).

Its pathogenesis is not fully understood, but it seems to be the results of an active cell-mediated process. Uhthoff and colleagues have proposed a model which divides the evolution of the disease into three distinct stages: the pre-calcific, calcific and post-calcific stages. They hypothesize that a favorable environment allows for an active cell-mediated calcification process, usually followed by spontaneous phagocytic resorption, and the time scale of these different stages can be anything from a few months to several years (5).

Based on radiographic findings, Gartner classified the calcification into three types: well-circumscribed and dense (Type 1), soft counter/dense or sharp/transparent (Type 2), and translucent and cloudy with no precise circumscription (Type 3) (6). Softer calcifications may not be visible on radiographs, and in these cases, ultrasound (US) can be considered as a tool for diagnosis. Ultrasound can define calcific locations in the tendon, as well as their size and texture, and has proved helpful in determining associated tendon tear (7, 8), with 98% sensitivity and 94% specificity (9).

Rotator cuff tear is found in approximately 25% of patients with calcific tendinitis, although such tears tend to be associated more with small calcific deposits than with large calcific deposits (10).

Conservative management is the first line of treatment, which entails a combination of medication (non-steroidal anti-inflammatory drugs – NSAIDs), subacromial corticosteroid injections, and physical therapy. Other non-operative treatments include extracorporeal shockwave therapy (ESWT) and ultrasound-guided needling and lavage/barbotage (UGL). Surgical intervention is indicated in severe or refractory cases (11, 12).

A combined approach to calcific tendinopathy using UGL and ESWT could lead to the quicker reduction of pain and size of calcification deposits, along with functional recovery (13).

The primary objective of this study is to evaluate the safety and the short-term effects of combined treatment with UGL and ESWT when compared to ESWT alone in terms of pain reduction at one month follow-up (T1) in patients with symptomatic calcific tendinopathy of the shoulder.

The secondary objective of the study is to investigate pain reduction at three (T2) months follow-up, to assess functional recovery at one (T1) and three (T2) months follow-up, and to assess calcific deposit resorption at three months follow-up (T2) in the patient's sample.

MATERIALS AND METHODS

Study design

This is a prospective observational study conducted according to good clinical practice and the ethics of the Helsinki Declaration and approved by the Institutional Review Board of the University of Rome La Sapienza (RS 6532/2021 – Date of approval: October 15, 2021).

Eligibility criteria and enrollment

Participants were recruited between October 2021 and January 2022, among patients affected by painful calcific tendinitis of the shoulder diagnosed after clinical and radiological assessment.

The total number of patients evaluated was 53. Three patients were excluded: one patient had received a subacromial injection (SAI) and two patients had received ESWT, three weeks and one month previously, respectively. 50 patients were found eligible, and they all agreed to participate. 27 refused to undergo UGL for personal reasons and were therefore allocated to the control group. Overall, 23 patients were enrolled in the intervention group (IG) and 27 patients in the control group (CG). The Consort Flow Diagram is shown in **figure 1**.

The inclusion criteria were as follows: age greater than or equal to 18 years, shoulder pain lasting for more than 6 months, Numeric Rating Scale (NRS) greater than or equal to 5, radiographic finding of calcific deposits in the supraspinatus larger than 5 mm.

Exclusion criteria were Magnetic Resonance Imaging (MRI) or US diagnosis of rotator cuff tendon tear, subacromial injection with a corticosteroid or ESWT in the previous 3 months, history of prior allergic/hypersensitivity reactions relating to the study medications, coagulation disorders, therapy with oral anticoagulants, rheumatic diseases, fibromyalgia, pregnancy, and magneto-compatible devices. Eligible patients who agreed to participate signed written informed consent. Fifty-three patients met the inclusion criteria.

After completing the baseline data, eligible patients were assigned to the Intervention Group (IG) with combined treatment UGL and ESWT. Those patients not willing to undergo UGL were considered as the Control Group (CG) and treated with ESWT alone (**figure 1**).

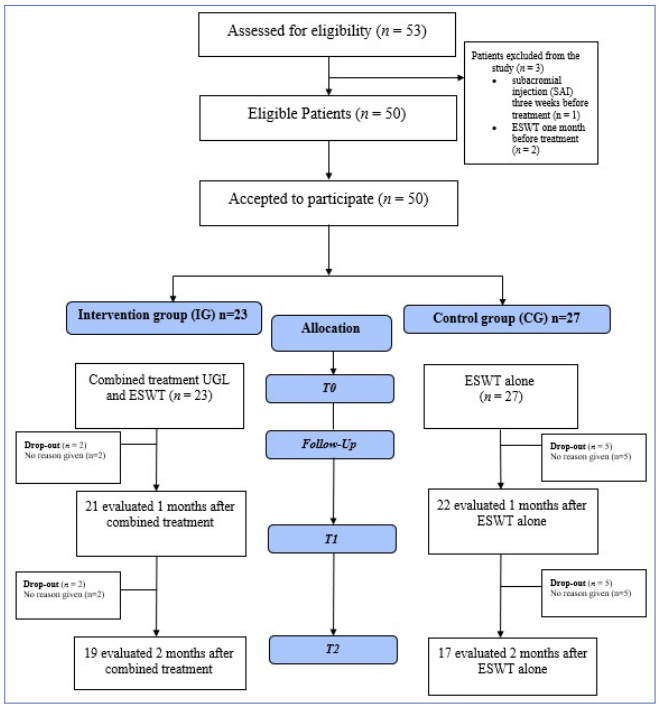

Figure 1. Consort flow diagram.

Outcome measures

The Numeric Rating Scale (NRS) was used to assess pain, (14) and the Constant and Murley Score (CMS) was used for functional assessment (15).

Calcific deposit size was collected from standard X-ray projections (anterior-posterior, lateral and acromioclavicular views) by measuring the larger diameter.

Clinical data were collected before treatment (T0) and at one (T1) and three months (T2) after the last ESWT session. At T0, diagnostic US of the supraspinatus tendon (Sonoscape X5 with linear probe 4-16 MHz) was performed to determine the characteristics of calcific deposits, including position, morphology and Power/Color Doppler signal. Calcific deposits were classified according to radiographic morphology, and size was ascertained by measuring the larger diameter, with standard shoulder radiographs performed not more than four weeks prior to the intervention. Furthermore, an X-ray of the shoulder was repeated to evaluate the presence or the modification of calcific deposits at T2.

Intervention group

The IG underwent UGL performed by a medical team with experience in both interventional and diagnostic musculoskeletal sonography, on an outpatient setting, with the patient in a supine position, their arm lying across their abdomen. After sterilization of the skin, the calcific deposit was identified with a 4-16 MHz probe wrapped in a sterile drape; under US guidance the subacromial-subdeltoid bursa was anaesthetized with 5 ml of 2% lidocaine hydrochloride, injected with a 21-gauge 40 mm needle. After 10 minutes, an 18-gauge single needle was positioned in the center of the calcification under sonographic guidance and connected to a sterile tube filled with 8 ml of saline solution 0.9% and 1 ml of 2% lidocaine hydrochloride. The other end of the tube was linked to a 5 ml syringe, after which the operator started to flush the calcification out by applying constant force on the syringe plunger until the calcific material started to back-flow into the connection tube as a milky substance. To avoid calcium reinjection, the liquid in the tube was emptied several times into a sterile container, until the calcification was entirely or partially removed and the back flow in the tube was free of visible calcium detritus. At the end of the procedure, the needle was gradually extracted and re-directed towards the subacromial-subdeltoid bursa, which was injected with 1 mL of triamcinolone (40 mg). The entire procedure took no longer than 30 minutes. Analgesic therapy with 1 gram of acetaminophen was recommended if needed, and broad-spectrum antibiotic therapy was prescribed to avoid bacterial infections.

Immediately afterwards, patients underwent the first session of ESWT with a focused electromagnetic shock wave device (Modulith SLK, STORZ Medical, Switzerland) with in-line sonographic guidance on the supraspinatus tendon area. The number of impulses administered was 2,400, with an energy flux density of 0.15 to 0.25 mJ/mm^2. Each participant received two more ESWT sessions with the same treatment parameters, one per week.

Control group

The CG underwent three sessions of focused ESWT (Modulith SLK, STORZ Medical, Switzerland) on a weekly basis, with in-line sonographic guidance on the supraspinatus tendon area using the same parameters as the IG group. Patients in both groups were advised to rest and to avoid overhead movements and overloading on the treated shoulder. They were also given a home-based exercise program consisting of eccentric exercise for the shoulder, to recover and maintain the full range of motion (ROM).

Statistical methods

Statistical analysis

Continuous variables are presented as mean and standard deviation (SD), while categorical variables are presented as frequency and percentage. Repeated measures ANOVA were used to analyze changes in mean NRS and CMS during the follow-up periods. The independent samples t-test was used to test the statistical difference in the maximum size of shoulder calcification before and after treatment. The Paired t-test was used to assess intra-group changes in all outcome measures. All tests were two-tailed with a level of significance of $p < 0.05$. All analyses were conducted with IBM SPSS Statistics for Mac, version 25. The eligibility rate was assessed by the number of eligible patients divided by the total number of elements on the sampling frame. The enrollment rate was assessed by the number of patients included in the study divided by the total number of eligible patients. Safety was assessed by monitoring any serious adverse events that occurred during follow-up.

RESULTS

Demographic, clinical and radiographic variables

The mean age of the intervention group was 51.1 years (41.0-74.0); 34.8% were male and 65.2% female. The mean age of the control group was 51.3 years (44.0-70.0); 44.4% were male and 55.6% female. The mean BMI of the IG was 23.9 ± 2.7; the median BMI of the CG was 24.1 ± 3.2. 21.7% of IG and 12% of CG were found to have a smoking habit. The right side was affected in 56.5% of IG and 59.3% of CG. No significant intergroup differences were found at baseline assessment except for calcific size ($p < 0.01$). Patients' demographic, clinical-pathological features, onset of symptoms, NRS, Constant Murley Score, calcific deposit size at baseline are summarized in **table I**.

Clinical results

Primary outcome

At the evaluation times between groups, a statistically significant difference ($p < 0.01$) in the NRS was found at T1 in favor of the intervention group (IG) (**table II**).

Table I. Baseline characteristics of patients.

	IG (n = 23)	CG (n = 27)	P-value
Age, mean (SD) years	51.1 (10.4)	51.3 (11.1)	0.96
Gender, female, n (%)	15 (65.2)	15 (55.6)	0.49
Side, right, n (%)	13 (56.5)	16 (59.3)	0.85
BMI, mean (SD)	23.9 (2.7)	24.1 (3.2)	0.37
Smokers, n (%)	5 (21.7)	3 (12)	
Gartner Classification, n (%)			
Type I	6 (26.1)	9 (33.3)	0.57
Type II	12 (52.2)	15 (55.6)	
Type III	5 (21.7)	3 (11.1)	
Symptom onset, mean (SD) months	13.5 (9.4)	13.5 (9.7)	1.00
NRS T0, mean (SD)	6.9 (1.6)	6.5 (1.1)	0.21
Constant Murley Scale T0, mean (SD)	65.5 (20.2)	68.8 (9.9)	0.46
Calcific deposit size T0, mean (SD) mm	1.9 (0.7)	1.3 (0.5)	**< 0.01**

Table II. Primary outcome.

NRS T1								95% Confidence Interval	
	Mean	SD	Statistic	df	P-value	Mean difference	SE difference	Lower	Upper
IG	2.7	2.3	-3.4239	41.0	**0.001**	-2.15	0.628	-3.421	-0.882
CG	4.8	1.8							

Secondary outcome

Comparison between groups

At the evaluation times, a statistically significant difference in the NRS was maintained at T2. Significant differences between IG and CG were not observed in CMS at T1, but were found at T2 (p = 0.005). In calcific deposit resorption, a statistically significant difference at T2 was found, with total resorption in 15 patients (79%) of the IG and 3 (17.6%) patients of the CG (p < 0.001) (**table III**).

Intra-group analysis

In the intervention group, a statistically significant difference in the NRS and CMS at T0 *vs* T1 (p < 0.001) was observed. No significant difference was found at T1 *vs* T2 in either NRS (p = 0.15) or CMS (p = 0.34). At T0 *vs* T2, a statistically significant difference in NRS (p < 0.001), CMS (p < 0.001) and calcific resorption (p < 0.001) was observed.

In the control group, a statistically significant difference in the NRS and CMS at T0 *vs* T1 (p < 0.001) was observed. No significant difference was found at T1 *vs* T2 in either NRS (p = 0.15) or CMS (p = 0.34). No statistically significant difference was observed in CMS at T1 *vs* T2 (p = 0.51) or T0 *vs* T2 (p = 0.06). At T0 *vs* T2, a statistically significant difference in NRS (p = 0.002) and calcific resorption (p < 0.001) was observed (**tables IV** and **V**).

Table III. Between group differences in secondary outcomes.

		Mean	SD	Statistic	df	P-value	Mean difference	SE difference	95% Confidence Interval	
									Lower	Upper
NRS T2	IG	2.3	1.9	-2.7432	34.0	**0.010**	-2.03	0.740	-3.536	-0.526
	CG	4.3	2.5							
CMS T1	IG	84.9	13.7	1.9666	41.0	0.056	7.23	3.674	-0.194	14.645
	CG	77.7	10.2							
CMS T2	IG	87.2	9.9	3.0320	34.0	**0.005**	11.00	3.628	3.628	18.375
	CG	76.2	11.8							
Calcific deposit size T2	IG	0.13	0.3	-4.514	34.0	**< 0.001**	-0.62	0.137	-0.897	-0.340
	CG	0.75	0.5							

Table IV. Intragroup differences in the outcome's measures.

	IG	CG
NRS, mean (SD)		
T0	6.9 (1.6)	6.5 (1.1)
T1	2.7 (2.3)	4.8 (1.8)
T2	2.3 (1.9)	4.3 (2.5)
P-value T0-T1	**< 0.001**	**< 0.001**
P-value T0-T2	**< 0.001**	**0.002**
P-value T1-T2	0.153	0.441
Constant Murley Scale, mean (SD)		
T0	65.5 (20.2)	68.8 (9.9)
T1	84.9 (13.7)	77.7 (10.2)
T2	87.2 (9.9)	76.2 (11.8)
P-value T0-T1	**< 0.001**	**0.001**
P-value T0-T2	**< 0.001**	0.063
P-value T1-T2	0.340	0.512

Table V. Calcific deposit size variation at T2.

	IG (n = 23)	CG (n = 27)	P-value
Size variation, n (%)			
Unvaried	0	8 (47.1)	
Reduction	4 (21)	6 (35.3)	**< 0.001**
Resorption	15 (79)	3 (17.6)	

Safety

No adverse effects were observed in either group at each follow up. Nonetheless, 6 patients from the IG suffered from pain exacerbation, which was resolved with the administration of NSAIDs (4 patients) or SAI (2 patients).

In the CG 12 patients required additional treatment due to pain exacerbation, which was resolved with the administration of NSAIDs (10 patients) or SAI (2 patients).

DISCUSSION

Rotator cuff calcific tendinopathy is a self-limiting disorder of the shoulder characterized by deposition of calcium in the rotator cuff tendons. Its pathogenesis is not fully understood, but it seems to be the results of an active cell-mediated process (2, 16).

In this work we found that combined treatment UGL and ESWT was more effective in pain relief at one month follow-up (T1) if compared to ESWT alone. In our sample, the intervention group also showed greater improvements in pain, function and calcific resorption at T2 compared to the control group.

These findings were partly expected, in fact according to the literature such as Ioppolo *et al*., when UGL is combined with other procedures, such as ESWT, it has proved to be more effective and faster than ESWT alone in terms of pain reduction, functional recovery and calcific deposit resorption (17).

UGL is a technique that uses sonographic guidance to aspirate calcium deposits from a particular area. It is performed under local anesthesia, is fully accepted as a safe and effective treatment. Moosmayer *et al*. described positive outcomes in terms of pain reduction, functional recovery and calcific resorption, with a low complication rate (0-10%) (18, 19); Del Castillo *et al*. showed that these outcomes last in the medium and long term (20).

In our study we have treated all type of calcification because, while UGL is always indicated in type 2 or type 3 calcification of the shoulder, it should be also considered for harder symptomatic calcification (Type 1) like Oudelaar says (21, 22). Furthermore, the combined treatment showed no difference in terms of side effects when compared to those involving ESWT, UGL or SAI alone (13, 23).

In the IG, 13 patients at T1 (61.9%) and 14 patients at T2 (73.7%) achieved a variation > 2.5 points on the NRS scale; in the CG only 6 patients (27.2 %) at T1 and 5 patients (29.4%) at T2 achieved such a variation, which is described in literature as the minimal clinically important difference (MCID) for NRS in RCCT patients (24).

Functional recovery improved in both groups at T1 without any statistically significant difference, but we observed a variation > 17 points - described as the MCID for CMS (25) - in 12 patients (57.1%) of the combined group, while in the control group only 5 patients (22.7%) achieved this result.

The therapeutic exercise could positively contribute in the management of RCCT, even if there are no available studies that outline a specific protocol for this pathology (26). Patients of both groups were administrated a home-based exercise protocol, and we can hypothesize that an early pain relief allows a faster ROM recovery and avoid the under-stimulation of the upper limb. This may have contributed to the functional improvement we observed at each follow-up time in both groups, but more in the IG than in the CG. Moreover, in order to achieve an early mobilization and to manage post-intervention pain and the risk of bursitis, a subacromial injection (SAI) with triamcinolone was also administered at the end of the treatment.

UGL has been shown to be quite effective in calcium removal (27). In our study, calcific deposit was eradicated more effectively by combined treatment, with total resorption in 15 patients (79%), even if baseline calcification size was larger than in the control group.

In the CG we observed a variation in calcific deposit, but total resorption was achieved in 3 patients only (17.6%). In fact, there is no complete agreement on the role of ESWT in the resorption of calcification (28), even though clinical improvements in shoulder function and pain are shown in the literature at a mid-term follow-up (29). We also can hypothesize that some participants were not symptomatic because of the calcification deposit. In fact, calcification in the middle of the tendon or at the articular surface could be less symptomatic than calcification on the bursal surface of the tendon (30).

Calcification size > 15 mm and Type I according to Gartner classification seem to be poor outcome prognostic factors when ESWT is performed (31), hence the idea to perform combined treatment with UGL.

In fact, ESWT stimulates proliferation, migration, and differentiation of supporting cells, all of which contribute to tendon self-healing (32-34).
Different energy levels and a different number of sessions can be performed, but there is no agreement on the gold standard (11, 35, 36).
All the patients treated in the study were symptomatic, with functional impairment and radiographic evidence of calcific deposits in the supraspinatus ≥ 5 mm (37).
For the UGL, an 18-gauge single needle was chosen, being easier to use than the double-needle technique, less invasive and equally effective (38-40).
Pain seems to be exacerbated in the resorption phase of the natural calcific tendinopathy cycle, probably sustained by bursal inflammatory reaction, leading to the remodeling of calcium deposit (41). It can be easily managed with NSAIDs or SAI, but it demands an accurate monitoring of the patient in the weeks after the procedure.
Based on our hypotheses and our data, combined UGL and ESWT treatment may be effective, safe, and rapid in patients with painful calcific tendinopathy.

Study limitations

The most important limitation in our work is the short time follow-up; in fact, ESWT expected effects, in particular tendon self-healing could take more than three months to be observed. Other limitations are the lack of randomization, and the drop-out rate: 14 patients (28%) were lost to follow-up from T0 to T2, no reasons given. COVID-19 promulgated restrictions, and patients' reluctance to go to hospital in a pandemic might also have played a role.

CONCLUSIONS

The combined treatment UGL and EWST is safe and more effective in reducing pain at one month follow-up than ESWT alone. Patients of both groups achieved pain relief, functional improvement and calcific deposit reduction, although patients in the IC had better results. We suggest that the combined treatment, which exploits the washing of the UGL and the biological effects of the EWST, could maintain the positive effects we observed for a longer period of time.
These results should be confirmed by future high-quality randomized clinical trials.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

DDR, SZ, AAB, MV: conceptualization, design. DDR, SZ, MM, LP, DT, MCV: data collection. DDR, SZ, MV: results analysis and interpretation. DDR, SZ: writing – original draft. All authors: writing – review & editing.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Deadlift Exercise with Shoes or Barefoot: Effects on Balance and Postural Control in Men and Women

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SUMMARY

Objective. The purpose of this study was to compare the plantar surface area, maximum peak pressure, mean pressure and stabilometry variables between men and women before and after performing the deadlift exercise with shoes *vs* barefoot.

Methods. Thirty healthy participants were selected and separated into two groups: men (n = 15) and women (n = 15). All study participants performed the deadlift exercise with shoes and barefoot at random. Participants performed 3 sets maximal repetitions trials, with intensity of 80% of the body mass and 2-minute rest between the sets. The interval between exercise sessions was separated by 48 hours. Participants underwent evaluations in the baropodometry platform (static conditions) during baseline, immediately post effort, 5-, 10- and 30-minutes post deadlift exercise, with the participant barefoot, to assess of the plantar surface area of both feet (cm^2), maximum peak pressure (kgf/cm^2), mean pressure (kgf/cm^2), anteroposterior (mm/s) and anteroposterior oscillation (mm/s).

Results. Two-way ANOVA showed significant decrease in both anteroposterior ($p < 0.05$) and laterolateral ($p < 0.001$) oscillations at men and women post-barefoot training. Plantar surface area maximal and mean pressure were significantly lower ($p < 0.05$) from 10 min at men and women post-barefoot training. On the other hand, plantar surface area maximal pressure in the right foot of women was significantly lower ($p < 0.001$) from 5 min post-barefoot training.

Conclusions. The results of this investigation confirm that barefoot deadlift exercise contributed to smaller anteroposterior oscillation, laterolateral oscillation and decrease of the plantar surface area pressure in both sexes.

KEY WORDS

Deadlift exercise; stability; baropometry platform; sex difference; postural control.

INTRODUCTION

Free-weights for resistance training utilize isotonic resistance that provides the same amount of resistance throughout the range of motion; thus, free-weights allow for movement in multiple planes requiring balance by the executioner himself (1, 2). Furthermore, free-weights training has been an important tool for joint rehabilitation and neuromuscular conditioning, consequently, provide an important role in the coordination, pattern of neuromuscular recruitment, balance and postural stability, not only when motionless, but also during movement (3, 4). Particularly, the deadlift is a multiple-joint exercise, thus presents a large mechanical stimulus to legs, hip, back, and torso muscles that lead to adaptations for the development of strength, power and balance (5, 6). But, interestingly, regarding balance and postural stability, there are a limited number of studies that comparing deadlift exercise with shoes *versus* barefoot between men and women.

The balance is defined as the condition in which all the forces acting on the body are balanced in the center of the mass and controlled by the support base, in a static or dynamic condition (7-9). These balance conditions are

characterized, respectively, by the absence or presence of speed. However, the ability to maintain balance during voluntary activities and to react to external perturbations becomes considerably more complex due to different changes, such as the decrease in the size of the support base, changes in the center of pressure, and postural changes (7-9). Hence, a body presents its state of normal balance when the sum of all external forces and all external torques is equal to zero (8-10). It is noteworthy that the foot helps support, move the body and to absorb ground reaction forces during locomotion, which are the foundations of the human balance and posture, *i.e.*, these functions depend largely on the plantar vault, formed by the longitudinal medial and transverse arches (7, 9, 10).

Anatomical or biomechanical variations between men and women can directly intervene in balance and plantar pressure. Some studies reported differences in feet and gait-related anatomy and habits between men and women (11, 12). Other studies showed that men had a foot longer, higher plantar fascia and heel fat pad thickness compared with women (13, 14). In general, men and women feet are different to varying degrees with respect to arch lateral side of the foot, the first toe, heel-to-toe length, ball length, ball width, ball circumference, malleoli height, and arch dimensions (11, 13, 14).

These differences anatomical or biomechanical of the feet between sex should be taken into account in relation balance and postural stability during deadlift exercise with shoes *versus* barefoot. The absence of data supports the need for additional studies in this area. Hence, the purpose of this study was to compare the plantar surface area, maximum peak pressure, mean pressure and stabilometry variables between men and women before and after performing the deadlift exercise with shoes *vs* barefoot. We hypothesized that both sexes would show a better of the balance and postural stability training barefoot.

METHODS

Study design

This is an analytic observational study. The sample size was determined by including all participants that complied with the eligibility criteria. All participants (men and women) were regular practitioners of resistance exercise and performed 3 sets of maximum repetitions of the deadlift exercise with shoes and barefoot at random. Participants underwent to two evaluations (when training with shoes and when training barefoot) in the baropodometry platform (static conditions) during baseline, immediately post effort, 5-, 10- and 30-minutes post deadlift exercise. All evaluations were performed in a two-session separated by 48 hours, with the participant barefoot, to assess of the plantar surface area of both feet (cm^2), maximum peak pressure (kgf/cm^2), mean pressure (kgf/cm^2), anteroposterior (mm/s) and anteroposterior oscillation (mm/s). All assessment were taken in a temperature-controlled environment (temperature 21 °C, 65% relative humidity) by a Hygro-Thermometer with Humidity Alert (Extech Instruments, Massachusetts, EUA). All assessments occurred between 2:00 and 4:00 P.M.

Participants

This study included 30 participants healthy and separated into two groups: men (age: 28.6 ± 6.7 years; height: 178.2 ± 6.5 cm; body mass: 82.5 ± 5.5 kg; body fat: 15.1 ± 3.7%; n = 15) and women (age: 27.5 ± 7.1 years; height: 165.2 ± 4.5 cm; body mass: 63.6 ± 6.8 kg; body fat: 19.2 ± 4.2%, n = 15). The participants' training frequency was 5.2 ± 0.6 days/week^{-1} with a mean duration for each session training of 65 min^{-1} using resistance-training programs. Subjects with at least one year of resistance exercise experience were included to participate in the current study. All participants performed a routine of resistance training programs used an intensity between 60% and 80% 1RM and a routine of strength training that engaged the whole body with resistance bands, free-weights, dumbbells and medicine balls. The personal shoes selected were shoes usually worn during daily activities within the last 2 months (15).

The participants were eligible if they weren't smokers for the previous 3 months or more, had no cardiovascular or metabolic diseases, systemic hypertension (140/90 mm Hg or use of antihypertensive medication), recent musculoskeletal injury and surgery (in the last 6 months), or pain in any region of the body, and had not used anabolic steroids, drugs or any medication with the potential to impact physical performance (self-reported). This study was approved by the Ethical Committee for Human Experiments of the Augusto Motta University Center, Rio de Janeiro, Brazil (CAAE: 53875421.0.0000.5235 – Date of approval: October 10, 2021). The present study was conducted at the A&D training center high performance, Rio de Janeiro, Brazil. All participants were informed of the experimental procedures and gave written informed consent prior to participation. No clinical problems occurred during the study.

Anthropometric measurements

Body composition was measured following an 8-h overnight fast by bioelectrical impedance analysis using a device with built-in hand and foot electrodes (BIO 720, Avanutri, Rio de Janeiro, Brasil). The participants wore their normal indoor clothing and were instructed to stand barefoot in an

upright position with both feet on separate electrodes on the device's surface and with their arms abducted and both hands gripping two separate electrodes on each handle of the device. All biometric measurements were carried out in an air-conditioned room (21 °C). No clinical problems occurred during the study.

Baropodometry assessment

The baropodometry platform consisted of a support with a 655 mm long and 534 mm wide (BaroScan®, Londrina, Brazil). The board contained 4,096 platinums electronic sensors covered by an alveolar rubber captor that gives pressure information from each foot through a USB cable to the computer for an appropriate software (BaroSys). The sampling rate was set at 100 Hz for static assessment. Before assessments, all individuals remained in a standing, bipedal position with the arms pending along the body over the platform with their eyes open mirrored to a fixed point on the wall of the examination room. All assessments took place with the participant barefoot. During static conditions, the subjects stood on the platform in an orthostatic position for 5 s (**figure 1**). The following parameters were considered in static condition: plantar surface area of both feet (cm^2), maximum peak pressure (kgf/cm^2), mean pressure (kgf/cm^2), anteroposterior (mm/s) and anteroposterior oscillation (mm/s). The forefoot was assumed as the foot part anterior to the gravity center and the hindfoot as the part posterior to the center of gravity registered on the device.

