

High Frequency Transcutaneous Electrical Nerve Stimulation in the Immediate Postoperative Period of Anterior Cruciate Ligament Reconstruction and Its Effects on Drug Costs During Hospitalization

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SUMMARY

Introduction. The anterior cruciate ligament (ACL) is an important structure for knee stability. Transcutaneous electrical nerve stimulation (TENS) is an electrical current that significantly reduces pain.

Objective. To assess drug costs associated with high frequency TENS in the immediate postoperative period of ACL reconstruction.

Methods. A single-blind randomized clinical trial with 46 patients randomly assigned to a control group (CG = 23) and a TENS group (TG = 23). Individual and total drug costs were assessed in both intervention groups. The TENS intervention protocol started in the recovery room shortly after surgery, being maintained uninterruptedly for the first 48 hours after surgery. The parameters used were pulse width of 100 μ s, frequency of 120 Hz, and intensity according to the patient's tolerance.

Results. The average cost of drugs was US \$ 3.12 in the TG and US \$ 9.12 in the CG ($p = 0.0001$). Tramadol accounted for the biggest difference in costs: US \$ 4.34 \pm 1.36 in the CG and US \$ 0.81 \pm 0.95 in the TG ($p = 0.0001$). The total cost of drugs was US \$ 13.48 in the TG and US \$ 39.62 in the CG ($p = 0.0001$).

Conclusions. The treatment with high frequency TENS application was three times less expensive regarding drug costs, which makes it a promising resource for postoperative analgesia. Using this technique minimizes drug side effects and reduces costs for health systems.

KEY WORDS

Transcutaneous electrical nerve stimulation; anterior cruciate ligament; physical therapy specialty; knee; anterior cruciate ligament reconstruction.

INTRODUCTION

The anterior cruciate ligament (ACL) is an important knee stabilizer against tibial translational and rotational forces on the femoral condyle (1). Individuals who present ACL injury develop changes in motor control as this injury usually leads to a loss of sensory information, impairing proprioception and postural control (2). It is a very common sports injury, affecting approximately 1 in every 3,000 people in the USA (3). The ACL reconstruction surgery is one of the most frequent orthopedic surgical procedures and generally produces good results. However, development of postoperative complications may hamper the patient's recovery (4). In the immediate postoperative period, this injury is usually accompanied by pain and functional limitation (5).

Transcutaneous electrical nerve stimulation (TENS) is a technique that transmits low voltage electrical impulses through electrodes applied to the painful area (6-8). This technique is effective in treating various musculoskeletal disorders as it influences and modulates nerve conduction of pain (6). In association with other physiotherapeutic approaches, TENS may increase the level of activity, reduce hospital stay, and improve function in the affected region (9). Moreover, it is a relatively low cost therapeutic resource (7, 9).

Transcutaneous electrical nerve stimulation (TENS) is a nonpharmacological method of analgesia (10) approved by the Food and Drug Administration (FDA). It is a fast, safe, noninvasive, and low cost physical therapy. In comparison to other analgesic methods, it also has the advantage of minor side effects (10). Due to this analgesic effect, TENS can be administered in the postoperative routine of several surgical conditions as an adjunct to conventional opioid analgesia (11).

This study evaluates the effects of using high frequency TENS on pain, function, and opioid analgesic consumption in the immediate postoperative period of ACL reconstruction.

METHODS

Study design

This is a randomized, single-blind clinical trial with 46 male patients who underwent reconstructive surgery (bone-tendon-bone graft). Outcome measures were evaluated prior to surgery, on the 1st and 2nd postoperative days. The study received ethical approval from the Ethics Committee of the Lutheran University of Brazil (2,175,301) and is registered in the Brazilian Registry of Clinical Trials (ReBEC) under the number RBR-9FZFYS. This study meets the ethical standards of Muscles, Ligaments and Tendons Journal (12).

Participants

Figure 1 shows the study flowchart. Initially, 47 male participants who were candidates for ACL reconstruction using arthroscopic bone-tendon-bone graft were referred for physical therapy. The same surgeon would perform the surgery for all these patients. All participants were assisted by the Brazilian Unified Health System (SUS). The participants were examined by the evaluating researcher, and were aware of the inclusion and exclusion criteria. Only one patient did not consent to participate in the study. Therefore, 46 consecutive patients were considered eligible for the study.

