Original Article

Evaluation of Efficacy of Neuro Muscular Electrical Stimulation and Electro Acupuncture in Improving the Pain and Disability in Patients with the Lumbar Degenerative Intervertebral Disk Disease

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Abstract

Background: Chronic low back pain (CLBP) due to the degenerative intervertebral disk diseases is one of the most common musculoskeletal conditions in contemporary societies. A variety of pharmacological, non-pharmacological and surgical options is available for treatment of CLBP. The use of non-pharmacological methods have drastically increased in recent years, offering fewer complications and expenses. This study was conducted to compare the efficacy of the neuromuscular electrical stimulation (NMES) and electro acupuncture (EAP) with exercise therapy alone in patients with chronic low back pain.

Materials and Methods: This was a randomized case-controlled clinical trial. Sixty patients with CLBP were randomly assigned to 3 groups (20 cases each) of the EAP with exercise therapy, NMES with exercise therapy, and exercise therapy only. Severity of pain and disability improvement were assessed using the visual analog scale (VAS) and Quebec back pain disability scale respectively.

Results: A total of 66 individuals were enrolled, out of which 6 were excluded due to patients' lack of cooperation. A significant decline in the amounts of Quebec and VAS was observed in the three groups (p<0.001). The pain and disability improvements did not display any significant difference in the NMES or EAP groups compared to the control group. However, the severity of disability and pain in the NMES group were significantly higher than the EAP group (p<0.05).

Conclusion: These findings may indicate an almost identical efficacy of exercise therapy alone compared to the combination with electrical stimulation techniques in improving the pain and disability in patients suffering CLBP.

Keywords: Back pain, Exercise therapy, Electrical stimulation, Acupuncture

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Introduction

Low back pain due to the lumbar degenerative intervertebral disk diseases is a common problem in contemporary societies and one of the most common causes of job-related disability and a leading contributor to missed workdays. The point prevalence in some studies was reported from 12 to 35%. About 10 percent of this amount are patients who are chronically affected. About 20 percent of people in adolescence have mild symptoms of disk degeneration that gradually increase with age, especially in men. In addition, the remaining 60% of the discs degenerations is found in people above 70 years old. On the other side, the annual socio-economic cost dedicated by the low back pain medical management and physiotherapy is enormous[1-4].

Among the variety of clinical symptoms of the lumbar degenerative intervertebral disk diseases such as radicular pain, sensory and motor deficit, dysreflexia, incontinency secondary to sphincter defect and sexual disfunction, the most prominent and incapacitated one is the pain[1-8].

A variety of pharmacological, non-pharmacological and surgical treatment options have been proposed to control CLBP. Although, all above-mentioned methods showed some improvement in CLBP, they do not provide satisfying results for all individuals. Even surgery could not be sufficient in improving the pain. Some cases report a various stable pain despite of surgery[9-18]. Use of non-pharmacological methods, due to fewer complications and expenses, are desired. Non-pharmacological methods such as physiotherapy, exercise therapy, acupuncture, and electrical stimulation can modify the pain and improve the lifestyle. Electrical stimulation is a non-invasive procedure and is relatively simple whose efficacy in managing in chronic pain has been shown previously[12,16-21].

Electroacupuncture

This method is similar to traditional acupuncture, and the same treatment points are stimulated. Like traditional acupuncture, needles are placed on certain parts of the body. The needles are connected to a generator producing continuous electrical pulses. This method uses two or multiple needles simultaneously; therefore the impulses are able to be transferred from one needle to others[16].

Neuro muscular electrical stimulation

Muscle electrostimulation is a process in which the electric current is applied to stimulate the muscles to contract. This method has been used for managing chronic pain with proven results[12,19].

There are few studies regarding the effectiveness of acupuncture and electronic stimulation methods in improving muscle pains. There are more methods being used in East Asia, and patients have reported some recovery. However, still their efficacy have not been completely proven. This study was conducted to compare the efficacy of the neuro muscular electrical stimulation and electro acupuncture with exercise therapy only in patients with chronic low back pain caused by lumbar degenerative intervertebral disk diseases.

