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Therapeutic effectiveness of neuromuscular electrical stimulation for treating patients with chronic low back pain

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Abstract

This retrospective study investigated the effectiveness and safety of neuromuscular electrical stimulation (NMES) for patients with chronic low back pain (CLBP).

A total of 72 patients with CLBP were included in this retrospective study. All patients received usual care, and were assigned to a NMES group (n = 36) and a control group (n = 36). In addition, patients in the NMES group also received NMES for a total of 4 weeks. The primary outcome was pain intensity, measured by numerical rating scale (NRS). The secondary outcome was disability, assessed by the Roland–Morris Disability Questionnaire (RMDQ), and the Quebec Back Pain Disability Scale (QBPDS). The outcomes were evaluated before and after 4-week treatment.

After 4-week treatment, the patients in the NMES group did not show better effectiveness in pain intensity relief, as measured by NRS ($P = .11$); and disability improvement, as evaluated by the RMDQ ($P = .14$), and QBPDS ($P = .33$), when compared with the patients in the control group. Additionally, no adverse events related to the NNES were recorded.

The results of this study did not show promising effectiveness of NMES for patients with CLBP after 4-week treatment.

Abbreviations: CLBP = chronic low back pain, NMES = neuromuscular electrical stimulation, NRS = numerical rating scale, QBPDS = Quebec Back Pain Disability Scale, RMDQ = Roland–Morris Disability Questionnaire, TMT = trunk muscle training.

Keywords: chronic low back pain, effectiveness, neuromuscular electrical stimulation

1. Introduction

Chronic low back pain (CLBP) is a major common public health condition;[1–3] with a 12- month prevalence of 66% in women and 58% in men,[4] and a lifetime prevalence of 84%.[5,6] This condition is also a leading cause of disability worldwide.[6] It has been reported that a variety of factors account for the development and/or maintenance of CLBP.[5] Additionally, patients with such condition often are accompanied by high treatment costs, sick leave, and low quality of life.[7–9]

Although a wide variety of treatment options are available for the treatment of CLBP, such as pharmacologic interventions, the efficacy and safety of the most of those medications are not yet to be established.[10,11]

There has been an increasing interest in alternative therapy for the treatment of CLBP among the public and physicians. These therapy modality options include acupuncture, moxibustion, yoga, exercise, physical therapy, Qigong, transcutaneous electrical nerve stimulation, and neuromuscular electrical stimulation (NMES).[12–20] However, no guidance of such kind of therapies is available for the treatment of CLBP, especially for the NMES. Additionally, there is significant disparity in the technique device, and treatment standardization. Furthermore, limit data of NMES for the treatment of CLBP are still available. Thus, in this study, we investigated the effectiveness and safety of NMES for treating patients with CLBP.

2. Methods

2.1. Ethics

This study was approved by the medical ethics committee of The People's Hospital of Yan'an. It was performed at this hospital between June 2016 and August 2017. The written informed consent was obtained from the patients.

2.2. Study design

Seventy-two patients with CLBP were included. All the patients were assigned to the NMES group and the control group according to the different interventions they received. No randomization procedure was applied in this study. All the patients in both the groups received usual care. Additionally, the patients in the NMES group also underwent NMES. Both the groups received a total of 4-week treatment. On the other hand, the safety was also recorded in this study. The effectiveness and safety were evaluated after 4-week treatment.

2.3. Patients

Patients were included with the below criteria: by a physical confirmed diagnosis of CLBP;[21] all subjects with nonspecific low

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back pain without any pathophysiologic and anatomic diseases, and was supported by physical and radiographic examination; aged 18 to 75 years old; have a history of CLBP longer than 3 months; have a minimum pain intensity score of 4 in the numerical rating scale (NRS); and no NMES has been received 4 weeks prior the study.