Elegibility criteria

The study included men aged between 18 and 40 years, with ACL rupture, who underwent surgery using arthroscopic bone-tendon-bone graft. All participants were assisted by the Unified Health System (SUS), and were admitted to a regional hospital that is a reference in Orthopedics and Traumatology.

The study excluded participants with previous meniscus rupture requiring intervention, with evidence of degenerative disease on radiological or magnetic resonance imaging (MRI), with superficial sensitivity deficit, with loss of consciousness and cognitive impairment that prevented understanding, with stroke sequelae, and those that developed infection in the surgical wound or died during the research period.

Sampling and randomization

The primary outcome of the study was the administered dose of dipyrone. Following the study by Silva *et al.* (13), we estimated the sample size through the differences between the mean and standard deviation of the initial and final dose of dipyrone of participants who received TENS application. In the first postoperative evaluation, the dipyrone dose in the TENS group was $1,000 \pm 1,240.35$ mg, and the final dipyrone dose was $500.00 \pm 1,091.93$ mg. In the control group, the initial dipyrone dose was $1,357.14 \pm 744.95$ mg, and the final dipyrone dose was 857.14 ± 534.52 mg. Using a study power of 80%, a significance level of 95%, and a sample size ratio of 1:1 (intervention group:control group), we reached the estimated number of 23 subjects for each group, totaling a sample of 46 participants.

Participants were randomly assigned to two groups according to a list of random numbers provided by the EPI-IN-FO® software, with 23 patients in the TENS group (TG) and 23 patients in the control group (CG). An external researcher, not involved neither in the recruitment nor in the evaluation of patients, performed the allocation.

