The Effects of Transcutaneous Electrical Nerve Stimulation on Postural Control in Patients with Chronic Low Back Pain

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Abstract

Introduction: To study the effects of transcutaneous electrical nerve stimulation (TENS) on postural control in chronic low back pain (CLBP) patients. **Materials and Methods:** The current study is an experimental one with twenty eight patients suffering from chronic LBP (25-45 Y/O). At first non-random sampling technique was used to have the study subjects selected, using block randomization, then, we assigned them to main groups known as intervention and control. The mean center of pressure (COP) velocity and displacement were measured at three time intervals; prior to the intervention, once the intervention was provided and thirty minutes after it. The tests were done with eyes open and closed on a force platform. Sensory electrical stimulation was applied through the TENS device. Descriptive statistics, independent sample test, repeated measurement and ANOVA with repeated measurement on time were used for data analysis. **Results:** The results of the present study demonstrated that the application of sensory electrical stimulation among patients with CLBP could improve the postural control in Medio-lateral immediately after and 30 minutes following the application of TENS among the patients with their eyes closed (*P*<0.05). Also, COP displacement and velocity in ML direction with eyes closed significantly decreased immediately and 30 min after application of sensory electrical stimulation group in comparison with the control group (*P*<0.05). **Conclusion:** Low frequency TENS with contraction level amplitude seems to have positive effects on postural control in patients suffering from CLBP. So, this study showed the effectiveness of low frequency TENS to imprive postural control in patients with CLBP.

Key words: Chronic Low Back Pain, Postural Control, Transcutaneus Electrical Nerve Stimulation

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Introduction

Posture is one of the important factors which has many effect Low back pain (LBP) is a very common disorder, and studies have shown that more than 80% of people are likely to suffer from LBP over their life time (1- 3). Many of acute patients diagnosed with LBP develop this disorder during 4 weeks, but recurrence of pain episodes is common (4). In 10–40% of individuals, LBP changes into the chronic LBP which is considered as the most costly musculoskeletal disorder for society (1, 4).

One of the most important factors in the genesis and persistence of nonspecific LBP is stability and control of the spine. Studies on/into patients with LBP have indicated that impairments in the deep trunk muscles (e.g. transverses abdominis and multifidus) was responsible for maintaining the stability of the spine (5, 6)

The human postural system is controlled by the coordination between three sensory sources including visual, vestibular and proprioceptive inputs. These systems provide information about the status and movements of the body in the space and continuously transmit and generate enough force to control and maintain the body balance in various situations (7, 8). Therefore, it is clear that a disruption sensory impairment will affect postural control.

Previous studies revealed that in subjects with chronic low back pain postural control and some components of these systems such as the physiology of afferent and efferent nerves

may be affected (9,10). This damage can lead to significantly greater sway in upright standing which may play a role in recurrence of low back pain (9).

The mechanism of poor postural control in subjects with low back pain is not completely known yet (11). Proprioceptive inputs or sensory integration deficits have been supposed to be the possible causes of balance impairments in people with chronic low back pain although there is no sufficient evidence for this supposition (12).

Since subjects with low back pain demonstrate postural control impairment, researchers could find new insight into rehabilitating postural control impairment in them.

One potential means leading into the improvement of in proprioception is subsensory stochastic resonance (SR) electrical stimulation. SR stimulation is a type of electrical or mechanical stimulation with an alternating electric field that, at a subsensory level, has shown to enhance the detection and transmission of weak sensory signals (14). Stochastic resonance is thought to alter the transmembrane potential of neurons causing the cell to depolarize and and increasing the likelihood of action potential to be resulted (13). It has shown promise as a way to improve the balance among various populations including the elderly (15, 17) and those recovering from stroke (25). As somatosensory feedback is an important component of the balance control system, it has been theorized that the improved balance observed with SR stimulation is a result of enhanced proprioceptive input (17).

In 2002, Gravelle *et al.* tested the effect of SR with low-level electrical noise, applied at the knee, on balance control in healthy elderly volunteers. They showed that the low level input noise (electrical or mechanical) can enhance the sensitivity of the human somatosensory system. The results suggested that imperceptible electrical noise, when applied to the knee, can enhance the balance performance of healthy older adults (17).