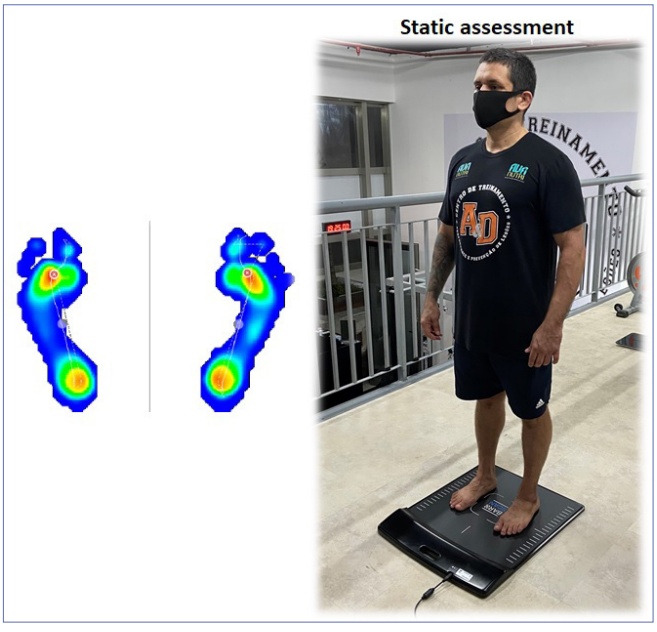

Figure 1. Positioning for performing static assessments on the stability platform.

Exercise protocol

To measure balance and postural stability, the deadlift exercise was selected for promoting greater safety during the execution of the movement (3). All study participants performed the deadlift exercise with shoes and barefoot at random. The interval between exercise sessions (shoes and barefoot) was separated by 48 hours.

Prior to the deadlift exercise protocol, a 10-minute warm-up was performed that included 5 minutes of cycling at 50 W while maintaining a cadence of 60-70 rpm on a cycle ergometer, followed by 10 repetitions in the deadlift exercise at 40% of the athlete's body mass (BM). After the warm-up, the subjects were allowed 4 minutes of passive rest, followed by 3 sets maximal repetitions trials during the deadlift exercise at 80% of the BM, with a 2-minute rest between the sets.

The conventional deadlift was performed with bar was positioned on the floor over the distal end of the metatarsals, the equal load on each side, both hands pronated, and toes should be pointed forward. During concentric phase, the participants kept the head neutral, core muscle activated, and the arms fully extended. When lifting the bar off the floor, all participants should extend their hips and knees. During eccentric phase, the participants kept the head neutral, flat back position and performed a hip and knee flexion returning the bar to the starting position. Training load was calculated by the multiplication of rate of perceived exertion (RPE) by the training session duration *Training load = session RPE × duration (minutes)*. On the other hand, absolute volume load was calculated using the equation: number of sets × number of repetitions × weight lifted (kg) (16).

Statistical analysis

All data are presented as mean ± SD. Statistical analysis was initially performed using the Shapiro-Wilk normality test and the homocedasticity test (Bartlett criterion). To test the reproducibility between the tests, the intraclass correlation coefficient (ICC) was used. For between groups comparisons for change in training session duration, volume load and training load, independent samples t-test was employed. However, to express the differences in RPE values the Chi Squared non-parametric null hypothesis test was also performed. Two-way analysis of variance (ANOVA) was used to test for main and interaction effects of the group (men *vs* women) and timing of measurement for each outcome variable independently (right *vs* left) and the *post hoc* Bonferroni was used to possibility a statistically significant. The significance level was set at 0.05 and the software used for statistics was GraphPad® (Prism 6.0, San Diego, CA, USA).

Table I. Mea n ± SD values of performance variables during deadlift exercise.

		Shoes	Barefoot	95%CI	p
Training session duration (min.)	Men	11.87 ± 2.9	11.40 ± 2.75	0.46 (-1.64 to 2.57)	0.65
	Women	12.67 ± 2.38	12.33 ± 2.29	0.33 (-1.41 to 2.08)	0.69
Volume load (kg)	Men	3673.41 ± 1337.40	4419.79 ± 1807.63	-746.4 (-1935 to 442.7)	0.20
	Women	3104.49 ± 991.42	3430.43 ± 1492.57	-325.9 (-1273 to 621.6)	0.48
Training load (A.U.)	Men	83.33 ± 24.84	81.73 ± 28.40	1.60 (-18.35 to 21.55)	0.87
	Women	89.27 ± 21.85	86.40 ± 19.20	2.86 (-12.51 to 18.25)	0.70
RPE (A.U.)	Men	7 ± 1.07	7.13 ± 1.46	-0.13 (-1.08 to 0.82)	0.77
	Women	7 ± 0.93	7 ± 0.93	-0.00 (-0.69 to 0.69)	1.0

RPE: Rate of Perceived Exertion; A.U.: arbitrary unit.

RESULTS

Table I represents the values of training session duration, volume load, training load and RPE during deadlift exercise. Statistical results no showed a significant difference between men and women with shoes *vs* barefoot.

All analyzed data presented normal distribution. The two-way ANOVA yielded main effects for group at men and women in the anteroposterior oscillation (men: $F_{1,140} = 25.66$, $p < 0.0001$; women: $F_{1,140} = 46.16$, $p < 0.0001$) and laterolateral oscillation (men: $F_{1,140} = 19.61$, $p < 0.0001$; women: $F_{1,140} = 30.87$, $p < 0.0001$) such that Bonferroni *post-hoc* showed significant decrease at men (**figure 2**) and women (**figure 3**) barefoot immediately post-effort in anteroposterior oscillations and laterolateral oscillation from 10 min post effort.

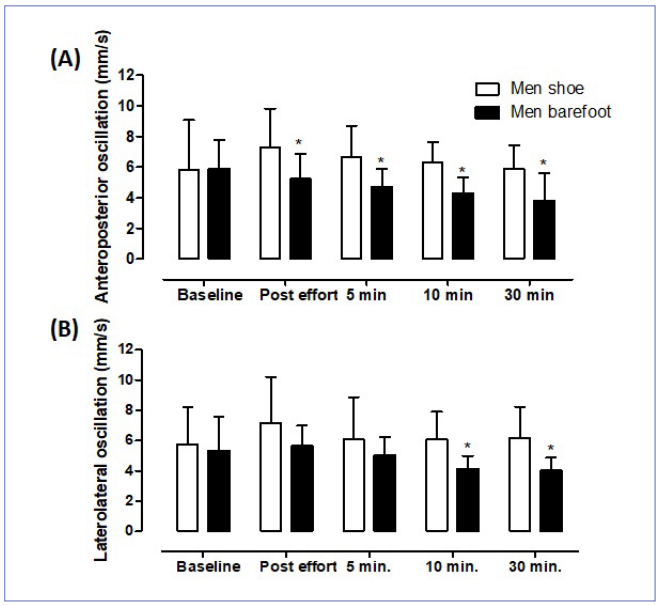

Figure 2. Comparisons of stabilometry variables between shoes and barefoot men.

*p < 0.05 shoes *vs* barefoot.

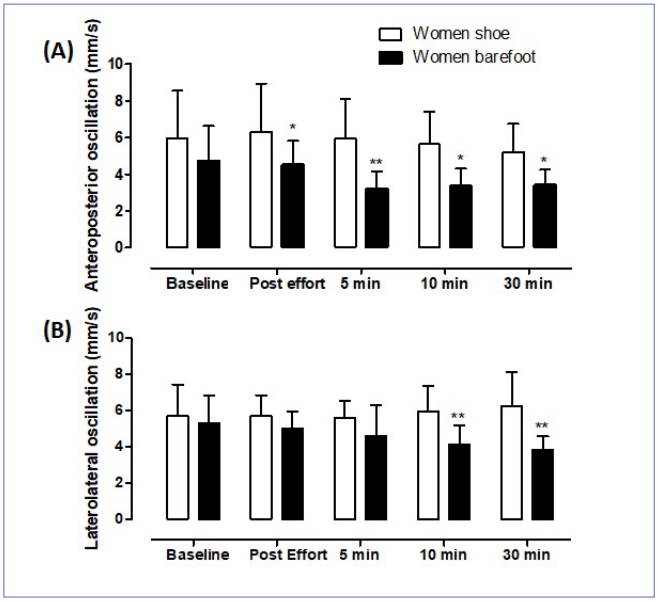

Figure 3. Comparisons of stabilometry variables between shoes and barefoot women.

*p < 0.05 shoes *vs* barefoot; **p < 0.001 shoes *vs* barefoot.

Figure 4 showed that two-way ANOVA yielded main effects for group at men and women in right foot (men: $F_{1,140} = 20.06$, $p < 0.0001$; women: $F_{1,140} = 25.07$, $p < 0.0001$) and left foot (men: $F_{1,140} = 15.63$, $p < 0.0001$; women: $F_{1,140} = 17.99$, $p < 0.0001$) in the plantar surface area maximal pressure (kgf/cm^2), such that Bonferroni *post-hoc* showed significant differences from 10 min post effort between shoes *vs* barefoot at men and women (**figure 4A,B,D**). On the other hand, plantar surface area maximal pressure in the right foot of women was significantly lower ($p < 0.001$) from 5 min post effort to barefoot training (**figure 4C**).

Figure 5 showed that two-way ANOVA yielded main effects for group at men and women in right foot (men: $F_{1,140} =$

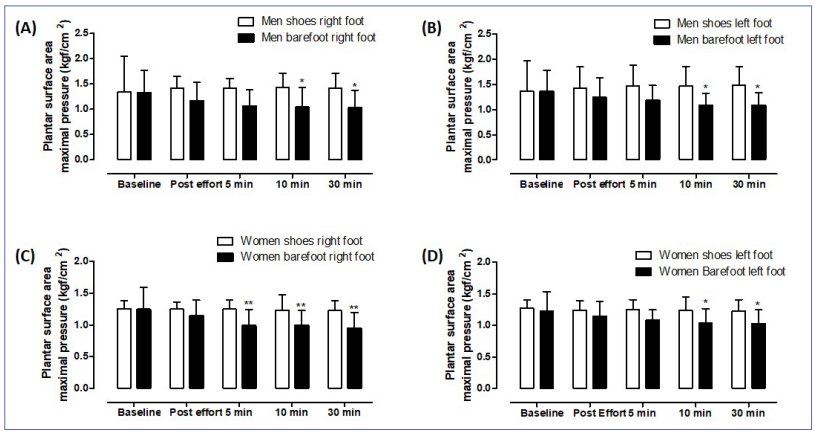

Figure 4. Comparisons of plantar surface area maximal pressure (kgf/cm²) between shoes *vs* barefoot at men and women.

*p < 0.05 shoes *vs* barefoot; **p < 0.001 shoes *vs* barefoot.

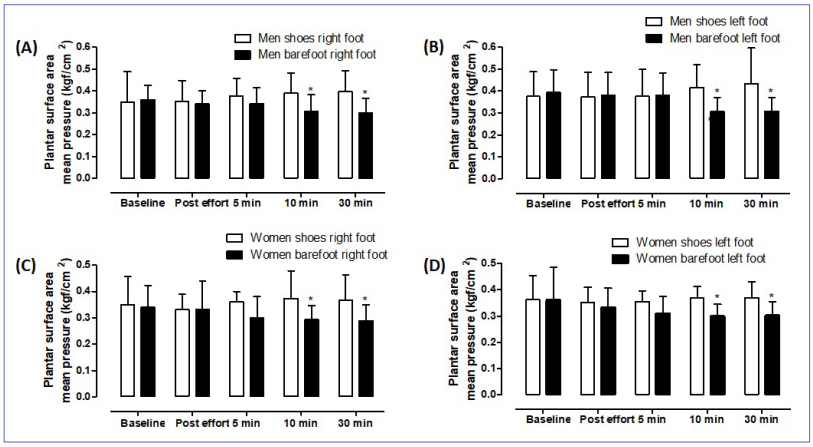

Figure 5. Comparisons of plantar surface area mean pressure (kgf/cm²) between shoes *vs* barefoot at men and women.

*p < 0.05 shoes *vs* barefoot.

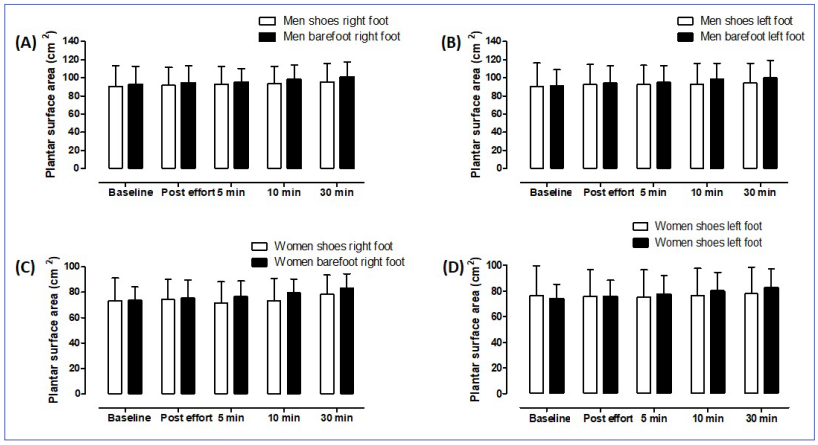

Figure 6. Comparisons of plantar surface area (cm²) between shoes *vs* barefoot at men and women.

9.47, p < 0.002; women: $F_{1,140}$ = 11.54, p < 0.000) and left foot (men: $F_{1,140}$ = 5.24, p < 0.002; women: $F_{1,140}$ = 12.56, p < 0.000) in the plantar surface area mean pressure (kgf/cm²), such that Bonferroni *post-hoc* showed significant differences from 10 min post effort between shoes *vs* barefoot at men and women (**figure 5A-D**). On the other hand, no significant difference was observed in plantar surface area (cm²) between men and women with shoes *vs* barefoot (**figure 6**).

DISCUSSION

This study aimed at investigating the effects of deadlift exercise with shoes or barefoot in the balance and postural stability between men and women trained. The main results obtained with this study were that 1) men and women showed significant decrease immediately post-effort in anteroposterior and laterolateral oscillation from 10 min post effort when to train barefoot, 2) plantar surface area maximal and mean pressure showed significant decrease when men and women performed barefoot deadlift exercise. Postural control is defined as the ability to maintain an erect posture of the body. Thus, for the proper functioning of postural control, the integration of sensory motor information into the central nervous system is necessary. Specifically, the control of body position is closely integrated with the somatosensory (sensory receptors located in skin, joints, muscles, and tendons), vestibular (labyrinth, cochlear nerves, nuclei, pathways, and interrelations in the central nervous system) and visual systems (8, 9, 17). When these three systems are is a perfect spatial orientation that triggers ocular (vestibule-ocular, optokinetic, cervical-ocular) and spinal (vestibulospinal, vestibular-colic, cervical-colic, cervical-spinal) reflexes appropriate to the automatic and unconscious maintenance of postural control in the environment (10, 17). Furthermore, the muscular control and the dynamic maintenance of balance, involve the coordinated activity of the muscular kinetic chains organized in directions and planes in which the propulsive forces of the body propagate (3, 18). Specifically, the participa-

tion of the feet in postural control depends on the plantar cutaneous stimulations, shape of the arch and the location of the line of gravity at a given moment (19).

Our results showed a worsened postural control by increasing the laterolateral and anteroposterior oscillations after deadlift exercise with shoes in men and women. On the other hand, it becomes evident that smaller the oscillations, the greater the tendency to postural control in the orthostatic position observed in barefoot training. Despite the limitation of studies investigating postural control with shoes *vs* barefoot, one study observed larger displacements in the laterolateral oscillations during performing the deadlift exercise with shoes (3). However, the authors found no significant differences in anteriorposterior oscillations. In contrast, shoes produce instability, decrease rate of force development and indirect ground reaction force (GRF) transmission, thereby compromising lifting performance (3, 15, 20). Contrary, the barefoot lifting could be considered more efficient than shod lifting by integration of the force × velocity curve during the concentric phase and resulting in better motor control that contribute with a steady state sooner which could potentially explain the increased rate of force development while barefoot (3, 21). We hypothesized that the barefoot training contributes with improvement plantar cutaneous sensitivity and somatosensory information from the foot, which help in postural control when exercises were performed barefoot (22). It has also been observed that walk barefoot or minimally-shod showed stronger and larger abductor hallucis and abductor digiti minimi muscles (15, 20). Furthermore, during barefoot training, it seems that the plantar flexors and dorsiflexors muscles are of great importance during postural control in the sagittal plane and the maintenance of frontal plane postural control is modulated by hip flexores and extensores muscles (10, 23, 24). On the other hand, it has been observed that the footwear features affect the cross-sectional areas of foot muscles contributing with weaker intrinsic foot muscles that may predispose individuals to reduced foot stiffness and potentially flat foot (20). In view of these concepts, the shoe may selectively activate specific muscle fiber types, with potential for implications on muscle fatigue, postural control and athletic performance (20, 22).

Despite the anatomical or biomechanical variations between sex can directly intervene in plantar surface area, studies measuring plantar surface area pressure in men and women with shoes *vs* barefoot before and after deadlift exercise are limited. Our results showed decrease of the plantar surface area maximal and mean pressure when men and women performed barefoot deadlift exercise. Despite limited scientific evidence, it has been observed that habitually barefoot training contributes with wider feet, particular in the toe region feature, that enhances three points of contact (heel, first metatarsal, and fifth metatarsal) (25-27). Hence, less center of pressure shift, less energy is wasted on controlling an unstable foot (*i.e.*, increased center of pressure shifts while in shod conditions) and more even distribution of pressure across the foot when habitually barefoot training (25-27). This response possibly promotes reduced muscle tension and may contribute to the increase in plantar surface area due to the impact on motor control, thus it favors the reduction in the plantar surface area maximal and mean pressure by efficiency of the movement with barefoot training in both sexes. In general, shod training can constrict the structure and function of the foot and affects the kinematics and kinetics of movement (11, 14, 20, 27).

The limitations of the study include the absence of measures of muscle thickness and electromyographic evaluation, which would be interesting; however, this yet does not limit the answer to the study question. In addition, longitudinal studies are needed to define a cause-and-effect relationship between sex differences.

CONCLUSIONS

The results of this investigation confirm that barefoot deadlift exercise contributed to smaller anteroposterior oscillation, laterolateral oscillation and decrease of the plantar surface area pressure (maximal and mean) in both sexes. These data contribute to the qualitative and quantitative understanding that barefoot training should be recognized and utilized in both fitness and rehabilitative fields for its potential benefits, especially considering the potential gains in balance and stability. Thus, these results may be a helpful for coaches, physicians and physical therapists regarding neuromuscular performance, injury prevention and recovery strategies.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

ASM: design, analysis and interpretation of data, writing – original draft, writing – review & editing. LFdS: design, analysis and interpretation of data, writing – review & editing.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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REVIEW

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Physiotherapy Interventions and Assessment Methods for Diastasis Recti Abdominis in Postpartum Women: A Systematic Review Protocol

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SUMMARY

Background. Diastasis recti (DR) or separation of the bulks of rectus abdominis muscle is often caused by pregnancy. Physiotherapy of DR includes exercise therapy, electrical stimulation (ES), kinesiotaping and bracing. Additionally, there are several measurement methods and levels for inter rectus distance (IRD) assessment, but their effects on the significance of the results following physiotherapy are unclear. This study aims to determine the effects of different physiotherapy interventions on DR in postpartum women, as well as reviewing the measurement method of DR, following physiotherapy.
Methods. Databases including Cochrane, Scopus, Pro Quest, PubMed, Embase, Web of Science, Google Scholar, and Magiran will be searched. The articles will be reviewed in terms of title, abstract and full text. The JBI quality assessment checklist and Cochrane Collaboration RoB 2.0 tool will be used by two independent assessors. Disagreements will be referred to the third assessor. The results will be analyzed using Review Manager software. The subgroups will be based on the type of measurement method and level, type of exercise, and the adjunct intervention.
Results. The findings of this study will probably determine the effects of different physiotherapy interventions on IRD and may also determine the most effective combination therapy. Furthermore, our findings may identify the most appropriate IRD measurement method to show the effectiveness of physiotherapy intervention.
Conclusions. This study is designed to promote postpartum women's health and assist physiotherapists in treatment of DR.
Study registration. This article is registered in PROSPERO with registration number CRD42022382998.

KEY WORDS

Exercise therapy; physiotherapy; adjunct intervention; inter rectus distance; caliper; ultrasonography.

INTRODUCTION

Diastasis recti (DR) is the separation of the two bulks of the rectus abdominis muscle in the midline due to the widening and thinning of the linea alba (1). Abdominal muscles play an important role in posture, trunk and pelvic stability, respiration, and abdominal visceral support (2). DR reduces the strength and endurance of the abdominal muscles; also, through its effect on the connective tissue and ligaments, it reduces the stability of the lumbar vertebrae and pelvic. Consequently, musculoskeletal problems such as low back pain and lumbopelvic pain may occur (3). There is a possibility of other complications, including activity limitation (1), pelvic organ prolapse (4), urinary incontinence (5), fecal incontinence (5), respiratory dysfunctions (6), and cosmetic problem (7) in patients with DR. These complications may affect a person's mood and reduce their quality of life (8). DR has different causes, but it is frequently seen in pregnant women due to the effects of hormonal changes on the connective tissue and biomechanical changes in pregnancy (9). The prevalence of DR in the third trimesters of gestation is 66-100% and 12 months after delivery is 36%. So, in 36% of the cases, recovery may not happen spontaneously and it needs to be treated (9).

The therapeutic methods for reducing IRD include surgery and physiotherapy (10, 11). The first step in the treatment of these patients is physiotherapy (11). Studies show that there is no adverse effects or recurrence in treating DR patients with physical therapy (12). However, if conservative treatment is not effective, surgery can be used (11). Surgery in these patients is open or laparoscopic and has different plication techniques (11). The surgical recurrence rate is also low, but this method is invasive, expensive for the patients, and it may have adverse effects such as seroma, sensory disorders in abdominal skin, and scarring (13). Physiotherapy interventions such as exercise therapy, electrical stimulation (ES), kinesiotape and brace are used in patients suffering from the DR (14). The results of previous systematic review studies showed that postpartum exercise therapy reduces IRD and symptoms in women with DR (15, 16). It is worth mentioning that in patients with DR who are unable to exercise and also to speed up the treatment process, the physiotherapy interventions such as ES, kinesiotape, and brace are used as an adjunct to exercise. The effect of these modalities has not been compared in previous reviews, to realize which one has better effectiveness in the treatment of DR. It is also unknown whether combining these modalities with exercise is more effective than exercise or not. So far, no specific protocol has been provided for the physiotherapy of these patients, therefore, determining the best modality and the best type of exercise will help therapists in treating this disorder.

The measurement index of DR is inter rectus distance (IRD), that may show different values depending on the measurement site, patient position, and measurement method (9). IRD is measured with clinical methods such as finger width (FW) and caliper, and imaging methods such as ultrasonography (US), magnetic resonance imaging (MRI) and computed tomography (CT-scan) (17). MRI and CT-scan are very expensive, and MRI in people with pacemakers or platinum and people with claustrophobia, and CT-scan in pregnant women is not applicable (18). US has been used as non-invasive technique for real time imaging of the abdominal muscles and evidence shows that is the golden standard in the evaluation of DR and has good to excellent reliability. This method application is not easy, images can be difficult to interpret and requires experienced operators or radiologists, and also is operator and equipment dependent (17, 19). FW technique is an easy method to measure IRD, but it is not a reliable method (20). On the other hand, the caliper method has good reliability and its application is simple and cheap (10, 21). It is unknown whether the use of all these methods will show the same results during assessment or not. Therefore, the diversity of DR measurement methods, make it difficult to draw a strong conclusion. Indeed, comparing different measurement method on the significance of results following treatment of DR, shows therapists whether the choice of measurement method is important or not, and helping them to speed up the assessment and treatment process of DR. IRD has been measured at above, below and umbilical levels in different studies (19). However, according to the previous studies, the evaluation of the above umbilicus is more reliable (19), but the effect of treatment at different levels has not been compared yet, and the amount of improvement of DR at different levels is unclear. Therefore, the comparison of different levels could show therapists which level is more responsive to treatment and helping them choose the best level for assessment of IRD.

A recent meta-analysis by Berg-Poppe *et al.* (22) explored the effects of exercise and companion modalities on DR in postpartum women and included 14 studies. The intervention group (exercise or exercise + other intervention) was compared with the control group (no intervention), and only 4 studies were included in the meta-analysis. The results showed that exercise therapy alone and in combination with other non-invasive modalities reduces IRD and improves the quality of life after pregnancy. In this review, the effectiveness of exercise alone has not been compared with combination therapy. Also, they have not compared the effect of ES, kinesiotape, and corset in these patients, and it is unclear which of these modalities is more effective in reducing IRD. Although there are many studies in this field, an ideal physiotherapy protocol for patients with DR has not been deter-

mined, and some aspects of the treatment of these patients have not yet been clearly elucidated. Therefore, the proposed systematic review will focus on the comparison among exercise and exercise in combination with adjunct interventions, comparison among the effect of kinesiotape, ES, and brace, and the comparison between different measurement methods and levels in postpartum women with DR following physiotherapy.

MATERIALS AND METHODS

This study has been approved by the ethics committee of Tabriz University of Medical Sciences with approval ID IR.TBZMED.REC.1400.241 - Date of approval: May 31, 2021.

Review objectives

Main objectives

- Comparing the effects of exercise therapy alone and combination therapy (exercise therapy in addition to kinesiotape, brace, and ES) on IRD in postpartum women.
- Comparing the effect of ES, kinesiotape and brace in combination with exercise therapy on IRD in postpartum women.
- Comparing different measurement methods in determining the effectiveness of the results.
- Comparing different measurement levels in determining the effectiveness of the results.
- Comparing the effects of exercise therapy compared to non-intervention on IRD in postpartum women.

Secondary objectives

- Determining the effects of exercise therapy on low back and pelvic pain in postpartum women with DR.
- Determining the effects of exercise therapy on disability based on ODI in postpartum women with DR.
- Determining the effects of exercise therapy on pelvic floor dysfunction in postpartum women with DR.
- Determining the effects of exercise therapy on abdominal muscle strength, endurance, and power in postpartum women with DR.
- Determining the effects of exercise therapy on quality of life in postpartum women with DR.

Inclusion criteria

Types of studies

In this systematic review study, only RCT studies evaluating the effects of exercise therapy on DR will be searched and included. According to the level of evidence hierarchy, systematic reviews of RCTs have the highest level among studies.

Types of participants

In this review, studies considering postpartum women with DR will be included.

Exclusions:

- Women with neurological, respiratory, and heart diseases.
- The recent pelvic, spinal cord, and abdominal surgery except for cesarean.

Types of intervention(s)

All studies using any type of physiotherapy intervention will be included, such as:

- Abdominal exercises.
- Core stability exercises.
- Pelvic floor exercises.
- Upper and lower extremity exercises.
- Electrical stimulation.
- Kinesiotape.
- Brace or corset.

Types of outcomes measured

In this review, RCT studies evaluating the following outcomes will be included:

Primary:

- IRD (measurement method including US, caliper, FW, MRI).

Secondary:

- Low back and pelvic pain (evaluation by visual analog scale (VAS)).
- Pelvic floor dysfunctions (evaluation by pelvic floor disability index (PFDI)).
- Disability (evaluation by Oswestry disability index (ODI)).
- Abdominal muscles strength, endurance and power (evaluation by manual muscle test (MMT), isokinetic, dynamometer).
- Quality of life (evaluation by physical functioning scale (PFS) or ODI).

Search strategy

The databases such as Cochrane, PubMed, Scopus, Embase, ProQuest, Web of Sciences, Google Scholar, and Magiran will be searched by a medical librarian. Also, references of the related articles will be manually searched. There will be no time limitation and the search will include all Persian and English RCT studies conducted until the end of 2022.

The search strategy includes a combination of Mesh and entry keywords based on PICO: "Diastasis recti" OR "Diastasis rectus abdominis" OR "Rectus diastasis" OR "Pregnancy" OR "Postnatal women" AND "Exercise Therapy"

OR "Abdominal Exercises" OR "Transverse Exercises" OR "Core stability exercises" OR "Pelvic floor exercises" OR "Noble technique" OR "Strength training" OR "Resistance training" OR "Endurance training" OR "Physiotherapy" OR "Rehabilitation" AND "Taping" OR "Neuromuscular electrical stimulation" OR "Manual therapy" OR "Postural training" OR "Physical activity" OR "Splint" OR "Corset" OR "Brace" OR "Adjunct intervention" AND "Diastasis recti width" OR "Inter rectus distance" OR "Pelvic floor dysfunction" OR "Quality of life" OR "Pain" OR "Caliper" OR "Ultrasonography".

