ORIGINAL ARTICLE

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Ultrasound Guided Dry Needling for Treatment of Patients with Jumper's Knee: a Study Protocol for Randomized Controlled Trial

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SUMMARY

Background. Jumper's knee, also known as Patellar tendinopathy (PT) is an overuse injury in athletes from various sports especially involving high impact activities. It is degenerative disease, associated with pain and dysfunction in activities that load the patellar tendon. The aim of this study is to find the effects of ultrasound guided dry needling in addition to conventional physical therapy in patients with jumper's knee. Studies addressing role of ultrasound guided dry needling for tendinopathies in prospective randomized method are currently lacking.

Methods. This study is a prospective randomized controlled trial a single blinded study based on SPIRIT guidelines. The measurements will be taken by a blinded assessor. A total of 96 patients with medical diagnosis of Jumper's knee will participate in this study and will be randomly assigned into two groups in 1:1 allocation ratio to either: a) conventional physical therapy and b) dry needling with conventional physical therapy. Functional Outcomes of pain intensity and functional disability at knee joint will be assessed with the Victorian Institute of Sports Assessment for patellar (VISA-P), Knee injury and osteoarthritis outcome score (KOOS scale), Lysholm knee scoring scale and ultrasonographic findings of patellar tendinopathy at baseline, 1st, 2nd and 4th week after baseline.

Discussion. Several cohort and case studies have shown encouraging results using this technique, but randomized control trials are lacking. Therefore, this trial has designed to assess the effectiveness of ultrasound guided dry needling for jumper's knee.

Conclusions. The expected outcomes of this study will help us in finding and promoting the most appropriate treatment protocol of jumper's knee and to prevent the correlated results, such as to avoid the recurrences and decreasing the probable effect on the musculoskeletal system.

Study registration. Iranian registry of clinical trials (IRCT20210409050913N1). Registered on 17 April 2021-prospectively registered: https://www.irct.ir/trial/55607.

KEY WORDS

Athletes; dry needling; Jumper's knee; patellar tendinopathy; tendinosis; ultrasound.

BACKGROUND

Jumper's knee, also known as Patellar tendinopathy (PT) is an overuse injury of patellar tendon that results in anterior knee pain (1) accompanied by central tenderness that can be palpated at the inferior margin of the patella (2, 3). This degenerative disorder has nearly same histological features as of other tendon disorders depicted by an increased tendon thickness and altered vascular and cellular characteristics, associated with incomplete healing of the tendon micro ruptures and interrupted collagen arrangements (4).

The athletes especially involved in high impact sports are mostly affected with this disorder (5). The prevalence of Jumper's knee varies among non-elite players and those involved in high impact sports that stresses patellar tendon more such as volleyball athletes (8.5% and 14.2% respectively) (6). However, this number increases up to 50% and 32% in elite volleyball and basketball players, respectively (7). In addition, it is twice as common among male non-elite athletes as compared to female athletes (8).

The diagnosis of jumper's knee is mainly dependent on clinical history and characteristics outcomes. At present, imaging techniques, such as color Doppler ultrasound (CD-US) and grey scale ultrasound (GS-US) can be used to confirm the clinical diagnosis of patellar tendinopathy (9).

Treatments for Jumper's knee can be categorized into two categories. The first category consists of medical interventions which include non-steroidal anti-inflammatory drugs (NSAIDs), autologous growth factors and platelet-rich plasma (PRP) injection (10, 11), high volume injections at the site between deep patellar tendon surface and Hoffa body improves the symptoms and function in athletes with recalcitrant patellar tendinopathy (12). The second category comprises of conservative and minimally invasive (needling techniques) physical therapy interventions. Conservative treatments such as eccentric exercises (EE) or high slow resistance training programs (gold standards) are usually considered as first line of treatment for patellar tendinopathies (13, 14). Similarly, sub-maximal eccentric training supervised by physical therapist can effectively improve symptoms in patients with chronic patellar tendinopathy following platelet-rich infiltration (15). In recent times, additional evidence assists the effectiveness of exercise more than other conventional treatments for tendinopathy, such as electrotherapeutic modalities of iontophoresis, ultrasound (US) or Cyriax treatment, *etc.* (16, 17). When conservative treatment fails, a small percentage of athletes will develop refractory patellar tendinopathy and need to undergo surgery or sometimes revision surgery and able to return to sports activities at a follow-up of 30 months (18).