In 2002, Dhruv and colleagues showed that by using Semmes-Weinstein monofilaments,

low-level electrical noise could significantly improve finetouch sensitivity on the plantar surface of the foot in the elderly, so the study suggests that electrical noise-based techniques may enable people to overcome functional difficulties caused due to the age-related sensory loss (1).

Transcutaneous electrical nerve stimulation (TENS) is one of these modalities that can improve neuromuscular function/pain status and therefore it is beneficial for patients who suffer from low back pain and other difficulties such as pain and muscle weakness around the pelvis,trunk and lower limbs which in the end lead to low back pain. TENS, which involves the pulsatile stimulation of sensory fibers, is used primarily for the purpose of pain modulation in physiotherapy (18).Different types of TENS treatment are often referred to as Hi-TENS and Low-TENS, Which can be applied for multiple purposes. For the purpose of pain high frequency stimulation is required, on the contrary, excitatory effects of sensory inputs on the motor system lower frequencies are applied (10 Hz). Studies using Trans-Cranial Magnetic Stimulation (TMS) have obtained evidence that the application of TENS at different body sites influences corticomotor excitability. Therefore, application of TENS may interfere in the modulation of cortical motor responses including postural control responses (19). Fraser *et al.* stated that the motor effects are expected to depend critically on the frequency of the sensory stimulation (20).

Gravelle *et al.* in 2002 investigated the effect of electrical noise, used on the knee, on postural control in healthy older adults. They showed that electrical or mechanical noise can improve the human somatosensory system. The results indicated that electrical noise, when used on the knee, can improve the postural performance of the healthy elderly people (17).

Application of TENS to the neck muscles in patients with hemispatial neglect has shown potential to improve the spatial orientation and postural control (21).

Therefore, TENS usually is used with sensory threshold or supra-threshold amplitude compared with sub-threshold sensorimotor signals of SR. Although TENS seems to be more acceptable than SR stimulation among patients because of its perceptible stimulation current, its effect on postural control is unknown (22).

The results of several investigations on the SR have reported its effect on improving the balance control when an electrical or mechanical noise was applied (17, 25).

To the best of our knowledge, no study has investigated the possible effect of TENS on postural control in patients with low back pain; consequently, the purpose of the study was to investigate the acute effect of the application of TENS on the static postural control in patients with low back.

MATRIALS AND METHODS

Participants

The current study was conducted on twenty eight patients suffering from chronic low back pain (CLBP). Low back pain is defined as the pain in the area between the 12th rib and the gluteal folds, the level of disability among the

patients ranged from mild to moderate (0 ta 40%) achieved by applying the Oswestry questionnaire. All participants (24 women, 4 men) in the 25-45 age range who were previously diagnosed with a chronic low back pain by the specialist were recruited from different physiotherapy clinics in Shiraz. They all had main compatible features, including weight, height and BMI. On the one hand, the age range between 24 to 45, having localized back pain lasting more than 6 months and not radiating further than the buttock, not having medical history of sciatica or other radicular involvement, using at least 3 out of 10 visual analog scale (VAS) and mild to moderate level of disability assessed by Oswestry questionnaire were all considered as the inclusion criteria of the current study. On the other hand, there were several important exclusion criteria including the history of neurological signs such as sensory deficits or motor paralysis or vestibular system impairment, dizziness and medication with known effects on balance, medical history of spinal surgery, rheumatic diseases, diabetes, mental disorders, pregnancy, lower extremity injuries, and neuromuscular diseases.

Procedures

First the inclusion criteria were checked among participants, then all of them were asked to read and sign the consent form approved by the ethics committee of Shiraz University of Medical Sciences to begin the participation in the study.

Through non-random sampling, twenty eight patients with CLBP (25-45 y/o) were selected to participate in this study. Using block randomization, we divided them into two intervention and control groups. Fourteen subjects received TENS, while the remaining fourteen received sham intervention. Also, the patients did the tests with eyes open and closed. A randomized block design was used to determine the test order. In the intervention group, measurements were performed with eyes open and closed on a force platform, prior to, immediately after and 30 minutes after the intervention. It should be mentioned that all measurement tests were repeated twice. In the control group, the tests were done similar to the intervention group, the only difference was that they received sham electrical stimulation.

Postural Control

To measure the postural control, a force platform (Kistler Instrument^{*}, Switzerland), sampling at 100 Hz was used. The anteroposterior (AP) and mediolateral (ML) displacements (mm) of COP were stored for analysis. Raw data were exported to Visual 3D° software and filtered using a fourth order low-pass Butterworth filter with a cut off frequency of 12 Hz.

