

Immediate effect of transcutaneous electrical nerve stimulation on spasticity in patients with spinal cord injury

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Objective: To investigate the immediate effect of transcutaneous electrical nerve stimulation (TENS) on spasticity in patients with spinal cord injury.

Design: Randomized controlled trial.

Setting: Extended rehabilitation centre.

Subjects and intervention: Eighteen subjects with spinal cord injury and symptoms of spasticity over lower limbs were randomly assigned to receive either 60 minutes of active TENS (0.25 ms, 100 Hz, 15 mA) or 60 minutes of placebo non-electrically stimulated TENS over the common peroneal nerve.

Outcome measures: Composite Spasticity Score was used to assess the spasticity level of ankle plantar flexors immediately before and after TENS application. Composite Spasticity Score consisted of Achilles tendon jerks, resistance to full-range passive ankle dorsiflexion and ankle clonus. Between-group statistical differences of reduction of Composite Spasticity Score, Achilles tendon jerks, resistance to full-range passive ankle dorsiflexion and ankle clonus were calculated using the Mann-Whitney test. Within-group statistical differences of Composite Spasticity Score, Achilles tendon jerks, resistance to full-range passive ankle dorsiflexion and ankle clonus were calculated using the Wilcoxon signed ranks test.

Results: Significant reductions were shown in Composite Spasticity Score by 29.5% ($p=0.017$), resistance to full-range passive ankle dorsiflexion by 31.0% ($p=0.024$) and ankle clonus by 29.6% ($p=0.023$) in the TENS group but these reductions were not found in the placebo TENS group. The between-group differences of both Composite Spasticity Score and resistance to full-range passive ankle dorsiflexion were significant ($p=0.027$ and $p=0.024$, respectively).

Conclusion: This study showed that a single session of TENS could immediately reduce spasticity.

Introduction

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Spasticity can cause pain,¹ contractures,² impairment of ambulation,³ and restrictions in activities of daily life.^{1,3} Transcutaneous electrical nerve stimulation (TENS) has been used to reduce

spasticity in patients with stroke,⁴⁻⁷ which enables stretching, mobility training and functional training to take place.

It is believed that TENS to peripheral sensory nerves may reduce spasticity in patients with spinal cord injury by modulating abnormal spinal inhibitory circuits.^{8,9} Previous studies have demonstrated that high-frequency TENS to the common peroneal nerve in patients with spinal cord injury can have a short-term effect in reducing spasticity as revealed by the reduction of the Achilles tendon reflex¹⁰ and knee extensors spasticity found by relaxation index in the pendulum test.¹¹ However, these studies were limited by the absence of a placebo control group and small sample size. Further studies are needed to investigate the effectiveness of TENS for controlling the spasticity of spinal cord injury using randomized, placebo-controlled trials.

The objective of the present study was to determine whether TENS could have an immediate effect on reduction of spasticity in patients with spinal cord injury by studying the change of spasticity of ankle plantarflexors immediately after applying high-frequency TENS to the common peroneal nerve that supplies the ankle dorsiflexors.

Methods

Subject selection

Subjects were recruited from a local rehabilitation hospital. They were inpatients undergoing spinal cord injury rehabilitation programme (Figure 1). The local ethics committee approved the study protocol.

Subjects were included if they met the following inclusion criteria: (1) spasticity over lower limb(s) caused by spinal cord injury; (2) between 18 and 80 years of age; (3) having the return of ankle jerk indicating the recovery from spinal shock.¹²

Subjects were excluded if they had: (1) a cardiac pacemaker; (2) metal implants in the affected leg; (3) severe cognitive impairments or severe aphasia; (4) history of other neurological disorder; (5) unstable medical conditions; (6) skin problems underneath the electrodes; (7) no tolerance for surface stimulation; (8) pain in both lower limbs; or (9) previous experiences with TENS therapy.

