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Transcutaneous Electrical Nerve Stimulation (TENS) in the Immediate Postoperative Period Following Proximal Femoral Fractures Reduces Drug Costs

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Authors' contributions

This work was carried out in collaboration between all authors. Author MBD designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors FSS, MMS and ABMZR managed the analyses of the study. Author FSS managed the literature searches. All authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aim: The aim of this study was to evaluate the effect of TENS on the costs generated with the intake of analgesic drugs in patients with proximal femoral fractures.

Study Design: Randomized, double-blind, placebo-controlled clinical trial.

Place and Duration of Study: Department of Orthopedics and Traumatology. Santa Luzia Hospital, between September 2015 and July 2016.

Methodology: Forty-two patients, homogeneous for age, color and sex, were allocated into three groups. These were divided into TENS treatment (n=14), Placebo TENS (n=14) and Control (n=14), with application for a period of seventy-two hours postoperatively, assessing pain, by visual analogue scale, and drug intake (tenoxicam, dipyrone, tramadol, morphine and diazepam).

Results: Long-term TENS reduced pain and drug intake by 62.96% (tramadol), 45.61% (tenoxicam), 24% (dipyrone) and 87.5% (morphine) in patients in the postoperative period following femoral fracture. This reduction represented a decrease of US\$ 3,975.34 for every 1,000 patients with proximal femoral fractures treated with TENS on the three days after surgery. **Conclusion:** TENS, when used ininterrupedly, was shown to be effective for pain reduction and generated a significant reduction in drug-related costs in the immediate postoperative period of patients with proximal femoral fractures.

Keywords: Transcutaneous electrical stimulation; femoral fractures; analgesics; drug costs.

ABBREVIATIONS

- VAS : Visual Analogue Pain Scale.
- TENS : Transcutaneous Electrical Nerve Stimulation

1. INTRODUCTION

Proximal femoral fractures are considered a major health problem worldwide [1]. This type of fracture is increasingly present in hospital routines and daily life due to the population's increased life expectancy in recent decades [1]. Increased survival further influences the risk of developing comorbidities in the elderly population, such as changes in muscle strength, balance, reflexes, visual impairment, neurological deficiency, reduction of physical activity and bone mineral density, resulting in osteopenia and, later, in osteoporosis [2]. The treatment recommended for patients with proximal femoral fractures is, preferably, the surgical one, with placement of synthesis material or prosthesis, aiming at stability and an earlier functional return [3].

Proximal femoral fractures are one of the main causes of mortality and functional disability among the elderly, representing today one of the major public health problems in several countries [4]. These traumas have considerable economic repercussions in society, such as direct costs, which are defined as costs of hospital care, and indirect costs, which take place after discharge, taking into account non-productivity, that is, withdrawal from work due to illness [4,5]. In the United States of America, the total number of hip fractures is estimated to be 289,000 by 2030 [6]. In the United Kingdom, it is estimated that 100,000 proximal femoral fractures will occur by 2033 [6]. The average number of fractures per year reaches 86,000, with an expenditure of 1.7 billion euros for the National Health Service [7]. In the USA, fracture costs exceed US\$ 20 billion [8]. In England, there are 65,000 proximal femoral fractures per year, representing

an expenditure of \in 2,000,000,000 per year [9].

With high costs and increased responsibilities in the care of these patients, there has been interest in new methods to increase the efficiency of [10]. Transcutaneous electrical care stimulation (TENS) is a low frequency electrical modality, which is used as a physiotherapeutic resource of clinical purpose in the symptomatic relief of pain [11]. It is considered an efficient, non-invasive, easy-to-apply, non-toxic, comfortable procedure for the patient in 95% of cases, and is a relatively low-cost method [12,13]. The application is made through an electric current generated by the device and transmitted by means of electrodes that are placed on the skin [14]. The mechanism of action of TENS works according to the gate control theory postulated by Melzack and Wall [15]. Due to the effect of TENS, it can be administered in the postoperative routine of several surgical conditions, as an adjunct to conventional opioid analgesia [16].

The aim of this study was to evaluate the repercussion of the use of TENS on the costs of analgesic and anti-inflammatory drugs in the immediate postoperative period in patients with proximal femoral fractures.