Participants were barefoot on the double leg stance with eyes open and closed on the force plate for two trials of 20s. Participants were asked to stand relaxed, immobile. The participants were instructed to stand comfortably with normal posture during the double leg stance condition, they o had their feet approximately at the pelvis width and the arms hanging loosely by their sides (23). They were standing at upright position with eye open, focusing on a target placed at the eye level two meters in front of them. Postural stability measurements were recorded prior to, immediately after and 30minutes after the intervention.

Intervention Group:

In order to apply the TENS technique, the subjects were positioned prone on a treatment bench; then, electrical stimulation was applied via an electrical stimulator device (low frequency TENS with a duration of 250 μ s and 7 HZ frequency). The stimulation was acted through pairs of electrodes placed at 1cm away from the spinus process L₁ and L₅ on each sides for 15 minutes at tolerance level.

The data were re-evaluated prior to, immediately after and 30minutes after the intervention (Figure 3).

Control Group:

Subjects in the control group on the other hand, received the sham electrical stimulation which was generated by an electrical stimulator device (low frequency TENS with a duration of 250 μ s and 7 HZ frequency). Participants were positioned prone on a treatment bench then, while they were given the stimulation through the pairs of electrodes placed at 1cm away from the spinus process L₁ and L₅ on each sides for 15 minutes but intensity was zero.

The data were re-evaluated before, immediately after and 30minutes after the intervention (Figure 3).

Statistical analysis

The data were analyzed by puttig SPSS version 16 to use,. The homogeneity of the variance of COP variables was assessed by Shapiro-Wilk test of normality. The descriptive statistics, independent sample T-test, repeated measurement and ANOVA with repeated measurement on time were used to have data analysed. Post-hoc test was also applied wherever necessary. The level of significance for all the tests was set at 0.05.

Table 1. Mean±SD demographic information of all test subjects (n=14)						
Vareiable	TENS	Placebo TENS	Total			
Age	31.64±12.49	30.57±7.51	30.89±7.29			
Height (cm.)	164±0.05	160 ± 0.05	162 ± 0.05			
Weight (kg.)	66.85±12.06	57.85±12.29	62.35±1.27			
BMI(kg/m ²)	27.69 ± 2.97	26.40 ± 2.42	27.05 ± 2.74			
Gender (Female/Male)	12/2	12/2	24/4			
VAS	4.64 ± 1.08	4.35±1.27	4.50 ± 1.17			

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Table 2. The Comparison of the mean COP displacement and velocity prior to, immediately after and 30 minutes after the application of TENS with eyes closed and open

Variables		of TENS with eyes cit	TENS	Placebo-TENS	<i>P</i> -value ^{**}
		D (
	ML	Before	2.92±1.07	3.56±1.97	0.30
		Immediate	2.40 ± 0.78	3.42±1.66	0.05
		After 30 minutes	2.32±0.79	3.37±2.14	0.09
COP displacement (mm) Eye Open		lue	0.08	0.85	
	AP	Before	2.19±0.94	2.31±1.27	0.78
		Immediate	2.18±1.15	1.98±0.79	0.59
		After 30 minutes	1.85 ± 1.73	2.89±2.27	0.18
		lue	0.55	0.25	
COP displacement (mm) Eye		Before	2.95±0.83	3.57±1.63	0.22
	ML	Immediate	2.27 ± 0.45	3.54±1.91	0.02#
		After 30 minutes	2.21 ± 0.52	3.50 ± 2.21	0.04#
	*P-va	lue	0.001#	0.97	
Closed		Before	1.98±1.2	2.02±1.6	0.93
	AP	Immediate	1.81±0.72	2.18±1.43	0.39
		After 30 minutes	1.66 ± 0.58	2.52±0.67	0.22
		lue	0.34	0.25	
	ML	Before	0.09±0.03	0.11±0.06	0.24
		Immediate	0.072 ± 0.02	0.10 ± 0.05	0.05
		After 30 minutes	0.072 ± 0.02	0.10 ± 0.07	0.10
	*P-va	lue	0.14	0.82	
COP Velocity (mm/s) Eye Open		Before	0.06±0.03	0.071±0.04	0.80
	AP	Immediate	0.06 ± 0.03	0.06±0.02	0.57
		After 30 minutes	0.058 ± 0.05	0.072 ± 0.04	0.48
	*P-value		0.65	0.34	
COP Velocity (mm/s) Eye Closed		Before	0.09±0.02	0.11±0.05	0.10
	ML	Immediate	0.072 ± 0.01	0.11±0.06	0.03#
		After 30 minutes	0.068 ± 0.01	0.11 ± 0.07	0.04#
	*P-va	lue	0.001#	0.78	
		Before	0.062±0.03	0.065±0.05	0.87
		Immediate	0.055 ± 0.02	0.067 ± 0.04	0.38
		After 30 minutes	0.052 ± 0.01	0.079 ± 0.02	0.24
	*P-va	lue	0.36	0.30	
					4. 44