Exclusion criteria included patients who had serious diseases, such as cancer, spinal infection that result in CLBP; chronic disease that may affect the effectiveness or results of the NMES, such as severe cardiovascular or neurological disease, epilepsy; pain caused by spinal surgery, fractures, tumors, and inflammatory diseases; had a pacemaker or metal implants; pregnant. Additionally, patients were also excluded if they had received NMES 1 month before the study, as well as had insufficient information.

2.4. Intervention

Patients in both the groups received usual care for a total of 4 weeks. The usual care consisted of pain medication and educational program. The pain medication was utilized with Nonsteroidal Anti-Inflammatory Drugs (zaltoprofen, 80 mg), 3 times daily, for 4 weeks. The educational program mainly instructed the patient knowledge about the physiology, pathology, and epidemiology of CLBP.

Additionally, the patients in the NMES group also underwent NMEST. It was applied by NMES device (Globus ACTIVA 600 Pro, Globus, Italy) with 2 electrodes at bilateral lumbar paraspinals (L2–L5) at a 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 maximum tolerance of individuals. Each painful area was treated for a total of 30 minutes each session, once daily, once weekly for a total of 4 weeks.

2.5. Outcome measurements

The primary outcome of pain intensity was measured by NRS (ranging from 0, no pain to 10, worst pain).[22] The secondary outcome of disability was measured by the Roland–Morris Disability Questionnaire (RMDQ),[23] and the Quebec Back Pain Disability Scale (QBPDS).[24] RMDQ evaluated the daily function and physical activities. It ranges from 0 (no disability) to 24 (maximal disability). QBPDS assessed the elementary daily activities. It consists of 6 domains of activity affected by back pain. The scores range from 0 (no disability) to 100 (maximal disability). In addition, adverse events were also recorded duration the treatment period.

2.6. Statistical analysis

This study was designed as to assess the superiority effectiveness of NMES for CLBP. The sample size was calculated according to the previous study by utilizing the mean difference and standard difference derived from other similar studies.[25] The desired number of participants required for each group was 36.

All the data were analyzed by using SAS package 8.2 (SAS Institute Inc, Cary, NC). The *t* test or Mann–Whitney rank sum test was utilized to analyze the continuous data, while the Pearson χ^2 test or Fisher exact test was performed to analyze the categorical data. The value of $P < .05$ was regarded as the statistical significance level.

3. Results

A total of 72 cases were analyzed (Fig. 1). The characteristics of all included patients in both the groups are listed in Table 1. The comparison of all these characteristics did not differ significantly between 2 groups (Table 1).

After 4 weeks treatment, the patients in the NMES group did not show more promising effectiveness in pain reduction of CLBP, as measured by the NRS ($P = .11$, Table 2); and the disability improvement, as assessed by the RMDQ ($P = .14$, Table 3), and QBPDS ($P = .33$, Table 4), compared with the patients in the control group.

No adverse events, such as discomfort related to NMES, occurred in the NMES group. No death related to the treatment was found in both the groups.

4. Discussion

Two previous studies have addressed the effectiveness of NMES for the treatment of CLBP.[19,20] One study performed a case

Table 1

Comparison of patient characteristics.

Characteristics	NMES group (n = 36)	Control group (n = 36)	*P* value
Mean age, y	66.2 (10.1)	63.9 (12.4)	.39
Gender			
Male	17 (47.2)	15 (41.7)	.64
Female	19 (52.8)	21 (58.3)	—
Race (Asian China)	36 (100.0)	36 (100.0)	—
BMI, kg/m^2	24.7 (3.3)	25.1 (3.6)	.62
Duration of CLBP, mo	28.8 (5.1)	27.0 (6.4)	.19
Analgesic use	36 (100.0)	36 (100.0)	—
Education	1 (2.8)	3 (8.3)	.56

Data are present as mean ± standard deviation or number (%).
BMI = body mass index, CLBP = chronic low back pain, NMES = neuromuscular electrical stimulation.

Table 2

Comparison of NRS before and after 4-week treatment between 2 groups.