Study selection

The studies will be reviewed in two stages in terms of title and abstract and then full text. Studies that meet the inclusion criteria will be included in the study.

The whole processes of the systematic review will be conducted by two authors independently in terms of electronic database searching, screening of the retrieved articles, data extraction, and critical appraising. The reviewers discussed until they came to an agreement to settle any differences in various research sections. In case of remained ambiguous points, there will be a communication with the author of the related paper. Finally, any disagreements will be resolved by the third author.

Assessment of methodological quality

The selected studies will be critically appraised by two independent reviewers for methodological quality using the JBI checklists that approved by JBI International Scientific Committee. For the inter-rater agreement of this checklist, kappa is 0.714 and this checklist is a suitable guide for quality assessment (23). Also, JBI checklist has more questions compared to checklists such as Pedro, and examines more details in RCT studies. The risk of bias (ROB) will be assessed by using the revised Cochrane Collaboration RoB 2.0 tool (24). Any disagreements between the reviewers will be resolved through discussion or referred to a third reviewer. Following the critical appraisal, the studies that do not earn certain quality will be excluded.

Data extraction

The data from the articles included in this review will be extracted using the standardized data extraction instrument from the JBI by two independent reviewers. The extracted data will include specific details about the interventions, populations, measurement methods, assessment levels, and duration of intervention based on the review questions and objectives. In addition, the adverse events mentioned in the included studies will be extracted and reported. In case of remained ambiguous points, there will be a communication with the author of the related paper. Any disagreements between the reviewers will be resolved through discussion or referred to a third reviewer. The extracted data will be summarized in the extraction table by Excel software. Authors of the papers will be contacted to request the missing or additional data where required.

Data synthesis

If the studies are homogeneous and it is possible to combine the results, RevMan (Review Manager) software will be used for meta-analysis. The random effect will be used to reduce possible heterogeneity and a Funnel plot will be drawn to examine the selection bias of the studies. Then the results will be reported using a Forest plot. In this systematic review, if possible, the meta-analysis will be performed for any of the following parameters:

- Comparing the effects of exercise therapy and combination therapy (exercise therapy + adjunct intervention) on IRD.
- Comparing the effect of ES, kinesiotape, and brace on IRD.
- Comparing the measurement methods of IRD.
- Comparing the measurement levels of IRD.
- Comparing the effects of exercise therapy and non-intervention on IRD.
- Evaluation of the effects of exercise therapy on low back pain, ODI, pelvic floor dysfunction, abdominal muscle function, and the quality of life in women with DR.

Subgroup analysis

In this review study, subgroup analysis will also be performed, and the studies will be reviewed in more detail than in previous studies (16, 22). Subgroups will be performed based on:

- Measurement method.
- Measurement level.
- Adjunct intervention.
- Type of exercise.

Results from the intention-to-treat analysis and, if not reported, those from the per-protocol analysis will be used for meta-analysis. In this study, mean and standard deviation will be employed for analysis both before and after the intervention along with quantitative variables. These indices will be derived from the median and interquartile range in the absence of access. To determine MD change with a 95% confidence interval, mean changes and standard deviation in each group following the intervention compared to baseline will be employed. The fallow up mean will be used to calculate the mean change from the baseline mean subtraction for this purpose. Standard deviation change will be calculated from the previously reported formula (25).

The I^2 index will be used to assess the degree of heterogeneity among the outcomes of the included studies. If the index is greater than 50%, it implies high heterogeneity and a random effect will be used to present the meta-analysis. This index shows the percentage of variability between studies. The fixed-effect model will be utilized for analysis when the degree of heterogeneity is less than 50%. If there are at least two POOL articles for that outcome, a forest plot will be utilized to display the meta-analysis results.

DISCUSSION

This protocol of a systematic review deals with the multidimensional investigation of DR through physiotherapy perspective, including its treatment methods, measurement methods and levels.

DR affects at least two-thirds of women after pregnancy has various complications, and reduces the quality of life of the women (9). Studies have shown that there is a significant negative correlation between DR and abdominal flexor muscle strength in postpartum women (26, 27), and they have weaker abdominal muscles compared to women without DR (28). Studies suggest that the activation of transverse abdominis muscle increases the tension and decreases the distortion of the linea alba and removes the force from the midline (29). Therefore, therapeutic exercises of abdominal muscles and their synergists such as the diaphragm, multifidus, and pelvic floor muscles may reduce the IRD, pain, and pelvic floor dysfunctions and improve the quality of life (30, 31).

However, exercise therapy is one of the most common physiotherapy interventions to cure these patients, but some patients may not be able to exercise. Thus, it is important to determine the effectiveness of other non-invasive interventions such as ES, kinesiotape and braces in people with DR. ES is the application of electrical current to increase muscle contraction recruitment which induces higher loads on the muscles and results in stronger contractions of the abdominal muscles in patients with DR. Kinesioape is also used to increases abdominal and core muscle function, proprioception, joints support and reduces discomfort in these patients (32). As well, using corsets or braces increases the intra-abdominal pressure and the abdomen becomes firm like a cylinder, which stabilizes the spine, improves muscle strength, and reduces IRD (33). Currently, there is a lack of information about this issue. Therefore, in this review study, the comparison among the effects of kinesiotape, ES, and brace and the combination of these modalities with exercise therapy may be beneficial to help the physiotherapists facilitate treatment and choose the best type of interventions in the treatment of women with DR.

Another important issue in these patients is the necessity of performing a systematic review of the evaluation methods. Despite the numerous studies in this field, assessment methods to determine the severity of DR are not equivalent and this variety of assessment methods and levels of IRD may make judgment and final conclusions difficult. This is an issue that has not been investigated yet. Therefore, standardization in this field seems necessary and this study may be helpful in this regard and speed up the process of evaluating patients.

It seems that, the findings from this systematic review will add to previous literature in the field of DR and may be valuable to promote postpartum women's health, assist physiotherapists in the treatment of DR and researchers in the assessment of this disorder. As formerly mentioned, this disease can cause many secondary complications for women after childbirth, and the lack of the definite protocol led to confuse of patients and therapists.

CONCLUSIONS

In this systematic review, the effects of therapeutic interventions will be investigated and presented from different aspects. Physiotherapists are likely to be able to use the evidence from this study in the evaluation and treatment of women with DR, and enhance the outcomes of their treatment and increase the quality of life of the patients.

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DATA AVAILABILITY

The search has been performed and the data are available. Also, the study selection has been performed.

CONTRIBUTIONS

ES, HA: conceptualization, design. HSP, FGh: search study. ES, TGh: study selection. ES, HA: writing – original draft; writing – review & editing.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Quality and Reliability of Trigger Finger YouTube Videos

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LEVEL OF EVIDENCE: 5

SUMMARY

Introduction. Orthopedic video contents published on YouTube are not scanned and do not go through an editorial evaluation process. It is important to determine the quality and content accuracy of health-related videos. Trigger finger is a common disease and the deterioration in quality of life. However, the quality, content and adequacy of YouTube videos as a source of information about this disease have not been evaluated. The aim of this study is to investigate the quality and adequacy of the medical content of the videos on YouTube about trigger finger disease.

Methods. In September 2022, the phrase "trigger finger" was entered in the YouTube search bar and the 50 most watched videos were included in the study, provided that the language of the video was English. Who uploaded the videos, real or animated content, number of views, upload date, number of comments, number of like-dislikes and video length were recorded. 3 orthopedic surgeons and 1 hand surgeon watched the videos simultaneously and separately. JAMA, DISCERN and GQS scores were calculated.

Results. Average length of 50 videos is 321 seconds, number of views is 244,150, number of days from upload date to evaluation date is 1,789 days, VPI was 94, view ratio was 300. The average scores of 4 different surgeons from the parameters used for the quality and relevance analysis of the videos: JAMA 2, DISCERN 36, and GQS 2. The scores of 4 different surgeons were statistically compatible with each other ($p = 0.000$). The interclass correlation coefficient (ICC) was 0.906 for the JAMA score, 0.889 for the DISCERN score, and 0.831 for the GQS score.

Conclusions. YouTube videos about trigger finger were low quality and unreliable. In the light of our study and other studies, the possibility of high-quality and reliable videos for patients can be increased by the evaluation and inspection of videos presented by YouTube.

KEY WORDS

Patient education; reliability; social media; trigger finger; YouTube; quality.

INTRODUCTION

Currently, the first source that patients refer to in order to get information about their diseases is the internet. Although the Internet provides easy access to information, it is not always possible to evaluate the quality and accuracy of this information. YouTube is the second largest search engine and social media platform after Google, with more than 6 billion hours of video watched every month. Although YouTube is mostly used for entertainment purposes, it also contains many academic and educational videos. In this way, it is easier for patients to access information (1-3). It is thought that video-based information will be the primary data source in the coming years, emphasizing the increasing importance of video quality accuracy (4). Orthopedic video contents published on YouTube are not scanned and do not go through an editorial evaluation process (5). For this reason, it is important to determine the quality and content accuracy of health-related videos.

Trigger finger is a disease that causes pain, triggering and locking in the finger that occurs as a result of the size

disproportion between the flexor tendon and the A1 pulley. It is seen in 2-3% of the society and is more common in women (6, 7). It is most commonly seen in the long and ring fingers (6). Splinting, physical therapy, anti-inflammatory drugs and corticosteroid injection can be applied in non-surgical treatment. Open or percutaneous release of the A1 pulley is commonly used when nonsurgical treatment has failed. Although the success rate of surgical treatment is high, it is not completely uncomplicated. Infection, stiffness, nerve injury, scarring, recurrence, and flexor tendon bowstring are among the complications of surgical treatment (6-9). Due to the fact that the trigger finger is a common disease and the deterioration in the quality of life caused by delayed diagnosis and treatment, patients need to be informed correctly, diagnosed quickly, and guided accordingly. However, the quality, content and adequacy of YouTube videos as a source of information about this disease have not been evaluated.

The aim of our study is to investigate the quality and adequacy of the medical content of the videos on the YouTube social media platform about trigger finger disease. We planned such a study because we did not find a similar study published before on trigger finger video evaluation in the literature.

MATERIALS AND METHODS

In September 2022, the phrase "trigger finger" was entered in the YouTube search bar and the 50 most watched videos were included in the study, provided that the language of the video was English. Who uploaded the videos, real or animated content, number of views, upload date, number of comments, number of like-dislikes and video length were recorded. Video power index (VPI) was calculated to determine the popularity of the videos. The video power index is an index that defines the popularity of YouTube videos. It is calculated as like ratio × view ratio/100.

In order to evaluate the quality and reliability, 3 orthopedic surgeons and 1 hand surgeon watched the videos simultaneously and separately. JAMA (Journal of the American Medical Association), DISCERN (Quality Criteria for Consumer Health Information) and GQS (Global Quality Score) scores were calculated.

The JAMA scoring system is a scoring system used to evaluate health-related videos (10). It consists of four main titles. The scoring system ranges from 0 to 4. Each criterion is scored with 1 point. The highest possible score is 4. Transparency and reliability of information are evaluated (**table I**).

DISCERN was jointly developed by Oxford University and British Library staff and evaluates the reliability, relevance and quality of treatment options of video. DISCERN scoring system consists of 15 questions. The first 8 questions evaluate the reliability of the video, the next 6 questions the details of the treatment options, and the 15th question the overall quality of the video. Each question is scaled from 1 to 5 points from No to Yes. The total score varies between 15-75. Scoring results are evaluated as excellent (63-75), good (51-62), moderate (39-50), bad (28-38) and very bad (16-27) (11). The criteria evaluated in scoring are given in **table II**.

GQS is a non-specific assessment of health-related website quality and evaluates the educational content of videos based on 5 criteria. The maximum score that can be obtained is 5. A video with a score of 5 is considered to be of high educational quality (12, 13) (**table III**).

Ethical approval was not required as this article does not contain any studies with human participants or animals performed by any of the authors.

Statistical analysis

Data were analyzed with International Business Machines Statistical Package for the Social Sciences Statistics, version 20 software (IBM SPSS Corp., Armonk, NY, USA). Continuous variables were presented as means with standard deviations and ranges. Cate-

Table I. JAMA Scoring System.

	JAMA Scoring System	Rating	
Section		**No**	**Yes**
Authorship	Authors and contributors, their affiliations and relevant credentials should be provided	0	1
Attribution	References and sources for all content should be clearly and all relevant copyright information should be noted	0	1
Disclosure	Website "ownership" should be prominently and fully disclosed, as should any sponsorship, advertising, underwriting, commercial funding arrangements or support, or potential conflicts of interest	0	1
Currency	Dates when the content was posted and updated should be indicated	0	1

Table II. Discern Scoring System.

	No		Partly		Yes
Section 1 – Is the publication reliable?					
1. Are the aims clear?	1	2	3	4	5
2. Does it achieve its aims?	1	2	3	4	5
3. Is it relevant?	1	2	3	4	5
4. Is it clear what sources of information were used to compile the publication?	1	2	3	4	5
5. Is it clear when the information used in the publication was produced?	1	2	3	4	5
6. Is it balanced and unbiased?	1	2	3	4	5
7. Does it provide details of additional sources of support and information?	1	2	3	4	5
8. Does it refer to areas of uncertainty?	1	2	3	4	5
Section 2 – How good is the quality of information?					
9. Does it describe how each treatment works?	1	2	3	4	5
10. Does it describe the benefits of each treatment?	1	2	3	4	5
11. Does it describe the risks of each treatment?	1	2	3	4	5
12. Does it describe what would happen if no treatment is used?	1	2	3	4	5
13. Does it describe how the treatment choices affect overall quality of life?	1	2	3	4	5
14. Does it provide support for shared decision making?	1	2	3	4	5
Section 3 – Overall rating of the publication					
15. Based on the answers to all of these questions, rate the overall quality of the publication as a source of information about treatment choices?	1	2	3	4	5

Table III. GQS Scoring System.

Score	Global score description
1	Poor quality, poor flow of site, most information missing, not at all useful for patients
2	Generally poor quality and poor flow, some information listed but missing many important points, very limited use for patients
3	Moderate quality, suboptimal flow, some important information is adequately discussed but others poorly discussed, somewhat useful for patients
4	Good quality and generally good flow, most of the relevant information is listed but some issues not covered, useful for patients
5	Excellent quality and excellent flow, very useful for patients

gorical variables were shown as relative frequencies with percentages. One-way analysis of variance (ANOVA) tests (for normally distributed data) and Kruskal-Wallis tests (for non-normally distributed data) were used to determine whether the video reliability and quality differed based on video source and video content. The Spearman correlation test was used to analyze the relationships between quantitative variables. For video quality assessment, agreement between the 4 reviewers was analyzed using the interclass correlation coefficient (ICC). Interclass correlation coefficient values < 0.5 were categorized as poor reliability, values between 0.5 and 0.75 as moderate reliability, values between 0.75 and 0.9 as good reliability, and values > 0.90 as excellent reliability.

RESULTS

Average length of 50 videos is 321 seconds (min: 77- max: 858), average number of views is 244,150 (min: 517-max: 2,306,934), average number of days from upload date to evaluation date is 1,789 days (min: 128-max: 4,670), average VPI was 94 (min: 66.6-max: 100), average view ratio was 300 (min: 0-max: 5,172).

15 of the videos were uploaded by the Doctor, 14 by the hospital channel, 11 by the physiotherapist, 6 by the health channel, 1 by the fitness trainer, 1 by the chiropractor, and 2 by other accounts (**figure 1**). 43 of the videos consisted of real images and 7 of them were animations.

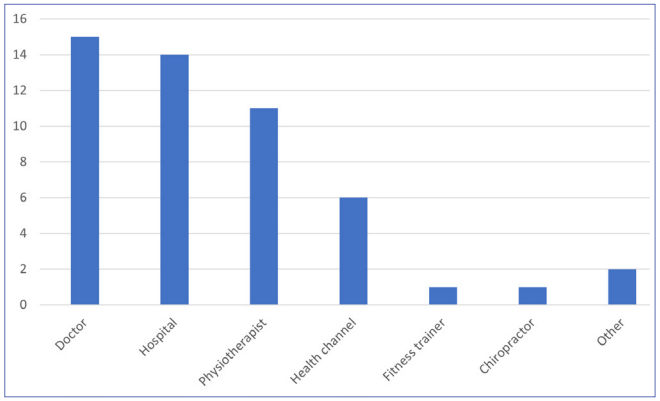

Figure 1. Distribution by video upload sources.

According to the DISCERN scoring system, 1 excellent, 4 good, 11 moderate, 24 bad and 10 very bad videos were evaluated. According to GQS, 6 videos were rated 1 point, 28 videos 2 points, 13 videos 3 points, and 3 videos 4 points. No statistically significant relationship was found between the number of views of the videos, the number of days uploaded to the YouTube, the type of content, the video power index and JAMA, DISCERN, GQS.

The average scores of 4 different surgeons from the parameters used for the quality and relevance analysis of the videos; They were JAMA 2 (Min: 1-Max: 2), DISCERN 36 (Min: 22-Max: 63), and GQS 2 (Min: 1-Max: 4).

When the videos uploaded by the doctors were compared with the others, a statistically significant difference was found only according to the JAMA score ($p = 0.000$), and no significant relationship was found between the DISCERN and GQS scores ($p = 0.655$, $p = 0.745$).

A significant correlation was found between JAMA score and minute, number of comments and VPI index ($p < 0.005$). A significant correlation was found between DISCERN and GQS among the scores ($p < 0.005$). No significant correlation was found between JAMA and other scorings ($p > 0.05$).

In addition, the scores of 4 different surgeons were statistically compatible with each other ($p = 0.000$). The interclass correlation coefficient (ICC) was 0.906 for the JAMA score, 0.889 for the DISCERN score, and 0.831 for the GQS score (**table IV**).

DISCUSSION

Trigger finger is a flexor tenosynovitis that is common in the community and presents with finger pain, triggering and locking. Conservative treatment methods, corticosteroid injection and surgical A1 pulley release methods can be used in the treatment (14). In particular, patients who are afraid of surgical treatment frequently watch YouTube videos about this disease in order to be informed about treatment options and possible complications.

However, the reliability and quality of these videos is a controversial issue.

Studies have been conducted to evaluate the content and quality of videos on many subjects such as hallux valgus, carpal tunnel syndrome, adhesive capsulitis, rotator cuff injury (2, 5, 11, 12, 15). There are also studies evaluating the quality of many websites in the medicine (16, 17). However, when we searched PubMed, it was seen that there was no study in this content about trigger finger and as we know, our study is the first study on this subject. In this study, it is aimed to evaluate the 50 most watched videos on YouTube about trigger finger in terms of quality, suitability and adequacy. According to the results of the evaluation analysis of the videos in our study, it has been determined that these videos are low quality and not reliable.

Low-quality and inappropriate videos cause patients to be misinformed and incompletely informed, but they can also negatively affect the patient-physician relationship (18). With this study and similar studies in the literature, we think that the number of better-quality videos that are properly informed and that go through the review process before publication will increase.

Various scores and scoring systems have been used in the literature to evaluate the quality and reliability of YouTube videos. Among these, the most frequently used are JAMA, DISCERN and GQS scoring systems (10-13). We also evaluated with these scoring systems in our study in order to

Table IV. The scores of 4 different surgeons were analyzed using the interclass correlation coefficient (ICC).

	Interclass Correlation Coefficient (ICC)	P-value
JAMA	0.906	0.000
DISCERN	0.889	
GQS	0.831	

make comparisons with the studies in the literature. The mean in our study was JAMA 2, DISCERN 36 and GQS 2. Tekin *et al.* (2) evaluated YouTube videos about Hallux valgus and found the average JAMA score as 2, GQS score as 3.02, and DISCERN score as 37.56. Mert *et al.* (13), in the study where they evaluated YouTube videos about carpal tunnel syndrome, they found the average JAMA 2.14, GQS 2.7 and DISCERN 33.62. Foster *et al.* (19) found an average of JAMA 0.7 and DISCERN 33.62 in the YouTube videos they evaluated regarding distal biceps tendon rupture. Kuru *et al.* (11) in his study, YouTube videos about rotator cuff tears were evaluated and the average was found to be JAMA 2.9 and DISCERN 35.7. Our results are similar to the literature. When the current studies in the literature and the evaluation results in our study are examined, it is seen that the videos are generally in the poor quality and weak category.

Although it is seen that the videos published by physicians are of higher quality than the videos published by non-physicians, it is not possible to consider these videos sufficient according to the current scores. In addition, such videos may not be understood by patients and are less viewed (11, 20, 21). There are also publications stating that academic videos are insufficient in terms of content and quality (19, 22). In our study, 15 (30%) videos published by doctors were found to be statistically significantly higher only in terms of JAMA score compared to other videos. A similar result was found by Foster *et al.* (19) in a YouTube video evaluation study of distal biceps tendon ruptures. The apparent lack of quality videos means that the vast majority of patients will continue to receive inadequate education on their health issues. We think that more high-quality and professional videos should be prepared in a language that patients can understand by doctors and professional organizations such as the European Federation of Hand Surgery Associations in order to inform patients more accurately and to reduce the negative effects that may occur in the patient-physician relationship.

It is stated that patients find animation videos more useful and understandable (11). 14% of the videos in our study were animation and no statistically significant difference was found between the animated video and the real videos according to the video evaluation scores. This result may be related to the low number of animated videos. When the animation video ratio in our study was compared with the literature, it was lower than the animation video ratios in other studies (2, 11, 13). Although the number of animation videos varies according to the researched subject, we think that the videos can be more educational and understandable by increasing this rate for the trigger finger.

The average number of views of the videos in our study was 244,150 (min: 517-max: 2,306,934). In the literature, the rate of viewing varies in the YouTube video evaluation studies on orthopedic diseases. In the study conducted on rotator cuff tears (11), the average viewing rate was found to be 401,329, 137,494 in adhesive capsulitis (5), 150,977 in carpal tunnel syndrome, and 74,031 in hallux valgus. Our results were found to be consistent with the literature. These rates show that trigger finger attracts as much attention as other diseases and is being investigated by patients.

The video power index is an index that defines the popularity of YouTube videos. Evaluation is made by calculating the number of views of the video and the likes it receives. In our study, the VPI was determined as 94. It was found to be VPI: 41.35 in the study on hallux valgus (2), VPI: 27.6 in the study on cervical disc replacement (4), and VPI: 42 in the study on distal biceps rupture (19). In our study, no statistically significant correlation was found between the number of views of the videos and between VPI and JAMA, DISCERN, GQS. According to our results, the video popularity of trigger finger is higher, but unfortunately the videos appear to contain low quality patient information.

Our study has some limitations. First, only the first 50 videos in English were included in the study. A video with high content quality may not be rated because not all videos, including other videos published in different languages, are rated. Secondly, the number of likes and views on YouTube videos is constantly changing. Therefore, our current results are valid for the evaluation date of the videos. It is possible that new videos will be added in searches to be made on different dates, and the first 50 videos and study results may change.

CONCLUSIONS

As a result, according to the evaluation scores in our study, YouTube videos about trigger finger were low quality and unreliable. The effect of videos on patients is undeniable due to the increasing use of the internet and the easier access of patients to information. In the light of our study and other studies in the literature, the possibility of high-quality and reliable videos for patients can be increased by the evaluation and inspection of videos presented by YouTube to patients by professionals before they are published.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

KU: video analysis, writing – original draft. MKY: video analysis, statistical analysis. MAC, MA: video analysis.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Physical Activity in Workers with Low Back Pain is Associated with Paraspinal Muscle Mass

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SUMMARY

Background. One of the common musculoskeletal problems that most workers will experience at some point in their lives is low back pain. The aim of this study is to investigate the relationship between physical activity level and pain, disability and paraspinal muscle mass in workers with chronic low back pain.

Methods. One hundred thirty workers with chronic low back pain were included in the study. Demographic characteristics, pain, physical activity levels of all patients were evaluated. Paraspinal muscle cross-sectional areas (CSA) at the lumbar spine were measured. Participants were grouped according to their physical activity levels at work and their results were analyzed.

Results. It was found that there were significantly more males in the groups with moderate and severe physical activity, and more females in the groups with sedentary and mild activity. L2-3 and L3-4 paraspinal CSAs were found to be higher in those with moderate/severe physical activity at work. Male gender for paraspinal CSA at L2-3 and L3-4 levels, body mass index for paraspinal CSA at L2-3 levels, and age were found to be independent risk factors for L4-5 and L5-S1 paraspinal CSA.

Conclusions. Paraspinal muscle CSA was affected by occupational physical activity and total physical activity level.

KEY WORDS

Low back pain; lumbar spine; paraspinal muscles; physical activity; workers.

INTRODUCTION

Low back pain (LBP) can affect patients of all ages and is the leading cause of years lost due to disability (1). It is estimated that 70% to 85% of people experience LBP at any point in their lives and 20% become chronic (2). In recent studies, it has been stated that more LBP is seen especially in young and productive adults, and this situation can create a serious socioeconomic burden by affecting productivity (3). LBP is a common health problem in workplaces, and most workers are expected to experience LBP symptoms throughout their work-life (4). Heavy physical activities, including certain strenuous activities at work, have been shown to increase the risk of LBP (lifting, bending, awkward postures, and tasks considered to be physically demanding) (5).

There is not only work in these people's lives, but also leisure time activities in their daily life. Individuals with LBP may limit their physical activity due to fear of pain. What is more, although they need to exercise with medical advice, they may not be able to. Ironically, too much or too little physical activity can be associated with LBP, suggesting that physical activity is complex as an intervention for LBP (6). Different results have been reported in many studies examining the relationship between physical activity and LBP. While one systematic review stated that strenuous physical activity increased the risk of LBP, another systematic review found no association between the two (7, 8). In a meta-analysis, moderate to high levels of physical activity have been shown to protect against the development of lumbar radicular pain (9).

The paraspinal muscles (erector spinae, multifidus, and psoas major) support the spine and act as dynamic stabilizers of the spine (10). Degeneration of these muscles is a common feature of LBP, and imbalance in muscle strength can cause kinetic imbalance of the spine (11). Over the past

decade, an increasing number of studies have examined the interaction between paraspinal muscles, LBP, and spinal pathology in more detail (12). However, the relation of paraspinal muscle morphology, which is thought to have an important place in the etiology of LBP, with physical activity at workplace or leisure time, has not been investigated yet. Hence, the aim of this study to evaluate the relationship between physical activity level at work and pain intensity, pain-related disability, and paraspinal muscle morphology of workers with chronic low back pain.

MATERIALS AND METHODS

Study setting and participants

This study was designed as a single-center, cross-sectional study of 133 workers who were admitted to the physical medicine and rehabilitation (PMR) outpatient clinic for chronic LBP between March 2021 and July 2021.

The inclusion criteria were patients aged 18-65, having LBP for more than 3 months, working in paid or unpaid work for at least 1 year, and literate enough to fill the scales.

Patients who changed their job within 1 year or took a break for more than 30 days, who received physical therapy or injection therapy for the low back in the last 6 months, who had chronic disease (cardiovascular, pulmonary, genitourinary, progressive/non-progressive neurological diseases) with a history of spinal structural deformity/instability/trauma/surgery, malignancy, and pregnancy were excluded from this study. In addition, patients with severe osteoarthritis and using wheelchairs were not included in the study. Approval was obtained from the National and local Ethics Committee for this study (University of Health Sciences, Ankara Bilkent City Hospital, Turkey with the approval number: E2-21-136 – Date of approval: February 10, 2021) and procedures were conducted in accordance with the relevant principles of the Declaration of Helsinki. Before evaluations, participants were informed about the nature of the study and signed consent was obtained from each participant.

Demographic and disease characteristics

Information such as age, gender, years of education, body mass index (BMI), working time of the participants were recorded in the forms.

Measurements

Pain intensity (Visual analog scale), disability level (Quebec Back Pain Disability Scale), total physical activity (International Physical Activity Questionnaire-Short Form), physical activity level at work and in leisure time of all patients were evaluated and recorded in the forms.