2. MATERIALS AND METHODS

The present study was characterized as a randomized, double-blind, placebo-controlled clinical trial. It was approved by the Ethics and Research Committee of the Mãe de Deus Hospital under opinion No. 1.228184. The research was applied during the period from September 2015 to July 2016 in the Department of Orthopedics and Traumatology of the Santa Luzia Hospital, in the city of Capão da Canoa/RS. In all, 65 patients hospitalized with a diagnosis of proximal femoral fracture participated in this study. Of these, 42 patients met the eligibility criteria and finalized the study.

The inclusion criteria of the study were as follows: patients older than 18 years who had a diagnosis of proximal femoral fracture and signed the free and informed consent form (FICF). Exclusion criteria were: age less than 18 years, cognitive impairment, sequelae of stroke (CVA), loss of consciousness, patients with proximal femoral fracture submitted to reintervention, death during the research, patients with lack of superficial sensitivity, and dropout during the study. 23 patients were excluded from the study, nine due to cognitive deficits, five with previous sequelae of stroke, two due to loss of consciousness, two undergoing reintervention of an old fracture, and one who withdrew from the study during the intervention period. Moreover, four patients died during the trans- or postoperative period.

After signing the free and informed consent form, patients were randomized through envelopes containing the name of the group to which the patient would belong: Control group (n=14), TENS group (n=14) and Placebo TENS group (n=14).

The analgesic routine adopted by the assistant doctors of the team was the same for all

subjects, maintained unchanged. The medication prescription protocol was adopted by all surgeons of the medical team in the Department of Orthopedics and Traumatology of the institution. This protocol included tenoxicam 20 mg every 12 hours in case of pain, sodium dipyrone 1000 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 in case of pain or excessive agitation.

The characteristics of the participants are presented in Table 1.

2.1 Evaluation Protocol

The evaluations were performed by a blind evaluator, that is, an evaluator who did not know to which group the patient belonged to. These were carried out in four different periods: the first evaluation was carried out during the period of preoperative hospitalization, shortly after hospitalization and prior to randomization. The second evaluation occurred 24 hours after the surgical procedure. The third one occurred 48 hours postoperatively and, ultimately, the final evaluation was carried out on the third postoperative day (Fig. 1).



Fig. 1. Study flowchart

Daily and total drug intake were recorded on an evaluation form, both in the preoperative evaluation and on each of the three days following the surgical procedure in each study group. After that, it was calculated the percentage of reduction (daily and total) of drug consumption in each of the intervention groups, compared to the Control group. Then, the total cost was calculated taking into account the use of each drug and the sum of all drugs in the study population. Finally, the values were expressed in percentages in relation to the cost of the TENS group.

2.2 Intervention Protocol

The TENS intervention protocol started in the surgical recovery room, after consent of the nurse responsible for the surgical block. Intervention was maintained 24 hours a day and finished after 72 hours of surgery. The equipment was only switched off for patient hygiene.

A pre-calibrated Neurodyn III portable TENS equipment, brand IBRAMED®, was used. The patients underwent TENS in the conventional mode. continuously, with two channels positioned to surround the surgical wound. 5x5cm self-adhesive electrodes were used. The parameters used were: pulse width of 100 µs, frequency of 120 Hz and stimulation intensity according to the patient's reported sensation, in order to promote intense stimulation without, however, causing discomfort. The intensity in the TENS group was increased every three hours in order to avoid current accommodation at the patient's sensory level. Patients in the Placebo TENS group received the same protocol, but at zero current intensity (Fig. 2). Both groups received the same standard protocol of physiotherapy during the study period. This protocol included resisted active exercises for upper limbs and contralateral lower limb, breathing exercises, isometric exercises for the femoral quadriceps, hamstring and gluteal muscles, active exercises for ankle/foot and assisted active exercises respecting the pain threshold for knee and hip.

2.3 Statistical Analysis

The data of the sample characterization variables were initially expressed in a descriptive way with absolute value, percentage, means and standard deviation. The chi-square test was used to compare the means of these variables between the groups. The results of costs generated with each drug and the total cost with drugs were expressed in absolute terms. Drug cost data were analyzed descriptively in US dollars, presenting the individual costs with each drug and the total cost with the drug protocol used in the study. Afterwards, a total cost projection was performed with the protocol for an estimated population of 1,000 patients with proximal femoral fracture.