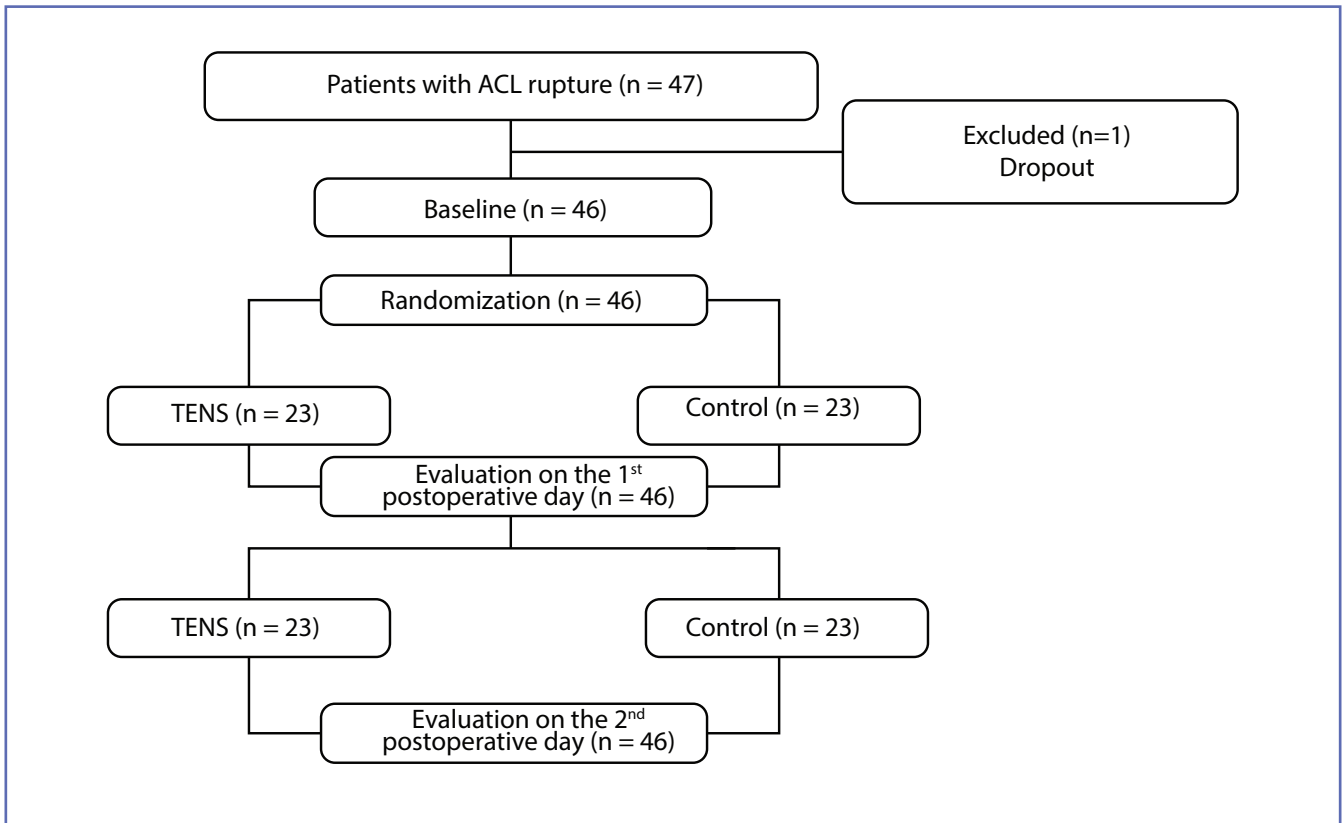


Figure 1. Study flowchart.

Intervention protocol

The intervention protocol was carried out by an independent researcher previously trained in TENS administration and who had not participated in the evaluation step. Both study groups received the standard postoperative rehabilitation protocol for ACL reconstruction. The protocol consisted of continuous passive motion (CPM) exercises, isometric exercises, and active assisted exercises for knee flexion and extension according to the patient's tolerance.

The TENS intervention started in the surgical recovery room, after approval by the nurse in charge. Intervention was maintained 24 hours a day, and ended 48 hours after surgery. The researchers turned off the equipment only for personal hygiene purposes. The patients underwent the application of continuous high frequency TENS (conventional mode) from two channels with 3×5 cm self-adhesive electrodes surrounding the surgical wound. The parameters used were: frequency of 120 Hz, pulse width of 100 μ s, and intensity of stimulation at the highest comfortable level reported by the patient so as to promote intense paresthesias without, however, causing discomfort.

The patient's companion was instructed to observe and control the positioning of the electrodes during the absence of any team member or researchers. In case of any disconnection of the device, the companion should immediately contact the nurse in charge, who would contact the intervening researcher to make the necessary adjustments.

Following the orientations of the Hospital Infection Control Commission (CCIH) of Santa Luzia Hospital, the electrodes were cleaned in running water after the end of each application. Moreover, for greater infection control, the device and cables were disinfected with a cloth moistened with Incidin®.

Outcomes and evaluation

The primary outcome was drug intake. Evaluations were carried out by a blind evaluator, that is, a researcher who did not know which group the participant belonged to. All results were measured before surgery, on the 1st and 2nd postoperative days.

Drug Intake

The analgesic routine adopted by the attending physician remained unaltered. The analgesic protocol adopted by the entire medical team in the Department of Orthopedics and Traumatology of the institution included ketoprofen (100 mg) every 12 hours, sodium dipyrone (2 mg) in case of pain or fever, tramadol (100 mg) in case of pain, morphine (3 mg) every 3 hours in case of pain, and diazepam (10 mg). We recorded the daily and total consumption of drugs on each of the first three postoperative days in each study group on a registration form. Afterwards, we calculated the total dose administered to each study participant in both groups.

Data analysis

Data were presented as mean \pm standard deviation or mean (95% confidence interval) and median (interquartile range). Initially, the data were tested for normal distribution using the Shapiro-Wilk test. Proportion comparisons were made using χ -square tests. One-way ANOVA was used to compare baseline characteristics between groups. Parametric data were analyzed statistically by one-way analysis of variance (ANOVA) for repeated measures, followed by

the Bonferroni post hoc test for intragroup analyses. The Student t test was used for intergroup analyses. Nonparametric data were analyzed using the Kruskal-Wallis test. A value of $p < 0.05$ was required for statistical significance. All statistical analyses were performed using commercial software (Statistical Package for the Social Sciences, version 23, SPSS Inc., Chicago, IL, USA).

RESULTS

A total of 46 patients underwent arthroscopic ACL reconstruction using bone-tendon-bone graft. All subjects who started the intervention completed the study and there were no losses or exclusions (**figure 1**). **Table I** shows demographic characteristics and outcome measures prior to the intervention and in both groups (TG and CG). Participants in the TG had more right knee injuries than participants in the CG.