Methods

The current study was a randomized single-blind case-controlled clinical trial among a Iranian population. All cases with chronic low back pain symptoms secondary to the degenerative intervertebral disk diseases referred to the Sports Medicine Clinic of Emam Hossain Hospital, Tehran, Iran, in 2019 were enrolled. The study approval by Institutional Review Board at the Shahid Beheshti University of Medical Science (IR.SMBU.MSP.REC.1397.537). After obtaining informed consents, checklists were expended to collect demographic and clinical characteristics data. Individuals filled out pain assessment questioners.

All degenerative intervertebral disks diagnosis were stablished by a neurologist using magnetic resonance imaging. Follow-ups were performed by one senior resident of sports medicine who was aware which patients belong to the control group. All pharmaceutical treatments related to degenerative intervertebral disk diseases were discontinued, except Acetaminophen 500 mg in case of severe discomfort.

Inclusion criteria: Individuals above 18-year old with chronic low back pain related to the lumbar degenerative intervertebral disk diseases such as mild disk herniation or disk protrusion that lasted for at least 3 months. All patients had been on medical therapy without surgical interventions.

Exclusion criteria: Any musculoskeletal disorders like Ankylosing spondylitis, Osteomyelitis, musculoskeletal pain and progressive muscle weakness explained by other pathophysiology conditions beside degenerative intervertebral disk, history of receiving Electroconvulsive, overwhelming pain or developing radiculopathy and urinary incontinently symptoms by pressure on the spinal cord on exercise, drug and alcohol consumers

The eligible individuals were randomly assigned into 3 groups of 20, neuromuscular electrical stimulation (NMES) along with exercise therapy, electro acupuncture (EAP) along with exercise therapy as two study groups; and exercise therapy only as the control group. All patients were randomly selected and divided into either NMES or EAP groups. All 8 exercise techniques for strengthening of the core muscles and increasing flexibility were based on the book "Rehabilitation Techniques for Sports Medicine and Athletic Training", by William E Prentice. The exercises included the Pelvic bridge, Side bridge, Curl up, Quadruped positions, Alternate arm and leg raises, Prone plank, Cat and Camel and Piriformis stretch[22]. All techniques were implemented daily in three intervals (10 times each, for 10 seconds) for 4 months. The individuals were followed weekly to confirm the consistency of the exercises.

Electro acupuncture method: The SDZ-II electronic acupuncture equipment made by the Suzhou Medical Applicant Factory, in China in 2015, was utilized. Individuals received 15 minutes of percutaneous electrical nerve stimulations at an alternative frequency of 15 and 30 Hz, for 12 sessions (3 sessions in a week for one month). The intensity of stimulation was close to the threshold of patients' pain tolerance. Five bipolar leads were connected to the pair of pads, overall 10 probes. The probe pads were placed on the paraspinal muscles in parallel with the T12, L2, L4, S1 vertebrae and one over the ischial tuberosities.

Neuro muscular electrical stimulation method: The Veinoplus equipment made in France in 2014 was used (Ad Rem Technology, Certified ISO 13485:2012). Individuals received 15 minutes of unipolar current neuro muscular electrical stimulations at an alternative frequency of 15 and 30 Hz, for 12 sessions (3 sessions in a week for one month). The intensity of stimulation was close to the threshold of patients' pain tolerance. The probe pads were placed on the paraspinal muscles in parallel with the L4, L5, S1 vertebrae.