- Quebec Back Pain Disability Scale (QBPDS) was performed to measure the functional disability in patients with LBP. This scale is a condition-specific questionnaire consisting of 20 questions and is scored between 0 and 5 points. High scores indicate a high disability (13).
- Visual Analogue Scale (VAS) is a scale for pain, and it consists of a 10 cm line with "no pain" at the left end (0 cm) and "worst pain imaginable" (10 cm) at the right end.
- International Physical Activity Questionnaire-Short Form (IPAQ) is used to evaluate the intensity of physical activity that individuals do in their daily life. It estimates total physical activity as MET-min/week (14).
- Physical activity levels at work grouped by formulation in the Nord-Trøndelag Health Study Physical Activity Level for Work (HUNT) study (15, 16). Hereby, the participants were grouped according to their workload and physical activity levels. The categories were determined as follows: 1) sedentary workers, 2) mild group - work that involves walking but does not require heavy lifting, 3) moderate group - work that mainly involve walking, 4) severe group - work that require heavy lifting and particularly strenuous physical activity (15).
- Physical activity in leisure-time: grouped by formulation in the HUNT-2 study. Accordingly, it is divided into three levels as no physical activity or light activity (level 1), ≤ 2 hours/week of strenuous physical activity (level 2), and ≥ 3 hours/week of strenuous physical activity in leisure time (level 3) (16).
- Paraspinal muscles: in the studies conducted, the lumbar vertebra level at which the paraspinal muscle area was best evaluated was defined as L3-4. In addition, studies of LBP have frequently evaluated the paraspinal muscle areas at the vertebral levels between L3 and S1 (17, 18). Therefore, in our study, the paraspinal muscle cross-sectional area (CSA) was evaluated with the MRI slice at the L2-3, L3-4, L4-5, and L5-S1 vertebra levels. Paraspinal muscle CSA measurements were evaluated in cm2 as applied in previous studies (19).

All calculations were used to trace the contour of the muscle of interest in the axial T2-weighted MRI image using a 1.5 Tesla MRI scanner with 5 mm slice thickness and the close polygon ROI tool (Image J 1.53 software program) for all CSA measurements.

Study protocol

Radiological evaluations in the study were made by two different experts to prevent bias. Then, by comparing the evaluations, a single result was obtained. After all evaluations, the participants were divided into 4 groups by their physical activities at work (**figure 1**). Each group was evaluated in terms of demographic, clinical, and radiological data.

The association between physical activity and pain intensity, disability, and paraspinal muscle morphology was examined. 3 participants in the severe group were not included in this study because they filled out the scales incompletely and the study was evaluated over 130 participants.

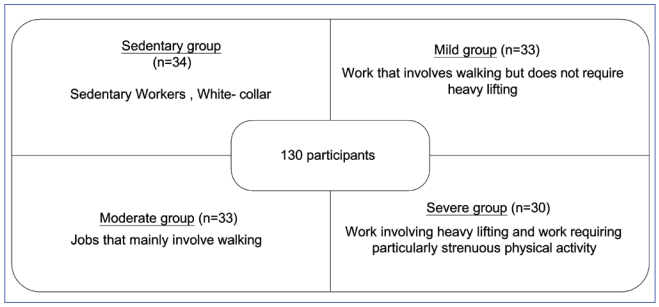

Figure 1. Groups of participants according to their physical activity at work.

Statistical analysis

Statistical Package for the Social Sciences (SPSS 15.0 for Windows) software was used for statistical analysis. In reporting descriptive statistics, the data were expressed as mean ± standard deviation (SD) and percentage (%) for categorical and nominal variables. Participants were grouped according to their physical activity (sedentary, mild, moderate, severe). The difference in demographic data and measurements between the groups was evaluated using ANOVA. Pearson's correlation test was performed to evaluate the relationship between work characteristics and muscle CSAs, and other assessment parameters. Models using age, gender, BMI, physical activities (work/leisure time) were analyzed with multivariate linear regression analysis to determine the predictor of physical activity at work and leisure time activity explaining variance of pain intensity, disability, and paraspinal CSA. A P-value of 0.05 or less was considered significant for all statistical results.

Table I. Sociodemographic data and clinical characteristics.

Variables	
Gender	
Female	73 (56.2%)
Male	57 (43.8%)
Age (years) mean (SD)	39.93 (12.89)
BMI (kg/cm^2) mean (SD)	26.48 (4.62)
Years of education mean (SD)	9.47 (4.19)
Work duration (years) mean (SD)	17.72 (11.89)
Leisure time physical activity n (%)	
Light only	29 (22.3%)
≤ 2 hours hard per week	51 (39.2%)
> 3 hours hard per week	50 (38.5%)
QBPDS mean (SD)	42.77 (15.33)
IPAQ mean (SD)	4826.31 (7111.13)
VAS mean (SD)	5.77 (1.32)

SD: standard deviation; BMI: body mass index; QBPDS: Quebec Back Pain Disability Scale; IPAQ: International Physical Activity Questionnaire-Short Form; VAS: Visual Analogue Scale.

RESULTS

The mean age of the participants was 39.93 ± 12.89 years, 57 (43.8%) were male and 73 (56.2%) were female, and the mean BMI was 26.48 ± 4.62. The mean duration of work was 17.72 ± 11.89 years, and the mean years of education was 9.47 ± 4.19. The general demographic and clinical information of the participants are given in **table I**.

The comparison of the groups in terms of demographic, clinical and paraspinal CSA was given in **table II**. There was no significant difference between the groups in terms of age, BMI, duration of work, education, pain, and disability. A significant difference was found between the groups in terms

Table II. Comparison of demographic and clinical data between groups.

	Sedentary group (n = 34)	Mild group (n = 33)	Moderate group (n = 33)	Severe group (n = 30)	P-value
Gender n (%)					
Female	31 (91.2 %)	26 (78.8 %)	10 (30.3 %)	6 (20.0 %)	0.000*
Male	3 (8.8 %)	7 (21.2 %)	23 (69.7 %)	24 (80.0 %)	
Age mean (SD)	38.88 (12.35)	44.64 (10.58)	37.39 (13.54)	38.73 (14.29)	0.101

	Sedentary group (n = 34)	Mild group (n = 33)	Moderate group (n = 33)	Severe group (n = 30)	P-value
BMI mean (SD)	26.48 (5.07)	27.41 (4.41)	25.34 (4.08)	26.70 (4.85)	0.201
Work duration mean (SD)	17.94 (11.83)	20.91 (9.76)	15.21 (13.19)	16.73 (12.37)	0.157
Years of education mean (SD)	9.71 (4.43)	9.97 (4.76)	9.64 (3.81)	8.47 (3.66)	0.589
IPAQ mean (SD)	630.29 (506.52)	1892.82 (2787.56)	6659.73 (8231.26)	10791.87 (8380.80)	0.000*
Leisure time physical activity					
Light only	26 (76.5 %)	3 (9.1 %)	0 (0.0 %)	0 (0.0 %)	0.000*
≤ 2 hours hard per week	7 (20.6 %)	26 (78.8 %)	13 (39.4 %)	5 (16.7 %)	
> 3 hours hard per week	1 (2.9 %)	4 (12.1 %)	20 (60.6%)	25 (83.3 %)	
L2-L3 Paraspinal CSA mean (SD)	8.05 (2.53)	7.96 (2.45)	8.76 (2.11)	9.39 (1.92)	0.019*
L3-L4 Paraspinal CSA mean (SD)	8.61 (2.14)	9.26 (2.55)	9.92 (2.67)	10.66 (3.20)	0.031*
L4-L5 Paraspinal CSA mean (SD)	9.69 (3.00)	9.09 (1.97)	9.78 (2.25)	9.96 (2.59)	0.576
L5-S1 Paraspinal CSA mean (SD)	11.17 (3.46)	10.51 (3.14)	10.91 (2.72)	11.07 (4.37)	0.900
QBPDS mean (SD)	45.24 (14.89)	44.21 (16.91)	40.55 (14.21)	40.83 (15.37)	0.494
VAS mean (SD)	5.85 (1.26)	5.70 (1.55)	5.76 (1.25)	5.77 (1.22)	0.993

SD: standard deviation; BMI: body mass index; QBPDS: Quebec Back Pain Disability Scale; IPAQ: International Physical Activity Questionnaire-Short Form; VAS: Visual Analogue Scale; *p < 0.05.

of gender, total physical activity level, leisure time activities, L2-3, and L3-4 paraspinal CSA levels (p < 0.001, p < 0.001, p < 0.001, p = 0.019, p = 0.031, respectively).

The correlation analysis between physical activity at work and leisure time based on VAS, QBPDS, paraspinal CSA were shown in **table III**. A positive correlation was found between physical activity at work and paraspinal CSA at L2-3, L3-4 levels, and IPAQ (r = 0.264, p = 0.002; r = 0.265, p = 0.002; r = 0.596, p = 0.001, respectively). Also, correlations were found between physical activity in leisure time and L2-3 paraspinal CSA, and IPAQ (r = 0.207, p = 0.008; r = 0.011, p = 0.001, respectively).

The results for the multivariate regression analyses were presented in **table IV**. Pain, disability, and physical activity (work/leisure time) were not determined as independent risk factors for paraspinal CSA (p > 0.05). Male gender was found to be effective in paraspinal CSA elevation at L2-3 and L3-4 levels (B = 1.956 (0.993/2.918), p < 0.001; B = 1.936 (0.788/3.084), p = 0.001). BMI was determined as a positive predictive risk factor for paraspinal CSA at the L2-L3 level (B = 0.096 (0.008/0.185), p = 0.034). Age was determined as the negative predictive risk factor for the increase in paraspinal CSA at L4-5 and L5-S1 levels (B = -0.045 (-0.082/-0.007), p = 0.019; B = -0.174 (-0.291/-0.057), p = 0.004).

Table III. Correlation between physical activity at work and leisure time, pain intensity, disability, paraspinal muscle cross-sectional area, age, BMI, and duration of work.

	Physical activity at work	Physical activity in leisure time
Age r/p	-0.072/0.418	-0.093/0.292
BMI r/p	-0.033/0.259	-0.072/0.418
Work duration r/p	-0.100/0.259	-0.048/0.591
VAS r/p	-0.010/ 0.908	-0.014/0.877
QBPDS r/p	-0.101/0.254	-0.012/0.894
L2-L3 Paraspinal CSA r/p	**0.264/0.002**	**0.207/0.018**
L3-L4 Paraspinal CSA r/p	**0.265/0.002**	0.099/0.261
L4-L5 Paraspinal CSA r/p	0.095/0.283	0.044/0.623
L5-S1 Paraspinal CSA r/p	-0.011/0.906	0.050/0.575
IPAQ r/p	**0.596/0.001**	**0.611/0.001**

r: correlation coefficient; BMI: body mass index; QBPDS: Quebec Back Pain Disability Scale; IPAQ: International Physical Activity Questionnaire-Short Form; VAS: Visual Analogue Scale; CSA: cross sectional area.

Table IV. Multivariate linear regression analysis.

	R2	B	SE	B	95%CI (lower-upper) for B	P-value
L2-L3 paraspinal muscle CSA	**0.173**					
Gender		1.956	0.486	0.420	(0.993_2.918)	0.000*
BMI		0.096	0.045	0.192	(0.008-0.185)	0.034*
L3-L4 paraspinal muscle CSA	**0.146**					
Gender		1.936	0.580	0.354	(0.788-3.084)	0.001*
L4-L5 paraspinal muscle CSA	**0.065**					
Age		-0.045	0.19	-0.232	(-0.082_-0.007)	0.019*
L5-S1 paraspinal muscle CSA	**0.164**					
Age		-0.174	0.059	-0.655	(-0.291_-0.057)	0.004*

B: Regression coefficients; CI: coefficient interval; SE: Standard error; P-values of multivariate linear regression analysis; CSA: cross sectional area; *p < 0.05.

DISCUSSION

In the current study, the effects of physical activity at work and in leisure time on pain intensity, pain-related disability, and paraspinal muscle mass were investigated in workers with chronic LBP. According to the data of the study, it was found that there were significantly more males in the groups with moderate and severe groups, and more females in the groups with sedentary and mild activity. Total physical activity levels were found to be significantly higher in the moderate and severe groups than in the sedentary and mild groups. It was found that patients who were more active during work were also more active in leisure-time activities. L2-3 and L3-4 paraspinal CSA levels were found to be significantly higher in those with moderate and severe groups, and L2-3 and L3-4 paraspinal CSA increased as the level of physical activity at work increased. Also, L2-3 paraspinal CSA increased as leisure-time physical activity increased. Male sex was found to be an independent risk factor for paraspinal CSA at L2-3 and L3-4 levels, BMI for paraspinal CSA at the L2-3 level, and age as an independent risk factor for L4-5 and L5-S1 paraspinal CSA.

Many adults are constantly exposed to physically demanding jobs, both in daily life and at work, and work productivity is affected by diseases of the musculoskeletal system. Work and leisure-time physical activities may not have similar effects on the low back area. Two studies that address both types of activity separately have shown that there were inverse

correlations between leisure-time activities and LBP, and positive correlations between work activities and LBP (20).
The level of physical activity in the workplace shows subjective differences between individuals and requires a common objective classification. Grouping occupations according to physical activity level may provide more comparable data. In a review comparing questionnaires evaluating occupational physical activity, the formulation applied in HUNT was considered to have good validity (15, 21). Therefore, we classified the participants in this study according to the formulation in the HUNT study.
Studies have shown that strenuous physical work conditions increase the risk of chronic LBP (20). In this study, when we compared the workers with a light and heavy workload, no significant difference was found between the groups in terms of pain and disability, and the level of physical activity during work was not found to be effective on pain severity and disability. This may be since physical work demands affect individuals differently according to their physical capacities. An imbalance between hard work-related physical exposure and physical capacity may be a risk factor for LBP. In addition, it can be thought that the physical capacity of the individual, regardless of the workload, may be a risk factor for LBP. In our study, we found that as the level of physical activity in the workplace increased, paraspinal CSAs increased at L2-3 and L3-4 levels. The reason for this may be hypertrophy in the muscles due to high physical activity, as well as the development of atrophy in the muscles due to low physical activity. In addition, no significant difference was found in L4-5 and L5-S1 segments. These differences may be due to the biomechanical and anatomical differences between the L5 and other lumbar levels (22).
Previous studies have shown that the CSA of the paraspinal muscle tends to decrease with age (23, 24). In our study, we found that age was a negative predictive factor for L4-5 and L5-S1 paraspinal CSA. An age-related decrease in CSA suggests the development of progressive muscle atrophy and sarcopenia as part of the normal aging process. In future studies, age can be used as a variable in evaluating the relationship between paraspinal muscles and LBP.
In our study, BMI was found to be a positive predictor for L2-3 paraspinal CSA. Paraspinal muscles, like other parts of the body, are affected by the accumulation of fat in the body due to obesity. However, especially the lower lumbar region may not be affected by this fat accumulation (25). Similarly, in our study, it was observed that paraspinal CSAs at lower lumbar levels were independent of BMI.
In a meta-analysis, it was reported that there was no definite relationship between physical activity and the risk of low back pain (26). In our study, we found no association between leisure time physical activity and pain and disability. In a study examining the relationship between physical activity level and paraspinal muscle CSA, no relationship was found between these two (27). In this study, we showed that as the level of leisure-time physical activity increases, the CSA level increases at the L2-3 level. However, it should be kept in mind that physical activity is reported according to the individual's own perception and can be overestimated or underestimated (28, 29).
There are some limitations of our study. Our study was conducted on a small sample group, and with a larger group of participants, more precise data can be found between the level of physical activity at work and paraspinal muscle mass. The fact that the muscle and fat infiltration were not evaluated separately while evaluating the paraspinal muscle CSA may cause the paraspinal muscle mass to be measured excessively in our study. Also, measuring physical activity using a step counter tool such as a pedometer or accelerometer, rather than a self-report scale, can provide more objective data.

CONCLUSIONS

The association between physical work demands and the risk of LBP has been examined in different studies. However, this study is the first to evaluate the relationship between physical workload and paraspinal muscle mass in workers. Paraspinal muscle mass was affected by the duration of the profession, occupational physical activity, and total physical activity level, and we think that more comprehensive studies are needed on this subject. To understand the effect of physical activity on LBP and paraspinal muscle mass, more detailed evaluations of both physical activity and paraspinal muscle CSA (such as the presence of fat infiltration, multifidus, erector spinae, psoas major muscle areas) are needed. Studies on LBP should consider not only all aspects of physical activity (type, duration, frequency, and intensity) but also all areas of physical activity (leisure time, at home, and at work).

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

ZAY, DC, EU: conceptualization, study design, acquisition of subjects and/or data, data analysis and interpretation, writing – original draft, writing – review & editing.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Three-Dimensional Silicon Mold Analysis of the Carpal Tunnel: A Morphometric Study in Human Cadavers

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SUMMARY

Purpose. Carpal tunnel syndrome (CTS) is a common entrapment neuropathy with an incidence rate of 6%. The significance of carpal tunnel shape and dimensions in idiopathic carpal tunnel syndrome has long been debated. Recent studies have examined the accuracy of previous morphometric studies, as the reported dimensions have conflicting results. The purpose of this study was to use cadavers to determine the dimensions and shape of the carpal tunnel using a three-dimensional digitization approach.

Methods. The carpal tunnels of 35 cadavers were evacuated, and 210 silicon molds were created from 70 hands by inserting them into the soft tissue-carpeted tunnel. The mold was then scanned by a Structured Light Scanner from Steinbichler 3D scanner to obtain a three-dimensional image of the carpal tunnel, from which various carpal tunnel measures were calculated.

Results. The width, height, and cross-sectional area (CSA) of the carpal tunnel decreased significantly from proximal to distal, with a narrow CSA at the distal end. Furthermore, the ulnar side of the tunnel was observed to be significantly deeper than the radial side.

Conclusions. In this study our measured dimensions render a truncated elliptical cone-shaped carpal tunnel tapering distally. Based on our analysis, the CSA of the distal carpal tunnel may be estimated by knowledge of the proximal tunnel CSA by using the formula ($Distal_{CSA}$ = 22.137 + 0.734 ($Proximal_{CSA}$). Knowledge of the tunnel's structural architecture is important in determining the aetiology of carpal tunnel syndrome associated with variant anatomy.

KEY WORDS

Carpal tunnel syndrome; morphology; three-dimensional; morphometry; cross-sectional area; carpal tunnel shape.

INTRODUCTION

Carpal tunnel syndrome (CTS) is the most common entrapment neuropathy, affecting approximately 6% of the general population (1). Entrapment neuropathies are caused by nerve compression as it travels through constrained spaces. An increase in canal contents or a decrease in canal size raises the pressure within the tunnel, compressing the median nerve and causing CTS. Although this only affects a portion of the median nerve as it travels through the tunnel, it has significant physical, psychological, and economic consequences (2).

The causative factors of CTS are multifactorial, including risk factors such as diabetes mellitus, menopause, hypothyroidism, obesity, rheumatoid arthritis, pregnancy, injury, or trauma (3), and anatomical anomalies (4). Most cases of CTS encountered do not have an immediate evident cause. Such cases are usually termed as "idiopathic" and result usually due to a discordancy between the tunnel size and the volume of tunnel contents, thus causing an elevated pressure within the tunnel (5). Predisposing conditions correlating well with the definition of idiopathic would be pressure changes within the tunnel owing to the hypertrophied synovial membrane of the flexor tendons (6), anthropometric factors, genetic factors, advancing age as well as gender (7).

The carpal tunnel morphology is a vital factor in the etiology and management of CTS (8, 9). Among the morphological parameters, a narrow tunnel size has been underlined as a predisposing cause for idiopathic CTS, as a smaller tunnel results in a reduced space to accommodate tunnel contents (8, 10-12). The morphology of the carpal tunnel is critical in the etiology and management of CTS (8, 9). A narrow tunnel size has been highlighted as a predisposing cause for idiopathic CTS among the morphological parameters, as a smaller tunnel results in less space to accommodate tunnel contents (8, 10-12).

To attest this notion, extensive research began in the early 1980s using various techniques such as radiography (13), computed tomography (12, 14), magnetic resonance imaging (15-18), ultrasonography (19, 20), and molding (21) to study the morphological characteristics of the tunnel. The tunnel's volume, CSA, width, and length were all calculated using the methods described above. However, the reported results for volume and CSA vary greatly across studies. We believe that the inconsistencies and wide disparities in reported results are due to the researchers' disparate approaches and imaging modalities. As a result, the role of the tunnel's morphology remains unknown.

The goal of this study was to evaluate the tunnel's shape by computing its dimensions using three-dimensional scanning technology. Using the aforementioned method would allow for a near-accurate assessment of the tunnel which would also define the morphological role of the tunnel in the development of CTS.

MATERIALS AND METHODS

After seeking Institutional Ethical Clearance (this study was approved by the Kasturba Medical College and Kasturba Hospital Institutional Ethics Committee (Registration No. ECR/146/Inst/KA/2013 - Date of approval: November 17, 2015) (IEC 738/2015), 35 cadavers with a mean age of 55 were obtained from the Department of Anatomy.

Cadavers that presented any hand deformity were not included in the study. Seventy hands of the selected cadavers were dissected after placing them in anatomical position. Dissection of the tunnel was through an incision along the lateral margin of the ring finger on the palmar surface. Following this, a deeper incision was made to carefully expose the flexor retinaculum and the carpal tunnel. The median nerve and flexor tendons enclosed in their synovial sheath were emptied from the tunnel (**figure 1A**). The tunnel margins were demarcated by following the bone surfaces. The proximal border was outlined between the pisiform and scaphoid tubercle and the distal border between the hook of the hamate and trapezoidal crest (22). The proximal and distal border of the flexor retinaculum was traced.

Silicon mold was fit into the carpal tunnel to accommodate the maximum space permitted from its proximal aspect (**figure 1B**). The flexor retinaculum limits the roof of the tunnel. The retinaculum is composed of collagen fibers and having a thickness ten times more than the antebrachial fascia (13), defined the upper limit of the space available, beyond which the mold could not be fitted. In parallel, it abutted the soft tissue and the carpal bones in the tunnel floor to evaluate the actual carpal tunnel area available. After half an hour, the mold was removed and set aside to dry. This method was repeated three consecutive times on every hand to obtain three molds for each hand, and each was labelled accordingly.

The molds were then scanned by a 3-Dimensional scanner (**figure 1C**) to obtain a 3D reconstruction of the tunnel. The 3D scanner used was a Structured Light Scanner/Blue Light Scanner from Steinbichler (Germany). COMET LÆŐD is particularly well suited to measure the surfaces and profiles of objects varying from sizes as small as a few millimeters to meters long. Scanning was done by placing it in front of the scanner, followed by calibration of the machine. The area to be scanned was prepped by spraying a developer for better data extraction. The scanned mold was moved around to get as much data as possible, thereby scanned multiple times from different angles, then collated to one file and transferred

into raw data to software for post-processing. Post-processing includes deriving Iges/Step from the STL (STereoLithography) Format to CAD (Computer-Aided Design) Model for engineering applications. The STL files were then viewed in ParaView. This software is an open-source, multi-platform data analysis and visualization application to analyze three-dimensional structures. A representation of the digitized silicon mold of the carpal tunnel is shown in **figure 1D,E**.

Using the slicer tool (a filter that draws a 2-dimensional slice through a 3D data set), the 3D block was sliced from the tunnel's proximal to the distal aspect. The slices were taken at all blocks' proximal, middle, distal, and two intermediate sections (**figure 1F**). Each block was measured for volume, and each slice was measured for height, width, and CSA, respectively. The height was measured at the radial, ulnar and intermediate aspects. The widest distance represented the carpal tunnel width, and the depth was measured perpendicular to the width. The average value of the three molds of each hand was considered as the final data for the respective hand. Using SPSS 16 statistical software, a one-way analysis of variance was performed to evaluate and analyze the calculated carpal tunnel dimension differences. To compare the proximal and distal measurements, paired t was used. Using the Pearson correlation test, the relationships between proximal and distal CSAs were evaluated. Utilizing linear regression, the impact of proximal CSA on distal CSA was determined.

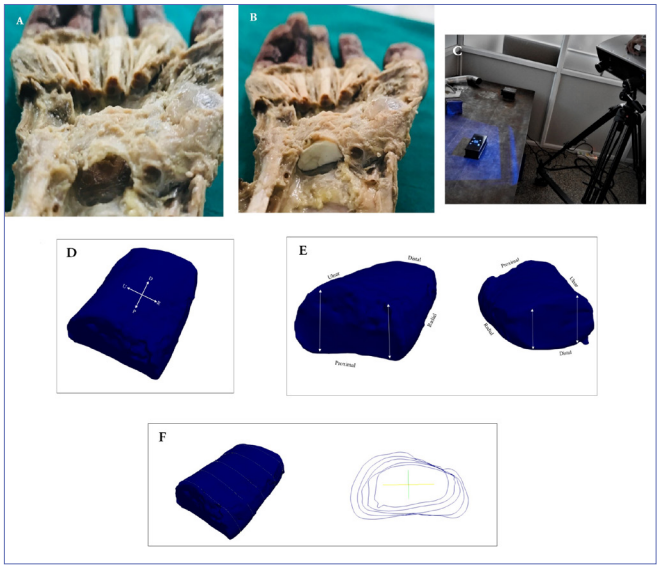

Figure 1. (A) Carpal tunnel after evacuation of contents; **(B)** Silicon mold in the evacuated carpal tunnel; **(C)** Scanning of silicon mold by 3D scanner; **(D)** Three-dimensional image of the tunnel; **(E)** Three-dimensional image of the tunnel viewed from its proximal and distal extent; **(F)** Slices taken at five intervals through the length of the tunnel.

RESULTS

The 70 cadaveric hands (n = 70) had an average carpal tunnel length of 23.5 ± 2.7 mm and volume of 3,865.5 ± 565.7 mm^3. The distal tunnel width measuring 18 ± 1.2 mm was significantly (p = 0.000) narrower in comparison with the proximal tunnel width of 19.7 ± 1.4 mm (**figure 2**). The similar modifications were observed at the tunnel's depth. The mid proximal tunnel depth was significantly larger than that of the distal end, with 10.09 ± 0.9 mm and 9.2 ± 0.9 mm respectively (p = 0.002). The depth at the proximal ulnar aspect of the tunnel was significantly (p = 0.000) greater than the radial side, measuring 9.6 ± 1.1 mm 9.0 ± 0.9 mm. Distal ulnar and radial depth were 8.35 ± 1.0 mm against 7.5 ± 1.0 mm, respectively.

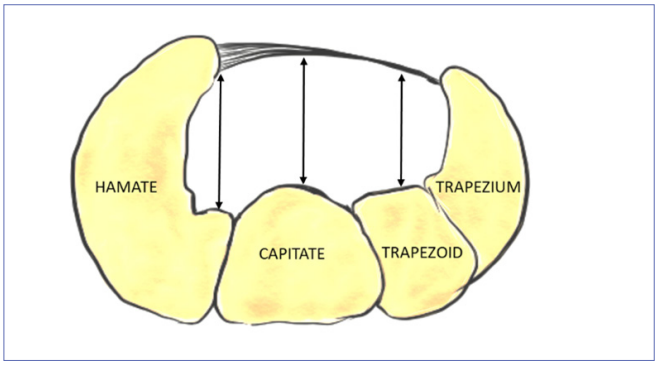

Figure 2. Impact of proximal cross-sectional area on distal cross-sectional area.

The internal dimensions of the carpal tunnel significantly correlated with the cross-sectional area (CSA). Decrease in the depth and width along the tunnel's length resulted in a significant (p = 0.000) decrease in the tunnel's CSA, which measures 182 ± 16.3 mm^2 proximally and 156 ± 16.2 mm^2 distally, rendering an elliptical truncated cone shape to the tunnel.

Paired t-test (**table I**) compares the measures between the proximal and distal in cross sectional area, ulnar height, middle height, radial height and width. From the result, it can be concluded that there exists a significant difference.

Pearson correlation test revealed a strong positive correlation between the proximal and distal cross-sectional area (r = 0.871) at $p < 0.01$ (**table II**).

Linear regression analysis proved that the proximal CSA was a significant determinant for the distal CSA ($p < 0.01$) (**table III**, **figure 3**).

From the analysis, the following regression equation can be formed to predict the impact of proximal cross-sectional on the distal cross-sectional area:

Distal cross-sectional area = 22.137 + 0.734 (Proximal cross-sectional area)

Table I. Difference between proximal and the distal.

	Proximal	Distal	t	P-value
Cross-sectional area	182.514 ± 19.547	156.057 ± 16.467	16.270	0.000
Ulnar height	9.669 ± 0.961	8.337 ± 1.082	8.631	0.000
Middle height	10.094 ± 0.973	9.411 ± 0.871	15.433	0.000
Radial height	9.023 ± 1.131	7.589 ± 1.086	9.185	0.000
Width	19.743 ± 1.486	18.069 ± 1.200	12.234	0.000

Table II. Correlation between proximal and the distal.