Drug Costs

The TG showed a significant cost reduction (US \$) for all drugs administered in the postoperative protocol ($p < 0.05$) (**table II**).

Table I. Demographic characteristics of the sample (n = 46).

	Intervention Group		
	TG (n = 23)	CG (n = 23)	p value
Age, years (\pm sd)	26.52 \pm 6.27	29.68 \pm 6.73	0.110 [#]
Gender, n (%)			1.000 [§]
Male	23 (100.0)	23 (100.0)	
Female	0 (0.0)	0 (0.0)	
Time of injury, months (\pm sd)	19.61 \pm 22.82	32.55 \pm 36.39	0.158 [#]
Smoking, n (%)			0.524 [§]
Yes	1 (4.3)	2 (9.1)	
No	22 (95.7)	20 (90.9)	
Skin color, n (%)			1.000 [§]
White	23 (100.0)	22 (100.0)	
Black	0 (0.0)	0 (0.0)	
Affected knee, n (%)			0.023 [§]
Right	18 (78.3)	10 (45.5)	
Left	5 (21.7)	12 (54.5)	
Dominant limb			0.963 [§]
Right	21 (91.3)	20 (90.9)	
Left	2 (8.7)	2 (9.1)	

[#]Student t, [§]Chi-square.

Table II. Average cost (US \$) of each drug per participant in the intervention groups during the study period.

Drug	CG (mean ± sd)	TG (mean ± sd)	Mean difference (95% CI)	t	P ^a
Ketoprofen	0.44 ± 0.11	0.29 ± 0.59	- 0.141 (- 0.195 to - 0.088)	5.348	0.0001
Dipyrone	0.43 ± 0.14	0.19 ± 0.12	- 0.233 (0.311 to - 0.154)	5.990	0.0001
Tramadol	0.43 ± 0.14	0.08 ± 0.10	- 0.354 (- 0.425 to - 0.284)	- 10.170	0.0001
Morphine	0.16 ± 0.10	0.005 ± 0.024	- 0.157 (- 0.202 to - 0.112)	- 7.061	0.0001
Diazepam	0.25 ± 0.13	0.07 ± 0.08	- 0.182 (- 0.247 to - 0.117)	- 5.651	0.0001
Total	1.71 ± 0.38	0.64 ± 0.20	- 1.070 (- 1.250 to - 0.889)	- 11.939	0.0001

Bold values are statistically significant. CI: Confidence interval; sd: standard deviation. a: Student t test for intragroup comparisons.

Total Costs in the Intervention Groups

The total drug cost (US \$) for the TG was about 1/3 of the total drug cost for the CG ($p < 0.05$) (table III).

DISCUSSION

This randomized clinical trial evaluated the costs of adding TENS to the exercise protocol applied in the first 48 hours after ACL reconstruction. Few studies have evaluated the effect of using TENS on drug costs in the postoperative period of orthopedic trauma.

The standard analgesic drugs used in surgical procedures in the Department of Orthopedics and Traumatology of the hospital where the study was carried out are ketoprofen, dipyrone, tramadol, and morphine. The CG had a higher drug intake than the TG ($P < 0.0001$). Such findings are parallel to previous studies that analyzed analgesic consumption associated with TENS after several types of surgical procedures (13-15).

The results of this clinical trial showed that continuous use of TENS in the first 48 hours after anterior cruciate ligament (ACL) reconstruction significantly reduced the costs of all drugs included in the postoperative protocol, reducing about 1/3 of the total cost for the TG in comparison to the CG ($p < 0.0001$).

Corroborating the findings of this study, Pivec *et al.* (8) observed that TENS was a noninvasive option that provided clinical and economic advantages in comparison with not using TENS. Several variables can interfere so that TENS may not achieve the desired analgesic effect. Vari-

ation in the intensity and frequency used, as well as the stimulation time, may not be sufficient to achieve significant analgesia in the acute phase, thus not closing the pain gate.