Fig. 2. Positioning of the electrodes of the TENS current

3. RESULTS AND DISCUSSION

65 patients with proximal femoral fractures were initially hospitalized in the Department of Orthopedics and Traumatology of the hospital. Of these, 42 patients met the inclusion criteria and participated in the study. The mean age was 79.4 \pm 13.32 years. 25 patients were female (59.53%). All patients were white. The most prevalent type of fracture was femoral neck fracture (50%), followed by transtrochanteric fractures (40.47%). The groups were homogenous regarding gender, age, skin color and type of fracture (Table 1).

The TENS group showed a significant reduction in the cost of drug administration compared to the other two groups. The cost of administering tramadol 100 mg was US\$ 0.80 per patient during the 72 hours after surgery in the group that administered TENS. The Placebo TENS group spent US\$ 2.03/patient, and the Control group, US\$ 2.16/patient (Table 2). When analyzing the total cost generated for all patients participating in the study, the TENS group presented a total cost of US\$ 9.62, the Placebo TENS group presented US\$ 24.42 and the Control group, US\$ 25.90. When calculating the cost generated with tramadol for every 1,000 patients admitted to the hospital with a proximal femoral fracture, the cost generated in the TENS group would be, on average, US\$ 801.66. For Placebo TENS, this cost would increase to US\$ 2,035.00, and in the Control group, it would correspond to US\$ 2,158.33. In terms of percentages, the TENS group represented a reduction of 60.59% compared to Placebo TENS,

and 62.96% compared to the Control group, in the costs generated for the institution and for the government's Unified Health System (SUS) (Table 2).

The administration of Tenoxicam 20 mg costed, on average, US\$ 2.15 per day to patients in the TENS group. In the Placebo TENS group, this cost was increased to US\$ 3.63, and in the Control group, to US\$ 3.97. In the total sum of the cost with Tenoxicam during the period of the study, the TENS group had an expense of US\$ 25.84, while in Placebo TENS, the total cost was US\$ 43.52, and in the Control group, US\$ 47.60. For every 1,000 patients hospitalized with a proximal femoral fracture, the cost would be US\$ 2,153.00 for the TENS group, while in the Placebo TENS group, this cost would increase to US\$ 3,626.66, and in the Control group, to US\$ 3,966.67. Therefore, the TENS group demonstrated a reduction in Tenoxicam expenditures of 40.62% compared to the Placebo TENS group, and 45.61% compared to the Control group (Table 2).

The administration of dipyrone 500mg generated a daily cost of US\$ 0.73 per patient in the TENS group. In the Placebo TENS group, the daily cost increased to US\$ 0.94, and in the Control group, to US\$ 0.96. The total amount spent for the TENS group was US\$ 8.75, in the Placebo TENS group, it was US\$ 11.25, and in the Control group, US\$ 11.50. For every 1,000 hospitalized patients with this type of fracture, the cost for the TENS group would be US\$ 729.17, for the Placebo TENS group, it would be US\$ 937.50, and for the Control group, US\$ 958.33. This represents a total cost reduction in the TENS group of 23.20% compared to the Placebo TENS group, and 24% compared to the Control group (Table 2).

Regarding the costs generated with the administration of morphine 3 mg, the daily average of each patient in the TENS group was US\$ 0.08. An increase was observed in the other groups, with the Placebo TENS group generating an individual cost of US\$ 0.57, and the Control group showing the value of US\$ 0.65. In the total sum during the 72 hours of intervention, the TENS group generated a cost of US\$ 0.97. For the Placebo TENS group, this value was US\$ 6.79, and for the Control group, US\$ 7.76. For 1,000 hospitalized patients, the cost with morphine for the TENS group corresponds to a value of US\$ 80.83, for the Placebo TENS group, a value of US\$ 565.83, and for the Control group, US\$ 646.67. The reduction percentage

corresponds to 85.72% compared to the Placebo TENS group, and 87.50% compared to the Control group (Table 2).

In the sum of the costs generated with the drugs administered to patients with proximal femoral fractures in this study, the TENS group showed a significant reduction of costs in relation to the other groups. The TENS group generated a cost of US\$ 3.88/patient. In the remaining groups, there was a significant increase in the cost of drug administration. The Placebo TENS group generated a cost of US\$ 7.45/patient and the Control group showed a cost of US\$ 7.84/patient. In the sample used in the study, the total cost of the TENS group averaged US\$ 46.62. In the Placebo TENS group, this cost increased to US\$ 89.34, and in the Control group, to US\$ 94.32. When representing the cost generated with the treatment offered for every 1,000 hospitalized patients, the total cost for the TENS group would be US\$ 3,884.66, while for the Placebo TENS group, the total cost would be US\$ 7,444.99, and, finally, the total cost for the Control group would correspond to US\$ 7,860.00. This means that the TENS approach reduced the cost of drug administration by 47.83% compared to the Placebo TENS group, and 50.58% compared to the Control group (Table 3).