Baseline characteristics

At baseline the following data were collected: gender, age, duration post-spinal cord injury and injury characteristics, type of anti-spasticity medications prescribed, the level of spinal cord injury, and American Spinal Injury Association (ASIA) score.¹³ Details of ASIA score are shown in the appendix.

Sample size

By using Composite Spasticity Score as the outcome measure, the effect size of TENS for managing the spasticity of patients with spinal cord injury was calculated from the study conducted by Goulet *et al.*¹⁰ The sample size of the present study was estimated with computer software PASS (Window Version, NCSS Statistical Software, USA). It was estimated that nine subjects per arm are needed to achieve 84% power to detect significant between-group differences using an *F* test at a significance level of 0.01.

Intervention

The skin was cleaned by 75% alcohol before two surface electrodes were attached over the common peroneal nerve posterior to the head of the fibula. TENS stimulation was given to the limb with dominant spasticity as assessed by Composite Spasticity Score or decided by tossing a coin if the level of spasticity was the same in both limbs.

A PRO-TENS (Unilax, TE-2000, USA) machine with zero net direct current charge and square carbon-rubber electrodes (4.5 cm × 5 cm) was used to apply TENS stimulation in both groups. The pulse-width control and pulse-frequency control knobs were permanently fixed by adhesive tape at 0.25 ms and 100 Hz, respectively. The electrical intensity of the TENS stimulators were calibrated by the Electrical and Mechanical Services Department of the Government of the Hong Kong Special Administrative Region. The intensity control knobs were permanently fixed by adhesive tape to make sure the output was 15 mA, with the resistance at 680 ohm and a brand new 9 V battery. In healthy subjects it has been found that 15 mA is twice the average

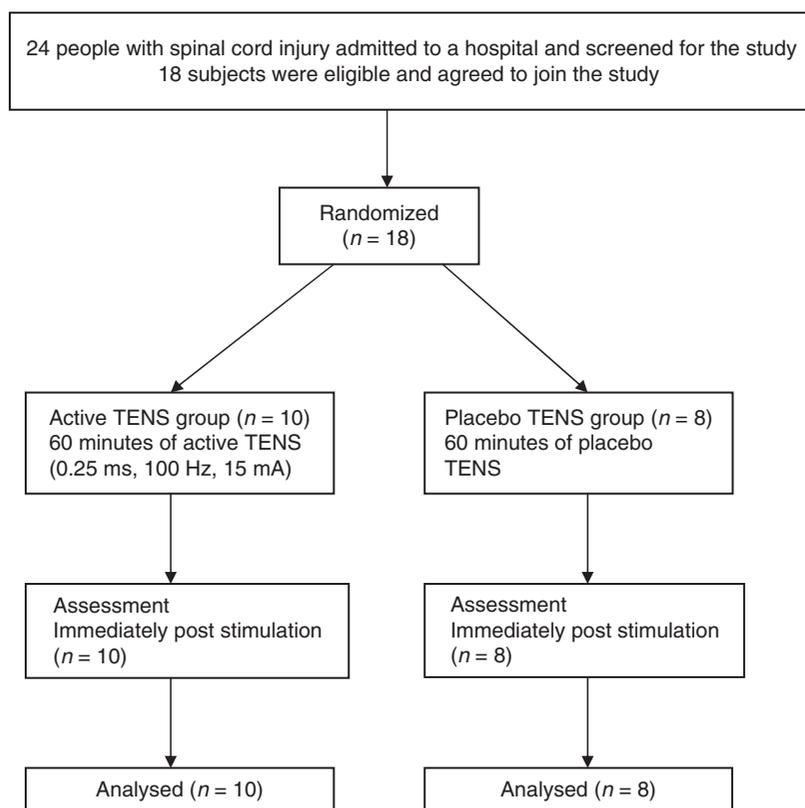


Figure 1 Consort flowchart of the study.

perceptual threshold to sensation of TENS stimulation.¹⁰

The settings for the TENS stimulators for both active TENS and placebo TENS groups were the same except the battery placement. The TENS stimulator was switched on with the battery in the right position for the active TENS group and switched off with the battery in a reversed position for the placebo TENS. For the active TENS group, the intensity of stimulation delivered by the TENS stimulator was 15 mA with pulse-width of 0.25 ms and pulse frequency of 100 Hz for 60 minutes. No muscle contraction, especially the peroneal muscle group, should be elicited. Subjects in the placebo TENS group received 60 minutes application of non-electrically stimulated TENS. Both groups were instructed to relax and informed that they may or may not feel any sensation associated with the stimulation.