*Significant at P<0.05; 'Repeated measurement of ANOVA for within group differences was used; ** Independent T-test for between group differences was used

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<i>`</i>			11		<i>P</i> -value [#]		
Variables			TENS	Placebo-TENS	Time	Time*group	Group
COP displacement (mm) Eye Open	ML	Before	2.92±1.07	3.56±1.97			
		Immediate	2.40 ± 0.78	3.42±1.66	0.28	0.61	0.07
		After 30 minutes	2.32±0.79	3.37±2.14			
		Before	2.19±0.94	2.31±1.27			
	AP	Immediate	2.18±1.15	1.98±0.79	0.61	0.16	0.42
		After 30 minutes	1.85±1.73	2.89±2.27			
COP displacement (mm) Eye Closed	ML	Before	2.95±0.83	3.57±1.63			
		Immediate	2.27±0.45	3.54±1.91	0.04^{*}	0.09	0.04^{*}
		After 30 minutes	2.21±0.52	3.50 ± 2.21			
	AP	Before	1.98±1.2	2.02±1.6			
		Immediate	1.81±0.72	2.18±1.43	0.8	0.10	0.4
		30After	1.66 ± 0.58	2.52 ± 0.67			
COP Velocity (mm/s) Eye Open		Before	0.09±0.03	0.11±0.06			
	ML	Immediate	0.07 ± 0.02	0.10 ± 0.05	0.09	0.30	0.24
		After 30 minutes	0.07 ± 0.02	$0.10 {\pm} 0.07$			
		Before	0.06±0.03	0.07 ± 0.04			
	AP	Immediate	0.06 ± 0.03	0.06 ± 0.02	0.73	0.39	0.79
		After 30 minutes	0.058 ± 0.05	0.07 ± 0.04			
COP Velocity (mm/s) Eye Closed		Before	0.09 ± 0.02	0.11±0.05			
	ML	Immediate	0.07 ± 0.01	0.11 ± 0.06	0.02^{*}	0.26	0.03*
		After 30 minutes	0.06 ± 0.01	0.11 ± 0.07			
		Before	0.06 ± 0.03	0.06 ± 0.05			
	AP	Immediate	0.05 ± 0.02	0.06 ± 0.04	0.75	0.14	0.41
		After 30 minutes	0.05 ± 0.01	0.07 ± 0.02			
-							

Table 3. The Comparison of the mean COP displacement and velocity between the intervention and the control group prior to, immediately after and 30 minutes after the application of TENS with eyes closed and open

^{*}Significant at P<0.05; [#] Repeated measurement for between group differences over time was done

Results

Displacement and velocity of CoP

All the participants were able to stand for only 20s during the test. There were no significant differences between two groups regarding the anthropometric data. The mean age, BMI, pain score and disability score of these patients were $30.89 \ (\pm 7.29), \ 27.05 \ years \ (\pm 2.74), \ 4.50(\pm 1.17) \ and 20.91(\pm 11.07) \ respectively \ (Table1). The Oswestry Questionnaire was employed to have the patients' level of disability identified. The range of disability level of patients was calculated to be between 0 to 40% range. It indicated that they were slightly to moderately disable, additionally, none was excessively obese or old. It should be also mentioned that none of the patients was excessively obese or old.$

Electrical stimulation and postural control in low back pain patients

We used ANOVA to examine the effect of time (pre,post and follow-up) on each group separately, and Independent T-test to compare two groups(at each assessment ,and at each condition i.e eyes open and closed). However, the correct model for this design would be a 2(groups) \times 2 (conditions) \times 3 time (pre, post, follow-up) ANOVA. We chose to do 2 \times 3 for the eyes open and the eyes closed separately. Also, we used repeated measurement to evaluate the effect of time (pre, post and follow-up) on differences exciting between the groups.