NRS	NMES group (n = 36)	Control group (n = 36)	*P* value
Before treatment	6.3 (1.2)	6.1 (1.6)	.46
Difference from treatment before	−2.2 (−3.3, −1.0)	−1.4 (−2.2, −0.5)	
Difference between groups		− 0.7 (−1.1, −0.3)	.11

Data are present as mean ± standard deviation.
NRS = numerical rating scale.

Table 3

Comparison of RMDQ before and after 4-week treatment between 2 groups.

RMDQ	NMES group (n = 36)	Control group (n = 36)	*P* value
Before treatment	13.8 (2.4)	14.1 (2.1)	.57
Difference from treatment before	−2.3 (−3.6, −1.1)	−1.7 (−2.9, −0.8)	
Difference between groups		− 0.6 (−1.0, −0.2)	.14

Data are present as mean ± standard deviation.
RMDQ = Roland–Morris Disability Questionnaire.

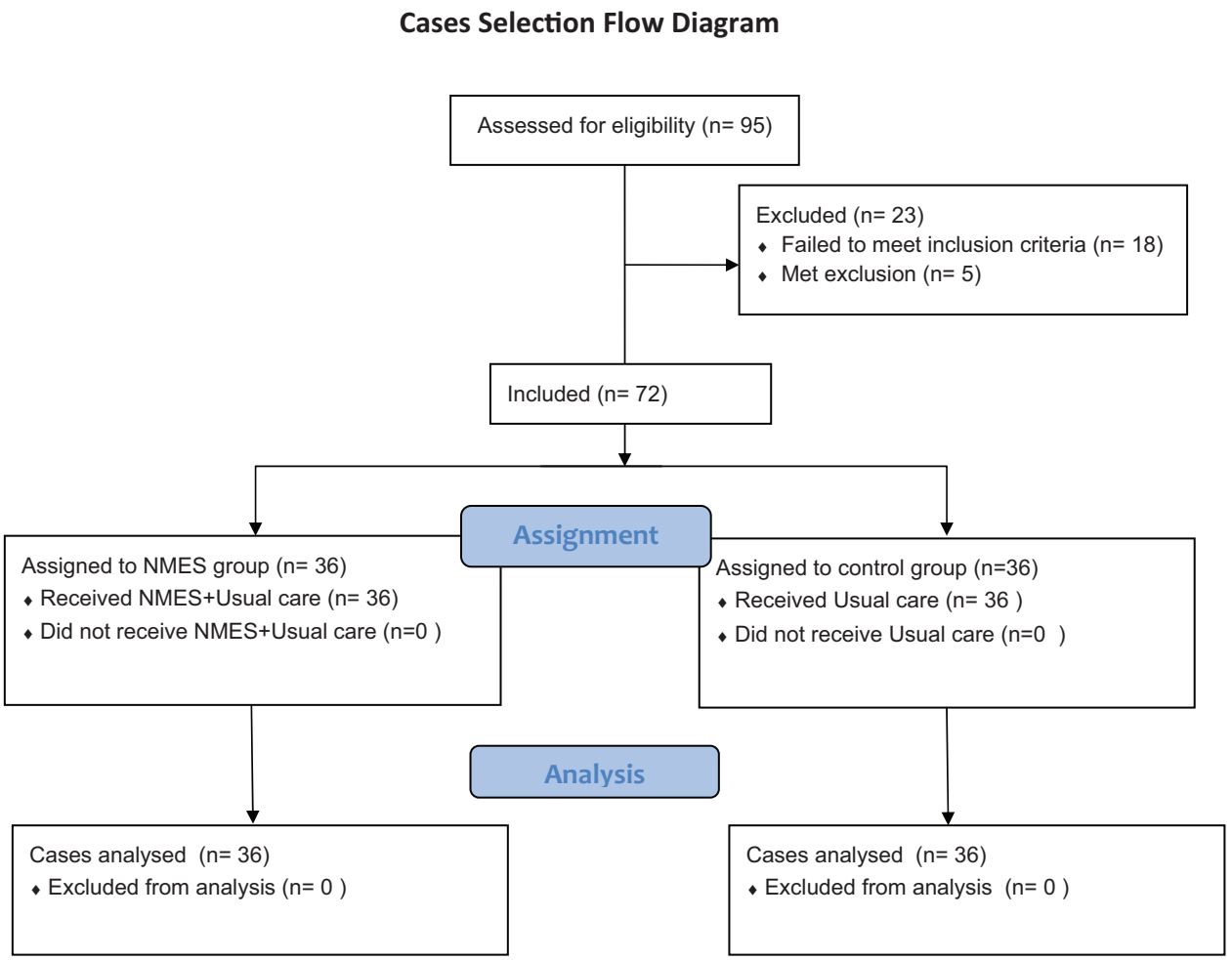

Figure 1. Cases selection flow diagram.

report using trunk muscle training (TMT) and NMES for pain relief and disability in an older adult with CLBP.[19] Its results demonstrated a promising short-term treatment response to TMT plus NMES for CLBP, with either enhancing CLBP, or improving the physical function and disability.[19] The other study designed as a randomized controlled trial to assess the feasibility efficacy of TMT and NMES for elderly with CLBP.[20] It found that TMT plus NMES may be efficacious for CLBP.[20]

The results of our study are inconsistent with the previous studies.[19,20] To our best knowledge, the present study first and specifically focused on the NMES monotherapy for the treatment of patients with CLBP, which is different from the previous studies.[19,20]

The results of this study demonstrated that NMES did not exert better outcomes in pain intensity relief, as measured by NRS, and in disability enhancement, as evaluated by the RMDQ and QBPDS after 4 weeks treatment. It indicated that NMES may not benefit for adult patients with NMES after 4-week treatment.

