

Effects of transcutaneous electrical nerve stimulation on pain in patients with spinal cord injury: a randomized controlled trial

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Abstract. [Purpose] To investigate the effects of transcutaneous electrical nerve stimulation (TENS) on pain in patients with spinal cord injury. [Subjects and Methods] Fifty-two spinal cord injury patients with central pain were randomly allocated into two groups TENS and control with 26 subjects per group. The patients in TENS and control groups were treated with TENS and sham TENS for 20 min (three times a week) for 12 consecutive weeks, respectively. The two group's pain was assessed using visual analog scale (VAS) and the McGill Pain Questionnaire (including pain rating index-total, pain rating index-affective, pain rating index-sensory, present pain intensity, and number of words chosen) before and after the treatment. [Results] After the intervention, we found significant differences in VAS, pain rating index-total, pain rating index-affective, pain rating index-sensory, present pain intensity, and number of words chosen between the TENS group and the control group. [Conclusion] Our results suggest that TENS effectively decreases pain in patients with spinal cord injury.

Key words: Transcutaneous electrical nerve stimulation, Pain, Spinal cord injury

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INTRODUCTION

Pain is a common and serious problem in patients with spinal cord injuries (SCI), and it may have negative effects on quality of life¹⁾. SCI patients with severe pain have difficulty in performing daily activities and participating in social events. A recent survey²⁾ showed that 77.7% of SCI patients have moderate or severe pain and pain interference with function and health status is significantly high among the subjects with more severe pain. Moreover, in the USA, the total annualized cost due to pain is \$26,270 (direct cost: \$8,636, indirect cost: \$17,634) per SCI patient.

Different drugs are used to relieve pain in SCI patients³⁾. However, all medications have potential side effects and some are serious⁴⁾. Electrotherapy, a noninvasive and inexpensive technique, is being used by an increasing number of physical therapists to treat pain in SCI patients. Transcutaneous electrical nerve stimulation (TENS) is mostly used in electrotherapy methods to relieve pain. Many studies have shown that TENS is effective for a wide variety of pain, e.g. cancer pain⁵⁾, neuropathic pain⁶⁾, and low back pain⁷⁾.

TENS is a safe therapeutic intervention with few or no associated side effects for most people. Many clinical

papers have reported the positive effects of TENS in pain management, but controversy exists over the treatment conditions for TENS and the appropriate parameters of its use^{8, 9)}. Furthermore, a few randomized controlled trials have focused on TENS for relieving pain to determine its therapeutic effect on SCI patients. If TENS were shown to be an effective method of alleviating pain in SCI patients, it would decrease medical costs and improve quality of life.

We conducted this study to determine the efficacy of a 12-week TENS treatment versus sham TENS treatment on the pain intensity of SCI patients. We hypothesized that TENS treatment would greatly reduce pain intensity compared to sham TENS.

SUBJECTS AND METHODS

Subjects

The SCI patients ($n = 52$) were recruited from the Department of Orthopedic Surgery and Rehabilitation Medicine, Shanghai Kaiyuan Orthopedics Hospital in Shanghai, China. None of the SCI patients had previously received TENS treatment. A computer-generated random-number sequence was used to assign the patients to either the TENS group ($n = 26$; mean age \pm SD, 35.5 ± 9.0 years) or to the control group ($n = 26$; mean age \pm SD, 33.6 ± 8.5 years). The inclusion criteria were: over 18 years old; suffering from pain; and diagnosed as having SCI. The exclusion criteria were previous treatment with TENS or pain evoked by specific conditions or pathologies, such as urinary infection, severe spasticity, or a pressure ulcer.