To identify the within group differences ,the repeated measurment of ANOVA and Bonferroni Post Hoc were used.The result showed that immediately after and 30 min after application of sensory electrical stimulation, COP

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displacement and Velocity decreased in ML direction with eyes closed(*P*=0.001)

According to Post Hoc, it was reported that immediately after the application of sensory electrical stimulation, COP displacement (before: 2.95 ± 0.83 mm, immediately: 2.27 ± 0.45 mm) (*P*=0.01) and COP velocity in ML direction with eyes closed (before: 0.092 ± 0.02 mm/s, immediately: 0.072 ± 0.01 mm/s) (*P*=0.02) significantly decreased in the intervention group as compared to the baseline.

Additionally, 30 minutes after the invention, displacement of COP in ML direction with eyes closed (before: 2.95 ± 0.83 mm, 30min: 2.21 ± 0.52 mm) (*P*=0.007) and velocity of COP in ML direction with eyes closed (before: 0.092 ± 0.02 mm/s, 30min: 0.068 ± 0.01) (*P*=0.004) significantly decreased in the intervention group as compared to the baseline.

The results of the independent T-test for between group differences showed that immediately after the application of sensory electrical stimulation, COP displacement and velocity in ML direction with eyes closed significantly decreased in the intervention group in comparison with the control group (Table 2).

30 minutes after the invention, COP displacement and velocity in ML direction with eyes closed significantly decreased in the intervention group compared to the control group (Table 2).

The repeated measurement for the between group differences was done and the results of between group test indicated that variable group at COP displacement in ML direction with eyes closed (f= 4.39, P=0.04) and at COP velocity in ML direction with eyes closed (f= 4.8, P=0.03) was significant(Figures 1, 2) .The within subject test illustrated that there was a significant time effect; in other words, the groups changed in COP displacement and velocity over time (f=3.31, P=0.04, f=4.04, P=0.02). Moreover, the interaction between time and group was not significant (Table 3).

Discussion

Our study was designed to investigate whether TENS is an effective techniques for the postural control. Displacement and velocity were used as the main criteria of the estimation of postural control. The results of this study showed that low-frequency TENS stimulation can effectively improve postural control in LBP patients and this effect was still significant even 30 minutes after the protocol.

According to our results, the application of sensory electrical stimulation in CLBP patients revealed a statistically significant improvement in postural control in medio-lateral direction immediately following the application of TENS and 30minutes after it with eyes closed as compared to the baseline. It means that application of TENS led into the decrease in the displacement and velocity of COP.

This finding was consistent with the results of Laufer and Dickstein (24, 26). They measured postural control parameters during the double stance with force platform. The results showed that the application of TENS induced significant reduction in mean velocity in the medio-lateral direction of the center of pressure. These findings; therefore, indicated that the electrical stimulation applied to the knees may be effective in improving postural control (24, 26).

In another study conducted in 2006, Priplata et al showed that COP displacement among the patients with diabetic neuropathy, stroke and healthy elderly subjects decreased by the application of noise. So, they concluded that the application of subsensory mechanical noise to the feet of patients with diabetic neuropathy and stroke reduced the postural control (25).

The results of the present study confirmed that displacement and velocity of COP change when the electrical stimulation is applied instead of placebo-TENS. The result showed that immediately after and 30 minutes after the application of sensory electrical stimulation, COP displacement and velocity in ML direction with eyes closed significantly decreased in the intervention group compared to the controls.

Also, Dickstein (26) confirmed these results. He investigated the effect of TENS applied to the posterior aspect of the legs, on postural control during stance. The results indicated that as the decrease in the mean of COP velocity in both of medio-lateral and anterior-posterior direction was observed, the application of the TENS decreased the postural control. Thus, it showed that the application of the low-amplitude TENS to the lower limbs decreases the postural sway during the stance (26).

