Original Article

Dose postural control improve following application of transcutaneous electrical nerve stimulation in diabetic peripheral neuropathic patients? A randomized placebo control trial

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\begin{abstract}
\textbf{Background:} peripheral neuropathy is the most common problem of diabetes. Neuropathy leads to lower extremity somatosensory deficits and postural instability in these patients. However, there are not sufficient evidences for improving postural control in these patients.

\textbf{Aim:} To investigate the effects of transcutaneous electrical nerve stimulation (TENS) on postural control in patients with diabetic neuropathy.

\textbf{Methods:} Twenty eighth patients with diabetic neuropathy (40–55 Y/O) participated in this RCT study. Fourteen patients in case group received TENS and sham TENS was used for control group. Force plate platform was used to extract sway velocity and COP displacement parameters for postural control evaluation.

\textbf{Results:} The mean sway velocity and center of pressure displacement along the mediolateral and anteroposterior axes were not significantly different between two groups after TENS application \((p > 0.05).\)

\textbf{Conclusion:} Application of 5 min high frequency TENS on the knee joint could not improve postural control in patients with diabetic neuropathy.

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1. Introduction

The number of diabetic patients is going to increase \cite{1}. In 2002, the prevalence of this disease was estimated 2.8\% of the population, which will increase to 4.4\% in 2030 \cite{2}. Peripheral neuropathy is one of the most common long-term complications of diabetes that affects more than 50\% of diabetic patients \cite{3,4}. Diabetic peripheral neuropathy (DPN) leads to lower extremity somatosensory deficits which results in lack of accurate proprioceptive information that finally causes postural instability in these patients \cite{2,5}. Therefore, they have a high risk of falling \cite{6,7}.

In some studies it was claimed that electrical and mechanical noise via augmentation of somatosensory inputs could ameliorate impairment in postural control in older adults and patients with diabetic neuropathy \cite{8–11}. Different studies have been shown the positive effects of the sensory stimulations in improvement of postural control in healthy young subjects \cite{12,13},elderly \cite{8} and patients with diabetic neuropathy \cite{14}.

It is alleged that Transcutaneous electrical nerve stimulation (TENS) as an electrical stimulation for pain relief \cite{15} could enhance upper motor neuron and motor cortex excitability\cite{16}, functional stability improvement \cite{17} and altering spatial orientation and postural control \cite{18,12}.

According to the TENS low cost, widespread use, most accessible and ease of application, it frequently is used with DPN patients like for their pain reduction. But the effects of these sensory stimulation has been studied only during application. The aim of this study was to investigate whether this positive effect continues after stopping the current of sensory stimulation?

2. Materials and methods

2.1. Subjects

Twenty-eight women with DPN were referred to Motahari diabetes clinic of Shiraz University of Medical Sciences with age
between 40 and 55 years participated in the randomized clinical study. Patients with score 7 and above in Michigan Neuropathy Screening Instrument (MNSI) questionnaire and score 2 and above in MNSI were included [19]. Patients were excluded if they had any history of lower extremity injuries such as fractures, dislocations, muscle lesions, soft tissue damage at least during the previous six months, ankle and knee pain during the study, musculoskeletal diseases such as myopathy, doing regular exercise (at least 3 sessions in a week, for 30–45 min in each session), knee joint flexion contracture, disorders of middle ear and the vestibular system and the use of assistive walking devices.

2.2. Procedures

Prior to the data collection patients signed an informed consent approved by the ethics committee of Shiraz University of Medical Sciences (CT-91-6462) (RCT SN201304062391N10). The patients were divided into two groups by random allocation. Fourteen subjects received TENS and control group received the sham-TENS.

Electrodes of TENS were attached to the medial and lateral aspects of both knee joints in a relaxed supine position. In the case group, stimulation was delivered by a dual channel TENS (Novin instrument, 710L, Iran) for 5 min, with a pulse width of 200 μs and frequency of 100Hz. The amplitude of stimulation was at the sensory detection threshold. The control group received sham-TENS, with zero amplitude of stimulation.