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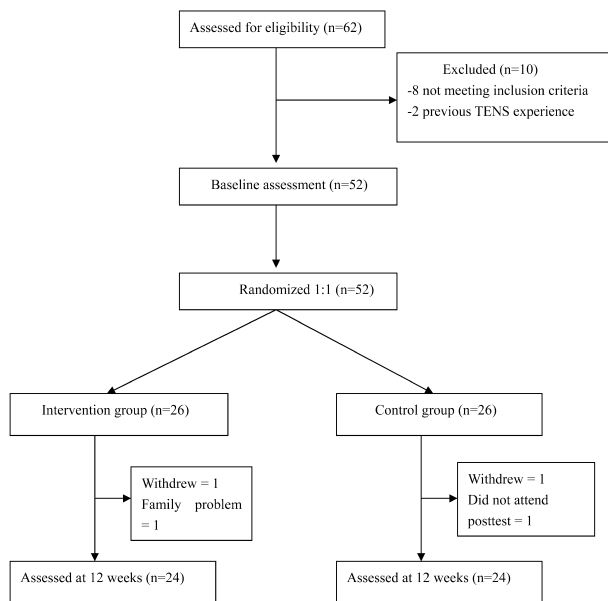


Fig. 1. Flow diagram showing the study protocol

Prior to the study, all patients completed a questionnaire on their personal details, including age, sex, and medical history. Informed consent was obtained from all subjects prior to their inclusion in the study. This study was approved by the Ethics Committee of the Shanghai Kaiyuan Orthopedics Hospital, China.

Methods

The SCI patients were treated with TENS using a PHYSIOMED machine (PHYSIOMED-Expert, Physiomed Elektromedizin, Germany). Two electrodes were placed on the region with pain. The patients in the TENS group were treated with TENS for 20 min three times a week for 12 weeks. The treatment parameters of TENS were as follows: pulse frequency, 2 Hz; pulse duration, less than 200 ms; and pulse amplitude, 50 mA. The patients in the control group were treated with sham TENS (electrodes were placed but no stimulation was given) for 20 min three times a week for 12 weeks. All TENS applications in each group were conducted by the same licensed physiatrist. We ensured that the treatment parameters of the machine were not changed by the patients.

The measurement of pain intensity was administered by the main research assistant who was blinded to the group allocation before and after the treatment. The McGill Pain Questionnaire (MPQ)¹⁰ is a self-report questionnaire used to assess the pain intensity of SCI patients. A higher MPQ score indicates a more serious pain. The quantitative data of the MPQ used in this study included the Pain-Rating Index-Total (PRI-T; score 0 to 78), the PRI-Affective (PRI-A; score 0- to 14), the PRI-Sensory (PRI-S; score 0 to 42), the present pain intensity (PPI, score 0 to 5), and the number of words chosen (NWC; range 0 to 20). Visual analog scale (VAS)¹¹ was also used to evaluate pain intensity. VAS uses a 100-mm horizontal line marked from 0 to 10 from left to right, with zero representing “no pain”, and 10 representing

Table 1. Baseline values of the two groups

Variable	TENS group (n=26)	Control group (n=26)	p value
Male/Female	17/7	15/9	*
Age (years)	35.5 ± 9.0	33.6 ± 8.5	#
Duration of SCI (months)	7.0 ± 4.1	6.8 ± 3.1	#
Type of injury			
Complete injury (n)	15	18	*
Incomplete injury (n)	11	8	
Level of injury			
Tetraplegia (n)	10	7	*
Paraplegia (n)	16	19	

Data reported as mean ± SD. SCI: spinal cord injury; TENS: transcutaneous electrical nerve stimulation. * χ^2 test ($p > 0.05$); # t test ($p > 0.05$)

the “worst possible pain”. Subjects marked the point on the line that represented their perception of their current state. The amount of pain that patients feel ranges across a continuum from none to an extreme amount of pain.

SPSS 17.0 and Microsoft Excel 2007 software were used to perform statistical analyses. Data are expressed as the mean ± standard deviation. The independent samples t-test and the χ^2 test were used to compare the two groups at the baseline. Two-way repeated measures ANOVA (group × time) was used to compare the MPQ and VAS outcomes of the TENS group with those of the sham TENS group. The paired t-test was used to compare the changes in the measurement values within the groups when the ANOVA result was significant. Statistical significance was accepted for values of $p < 0.05$.