Pain appraisal was performed in three measurement sessions, prior to NMES and EAP and exercise therapy, after completing intervention periods (following one month) and 4 months after the beginning of the intervention. Severity of pain and disability improvement were assessed using the Visual Analog Scale (VAS) and Quebec Back Pain Disability Scale respectively.[23,24]

The Quebec questionnaire was developed by Kopeck et al. in 1995 to assess patient performance and daily activities. The questionnaire consists of 20 questions. Each question scores pain level from zero (no pain) to five (unable to perform) ratings. This questionnaire also measures the rate of low back pain between zero and one hundred. Total points of zero represents the patient as being healthy, 25 as a mild pain, 50 as moderate, 75 as sever, and above as an intensive pain that one is unable to perform any movement.[23]

Analysis: Data analysis was performed using Statistical Package for Social Sciences version 25 software. For each measured variable, descriptive values are expressed as the mean-standard deviation, and for qualitative variables, frequency was recorded. Analysis of quantitative variables was completed using t-test, one way ANOVA with Bonferroni correction. Categorical variables were compared using the Chi square test. Reported p values are 2-tailed and $p < 0.05$ is considered statistically significant.

Results

Out of 66 individuals, 6 were excluded due to patients' lack of cooperation. The remaining 60 patients [35 females (58%)] had the mean age of 41±2 years old. Table 1 demonstrates the demographic and clinical characteristics of the three groups. There was no significant difference in age, gender, underlying disease, duration of the disease and initial pain appraisement scores in the three groups. (Table 1).

The severity of pain was significantly different in all three groups one month after the intervention ($p<0.001$) (Table 2). Comparing the groups two by two, the severity of pain after one month of intervention in the EAP group compared to the control group was statically

Table 1: Demographic and clinical characteristics of the 60 patients.

	EAP[1]	NMES[2]	Control	*p*-value
Age	43.1 ±13.6	38.2 ± 8.6	42.4 ±10.9	.339
Sex (Female%)	12 (60%)	12 (60)	11 (55)	.934
Body Mass Index	25.9 ± 3.3	25.7 ± 4.4	24.5 ± 4.3	.511
Underlying Disease				.455
None				
Hypo thyroids	15 (75%)	18 (90%)	16 (80%)	
Hyperlipidemia	2 (10%)	1 (5%)	0	
Hyper tension	1 (5%)	1 (5%)	1 (5%)	
Asthma	1 (5%)	0	3 (15%)	
	1 (5%)	0	0	
Smoking	2 (10%)	0	3 (15%)	.217
Duration of Pain	14 ±10.6	12.1 ± 5.9	11.2 ± 2.8	.483
Primary VAS[3] Score	5.8 ± 2.1	4.9 ±1	5.6 ± 0.9	.152
Primary Quebec Score	37.8 ±18.9	41.4 ±13.9	35.4 ± 7.5	.412

[1]Electro acupuncture
[2]Neuro muscular electrical stimulation
[3]Visual Analog Scale

Table 2: The means of Visual Analog Scale scores in all groups prior and following the interventions.

	EAP[1]	NMES[2]	Control	*p*-value
Prior to Intervention	5.8 ± 2.1	4.9 ±1	5.6 ± 0.9	0.152
One Month of Intervention	1.7 ±1.1	4.8 ±1.2	2.8 ±1.6	**.001**
Four Months after Intervention Initiation	1.7 ±1.1	3.3 ±1.4	2.6 ±1.6	**.003**

[1]Electro acupuncture
[2]Neuro muscular electrical stimulation

Table 3: The means of Quebec Scale scores in all groups prior and following the interventions.

	EAP[1]	NMES[2]	Control	*p*-value
Prior to Intervention	37.8 ± 18.9	41.4 ±13.9	35.4 ± 7.5	0.412
One Month of Intervention	22.7 ±14.6	40.4 ±12.4	28.8 ± 7.5	**.001**
Four Months after Intervention Initiation	20.5 ±13.5	31.9 ±13.2	25 ± 7.6	**.012**

[1]Electro acupuncture
[2]Neuro muscular electrical stimulation

lower (p=0.03), while the severity of pain after one month of intervention in the NMES group compared to the control group was statically higher (p<0.001). The NMES group significantly demonstrated a higher pain severity compared to the EAP group (p<0.001).

The severity of pain was significantly different in all three groups four months after the intervention initiation as well (p<0.003) (Table 2). Comparing the groups two by two, there is no significant difference in the severity of pain four months after the intervention initiation in the EAP and NMES group compared to the control group (p=0.145, 0.366 respectively). The NMES group demonstrated a significantly higher pain severity compared to the EAP group as well (p<0.002).