3.1 Discussion

Proximal femoral fractures, in addition to the high mortality rate and comorbidities that they generate in patients, represent a considerable burden of costs for health systems and societies worldwide. Maciel et al. [4], in an epidemiological study conducted in the state of Pernambuco, Brazil, showed that the incidence rate of femoral fractures exceeded 250 cases per 100,000 men and 110 cases per 100,000 women. The mean length of stay of these patients in the hospital was more than six days [4]. The total cost with these patients with femoral fracture during the hospitalization period was high, R\$ 9,000,000.00 (US\$ 2,812,500.00). Marques et al. [15] carried out a retrospective study in Portugal on the use of resources and changes in the quality of life of patients with proximal femoral fractures. In all, they selected 186 patients and analyzed gender, age and geographical origin. The average cost of each patient in the first year was € 13,434 [12,290 ± 14,576], and € 5,985 [4,982 ± 7,045] for the second year after fracture. The decrease in quality of life was related to age, but there was no difference regarding gender. The mortality rate was high, reaching up to 12% in the first year.

Variable	Group P			P value
	TENS (n=14)	Placebo TENS (n=14)	Control (n=14)	
Gender, M/F	7/7	5/9	5/9	0.67
Age, years (mean ± sd)	82.29 ± 10.96	77.79 ± 11.94	78.14 ± 16.83	0.50
Skin color, n (%)				1.00
White	14 (100.0)	14 (100.0)	14 (100.0)	
Black	0 (0,0)	0 (0,0)	0 (0,0)	
Type of fracture, n (%)				0.31
Femoral neck	9 (64.3)	6 (42.9)	6 (42.9)	
Transtrochanteric	5 (35.7)	5 (35.7)	7 (50.0)	
Subtrochanteric	0 (0.0)	3 (21.4)	1 (7,1)	
M=male; F=female				

Table 1. Characterization of the study sample (n=42)

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Table 2. Relationshi	p of cost of arug	j auministration to	scuay group	JS (US ֆ)

	Average costs per patient (US\$)	Total group costs (US\$)	Costs for 1,000 patients (US\$)
Tramadol 100 mg			· · ·
TENS	0.80	9.62	801.66
Placebo	2.03	24.42	2,035.00
TENS			
Control	2.16	25.90	2,158.33
Tenoxicam 20 mg			
TENS	2.15	25.84	2,153.00
Placebo	3.63	43.52	3,626.66
TENS			
Control	3.97	47.60	3,966.67
Dipyrone 500 mg			
TENS	0.73	8.75	729.17
Placebo	0.94	11.25	937.50
TENS			
Control	0.96	11.50	958.33
Morphine 3 mg			
TENS	0.08	0.97	80.83
Placebo	0.57	6.79	565.83
TENS			
Control	0.65	7.76	646.67
Diazepam 10 mg			
TENS	0.12	1.44	120.00
Placebo	0.28	3.36	280.00
TENS			
Control	0.13	1.56	130.00

	Average costs per patient (US\$)	Total group costs (US\$)	Costs for 1,000 patients (US\$)
TENS Group	3.88	46.62	3,884.66
Placebo TENS Group	7.45	89.34	7,444.99
Control Group	7.84	94.32	7,860.00

Yan et al. [16] performed an analysis of estimates of hospital costs per admission and length of hospital stay related to osteoporotic fractures in China. Data were obtained by the China Health Insurance Research Association. Regions of fractures were humerus, femur, wrist, pelvis, rib, ankle, foot and other unspecified sites, identified by a code of the International

Classification of Diseases and Related Health Problems, 10th Revision (ICD-10). The analysis included 830 patients, being 77.3% female. The mean age was 73.4 ± 9.8 years. The average hospital stay was 19 days and the costs generated were around ¥ 18,587. Hip fractures corresponded to a longer hospital stay among all types of fractures, with an average of 22 days, and also the highest cost, about ¥ 32,594. During the period between 2008 and 2010, there was an increase of 60 and 89% of hospital admissions and hospital costs because of osteoporotic fractures. The incidence and prevalence of osteoporosis and, consequently, a greater number of fractures, are increasingly predicted. This will lead to increased hospital costs, resulting in a major economic problem in the future.

