

ARTIGO ORIGINAL**Effect of transcutaneous electrical nerve stimulation (TENS) for the management of postoperative surgical pain after lower extremity amputation: a pilot study****Efeito da estimulação elétrica nervosa transcutânea (TENS) no tratamento de dor pós-cirúrgica após amputação de membro inferior: estudo piloto***Aleksandar Djurovic¹, Dejan Ilic, Zorica Brdareski¹, Aleksandra Plavsic¹, Slavisa Djurdjevic, Gordana Lukovic***ABSTRACT**

Introduction: Transcutaneous electrical nerve stimulation (TENS) is a noninvasive, nonmedical modality. There are a lot of dilemmas and opposing attitudes regarding the use of TENS in pain management after lower limb amputations. **Objective:** To establish the role of TENS for the management of postoperative surgical pain after lower limb amputations. **Material and methods:** Randomized controlled trial, which included forty-six subjects who had undergone lower limb amputations, randomly divided into control and treatment group. The control group received standard postoperative care, whereas the treatment group received standard postoperative care plus TENS. Forty subjects successfully completed the study according to the study protocol. The majority of the individuals had undergone transtibial amputation due to complication of diabetes. Five TENS XL-A1 portable devices with four self-adhesive electrodes were used. This was the conventional TENS mode, characterized by the delivery of electrical impulses with a duration of 200 microseconds, frequency of 110 Hz, and amplitude of 44V. Treatment was carried out for 2 hours a day, during 10 days. The evaluation of TENS efficacy was performed using the horizontal VAS (0-100 mm). Student T test was used in the statistical analysis. **Results:** Pain intensity was significantly diminished in both groups at the tenth in comparison with the first postoperative day. There were no significant differences between the control (VAS = 4.18±1.48) and the treatment group (VAS= 3.59±1.44) according to the daily mean pain intensity (t = 1.25; df =38). Pain intensity on the tenth postoperative day was significantly lower in the treatment (VAS = 1.65± 0.80) when compared with the control group (VAS = 3.2± 1.15; t = 5; df = 38; p< 0.01). **Conclusion:** Conventional TENS (dose: 200 microseconds, 110 Hz, 44V), administered two hours a day during ten days, significantly reduced postoperative surgical pain in twenty subjects who had undergone lower limb amputations.

KEYWORDS

transcutaneous electric nerve stimulation, amputation, pain, postoperative

RESUMO

Introdução: A estimulação elétrica nervosa transcutânea (TENS) é uma modalidade não-médica e não-invasiva. Há muita controvérsia e atitudes contrárias em relação ao lugar que a TENS ocupa no tratamento da dor após amputação de membro inferior. **Objetivo:** Avaliar o papel da TENS no tratamento de dor cirúrgica pós-operatória após amputação de membro inferior. **Material e métodos:** Teste controlado randomizado, conduzido com 46 indivíduos submetidos à amputação de membro inferior, que foram aleatoriamente divididos em grupo controle e grupo tratado. O grupo controle recebeu cuidados-padrão no pós-operatório; o grupo tratado recebeu cuidados-padrão e aplicação de TENS. Quarenta indivíduos completaram efetivamente o estudo de acordo com o protocolo de estudo. A maior parte das amputações consistiu de amputação transtibial devido a complicações da diabete. Foram utilizados cinco dispositivos portáteis Ultima TENS XL-A1 com eletrodos auto-adesivos. Esta é a aplicação convencional da TENS, caracterizada pela aplicação de impulsos elétricos com a duração de 200 microssegundos, frequência de 110 Hz e amplitude de 44 V. O tratamento foi administrado durante 10 dias, 2 horas por dia. A avaliação da eficácia da TENS foi feita utilizando-se a escala visual analógica (EVA) horizontal (0-100 mm). O teste

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t de Student foi usado na análise estatística. Resultados: A intensidade da dor estava significativamente diminuída em ambos os grupos no 10º dia em comparação ao 1º dia de pós-operatório. Não houve diferenças significantes entre o grupo controle (EVA = 4,18±1,48) e o grupo tratado (EVA = 3,59±1,44), de acordo com a intensidade média diária da dor ($t = 1,25$; $df = 38$). A intensidade da dor no 10º dia de pós-operatório foi significativamente menor no grupo tratado (EVA = 1,65±0,80) versus o grupo controle (EVA = 3,2±1,15; $t = 5$; $df = 38$; $p < 0,01$). Conclusão: A TENS convencional (dose: 200 microssegundos, 110 Hz, 44 V), administrada 2 horas por dia, durante 10 dias, significativamente reduziu a dor cirúrgica pós-operatória em 20 indivíduos com amputação de membro inferior.