Outcome measures

Composite Spasticity Score was used to assess the spasticity of the ankle plantarflexors.⁶ The test-retest reliability of the instrument (intraclass correlation coefficient = 0.87) in rating the spasticity of hemiplegic subjects was established.⁵ Composite Spasticity Score consisted of three scores: Achilles tendon jerks, resistance to full-range passive ankle dorsiflexion, and ankle clonus. The Achilles tendon jerks was assessed with a 5-point scale, where 0 indicates no response and 4 indicates maximally hyperactive response. The resistance to full-range passive ankle dorsiflexion at a moderate speed was assessed on a modified double weighted 5-point Ashworth Scale,¹⁴ where 0 indicates no resistance and 8 corresponds to maximally increased resistance. Ankle clonus was scored on a 4-point scale where 1

denotes clonus not elicited and 4 represents denote sustained clonus.

Randomization and blinding

Two physiotherapists conducted the study, one of them being the investigator and the other one the assistant. Their roles were unchanged throughout the study. Simple randomization was performed by using fair coin-tossing before the subjects joined the study by the assistant¹⁵ who was not allowed to change the results of the tosses. The subject allocation results were then concealed in a password-protected personal computer by the assistant and released to the investigator after the data analysis of the study was completed.

After the spasticity of the ankle was measured using the Composite Spasticity Score, square carbon-rubber electrodes were attached to the calf of the subjects by the investigator. The subjects were approached by the assistant who connected the leads to the TENS stimulator according to the result of the coin tossing in the absence of the investigator. The TENS stimulator was either switched on with the battery in the right position for the active TENS group, or switched off with the battery in a reverse position for the placebo TENS group. The TENS stimulator was kept in a non-transparent locked box to blind the subjects. When the study sessions were over, the TENS stimulators was turned off by the assistant, who also examined the skin conditions over the stimulation sites for any unusual changes. After that, the assistant left the treatment room and took the TENS stimulators away with him. The subjects were then reassessed by the investigator using the Composite Spasticity Score.

Data analysis

The percentage change of Composite Spasticity Score, Achilles tendon jerks, resistance to full-range passive ankle dorsiflexion and ankle clonus were obtained by deducting the initial score from the final score and dividing by the initial score for each measurement. Between-group differences of initial Composite Spasticity Score, Achilles tendon jerks, resistance to full-range passive

ankle dorsiflexion, ankle clonus and ASIA score were calculated using the Mann–Whitney test. Within-group statistical differences of Composite Spasticity Score, Achilles tendon jerks, resistance to full-range passive ankle dorsiflexion and ankle clonus were calculated using the Wilcoxon signed ranks test. The between-group differences of the demographic data were calculated using independent sample *t*-test. A *p*-value of less than 0.05 denoted the presence of a statistically significant difference. The statistical tests were conducted by SPSS 8.0 (Windows Student Version, SPSS Inc, Chicago, IL, USA).

Results

Eighteen subjects fulfilled the entry criteria for the study. Ten subjects were randomly allocated to the active treatment group and eight to the placebo group. During the entire study period, no subjects withdrew or dropped out. Thus, all the patients were evaluated. At baseline, there was no statistically significant difference between the two groups with respect to age, period post the spinal cord injury, and any of the variables measured in our study to evaluate outcome with treatment, suggesting similar disease severity in both treatment groups. All subjects could determine the leg with more severe level of spasticity using the Composite Spasticity Score. Eleven subjects were studied on the right leg and seven subjects were studied on the left leg. All of the subjects had spasticity, with half of them taking medication for spasticity control (Table 1). Four of the subjects had complete spinal cord injury (ASIA score A) while the rest had incomplete spinal cord injuries (ASIA scores B–D). Details of the ASIA score are listed in the appendix.

