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A pilot study of neuromuscular electrical stimulation for neuropathic pain caused by spinal cord injury

Fu-chun Chen, MM[a], Hai-long Shao, MB[a], Feng-li Han, MB[b,*]

Abstract

This pilot study retrospectively investigated the feasible effect and safety of neuromuscular electrical stimulation (NMES) for the management of neuropathic pain (NPP) caused by spinal cord injury (SCI).

A total of 54 patient cases with NPP after SCI were included. Of these, 27 cases underwent carbamazepine plus NMES treatment, and were assigned to an NMES group; while the other 27 cases received carbamazepine only, and were assigned to a control group. The primary outcome of pain intensity was measured by numerical rating scale (NRS). The secondary outcome of quality of life was measured by the Short Form 36 (SF-36) Scale. Furthermore, adverse events were also documented in this study. All outcomes were measured and analyzed before and after 3-month treatment.

After 3-month treatment, the cases in the NMES group neither reduced the pain intensity of NPP, measured by the NRS ($P > .05$), nor improved the quality of life, measured by the SF-36 ($P > .05$), compared with cases in the control group. Moreover, both groups had similar adverse events.

The results of this study showed that NMES might be not efficacious for NPP caused by SCI after 3 months treatment with quite low intervention dose.

Abbreviations: NMES = neuromuscular electrical stimulation, NPP = neuropathic pain, NRS = numerical rating scale, SCI = spinal cord injury, SF-36 = the Short Form 36.

Keywords: acute stroke, effect, neuromuscular electrical stimulation, wrist dysfunction

1. Introduction

Neuropathic pain (NPP) is considered to be one of the most challenging issues after spinal cord injury (SCI).[1–4] It has been reported that NPP often impacts quality of daily life in patients with SCI.[5] The prevalence rates for NPP following SCI are very high, with overall prevalence rates of 53%, at-level NPP of 27%, and below-level NPP of 27%, respectively.[6]

Despite a wide range of treatment options is available for the treatment for such condition, it is still difficult for patients with NPP after SCI to achieve sufficient pain relief.[3] These treatment strategies included pharmacotherapy, such as tricyclic antidepressants, Calcium channel α2δ ligands, serotonin-noradrenalin reuptake inhibitor, tramadol–acetaminophen combination formulation, antiepileptic agents, topical capsaicin, and Chinese herbal medicines; physical therapy, including the transcranial direct current stimulation, acupuncture, and laser therapy; as well as the behavioral therapeutic intervention.[7–13] It is also reported that evidence from clinical trials indicates that only one third patients experienced 50% pain reduction.[14]

Neuromuscular electrical stimulation (NMES) is supposed to be one of the most potential effective alternative candidates to treat this condition. It has been reported that NMES can help to reduce a variety of pain conditions, such as back pain, shoulder pain, wrist pain, knee pain and so on.[15–18] However, no study has reported using NMES for the management in patients with NPP after SCI. Thus, in this pilot study, we retrospectively explored the feasible effect of NMES for the treatment of patients with NPP following SCI.

2. Methods

2.1. Design

This study was approved by the Ethical Committee of The Fourth People's Hospital of Shaanxi. All included subjects provided the written informed consent. All cases of this study were conducted between April 2016 and November 2017 at the same hospital.

All 54 eligible patient cases diagnosed with NPP following SCI were included in this study. Of these cases, 27 were assigned to the NMES group, while the other 27 were assigned to the control group. All of these patients received carbamazepine (200 mg) with the maximum dose of 600 mg daily for a total of 3-month treatment. Additionally, patients in the NMES group also underwent NMES intervention for a total of 3-month therapy. After 3-month treatment, all outcome measurements were evaluated and analyzed.

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[a] Department of Spinal Surgery, [b] Department of Neurology, The Fourth People's Hospital of Shaanxi, Xi'an, Shaanxi, China.

[*] Correspondence: Feng-li Han, Department of Neurology, The Fourth People's Hospital of Shaanxi, No. 512 Xianning E Rd, Xincheng District, Xi'an, Shaanxi, 710043, China (e-mail: Fenglihan@163.com).

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2.2. Patients

A total of 54 eligible patients aged >18 years old with the confirmed diagnosis of NPP after SCI were included. All of them experienced NPP for more than one year. Additionally, all pain conditions were attributable to the SCI, and the pain intensity was more than 4 of numerical rating scale (NRS) scores (NRS≥4). Furthermore, patient cases were excluded if the patients had epileptic attacks, cardiac pacemaker, and psychiatric problems. In addition, the cases were also excluded if the patients had incomplete outcome data, and had received the NMES treatment 1 month before this study.