PALAVRAS-CHAVE

estimulação elétrica transcutânea do nervo, amputação, dor pós-operatória

INTRODUCTION

Transcutaneous electrical nerve stimulation (TENS) is a noninvasive, nonmedical modality. It is the most frequently used electrotherapy for producing pain relief.¹ TENS mean the application of controlled low-voltage electrical pulses to the nervous system by passing electricity through the skin via electrodes placed on the skin. It is easy to administer and has few side-effects and no drug interactions. There is no potential for overdose or toxicity. Patients can administer TENS themselves and titrate the dosage of treatment. TENS is cheap when compared with long-term drug therapy. Its effects can be subdivided into analgesic and non-analgesic effects. It is using for relief acute as well as chronic pain. Acute postoperative pain is important indication for analgesic effects of TENS.^{1,2}

The incidence of major amputations, in the USA for example, is estimated to be at least 70 000 cases annually. Prevalence is estimated to be over 500 000 cases of major amputation.³ Approximately 70% of lower extremity amputations in adults are the results of complications of diabetes and peripheral vascular disease. Most of these amputations occur in people age 60 years and older.⁴ With the increasing trend in the incidence of limb loss, there is a growing interest for the better treatment and rehabilitation of amputees.⁵ The postoperative management after lower extremity amputations implies the rigid removal dressing, application of immediate postoperative prosthesis, soft or semi rigid postoperative dressing, pain management, treating of skin complications and other complications. The pain after lower extremity amputations can be subdivided into postoperative surgical pain, phantom limb pain (PLP), phantom sensation, and the pain caused by tumor or vascular disorders.⁶ Esquenazi divides this pain into post surgical pain, residual limb pain, prosthetic pain, and phantom pain.⁷

There are a lot of dilemmas and contrary attitudes in regard to place of TENS in the pain management after lower extremity amputations. Most of the authors emphasize a benefit of using TENS in treatment of post amputation pain: especially for treatment of PLP.^{3,6,8, 9,10} However, there are authors who do not suggest administration of TENS in this condition.^{4,11,12} Gnezdilov et al,¹³ for example, have found only 25% of 24 patients with PLP who had

completely relieved pain after TENS administration. Hanley et al¹⁴ have found that TENS was “not at all helpful” in 60,3% of 101 patient with PLP. Similarly, there are no overall acceptable attitudes in regard to TENS administration in the postoperative surgical pain. There is practical guideline for the management of post-operative pain.² TENS was suggested as an effective adjunct for providing postoperative pain control. Toward this guideline TENS can facilitate movement and exercise by decreasing pain perception and improved physical functioning. Thorsteinsson¹⁵ asserts that TENS can be important adjunct to the management of pain in elderly patients. Linchitz et al¹⁶ consider TENS as the important adjunct method for all types of musculoskeletal pain. Beside this, there are some rehabilitation authorities who do not mention TENS for the management of postoperative surgical pain.^{4,6,12}

Esquenazi, writing about management of acute post surgical pain after extremity amputation, suggests galvanic and electrical stimulation. But it was not specific. What kind of electrical stimulation? What mode of transcutaneous electrical nerve stimulation? What about of dose of this treatment? There are many reports in a literature about effect of TENS in the acute post surgical pain conditions.^{1,17,18} We found only one report of TENS administration in the acute post surgical pain after major amputation.¹⁹

AIM OF THE STUDY

The aim of this study was to ascertain the role of TENS for the management of postoperative surgical pain after lower extremity amputations.

MATERIALS AND METHODS

This was randomized controlled trial. Forty six inpatient subjects from The Military Medical Academy at Belgrade, Serbia, were recruited to participate in this study. Potential subjects were asked if they were willing to volunteer for a research study looking at a treatment for the management of postoperative surgical pain after lower extremity amputations. Inclusion criteria were as follows: male or female patients between the ages of 30 and 90 with lower extremity amputation; preserve mental capability measured by mini mental state exam; complains of pain that rated at least 3 of 10 on a visual analog scale (VAS), at first postoperative day. All amputation etiologies were included in this study. Exclusion criteria included a history of epilepsy and/or a pacemaker as well as a severe heart disease, because the use of TENS is not indicated in these patients population.¹

Subjects were randomly assigned into a control group or a treatment group. The control group received the standard of care treatment after lower extremity amputation. This involved soft dressing, positioning of the stump, early mobilization, exercise therapy and administration of nonsteroidal anti-inflammatory drugs (diclofenac sodium – Diklofenak, one or two amp. per day) as indicated. The treatment group continued to receive the standard of care in addition to their assigned TENS parameter for 2 hour a day, 10 days. TENS therapy started at first postoperative day. The

treatment group received conventional TENS using the high frequency, low intensity mode. This mode is characterized by delivery of electrical impulses having duration 200 microseconds, frequency 110 Hz and amplitude 44 V. This mode was selected towards the manufacturer's suggestions and in the direction of attitudes of some rehabilitation authorities.^{1,10}

Five TENS XL-A1 (Manufacturer "Tens Care", England) units were purchased for this study. This is the portable units with four self-adhesive electrodes. Subjects were educated regarding the proper use of TENS and the proper application of electrodes. The education entailed verbal instruction and demonstration by the therapist. Electrodes were applied on the healthy skin in the proximally parts of the stump, over the main nerve trunk arising from the site of pain.