A force platform (Kistler Instrument AG, Switzerland), sampling at 50 Hz, was used to measure the displacement and velocity of the foot center of pressure (COP). The measurements were obtained before, immediately, and after 15 and 30 min following intervention with open eyes during standing on a force platform. All measurements were repeated three time with a resting period of 1 min between each trial. Testing conducted while patient was standing with socks on a force plate, while 10 cm distance between the heel centers and each foot 10° abducted [20]. When the feet were placed for the first time, the circumferences of the feet were drawn on the surface of the force platform in order to assure patient returning to the same place of force plate in each trial [13]. Raw data were exported to the Visual 3D® software and filtered using a fourth order low-pass Butterworth filter with a cut off frequency of 12Hz. Postural control was assessed with COP displacement and velocity along the mediolateral (ML) and anteroposterior (AP) axes.

2.3. Statistical analysis

The data were analyzed in SPSS, version 19. The normality of data was evaluated by the Kolmogorov-Smirnov test. Independent T-test and repeated-measurement ANOVA test were used for analysis. The level of the significance for all the tests was set at 0.05.

3. Results

The mean age, weight and height of the participants were 50.62 (±3.6) years, 66.66 (±8.9) and 155.10 (±4.1), respectively. The two groups were matched in anthropometric measures and initial postural control variables (Table 1).

The results showed that the mean COP displacement and velocity in mediolateral (ML) and anteroposterior (AP) directions decreased after applying TENS, but the changes were not significant (P > 0.05) (Figs. 1 and 2).

The results also revealed that the mean COP displacement and velocity in ML and AP directions in TENS group compared to sham-TENS group were not significantly different (P > 0.05) (Figs. 1 and 2).

4. Discussion

In this study the Mean COP displacement and velocity variables were used to determine postural control changes. The findings of this study showed that the mean COP displacement and velocity along the ML and AL axes in both TENS and sham-TENS groups did not change significantly after applying sensory electrical stimulation. So TENS modality probably does not have effect on postural control. Hylton et al., used a type of sensory stimulation in their study and showed that the positive effects of passive tactile stimulus to the leg on the postural control in healthy young control, older people and diabetic peripheral neuropathy patients [14]. Hylton study showed that passive tactile cues to the leg could significantly decrease postural sway during standing. Gravelle et al. also noted that balance control in healthy older adult enhanced by
using electrical noise to the knee. They assumed that reduction in postural sway was due to improvement in somatosensory systems and proprioception [8].

In the previous studies the evaluation of postural control was done simultaneously through applying sensory electrical stimulation and this synchronization is likely to have cumulative effects with other sensory information and probably it could improve the postural control. [8,13] This could be one of the causes of different outcomes. Moreover, in some previous studies there was no control group or the control group was not considered as the sham group. The literature have shown that sham-TENS could exert a placebo effect up to 40% [21,22]. The placebo effect could mask the results, so the differences between the intervention and sham group did not become significant. Moreover the limited number of patients and the short duration of stimulation application could have an impact on the results. On the other hand, it is possible that the effect of TENS has been stopped immediately after stopping the application, so it could be effective just during application. The characteristics of the participants and the used TENS parameters may be effective too.

The results showed that the differences of the COP mean velocity and displacement in both groups were not significant. It seems that the short-term application of TENS in patients with diabetic neuropathy cannot have any effect on postural control improvement. Further researches are required to assess the long-term effects of TENS on the other postural control impairments in these patients.

5. Conclusion

In conclusion, there was no significant difference in the postural control before and after TENS application for diabetic neuropathic patients. It seems that the conventional high frequency TENS with sensory threshold cannot have the positive impact on the postural control of these patients. Future studies are recommended to determine if applying different types of TENS with different durations would improve the postural control.

Declarations of interest

The authors report no declarations of interest

Contributions

All authors including Zahra Rajhani Shirazi (rojhani@sums.ac.ir), Zahra Saadat (saadatzahr@gmail.com) and Leila Abbasi (leabassi@sums.ac.ir) have made substantial contributions to all three of sections (1), (2) and (3) below:

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

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

(3) Final approval of the version to be submitted.

Role of the funding source

The present study is extracted from the proposal number 91-6462 and Z. Saadat’s MSc thesis. This work was financially supported by Shiraz University of Medical Sciences.

Acknowledgements

We would like to thank the patients who participated in the study and also Dr. Nasrin Shokproun at Center for Development of Clinical Research of Nemazee Hospital for editorial assistance.

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