Clinical Trial/Experimental Study

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Effectiveness of percutaneous neuromuscular electrical stimulation for neck pain relief in patients with cervical spondylosis

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Abstract

Background: This study aimed to evaluate the effectiveness and safety of percutaneous neuromuscular electrical stimulation (PNMES) for treating neck pain in patients with cervical spondylosis (CS).

Methods: One hundred and twenty four patients with neck pain of CS were included, and then they were randomly divided into a PNMES group and a control group in a ratio of 1:1. All patients received PNMES or sham PNMES 30 minutes daily, 3 times weekly for 12 weeks. The primary outcome was assessed by the visual analog scale (VAS). The secondary outcomes were evaluated by the cervical range of motion (ROM), neck disability index (NDI) score, as well as the adverse events (AEs). All outcome measurements were measured at the end of 12-week treatment, and 4-week follow-up after treatment.

Results: At the end of the 12-week treatment, and 4-week follow-up, the patients receiving PNMES exhibited more decrease in the mean VAS ($P < .01$), and NDI ($P < .01$) respectively, compared with the patients receiving sham PNMES. Additionally, the increase in the mean ROM was also significantly higher in the PNMES group than that in the sham PNMES group at the end of the 12-week treatment, and 4-week follow-up, respectively ($P < .01$). No AEs were found in either group.

Conclusions: The results of this study demonstrated that PNMES is more effective than Sham PNMES for neck pain relief in patients with CS.

Abbreviations: AEs = adverse events, CS = cervical spondylosis, DN = dry needling, NDI = neck disability index, PNMES = percutaneous neuromuscular electrical stimulation, ROM = range of motion, VAS = visual analog scale.

Keywords: cervical spondylosis, clinical trial, effect, neck pain, percutaneous neuromuscular electrical stimulation, safety

1. Introduction

Cervical spondylosis (CS) is a very common age-related chronic disc degeneration condition.[1–4] It often involves the unspecified degenerative changes of the muscles, tendons, joints, and bones of the neck and shoulder.[5–9] Many etiological factors can lead to this condition, including poor posture, anxiety, depression, neck strain, and sporting activities.[10–13] It mainly manifests with neck pain, neck stiffness, and sometimes accompanied by numbness and radicular pain in the shoulders, arms, and fingers. It is reported that the overall prevalence of neck pain ranges from 0.4% to 86.8%, and its incidence varies from 10.4% to 21.3% in a high-risk population.[14] For example, previous UK study reported that around two-thirds of adults experienced the neck pain at some time in their lives.[15] Other study in Hong Kong found that its prevalence was from 15% to 17%, and the lifetime prevalence was 30% to 50%.[16]

Presently, although a variety of treatments are available for neck pain relief of CS, such as nonsteroidal anti-inflammatory drugs,[17] physiotherapy,[18,19] analgesics,[20,21] among others, those therapies have limited efficacy in relieving neck pain and many of them are associated with cumbersome side effects. It has been reported that alternative medicine, such as acupuncture,[22] neck exercise,[18,23] percutaneous neuromuscular electrical stimulation (PNMES),[24] herbal medication,[25] and so on, has been widely used to treat neck pain of CS, and with few adverse events (AEs), or even without AEs. However, no randomized controlled trials focused to explore the effectiveness and safety of PNMES for neck pain relief in patients with CS.

In this study, we hypothesized that PNMES therapy for neck pain relief in patients with CS after 12 weeks of treatment would be superior to the effectiveness of sham PNMES intervention. Thus, we designed this double-blinded, randomized, sham-controlled trial to assess the effectiveness of PNMES therapy for neck pain relief in patients with CS.

2. Methods

2.1. Study design

A 2-arm, double-blinded, randomized, sham-controlled trial compared a PNMES group with a control group were consisted in this study. This trial was approved by the ethics committee of The People's Hospital of Yan'an and it was also conducted at the

Editor: Qinhong Zhang.

The authors report no conflicts of interest.

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Medicine (2018) 97:26(e11080)

Received: 18 March 2018 / Accepted: 18 May 2018

http://dx.doi.org/10.1097/MD.0000000000011080

same hospital from November 2014 to October 2016. One hundred and twenty-four patients with neck pain of CS were included and were randomly allocated to a PNMES group and a control group in a 1:1 ratio. The participants in the PNMES group were given PNMES, whereas the patients in the control group received sham PNMES at the same administration of treatment schedule as the PNMES group. The outcome measurements were assessed at the end of 12-week treatment, and 4-week follow-up after the treatment. All patients were required to provide written informed consent.

2.2. Patients

Patients were included with the following criteria: confirmed diagnosis of neck pain of CS according to the diagnostic criteria published by the *International Classification of Diseases, 10th edition* code: M47.812;[26] diagnosis of CS supported by a physical examination, and cervical radiographic examination, including anteroposterior and lateral x-rays, or magnetic resonance imaging/computed tomography scans; 18 to 70 years' old; have a history of neck pain longer than 3 months; and no PNMES or other related treatment has been received 1 month before the study. Exclusion criteria were previous history of neck trauma, cervical facture or surgery, congenital spinal abnormality, spinal tumor or cancer, and other systematic disease of the neck including bones and joints conditions, or other severe neurologic, psychiatric, kidney, digestive system disorders, and pregnancy.