	Correlation
Proximal cross-sectional area and distal cross-sectional area	0.871**
Proximal ulnar height and distal ulnar height	0.607**
Proximal middle height and distal middle height	0.966**
Proximal radial height and distal radial height	0.653**
Proximal width and distal width	0.839**

**Correlation is significant at the 0.01 level (2-tailed).

Table III. Model summary for the impact of proximal cross-sectional area on distal cross-sectional area.

R	R square	Adjusted R square	Std. Error of the estimate	R square change	Change statistics			Sig. F Change
					F change	df1	df2	
0.871	0.759	0.751	8.213	0.759	103.696	1	33	0.000

	Unstandardized coefficients		Standardized coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	22.137	13.224		1.674	0.104
Proximal cross-sectional area	0.734	0.072	0.871	10.183	0.000

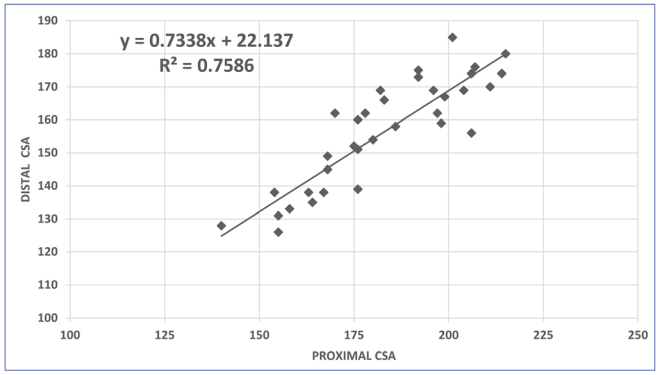

Figure 3. Diagrammatic representation of decrease in distal tunnel depth.

DISCUSSION

Our study mainly focused on the details of the structural anatomy using a cadaveric approach. The results obtained by a three-dimensional analysis indicate that the tunnel is an elliptical truncated cone-shaped passage with a wider inlet than the outlet and the ulnar depth being significantly more than the radial. Anatomical narrowing of the carpal tunnel, particularly at its outlet near the hook of the hamate, has been proposed as a factor in the development of CTS (13, 23), and our findings support this morphology.

The proximal and distal extents were determined using the bony landmarks of the tunnel margins, yielding a length of 23.5 ± 2.7 mm. Our length determination agrees well with Cobb *et al.*'s reported length of 21.7 ± 6 mm (13). Corey *et al.* (21) reported a shorter tunnel length of 12.7 ± 2.5 mm. The apparent disparity in the measures is due to different researchers' definitions of the carpal tunnel boundary. In the study by Corey *et al.* (21), the tunnel boundary was defined along the edges of the transverse carpal ligament. In contrast, we followed the bony margins to outline the tunnel's inlet and outlet. We observed a reduction in width from the inlet to the outlet, indicating that the tunnel's outlet is the segment

that is contracted. In terms of structure, it agrees with Cobb *et al.*'s findings (13), which showed that the width tapered toward the hook of the hamate. However, there is a stark difference in the computed width values when compared to ours (**table IV**). Cobb *et al.* evaluated the dimensions from radiographs after injecting the tunnel with a radio-opaque material, so the discrepancy can be attributed to a difference in technique. Their data also indicated that the tunnel's width increased beyond the hamate's hook, as they considered the base of the third metacarpal to be the tunnel's distal extent, thus visualizing the tunnel as an hourglass-shaped structure (13). In contrast, Corey *et al.* (21) cadaveric study revealed that the tunnel's width remained constant throughout its length at 19.2 ± 1.7 mm. The disparities can be explained by each individual's identification of the tunnel's extent (**table IV**).

Knowledge of the tunnel's depth is crucial for surgical planning, as it may indicate the required approach for carpal tunnel release, particularly when performing endoscopic carpal tunnel release. Elsaman *et al.* (24) used ultrasonography to measure the depth of the tunnel in the distal aspect in healthy controls and found it to be 7.91 mm. Corey *et al.* (21) reported a constant value of 8.3 ± 0.9 mm throughout the tunnel. We measured the tunnel depth from the inlet to the outlet and observed that it decreased along the length of the tunnel. The prominence of capitate along the tunnel floor (**figure 2**) and thickening of the transverse carpal ligament along the roof explains the distal decrease in tunnel depth (25). We also measured the depth along the tunnel's medial and lateral margins and discovered that the depth on the ulnar side was greater than the depth on the radial side. The greater depth can be attributed to the curvature of the hamate's hook. This measurement is critical as Alp *et al.* (26) found a strong correlation between the angle of hamate curvature and tunnel volume, emphasizing its role as a risk factor for idiopathic carpal tunnel syndrome. Surgically, this finding is consistent with the Kaplan incision line, as the ulnar aspect of the tunnel provides more room for instruments than the radial aspect of the tunnel. No prior studies have

Table IV. Cadaveric estimations of volume, cross-sectional area, width, and depth of the carpal tunnel.

	Number	Method	Volume (mm^3)	Level of section	Cross-sectional area (mm2)	Width (mm)	Depth (mm)
Current study	35	Silicon mold	3,865 ± 568	P (anatomical landmarks of inlet)	182 ± 16.3	19.7 ± 1.4	10 ± 0.9
				D (anatomical landmarks of outlet	156 ± 16.2	18 ± 1.2	9.2 ± 0.9
Corey *et al.* (2010)	10	Silicon mold	1,737 ± 542	P (proximal border of TCL)	134.9 ± 23.6	19.2 ± 1.7	8.3 ± 0.9
				D (distal border of TCL)	134.9 ± 23.6	19.2 ± 1.7	8.3 ± 0.9
Cobb *et al.* (1992)	5	MRI	3,400	P (radial styloid process)	184.7 ± 16.65	24.7 ± 1.2	-
				Hook of hamate		19.8 ± 1.2	
				D (base of third metacarpal)	155.78 ± 11.74	25.2 ± 1.5	
Gabra *et al.* (2013)	8	MRI	-	P	-	-	-
				D (hook of hamate and ridge of trapezium)	183 ± 29.7	-	-
Zong-Ming Li *et al.* (2011)	8	MRI	-	P	-	-	-
				D (hook of hamate and ridge of trapezium)	169.3 ± 29.3		

P: proximal/inlet of the tunnel; D: distal/outlet of the tunnel.

compared radial and ulnar depths. Consequently, this finding is reported for the first time.

The current study calculated the tunnel volume, which ranged from 3,300 mm^3 to 4,300 mm^3. Our volumetric data is consistent with previous studies ranging from 3,500 mm^3 to 4,500 mm^3. Corey *et al.* (21), on the other hand, reported a volume of 1,737 ± 542 mm^3. Volume is calculated from the tunnel's length, width, and height, which explains the wide disparity in reported values, as Corey *et al.* reported a smaller length, width, and depth of the tunnel as previously described. Clinically decreased tunnel volumes would increase the pressure within the tunnel thereby pinching the nerve at the narrow outlet.

The tunnel's CSA is one of the important morphological measurements as it provides a comprehensive understanding of the tunnel's anatomy. Using CSA as a metric, Dekel *et al.* (11) determined the association between tunnel stenosis and the development of idiopathic carpal tunnel syndrome via computed tomography. In addition, they reported that the narrowest portion of the tunnel was located distally in healthy subjects. Several additional authors also cited similar reports. Contrary to this, recent MRI studies have shown that the area of the hamate's hook is larger than the area of the pisiform (31). Correspondingly, Corey *et al.* found no change in the CSA and width from the inlet to the outlet in their cadaveric morphological study (19). However, we found that the tunnel gradually narrowed from the proximal to the distal extent, exhibiting a narrow CSA distally at the hook of hamate. Some studies reported CSAs as high as 275 mm^2 (11). Gabra *et al.* (32) provided a plausible explanation for this in their study. Using MRI, they calculated the carpal tunnel area by following an osseous boundary and balloon-based area. The cross-sectional value of the balloon-based area (183.9 ± 29.7 mm^2) was significantly smaller than the osseous boundary bound area (243.0 ± 40.4 mm^2). If the CSA is calculated by following the bony margin of the tunnel floor, the flexor carpi radialis tendon and soft tissue content flooring the tunnel may be included within the total cross-sectional area. **Table IV** displays the results of other reported cadaveric data. In this study we attempted to measure and subsequently identify the shape of the tunnel to almost exact precision. Consequently, we evacuated the tunnel contents, including the nerve, vessels, and tendons enclosed in their synovium. The mold was inserted abutting the soft tissue along with the carpal bones. The intercarpal ligaments over the floor were undisturbed, hence not included in the estimation of the CSA, thereby calculating the actual available carpal tunnel area.

Pearson's correlation shows that that proximal CSA is positively and significantly related to distal CSA ($r = 0.871$) at $p < 0.01$. This linear relationship implies that an increase in proximal CSA must normally be accompanied by an increase in distal CSA. Furthermore, linear regression demonstrates that the proximal cross-sectional area is a statistically significant predictor of the distal cross sectional ($p < 0.01$) and the regression model predicts the dependent variable significantly well. The impact of proximal cross-sectional area was found to be positive with $B = 0.734$ ($p < 0.01$), indicating that every unit increase in proximal cross sectional area increases distal cross sectional area by 0.734 units. This implies that the tunnel gradually narrows as we move from the inlet to the outlet. If this relationship changes and the narrowing become steeper, the pressure distally increases, predisposing to CTS. The distal carpal tunnel assessment equation may be helpful in assessing and diagnosing idiopathic CTS. Given a proximal tunnel CSA, the model provided can be used to estimate the expected distal tunnel CSA. This estimate would be useful in determining the role of structural anatomy in the onset of CTS as well as the best treatment strategy.

The present study has some limitations. It is well known that soft tissues and water content strongly influence carpal morphology in live individuals, hence, the volume of the carpal tunnel in cadavers would differ from the volume of the carpal tunnel in the living. Additionally, conditions such as hormonal variations, estrogen and diabetes, can further alter the internal dimensions of the tunnel. As cadaveric samples are standardized, we employed the same to study the shape of the tunnel precisely. Future studies involving quantitative measurements of the tunnel and its contents can be conducted utilizing this information. To comprehend the morphological differences between the sexes, these measurements must be analyzed in depth. Similarly, additional research into the differences in structural anatomy between patients and controls is required to describe the association between carpal tunnel morphology and CTS.

CONCLUSIONS

The present study used clear and easily definable anatomical landmarks and attempted to measure the available carpal tunnel space with 3D visualization. After determining the volume, length, width, height, and CSA of the carpal tunnel, we conclude that the tunnel has characteristics of an elliptical truncated cone, and that the tunnel's outlet is the narrowest segment, with the narrowing occurring gradually. The ulnar aspect of the tunnel was also found to be significantly more profound than the radial aspect. The curvature of the hamate therefore acts as a variable in contributing to the CSA and volume of the tunnel. Any alteration from the standard shape or structure of the carpal tunnel may be a predisposing factor in idiopathic carpal tunnel syndrome.

FUNDINGS

None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

MRD, AKB, SGK: conceptualization, design. MRD: material preparation and data collection. SAJ: statistical analysis. MRD: writing – original draft. AKB: writing – review and editing.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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Peripheral Muscle Function and Myoelectric Activity of the Suprahyoid Region in Deglutition of Post-COVID-19 Patients

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SUMMARY

Objective. To investigate the prevalence of sarcopenia and its association with myoelectric activity of the SH region in post-COVID-19 patients, stratified by disease severity and gender**.**

Methods. A cross-sectional study conducted in the post-COVID-19 Outpatient Clinic of a University Hospital. The following outcomes were assessed: swallowing (Dysphagia Risk Evaluation Protocol), electromyography of the SH region, muscle strength and muscle mass (dynamometry, ultrasound, and bioimpedance analysis).

Results. The sample consisted of 50 patients (50.4 ± 13.35 years), who were admitted to the COVID-19 ICU and referred to the Outpatient Clinic. Critical-COVID group (n = 19) had a loss of muscle strength, without loss of muscle mass, no altered myoelectric activity of the SH region. Deglutition was classified as normal. Female patients showed low strength and male patients presented loss of muscle mass, in both groups. In the Severe-COVID group (n = 31), female patients had higher myoelectric activity in the SH region at rest, when deglutition pasty and when swallowing liquids, and at the clinical evaluation of swallowing, multiple deglutition in the pasty consistency and coughing in the liquid consistency. The correlations were significant only in the Severe-COVID group.

Conclusions. Male Critical-COVID patients showed sarcopenia, while female patients demonstrated pre-sarcopenia. The correlation observed in the Severe-COVID group, suggests that COVID-19 may compromise the muscles involved in swallowing even in non-critical patients. It is noteworthy the evaluation of these outcomes in post-COVID-19 patients to focus on individualized rehabilitation plan to provide functional recovery after hospital discharge.

KEY WORDS

COVID-19; deglutition; intensive care units; muscles; sarcopenia.

INTRODUCTION

Severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) is a novel, highly infectious respiratory pathogen responsible for Coronavirus disease 2019 (COVID-19) (1). Although COVID-19 is a respiratory disease, it has a multisystemic character, which in 20% of the cases can evolve to a severe form, with the need for admission to the Intensive Care Unit (ICU) (2). In this sense, some factors are determinants for the development of severe symptoms such as male gender, advanced age, obesity, smoking history, hypertension, and diabetes (3).

Studies demonstrated that critically ill patients, infected with COVID-19, often exhibit musculoskeletal impairment (4). Such changes have been attributed to the direct and indirect effects of the exacerbated inflammatory process, characteristic of the disease. Besides the process of muscle catabolism triggered by long periods in ICU, prolonged immobilization, nutritional imbalance, and administration of medications (5). Thus, this critical phase, marked by intense protein destruction and hypercatabolism and prolonged physical inactivity, leads to loss of muscle strength, mass, and function (4), which characterizes sarcopenia (6).

Peripheral muscle weakness is an independent predictor of mortality to increased mechanical ventilation time, and ICU stays (7). In a study of 196 COVID-19 patients, greater peripheral muscle strength was associated with shorter hospital stays (8). Also, in a recent study, critically ill patients hospitalized for COVID-19 showed a reduction in peripheral muscle strength, assessed by dynamometry, when compared to non-severe patients (9). Regarding muscle mass, depletion is cited in post-COVID-19 patients (4). The ultrasonographic study of quadriceps muscle thickness in COVID-19 patients admitted to the ICU demonstrated that the muscle wasting and decreased muscle strength occurred early and rapidly during 10 days of ICU stay (10). Bioimpedance analysis (BIA) is another useful tool to estimate body composition and fractionation of body weight into lean mass, body fat, and water (11).

Besides musculoskeletal impairment, central and peripheral neuroinvasion by SARS-CoV-2 causing anosmia and ageusia, as well as the sensory alteration in the pharynx, favors swallowing problems (12). Also, post-ICU patients, in general, present swallowing dysfunction related to prolonged intubation (> 48 h), tracheostomy, or nasogastric tube (13). A study conducted with 101 ICU patients diagnosed with COVID-19 showed that dysphagia after extubation was common in ICU patients with COVID-19 and also at ICU discharge. The study also demonstrated that patients with COVID-19 remained intubated longer and needed fewer swallowing rehabilitation sessions to return to safe oral feeding (14).

The implications of COVID-19 on swallowing muscles are still unclear. Thus, it becomes pertinent to highlight that in ICU patients without COVID-19, the electromyographic activity of the suprahyoid region after speech therapy demonstrated increased neuromuscular recruitment and improved function (15). It is believed that peripheral myopathy arising from the musculoskeletal and neuronal impairment of COVID-19, could also comprise the skeletal muscles of the head and neck. Furthermore, it is suggested that patients with higher severity of COVID-19 disease may be more likely to develop sarcopenia, the altered myoelectric activity of the suprahyoid region, and deglutition.

In this sense, after the acute phase of the disease, about 16% of patients who were hospitalized present loss of muscle mass and strength after 3 months of hospital discharge, and 4% of these after 6 months (16). However, to the best of our knowledge, there are no studies that evaluated the myoelectric activity of swallowing in post-COVID-19 patients. Based on the assumption that the healthcare workers need to be vigilant about the persistence of musculoskeletal disorders after recovery from acute illness (17) and considering the clinical demand of post-COVID-19 patients for multi-professional rehabilitation, to understanding the peripheral muscle condition, investigate the prevalence of sarcopenia, and its association with swallowing is fundamental.

Therefore, the aim of this study was to investigate the prevalence of sarcopenia and its association with myoelectric activity of the SH region in post-COVID-19 patients, stratified by disease severity and gender.

MATERIALS AND METHODS

A cross-sectional study was conducted at the post-COVID-19 Outpatient Rehabilitation Unit Rehabilitation of University Hospital of Santa Maria, Rio Grande do Sul, Brazil. The study was approved by the ethics committee (CAAE 42610921.2.0000.5346 – Date of approval: February 05, 2021) and performed in accordance with the Declaration of Helsinki. The STROBE guidelines were used to ensure the reporting of this observational study. The sample consisted of 50 patients of both genders, aged over 18 years, who were admitted to the ICU COVID-19 of the same hospital and were referred from the Pulmonology Service to the post COVID-19 Outpatient Rehabilitation Unit of the same hospital. We included patients who were referred from April to September 2021, with a minimum time between hospital discharge and outpatient evaluation of 30 days and agreed to participate by signing a consent form. Patients with neurological impairment, difficulty standing without support or amputation, tracheostomy, gastrostomy, and stage 3 hypertension (systolic blood pressure at rest >

180 mmHg and/or diastolic blood pressure at rest > 110 mmHg), which precluded the performance of deglutition, muscle electrical activity, body composition, and muscle architecture assessments, were excluded.

Participants

The individuals eligible for the research were submitted to a series of evaluations with speech therapists and physical therapists, members of the research group, previously trained to conduct the protocols, and blinded to the study outcomes. The order established for the evaluations was: deglutition assessment, peripheral muscle strength, quadriceps femoris muscular ultrasound, BIA, and electromyographic. Demographic (age, sex, and body-mass index (BMI)), clinical (COVID-19–associated symptoms at onset and preexisting medical comorbidities), and hospitalization (intensive care unit admission, duration of IMV and of hospital stay and chest CT scan at admission) data were collected from eletronic health record. Patients also underwent physical examination and assessment of the pulmonary function at the outpatient pneumology clinic. We followed the WHO (2020) (1) classification to stratify the sample by disease severity (Critical-COVID or Severe--COVID). Two groups of patients were included in the study:

1. Critical-COVID: patients surviving COVID-19 that required > 24 h of invasive mechanical ventilation (IMV) via endotracheal tube.
2. Severe-COVID: patients recovering from COVID-19 that required an acute hospitalization and supplemental oxygen (high-flow nasal cannula, venturi mask, and/or nasal cannula).

Data collection procedures

Swallowing assessment

The risk of dysphagia and swallowing evaluation was assessed using the Dysphagia Risk Evaluation Protocol (PARD). The swallowing was classified as normal (level 1), functional (level 2), mild dysphagia (level 3), mild-moderate dysphagia (level 4), moderate dysphagia (level 5), severe moderate dysphagia (level 6) and severe dysphagia (level 7) (18).

Peripheral muscle strength

The handgrip strength (HGS) was checked on the dominant hand using a hydraulic dynamometer (Saehan, SaehanCorporation, 973, Yangdeok-Dong, Masan 630-728, Korea), duly calibrated. To perform the test the individual remained seated, arm adducted parallel to the trunk and shoulder in neutral rotation, with the elbow flexed at 90°. The individual exerted maximum force to bring the two rods of the device closer to the evaluator's voice command, receiving incentive phrases for six seconds. Three maneuvers were performed with a one-minute rest interval between them, and the highest score was chosen. The HGS values below the 30th percentile of the reference adjusted for age and sex, obtained in the Brazilian population (19) were considered muscle strength loss. Also, the percentage of muscle strength loss was calculated by the dominant HGS prediction equation proposed by Novaes *et al.* (20).

Peripheral muscle mass

To measure muscle mass, another musculoskeletal variable, BIA was performed using body composition analyzer (BIA: Tanita BC601 Inner Scan® - Tanita Corp., Tokyo, Japan) with contact electrodes for the subject's feet and hands, in the vertical position. The patient was previously instructed not to consume diuretic drugs, alcoholic beverages, and caffeine, not to practice intense physical exercises, to sleep at least seven hours or to rest five to ten minutes before the evaluation, to fast for at least three hours, and to empty the bladder before the exam. Fat-free lean mass depletion was calculated according to the Appendicular Skeletal Muscle Mass Index (ASMI) (limb lean mass/height^2) with values less than 6.76 kg/m^2 for women and less than 10.76 kg/m^2 for men (21).

The assessment of quadriceps femoris muscle thickness (QFMT) was performed from ultrasound images obtained by a high-resolution device (Mindray ultrasound, DP-2200 portable, China), in B mode, with a micro convex echocardiographic transducer, 65C15EA 5.0-9.0 MHz, 4W) by a previously trained professional. The patient was positioned in dorsal decubitus, with the headboard elevated 30°, lower limbs extended, relaxed, and in a neutral position. The gel-covered transducer was positioned perpendicular to the skin, with minimal pressure (muscle and subcutaneous fat can be easily compressed), at the midpoint of the quadriceps femoris (the region between the anterosuperior iliac spine and the superior pole of the patella). The QFMT was visualized between the superior aponeurosis of the rectus femoris and the cortex of the femur. The image analysis was performed in ImageJ® software (NIH, Bethesda, MD, USA).

Assessment of sarcopenia

A sarcopenia diagnosis was confirmed by the presence of of low muscle quantity or quality. For the study, we considered any loss of muscle strength by the research criteria, associated with loss of muscle mass by ASMI (21).

Evaluation of the myometrial activity of the suprahyoid region

The electrical activity of the muscles of the right and left suprahyoid region was captured by a portable Miotool

electromyograph, Miotec® brand, which used 2 channels. The signals were acquired with electrical isolation of 5000 volts, 14-bit resolution, and 2000 samples/second/channel, with a 20Hz high-pass and 500Hz low-pass filter.

For the capture of the electromyographic recordings, we followed the recommendations of SENIAN (22). The skin was sanitized with cotton soaked in 70° ethyl alcohol in the region of the muscles to be studied. When necessary, trichotomy was performed in the region. To avoid electromagnetic interference during the exam, a reference electrode was positioned in the glabella region. The patient remained seated on a wooden stool and had his feet placed on a rubber mat. To place the electrodes on the suprahyoid muscles, the patients were instructed to press their tongue against the palate and the researcher identified the muscle group by palpation. Each bipolar electrode was positioned parallel to the direction of the fibers of the anterior digastric muscle, to maximize the uptake of electrical activity and minimize noise interference.

The evaluation of muscle activity was performed using electromyographic recordings of the aforementioned region, through an evaluation protocol of swallowing electromyographic activity:

- Test 1 - Resting: for the collection of the signal at rest, the volunteer was instructed to swallow the saliva and then not to move the tongue any further, not to clench the teeth, nor swallow; close the eyes and remain as still as possible for 15 seconds. Ten seconds of the best signal were used.
- Test 2 - Maximum voluntary contraction (MVC): to perform the MVC test of the DS and SS muscles, the volunteer was instructed to place the tongue against the palate, keeping the contraction as strong as possible for seven seconds. The evaluator encouraged the action by saying, "force, force, force...relax". Five center seconds of the best signal were used.
- Test 3 - Liquid deglutition: to perform this test, the volunteer was instructed to swallow 100 ml of water continuously, but without haste, at the usual speed. The three central swallows of the best signal were used.
- Test 4 -Pasta deglutition: to perform this function, the volunteer was instructed to swallow each time the evaluator offered him/her a pasty swallow and not to talk between offers. They were offered 50 ml of medium paste (consistency prepared according to the PARD protocol), in five spoonfuls and used the three central swallows of the best signal.

For each of the tests, two to three samplings were performed, with a time interval of at least one minute of rest between them. From this collection, the signal with the best electromyographic quality was chosen based on the Fast Fourier Transform (FFT). After collecting the signal in Root Mean Square (RMS) (in the unit of microvolts), for comparisons between groups and correlations the amplitude signals were normalized by the CVM of the target muscles of the study (22).

Sample size calculation

The sample size was calculated in the G-Power 3.1 software, based on the evaluation of the first ten patients, considering a test power of 80% correlation between QFMT and body muscle mass with the myoelectric activity of the suprahyoid and a 5% error. A minimum sample size of 47 patients was required.

Data analysis

The Statistical Package for the Social Sciences software, version 20.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis, assuming a 5% significance level ($p < 0.05$). The normality of the variables was assessed by the Shapiro-Wilk test. The continuous variables are reported as a mean and standard deviation (SD) and non-parametric variables as median and minimum and maximum values. Categorical variables are presented in absolute frequencies and percentages.

In the comparisons regarding severity and gender, the Student's t-test for independent samples, Mann-Whitney U test, chi-square test, and Fisher's exact test was used, according to data distribution. The Pearson's correlation coefficient was used to evaluate associations between the quantitative variables.

RESULTS

The sample consisted of 50 patients (50.4 ± 13.35 years) classified by disease severity into two groups: Severe-COVID 31 patients (62%) and Critical-COVID 19 patients (38%), and by gender within each group. Of the total sample, 25 (50%) were female and 25 (50%) were male, with a predominant age range between 40 and 59 years. No adverse events were observed during the study.

The demographic and clinical characteristics and the risk of dysphagia of patients with COVID-19, in terms of disease severity and gender, are presented in **table I**. Patients in the Critical-COVID group had higher hospital length of stay ($p \leq 0.001$). When considering gender, male patients in the Severe-COVID group had higher hospital length of stay compared to female patients. In the clinical evaluation of the PARD protocol, the female

Table I. Clinical and demographic characteristics of the sample.

Variables	Severe COVID-19 (n = 31)			Critical COVID-19 (n = 19)			Total (n = 50)		
	Female (n = 14)	Male (n = 17)	P-value	Female (n= 11)	Male (n = 8)	P-value	Severe (n = 31)	Critical (n = 19)	P-value
Age (years)	50.2 ± 12.5	54.1 ± 15.6	0.459[a]	46.0 ± 13.0	48.6 ± 8.9	0.630[a]	52.4 ± 14.2	47.1 ± 11.2	0.218[a]
Age									
20-39, n (%)	2 (14.3)	3 (17.6)	0.800[d]	3 (27.3)	1 (12.5)	0.435[d]	5 (16.1)	4 (21.1)	0.660[b]
40 -59, n (%)	10 (71.4)	7 (41.2)	0.092[b]	7 (63.6)	6 (75.5)	0.599[b]	17 (54.8)	13 (68.4)	0.341[b]
60 -79, n (%)	1 (7.1)	6 (35.3)	0.062[d]	1 (9.1)	1 (12.5)	0.811[d]	7 (22.6)	2 (10.5)	0.282[d]
≥ 80, n (%)	1 (7.1)	1 (5.9)	0.887[d]	1 (4.0)	-	0.889[d]	2 (6.5)	-	0.252[d]
Hospitalization time (days)	8.5 (6.5 – 10.7)	12.0 (9.5 – 17.5)	0.010[c]	22.0 (16.0-43.0)	26.0 (21.0-34.7)	0.657[c]	10.0 (8.0-14.0)	23.0 (16.0 – 36.0)	< 0.001[c]
MV time (days)	-	-	-	11.0 (8.0-13.0)	12.0 (7.7-13.7)	0.717[c]	-	11.0 (8.0 – 13.0)	-
Time to assessment (days)							61.0 (47.0-96.0)	77.0 (43.0 – 89.0)	0.952[c]
Comorbidities									
SAH, n (%)	6 (42.9)	12 (70.6)	0.119[b]	14 (56.0)	4 (50.0)	0.311[b]	18 (58.1)	12 (63.2)	0.721[b]
DM, n (%)	3 (21.4)	5 (29.4)	0.613[b]	2 (18.2)	1 (12.5)	0.737[d]	8 (25.8)	3 (15.8)	0.407[b]
Obesity, n (%)	8 (57.1)	10 (58.8)	0.925[b]	8 (80.0)	5 (62.5)	0.410[b]	18 (58.1)	13 (72.2)	0.322[b]
Dyslipidemia, n (%)	4 (28.6)	5 (29.4)	0.959[b]	3 (27.3)	3 (37.5)	0.636[b]	9 (29.0)	6 (31.6)	0.849[b]
Thyroid disease, n (%)	-	1 (5.9)	0.356[d]	2 (18.2)	1 (12.5)	0.364[d]	1 (3.2)	3 (15.8)	0.112[b]
COPD, n (%)	1 (7.1)	2 (11.8)	0.665[d]	-	-	-	3 (9.7)	-	0.162[b]
PARD									
Normal deglutition, n (%)	10 (71.4)	16 (94.1)	0.087[b]	7 (63.6)	7 (87.5)	0.253[b]	26 (83.9)	14 (73.7)	0.382[b]
Functional degl, n (%)	3 (21.4)	1 (5.9)	0.199[d]	3 (27.3)	1 (12.5)	0.435[d]	4 (12.9)	4 (21.1)	0.445[b]
Mild dysphagia, n (%)	1 (7.1)	-	0.263[d]	1 (9.1)	-	0.381[d]	1 (3.2)	1 (5.3)	0.721[d]
Multiple degl Liq 5 ml	2 (14.3)	-	0.196[d]	3 (27.3)	-	0.228[d]	2 (6.5)	3 (15.8)	0.355[d]
Multiple degl. Pas 5 ml	5 (35.7)	-	0.007[d*]	4 (36.4)	1 (12.5)	0.338[d]	5 (16.2)	5 (26.3)	0.382[b]
Multiple degl Pas 10 ml	8 (57.1)	1 (5.9)	0.004 [d*]	7 (63.6)	3 (37.5)	0.370[d]	9 (29.1)	10 (5.3)	0.095[b]
Cough_Water 5 ml, n (%)	3 (21.4)	-	0.045[d]	1 (9.1)	-	0.381[d]	3 (9.7)	1 (5.3)	0.577[d]
Cough_Pas 5 ml, n (%)	2 (14.3)	-	0.107[d]	-	-	-	2 (6.5)	-	0.258[d]
Cough_Pas 10 ml, n (%)	2 (14.3)	-	0.107[d]	-	-	-	2 (6.5)	-	0.258[d]

MV: Mechanical Ventilation; SAH: Systemic Arterial Hypertension; DM: Diabetes Mellitus; COPD: Chronic Obstructive Pulmonary Disease; PARD: Dysphagia Risk Evaluation Protocol; Degl.: Deglutition; Liq: Liquid; Pas: Pasty; [a]Student's t-test for independent samples; [b]chi-square test; [c] Mann-Whitney U test; [d]Fisher's exact test; *p < 0.05.