RESULTS

The study design is outlined in Fig. 1. Ten of the 62 initially recruited patients were deemed ineligible to participate in the study, eight patients did not meet the inclusion criteria, and two patients had previous TENS experience. A total of 48 patients completed the 12 weeks of treatment. Four patients (TENS group $n = 2$, control group $n = 2$) were lost to follow-up because of illness or withdrawal. Table 1 presents the baseline characteristics of the two groups. The groups were well matched at the baseline assessment and showed no apparent differences in the key outcome variables.

Table 2 shows the pain outcomes before and after the TENS intervention. After the intervention, there was a significant difference in the pain severity scores (VAS, PPI-T, PRI-S, PRI-A, PPI, and NWC) of the TENS and control groups ($p < 0.05$).

DISCUSSION

This randomized controlled study aimed to prove that TENS treatment is effective at relieving the pain of SCI patients. Based on the VAS, PPI-T, PRI-S, PRI-A, PPI, and NWC outcomes, our results suggest that 12 weeks of TENS

Table 2. Pain outcomes before and after the intervention

Variable	TENS group (n=24)		Control group (n=24)	
	Pre	Post	Pre	Post
VAS score	5.17 ± 2.34	2.14 ± 0.91	5.56 ± 2.07	3.87 ± 1.45 *
PPI-T	38.82 ± 7.24	20.28 ± 5.77	36.51 ± 6.69	28.34 ± 5.94 *
PRI-S	23.27 ± 6.61	7.05 ± 2.34	22.78 ± 5.38	12.14 ± 4.69 *
PRI-A	7.98 ± 1.82	2.74 ± 1.01	7.55 ± 1.69	4.81 ± 1.39 *
PPI	3.67 ± 0.92	1.87 ± 0.52	3.14 ± 0.66	2.58 ± 0.73 *
NWC	9.21 ± 2.54	5.82 ± 1.35	8.97 ± 2.33	7.19 ± 2.11 *

Data reported as mean ± SD. NWC: number of words chosen; PPI: present pain intensity; PRI-A: pain rating index-affective; PRI-S: pain rating index-sensory; PRI-T: pain rating index-total; TENS: transcutaneous electrical nerve stimulation; VAS: visual analogue scale; *: $p < 0.05$, two way analysis of variance

relieves the pain of SCI patients. Our results also show that pain was significantly relieved in the TENS group unlike in the control group. The results demonstrate that TENS treatment demonstrate beneficial effects for SCI patients.

TENS is a simple and non-invasive analgesic treatment, which is extensively used by physiotherapists¹². TENS is mainly used to relieve acute and non-malignant chronic pain. The mechanism of TENS in pain relief is not well understood; however, gate control theory provides the most widely accepted explanation of the mechanism¹³. Gate control theory postulates that the pain gate can be closed by the activity of large diameter A β afferents, preventing the transmission of noxious information. The closed pain gate results in low noxious information reaching the brain from the spinal cord, decreasing the sensation of pain. Therefore, the aim of TENS interventions is to activate A β fibers using electrical currents.

Our results are consistent with those of previous studies^{14, 15} which reported the effectiveness of TENS in the pain relief of SCI patients. Celik et al.¹⁴ assessed the effects of TENS treatment versus sham TENS on pain intensity. A total of 33 SCI patients with pain were enrolled in their study, and the patients were randomly assigned to the TENS and control groups. The TENS group was treated with 30 min of TENS and the control group with 30 min of sham TENS, daily for 10 days. Celik et al. reported that TENS effectively relieved the pain of SCI patients. A limitation of their study was the treatment period (only 10 days). In our study, SCI patients were treated with TENS for 20 min three times a week for 12 weeks. Another study¹⁵ reported the effects of TENS on 24 SCI patients with pain. The results revealed the positive effect of TENS on the pain of SCI patients. However, a control group was not included in that study. In contrast, we conducted this study to determine the efficacy of a 12-week TENS treatment versus sham TENS treatment on the pain intensity of SCI patients.

Our study had several limitations. First, the sample size of the subjects was insufficient for generalization of the re-

sults. Second, a follow-up was not performed, and finally, we did not compare the efficacy of low frequency TENS with that of high frequency TENS or any other electrotherapy because of the limited number of subjects.

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