The present study has 4 limitations. First, it was impossible for the patients with CLBP to quit their standard daily medication during the period of therapy. Therefore, the observed outcome results were the combination of regular medication, NMES and usual care, rather than regular medication plus NMES, though all the patients in both the groups received usual care. Second, this study did not consist of comprehensive outcome measurements, such as the quality of life for patients in both groups. Third, the

Table 4

Comparison of QBPDS before and after 4-week treatment between 2 groups.

QBPDS	NMES group (n = 36)	Control group (n = 36)	*P* value
Before treatment	64.5 (7.8)	65.1 (8.3)	.75
Difference from treatment before	−12.3 (−17.1, −8.5)	−9.4 (−12.6, −6.8)	
Difference between groups		− 2.9 (−4.2, −1.7)	.33

Data are present as mean ± standard deviation.
QBPDS = Quebec Back Pain Disability Scale.

treatment period of this study is quite short, with only 4 weeks treatment. Fourth, the sample size of this study may be still small for evaluating the effectiveness and safety of NMES. Fifth, this study did not apply randomization procedure, which may increase the risk of patient selection. Overall, all these limitations may impact the results of this study. Future studies should avoid them.

5. Conclusion

This study found that NMES may be not efficacious in patients with CLBP after 4-week treatment. Future studies with larger sample size and longer treatment duration are still needed to warrant the results of this study.

Author contributions

Conceptualization: An Tong, Jian-wei Wang.
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References