Changes in pain severity in patients during the study in all the groups is demonstrated in table 2 and figure 2.

The severity of disability was statistically different in all three groups one month after intervention (p<0.001) (Table 3). Comparing the groups two by two, there is no significant difference in the severity of disability one month after intervention in the EAP group compared to the control group (p=0.322), while the severity of disability one month after intervention in the NMES group compared to the control group and EAP groups was statically higher (p<0.009 and p<0.001, respectively).

The severity of disability was significantly different in all three groups four months after intervention initiation as well (p<0.012) (Table 3). Comparing the groups two

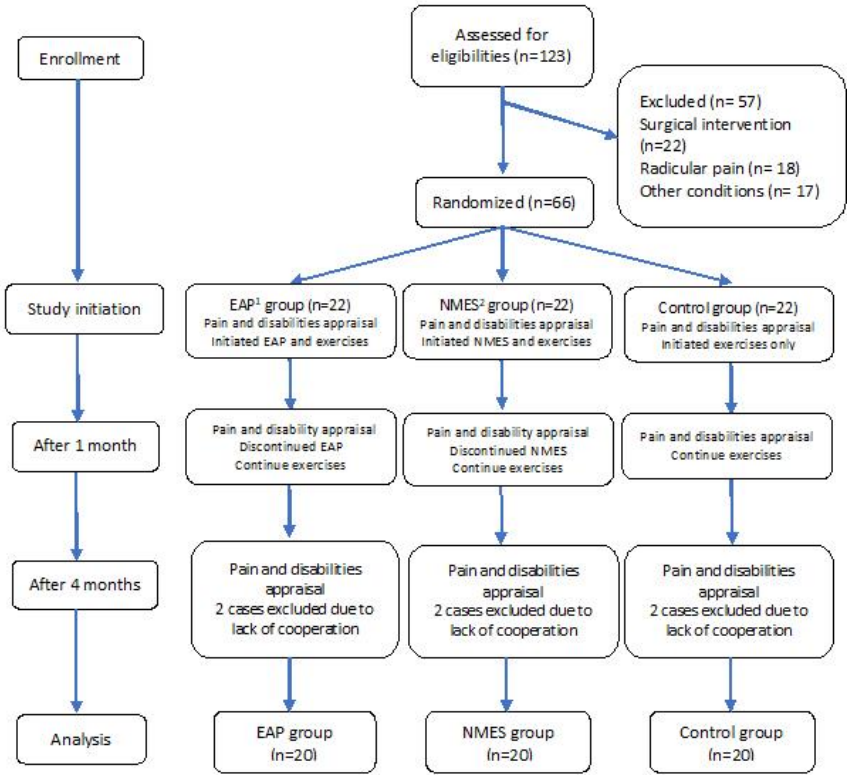

Figure 1. Study group diagram.
[1] Electro acupuncture, [2] Neuro muscular electrical stimulation

by two, there is no significant difference in the severity of disability four months after the intervention initiation in the EAP and NMES group compared to the control group (p=0.676 and p=0.211, respectively). The NMES group demonstrated a significantly higher disability severity compared to the EAP group (p<0.01).

Changes in severity of disability in patients during the study in the all groups is demonstrated in table 3 and figure 3.

Discussion

Low back pain is one of the most common health problems in today's societies with disability and significant economic impacts. In recent years, the interest in non-pharmaceutical treatments for chronic low back pain has increased. Exercise therapy and electrical stimulation techniques are currently used treatments whose efficacy in reducing pain and improving the disability of patients has been previously shown[25]. For the first time, in the current study we aimed to compare the efficacy of the electro acupuncture (EAP) and neuro muscular electrical stimulation (NMES) with exercise therapy alone, in patients with chronic low back pain (CLBP) due to lumbar degenerative intervertebral disk diseases.