Physical therapy treatments for jumper's knee continue to advance and many revolutionary treatment alternatives both minimally invasive and conservative such as dry needling (DN) (19), electrotherapeutic invasive modalities (*e.g.*, electrolysis) (20-22) and extracorporeal shockwave therapy respectively are now available (23). Deep dry needling immediately improves pain, cervical range of motion and pain pressure threshold in patients with myofascial pain syndrome (24). Currently, research has evolved and concentrated on regenerative therapies with high supposition of advancement due to the fact of quick regeneration of the injured tendon (20, 25, 26). However, evidence on such regenerative therapies is inadequate and there is no consensus up till now on most effective treatment of tendinopathy (27).

Sonography has been frequently used for the diagnosis of patellar tendinopathy where focal degeneration appears as hypoechoic tendon swelling with probable raised flow on color and power Doppler imaging; with concurrent interstitial tears reveal as anechoic clefts (1, 28). In addition to sonographic role in the diagnosis of tendon pathologies, it has also been useful to guide minimally invasive and invasive percutaneous treatments of the tendon (29, 30). Dry needling treatment involves needle (solid, fusiform, non-abraded) insertion to provoke a local injury that leads to an inflammatory response (31) and the following healing of the injured tendon in round about 1 week (32, 33).

Inadequate data is available on the advantages of tendon needling as a sole treatment for tendinopathy, although certain case series exist in the literature advocating the procedure as stand-alone treatment for tendinopathies. Hitherto, dry needling work has been done on muscles and trigger points whereas as per our limited knowledge there are very few studies on the role of ultrasound guided dry needling on tendons. Similarly, we are unable to find a single high-quality study on ultrasound guided dry needling for patellar tendinopathy as a stand-alone treatment. This minimally invasive therapeutic modality, along with its pros and cons, is gradually paving its way among different techniques to treat musculoskeletal disorders. As approximated by the valuable information from the current articles in this study, many pending questions await to be resolved about the mechanism of action of dry needling, the optimal treatment protocol, and number of sessions required for the treatment of tendinopathies. Available evidence shows less quality, and a smaller number of randomized trials done, with no comparable groups and methodological deficie - cies of studies. For satisfactory and durable alleviation of symptoms, there is need for differential treatment which can contribute to improve patient's condition. In addition, only few articles describing the application of Ultrasound guided Dry Needling for the recovery of Jumper's knee were found, however, none of them were randomized controlled trials (RCTs), which warrant limited evidence for the efficacy of this technique. Moreover, there are no standardized protocols for the Ultrasound guided dry needling application, which gives great variation in the number of sessions and the time of application in the literature.

Objective

The aim is to compare the outcomes of ultrasound guided dry needling in addition to conventional physical therapy on

patellar tendonitis, tendon thickness, tendon width, fibrillar echo-pattern and echogenicity of patellar tendon in patients with jumper's knee.

METHODS

Participants, interventions, and outcomes

This study and manuscript have been designed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

Trial design

Parallel group, randomized controlled trial a single blinded study.

Study design and study setting

This study is RCT with randomization into two treatment arms: 1) conventional physical therapy alone and 2) dry needling with conventional physical therapy. This study will be conducted in the physical therapy department of University Teaching Hospital, The University of Lahore. The consent will be taken from the eligible patients with jumper's knee and will be randomized and will be followed up for 4 weeks prospectively. The study protocol is approved by Institutional Review Board, The University of Lahore (IRB-UOL-FAHS/829-I/2021). The trial is registered at Iranian registry of clinical trials (IRCT20210409050913N1).

Eligibility criteria

Potential candidates will be selected from sports clubs, physical therapy and orthopedic departments of University of Lahore. Inclusion and exclusion criteria for participation in the study are shown in **table I**. In general, potential inclusion involves all patients with chronic patellar tendinopathy that have a desire to return to pre-injury activities and exclusion involves all concomitant knee joint injuries, tendon pathologies and osteoarthritic joints. A flowchart of the study is shown in **figure 1**. Patients can withdraw their enrollment in this study at any time point, at which their data will be removed.