The evaluation of efficacy of TENS for the management of postoperative surgical pain after lower extremity amputation was performed using horizontal VAS (0-100 mm). All study subjects were educated regarding the use of the VAS scale. Subjects were instructed to record their pain at the same time every day to control for the degree of pain. Subjects were asked to view the scale and state the number that best represents his or her present level of pain. The scale ranges from 0 to 10, with 0 being no pain and 10 the worst possible pain. All subject rated their pain once a day, starting from the first postoperative day. Student T test was used in statistical analysis. We accepted $p < 0,05$ for the level of significance.

RESULTS

Forty subjects successfully completed the study according to the study protocol. Six of the 46 subject who were recruited initially withdrew from the study, died, or did not complete the study according to protocol. Of these 6 subjects, three were in the control group, and three were in the treatment group. Of these 3 subjects in control group two died, and one was withdrawn because of lack of protocol compliance. Of these 3 subjects in treatment group one died, one had contra lateral leg ischemia and one was withdrawn because of lack of protocol compliance. Of the 40 subjects who completed the study, 20 were in control group and 20 were in the treatment group. Most of the subjects in both group had transtibial amputation caused by complication of diabetes. No subjects reported complications or issues associated with the study. Two subjects in the treatment group had mild erythema after the first and the second application of TENS.

Evaluating the initial comparability between groups, it was found that the two groups not differ significantly from each other (Table 1.)

There were no significantly differences between control group (VAS=5,0±2,0) and treatment group (VAS=5,95±1,98) according to the pain intensity (t=1,39; df=38) at the first postoperative day (Fig 1.).

Pain intensity was significantly diminished in both group at the tenth day versus the first postoperative day (Fig 1.)

There were no significantly differences between control group (VAS=4,18±1,48) and treatment group (VAS=3,59±1,44) according

Table 1
Clinical characteristics of subjects

Clinical characteristics	Control group (X ± SD;%)	Treatment group (X ± SD;%)	t	p
AGE	67,5 ± 15,0	70,9 ± 9,85	0,82	ns.
SEX				
- males	14 (70)	15 (75)	0,21	ns.
- females	6 (30)	5 (25)		
MINI MENTAL SCORE	26,0 ± 2,73	25,8 ± 3,18		
LEVELS OF AMPUTATIONS				
- partial foot	3 (15)	1 (5)		
- transtibial	13 (65)	12 (60)		
- transfemoral	5 (25)	7 (35)		
CAUSE OF AMPUTATION				
- complications of diabetes	15 (75)	14 (70)		
- other	5 (5)	6 (6)		
Student t-test				

to the daily mean pain intensity (t=1,25; df=38). (Fig 2.)

Pain intensity at the tenth postoperative day was significantly lower in treatment group (VAS=1,65±0,80) versus in control group (VAS=3,2±1,15; t=5; df=38; $p < 0,01$). (Fig 3.)

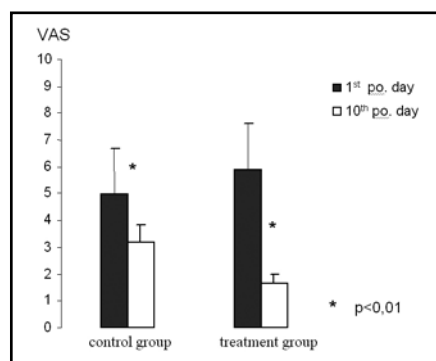


Figure 1
Pain intensity in both group at the first and the tenth postoperative day