There are few clinical trials regarding the efficacy of EAP in patients with chronic low back pain. Because of the additional electrical stimulation, EAP is more practical and effective compared to regular acupuncture. In the current study, the severity of pain and disability significantly improved in the three groups of EAP, NMES and exercise therapy after one and four months. There are controversial results regarding the efficacy of acupuncture. Some clinical trials and systematic review studies were established to compare acupuncture with a sham group[21,26-28]. Some of them were consistent with our results and could not display superiority of acupuncture. Leite et al. in 2018 did not succeed to demonstrate superiority of the EAP compared to three control groups (needle alone, needle withdrawal immediately after puncture and needle with 45 seconds electrical stimulus)[29]. In another metanalysis study including 7 clinical trials with 1768 patients, the efficacy of acupuncture was proven

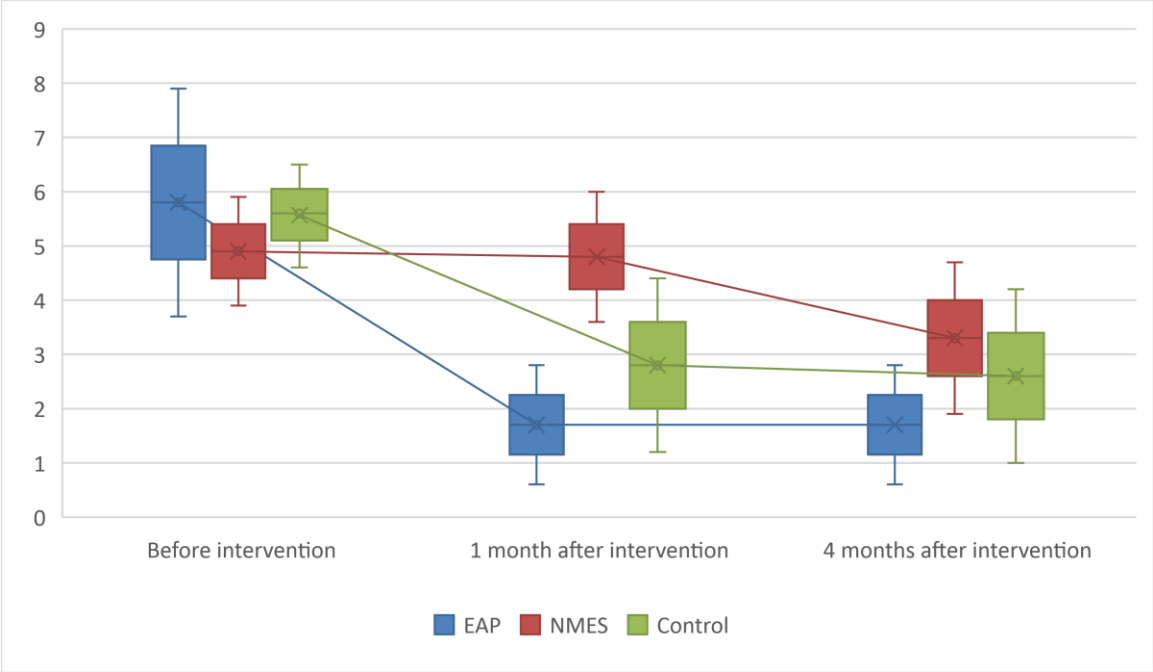

Figure 2. The comparison of severity of pain in the three groups following the intervention.