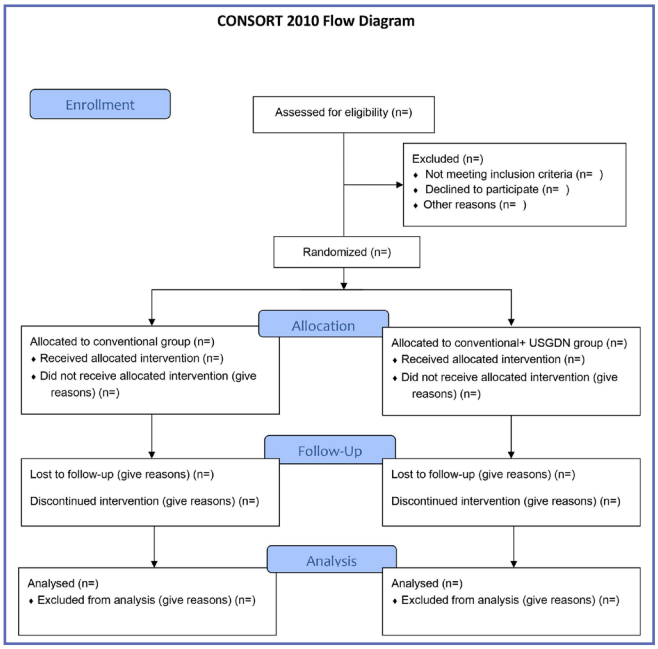

Figure 1. Randomization and data collection.
Data will be completed after RCT conduction.

Table I. Inclusion and exclusion criteria for participating in this trial.

Inclusion criteria	Exclusion criteria
Medical diagnosis of patellar tendinopathy and knee pain on anterior-inferior pole of patella for over 1 month	Surgery around knee joint within last 6 months
Age range 18-45 years	Chronic knee joint diseases
The intensity of pain of 3.0 or greater on visual analog scale (0-10) while ascending and descending stairs and high pain intensity in single leg decline squat test	Injection of corticosteroid in the patellar tendon within the last 3 months
Palpation tenderness of the patellar tendon on superior insertion pole	Relative and absolute contraindications for needling such as allergies, hypersensitivities, presence of implants, acute inflammation, acute systemic infections, on blood thinner or anticoagulants, with known history of bleeding disorders
A score of less than 80 on the Victorian Institute of Sports Assessment for PT (VISA-P) questionnaire.	Calcification within the proximal patellar tendon or radiographic fractures around the knee,
	Use of analgesics for last 48 hours
	Any other concomitant treatment for jumper's knee.

Randomization

The eligible participants will be randomly allocated to either ultrasound guided dry needling with conventional physical therapy group or only conventional physical therapy group. The table of random numbers will be used to generate randomization sequence, with a restricted randomization scheme to make sure equal number of allocations in each group. The data will be entered into computer randomization program immediately after random allocation of all groups.

Participants who will fulfil the inclusion criteria get the written informed consent and after signing it, they will be randomized into two groups.

Participants will be informed about the needling intervention and can be moderately painful, and that if there is unbearable pain during the treatment, they must let the researcher know to stop the treatment immediately. The physical therapist providing the treatments cannot be blinded, however he/she will be asked not to reveal the allocation of the patients during the intervention or follow up sessions.

Interventions

Conventional group

In this group, patients with jumper's knee will be given the conventional physical therapy which include:

- an exercise program consisted of stretching and strengthening of quadricep and hamstring muscles: lunges, seated knee extensions, mini-squats, and lateral steps. The frequency of above exercises was kept at 3 sets of 15 repetitions each, and every repetition starting with the concentric phase, accompanied by the eccentric phase of the exercise;
- physiotherapy modalities included 10 minutes of Heat Therapy by moist hot pack, phonophoresis (pulsed ultrasound) and transverse friction massage;
- the use of knee strap and activity modification

Dry needling + conventional group

In this group, the patients will be treated with conventional physical therapy and in addition with ultrasound guided dry needling. The patients will be positioned in supine or sitting with knee flexed at approximately 20° and pillow will be placed under the knee for patient's comfort. The treatment area of knee will be disinfected with an antiseptic solution (70% isopropyl alcohol) and an ultrasound probe will used to during the procedure to prevent infections. Two factors will be considered to find out the appropriate treatment area: 1) high sensitivity shown by the areas on palpation and that too reproduce the symptoms of the patients and (2) ultrasonographic examination of the tendon areas exhibiting degenerative changes. Specific 20-gauge (0.25 × 25 mm) stainless steel DN needles will be used during the intervention by considering the approach and thickness of the patellar tendon. The ultrasound will guide the procedure and to make sure the application specificity on the involved tendon area and assure the patients' safety. During the procedure, the DN needle will reach the appropriate involved areas with focal degenerative tendon changes. The three needles will be inserted during whole treatment session and that insertions will last for 3 seconds each. The total number of needle insertions can be varied from 15-30 passes, depending on the area of tendon degeneration. These needle insertions cause softening of the degenerated tendon and treatment session will continue till whole tendinosis area will be treated and softened during needles progression. Rest of the treatment session will have same interventions as given to the conventional group.

