# **Original Article**

# Transcutaneous electrical nerve stimulation reduces acute pain, and the use of analgesics after ankle fracture surgery

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# Abstract

**Objective:** To evaluate the applicability of transcutaneous electrical nerve stimulation (TENS) as a complementary treatment method to non-opioid analgesics for acute postoperative pain in patients undergoing surgical treatment due to ankle fractures.

**Methods:** A prospective, randomized, analytical, cross-sectional study performed after ankle fracture surgery. Two groups were randomized as follows: group 1 (Intervention) received TENS and non-opioid analgesic (dipyrone), and group 2 (Control) received non-opioid analgesic (dipyrone).

**Results:** This study demonstrated that TENS in patients undergoing surgical treatment of ankle fractures reduces the use of rescue opioids significantly to control postoperative pain.

**Conclusion:** TENS devices may be another safe option to control postoperative pain and reduce the use of opioids, avoiding adverse effects from this class of analgesic.

Level of Evidence II; Therapeutic Studies; Prospective Comparative Study.

Keywords: Pain, postoperative; Ankle fractures; Electric stimulation therapy; Analgesics.

# Introduction

According to the International Association for the Study of Pain (IASP), pain is an unpleasant sensory and emotional experience associated with tissue injury, which may be real or potential<sup>(1)</sup>.

An approach that includes pharmacological and non-pharmacological techniques is indicated for postoperative pain control. The objective is to block the generation, transmission, and perception of nociceptive stimuli, which can be done at different central and peripheral nervous system levels<sup>(2,3)</sup>. As a pharmacological approach, there are analgesics of peripheral and central action<sup>(2,3)</sup>. The prescription of analgesics should obey two aspects. One is the administration only when there is pain, and the other is the use with a certain regularity to achieve constant plasma levels avoiding acute pain peaks, the latter being a way to ensure greater effective-ness in the control of the painful stimulus<sup>(4)</sup>.

Numerous non-pharmacological techniques exist in the attempt to suppress pain, activating the discriminative sensory system, such as cryotherapy, heat, acupuncture, and transcutaneous electrical nerve stimulation (TENS), among others<sup>(5,6)</sup>.

Study performed at the Hospital Ipiranga, São Paulo, SP, Brazil.

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TENS is widely used for the control of chronic or postoperative pain, replacing or complementing analgesics<sup>(7,8)</sup>. It is based on the Pain Gate Theory, proposed by Melzack and Wall<sup>(9)</sup> in 1965, the modulation of pain perception performed by TENS is attributed to the recruitment of afferent A $\beta$  fibers in the posterior horn of the spinal cord, which would prevent or hinder the activation of fine fibers which lead to pain<sup>(10)</sup>. It is postulated that electrical stimulation through the skin would inhibit the transmissions of painful impulses through the spinal cord and stimulate the release of endogenous opioids by the brain<sup>(11)</sup>. The device used in the study (Tanyx®) produces a conventional TENS current, characterized by continuous stimulation with high frequency (85 Hz), with a 75  $\mu s$  wave duration and up to 30 mA intensity, with the potential to achieve painless paresthesia in the painful region or a tingling sensation<sup>(12)</sup>.

Thus, this study aims to evaluate the applicability of TENS as a complementary treatment method to non-opioid analgesics of acute postoperative pain in patients undergoing surgical treatment due to ankle fractures. We hypothesized that the use of TENS in the postoperative period is directly related to the reduction of pain and the use of opioid drugs.

#### Methods

This study was submitted under the number (CAAE 01563518.0.0000.5488) and approved by the Institution Research Ethics Committee under the number 4,011,157.

A prospective, randomized, analytical, cross-sectional study conducted after orthopedic surgery in ankle fractures Weber A, B, and C, to collect information about patients' perception of postoperative pain. Participants were selected according to the following inclusion criteria: age between 15 and 71 years, diagnosed with ankle fractures. In addition, patients allergic to dipyrone and/or tramadol, outside the age group described, with diseases and/or conditions that contraindicated the use of TENS, who abandoned the postoperative follow-up, who did not accept the proposed treatment, patients with extensive skin lesions and those who did not accept to participate in the research by signing the Informed Consent Form were excluded from the study. The patients underwent surgery from November 2019 to August 2020. Twenty-nine (51.8%) on the right side and 27 (48.2%) on the left side.

Two groups (n=56) were randomized as follows:

Group 1 (Intervention n=28) - TENS and non-opioid analgesic (dipyrone);

Group 2 (Control n=28) - non-opioid analgesic (dipyrone).

