Original Article

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Effects of Transcutaneous Electrical Nerve Stimulation in Patients with Chronic Non-specific Low Back Pain as an Add-on Therapy

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ABSTRACT

Background : *Transcutaneous Electrical Nerve Stimulation (TENS) is often used to treat Low-Back Pain (LBP). However, its effectiveness is controversial in non-specific chronic LBP (CLBP).*
The study aimed to determine TENS' efficacy in treating non-specific CLBP when added to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and Activities of Daily Living (ADL).

Materials and methods: *This randomized controlled clinical trial was conducted in the Department of Physical Medicine and Rehabilitation of Chittagong Medical College Hospital, Chattogram, over six months from January 2019 to June 2019. Ninety patients suffering from LBP for more than six weeks were enrolled and randomized into Group A, and Group B. Patients in both groups were treated with NSAID+ADL. TENS was added to the patients of Group B. Subjective pain intensity score, Visual Analogue Scale (VAS) Tenderness index, Disability due to pain, Spinal mobility index and Oswestry Disability Index was the outcome parameters assessed at baseline and after eight weeks of intervention.*

Results: *Ten patients were lost to follow-up (Five from each group) giving an effective sample of 80 (40 in each group). Both the groups were similar at enrollment in terms of the demographic, clinical and laboratory parameters. In Group A and B, the VAS score at baseline was 7.06±0.81 and 7.11±0.83, respectively. At eight weeks, the VAS score was 6.55±0.77 and 6.11±0.75, respectively, in Group A and B. Reduction of VAS scores was significant in both groups without any statistical differences. Similarly, Disability due to pain and Oswestry Disability Index scores reduced significantly from baseline to eight weeks after treatment in both groups, without statistically significant differences.*

Conclusion: *The study ascertained no additional benefit of TENS in patients of non specific CLBP when added to NSAID and ADL.*

Key words: Chronic low-back pain; Musculoskeletal symptom; Transcutaneous Electrical Nerve Stimulation (TENS).

Introduction

LBP is a common musculoskeletal symptom that occurs in all countries, from developing to developed countries, in all age groups from children to the elderly population and almost everyone with acute episodes or chronic conditions during their lifetime.[1] LBP can seriously affect the quality of life and has become the leading cause of years lived with disability worldwide (64.9 million) when compared with diabetes (38.6 million), chronic obstructive pulmonary disease (30.6 million), and other chronic diseases or disorders in 2017.[2,3]

Many treatments have been proposed, starting with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) and opioids alone or in association with paracetamol.[4] The American College of Physicians and the American Pain Society recommend non-drug therapies for patients who do not improve with conventional treatments. These therapies include intensive rehabilitation, physical exercise, acupuncture, massage therapy, spinal manipulation, yoga, and cognitive-behavioral therapy.[5] Transcutaneous Electrical Nerve Stimulation (TENS) is one of the oldest techniques for treating LBP, particularly chronic LBP (CLBP).[6-8] However, its effectiveness is controversial. Systematic reviews of the Cochrane database did not find robust evidence of TENS efficacy concerning pain, functional status or

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occupational status in the management of CLBP.[9,10] Recent study results do not support the use of TENS in the treatment of patients with CLBP.[11]

Nevertheless, TENS is widely used as a therapeutic adjunct in the management of CLBP. It is a relatively safe, non-invasive, and easy-to-use modality that can be conveniently self-administered by patients at home, making it an attractive treatment option.[8] Few studies from Bangladesh investigated the utility of TENS in nonspecific, but the results were inconsistent.[12,13] Therefore, the present study has been conducted to evaluate the effects of TENS on patients with nonspecific CLBP. The objective of this open Randomized Clinical Trial (RCT) in patients with CLBP was to investigate the efficacy of TENS as an add-on to Activities of Daily Living (ADL) and NSAIDs combinations. The hypothesis was that TENS, combined with ALD and NSAIDs, provides a better quality of life and functional status than ALD and NSAIDs without TENS.

Materials and methods

This RCT was conducted at the Department of Physical Medicine and Rehabilitation, Chittagong Medical College, Chattogram, Bangladesh, from January 2019 to June 2019. The Ethical Review Committee approved the study of Chittagong Medical College. The study participants were informed verbally about the study design, the purpose of the study, and their right to withdraw from the research at any time, for any reason whatsoever. Subjects who gave informed consent to participate in the study were included.

A total of 90 patients were enrolled in the study based on eligibility criteria. Patients aged 21 to 65 years, with LBP for > 3 months, who were able to complete the questionnaire and preferably residents of Chattogram City were included in the study. Patients were ineligible for the study if they had a contraindication to TENS (Epilepsy, pregnancy, wearing a pacemaker, an allodynia area, electrode allergy) if they had used TENS before their enrolment, if they had a mental, sensory, or cognitive disorder, if they lacked autonomy or were living alone without home help; and if they were involved in other pain management research.