One of the subjects from the active TENS group had a sacral sore which was treated with skin-flap and healed before joining the study. One subject from the placebo TENS group had urinary tract infection which subsided one week before joining the study.

The total decrease in clinical spasticity assessed by Composite Spasticity Score after 60 minutes of active TENS stimulation was statistically significantly (reduction in Composite Spasticity

Score = 29.5%, $p = 0.017$). No such reduction was found in patients receiving placebo stimulation (reduction in Composite Spasticity Score = 1.1%, $p = 0.705$). The magnitude of reduction in Composite Spasticity Score of active TENS group was statistically larger than that in the placebo group (difference in reduction of Composite Spasticity Score = 28.4%, $p = 0.027$) (Tables 2 and 3).

Among the component scores of Composite Spasticity Score, statistically significant reduction were observed in resistance to full-range passive ankle dorsiflexion (reduction = 31%, $p = 0.024$) and ankle clonus (reduction = 29.6%, $p = 0.023$) only. In contrast, none of the component scores of placebo group were reduced significantly. However, statistically significant differences between the component scores of active and placebo groups was only demonstrated in the resistance to full-range passive ankle dorsiflexion score (difference in reduction of resistance to full-range passive ankle dorsiflexion = 31%, $p = 0.034$).

Resistance to full-range passive ankle dorsiflexion score could reflect the muscle tone of soleus muscle which is a reliable assessment of the tonic component of spasticity.¹⁶ This suggested that active TENS could be more effective in reducing the tonic component of spasticity than the placebo TENS.

At study entry, the patients were instructed not to change their basic therapeutic regimen for the duration of the study, but they were not forbidden from doing so. During the entire study period, no patient in either group changed their dosage of baclofen, which is a commonly used anti-spasticity drug.

The only side-effect noted in this study was mild skin irritation with erythema in three patients, which resolved spontaneously within 1 hour after removing the electrodes. It is believed that the erythema was the result of dilatation of skin blood capillaries induced by electrical stimulation.¹⁷ This phenomenon is commonly seen after TENS therapy.¹⁸

Table 1 The baseline characteristics of the subjects

Age (year)	Gender	Aetiology	Weeks post SCI	ASIA score	Injury level	Leg receiving TENS	Anti-spasticity drug	Complications ^a
Active TENS								
51	Male	Trauma	10	C	C4	Left	Baclofen	Nil
39	Male	Trauma	50	B	C6	Right	Tizanidine and Baclofen	Nil
36	Male	Trauma	7	C	C6	Right	Baclofen	Nil
51	Male	Trauma	98	A	C7	Right	No	Nil
44	Male	Trauma	4	D	C4	Left	No	Nil
38	Female	Trauma	104	B	T3	Left	Baclofen	Nil
59	Male	Myelopathy	20	D	C6	Left	Baclofen	Nil
77	Female	Myelitis	192	C	T6	Right	No	Sacral sore
69	Male	Trauma	84	D	C5	Right	No	Nil
33	Male	Trauma	10	A	T4	Right	No	Nil
Placebo TENS								
67	Male	Trauma	30	C	C5	Left	Baclofen	Urinary tract infection
40	Male	Trauma	36	B	C6	Right	Baclofen	Nil
24	Male	Trauma	20	A	T6	Right	Baclofen	Nil
82	Female	Myelopathy	8	D	C3	Right	No	Nil
37	Male	Trauma	4	D	C6	Right	No	Nil
55	Male	Trauma	364	D	T12	Left	Baclofen	Nil
45	Male	Trauma	6	A	C5	Right	No	Nil
73	Female	Pathological fracture	4	C	T4	Left	No	Nil

No significant difference between the study groups in age and weeks post injury.