All patients were followed up in the immediate postoperative period within 48 hours. TENS was applied to the dermatomes related to the access route used at a distance of approximately 10 cm from the surgical incision. Therefore, if two access routes for osteosynthesis were performed, two devices were used in the dermatome corresponding to the route. TENS was used for up to 30 minutes with continuous stimulation with a frequency of 85 Hz<sup>(12)</sup>, sufficient time for pain relief at an intensity already pre-determined by the device that provides three options L (low), M (medium), and H (high). Our study used the H (high) intensity in all cases. There is no restriction on the number of daily applications<sup>(13)</sup>.

In case of intense pain and non-responsive to TENS and non-opioid analgesic medications, opioid analgesics, such as tramadol 100mg, were allowed as a rescue medication. The same was done in the control group.

A structured questionnaire was developed to evaluate the following criteria: Visual Pain Scale (6h, 12h, 36h, 48h postoperative (PO), time of TENS for 30 minutes (Immediate PO, 12h, 24h, 36h, 48h), comorbidities (Diabetes mellitus, Systemic Arterial Hypertension (SAH), Gout, Rheumatoid Arthritis, Dyslipidemia, and others), sex, weight, laterality of the operated limb, classification of fracture according to Weber (A, B or C), access pathway (lateral, medial, lateral and medial, posterior or other associated pathways), prescription of dipyrone 2mL + BW EV every 6h (6h, 12h, 18h, 24h, 30h, 36h, 42h, 48h PO), prescription of tramadol 100mg + 100mL SS 0.9% EV every 8h if the pain is exacerbated (8h, 16h, 24h, 32h, 48h PO) and evaluation of the physical examination.

Initially, all variables were analyzed descriptively. For quantitative variables, this analysis was performed by observing the minimum and maximum values and calculating means, standard deviations, and quartiles. Absolute and relative frequencies describe categorical variables.

The Student t-test was used to compare the means of two  $groups^{(14)}$ .

The chi-square test  $^{(14)}$  or Fisher's exact test  $^{(14)}$  was used to test the homogeneity between the proportions.

For groups' comparison throughout the evaluations, the non-parametric Mann-Whitney and Friedman tests with Bonferroni correction were used<sup>(14)</sup>.

The software used for the calculations was SPSS 17.0 for Windows.

The significance level used for the tests was 5.0%.

#### Results

Fifty-six patients aged between 15 and 71 years (mean of 39.93 with a standard deviation of 16.50 and median of 36) were evaluated.

Thirty-two (57.1%) patients were male, and 24 (42.9%) were female.

Figure 1 shows the descriptive values of weight, height, and Body Mass Index (BMI).

Figure 2 shows the patients' frequency distribution according to the BMI classification.

Most patients (80.4%) did not present any comorbidity or use of medications. Table 1 shows the absolute and relative frequencies of comorbidities and medications.

Considering the Weber classification for ankle fracture, 65.5% of the cases were classified as Weber B. Figure 3 shows the patients' frequency distribution according to the Weber classification.

Regarding the access routes, 51.8% of the cases had two incisions, one lateral and one medial, followed by the group with only lateral incisions (33.9%). Figure 4 shows the patients' frequency distribution according to the access route.

Patients were divided into two groups: 28 (50.0%) received TENS (intervention group), and 28 (50.0%) were selected for the control group.

Two devices were used in 14 (50.0%) patients in the intervention group and one in 14 (50.0%).

The pain was evaluated using the Visual Analog Scale (VAS) at 6h, 12h, 36h, and 48h.

Table 2 shows the descriptive pain values for the 56 patients, and the values reduced as time passed.

Most patients (91.1%) received eight doses of dipyrone in 48 hours, and the distribution of tramal doses varied between 0 and 2 in 48 hours. Table 3 shows the doses of dipyrone and tramal that patients used for pain relief.



**Figure 1.** Descriptive values of weight, height, and BMI of the 56 patients.

BMI: Body Mass Index.



**Figure 2.** Patients' frequency distribution according to the BMI classification.

BMI: Body Mass Index.

Tables 4, 5, and 6 show the comparison of the two groups.

A certain homogeneity between the groups was observed. Table 4 shows the epidemiology and distribution of the variables analyzed between the groups.

For the pain study, significant differences were considered p<0.008 (use of Bonferroni correction: 0.05/6) (Table 5).

 
 Table 1. Absolute and relative frequencies of comorbidities and medications used by the 56 patients

Variable	n	%
Comorbidity		
No	45	80.4
SAH	8	14.3
Diabetes	5	8.9
Bipolarity	1	1.8
Asthma	1	1.8
Medication		
Does not use	45	80.4
Hydrochlorothiazide	3	5.4
Enalapril	3	5.4
Losartan	3	5.4
Metformin	3	5.4
Captopril	2	3.6
Amlodipine	2	3.6
Insulin	2	3.6
Lithium	1	1.8
Quetiapine	1	1.8
Glicazide	1	1.8
Salbutamol	1	1.8

SAH: Systemic Arterial Hypertension



**Figure 3.** Patients' frequency distribution according to the Weber classification.



Figure 4. Patients' frequency distribution according to the access route.