For Ultrasound guided needling as well as pre- and post-procedure assessment of the patellar tendon, a high frequency ultrasound equipment (Xario Premium Toshiba) and a linear probe (7-14MHz) will be used. The assessments under ultrasound will be done in accordance with the Musculoskeletal Ultrasound Technical Guidelines: Knee, defined by the European Society of Musculoskeletal Radiology. The ultrasonographic assessment will involve longitudinal section of the tendon sequence from origin of the patellar tendon to its insertion, whereas transverse section will include pole of the patella, body of the patellar tendon, and its insertion on the tibial tuberosity, with the patient in supine position and knee at 20° of flexion. The target area of the involved tendon will be selected and assessed with the presence of degenerative signs in accordance with the medical diagnosis of jumper's knee. These degenerative sings include tendon thickness, hypoechoic areas, cortical bone irregularities and calcifications

Outcome measures

A written questionnaire consisting of the questions of baseline data and pathology of jumper's knee will be used. Different questionnaires and assessment tools (VISA-P, VAS, KOOS, Lysholm scale) will be given to each participant and will be given enough time to complete the same.

The participants will be measured at baseline, 1-, 2- and 4-weeks post randomization. Pain and function will be assessed using VISA-P questionnaire, KOOS Scale & Lysholm knee scoring scales, respectively and also sonographic patellar tendon assessment of all the participants (**table II**).

VISA-P questionnaire

The severity of patellar tendinopathy was measured with VISA-P questionnaire. This scale comprises of eight questions, out of which the initial six use visual analogue scale to allocate a score of 0-10, where 10 represents the maximum

Table II. Patient flow of enrolment, assessments, and interventions.

	Study Period						
	Enrolment	Allocation	Post-allocation				Close-out
Timepoint**	$-t_1$	0	t_1	t_2	t_3	t_4	t_x
Enrolment							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
Interventions							
[Conventional physical therapy]		—	—	—			
[Ultrasound guided dry needling + conventional physical therapy]		—	—	—			
Assessments (Outcome measure)							
[VISA-P Score]							
[KOOS Score]			X	X	X	X	X
[Lysholm Score]			X	X	X	X	X
Ultrasonographic assessment of tendon			X	X	X	X	X

state, and used to enumerate pain and function in various activities, whereas the last two questions evaluate the functional level and ability to perform physical activity (38).

The Knee Injury and Osteoarthritis Outcome Score (KOOS)

It is an instrument specific to knee, designed to assess patient reported outcomes (both short and long term) about their knee and associated problems. It has five separately scored subscales of Pain, other Symptoms, Function in daily living (ADL), Function in Sport and Recreation (Sport/Rec), and knee-related Quality of Life (QOL) (39).

The Lysholm score

It comprises of eight items and is scored on a scale of 0-100 assessing knee-related symptoms. These scores integrate both objective and subjective data. Objective data is clinically assessed by the physician and subjective functional data is obtained from the patients (40).

Sonographic assessment of the patellar tendon

The thickness of the tendon will be measured in the longitudinal section (with 0-degree knee angle). Therefore, to measure entire length of the patellar tendon from inferior margin of patella to tibial tuberosity and then find its mid-portion by dividing the entire length by 2. The epitendon and paratendon will not be included into the measurement. The echogenicity and fibrillar echo-pattern of the patellar tendon structures will be evaluated both in the longitudinal and in the transversal scans in comparison to Hoffa's fat pad.

Ultrasound guided dry needling will be performed by certified dry needling physiotherapist at the university of

Lahore. All the participants will be advised not to receive any other treatment for jumper's knee. However, nonsteroidal anti-inflammatory drugs (NSAIDs) will be permitted if patients have unbearable pain and there will be no schedule of outcome assessment in the next 48 hours. There will be complete documentation of all such concomitant treatments (such as name and dosages of the drugs and treatment duration) received by the patients during the study.