2.3. Randomization and blinding

Randomization scheme was conducted by the computerized number generator with SAS package 8.2 (SAS Institute Inc., Cary, NC. Patients who met the inclusion criteria were allocated randomly into a PNMES group and a control group in a 1:1 ratio. The randomization sequence schedule of group assignments and detail interventions were prepared by a statistician, who was blinded in this study, and were sealed in opaque envelops. The allocations were masked to the patients, investigators, and data analyst and outcome assessors.

2.4. Intervention

Patients received either PNMES or sham PNMES at bilateral acupoints of Jing-jiaji (EX-B2.C4, on the back of the neck, 0.5 cun lateral to the lower border of each spinous process between the fourth and fifth cervical vertebras), Jing-jiaji (EXB2. C5, on the back of the neck, 0.5 cun lateral to the lower border of each spinous process between the fifth and sixth cervical vertebras), and Jing-jiaji (EX-B2.C6, on the back of the neck, 0.5 cun lateral to the lower border of each spinous process between the fifth and sixth cervical vertebras) by using the PNMES device (HANS-100, Nanjing Jisheng Medical Technology Co., Ltd) at a frequency of 2 to 100 Hz for 30 minutes each session, 3 sessions weekly for a total of 12 weeks. Each device had 2 gel pads attached to a silicon patch. The patch was attached to the painful area. The power was turned on in the PNMES group, whereas it was kept off in the control group. The starting time of PNMES and the pain intensity were recorded immediately after its application.

2.5. Outcome measurements

The primary outcome was measured by the visual analog scale (VAS). The secondary measurements included cervical range of motion (ROM), and neck disability index (NDI) score. A ROM tool was used to measure ROM of the cervical spine.[27,28] It consists of flexion, extension, right bending, left bending, right rotation, and left rotation. Pain intensity was measured by a 10-cm VAS scale, with 0 = "no Pain" and 10 = "the worst imaginable pain,"[29] and first section in the NDI (1–100). In addition, NDI was also used to evaluate the functional activity of neck.[30,31] All outcome measurements were evaluated at the end of 12-week treatment, and 4-week follow-up after the treatment. In addition, AEs were also recorded duration the period of treatment.

2.6. Statistical analysis

The data analysis was conducted by using SAS package 8.2 (SAS Institute Inc., Cary, NC). The sample size was calculated based on the designed detection of a between group difference of 2.19 mm in pain intensity of VAS score. It was calculated according to the results of a previous study, with 1.61 mm in the intervention group, and 2.99 mm in the control group.[32] The minimum size of each group was estimated at 54 patients with $\alpha = 0.5$, $\beta = 0.8$. Assuming a 15% drop-out rate, the required sample size of this study was therefore estimated to be 124 patients, with 62 assigned to each group. All outcome data were analyzed by intention-to-treat approach. *t* Test or Mann–Whitney rank sum test was used to analyze the continuous data. Pearson χ^2 test or Fisher exact test was used to analyze the categorical data. The statistical significance level was set at $P < .05$.

3. Results

The patient's selection process is shown in Figure 1. At first, 197 participants were entered and were screened the study (Fig. 1). Then, 73 patients were excluded because of the failure to meet inclusion criteria (n = 45), rejection to sign informed consent (n = 16), and meeting the exclusion criteria (n = 12). Thus, 124 patients were included in this study, and were randomly and equally divided into 2 groups. Nine patients withdrew from this study because of the consent withdrawal (n = 5), and moved to the other cities (n = 4) (Fig. 1).

The characteristics of all included patients in both groups are listed in Table 1. No significant differences regarding all characteristics were found between 2 groups (Table 2).

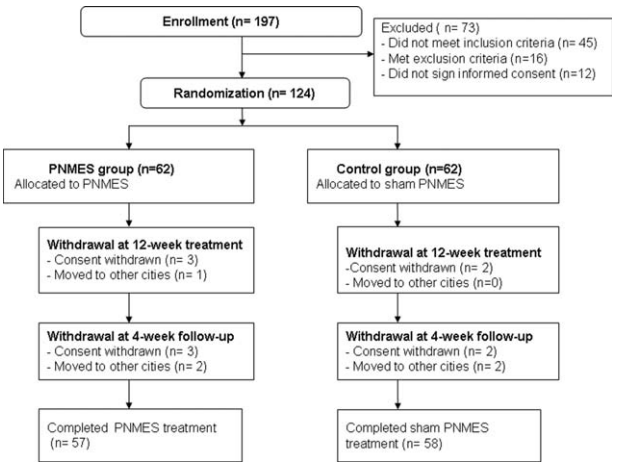

Figure 1. Flowchart of participants throughout the study.

Table 1

Comparison of patients characteristics at baseline.