The patients who fulfilled the inclusion criteria were randomly allocated into Group A (Controls, n=45) and Group B (TENS, n=45). NSAID and ADL were advised in both groups. In Group B TENS machine operated with a low frequency of 0.5 to 10 Hz and high intensity of 15 to 50 mA. Electrodes placed paravertebral region over lower back for 20 minutes 3 times/week for up to 8 weeks. NSAIDs have been prescribed in the form of Naproxen 250 mg twice daily orally. The therapeutic procedures were executed by the same physiotherapist in the department and advised to continue at home.

Main outcome variables include Subjective pain intensity score, Visual Analogue Scale, Tenderness index, Disability due to pain, Spinal mobility index, and Oswestry Disability Index.[14,15] Outcome measures were assessed at baseline and eight weeks. Assessments were done in the same manner and at the same time intervals for both treatment arms utilizing standardized methods.

Data were processed and analyzed using SPSS v23. All analyses were performed using the per-protocol analysis (Included only those available in the final follow-up). Quantitative data were expressed as mean (Standard deviation), and an independent sample t-test and paired sample t-test tested differences between the two groups and within the individual group. Categorical data were expressed as frequency (Percentage) and compared by the Chi-square test. $p<0.05$ was considered significant statistically.

Results

A total of 90 patients were included in the trial. In both groups, 45 patients started the study, and 80 (40 in each group) were assessable at the eight-week follow-up visit. The demographic characteristics of the study patients are presented in Figures 1 and 2. Both the groups were similar in terms of their age and sex distributions. The mean age was 41.82 (±11.95) and 42.70 (±12.52) years, respectively, in Group-A and Group B. Males were predominant in both groups.

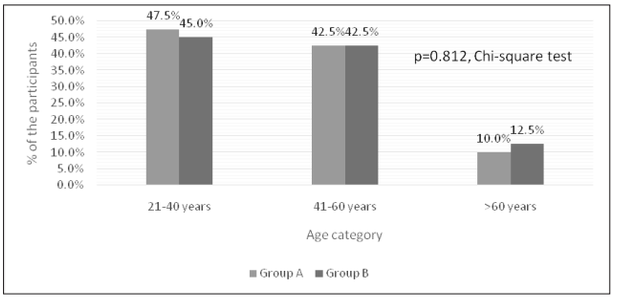

Figure 1 Age distribution of the participants stratified by study groups (Group A: NSAIDs+ADL, Group B: NSAIDs+ADL+TENS)

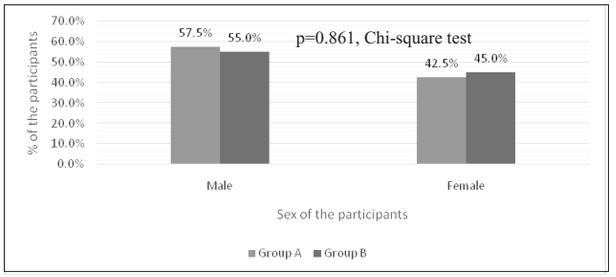

Figure 2 Sex distribution of the participants stratified by study groups (Group A: NSAIDs+ADL, Group B: NSAIDs+ADL+TENS)

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Table I depicted that both the groups were similar at baseline with regards to their clinical and laboratory parameters, including mean duration of pain, height, weight, pulse, Systolic and Diastolic Blood Pressure (SBP & DBP) Hemoglobin, Erythrocyte Sedimentation Rate (ESR) and Schober's test.

Table I Clinical and laboratory parameters of the participants at enrollment

Variables	Group A (n=40)	Group B (n=40)	p-value*
Duration of pain, days	23.9 ± 2.57	23.5 ± 1.50	0.862
Height (Inch)	62.42 ± 2.55	63.24 ± 3.15	0.954
Weight (kg)	57.28 ± 10.32	58.58 ± 10.75	0.760
Pulse/min	73.95 ± 4.73	74.56 ± 4.64	0.449
SBP (mmHg)	122.45 ± 9.13	117.10 ± 10.09	0.758
DBP (mmHg)	78.91 ± 6.23	76.43 ± 4.50	0.659
Hemoglobin (g/dl)	11.72 ± 1.45	12.05 ± 1.42	0.370
ESR mm 1sthr	17.43 ± 7.45	19.35 ± 9.42	0.149
Schober's test	4.32 ± 0.75	4.67 ± 0.73	0.750

Group A: NSAIDs+ADL, Group B: NSAIDs+ ADL+TENS. Data were expressed as mean ±SD. *Independent sample t-test.