2.3. Treatment schedules

Patients in both groups received the carbamazepine (200 mg/per capsule), one capsule daily for the first 3 days, 2 capsules daily for the next 3 days, and 3 capsules 1 week later to the week 3, with the maximum dose of 600 mg daily. After that, the dose was gradually decreased, and then discontinued at the end of 3-month treatment.

Patients in the NMES group also received NMES treatment. It was applied by a portable NMES stimulator to the painful area (Globus ACTIVA 600 Pro, Globus, Italy) with 2 electrodes. It delivered frequency of 50 Hz, pulse duration of 250 μs, and 10 seconds on and 30 seconds off. The current intensity was gradually increased to the subject's maximum tolerance. Each painful area was treated for a total of 20 minutes, once daily, twice weekly for a total of 3 months.

2.4. Outcome measurements

The primary outcome of pain intensity was measured by NRS (ranging from 0, no pain to 10, worst pain).[19] The secondary outcome was quality of life. It was measured by the Short Form 36 (SF-36) Scale.[20] It included 8 subscales ranging from 0 to 100, with lower scores indicating poorer quality of life. Additionally, adverse events were also recorded in this study. All outcomes were measured and analyzed before and after 3-month treatment.

2.5. Statistical analysis

All the characteristic and outcome data were analyzed by using SPSS software (SPSS V.19.0, IBM Corp., Armonk, NY). Continuous data were analyzed by *t* test for normally distributed variables, and Mann–Whitney *U*-test for non-normally distributed variables. Categorical data were performed by Fisher's exact test. A value of $P < .05$ was adopted for the statistical significance.

3. Results

The characteristics of patient cases in both groups are shown in Table 1. No values of all characteristics differ between the 2 groups. These characteristics consisted of age, gender, injury reasons and location, the severity of injury, duration of NPP, and pain types.

After 3-month treatment, patients in the NMES group did not show better outcomes in NPP reduction, as measured by the NRS ($P > .05$, Table 2); as well as the improvement of the quality of life, as measured by the SF-36 scores ($P > .05$, Table 3), compared with patients in the control group.

Adverse events in both groups are summarized in Table 4. No serious adverse events occurred in both groups. No treatment related death was found in both group. No significant differences regarding all the adverse events were found between the 2 groups.

Table 1

Patients' characteristics of all included patients.

Characteristics	NMES group (n = 27)	Control group (n = 27)	*P* value
Age, years	41.8 (12.6)	43.5 (13.7)	.64
Sex			
Male	25 (92.6)	23 (85.2)	.85
Female	2 (7.4)	4 (14.8)	.40
Race (Asian Chinese)	27 (100.0)	27 (100.0)	–
Duration of NPP (months)	31.2 (11.5)	29.7 (10.8)	.62
Injury cause			
Traffic accident	20 (74.1)	23 (85.2)	.32
Falls	5 (18.5)	3 (11.1)	.45
Transverse myelitis	2 (7.4)	1 (3.7)	.56
Injury location			
Cervical	12 (44.4)	14 (51.9)	.59
Thoracic	13 (48.2)	10 (37.0)	.41
Lumbar	2 (7.4)	3 (11.1)	.64
ASIA Grade			
A	16 (59.3)	18 (66.7)	.57
B	3 (11.1)	2 (7.4)	.64
C	5 (18.5)	3 (11.1)	.45
D	3 (11.1)	4 (14.8)	.69
SCI type			
Tetraplegia	20 (74.1)	18 (66.7)	.55
Paraplegia	7 (25.9)	9 (33.3)	.55
At-level pain	21 (77.8)	22 (81.5)	.74
Below-level pain	6 (22.2)	5 (18.5)	.74
Pain intensity			
Average	6.1 (1.2)	5.9 (1.4)	.57
Moderate (4.0–6.9)	23 (85.2)	22 (81.5)	.72
Intense (7.0–10.0)	4 (14.8)	5 (18.5)	.72
SF-36			
Bodily pain	32.9 (11.4)	34.5 (10.7)	.59
Emotional performance	46.8 (18.9)	50.1 (19.1)	.52
Physical performance	34.8 (15.7)	36.5 (17.0)	.70
Physical function	31.9 (14.4)	33.2 (15.6)	.75
Social function	43.5 (20.1)	46.6 (23.4)	.60
General health state	50.4 (22.5)	53.0 (24.1)	.68
Mental health	56.7 (25.3)	54.4 (22.9)	.73
Vitality	61.1 (26.0)	58.8 (28.4)	.76

Data are present as mean ± standard deviation or number (%).
ASIA = American Spinal Injury Association, NPP = neuropathic pain, SCI = spinal cord injury, SF-36 = the Short Form 36.