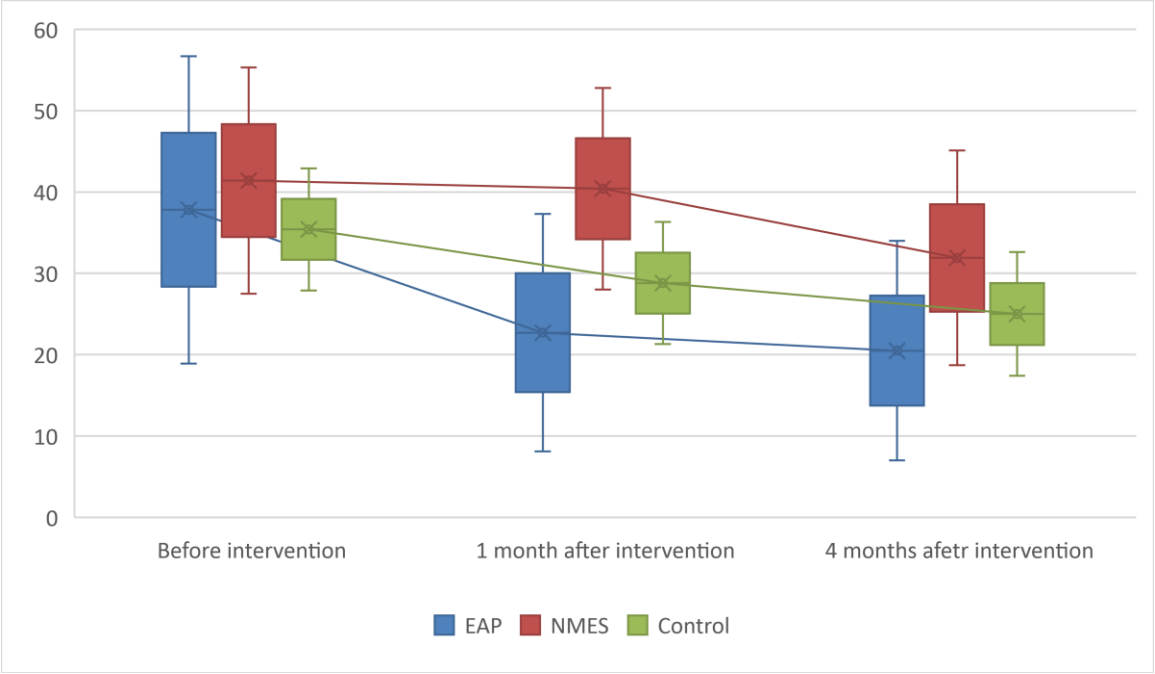

Figure 3. The comparison of severity of disability in the three groups following the intervention.

compared to placebo[30]. Furthermore, Yeung et al. reached the same conclusion in their assessment of 52 patients suffering from CLBP. They verified EAP in combination with exercise therapy could be beneficial for pain and disability but not effective on the range of movement of vertebral column and trunk muscle strength[31].

There are few clinical trials evaluating the efficacy of NMES in patients with chronic low back pain. Although, in this study, the severity of pain and disability were higher in the NMES group one month of intervention and four months after intervention,

initiation compared to the EAP group, there was no significant difference with the control group. Our findings are affirming Guo el al.'s investigation where the same assessment methods were applied to appraise pain and disability improvement. Their results showed lack of superiority of NMES in reducing pain and disability in patients with chronic low back pain compared to placebo[32]. Based on Alrwaily et al.'s investigation in 2019, we considered three groups instead of two groups in Alrwaily's study (one NMES combined with exercise therapy, one exercise therapy alone). In their clinical, both groups indicated similar pain and functional improvements[33]. Contradictory to our results, in assessments of Glaser et al. and Moore et al., there was a performance and pain improvement in a NMES group compared to the control[19,20]. Difference in sample size, executive methods and evaluation could partially justify the contradictions found between the results of various studies.

The present study has a few notable limitations. The small sample size is the first and most essential limitation reducing the power of the study. Lack of a control group with no treatment and not considering the patients' diagnostic radiographic results, were the other limitations.

In the future, we plan to conduct a comparative study to assess the current patients' radiographic results and correlate them with the responses (pain improvement) in the three groups. In order to determine the effectiveness of electrical stimulation methods, it is recommended to carry out future studies with the higher volume samples, more complementary methods (taking control group without treatment or with pharmaceutical treatment), consideration of radiological findings and other scales such as muscle strength, movement amplitude, and longer follow-ups.

Conclusion

In conclusion, these findings may indicate an almost identical efficacy of exercise therapy alone versus in combination with electrical stimulation techniques in improving the pain and disability in patients suffering CLBP due to the lumbar degenerative intervertebral disk diseases.

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