^aComplications include pressure sore, urinary tract infection, heterotopic ossification, joint contracture.

Discussion

The results of this study showed that a statistically significant reduction of spasticity developed in the lower limbs of patients with spinal cord injury in the active treatment group but not in the patients who received placebo TENS stimulation.

TENS therapy systems vary significantly in methods of application, size and shape of electrode, and type of waveform used. This makes comparison of studies based on TENS treatment notoriously difficult.¹⁹ Comparative analysis is further complicated by the fact that there is no standardized treatment protocol for TENS, and no study has managed to investigate systematically the dose–response to spasticity relief provided by

electrical stimulation.²⁰ Previous trials have shown that TENS may have a role in reducing spasticity in the lower limbs of patients with spinal cord injury.^{10,11} However, these studies did not evaluate the efficacy of TENS with randomized controlled trials. In view of that, the current study was implemented with a placebo control group. It was found that significant reduction of spasticity ($p < 0.05$) observed in active TENS group was not observed in the placebo group. This indicated that 60 minutes of active TENS stimulation (0.25 ms, 100 Hz, 15 mA) may have an effect on reducing spasticity in patients with spinal cord injury. However, the accumulative effects of TENS stimulation on the spasticity of patients with spinal cord injury remained unanswered by this study.

Patients with spinal cord injury usually encounter spasticity in their lower limbs. Although some patients utilize this spasticity to maintain muscle tone and some use it to assist them in transfer and ambulatory activities, it can also cause pain and dysfunction.² Therefore, clinical decisions for spasticity treatment in patients with spinal cord injury should be made with caution. Spasticity should only be treated if the patient may have a significant improvement in function and/or quality of life after the treatment. The subjects recruited in the current study had developed different degrees of spasticity in their plantar flexors. This could make stretching of the calf muscles difficult and result in muscle tightness which in turn dampens the progress of functional training such as gait re-education. In fact, half of the patients were

Table 2 The between-group differences of the baseline characteristics

	Active TENS group (n=10)	Placebo TENS (n=8)	p-value ^a
Age (year)	49.7 ± 14.8	52.9 ± 19.9	0.657
Weeks post SCI	57.90 ± 61.5	59.00 ± 123.9	0.305
Initial CSS	10.50 ± 1.51	11.63 ± 1.77	0.147
Initial ATJ	2.00 ± 1.15	2.88 ± 0.64	0.081
Initial RFPAD	5.80 ± 1.48	6.25 ± 1.28	0.489
Initial AC	2.70 ± 0.67	2.50 ± 0.93	0.476

Values are means ± standard deviations.

^aMann–Whitney test.

SCI, spinal cord injury; CSS, Composite Spasticity Score; ATJ, Achilles tendon jerk; RFPAD, resistance to full-range passive ankle dorsiflexion; AC, ankle clonus.

Table 3 Comparison of spasticity measurements

Score	Active TENS group (n=10)			Within-group p-value	Placebo TENS group (n=8)			Within-group p-value	Between-group p-value
	Initial	Final	% change		Initial	Final	% change		
CSS	10.50 ± 1.51	7.40 ± 2.84	29.5	0.017**	11.63 ± 1.77	11.50 ± 1.93	1.1	0.705	0.027*
ATJ	2.00 ± 1.15	1.50 ± 1.08	25.0	0.102	2.88 ± 0.64	2.75 ± 0.71	4.5	0.317	0.515
RFPAD	5.80 ± 1.48	4.00 ± 1.63	31.0	0.024**	6.25 ± 1.28	6.25 ± 1.28	0.0	1.000	0.034*
AC	2.70 ± 0.67	1.90 ± 0.88	29.6	0.023**	2.50 ± 0.93	2.50 ± 0.76	0.0	1.000	0.122

Values are means ± standard deviations.