4. Discussion

No study has specifically addressed to explore the effect and safety of NMES for patients with NPP following the SCI presently. To our best knowledge, this pilot study firstly

Table 2

Outcome measurements of pain intensity after 3-month treatment.

NRS	NMES group (n = 27)	Control group (n = 27)	*P* value
Average NRS score	5.2 (1.5)	5.7 (1.7)	.25
Mild (0–3.9)	4 (14.8)	0 (0)	.12
Moderate (4.0–6.9)	22 (81.5)	25 (92.6)	.24
Intense (7.0–10.0)	1 (3.7)	2 (7.4)	.56

Data are present as mean ± standard deviation or number (%)
NRS = numerical rating scale.

Table 3

Outcome measurements of quality of life after 3-month treatment.

SF-36	NMES group (n = 27)	Control group (n = 27)	*P* value
Bodily pain	50.3 (18.8)	45.9 (20.4)	.41
Emotional performance	60.2 (23.4)	57.7 (25.2)	.71
Physical performance	45.1 (19.3)	46.8 (21.5)	.76
Physical function	42.8 (20.7)	41.5 (19.8)	.81
Social function	53.0 (24.4)	54.2 (25.2)	.86
General health state	61.7 (26.0)	62.4 (25.6)	.92
Mental health	62.5 (27.2)	60.6 (25.1)	.79
Vitality	68.2 (30.3)	70.1 (32.4)	.82

Data are present as mean ± standard deviation
SF-36 = the Short Form 36.

Table 4

Comparison of adverse events between the 2 groups.

Adverse events	NMES group (n = 27)	Control group (n = 27)	*P* value
Exanthema	2 (7.4)	3 (11.1)	.64
Anorexia	3 (11.1)	1 (3.7)	.32
Nausea	1 (3.7)	2 (7.4)	.56
Vomit	0 (0)	1 (3.7)	.49
Dizziness	2 (7.4)	1 (3.7)	.56

Data are present as number (%).

retrospectively investigated the feasible effect and safety of NMES on this condition. Thus, it might provide helpful evidence for the future clinical practice to treat such condition, as well as the potential clues for the further studies on this issue.

The results of this study did not demonstrate that patients in the NMES group showed greater effectiveness in pain relief of NPP, measured by NRS, and quality of life improvement, as measured by the SF-36 score, when compared with the patients in the control group. It indicated that NMES might not benefit for the pain intensity reduction of the NPP, as well as the enhancement of quality of life in patients with NPP after SCI.

This pilot study has several limitations as below: The doses of NMES were twice weekly for a total of 3 months, which may be insufficient for patients with NPP after SCI. The outcome results were the combination of NMES and carbamazepine, but not the NMES alone, which may difficult to identify the effectiveness and safety of NMES alone in this study. The outcome assessment tools may be not comprehensive, because all outcome data were collected from the available completed patient cases in this retrospective study. This pilot study had an intrinsic limitation because of the retrospective study, which may increase the risk of selection. This retrospective study did not include a sham control intervention, which may result in negative results, although it already has concluded negative results.

5. Conclusion

This pilot study showed that NMES might not benefit for patients with NPP following SCI after 3 months treatment with quite low intervention dose.

Author contributions

Conceptualization: Fu-chun Chen, Hai-long Shao, Feng-li Han.
Data curation: Fu-chun Chen, Hai-long Shao, Feng-li Han.
Investigation: Hai-long Shao, Feng-li Han.
Methodology: Hai-long Shao.
Project administration: Feng-li Han.
Resources: Fu-chun Chen, Feng-li Han.
Software: Fu-chun Chen, Hai-long Shao.
Supervision: Feng-li Han.
Validation: Fu-chun Chen, Hai-long Shao, Feng-li Han.
Visualization: Fu-chun Chen, Hai-long Shao, Feng-li Han.
Writing – original draft: Fu-chun Chen, Hai-long Shao, Feng-li Han.
Writing – review & editing: Fu-chun Chen, Hai-long Shao, Feng-li Han.

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