Silva *et al.* (13) approached 42 patients with proximal femoral fractures divided into a TENS group, a placebo TENS group, and a control group. All groups received the same exercise protocol in the postoperative period (13). As in the present study, transcutaneous electrical nerve stimulation (TENS) was applied uninterruptedly (13). The authors observed a significant reduction in pain and drug intake, the latter decreasing by 62.96% (tramadol), 45.61% (tenoxicam), 24% (dipyrone), and 87.5% (morphine) in groups of patients in the postoperative period of proximal femoral fractures who used continuous high frequency TENS (13). The costs decreased by US \$ 3,975.34 for every 1,000 patients with proximal femoral fracture treated with TENS in the first three days after surgery (13).

Pivec *et al.* (8) demonstrated that patients with chronic low back pain, without neurological impairment, and who were treated with TENS had significantly less hospitalizations and medical visits than those who did not receive TENS. The analysis of total annual costs showed that patients who received TENS had significantly lower total costs, although the difference was modest (US \$ 17,957 for patients treated with TENS versus US \$ 17,986 for patients who were not treated with TENS) (8). In addition, patients who used TENS had significantly lower hospital costs (US \$ 4,074 vs US \$ 4,772, respectively), but significantly higher outpatient costs (US \$ 10,489 vs US \$ 9,643, respectively; $P < 0.0001$) (8).

Table III. Total drug costs in the study groups (US \$).

Intervention Group	Average cost per patient (US\$) (mean ± sd)	Total costs of the group (US\$)	Costs for every 1,000 patients (US\$)
TG	3.12 ± 1.21	13.48	13,480
CG	9.12 ± 2.11	39.62	39,620

A study analyzed the use of opioids after thoracic surgery and demonstrated a lower opioid intake for patients receiving TENS in comparison to the control group. (11). Silva *et al.* (15) demonstrated that continuous use of TENS (24 hours a day, ending 72 hours after surgery) for proximal femoral fracture significantly decreased drug intake (15). According to the authors, the tramadol dose was significantly higher in the control group than in the TENS group at forty-eight hours after surgery (15).

Kara *et al.* (13) evaluated the effect of TENS on analgesic consumption in the immediate postoperative period of spinal surgery. The application started when the patients arrived at the postsurgical ward (two to three hours after surgery) (13). The researchers administered TENS twice a day, 30 to 40 minutes each time, with a rest interval of three to four hours between applications (13). The TENS group showed lower analgesic consumption in the first 24 hours and throughout the experiment (13). Even with a small reduction in opioid use in patients treated with TENS, its application can be an important general public health measure to reduce the exposure of patients with musculoskeletal pain to chronic use of opioids and related sequelae (8).

Gore *et al.* (16) evaluated the use and direct medical costs of pharmacological and alternative treatments for patients with osteoarthritis (OA) and chronic low back pain. Opioids were the most prescribed drugs (above 70%), followed by nonsteroidal anti-inflammatory drugs (above 50%). Transcutaneous electrical nerve stimulation was used in 14% of the OA cases. Opioids represented an average cost of US \$ 287.4 in the treatment of OA, and 364.5 in chronic low back pain. Tramadol represented an average cost of 137.6 and 119.4, respectively (16). Notwithstanding, TENS represented an average cost of US \$ 155.9 in OA and US \$ 115.20 in chronic low back pain (16). It is noteworthy that a substantial proportion of patients had baseline comorbidities associated or contraindicated with drugs, NSAIDs, and medications used during the study period, which have been documented to increase the risk of NSAID-related events (16). These side effects can technically increase the

total economic burden of patient management, although their contribution to total costs is difficult to assess.

Finally, the results of the present study demonstrate that TENS application in the immediate postoperative period of several traumatic orthopedic surgeries can significantly reduce drug consumption and costs in health systems. However, success with the use of TENS depends both on appropriate selection of parameters and on understanding the application principles. The current intensity for effective postoperative analgesia should be strong but comfortable for the patient, and the electrodes should be positioned around the surgical area or at corresponding acupuncture points.

Study limitations

The main limitation of the present study is the small number of patients. Another limitation is the absence of a placebo TENS group. Furthermore, the study did not analyze neither the side effects presented in the groups that received drugs, nor the cost generated by addressing these effects.

CONCLUSIONS

Drug costs were about three times lower in the group that used continuous high frequency TENS than in the control group. High frequency TENS can be a promising resource for postoperative analgesia, minimizing drug side effects and reducing costs for health systems in the postoperative period of musculoskeletal conditions.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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