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 = 1.11); and disability improvement, as evaluated by the RMDQ (P = 1.14), and QBPDS (P = .33), when compared with the patients in the control group. Additionally, no adverse events related to the NMES 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,[11–13] 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.[3,9]

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, limited 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
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, 80mg), 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). 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 during 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 χ² 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
report using trunk muscle training (TMT) and NMES for pain relief and disability in an older adult with CLBP. 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. The other study designed as a randomized controlled trial to assess the feasibility efficacy of TMT and NMES for elderly with CLBP. It found that TMT plus NMES may be efficacious for CLBP.

The results of our study are inconsistent with the previous studies. 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.

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 |
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| **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

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