Moreover, the differences were significant only in ML direction which could be attributed to the impairment in controlling antrioposterior direction due to the decrease in the motion of the lumbar spine and increase in the activity of lumbopelvic muscles (27); therefore, these patients may rely more on the muscles which act in the frontal plane. It is needless to say that the increase in the activity of these muscles may result in muscle fatigue. The influence of muscle fatigue due to the alteration in the trunk position

and pain may cause further change in the mediolateral direction. Luana Man reported higher variability in mediolateral direction and confirmed the deficit in antrioposterior direction in LBP patients (28).

Besides, hip muscles play an important role in shifting force from the lower limb up to the spine during upright tasks, this may influence the development of LBP. Poor endurance and delay in the firing of the hip abductor (gluteaus medius) and hip extensor (gluteaus maximus) muscles have been reported in patients with LBP (29). In 2002, Nadler reported that female athletes with weakness in the left abductors were significantly more likely to develop LBP (30); therefore, the probable Gluteus Medius muscle weakness may theoretically help to develop LBP occurrence and other changes in the mediolateral direction.

Also, Janda proposed that LBP patients have slower activity in the gluteus medius and maximus and the abdominal muscles (31).

The impaired balance control with eyes closed is consistent with the well-documented phenomenon of improved human balance control with visual input (32). It has been demonstrated that visual input plays a dominant role in the stance regulation (33). Thus, visual loss or visual deficit in human being can bring about different changes in the postural control. LBP is known as a reason to decrease proprioceptive capacity (34, 35), which may encourage dependence on the visual system (35). In 2010, Luana Man showed that deprivation of visual information in patients suffering from LBP will increase the postural instability (28). Also, according to those studies, no significant differences in the CoP parameters with eyes open was noticed. This may be due to the fact that patients had intact information systems (visual, vestibular and somatosensory).

Although some studies have been alreadycarried out on the effectiveness of TENS to relieve the pain, to decrease the level of disability and to increase the range of motion of the lumbar spine in patients with LBP, no studies yet have evaluated the effect of TENS on postural control in patients with CLBP. (36-39).

How exactly sensory electrical stimulation acts on postural control is not yet clear, but balance improvements shown by the application of TENS are stated to be the result of increase in the proprioception input. Electrical nerve stimulation improves corticomotoneural excitability by activating group Ia large muscle afferents, Ib afferents from Golgi organs, group II afferents from slow and rapidly skin afferents, and cutaneous afferent fibers. (20) Birmingham et al also noted that the patients with poorer proprioceptive ability showed greater improvement after the application of an external device (Birmingham et al. 2001). Also, Peurala et al in 2002 assessed the effects of the electrical stimulation by using glove or sock electrodes in chronic stroke patients. They showed that sensory stimulation may enhance limb function after stroke (41).

Proprioceptive input from the muscles of the legs and trunk is a key element in maintaining the postural stability (42.). This actually suggests that the balance dysfunction in CLBP may be due to the altered proprioception feedback from the lumbar spine (40). A somatosensory feedback is considered as a necessary factor in the proprioceptive system (13); consequently, improvement in this sense following the use of TENS increases the sensory afferents.

In this study, we applied the low frequency pattern because previous studies showed the beneficial effects of low frequency (1.7 and 5 Hz) and burst-type TENSon rehabilitating the motor impairments in patients with stroke 43).

We have faced several limitaions in conducting the current study. Firstly, duration of the follow-up was limited. Secondly, we did not assess electromyography muscular activity of erector spinea muscles, last but not least, the proprioception sense of the low back spines was not measured in this study. Therefore, further research is required to assess the effect of TENS on postural control and other outcomes (proprioception) for longer time periods among individuals with LBP.

Conclusion

Our study was done to determine if TENS might be effective to improve postural control. There were significant differences in the displacement and velocity prior to, immediately after and 30 minutes after the treatment application with eyes closed condition. According to the results obtained, low frequency TENS with contraction level amplitude seems to have positive effects on postural control in patients with CLBP, so the results of this study approved the effectiveness of low frequency TENS to improve postural control in patients with CLBP..

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Conflict of interest:

None

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Authors' contributions:

All authors including Zahra Rojhani Shirazi, Tahere Rezaeian, have made substantial contributions to all three following sections (1), (2) and (3) below:

(1) The conception and design of the study, acquisition of data, analysis and interpretation of data.

(2) Drafting the article and revising it critically for important intellectual content.

(3) Final approval of the version to be submitted

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Journal of Clinical Physiotherapy Research. 2017; 2(2): 61-69

68

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