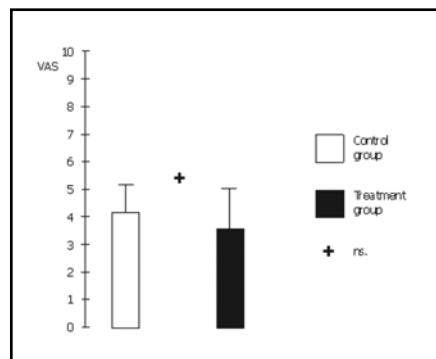


Figure 2
Daily mean VAS scores: control versus treatment group

DISCUSSION

The results of this study indicate that TENS significantly reduced postoperative surgical pain after lower extremity amputations in the patient population sampled. In the tenth postoperative day, pain intensity in treatment group was significantly lower in regard to control group. But, in the both group pain was significantly lower in the tenth day in regard to the first postoperative day. We can ascribe this to influence of postoperative care and administration of nonsteroidal anti-inflammatory drugs. Besides many dimensions of pain, average pain intensity is first component of the pain experience.²⁰ There were no significant differences between groups according to the daily mean pain intensity. Thus, TENS only contributed that postoperative pain would be significantly diminished after limited period of time. The question is: would be pain significantly lower in treatment group at the end of the third postoperative week for example? Post surgical pain is the sharp, localized pain experienced by the patient at the surgical site in the postoperative period, generally one to three weeks following the amputation.⁷ The subjects in both groups described pain as not only sharp, but pricking, aching and cramping pain. These are characteristics of cutaneous and muscle pain.²¹ This pain was moderate on the average, according to the VAS score. The post surgical pain is to be expected as part of surgical trauma to bone, nerve, and soft tissues and is usually self-limited. It will be gradually resolving as edema decreases and the amputation wound heals. According to our results, TENS significantly contributed to this self-limitation of pain after lower extremity amputations.

There are several theories of alternating the perception of pain by TENS. The gate control theory states that stimulation of non-nociceptors or their axons can interfere with the relay of sensation from nociceptors to higher centers in the brain where pain is perceived. TENS stimulates sensory A fibers with high-frequency stimulation. These impulses flood the pathway to the brain and close the "gate" to transmission of pain thus managing the pain threshold. TENS can produce neuromodulation by three routes: presynaptic inhibition of the spinal cord; direct inhibition of an excited, abnormally firing nerve or restoration of afferent input.^{22,23,24} Stimulation of sensory nerves with TENS causes release of the opiates, which minimize the perception of pain.^{25,26}

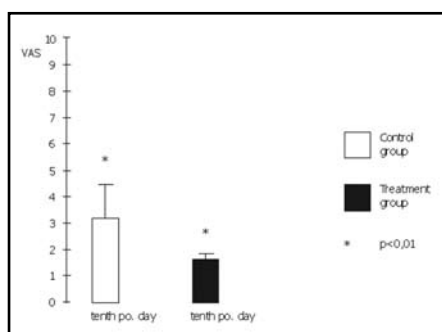


Figure 3

Pain intensity in the tenth postoperative day: control versus treatment group

Vasodilatation induced by TENS alters the ischemic area by enhancing blood flow, reducing the pain response.²⁷ There is theory relates to acupuncture, which is based on energy lines and entry points. Stimulating these points, TENS affects the flow of energy and altering the condition causing pain.²⁸ We think that the gate control theory best represents the affect of TENS on patients with postoperative surgical pain after lower extremity amputations. Additionally, TENS probably affected on the blood flow, improving of edema resorption, diminishing of inflammation and accelerating of wound healing.

We can not completely compare our results with results of other authors. They have treated different acute pain conditions by TENS or they have used different TENS modes or different research protocols in the same contrition.¹⁸ Finsen et al¹⁹ studied the effects of TENS on stump healing and postoperative and late phantom pain in the sample of 51 subjects with major amputation of the lower limb. They compared three different protocols: sham TENS and chlorpromazine medication, sham TENS only, and active low frequency TENS. They found no significant differences in the analgesic requirements or reported prevalence of phantom pain between groups during the first four weeks. In this randomized controlled trial the authors, contrary to us, did not establish any significant effects of TENS. Placebo controlled clinical trials should be used to determine absolute effectiveness of treatment so that the effects due to active ingredient (TENS) can be isolated from the effects associated with the act of giving the treatment. In this sense, Carroll et al. demonstrated the impact of using non-randomized trials in determining TENS effectiveness; 17 of 19 non-randomized controlled trials (non-RCTs) reported that TENS had a positive analgesic effect, whereas 15 of 17 randomized controlled trials (RCTs) reported that TENS had no effect for postoperative pain.¹ But, we agree with Johnson,²⁹ who says that we should be careful in accepting the findings of the systematic reviews on TENS and postoperative pain without further scrutiny.

Our results are in accordance with the attitudes of many authors.^{8,9,10,24,30} But these results must be accepted with some reserve. This was RCT but not placebo RCT. Pain is multidimensional phenomenon. There is the impact of patient motivation on the pain intensity.³¹ We can not exclude influence of self-suggestion on the rating of pain intensity in the treatment group. Besides the fact that VAS is good clinical tool for estimation of pain,^{23,26} it can not enclose all of its dimension.³¹

The results of this study relate specifically to the conventional TENS parameter; that is high- frequency, low-intensity mode. Additional studies looking at other TENS parameters for pain modulation could be explored.

CONCLUSION

Conventional TENS (dose: 200 microseconds, 110 Hz, 44 V), administered two hour a day in ten days, significantly reduced postoperative surgical pain in twenty subjects with lower extremity amputation.

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