Table 2. Descriptive pain values at the time of evaluation

Moment	n	Mean	sd	Median	Minimum	Maximum
6 hours	56	5.02	2.76	5.00	0.00	9.00
12 hours	56	4.50	2.56	5.00	0.00	8.00
36 hours	56	3.46	2.83	3.00	0.00	10.00
48 hours	56	2.02	2.00	2.00	0.00	6.00

Table 3. Relative and absolute frequencies to the number of doses of dipyrone and tramal used for pain relief by the 56 patients

Table 4. Descriptive values of pre and intraoperative variables ac-
cording to the group

Verichle	Grou	-	
variable	Intervention (n=28)	Control (n=28)	p
Age	38.2+16.45	41.57+16.68	0.461(1)
Sex			0.105(2)
Female	9 (32.1%)	15 (53.6)	
Male	19 (67.9%)	13 (46.4%)	
BMI	27.51 + 2.73	26.92 + 6.84	0.674(1)
Comorbidity			
Absent	24 (85.7%)	21 (75.0%)	0.313(2)
SAH	3 (10.7%)	5 (17.9%)	0.705(3)
Diabetes	2 (7.1%)	3 (10.7%)	1,000(3)
Medication use	4 (14.3%)	7 (25.0%)	0.313(2)
Side			0.422(2)
Right	16 (57.1%)	13 (46.4%)	
Left	12 (42.9%)	15 (53.6%)	
Weber			0.885(3)
А	1 (3.7%)	1 (3.6%)	
В	17 (63.0%)	19 (67.9%)	
С	9 (33.3%)	8 (28.6%)	
Access			0.750(3)
Lateral	10 (35.7%)	9 (32.1%)	
Lateral + Medial	14 (50.0%)	15 (53.6%)	
Medial	3 (10.7%)	2 (7.1%)	
Posterior	1 (3.6%)	0 (0.0%)	
Posterior + Medial	0 (0.0%)	2 (7.1%)	

Descriptive level of probability of Student's t-test
 Descriptive level of probability of chi-square test
 Descriptive level of probability of Fisher's exact test

SAH: Systemic Arterial Hypertension; BMI: Body Mass Index

Number of doses	n	%
Dipyrone		
2	3	5.4
3	2	3.6
8	51	91.1
Tramal		
0	15	26.8
1	19	33.9
2	11	19.6
3	7	12.5
4	2	3.6
5	2	3.6

It was observed in the non-parametric Mann-Whitney test the groups did not present significant differences at 6 hours (p=0.360), 12 hours (p=0.797), and 48 hours (p=0.016). At 36 hours, the intervention group had a lower significant value when compared to the control group (p=0.004).

Friedman's non-parametric test showed that both groups presented significant changes in pain at the moments evaluated (p<0.001).

At 6 hours, there is a significant difference (p<0.001) compared to the results at 48 hours.

At 12 hours, there is a significant difference (p<0.001) compared to the results at 48 hours.

At 36 hours, there was no significant difference at 48 hours (p=0.100).

The control group was observed:

- At 6 hours, a significant value higher than 48 hours \_ (p<0.001).
- At 12 hours, a significant value higher than 48 hours (p=0.025).
- At 36 hours, a significant value higher than 48 hours -(p=0.025).

Figure 5 shows the pain score according to the moment of evaluation and the group.

Table 6 shows that the groups had no significant difference in the number of dipyrone doses.

Group	Moment	n	Mean	sd	Minimum	Maximum	P25	Median	P75
Intervention	6 hours(b)	28	4.68	2.88	0.00	9.00	2.00	5.00	7.00
	12 hours(b)	28	4.57	2.62	0.00	8.00	3.00	5.00	7.00
	36 hours(a)	28	2.39	2.42	0.00	9.00	0.00	2.50	4.00
	48 hours	28	1.36	1.68	0.00	6.00	0.00	0.50	2.00
Control	6 hours(b)	28	5.36	2.64	0.00	8.00	3.25	6.00	8.00
	12 hours(b)	28	4.43	2.54	0.00	8.00	3.00	5.00	6.00
	36 hours(b)	28	4.54	2.83	0.00	10.00	2.25	5.00	6.75
	48 hours	28	2.68	2.11	0.00	6.00	0.00	3.00	4.75

Table 5. Descriptive values of pain according to the moment of evaluation and the group

Significant difference from the control group; (b) Significant difference at 48 hours.