Blinding

The physical therapist providing interventions will be aware of the group allocation of the patients however patients, the outcome assessor and statistician will be completely blinded to the randomization.

Sample size

The sample size is estimated based on the data provided by pilot study. The sample size calculation was based on the primary outcome (Lysholm score) of this study using mean Lysholm score in experimental group as 70.5 ± 20.695 and in control group as 55.50 ± 11.07 using 80% power of test, 95% confidence interval and 5% margin of error. Total of 40 cases in each group are estimated by adding 20% drop out rate, it will be 48 in each group. This sample size is also sufficient for the VISA-P score and KOOS score

Assignment of interventions (for controlled trials)

Blinding

It will be a single blinded trial in which the assessor will be kept blind.

Random allocation

The subjects will be randomly assigned to one of two groups by using a table of random numbers generated the randomization sequence, using a restricted randomization scheme to assure equal numbers in each group. Random allocation to all groups will be ensured, from all study personnel and participants by entry of data into computer randomization program immediately.

Concealment of allocation

Group assignments will be sealed in opaque envelopes and opened sequentially by the investigators.

Data collection, management, and analysis

Data collection and management

During the first evaluation, participants will complete the visual Analogue Scale (VAS), considering the level of pain they feel while practicing their sport's activity. Participants will be explained that a score of 0 indicates the absence of pain whereas a score of 10 represents the maximum tolerable pain. Participants will complete the VISA-P, KOOS scale, Lysholm knee scoring scale at baseline,1st, 2nd and 4th week.

Statistical method

SPSS (Statistical Package for Social Science) version 24 will be used for Statistical analysis. Descriptive statistics will be used to explore the data and will be presented in tables and figures Data will be displayed as mean and standard deviation (SD) or as median and interquartile range (IQR), depending on normal distribution of the data. Categorical data will be summarized by frequency (n) or percentage (%). Data will be analyzed on an intention-to-treat basis; missing data will be imputed using multiple imputation. The Kolmogorov-Smirnov and Levene's tests will be used to check the normality and homogeneity of variance, respectively, for all measures. An independent sample t test/Mann-Whitney test will be used to compare the mean/mode in both groups. For pairwise comparison and follow-up, repeated measures ANOVA/Friedman test will be used at baseline, second and fourth weeks after the commencement of treatment. Data-analysis will be performed by a researcher who is blinded to the group allocation. The significance level set for all the analysis will be $p \leq 0.05$.

DISCUSSION

This study will assess the effects of ultrasound guided dry needling in the treatment of patellar tendinopathy. The intervention protocol has been designed based on the critical review of the findings from the available literature, our trial has some strengths as compared to previous studies. Several outcome parameters will be included to measure the intensity of knee pain and function, including the VISA-P score, Lysholm score, KOOS score and ultrasonographic assessment. The consistency of these parameters will help to discover the potency of the results. It is described in detail so that the study results can be reproduced, interpreted, and compared any time.

CONCLUSIONS

We will make sure that this study is a genuinely randomized, controlled, single-blinded trial through the complete implementation of randomization, blindness, and concealment. We will strictly follow the guidelines of the Consolidated Standards of Reporting Trials (CONSORT). It is important to endorse that the results of this trial will provide scientific and rigorous clinical evidence for the application of ultrasound guided dry needling for treatment of jumper's knee.

STUDY REGISTRATION

This randomized controlled prospective study was registered with the Iranian Registry of clinical trials (IRCT20210409050913N1) on April 17, 2021. The recruitment process for the trial is in progress and the trial is expected to be completed in November 2021.

ETHICS

University of Lahore approved the study (IRB-UOL-FAHS/829-I/2021 - date of acceptance: 12/02/2021). Declaration of Helsinki was followed. Principal investigator will obtain informed consent from participants of the trial. We did everything we could to protect participants privacy. The participants identity will not be revealed in any publication resulting from this study.

FUNDINGS

None.

DATA AVAILABILITY

The data sets used and/or analyzed during the current study are available from the corresponding author on reasonable request at the study publication.

CONTRIBUTIONS

All authors have made a substantial, direct, and intellectual contribution to the work. FS, AA: conceptualization of the study. SAG, RB, AH: assistance in the study protocol development. All authors have contributed to the final design of the study protocol and have approved the final manuscript.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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