There are very few findings in the literature addressing drug costs and the effects of TENS on their reduction. Kim et al. [17] investigated, in their perspective study, the social cost of osteoporotic fractures with persons over 65 years of age in South Korea. The use of health care and the medical costs of the Korean population, from 2007 to 2011, were analyzed through the National Database. In this period, there were 244,798 patients with at least one osteoporosisrelated fracture. Regarding fracture sites, 75.6% were in the vertebral region, 9.67% in the hip region and 8.17% in the wrist. In 2007, the social cost was US\$ 88.8 million, which increased annually, reaching, in 2011, the cost of US\$ 149.3 million, representing an increase of almost 60%. With each passing year, people's life expectancy increases and strategies are needed to prevent these injuries and rehabilitate them. In the present study, TENS was used, being a low cost tool, with which it was possible to achieve a reduction of 50.58% in the cost of medication in the first three postoperative days of patients with proximal femoral fractures.

Budhia et al. [18] performed a systematic review in the databases searching for studies addressing the costs associated with osteoporosis-related fractures in the USA. The published studies analyzed were from 1990 to 2011. Of the 33 included studies, 26 described the total medical cost and the use of hospital resources associated with osteoporotic fractures. The studies indicated that these medical and hospitalization costs accounted for 1.6 to 6.2% of the costs per year and that this kind of fracture occurred 2.2 to 3.5 times more than the other fractures. The costs of hospitalizations for each type of fracture have shown that hip fractures are the most expensive. On average, the cost with each proximal femoral fracture ranged from US\$ 8,358 to US\$ 32,195, while wrist and forearm fractures were the ones with the lowest cost, each averaging US\$ 1,885 to US\$ 12,136. Patients over the age of 65 are related to a greater cost. The female population demanded a greater cost than men. Despite the difference in estimates, the literature has shown that osteoporotic fractures are associated with high medical and hospital costs in the United States, with a need for proper strategies for economic remodeling.

Another fundamental aspect is the absence of side effects generated when applying TENS. The efficacy and safety of administration of analgesic drugs should be paramount during the postoperative period. Montoya et al. [19] investigated the adverse effects and the increased costs generated by them, evaluating the drugs tramadol and dipyrone in the orthopedic and surgery wards of the University Hospital of Samaritan Women in Bogotá, Colombia. Dipyrone is a non-narcotic product. Its actions are anti-inflammatory, analgesic and antipyretic. It is prescribed primarily as an analgesic in 96% of cases and, in only 4% of cases, as antipyretics. Tramadol, in turn, is a narcotic analgesic, a synthetic derivative of codeine, used to control moderate to severe pain. In all, 171 of 2,547 patients suffered 213 side effects from the study drugs. The main effects caused by dipyrone were absence of therapy (21.59%), vomiting and nausea (14.77%), rash (7%) and pruritus (6%). As for tramadol, the effects were constipation (23.03%), vomiting and nausea (15.08%), absence of therapy (9.52%) and adynamic ileum (1.59%). In the classification of these side effects, 93.18% of effects generated by dipyrone were the considered serious, while for tramadol, this value was 92.06%. Patients, due to side effects, increased their length of hospital stay. In dipyrone administration, on average, there was an increase of 1.95 days, with an interval ranging from one to five days. With the use of tramadol, the average was 2.25 days, with an interval ranging from one to seven days. The total direct cost for the care of the side effects generated by dipyrone and tramadol reached US\$ 14.346.53. In the present study, the use of TENS uninterruptedly during the immediate postoperative period of patients with proximal femoral fractures led to a reduction in the drug cost of all drugs administered. In addition to reducing direct drug costs, TENS reduced side effects due to lower drug intakes, eliminating the possibility of increased costs to treat the side effects generated by the drugs and eliminating costs related to the need for increasing the length of hospitalization.

Our study presented some limitations. There are still few articles in the literature addressing the application of TENS in the most diverse traumatological conditions, among them this type of fracture. This was an aspect that hindered our initial definition of the parameters size and positioning of electrodes. We believe that further studies are needed to confirm our findings.

4. CONCLUSION

The administration of TENS in the immediate postoperative period of patients with proximal femoral fracture led to a significant reduction in the cost of drug administration to the hospital and to the country's Unified Health System.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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