**Table 6.** Absolute and relative frequencies of the number of doses of dipyrone and tramal used by patients, according to the study group

Number of docoo	Grou	*	
Number of doses	Intervention (n=28)	Control (n=28)	- p.
Dipyrone			1.000
2	1 (3.6%)	2 (7.1%)	
3	1 (3.6%)	1 (3.6%)	
8	26 (92.8%)	25 (89.3%)	
Tramal			0.045
0	11 (39.3%)	4 (14.3%)	
1	10 (35.7%)	9 (32.1%)	
2	6 (21.4%)	5 (17.9%)	
3	1 (3.6%)	6 (21.4%)	
4	0 (0.0%)	2 (7.1%)	
5	0 (0.0%)	2 (7.1%)	

The control group had a higher percentage of cases that used more than three doses of tramal when compared to the intervention group.

Most patients in the intervention group were administered fewer tramal doses when compared to the control group. Figure 6 shows the percentage of the number of doses of tramal according to the group.

# Discussion

It was observed that using TENS in postoperative cases of ankle fracture may contribute to minimizing the patients' pain since they used fewer rescue analgesics compared with the control group.

In this study, it was observed that all patients used the prescribed analgesics, alone or in combination, in the postoperative period. This practice is seen as a positive factor, as it helps reduce pain during hospitalization and as an adjuvant in reducing infectious processes and hospitalization costs; in addition to reducing the incidence of readmissions<sup>(15,16)</sup>, reducing morbidity and mortality, and providing a faster start of physiotherapy rehabilitation and earlier ambulation<sup>(17)</sup>.

Tramadol is the second drug prescribed according to the pain scale described by the World Health Organization<sup>(18)</sup>, is widely used in the orthopedic field in the control of moderate pain<sup>(19)</sup>, and may or may not be associated with adjuvant drugs<sup>(20)</sup>, as performed in this study.

Therefore, tramadol was used by most patients undergoing surgical treatment. However, this rescue opioid was used in 60.7% of the patients in the intervention group and 85.6% in the control group. Compared with the control group, the number of patients who used three or more doses of tramadol reduced significantly in the intervention group. In 39.3% of the patients in the intervention group, no rescue opioid dose was used, while in the control group, only 14.3% did not use tramadol. Another positive point when comparing the groups is the reduction of tramadol doses in the intervention group; therefore, the potential for side effects triggered using opioids such as nausea, vomiting, sweating, fatigue, sedation, and dry mouth. More severe side effects include angioedema, increased anticoagulant effects, and serotonin toxicity<sup>(21)</sup>.



**Figure 6.** Percentage of the number of doses of tramal according to the group.

Lauretti et al.<sup>(22)</sup> demonstrated in a study with 44 patients with cervical pain that there was a reduction in analgesics with the introduction of TENS to control pain, also demonstrating an improvement in comfort and well-being after using this technology.

Hess and Bonaca<sup>(23)</sup> demonstrated in a study with 42 patients that the use of TENS indicated a benefit of 46% in the initial distance covered by individuals with claudication due to peripheral arterial obstructive disease, indicating, once again, that this type of stimulation causes an improvement in the quality of life of patients<sup>(23,24)</sup>. The results of this study reinforce some data found in the literature and may be related to the decrease of the painful threshold since it acts as an opioid sparer in the postoperative follow-up; thus, the lower use of these analgesics considerably reduces their adverse effects, improving treatment adherence and quality of life of patients<sup>(25)</sup>. Furthermore, such adverse effects<sup>(21)</sup> were evaluated in a meta-analysis on knee osteoarthritis, which indicated that patients receiving opioids were more likely to give up treatment<sup>(25)</sup>.

As seen in these studies, TENS has its role in pain control as an adjunct in the multimodal treatment of pain processes and also contributes to the decrease in the use of analgesic opioids.

The same was demonstrated in a study in patients undergoing surgical treatment for hallux valgus, and the group that underwent neurostimulation received fewer opioids for pain control<sup>(26)</sup>.

Parseliunas et al.<sup>(27)</sup> used TENS in the acute postoperative period of inguinal hernia with an improvement of the painful condition and decreased opioids in the group that used it.

Lauretti et al.<sup>(28)</sup> demonstrated TENDS's efficacy in reducing pain in patients with fibromyalgia with improved results when two devices are applied simultaneously at different sites such as the cervical and lumbar spine. The same author also reported pain improvement in patients with dysmenorrhea and cramps using TENS devices<sup>(29)</sup>.

## Conclusion

This study demonstrated the applicability of TENS as a complementary treatment method to non-opioid analgesics of acute postoperative pain in patients undergoing surgical treatment due to ankle fractures and observed that the TENS in the postoperative period is directly related to reducing the use of opioid drugs.

There was a reduction in the use of opioids in the intervention group compared to the control group.

Given the results, using TENS may be another safe option to control postoperative pain and reduce the use of opioids.

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