Characteristics	PNMES group (n = 62)	Control group (n = 62)	P
Mean age, y	47.9 (15.3)	44.6 (14.8)	.23
Sex			
Male	36 (58.1)	33 (53.2)	.59
Female	26 (41.9)	29 (46.8)	.59
BMI, kg/m^2	26.3 (4.4)	26.2 (4.2)	.90
Duration of symptoms, mo	8.6 (2.2)	9.1 (2.5)	.24
VAS	6.1 (1.5)	6.3 (1.6)	.48
ROM			
Flexion	55.7 (25.2)	58.3 (27.5)	.59
Extension	64.2 (30.6)	67.1 (33.4)	.62
Right bending	38.5 (15.8)	40.1 (17.3)	.59
Left bending	42.8 (11.3)	46.2 (13.9)	.14
Right rotation	65.7 (28.7)	64.9 (30.1)	.88
Left rotation	68.4 (24.0)	65.7 (23.2)	.53
NDI	30.9 (14.3)	31.5 (15.1)	.82

Note: Data are present as mean ± standard deviation or number (%). BMI = body mass index, NDI = neck disability index, PNMES = percutaneous neuromuscular electrical stimulation, ROM = cervical range of motion, VAS = visual analog scale.

Results of the primary and secondary outcome measurements are shown in Table 2. At the end of the 12-week treatment, the patients in the PNMES group showed more decrease in VAS ($P < .01$) and NDI ($P < .01$) (Table 2), when compared patients in the control group. Additionally, it also demonstrated higher increase in ROM in patients receiving PNMES, compared with patients receiving sham PNMES ($P < .01$, Table 2). Furthermore, the significant differences were also found in VAS ($P < .01$), NDI ($P < .01$), and ROM ($P < .01$) at the end of 4-week follow-up after the treatment between 2 groups (Table 2). No AEs or side effects such as discomfort related to PNMES or sham PNMES intervention occurred in both groups during the period of the treatment and follow-up.

4. Discussion

Previous study investigated the immediate and short-term effects of the combination of the dry needling (DN) and percutaneous electrical nerve stimulation (PENS) compared to DN alone to treat the upper trapezius muscle.[24] It is designed as a 72-hour follow-up single-blinded randomized controlled trial and 62 subjects suffered from chronic myofascial neck pain with active myofascial trigger points in the upper trapezius muscle.[24] The results found that PENS combined with DN therapy was more effective than DN alone for reducing soreness in the short term and decreasing neck pain intensity immediately in patients with chronic neck pain.[24] The results of our study are consistent with this study. However, our study evaluated the effect of PNMES therapy with 12-week treatment and 4-week follow-up after the treatment.

The results of this study confirmed our hypothesis that PNMES intervention showed promising effectiveness for neck pain relief in patients with CS after 12-week treatment compared with sham PNMES intervention. To our knowledge, this study is the first double-blinded, randomized, sham-controlled trial that has been conducted among the Chinese population. It aimed to assess PNMES as an alternative therapy to treat neck pain of CS. Our results showed the encouraging effectiveness of PNMES therapy for neck pain relief in patients with CS.

The decrease in VAS and NDI was significantly greater for patients in the PNMES group compared with sham PNMES-treated patients. These results indicate the promising effect of PNMES for enhancing the symptoms of CS. Furthermore, this kind of intervention also appears encouraging for improving the ROM in patients with CS.

Although the promising effect of PNMES, this study still has 2 limitations. First, this study was conducted in only 1 center, which may impact the generalization of our results to the other hospitals. Second, this study failed to assess the comprehensive outcomes, such as the quality of life of patients in both groups.

5. Conclusion

This study found that PNMES can reduce neck pain in patients with CS effectively. However, further studies are still needed to warrant the present results.

Author contributions

Conceptualization: Yan-li Jin, Qiang Miao, Jian-hong Qiang.
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Table 2

Outcome measurements at the end of the 12-week treatment and 4-week follow-up.

Outcomes	12-Week treatment			4-Week follow-up		
	PNMES group (n = 62)	Control group (n = 62)	P	PNMES group (n = 62)	Control group (n = 62)	P
VAS	1.3 (0.5)	3.8 (1.7)	<.01	1.6 (0.7)	4.0 (1.9)	<.01
ROM						
Flexion	84.6 (31.5)	65.8 (29.9)	<.01	86.1 (34.0)	67.1 (31.7)	<.01
Extension	89.7 (36.8)	71.2 (35.7)	<.01	91.2 (37.3)	72.0 (36.6)	<.01
Right bending	74.3 (24.7)	47.0 (19.2)	<.01	75.4 (25.9)	48.7 (20.6)	<.01
Left bending	73.2 (27.3)	50.6 (17.7)	<.01	75.0 (28.4)	51.1 (18.9)	<.01
Right rotation	84.6 (34.5)	66.7 (31.2)	<.01	86.1 (35.7)	70.1 (32.4)	<.01
Left rotation	88.9 (31.3)	70.5 (28.8)	<.01	89.7 (33.0)	71.4 (29.5)	<.01
NDI	10.1 (3.6)	20.4 (7.8)	<.01	9.8 (4.0)	19.6 (8.1)	<.01

Note: Data are present as mean ± standard difference. BMI = body mass index, NDI = neck disability index, PNMES = percutaneous neuromuscular electrical stimulation, ROM = cervical range of motion, VAS = visual analog scale.

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