Table II shows significant improvement in Subjective pain intensity, VAS, tenderness index, disability due to pain, spinal mobility index, and Oswestry disability index in both groups from baseline to eight weeks post-treatment.

Table II Within-group changes in the outcome parameters in Group A and Group B from baseline to after eight weeks

Outcome parameters	Group A	P-value*	Group B	p-value*
Subject pain intensity				
Pretreatment score W_0	3.21±0.72	0.007	3.27±0.66	0.001
Post-treatment score W_8	2.56±0.62		2.11±0.67	
Pain score (VAS)				
Pretreatment score W_0	7.06±0.81	0.004	7.11±0.83	0.002
Post-treatment score W_8	6.55±0.77		6.11±0.75	
Tenderness index				
Pretreatment score W_0	2.49±0.71	0.020	2.72±0.46	0.001
Post-treatment score W_8	1.94±0.64		1.88±0.58	
Disability due to pain				
Pretreatment score W_0	2.05±0.72	0.021	2.44±0.61	0.021
Post-treatment score W_8	1.38±0.69		1.61±0.50	
Spinal mobility index				
Pretreatment score W_0	5.33±0.28	0.119	5.41±0.33	0.414
Post-treatment score W_8	5.37±0.27		5.45±0.32	
Oswestry disability index				
Pretreatment score W_0	54.00±4.96	0.002	53.40±4.96	0.002
Post-treatment score W_8	12.00±4.05		12.00±4.05	

Group A: NSAIDs+ADL, Group B: NSAIDs+ADL+TENS. Data were expressed as mean ±SD.*Paired sample t-test.

Table III compares the treatment responses between Group A and Group B. There were no significant differences between the two groups in pre-treatment assessment and the improvement during treatment.

Table III Comparison of outcome variables between Group-A & Group-B at different time points

Outcome parameters	Group A	Group B	p-value*
Subject pain intensity			
Pretreatment score W_0	3.21±0.72	3.27±0.66	0.887
Post-treatment score W_8	2.56±0.62	2.11±0.67	0.351
Pain score (VAS)			
Pretreatment score W_0	7.06±0.81	7.11±0.83	0.815
Post-treatment score W_8	6.55±0.77	6.11±0.75	0.415
Tenderness index			
Pretreatment score W_0	2.49±0.71	2.72±0.46	0.615
Post-treatment score W_8	1.94±0.64	1.88±0.58	0.112
Disability due to pain			
Pretreatment score W_0	2.05±0.72	2.44±0.61	0.162
Post-treatment score W_8	1.38±0.69	1.61±0.50	0.210
Spinal mobility index			
Pretreatment score W_0	5.33±0.28	5.41±0.33	0.752
Post-treatment score W_8	5.37±0.27	5.45±0.32	0.614
Oswestry disability index			
Pretreatment score W_0	54.00±4.96	53.40±4.96	0.272
Post-treatment score W_8	12.00±4.05	12.00±4.05	0.889

Group A: NSAIDs+ADL, Group B: NSAIDs+ADL+ TENS. Data were expressed as mean ±SD. *Independent sample t-test.

Discussion

CLBP is an important public health condition due to its impact on work disability, absenteeism, and treatment costs and a considerable amount of research on interventions for pain relief has been performed.[16,17,9,10,18] TENS is a nonpharmacological modality widely used to manage pain; however, its effectiveness for patients with CLBP has been questioned.[8,9,19,20] The current analysis showed that TENS intervention had no additional benefit when combined with NSAIDs and ADL for reducing pain intensity in those with non-specific CLBP during treatment, concordance with previous systematic reviews and meta-analyses. [8,9]

In this study, it was observed that all the outcome variables individually improved in Group-A and Group B, but these were not statistically significant in between two groups. The reduction of VAS score was more in patients who took TENS than in those who did not, but this difference was not statistically significant. Subjective pain intensity and tenderness index improved in both the groups and were statistically significant, but in between the groups, these are not statistically significant. Disability due to pain and

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spinal mobility index - both variables improved statistically significantly at the end of week eight. These were consistent with the previous reports.[11,19,20] Interestingly, the length of time a person uses TENS, that is, duration of treatment, can influence TENS efficacy. A recent meta-analysis showed that TENS reduced pain intensity in people treated with TENS for less than five weeks but not those treated for more than five weeks.[21] A possible explanation for these findings is the occurrence of analgesic tolerance due to repeated applications of TENS, as previously observed in animals and human studies.[22-24]

Limitations

Bergeron-Vezina et al. summarized the limiting factors for studies on TENS as follows: characteristics of the population, intensities, rhythms, and duration of TENS use, concomitant use of opioids, and collection method. Some of these factors posed a problem in our study. The sample size was small and collected from one center only. The duration of the follow-up was limited and done only once. Finally, another important limitation was the absence of Sham devices to operate the same exact way as a fully functional electrotherapy device.