Table II. Peripheral muscle status of the sample stratified by severity and gender.

Variables	Severe (n= 31)			Critical (n = 19)			Total (n = 50)		
	Female (n = 14)	Male (n = 17)	P-value	Female (n = 11)	Male (n = 8)	P-value	Severe (n = 31)	Critical (n = 19)	P-value
HGS (KgF)	25.7 ± 6.3	41.0 ± 10.8	< 0.001[a*]	20.5 ± 5.5	37.0 ± 10.0	< 0.001[a*]	34.1 ± 11.8	27.5 ± 11.2	0.079
HGS (% pred)	75.9 ± 27.6	84.4 ± 22.4	0.352	55.4 ± 16.4	71.8 ± 18.8	0.060	80.6 ± 24.8	62.3 ± 18.8	0.016[a*]
ASMI (kg/m²)	8.0 ± 1.1	9.9 ± 1.6	< 0.001[a*]	8.1 ± 0.7	10.0 ± 0.5	< 0.001[a*]	9.0 ± 1.7	8.9 ± 1.1	0.787
QFMT (cm)	40.2 ± 8.7	42.2 ± 11.1	0.555	42.3 ± 10.9	47.6 ± 7.5	0.252	41.4 ± 9.9	44.5 ± 9.9	0.220
Sarcopenia - n (%)	-	13 (76.47)	< 0.001[b*]	-	8 (100)	< 0.001[c*]	13 (41.93)	8 (42.10)	0.990

HGS: handgrip strength; ASMI: Appendicular Skeletal Muscle Mass Index; QFMT: quadriceps femoris muscle thickness; [a]Student's t-test for independent samples; [b]chi-square test; [c]Mann-Whitney U test; *p < 0.05.

Table III. Myoelectric activity of the suprahyoid region of the sample stratified by severity and gender.

Variables	Severe (n = 31)			Critical (n = 19)			Total (n = 50)		
	Female (n = 14)	Male (n = 17)	P-value	Female (n = 11)	Male (n = 8)	P-value	Severe (n = 31)	Critical (n = 19)	P-value
Rest									
RS	5.4 ± 2.6	3.5 ± 2.3	0.040[a]*	5.7 ± 3.4	3.5 ± 1.8	0.114[a]	4.4 ± 2.6	4.8 ± 3.0	0.839[a]
LS	5.0 ± 2.1	3.1 ± 1.7	0.010[a]*	6.4 ± 4.6	3.3 ± 1.9	0.086[a]	4.0 ± 2.1	5.1 ± 3.9	0.447[a]
MVC									
RS	102.6 ± 46.0	110.2 ± 23.3	0.557[a]	133.9 ± 54.4	112.8 ± 19.3	0.315[a]	106.7 ± 34.9	124.5 ± 42.8	0.214[a]
LS	109.2 ± 46.5	120.9 ± 51.2	0.539[a]	140.9 ± 55.9	106.7 ± 11.2	0.109[a]	116.0 ± 48.7	126.5 ± 45.7	0.111[a]
PASTY degl.									
RS	66.2 ± 29.3	38.7 ± 19.1	0.004[a]*	59.8 ± 27.7	48.6 ± 19.1	0.373[a]	51.1 ± 27.5	55.0 ± 26.1	0.273[a]
LS	71.6 ± 37.6	38.1 ± 14.6	0.002[a]*	62.4 ± 25.0	48.1 ± 33.0	0.296[a]	53.2 ± 31.8	56.4 ± 28.7	0.249[a]
LIQUID degl.									
RS	43.9 ± 25.6	33.2 ± 12.3	0.137[a]	51.9 ± 30.5	42.6 ± 29.4	0.512[a]	38.0 ± 19.8	48.0 ± 29.6	0.923[a]
LS	41.0 (21.8-59.4)	31.4 (20.9-36.1)	0.103[c]	53.3 (28.1-75.6)	27.8 (24.4-48.3)	0.238[c]	34.0 (22.1-48.6)	30.1 (27.3-69.5)	0.460[c]
Liquid degl. n	9.0 ± 1.7	8.5 ± 3.4	0.637[a]	10.9 ± 3.1	8.8 ± 1.2	0.103[a]	8.8 ± 2.7	10.0 ± 2.6	0.337[a]
Liquid degl. time	19.4 ± 6.8	14.1 ± 5.7	0.025[a]*	20.5 ± 10.3	14.5 ± 3.3	0.134[a]	16.5 ± 6.7	18.0 ± 8.5	0.874[a]

RS: Right Suprahyoid Region; LS: Left Suprahyoid Region; MVC: Maximum Voluntary Contraction; Degl.: deglutition; [a]Student's t-test for independent samples; [b]chi-square test; [c]Mann-Whitney U test; *p < 0.05.

gender in the Severe-COVID group presented multiple swallows in the pasty consistency (5 and 10 ml) and coughing when degluting liquid (5 ml).

Of the total sample 14.3% reported a feeling of food stuck in the throat, 18.4% need to force to swallow solids and 10.2% were forced to deglute liquids.

Table II shows the variables of peripheral muscle condition in post-COVID-19 patients. Critical-COVID group had significantly lower HGS than predicted when compared to Severe-COVID group. When comparing gender, all patients showed reduced muscle strength compared to predicted, but male patients had significantly higher values. Considering the normative values (18), patients of both genders in the Critical-COVID group had muscle strength loss. As for the ASMI, male patients had higher values than females and showed loss of mass. Thus, only male patients were classified as sarcopenic.

The electrical activity of the right and left suprahyoid region, at rest, VLC, and during deglutition of liquid and pasty is provided in **table III**. It is noteworthy that only in the analysis in the Severe-COVID group, females showed a higher electrical activity at rest and during the deglutition of pasty foods from the suprahyoid muscles, as well as during the liquid deglutition time (100 ml).

We found a correlation between variables of peripheral muscle condition and myoelectric activity of the SH region only in the Severe-COVID group (**figure 1**). Moderate negative correlations were demonstrated between HGS and resting SD (r = -0.39, p = 0.02), HGS and pasty swallow SD (r = -0.35, p = 0.05), and HGS and pasty swallow SE (r = -0.37, p = 0.03), also moderate negative correlations between QFMT and liquid swallowing time (r = -0.41, p = 0.01) and QFMT and number of liquid swallows (r = -0.38, p = 0.03), and moderate positive correlations between QFMT and CVM SD (r = 0.37, p = 0.03).

Regarding gender, intra-group correlations were also significant in male patients in the Severe-COVID group (**figure 2**). The male gender showed a strong negative correlation between FPP and myoelectric activity of the right suprahyoid region at rest (r = -0.582, p = 0.014), QFMT and number (r = -0.539, p = 0.026) and time of liquid swallowing (r = -0.592, p = 0.012). In addition, a strong positive correlation between QFMT and CVM of the right suprahyoid region (r = 0.510, p = 0.037) and ASMI and CVM of the right suprahyoid region (r = -0.541, p = 0.025) was observed.

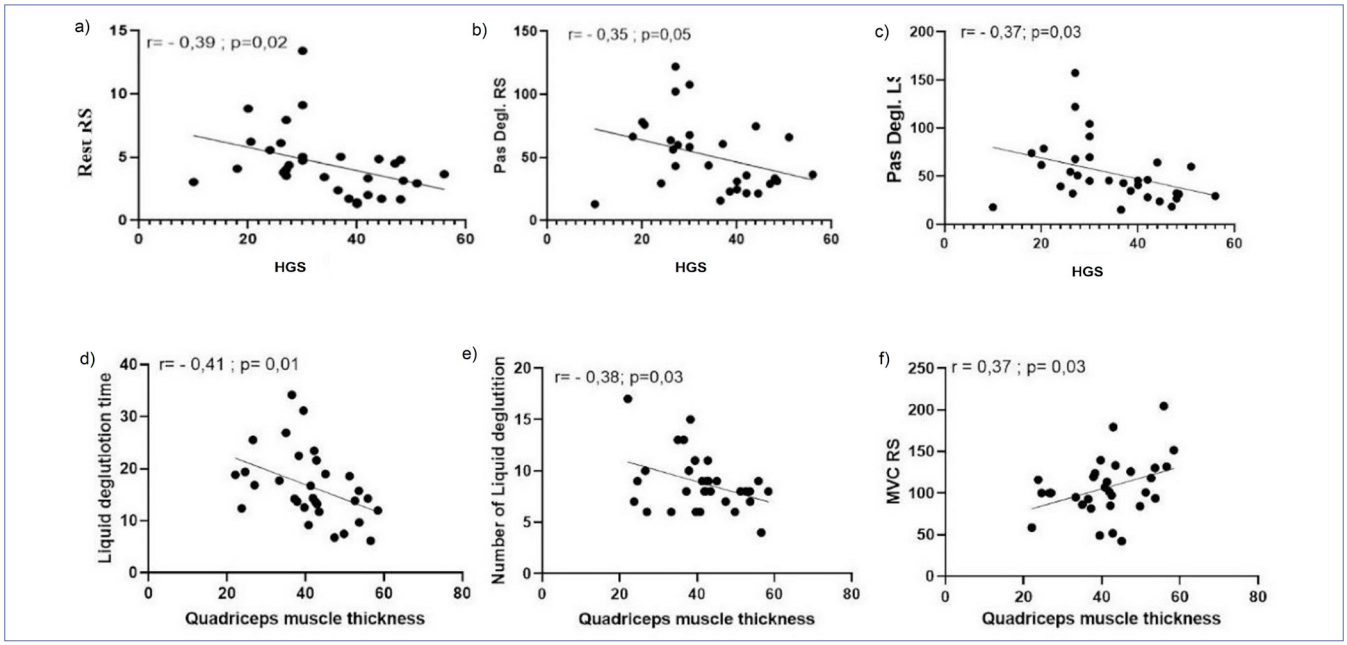

Figure 1. Correlations between peripheral muscle condition and myoelectric activity of the suprahyoid region in the Severe-COVID group.

(a) Handgrip strength (HGS) × Myoelectric activity at rest of the right suprahyoid region (RS); **(b)** Handgrip strength (HGS) × Myoelectric activity in Slurry Deglutition of the right suprahyoid region (Pas Degl. RS); **(c)** Handgrip strength (HGS) × Myoelectric activity in Slurry Swallowing of the left suprahyoid region (Pas Degl. LS); **(d)** Quadriceps muscle thickness × Liquid deglutiotion time (Liq Degl.); **(e)** Quadriceps muscle thickness x Number of Liquid deglutition (No. Liq Degl.); **(f)** Quadriceps muscle thickness × Maximum Voluntary Contraction of the Right Suprahyoid region (MVC RS).

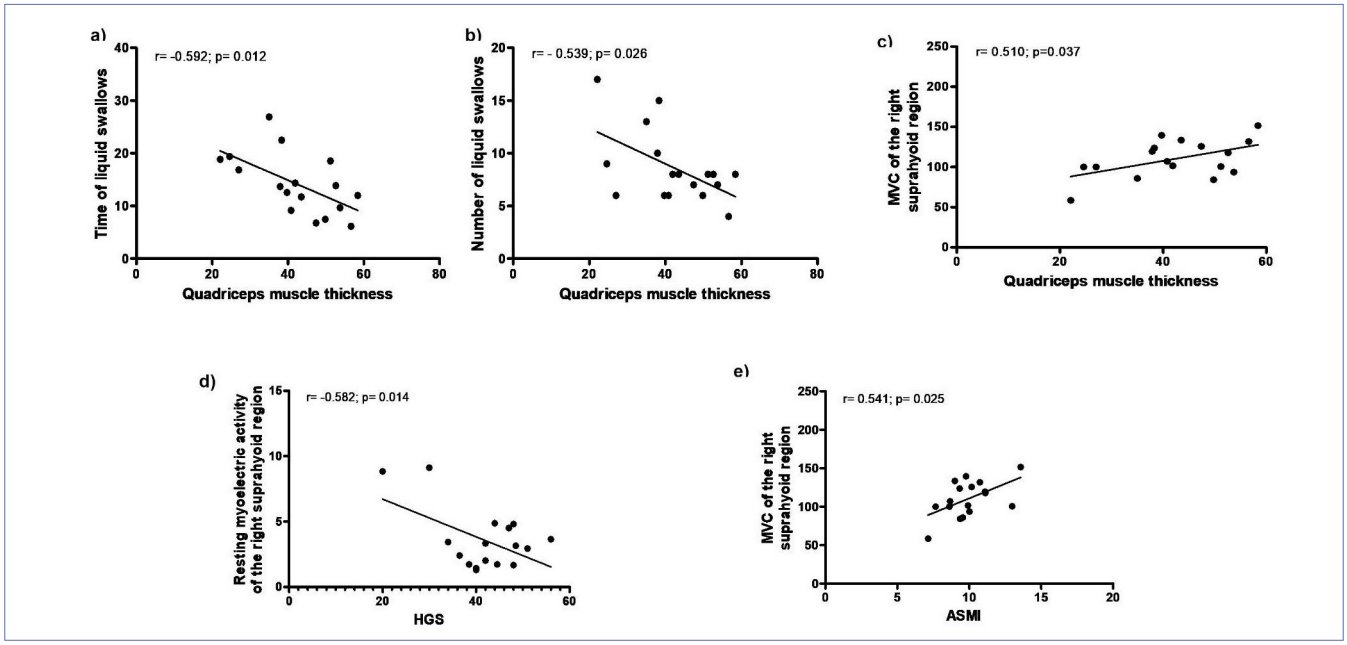

Figure 2. Correlations between peripheral muscle condition and myoelectric activity of the suprahyoid region in males in the Severe-COVID group.

(a) Time of liquid swallows × quadriceps muscle thickness; **(b)** Number of liquid swallows × quadriceps muscle thickness; **(c)** Maximum Voluntary Contraction (MVC) of the right suprahyoid region × quadriceps muscle thickness; **(d)** Resting myoelectric activity of the right suprahyoid region × Handgrip strength (HGS); **(e)** Maximum Voluntary Contraction (MVC) of the right suprahyoid region x Appendicular Skeletal Muscle Mass Index (ASMI).

DISCUSSION

This study hypothesized that patients with higher severity of COVID-19 would present greater muscle impairment, including the swallowing muscles. Patients in the Critical-COVID had higher hospital and ICU length of stay and had lower handgrip strength. However, in these patients, there was no loss of muscle mass and no change in the myoelectric activity of the SH region. In the evaluation of the risk of dysphagia, swallowing was classified as normal. Refuting, at least in part, the research hypothesis.

The production of pro-inflammatory cytokines and reactive oxygen species, resulting from immobility, accelerates skeletal muscle atrophy by proteolysis. The loss of contractile protein and fiber size are some of the components of the reduced ability to generate force. In the COVID-19 patients, regardless of disease severity, the handgrip strength values were below the specified normative values (9). These findings were confirmed in the present study since all patients showed values below the normative values, and patients in the Critical-COVID group, the handgrip strength values were significantly lower than in Severe-COVID group.

The involvement of the musculoskeletal system are attributed to indirect effects, mainly arising from inflammatory and/or immune response, but other mechanisms can be hypothesized, such as direct damage by the virus on the endothelium or peripheral nerves (23). In this sense, it is still unclear how the effects of COVID-19 on the musculoskeletal system are mediated (23).

With regard to muscle mass, in the BIA evaluation, there was no difference between the groups. It is noteworthy that excess fat mass often hides a loss of lean mass in obese individuals (24) and obesity was frequent in our sample. In the US analysis, QFMT was also not significant. As would be expected, there are fewer studies that have measured in survivors of COVID-19 Few studies have investigated peripheral muscle ultrasonography in survivors of COVID-19. Reduced lateral vastus transverse area was predictive of hospital stay (8) and severity of clinical outcome in these patients (25). Another study showed a reduction of 2.1% per day in QFMT during 10 days of hospitalization (10).

Several risk factors for dysphagia in ICU patients (intubation, loss of muscle strength, comorbidities, and bed restriction due to prolonged hospitalization) may also be present in critically ill COVID-19 patients (26). Dysphagia was present in 28.9% of patients hospitalized for COVID-19 in the study by Dawson *et al.* (12), and at 51.7% in the study conducted by Martin-Martinez *et al.* (27). However, dysphagia was not frequent in the present study. Probably, the time between discharge and outpatient evaluation (median 77 days) and the age of the patients in the sample may have influenced the swallowing results.

The prevalence of dysphagia was significantly reduced from discharge to three months follow-up (44.8% *vs* 24.0%) in 205 COVID-19 patients, with a median age of 69 years (27). Also, severe and critical post-COVID-19 patients who were assisted by the multidisciplinary team during the hospitalization period can recover normal or near-normal swallowing function after intubation and tracheostomy (12). Thus, considering that in the ICU/COVID of the hospital in question the assistance is multidisciplinary, such aspects may justify the findings related to deglutition in our study.

Considering the gender particularities, the higher electrical activity of the muscles of the suprahyoid region in the female patients in the Severe-COVID group could be explained as a compensatory mechanism due to the lower strength and peripheral muscle mass of these patients compared to males. It should be noted that in the oral phase of deglutition the muscles of the suprahyoid region are directly involved in stabilizing the jaw and in the pharyngeal phase, in the active elevation of the hyoid bone and larynx, ensuring a safe swallow (28). In this sense, an electromyographic study of the swallowing of healthy individuals (supra and infrahyoid region), classified by age group and sex, found that the female sex presents the slowest laryngeal elevation, consistent with the longer duration of swallowing. Anatomical differences in neck length determine a shorter excursion of the hyoid, longer upper esophageal sphincter opening time, and longer oropharyngeal transit time in females (29).

It is emphasized that in the presence of sarcopenia the muscle strength of the suprahyoid region may be compromised, requiring greater activation of muscle fibers to compensate for this weakness (30). However, there is no simple relationship between the electromyographic signal and muscle strength. Evidence indicates that several aspects interfere with the muscle activity of the suprahyoid region, such as head posture, dental occlusion, temporomandibular dysfunction, nasal obstruction, and stress (31). Another aspect to be considered includes the different food consistencies, which may result in a higher intensity electrical activity of the muscles in this region, with increased muscle recruitment in swallowing solid food (32).

Even before the relevance of the findings of this study, some limitations should be considered. First, although the vast majority of patients showed normal and/or functional deglutition by PARD protocol, the presence of dysphagia cannot be ruled out. This assessment tool is limited to liquid and pasty consistency, and the changes could appear in the swallowing of solids, for example. Such consistency involves greater muscle strength and the need for a more present muscle mass even for occlusal stability. Second, the use of more quantifying swallowing assessment tools, such as videofluoroscopy, is considered the gold standard in aspi-

ration investigation. However, its use was restricted during the pandemic at the hospital in question. The third limitation would be that the muscle condition before COVID-19 of these patients was not considered.

The potential clinical practice implications of this study support the importance to evaluate the peripheral and deglutition muscle function of patients who were hospitalized for COVID-19, after recovery from acute COVID-19, considering disease severity and gender. Further studies are needed to investigate the prevalence of sarcopenia and explained its association with myoelectric activity of the SH region and also the possible influence of other factors such as the role of human leukocyte antigens (HLA) genotypes for the different rates of infection and outcomes (33) among post-COVID-19 patients. We also suggest the inclusion of the electromyography as a complementary tool to evaluate swallowing in this population.

CONCLUSIONS

In summary, post-COVID-19 critically ill patients showed a loss of muscle strength compared to what was predicted. In this group, male patients showed sarcopenia, while female patients showed only pre-sarcopenia. On the other hand, male patients in Severe-COVID group showed loss of muscle mass by bioimpedance. The association between peripheral muscle condition and myoelectric activity was demonstrated only in the Severe-COVID group, suggesting that COVID-19 may compromise the muscles involved in swallowing even in non-critical patients. It is noteworthy the evaluation of these outcomes in post-COVID-19 patients to focus on individualized rehabilitation plan to provide functional recovery after hospital discharge.

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None.

DATA AVAILABILITY

Data are available under reasonable request to the corresponding author.

CONTRIBUTIONS

VBB: conceptualization, design, data collection, writing – original draft. JAS: data collection, manuscript writing, writing – original draft. TDS: methods, data analysis writing – original draft. EAVA: methods. ACLD: writing – review & editing. IMA: writing – original draft, writing – review & editing. ARBS: design, supervision, writing – review & editing. ASP: design, guidance, writing – review & editing.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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ORIGINAL ARTICLE

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The "Fat or Fit Paradox" in Postmenopausal Women: A Cross-Sectional Study on the Association Between Skeletal Muscle Mass, Adiposity, and Muscle Strength

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SUMMARY

Background. The "Fat or Fit Paradox" denotes an intriguing association between muscle mass and adiposity in older individuals, challenging conventional beliefs on health and fitness. This investigation seeks to elucidate this paradoxical relationship in a cohort of postmenopausal women.

Methods. In a cross-sectional study, we assessed the correlation between skeletal muscle mass and body fat percentage in 134 community-dwelling Malaysian postmenopausal women, aged 45-88 years. Body composition parameters, including skeletal muscle mass and fat indices, were measured utilizing a multi-segmental bioelectrical impedance analyzer (InBody 230), while muscle strength was indirectly determined by handgrip strength assessment using a JAMAR HAND dynamometer.

Results. Our analysis revealed a significant positive correlation between appendicular skeletal muscle mass index (ASMI) and body fat percentage ($r = 0.359$, $p < 0.001$), indicating that increased adiposity is linked to higher muscle mass in older women. Linear regression analyses further demonstrated a significant positive association between muscle strength and ASMI ($R2 = 0.195$, $p < 0.001$). Importantly, upon stratification by obesity status, muscle mass emerged as a significant predictor of muscle strength in low-obese participants; however, the predictive power decreased with escalating obesity levels.

Conclusions. Our findings confirm a positive association between skeletal muscle mass and body fat percentage in postmenopausal women, although muscle strength exhibits caveats contingent on obesity status. This study accentuates the importance of appraising both muscle mass and adiposity when evaluating overall health and fitness in an aging population.

KEY WORDS

Fat or Fit Paradox; skeletal muscle mass; muscle function; obesity; muscle strength.

INTRODUCTION

The complex relationship between muscle mass and body fat in the aging population has been a topic of ongoing interest in gerontological research (1, 2). As people age, they typically experience a decrease in skeletal muscle mass along with an increase in body fat percentage, which can lead to reduced physical function and increased vulnerability to various health problems (3). This seemingly contradictory association is referred to as the "Fat or Fit Paradox." Some studies have found negative correlations between skeletal muscle mass and body fat percentage (1), while others have reported positive correlations (4-6).

The negative correlation suggests that as body fat accumulates, skeletal muscle mass decreases, and *vice versa*. On the other hand, the positive correlation indicates that an increase in body fat is accompanied by a simultaneous gain in muscle mass (6). Unravelling this paradox has significant implications for the health and fitness of older individuals. Understanding the complex interplay between muscle mass and body fat is crucial for developing effective interventions to improve overall health and well-being in later life.

At present, the diagnosis of reduced muscle mass is hindered by a lack of standardized diagnostic approaches, leading to the variable use of body composition indices and cut-offs. Consequently, disparate terminologies have emerged across various fields to describe muscle mass depletion, including gerontology's sarcopenia, obesity research's sarcopenic obesity, and oncology's cachexia, all of which encompass a multifactorial pathophysiology (7). For example, the concurrent manifestation of sarcopenic obesity and cancer cachexia is frequently observed in obese cancer patients (8). Despite these distinct classifications, the shared pathophysiology underscores the necessity for a more cohesive strategy to diagnose and address muscle mass depletion (8). Moreover, the confluence of an aging population and the obesity epidemic has resulted in a heightened prevalence of sarcopenic obesity, where individuals exhibit both obesity and reduced muscle mass (9, 10). This intersection between age-related sarcopenia and sarcopenic obesity is anticipated to become increasingly prevalent, given current demographic trajectories. This overlap presents unique challenges for the clinical evaluation and management of muscle mass depletion, as the presence of surplus adipose tissue may obscure the detection of muscle loss, consequently delaying diagnosis and treatment.

Given the conflicting findings from previous research, it is essential to further explore the paradoxical relationship between muscle mass and body fat in older adults. The aim of this study was to examine the association between these variables in a group of community-dwelling postmenopausal women. Postmenopausal women represent a unique population where the standard BMI threshold for being overweight might not accurately reflect the health risks associated with excessive body fat. Specifically, recent evidence suggests that a significant number of postmenopausal women with "normal" BMI have high body fat percentages, indicating that they may actually be overweight or obese when considering body composition (11). The consequences of hidden overweight or obesity in postmenopausal women are significant, as undetected excess body fat can increase the risk of chronic diseases such as type 2 diabetes, cardiovascular disease, and certain cancers. It can also negatively affect physical function and quality of life. To better assess the health risks related to excess body fat in postmenopausal women, healthcare providers should consider using comprehensive body composition measurements, like bioelectrical impedance analysis, in addition to BMI. Adopting a multifaceted approach to evaluate obesity status in this population can help healthcare professionals more accurately identify those at risk, allowing for timely intervention and proper management of potential health issues. Our study aimed to address the limitations of previous research by using a sample of postmenopausal women, accurate measurements of both skeletal muscle mass and body fat percentage, and a rigorous statistical analysis method.

METHODS

Recruiting and selecting participants

The University of Nottingham Malaysia's Science and Engineering Research Ethics Committee (SEREC- NZA051016 – Date of approval: November 10, 2016) granted ethical approval for this investigation, adhering to the Declaration of Helsinki. Prior to enrolment, all participants provided written informed consent. A minimum of 91 participants was deemed necessary for the study based on the cross-sectional sample size calculation (12), factoring in an estimated attrition rate of 15%. Through tactics such as flyer distribution, phone calls, e-marketing initiatives, and establishing liaisons, 200 postmenopausal Malaysian women were enlisted from diverse locations in Semenyih and the Klang Valley regions of Kuala Lumpur, Malaysia. Recruitment transpired between April 2017 and June 2018, culminating in the inclusion of 136 women (n = 136, aged 45 to 88) who met the screening criteria in the analysis. Eligibility prerequisites for participation entailed being female, a Malaysian national, and postmenopausal, denoted by the absence of menstrual periods, bleeding, or spotting for 12 consecutive months prior to enrolment. Participants received detailed information about the study's aims, methodologies, potential advantages, risks, and possible discomforts pre-enrolment. Exclusion criteria included the incapacity to stand for height and weight measurements, inability to execute the handgrip test; presence of prosthetic limbs or metal implants, severe cardiac, pulmonary, or musculoskeletal disorders, significant cognitive impairment or communication disabilities, and terminal illness.