[1] Chetty L. A critical review of low back pain guidelines. Workplace Health Saf 2017;65:388–94.
[2] Breen A. Low back pain: identifying sub-groups, clinical prediction rules and measuring results. Complement Ther Clin Pract 2018;31:335–7.
[3] Ledford C. Spine conditions: mechanical and inflammatory low back pain. FP Essent 2017;461:15–20.
[4] Neuhauser H, Ellert U, Ziese T. Chronic back pain in the general population in Germany 2002/2003: prevalence and highly affected population groups. Gesundheitswesen 2005;67:685–93.
[5] Denteneer L, Van Daele U, De Hertogh W, et al. Identification of preliminary prognostic indicators for back rehabilitation in patients with nonspecific chronic low back pain: a retrospective cohort study. Spine (Phila Pa 1976) 2016;41:522–9.
[6] Murray CJ, Richards MA, Newton JN, et al. UK health performance: findings of the global burden of disease study 2010. Lancet 2013;381:997–1020.
[7] Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systematic review. Rev Saude Publica 2015;49:1.
[8] Alleva J, Hudgins T, Belous J, et al. Chronic low back pain. Dis Mon 2016;62:330–3.
[9] Coulter ID, Crawford C, Hurwitz EL, et al. Manipulation and mobilization for treating chronic low back pain: a systematic review and meta-analysis. Spine J 2018;18:866–79.
[10] Shaughnessy AF. Opioid analgesia hard to tolerate and not effective for chronic low back pain. Am Fam Physician 2016;94:753–7.
[11] Enthoven WTM, Roelofs PD, Koes BW. NSAIDs for chronic low back pain. JAMA 2017;317:2327–8.
[12] Highland KB, Schoomaker A, Rojas W, et al. Benefits of the restorative exercise and strength training for operational resilience and excellence yoga program for chronic low back pain in service members: a pilot randomized controlled trial. Arch Phys Med Rehabil 2018;99:91–8.
[13] Blödt S, Pach D, Kaster T, et al. Qigong versus exercise therapy for chronic low back pain in adults—a randomized controlled non-inferiority trial. Eur J Pain 2015;19:123–31.
[14] Kim SY, Lee H, Lee H, et al. An observational study on the costs and consequences of acupuncture for the management of chronic low back pain in Korean patients. Acupunct Med 2015;33:148–53.
[15] Purepong N, Channak S, Boonyong S, et al. The effect of an acupressure backrest on pain and disability in office workers with chronic low back pain: a randomized, controlled study and patients' preferences. Complement Ther Med 2015;23:347–55.
[16] Frank B. Acupuncture for treatment of chronic low back pain. Am Fam Physician 2015;92:554.
[17] Jauregui JJ, Cherian JJ, Gwam CU, et al. A meta-analysis of transcutaneous electrical nerve stimulation for chronic low back pain. Surg Technol Int 2016;28:296–302.
[18] Gordon A, Glickman-Simon R. Moxibustion and breech presentation, breathing exercises and asthma, coenzyme Q10 and heart failure, acupuncture and chronic low back pain, and cinnamon and diabetes. Explore (NY) 2014;10:198–202.
[19] Pugliese JM, Sions JM, Velasco TO, et al. Use of trunk muscle training and neuromuscular electrical stimulation to reduce pain and disability in an older adult with chronic low back pain: a case report. Physiother Theory Pract 2018;4:1–8.
[20] Hicks GE, Sions JM, Velasco TO, et al. Trunk muscle training augmented with neuromuscular electrical stimulation appears to improve function in older adults with chronic low back pain: a randomized preliminary trial. Clin J Pain 2016;32:898–906.
[21] Reis S, Lahad A. Clinical guidelines for diagnosis and treatment of chronic low back pain. Harefuah 2008;147:735–8.
[22] Farrar JT, Young JPJr, LaMoreaux L, et al. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94:149–58.
[23] Dunn KM, Cherkin DC. The Roland-Morris Disability Questionnaire. Spine (Phila Pa 1976) 2007;32:287.
[24] Wei X, Yi H, Wu B, et al. A valid cross-culturally adapted simplified Chinese version of the Quebec Back Pain Disability Scale. J Clin Epidemiol 2012;65:1321–8.
[25] Hwang MS, Heo KH, Cho HW, et al. Electroacupuncture as a complement to usual care for patients with non-acute pain after back surgery: a study protocol for a pilot randomised controlled trial. BMJ Open 2015;5:e007031.