CSS, Composite Spasticity Score; ATJ, Achilles tendon jerk; RFPAD, resistance to full-range passive ankle dorsiflexion; AC, ankle clonus.

* $p < 0.05$ by Mann–Whitney test.

** $p < 0.05$ by Wilcoxon signed ranks test.

receiving medication for spasticity control (Table 1). It was therefore believed that the subjects recruited in the current study may benefit from TENS stimulation.

The Composite Spasticity Score was used as the outcome measurement in this study. Although it was originally developed for the measurement of spasticity in hemiplegic patients,⁵ it is also applicable for measuring spasticity in patients with spinal cord injuries. The nature of spasticity elicited by spinal cord injuries is similar to that induced by stroke; both of them involve lesions to upper motor neurons.²¹ The Composite Spasticity Score targets three major domains of spasticity in the ankle joint (i.e. Achilles tendon jerks, resistance to ankle dorsiflexion, and ankle clonus). Hyperactive Achilles tendon reflexes and clonus are included in this measurement tool as they provide extra information on the phasic component of the stretch reflex²² which is not addressed by commonly used measurement tools of spasticity such as the Modified Ashworth Score.²³

Theoretically, the action of TENS in reducing spasticity over the lower limbs post spinal cord injury could be mediated by two mechanisms: modulation of spinal inhibitory circuits^{4,5,8,9,24} and stimulation of the plasticity of the central nervous system.⁶ Pain and spasticity are interrelated in patients with spinal cord injury.²⁵ It is possible that spasticity of patients with spinal cord injury could be reduced after pain treatments.²⁶ However, it could be difficult to quantify pain in patients with spinal cord injury, as some of the patients may have complete loss of sensation below their waist. To standardize, patient without pain in their lower limbs were recruited in the present study. In practice, the mechanisms underlying the clinical effects observed in this and other studies remain largely unclear.

Based on the criteria outlined by Jadad *et al.*,²⁷ the methodological quality of the present study was considered adequate. However, some methodological limitations should be noted. First, the sample size was relatively small which may increase the risk of type II error, although great effort was put into subject recruitment for the current study. The success of subject blinding was not examined as was emphasized by some authors who considered this process important for double-blinded trials.^{27,28} However, there is no

consensus on how to examine the success of blinding in randomized controlled trials.^{29,30} In the present study, the use of subjects who had had no TENS therapy before and individual treatment policy may help to maintain subject blinding. Due to the limitation of resources, the randomization and treatment were performed by the same investigator. The assignment of each subject was established just before each subject received the treatment. This should be just the same as when the assignment sequence was established previously as the assistant was not allowed to change the results of the coin-tossing.

In conclusion, 60 minutes of high-frequency and low-intensity TENS stimulation applied to the nerve supplying the ankle dorsiflexors achieved a significant reduction of spasticity of the ankle plantar flexors. This improvement was not observed in the placebo TENS group. This study provided evidence that TENS could immediately and effectively relieve clinical spasticity in subjects with spinal cord injury. Future studies with a larger sample size investigating the long-term effects of TENS on reducing spasticity in patients with spinal cord injury are warranted.

Clinical message

- Evidence from the present study showed that active TENS is more effective in reducing spasticity of the affected leg in patients with spinal cord injury than placebo TENS.

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Competing interests

None.

Author contribution

Bryan Ping Ho Chung was the principal investigator responsible for study design and data analysis of the study as well as writing up the manuscript. Benson Kam Kwan Cheng was involved in data analysis and writing up the manuscript.

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Appendix – American Spinal Injury Association (ASIA) scores

A	Complete:	No motor or sensory function is preserved in the sacral segments S4–S5
B	Incomplete:	Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4–S5
C	Incomplete:	Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3
D	Incomplete:	Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more
E	Normal:	Motor and sensory functions are normal

Source: American Spinal Injury Association: International Standards for Neurological Classification of Spinal Cord Injury, revised 2000; Atlanta, GA. Reprinted 2008.