Height

Participant height was assessed using a portable stadiometer (SECA 217, Vogel & Halke GmbH & Co., Germany). Participants were instructed to stand erect with their shoulders, buttocks, and heels in contact with the stadiometer. Their toes were placed at a 45° angle, and the head was held in a

neutral position with the neck aligned naturally. The stadiometer was adjusted to each participant's appropriate height, and measurements were recorded to the nearest 0.1 cm.

Waist circumference

Waist circumference (WC) was evaluated using a measuring tape (SECA 203, GmbH & Co. Kg., Hamburg, Germany). Participants were instructed to stand erect with arms by their sides and feet together. WC was gauged at the midpoint between the final rib and the anterior superior iliac spine, signifying the narrowest point between the lower rib margin and the iliac crest (12). The measuring tape was positioned horizontally around the waist, snug but without compressing the skin. Measurements were taken at the end of normal expiration and documented to the nearest 0.1 cm. WC is a widely utilized anthropometric indicator for assessing central obesity and functions as a reliable predictor of metabolic syndrome and cardiovascular disease (13).

Muscle strength

In this study, muscular strength was gauged by measuring handgrip strength using a JAMAR Hydraulic Hand Dynamometer® Model PC-5030 J1 (Fred Sammons, Inc., Burr Ridge, IL, USA). For accurate measurement, the American Society of Hand Therapists advocates a specific positioning: the participant should be seated, with shoulders adducted and neutrally rotated, elbow flexed at 90°, forearm in neutral, and wrist between 0° and 30° of dorsiflexion (14). To obtain a dependable measure of handgrip strength, participants were instructed to grip the dynamometer with maximum effort twice using their dominant hand, with the highest value recorded for the analysis. Handgrip strength is extensively employed as a surrogate for overall muscular strength and has demonstrated reliability and validity in various populations (15).

Body composition, bioimpedance measurement

This study utilized a multi-frequency BIA device with eight-point tactile electrode system (Inbody 230, Biospace Corp., Seoul, Korea), to measure lean body mass (LBM), appendicular muscle mass (ALM), fat mass (FM), body mass index (BMI), skeletal muscle mass (SMM), fat-free mass (FFM) and body fat percent (BFP). The device uses two different frequencies to measure the five segments of the body (right leg, left leg, right arm, left arm, and trunk) and is suitable for individuals aged 3-99 years-old according to the manufacturer. Body composition estimates were calculated by the manufacturer's software (Lookin'Body 120, Biospace Corp., Seoul, Korea). While utilizing this device, the thumb needed to be placed on the electrode pad on the top surface of the handle. The reliability of this device was tested, and the test-retest reliability for whole body LBM and BFP estimates by this device were both ≥ 0.99 (n = 5) using ICC (16). Results obtained from the InBody 230 were then compared with the Gallagher's classification of body fat percentage for elderly (17). Gallagher's classification of body fat percentage for the elderly is a commonly used method for classifying body fat percentage in older adults. It is based on the idea that body fat percentage increases with age, and that the health risks associated with high body fat percentage also increase in older age. Gallagher's classification is useful for identifying older adults who may be at increased risk for obesity-related health conditions. Gallagher's classification for women is based on the following categories: low body fat percentage: < 33% for women; moderate body fat percentage: 33-38% for women; high body fat percentage: 39-45% for women; very high body fat percentage: > 45% for women. The formula is: *Body fat % = (1.46 × BMI) + (0.14 × Age) - (11.6 × gender) – 10* (18). The classification takes into account differences in body fat percentage between men and women, as well as the age-related increase in body fat percentage.

Statistical analysis

Descriptive statistics were presented as means ± SD. In **table I**, the measurements were divided into four groups based on BFP and further categorized according to muscle status into two groups. Obesity categories were defined using body fat percentage as follows: low body fat percentage: < 33% for women; moderate body fat percentage: 33-38% for women; high body fat percentage: 39-45% for women; very high body fat percentage: > 45% for women (17, 18). Muscle mass status was classified per AWGS (7) guidelines: normal muscle mass: ASMI > 5.7 kg/m^2; low muscle mass: ASMI ≤ 5.7 kg/m^2. Multiple linear regression analysis was employed to pinpoint body composition parameters that predict muscle strength. Adjusted r, standard error values, and multicollinearity statistics were utilized to ascertain the most appropriate equations, with all analyses conducted using IBM SPSS version 27 statistical software. A P-value less than 0.05 was deemed statistically significant.

RESULTS

The analyses included 134 participants (n = 134 postmenopausal women, mean ± SD = 60.4 yrs ± 7.5). **Table I** presents the descriptive statistics for the study population according to muscle mass status and body fat percentage (BFP) classification. Based on Gallagher's classification of body fat percentage for the elderly (17, 18) the majority of participants fell into the 'High' and 'Very High' categories (60%). A higher frequency of participants with normal muscle mass was observed within the elevated body fat

Table I. Participant characteristics by BFP classification and muscle mass status in postmenopausal Malaysian women.

Characteristics	Body Fat Percentage Classification*											
	Low < 33% for women (n = 23)			Moderate 33-38% for women (n = 26)			High 39-45% for women (n = 43)			Very high > 45% for women (n = 42)		
	Normal muscle mass ASMI > 5.7kg/m² (n = 10)	Low muscle mass ASMI ≤ 5.7kg/m² (n = 13)	P-value[1]	Normal muscle mass ASMI > 5.7 kg/m² (n = 16)	Low muscle mass ASMI ≤ 5.7 kg/m² (n = 10)	P-value[1]	Normal muscle mass ASMI > 5.7 kg/m² (n = 30)	Low muscle mass ASMI ≤ 5.7 kg/m² (n = 13)	P-value[1]	Normal muscle mass ASMI > 5.7 kg/m² (n = 37)	Low muscle mass ASMI ≤ 5.7 kg/m² (n = 5)	P-value[1]
Age (years)	60.0 (7.9)	64.15 (6.5)	.192	61.7 (7.5)	65.0 (8.0)	.292	59.0 (6.1)	61.4 (11.5)	.485	58.7 (6.4)	62.6 (8.9)	.225
Height (cm)	157.7 (4.9)	154.5 (6.6)	.223	157.2 (5.9)	152.4 (6.9)	.068	154.7 (5.4)	148.4 (5.0)	**.001**	151.9 (5.4)	149.9 (6.8)	.463
Weight (kg)	53.0 (2.9)	45.3 (5.6)	**.001**	63.2 (6.9)	49.2 (4.9)	**.000**	67.9 (6.1)	55.6 (5.2)	**.000**	76.4 (10.0)	60.8 (5.9)	**.002**
BMI (kg/m²)	21.3 (0.8)	18.9 (1.5)	**.000**	25.5 (2.3)	21.2 (1.2)	**.000**	28.4 (1.9)	25.2 (1.6)	**.000**	33.2 (4.2)	27.1 (3.0)	**.004**
WC (cm)	73.4 (3.4)	66.5 (7.4)	**.018**	82.4 (7.3)	71.2 (4.6)	**.000**	87.9 (6.8)	82.3 (7.4)	**.019**	96.5 (11.3)	79.6 (7.5)	**.003**
BFM (kg)	14.9 (2.5)	12.4 (2.7)	**.038**	22.6 (3.1)	17.5 (2.4)	**.000**	28.9 (3.1)	23.4 (3.0)	**.000**	37.8 (6.5)	29.0 (4.0)	**.006**
FFM (kg)	38.2 (2.6)	32.9 (3.9)	**.002**	40.6 (3.8)	31.7 (2.7)	**.000**	39.1 (3.3)	32.1 (2.4)	**.000**	38.6 (4.1)	31.8 (2.0)	**.001**
FFMI (kg/m²)	15.3 (0.9)	13.8 (0.9)	**.000**	16.4 (1.3)	13.7 (0.8)	**.000**	16.3 (1.0)	14.6 (0.6)	**.000**	16.7 (1.5)	14.2 (1.2)	**.001**
SMM (kg)	20.6 (1.6)	17.3 (2.3)	**.001**	22.0 (2.3)	16.5 (1.8)	**.000**	21.0 (2.0)	16.7 (1.3)	**.000**	20.8 (2.5)	16.6 (1.2)	**.001**
SMMI (kg/m²)	8.3 (0.5)	7.2 (0.6)	**.001**	8.9 (0.9)	7.1 (0.5)	**.000**	8.8 (0.6)	7.6 (0.3)	**.000**	9.0 (0.9)	7.4 (0.7)	**.000**
ALM (RA, kg)	1.8 (0.2)	1.4 (0.2)	**.000**	2.0 (0.3)	1.4 (0.2)	**.000**	2.0 (0.3)	1.5 (0.2)	**.000**	2.0 (0.3)	1.6 (0.2)	**.001**
ALM (LA, kg)	1.8 (0.2)	1.3 (0.2)	**.000**	1.9 (0.3)	1.3 (0.2)	**.000**	2.0 (0.3)	1.5 (0.2)	**.000**	2.0 (0.3)	1.6 (0.3)	**.002**
ALM (RL, kg)	5.8 (0.5)	4.9 (0.9)	**.011**	6.4 (1.4)	4.7 (0.8)	**.002**	5.7 (0.7)	4.3 (0.6)	**.000**	5.7 (0.8)	4.3 (0.5)	**.001**
ALM (LL, kg)	5.8 (0.5)	4.8 (0.9)	**.007**	6.2 (1.0)	4.7 (0.7)	**.000**	5.8 (0.7)	4.4 (0.6)	**.000**	5.6 (0.8)	4.3 (0.6)	**.001**
BMR	1194.2 (56.1)	1081.2 (84.5)	**.002**	1245.8 (82.5)	1055.2 (58.4)	**.000**	1214.0 (72.4)	1063.2 (50.7)	**.000**	1204.6 (89.0)	1057.8 (43.2)	**.001**
TRUNK MM (kg)	16.8 (1.1)	14.1 (1.5)	**.000**	17.8 (1.6)	14.1 (1.5)	**.000**	17.9 (1.7)	14.5 (1.3)	**.000**	18.1 (1.8)	15.3 (1.3)	**.001**
TRUNK FP (%)	28.4 (4.3)	26.9 (5.1)	.490	36.8 (2.5)	35.9 (1.6)	.339	43.4 (1.4)	43.3 (2.2)	.930	48.6 (2.0)	47.6 (1.9)	.328

ASMI: appendicular skeletal muscle mass index; BMI: body mass index; WC: waist circumference; BFM: body fat mass; FFM: fat-free mass; FFMI: fat-free mass index; SMM: skeletal mass index; SMMI: skeletal muscle mass index; ALM: appendicular lean mass; RA: right arm; LA: left arm; RL: right leg; LL: left leg; BMR: basal metabolic rate; MM: muscle mass; FP: fat percent. Data are expressed as mean (standard deviation) or frequency (n) and percent (%) based on Gallagher's classification of body fat percentage for elderly (16): [1] analysed using Independent Sample t-test, significant at $p < 0.05$.

DISCUSSION

This investigation explored the associations among muscle mass, muscle strength, and body fat percentage in postmenopausal women. Our sample comprised 134 community-dwelling postmenopausal women aged 45-88 years, enlisted from diverse locations in the Semenyih and Klang Valley regions of Kuala Lumpur, Malaysia. We employed a multi-segmental bio-electrical impedance analyzer to assess body composition, including body fat percentage (BFP) and appendicular skeletal muscle mass (ASM), while grip strength was evaluated using handgrip strength dynamometry. Our percentage categories (**table I**). A significant positive correlation between skeletal muscle mass and body fat percentage was found (**figure 1**, $r = 0.36$, $p < 0.001$), suggesting an increase in skeletal muscle mass as body fat percentage increased. Linear regression analyses revealed a significant positive association between muscle strength and appendicular skeletal muscle mass index (ASMI), with the inclusion of BFP slightly enhancing the model's predictive ability for muscle strength ($R2 = 0.195$, $p < 0.001$) (**table II**). Examining the relationship between muscle strength and muscle mass based on obesity classifications, muscle mass emerged as a significant predictor of muscle strength in low-obese participants, but the predictive power decreased with higher levels of obesity ($R2 = 0.572$, $p = 0.000 > R2 = 0.207$, $p = 0.022 > R2 = 0.183$, $p = 0.006 > R2 = 0.129$, $p = 0.025$) (**table III**).

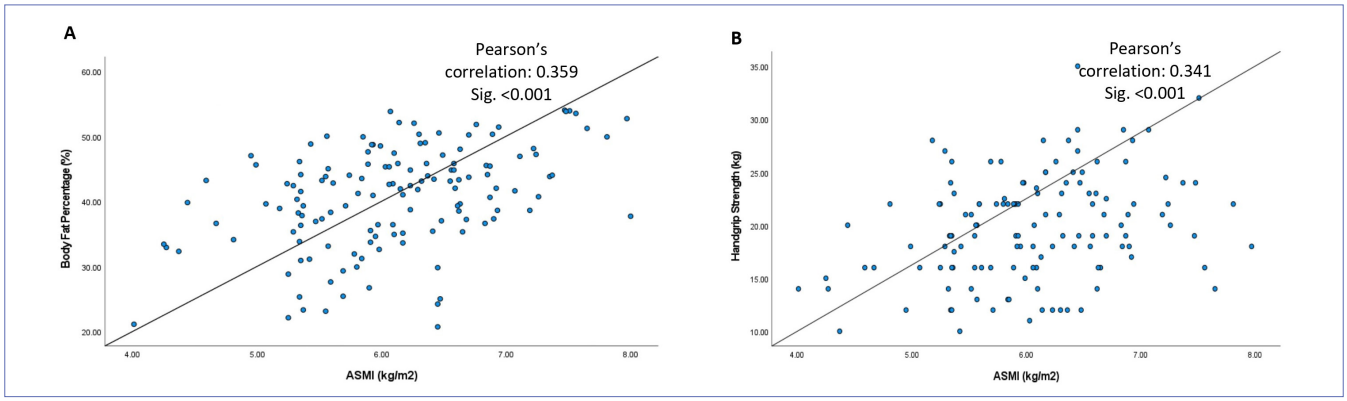

Figure 1. (A) Association between body fat percentage and muscle mass in postmenopausal Malaysian women; **(B)** Association between muscle strength and muscle mass in postmenopausal Malaysian women (n = 134).

Table II. Results of the multiple linear regression analysis examining the correlation between muscle mass, body fat percentage and muscle strength in postmenopausal women.

Model	Coefficient (B)	Standard error B	95%CI for B	Standardised β	R2	P-value*
Model 1					0.116	< 0.001
Constant	7.986	2.893	2.262, 13.710			
ASMI (kg/m²)	1.951	0.471	1.020, 2.883	0.341		
Model 2					0.195	< 0.001
Constant	11.931	2.984	6.028, 17.833			
ASMI (kg/m²)	2.569	0.483	1.614, 3.525	0.448		
BFP (%)	-0.191	0.053	-0.297, -0.085	-0.301		

ASMI: appendicular skeletal muscle mass index; BFP: body fat percentage; regression equation Model 1: muscle strength = 7.986 + 1.951 × (ASMI); regression equation Model 2: muscle strength = 11.931 + 2.569 × (ASMI) - 0.19 × (BFP). Dependent variable: muscle strength; *significant at p < 0.001.

Table III. Results of the multiple linear regression analysis investigating the impact of obesity on the correlation between muscle strength and muscle mass in older women.

Obesity categories	Model	Coefficient (B)	Standard error B	95% CI for B	Standardised β	R2	P-value*
Low	Constant	-17.458	7.506	-33.115, -1.801	0.756	0.572	0.000
	ASMI (kg/m²)	6.928	1.341	4.130, 9.726			
Moderate	Constant	9.517	4.370	0.477, 18.556	0.455	0.207	0.022
	ASMI (kg/m²)	1.745	0.713	0.270, 3.219			
High	Constant	2.609	5.998	-9.533, 14.752	0.428	0.183	0.006
	ASMI (kg/m²)	2.875	0.985	0.880, 4.869			
Very high	Constant	4.908	5.985	-7.219, 17.035	0.359	0.129	0.025
	ASMI (kg/m²)	2.157	0.922	0.290, 4.025			

ASMI: appendicular skeletal muscle mass index; dependent variable: muscle strength; *significant at p < 0.01.

results unveiled a positive correlation between ASMI and BFP (**table I** and **figure 1**), denoting that elevated body fat levels corresponded to increased muscle mass in older adults. Additionally, a positive correlation between muscle strength and ASMI was observed (t**able II**), signifying that greater muscle mass was linked to improved muscle strength in the study population. However, further analyses revealed that the relationship between muscle mass and muscle strength was impacted by participants' obesity levels. Specifically, muscle mass surfaced as a significant predictor of muscle

strength in low-obese participants, but its predictive power waned with escalating obesity levels (**table III**). Therefore, body fat percentage should be factored in when scrutinizing the relationship between muscle mass and muscle strength in older adults. The intricate relationship between muscle mass and fat mass in older adults poses a paradox, necessitating additional research for a deeper comprehension of its implications on the health and well-being of this demographic.

Lean and mean: the paradox of muscle and fat in older adults

Muscle mass is a crucial determinant of physical strength and metabolic health, playing an essential role in fostering overall health and wellness (19). As body mass increases, the body may respond by augmenting muscle mass to counterbalance the added load (2). This compensatory process is often observed in individuals engaging in regular physical activity or resistance training, as the heightened mechanical stress on muscles can stimulate muscle hypertrophy and growth. Muscle mass is typically evaluated using two parameters: fat-free mass (FFM) and lean mass. FFM is calculated chemically by summing all non-lipid components of the body, encompassing non-fat elements of adipose tissue, such as essential and non-essential tissues like muscles, organs, bones, and other connective tissues. Conversely, lean mass is anatomically defined as the total of all non-adipose tissues, incorporating necessary lipids found in cell membranes or the central nervous system. In body composition assessment, lean mass is often employed to quantify the amount of skeletal muscle mass in the body (2). Some researchers utilize a more specific definition of lean mass known as fat-free soft tissue mass (2). It includes the entire body mass, excluding bone mineral mass and fat mass. Various techniques, such as DXA, are used to measure this, considered one of the most reliable and accurate methods of body composition assessment. Moreover, if fat-free soft tissue mass is derived from the arms and legs, it can provide a more precise estimate of skeletal muscle mass than FFM (2). To account for variations in body size, fat-free mass (FFM) is often normalized using different methods. One approach is to express FFM as a percentage of total body weight, known as %FFM. Alternatively, FFM can be divided by height squared to obtain the fat-free mass index (FFMI), expressed in kg/m^2 units. FFMI is calculated by dividing FFM in kilograms by the square of height in meters. This index enables comparison of FFM between individuals with differing body sizes, as it considers the impact of height on FFM (20). FFM is a complex compartment comprising various structures, such as skeletal muscle mass, organ mass, and portions of connective tissue. Nevertheless, in the context of sarcopenia, the primary focus is on skeletal muscle mass. Sarcopenia, a condition typified by loss of muscle mass and strength with aging, is of particular interest to researchers studying FFM (7). However, using the fat-free mass index (FFMI) as a measure of skeletal muscle mass has limitations warranting consideration. One such limitation is demonstrated by Swiss reference data, which reveal that FFM increases with advancing age, while FFMI remains relatively constant across age groups (21). This implies that using FFMI as a proxy for skeletal muscle mass may not accurately represent age-related changes in muscle mass. The decline in muscle mass with age may be counterbalanced by an increase in connective tissue, a component of FFM, leading to a false sense of stability in FFMI. In their study, Baumgartner *et al*. (22) employed dual-energy x-ray absorptiometry (DXA) to measure the lean or fat-free soft tissue mass of the four limbs, which was then summed to determine appendicular skeletal muscle mass (ASM). To provide a more precise measure of muscle mass, a skeletal muscle index (SMI) was defined as appendicular skeletal muscle mass divided by height squared (kg/m^2, ASMI). This is particularly crucial when considering that bone density can vary due to factors such as age, ethnicity, and medication use. However, it is essential to note that ASMI also has limitations, particularly with increasing age or advancing body fat mass. A comparison of regional lean mass measured by DXA with skeletal muscle mass assessed by magnetic resonance imaging (MRI) demonstrated that the contribution of skeletal muscle to appendicular lean soft tissue decreases as adiposity increases, especially in women who tend to store more adipose tissue at the extremities (limbs) compared to men who store more adipose tissue at the trunk with increasing fat-free mass index (FMI) (2, 23). Consequently, as adiposity rises, and potentially as age increases, the augmentation of connective tissue could obscure a reduction in skeletal muscle mass, despite no change in total lean soft tissue or FFM (2). It is important to note that when individuals experience weight gain, it typically consists of both fat and lean mass. Therefore, overweight and obese individuals are expected to have a higher fat-free mass index (FFMI) or skeletal muscle index (SMI) compared to individuals of normal weight (6). In fact, studies have shown that individuals with higher levels of body fat percentage may have higher levels of muscle mass due to the anabolic effects of adipose tissue on muscle tissue (5). Therefore, relying solely on normal values of lean mass as a basis for diagnosing lean mass deficiency may potentially result in an underestimation of sarcopenia in overweight and obese individuals.

Fat or Fit Paradox

Obesity is a critical global health issue and is linked to various health conditions such as diabetes, cardiovascular disease, and specific cancer types (10). While it is well-es-

tablished that obese individuals tend to have higher body fat mass, it is also noteworthy that they have higher levels of muscle mass than non-obese individuals (5). This phenomenon is often referred to as the "fat or fit paradox", in which higher muscle mass in obese individuals is paradoxical to the expected outcome. In this part of the discussion, we will explore the mechanisms underlying the relationship between obesity and muscle mass and why the amount of muscle mass in obese individuals may not be sufficient for their needs.

Several factors contribute to the higher muscle mass observed in obese individuals. Firstly, the increased mechanical load due to carrying excess body weight leads to an adaptive response in the muscles, resulting in hypertrophy (24). Additionally, insulin resistance in obesity (hyperinsulinemia) leads to anabolic stimuli that promote muscle protein synthesis, thereby increasing muscle mass (25). Furthermore, inflammation and oxidative stress (at appropriate concentrations of reactive oxygen species) associated with obesity may also stimulate muscle protein synthesis, leading to higher muscle mass (myogenesis) (26). Despite the increased muscle mass, obese individuals often suffer from functional limitations and reduced muscle performance (hence, the paradox). The higher body weight in obese individuals poses an extra burden on their muscles, which can lead to fatigue and reduced endurance. This phenomenon is known as the "muscle quality" concept, in which muscle mass does not necessarily reflect muscle function. It is essential to note that muscle size and strength are not always synonymous. Obese individuals may have intramuscular fat and connective tissue that may hinder efficient muscle contraction and, consequently, reduce muscle function and performance (27). Furthermore, the quality of the muscle in obese individuals may be compromised due to extreme chronic low-grade inflammation and oxidative stress, which may contribute to muscle dysfunction (26). The intramuscular fat deposition in obese individuals is also associated with muscle insulin resistance and impaired glucose metabolism, further reducing muscle function (27). This evidence supports the fact that high muscle mass in obese individuals does not necessarily translate to better muscle function and performance. The present study provides support for the notion that muscle strength is decreased in obese individuals (**table III**). The results indicate that in low-obese individuals, muscle mass was a significant predictor of muscle strength. However, as the degree of obesity increased, the predictive power of muscle mass on muscle strength decreased. The observed relative weakness may be attributed to a variety of factors, including reduced mobility, neural adaptations, and alterations in muscle morphology. Furthermore, excessive body fat percentage may also be related. Excessive body fat percentage has been implicated in the decline of muscle quality (28), as the presence of fat within the muscle fibers can hinder their contractile capacity. This can lead to a reduction in muscle strength, even in individuals with a high amount of muscle mass. Previous research by Goodpaster and colleagues (29) has shown that higher levels of intramuscular lipid content are associated with lower muscle strength, even after accounting for muscle mass. This suggests that intramuscular lipid content may play a role in the development of muscle weakness and even sarcopenia in individuals with obesity. This is also particularly relevant in the context of aging and obesity, as both conditions are associated with an increase in intramuscular fat content.

Dynapenic obesity: the hidden link between muscle weakness and excess weight

The term "dynapenic obesity" has been introduced to describe a subset of obese individuals who exhibit reduced muscle strength and increased adiposity (30). In this context, it has been hypothesized that the energy expenditure and muscle force required for performing the same physical tasks are higher in obese individuals, ultimately leading to a reduced capacity to perform physical activities and an increased risk of developing disability. This suggests that at higher levels of adiposity, a given amount of muscle mass may confer lower functional capacity compared to individuals with lower levels of body fat (2). The negative impact of excessive body fat on muscle quality is thought to be mediated by several factors, including the disruption of intracellular signaling pathways and mitochondrial dysfunction (31). Consequently, this can result in muscle fiber atrophy and reduced force production, which can contribute to the development of functional limitations and disability in affected individuals.

Implications for the health and well-being of older adults

The paradoxical relationship between skeletal muscle mass and body fat percentage in older adults has significant implications for their health and well-being. Low muscle strength is a prevalent risk factor for falls and falls are a leading cause of morbidity and mortality among older adults (32). In addition, decreased muscle strength and mass are associated with functional limitations, disability, and poor quality of life in older adults (32). Increased body fat percentage is also associated with a range of health problems, including metabolic disorders, cardiovascular disease, and some types of cancer (33). Therefore, it is essential to accurately assess both muscle mass and body fat percentage in older adults to identify individuals at risk of falls and functional limitations and to develop effective interventions to address

these problems. The paradoxical connection between skeletal muscle mass and body fat percentage in older adults is a complex and multifaceted issue. While there is a growing body of research on this topic, more research is needed to fully understand the relationship between these two factors and their implications for the health and well-being of older adults. It is essential to accurately assess both muscle mass and body fat percentage in older adults to identify individuals at risk of falls and functional limitations and to develop effective interventions to address these problems.

CONCLUSIONS

The current study's findings add to the growing body of literature suggesting a positive association between skeletal muscle mass and body fat percentage in older adults. However, the observation of a positive correlation between skeletal muscle mass and body fat percentage warrants a contextual understanding of the functional implications, given that the augmentation of muscle mass may not necessarily translate into enhanced muscular strength. Due to the tendency for obese older adults to exhibit a decline in relative muscle mass rather than absolute muscle mass, the diagnosis of sarcopenia in this population should depends on alterations in muscle quality and/or relative levels of skeletal muscle mass, rather than absolute measurements. Further elucidation of this complex relationship may contribute to the development of targeted interventions aimed at improving both muscle mass and function. Moreover, there is a need for a more nuanced understanding of the relationship between these variables and their impact on health and fitness in later life. The positive relationship between skeletal muscle mass and body fat percentage suggests that gaining in body fat percentage may also lead to an increase in muscle mass. However, quantity does not equal quality. The presence of fat within the muscle fibers can impair the muscle's ability to contract effectively which may impair and negatively affect the muscle strength. In older adults, when examining the connections between muscle mass and muscle strength, it is important to take into account the body fat percentage. These results also highlight the importance of considering both skeletal muscle mass and body fat percentage when evaluating physical function and health outcomes in older adults. Additionally, future interventions aimed at improving physical function and health in older adults should consider both skeletal muscle mass and body fat percentage in their design and evaluation.

Limitations and strengths

There are some limitations to this study. Firstly, bioelectrical impedance analysis (BIA) was used to measure the body composition. While BIA is a convenient and non-invasive method, it may not be as accurate as the gold standard DXA. Therefore, the findings related to muscle mass and adiposity in this study should be interpreted with caution. The use of DXA would have been preferable to accurately measure muscle mass and body fat. It should also be mentioned that the study only involved postmenopausal women, which limits the generalizability of the findings to other populations. Since the study did not include men or premenopausal women, it is unclear if the same relationships between muscle mass, muscle strength, and adiposity would be observed in other groups. Therefore, caution should be exercised when attempting to apply these results to populations outside of postmenopausal women. Nevertheless, postmenopausal women are one subpopulation where the current classification based on BMI may not accurately reflect the health risks associated with excess adiposity (34). Therefore, they are the most in need for this type of study in order to accurately measure their health risk. Despite these limitations, this study boasts several strengths that bolster its contributions to gerontological research. Firstly, it addresses the intriguing Fat or Fit Paradox, delving into the complex relationship between muscle mass and adiposity in older adults, with a particular focus on postmenopausal women - a vulnerable population experiencing hormonal changes and increased health risks. The findings of this research offer valuable insights into the unique challenges faced by this demographic and enable the development of targeted interventions for maintaining and improving overall health and well-being. Furthermore, by identifying the factors that influence muscle mass and strength across different obesity levels, our study guides the design of tailored exercise, nutrition, and lifestyle programs, ultimately contributing to the enhancement of gerontological knowledge. Lastly, this investigation emphasizes the importance of appraising both muscle mass and adiposity in evaluating the health and fitness of older individuals, promoting the broader goal of healthy aging - an increasingly critical objective in the context of global population aging.

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DATA AVAILABILITY

The data are openly available in FigShare at https://doi.org/10.6084/m9.figshare.13786684.v1.

CONTRIBUTIONS

N.Z.A. entirely contributed to this work.

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CONFLICT OF INTERESTS

The author declares that she has no conflict of interests.

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REVIEW

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Whole-Body Vibration to Enhance Skeletal Muscle Performance and Flexibility in Healthy Adults: A Narrative Review

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LEVEL OF EVIDENCE: N/A

SUMMARY

Background. Flexibility and muscular performance assist in maintaining posture, encourage effective movement, prevent improper body alignment, maintain proper muscle length and balance, and also lower the chance of injury. The neuromuscular training technique known as whole-body vibration (WBV) has recently gained favor in health and fitness facilities. WBV has long been utilized as a non-invasive, physical therapy aid in rehabilitation, to improve muscle performance (strength, power, and endurance), encourage bone formation, and decrease the risk of injury.

Objective. The possibility of WBV exercise as a helpful and secure strategy for enhancing muscular performance and flexibility was therefore examined in the current review.

Methods. The current narrative review used a search strategy and conducted a literature search in January 2023, retrieving data from the following databases: Web of Science, PubMed, Scopus, and Google Scholar.

Results. Recommendations on how to increase muscle performance and flexibility, lower the chance of injury, and generally improve the overall quality of life are provided by the majority of the selected literature.

Conclusions. The usage of this paradigm in practice increases muscle performance and flexibility in both healthy adult athletic and non-athletic subjects is proposed.

KEY WORDS

Muscle performance; flexibility; whole body vibration training; risk of injury; healthy adult subject.

INTRODUCTION

The human body is subjected to whole-body vibration (WBV) through a variety of daily activities, such as operating industrial machinery, flying in airplanes, and driving cars. Ergonomists have previously pointed out the negative impacts of WBV on the human body (1, 2). However, in the last few decades, vibratory massagers have become more widely employed in massage therapy and in training sessions to improve muscle performance (3-6). In addition to or instead of conventional training and therapy, WBV exposure is a neuromuscular training technique that can be used in addition to or instead of conventional training and therapy. It has lately gained popularity in the healthcare sector, local gyms, and fitness and rehabilitation facilities (7-11). This is because WBV intervention has been shown to increase muscle power and strength in both athletic and non-athletic individuals (11-14), improves flexibility (15, 16), and provide additional medical benefits such as for COVID-19 patients (17, 18). A vibrating platform exposes a person's body to low frequency, low amplitude mechanical stimulation during WBV. According to the tonic vibration reflex (TVR), the vibration stimulates the muscle spindles and transmits nerve signals to begin muscular contractions (19).

Either a vibrating hand-grip device (Hand Arm Vibration) or a vibrating platform on which the subject is required to sit or stand (Whole-Body Vibration) can be used to undertake vibration training. The two prima-

ry categories of vibrating platforms are platforms that vibrate in a vertical direction (vertical platform) and platforms that vibrate by rotating in a horizontal direction (oscillating platform) (20, 21). There are primarily two ways to apply vibration to the targeted muscles: directly or indirectly. Vibration can be applied directly to the participant's tendon or the belly of the muscle when using the direct technique of application through vibrating units such as a vibrating pully or dumbbell (22). While in the indirect technique of application, vibration is applied to the subject's muscles from a vibrating source that is located far from the muscles being targeted (23, 24). Researchers' interest in WBV therapy as a means of managing patients with musculoskeletal conditions has recently been renewed, but the usefulness of short-term WBV training in improving lower-limb muscle strength, power, bone mineral density, and functional capacity, as well as in preventing falling in the healthy adult subjects is limited in the literature (25, 26). For improving balance and strength and preventing falls, WBV training has been shown to be more effective than balance training alone when combined with a supplementary exercise program (27, 28). Moreover, with the aid of sEMG recordings, multiple investigations have shown that applying (WBV) intervention acutely enhances muscle activity during exposure (29-31). Even though previous research has shown that WBV has positive effects on improving muscle performance and flexibility in the general population, the current review sought to determine whether WBV exercise has the potential to be a helpful and safe intervention for enhancing muscle performance (strength, power, and endurance) and flexibility in healthy adult subjects (athletes and non-athletes) in order to reduce the risk of injury and improve the overall quality of life.

MATERIALS AND METHODS

Search strategy

The protocol used for the literature search for the current narrative review was as follows:

- Potential effects of the WBV exercises on skeletal muscle performance (strength, power, and endurance) in healthy adult athletes and non-athletes.
- Potential effects of the WBV exercises on skeletal muscle flexibility in healthy adult athletes and non-athletes.

Literature search

The sources indicated in **table I** were used to compile the information required to produce this narrative literature.

Potential effects of the WBV exercises on skeletal muscle performance (strength, power, and endurance) in healthy adult athletes and non-athletes

Strength, power, and endurance are the three main components of muscle performance, which is the ability of muscles to accomplish work. The ability of a muscle or muscle group to exert force to overcome the greatest amount of resistance in a single effort is known as muscular strength. Work performed per unit of time is referred to as power. The capacity of a muscle or muscle group to exert force repeatedly to overcome resistance is known as muscular endurance (32). The foundation of vibration training is the capacity to increase muscle strength. Previous research demonstrated that the WBV technique is constantly evolving and improved up on. It can be used to improve the amount of force that a muscle group can exert to overcome resistance in healthy adults (33). As shown in **table II**, a study conducted by Osawa *et al.* (34), showed that body weight vibration exercise did not significantly improve

Table I. The sources consulted to create this narrative literature.

Sources
□ Google Scholar search 1968-2023. Keywords: Muscle Performance, Flexibility, Whole body vibration Training, Healthy adult subjects, Athletes, Non-athletes
□ PubMed search 1970-2023. Keywords: Muscle Performance, Flexibility, Whole body vibration Training, Narrative review, Healthy adult subjects
□ Web of Science search 2019-2023. Keywords: Muscle Performance, Flexibility, Whole body vibration Training, Healthy adult subjects
□ Scopus search 2019-2023. Keywords: Muscle Performance, Flexibility, Whole body vibration Training, Healthy adult subjects
□ Hand searches of the obtained literature's references
□ Examining books and research articles on vibration effect on muscle performance and flexibility in personal and academic libraries
□ Discussions with professionals in the fields of physical therapy and rehabilitation

muscular performance in healthy untrained young individuals after 12 weeks of exercise. This may return to the shorter time of exposure, which might have provided insufficient load and stimulation to have an impact on the lower extremity muscles' strength and endurance. On the other hand, Osawa and Oguma (35) found that adding WBV to a slow-velocity resistive training program during the first stage of regular resistive training in untrained healthy adults resulted in a significant additional increase in maximal isometric and concentric knee extension and lumbar extension strength. In addition, a study conducted on recreationally active young adults showed that 8 weeks of combined WBV and resistance training did not result in a greater improvement in muscular performance than a similar exercise regimen without vibration. Also, there was no effect on isokinetic strength or muscle power. The authors reported that the displacements produced by the vibrating platform were 2.5 and 5 mm, and frequencies at 35-40 Hz were only used during the latter two weeks of the intervention. Lack of assessment-exercise specificity may make it more difficult to spot significant changes, particularly when training time is short and with only a few subjects in each group (36).

Furthermore, a study on young, healthy, active men shows that a WBV intervention involving six sets of 60 seconds each resulted in better muscular performance as detected by squat jump, countermovement jump, and power output (37). A review article by Alam *et al.* in 2018 found that WBV improve muscle strength, power, and flexibility (38). Range of amplitude and frequency, type of vibration and application method, training intensity, exercise regimen, and participant characteristics are the primary variables linked to an improvement in muscle performance. Besides, a study was conducted on recreationally active students to detect the effects of varying foot-based vibration intensities on the number of repetitions completed, the mean speed, and the perceived effort during a set of elbow-extension exercises. The results of this study indicate that upper body resistance training can be enhanced by applying vibrating stimulation to the feet (39). Additionally, a study on young competitive artistic gymnasts found that a single bout of WBV training using various execution methods for three exercises with a total duration of 2 minutes improved lower limb flexibility and explosive strength and maintained the initial level of performance for at least 15 minutes after the WBV intervention program (40). A study on sub-elite male volleyball and beach volleyball players found that adding 6-week WBV training to regular practice increases leg strength and improves jump performance more than traditional strength training (41). In addition, a study that included high-level rhythmic female gymnasts found that single bout whole body vibration was superior to an equivalent exercise program performed without vibration

Table II. Intervention parameters in the included studies that enhance muscle performance.

Author	Participants (number, age)	Category	Study design	Frequency (Hz)	Amplitude (mm)	Vibration type/device	Position of exercise	Intervention Protocol	Footwear	Effect of vibration
Osawa *et al.*, 2011(34)	19 untrained healthy males and females (11 females, 8 males, 21-39 years old)	Untrained healthy men and women	A randomized controlled trial design	30, 35, 40	2	Whole platform-oscillating device (Power Plate® Next Generation, Power Plate International, Northbrook, IL, USA)	4 lower extremities and 4 trunk exercises	12-week WBV, 2-3 sets, twice weekly for 30 sec/set, with rest periods of 60 sec (total time of vibration 6.5 minutes)	No shoes, with socks	No significant effect
Osawa and Oguma, 2011 (35)	33 untrained healthy males and females (6 males (M) and 27 females (F), 22-49 years old)	Untrained healthy males and females	A randomized controlled trial design	35	2	Power Plate® Next Generation, Power Plate International, Northbrook, IL, USA	8 lower extremities, hip, and trunk exercise positioning	The training procedure involved two lower extremities (squats) and six trunk exercises containing 4 sec for concentric and 2 sec without relaxing period followed by 4 sec for eccentric in the cadence. The roll-back and hip walking exercises, 64 and 48 sec without any isometric exercise phase, respectively.	No shoes, with socks	Significant effect

Author	Participants (number, age)	Category	Study design	Frequency (Hz)	Amplitude (mm)	Vibration type/device	Position of exercise	Intervention Protocol	Footwear	Effect of vibration
Artero *et al.*, 2012 (36)	A group of 29 young adults (25 men, 4 women; age 21.8 ± 1.5)	Recreationally active young adults	Cross-over study	20, 25, 30, 35, 40	2.5, 5	A synchronous vibration (also called vertical) vibrating platform (Fitvibe Excel; N.V. GymnaUniphy, Bilzen, Belgium)	Standing position with half-squat exercises	8 weeks at a frequency of two times per week, with at least 1 day of rest period between sessions. Each training period lasted 35-40 min	Gymnastic shoes	No significant effect
Da Silva-Grigoletto *et al.*, 2011 (37)	Total number 57, age: 19.4 ± 1.6 years	Young, healthy physically active men	Randomized Trial	30	4	Vibrating platform producing sinusoidal oscillations (Nemes, Ergotest, Rome, Italy)	Isometric squat position	In phase 1, 3 sets of various durations (30, 60, and 90 seconds), whereas in phase 2, subjects experienced 3 interventions where the duration remained fixed at 60 seconds, and the number of sets achieved (3, 6 or 9) was modified. The recovery time among sets was set at 2 minutes	Sport shoes	Significant effect
Marín *et al.*, 2010 (39)	Total number 20 (14 men and 6 women), age 18.9 ± 0.8 years	Recreationally active students	Not mentioned	50 30	2.41 1.15	Uniform vertical oscillations Power Plate® Next Generation (Power Plate North America, Northbrook, IL, USA)	Squat position (30° knee flexion)	5 weeks with 1 testing session each week (a) High magnitude (HM) of vibration stimuli, the elbow-extension set was completed with overlaid vibration at 50 Hz and peak-to-peak vibration amplitude 2.41 mm; (b) low magnitude (LM) of vibration stimuli, the elbow-extension set was achieved with overlaid vibration at 30 Hz and peak-to-peak vibration amplitude 1.15 mm (LM)	Athletic shoes	Significant effect
Dallas *et al.*, (2014) (40)	Total number 32 (15 males and 19 Females), age 9.22 ±1.34 years	Young competitive artistic gymnasts	Randomized study	30	2	Vertical sinusoidal mechanical WBV (Power Plate North America, Northbrook, Illinois)	Standing position	A single session of WBV training using various execution forms of three exercises of total time 2 min. Training load on the vibration platform was as follows: two sets of 30 s for the 1st exercise and one set of 30 s for the 2nd and 3rd exercises with a rest of 30 s, to provide a suitable time for relaxation	Gymnastics shoes	Significant effect

Author	Participants (number, age)	Category	Study design	Frequency (Hz)	Amplitude (mm)	Vibration type/device	Position of exercise	Intervention Protocol	Footwear	Effect of vibration
Pérez-Turpin *et al.*, 2014 (41)	Total number 23 (12 male volleyball and 11 beach volleyball players)	Sub-elite male volleyball and beach volleyball	Randomized study	30-40	1.7-2.5	Vibration platform (Power Plate®, Power Plate International Ltd., London, UK)	Standing, squat, one-leg squat	The WBV training technique involved performing 4 sets × 30-second spurts of each exercise with WBV with a 2 minutes recovery after each repeat, 3 days a week, for 3 weeks. For the following 3 weeks, the duration of repetition was increased to 60 seconds	Not mentioned	Significant effect
Despina *et al.*, 2014 (42)	Total number 11, age 17.54 ± 0.52 years	Elite female rhythmic gymnasts	Cross-sectional study	30	2	Side-to-side alternating vertical sinusoidal mechanical vibration Galileo 900 platform (Galileo Fitness, Novotec, Germany)	Standing	The participants were exposed to WBV training using different implementation forms of five exercises each one lasting for 15 s for a total time of 75 s	Gymnastics shoes	Significant effect
Rønnestad *et al.*, 2012 (43)	Total number 12, age 24 ± 5 years	National-level, drug-free, male powerlifters	Randomized study	50	3	Vibration platform synchronously produced the vibration stimulus (Pneu-Vibe Pro, Pneumex, Inc. Sandpoint, ID, USA)	Standing in an erect position with the external load on their shoulders then squat	An acute bout of vibration was exchanged immediately after the participants were standing in an erect position with the external load on their shoulders (65 kg-100 kg)	Hard heel weightlifting shoes	Significant effect
Annino *et al.*, 2017 (44)	Total number 20, age 24.8±2.5 years	Young college male students	Randomized study	35	5	Vertical sinusoidal WBV (Nemes LC; Boscosystem, Rieti, Italy)	Stood on the vibration platform in half squat position	The vibration protocol consisted of 2 sets of five 60-second repetitions separated by 60seconds of passive recovery with resting periods between sets of 5minutes (10minutes of WBV, 25minutes all session)	Not mentioned	Significant effect

in terms of the short-term effect on performance in flexibility, strength, and a number of balance tests (42). Moreover, in a study applied to national-level, drug-free, male powerlifters, the findings of this study imply that in well-trained people, such as powerlifters, the administration of WBV50Hz acutely boosts peak power production during squat jump. This increase in power was followed by a rise in the quadriceps muscles' EMG activity (43). According to a study conducted on young male college students, 10 minutes of WBV had an impact on their flexibility and explosive strength performance by inhibiting antagonist muscles more than agonist muscles, which are involved in the stretch reflex (44).

Potential effects of the WBV exercises on skeletal muscle flexibility in healthy adult athletes and non-athletes

Aging-related changes in tendons and ligaments, as well as sedentary lifestyles, limit joint mobility and reduce flexibility. At least one expert recommends the regular practice of flexibility activities like yoga and stretching. To increase the range of motion of a joint, vibration, transcutaneous electrical nerve stimulation, and heated packs are frequently used as exogenous stimulation to skeletal muscles or tendons around the joint (45). The essential mechanism of vibration in enhancing muscle flexibility is presynaptic inhibition of group Ia afferent fibers or a "busy line" phenomenon that is formed when vibration stimulation and stretching influence the same Ia pathways. Additionally, combining a strong stretch stimulus with vibration may activate the Golgi tendon organ through Ib pathways, inhibiting the vibrated muscle's autogenic response (46 ,47).

Only a small number of experiments have addressed the use of mechanical vibration to increase flexibility (40, 42, 44) These studies have shown that vibration can improve flexibility, but more research is needed to confirm these findings as shown in **table III** and mentioned before in improving muscle performance. Similarly, as included in **table III**, another study detected a significant improvement in flexibility by applying three vibration procedures (VP4, VP6, and VP8) with peak-to-peak vibration amplitudes of 4 mm, 6 mm, and 8 mm and one control protocol (CP) for a total of 6 minutes. In addition, the frequency study included a control protocol (CP) for 6 minutes with a peak-to-peak vibration amplitude of 6 mm as well as three vibration protocols (VP15 Hz, VP20 Hz, and VP30 Hz) at 15 Hz, 20 Hz, and 30 Hz in the same study (48).

Also, the most recent study that investigated the effect of mechanical vibration on flexibility is the literature review conducted by Đorđević *et al.* (49) determined that artistic gymnasts' flexibility has improved as a result of using a WBV platform in both males and females. Additional-

Table III. Intervention parameters in the included studies that enhance muscle flexibility.

Author	Participants (number, age)	Category	Study design	Frequency (Hz)	Amplitude (mm)	Vibration type/device	Position of exercise	Intervention Protocol	Footwear	Effect of vibration
Dallas *et al.*, (2014) (40)	Total number 32 (15 males and 19 Females), age 9.22 ± 1.34 years	Young competitive artisticgymnasts	Randomized study	30	2	Vertical sinusoidal mechanical WBV (Power Plate North America, Northbrook, Illinois)	Standing position	A single session of WBV training using various execution forms of three exercises of total time 2 min. Training load on the vibration platform was as follows: two sets of 30 s for the 1st exercise and one set of 30 s for the 2nd and 3rd exercises with a rest of 30 s, to provide a suitable time for relaxation	Gymnastics shoes	Significant effect

Author	Participants (number, age)	Category	Study design	Frequency (Hz)	Amplitude (mm)	Vibration type/device	Position of exercise	Intervention Protocol	Footwear	Effect of vibration
Despina *et al.*, 2014 (42)	Total number 11, age 17.54 ± 0.52 years	Elite female rhythmic gymnasts	Cross-sectional study	30	2	Side-to-side alternating vertical sinusoidal mechanical vibration Galileo 900 platform (Galileo Fitness, Novotec, Germany)	Standing	The participants were exposed to WBV training using various execution forms of five exercises each one lasting for 15 s for a total time of 75 s	Gymnastics shoes	Significant effect
Annino *et al.*, 2017 (44)	Total number 20, age 24.8±2.5 years	Young college female students	Randomized study	35	5	Vertical sinusoidal WBV (Nemes LC; Boscosystem, Rieti, Italy)	Stood on the vibration platform in half squat position	The vibration procedure consisted of 2 sets of five 60-second repetitions parted by 60seconds of passive recovery with resting periods between sets of 5 minutes (10minutes of WBV, 25 minutes for all session)	Not mentioned	Significan effect
Gerodimos *et al.*, 2010 (48)	Total number 43 (25 in 1st study and 18 in 2nd study), (age: 20.5 ± 1.7 years in 1st study and (age: 20.2 ± 2.0 years in 2nd study)	Healthy and physically active female subjects	Randomized balanced design	25 15, 20, 30	4, 6, 8 6	Side-to-side alternating vertical sinusoidal vibrating platform (Galileo Fitness, Novotec, Germany)	Maintained an upright position with their knees flexed at 170- and their feet in full contact with the platform	The participants in the amplitude study experienced three vibration protocols (VP4, VP6, and VP8) with amplitudes of 4 mm, 6 mm, and 8 mm and one control procedure (CP) for a total of six minutes. The frequency study included a control protocol (CP) for 6 minutes, 6 mm as well as three vibration protocols (VP15 Hz, VP20 Hz, and VP30 Hz) at 15 Hz, 20 Hz, and 30 Hz	Non-slippery socks	Significant effect
Lim and Park, 2019 (51)	Total number 20 (14 Male and 6 Female), aged 20.21 ± 1.01 for the vibration group and 21.72 ± 2.16 with the non-vibration group	College students participated in this study	Randomized control trial	30	Not mentioned	Foam roller with vibration	Sitting on the floor	The application of a foam roller with vibration to the hamstring for 1 min 5 times for a total of 10 min	Not mentioned	Significant effect

Author	Participants (number, age)	Category	Study design	Frequency (Hz)	Amplitude (mm)	Vibration type/device	Position of exercise	Intervention Protocol	Footwear	Effect of vibration
Azizi *et al.*, 2021 (52)	Total number- 56, aged 23.82 ± 3.17 years	Healthy young women	Randomized control trial	30	2	The platform of the Power plate	Standing with bending knees (about 20 degrees) while their legs were open as much as the shoulder width	Each participant was treated in three 30-second sets with 30 seconds of rest between each set. WBV platforms transmit vibrations in two ways. The first type is synchronous, which transmits vibration to both legs simultaneously and applies a straight linear acceleration to the trunk. The second type is side-alternating, which transmits vibrations intermittently, so when the right leg is at the lowest amplitude level, the left one is at the highest	Without shoes and socks	Significant effect

ly, combining typical static stretching with WBV may help artistic gymnasts become more flexible. However, care should be taken when interpreting these findings. Further studies are necessary since this evaluation did not identify the most effective vibrational procedure, and time should be considered to develop several vibrational experimental methods. According to another study, the best acceleration for boosting flexibility was between 5 and 10 g. Although there is a lack of published data on muscle and tendon stiffness, what is known is that accelerations below 6.4 g were the most effective, despite the fact that WBV is normally substantially less successful at building stiffness than at increasing flexibility (50). In a study conducted by Lim and Park (51), on young healthy adults, active straight leg raising and active knee extension tests significantly improved with the use of a vibrating foam roller with a frequency of 32 Hz, and hamstring flexibility also increased. Another study was conducted on healthy young women using WBV with muscle energy technique (MET) to detect their effect on flexibility and hamstring muscle stiffness, the results of this study demonstrated that a single WBV and MET session improved hamstring flexibility and reduced stiffness, although there was little difference in the effectiveness of the two techniques (52).

DISCUSSION

A review study of the available literature has been conducted based on the effects of various WBV applications on the population of healthy adult athletes and non-athletes at various frequencies, intensities, and application methods. Studies on the impact of WBV on the performance of skeletal muscles have highlighted the importance of vibration as a tool for enhancing muscle power, strength, and endurance. Only a small number of studies (2 studies out of 10 chosen studies) revealed a non-significant impact of vibration on muscle performance (34, 36). The lack of load and stimulation at the time of exposure may have prevented any non-significant effects from having an impact on the strength and endurance of the muscles in the lower extremities. Furthermore, when training time is limited and there are few participants in each group, a lack of assessment-exercise specificity may make it more challenging to detect substantial changes.

In the other 8 selected studies (35, 37, 39-44) the significant improvement in muscle performance due to the WBV returned to neural adaptation enhancement during the initial phases of training. Despite the fact that the precise processes are still unknown, the additional gain in knee extension strength seen in the resistive training with WBV group implies that WBV may be a useful workout stimulus for beginners

(35). For exercises involving explosive motions, such as jumping as a warm-up exercise, WBV training is advised. The best dose-response relationship for this approach is still unknown, though. The frequency and peak-to-peak displacement of WBV have been the subject of numerous studies that have concentrated on the short-term effects of WBV on boosting muscle responsiveness. The ideal time frame and quantity of sets for reaching this goal are still unknown. Jumping ability and power performance can be improved by performing 6 sets of 60 seconds each. Coaches may want to consider employing WBV despite the fact that its impact on performance is probably variable and negligible for the majority of athletes due to the potential benefit it may have when the WBV time is optimized (37). In addition, compared to standard strength training, the incorporation of 6-week WBV training into everyday practice by volleyball and beach volleyball players develops more leg strength (41). Furthermore, when compared to the no-WBV condition, introducing acute WBV (50 Hz) during loaded squat jumps causes well-trained participants like powerlifters to produce more peak power through the stimulation of the neuromuscular system during overloaded power exercise (43).

Vibrating stimulus not only affect the performance of lower limbs, but vibration delivered to the foot may enhance upper body resistance workout performance. They also show that higher vibrations generate bigger advancements than lower vibrations. Fitness and exercise practitioners can use a high magnitude of vibration in the lower body to enhance upper body muscle function. Even when certain upper body workouts are not possible with direct vibration exposure, these discoveries can increase the utilization of vibration in the upper body (39).

Additionally, WBV affects not only muscle performance but also ligament, tendon, and muscle flexibility. All of the studies included in the review revealed that WBV has a beneficial effect on muscle flexibility. Athletes with a high degree of lower limb flexibility and explosive strength may see a sharp effect from employing WBV. Additionally, WBV might be useful as a pre-training exercise in gymnastics sports where muscle strength and flexibility are key components. Young artistic gymnasts who trained for 120 seconds using WBV showed larger improvements in lower limb flexibility and explosive strength than those who trained with standard body weight (40). An acute bout of WBV can improve an athlete's flexibility; this improvement in flexibility following WBV suggests that the vibration exposure may have activated the Ia inhibitory interneurons of the antagonist muscle (42, 44, 53). Additionally, under specific circumstances, a single WBV bout may dramatically enhance flexibility, which is maintained for at least 15 minutes. The size of this benefit is independent of frequency and amplitude (48). Also, the hamstring's flexibility and stiffness might both be improved after just one session of WBV and muscular energy technique (MET) (52).

Moreover, a different type of vibration training, like using a foam vibration roller rather than a WBV platform, seems to significantly improve muscular flexibility. Below 20 Hz vibrations create excessive relaxation, above 50 Hz vibrations cause muscle discomfort, and between 20 and 50 Hz vibrations would be therapeutic (51, 54). According to a study, using a vibrating foam roller with a 30-50 Hz vibration improved the hip joint range of motion and pain (55) by boosting muscular strength and increasing the sensitivity of involuntary relaxation caused by the tonic vibration reflex, the muscles' activation appears to promote flexibility. Furthermore, The FRV increased the ankle joint's range of motion and reduced discomfort among university students (56, 57). Also, a study conducted by Mukhtar *et al.* (58) showed that construction industry employees may benefit from vibration treatment. The neuromuscular performance and flexibility, grip power, and grip endurance time may all be improved by this therapy. Additionally, Zazula *et al.*'s basic research study (59) supports the significance of vibration therapy in improving muscular flexibility and malleability.

The studies included in the review used a variety of parameters, including frequency, amplitude, duration, and method of application. Future studies should focus on identifying the optimal parameters for improving muscle performance and flexibility. Additionally, it would be beneficial to have consistency in study protocols and methodology to allow for better comparison of results across different studies.

The acute effects of WBV have been extensively investigated, but there is still a lack of research on the long-term effects. The review found that WBV can improve muscle performance and flexibility in major muscle groups in the upper and lower extremities. However, more research is needed to investigate the effects of WBV on other muscle groups during dynamic activities in athletic and non-athletic population.

CONCLUSIONS

The majority of the studies included in the review indicate that WBV training can improve muscle performance and flexibility in both athletes and nonathletes. This low-cost and safe therapeutic modality can enhance muscle performance, reduce the risk of injury, and improve the overall quality of life by using different frequencies, amplitudes, durations, and methods of application.

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None.

DATA AVAILABILITY

N/A.

CONTRIBUTIONS

MA: writing – original draft, writing – review & editing, studies selection, data analysis, methodology, final approval. AA: writing – review & editing, studies selection, data analysis, results evaluation, final approval.

CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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