Conclusion

In conclusion, the overall results of this study do not support the use of TENS in treating patients with CLBP as an add-on to NSAIDs and ADL training.

Recommendations

Considering the limitations of the present study, a further multicenter survey with a large sample and repeated longer follow-up is necessary to validate the effect of TENS therapy in CLBP.

Disclosure

All the authors declared no competing interests.

References

1. Chen S, Chen M, Wu X, Lin S, Tao C, Cao H, et al. Global, regional and national burden of low back pain 1990–2019: A systematic analysis of the Global Burden of Disease study 2019. Journal of orthopaedic translation. 2022;32:49-58.

2. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. The Lancet. 2017;389(10070):736-747.

3. James SL, Abate D, Abate KH, Abay SM, Abbafati C, Abbasi N, et al. Global, regional, and national incidence, prevalence and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: A systematic analysis for the Global Burden of Disease Study 2017. The Lancet. 2018;392(10159):1789-858.

4. Webster LR, Markman J. Medical management of chronic low back pain: Efficacy and outcomes. Neuromodulation. 2014;17(Suppl 2):18–23.

5. Chou R, Huffman LH, American Pain S. American College of P. Medications for acute and chronic low back pain: A review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Ann Intern Med. 2007;147:505–514.

6. Winter A. Pain relief—transcutaneous nerve stimulation. J Med Soc N J. 1974;71:365–367.

7. Schuster GD, Infante MC. Pain relief after low back surgery: the efficacy of transcutaneous electrical nerve stimulation. Pain. 1980;8:299–302.

8. Teoli D, An J. Transcutaneous Electrical Nerve Stimulation.In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. 2022.

9. Khadilkar A, Milne S, Brosseau L, Wells G, Tugwell P, Robinson V et al. Transcutaneous electrical nerve stimulation for the treatment of chronic low back pain: A systematic review. Spine. 2005;30(23):2657-2666.

10. Khadilkar A, Odebiyi DO, Brosseau L, Wells GA. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low back pain. Cochrane Database of Systematic Reviews. 2008(4):CD003008.

11. Garaud T, Gervais C, Szekely B, Michel-Cherqui M, Dreyfus JF, Fischler M. Randomized study of the impact of a therapeutic education program on patients suffering from chronic low-back pain who are treated with transcutaneous electrical nerve stimulation. Medicine. 2018;97(52):1-10.

12. Ahmed B, Alam S, Rashid I, Rahman N, Rahman A et al. Effects Of Transcutaneous Electrical Nerve Stimulation (Tens) On Patients With Acute Low Back Pain. J. Armed Forces Med. Coll. [Internet]. 2012 ;7(2):29-32.

13. Siddiquee N, Sobhan F, Newaz F, Rahim HR, Akhter T, Sadeque Z. Outcome of Transcutaneous Electrical Nerve Stimulation (TENS) device for patients with chronic non-specific low back pain. Bangladesh Critical Care Journal. 2022;10(1):26-32.

14. Langley GB, Sheppeard H. The visual analogue scale: Its use in pain measurement. Rheumatology international. 1985;5(4):145-148.

15. Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. Physiotherapy. 1980;66(8):271-273.

16. Airaksinen O, Brox JI, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. European guidelines for the management of chronic nonspecific low back pain. European spine journal. 2006;15(Suppl 2):s192-300.

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Volume 05 Issue 01 June 2022; 82-86

17. Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. The spine journal. 2008;8(1):8-20.

18. Resende L, Merriwether E, Rampazo ÉP, Dailey D, Embree J, Deberg J, et al. Meta analysis of transcutaneous electrical nerve stimulation for relief of spinal pain. European Journal of Pain. 2018 ;22(4):663-678.

19. Buchmuller A, Navez M, Milletre Bernardin M, Pouplin S, Presles E, Lantéri Minet M, et al. Value of TENS for relief of chronic low back pain with or without radicular pain. European Journal of Pain. 2012;16(5):656-665.

20. Van Middelkoop M, Rubinstein SM, Kuijpers T, Verhagen AP, Ostelo R, Koes BW, van Tulder MW. A systematic review on the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. European Spine Journal. 2011;20(1):19-39.

21. Jauregui JJ, Cherian JJ, Gwam CU, Chughtai M, Mistry JB, Elmallah RK, et al. A meta-analysis of transcutaneous electrical nerve stimulation for chronic low back pain. Surgical technology international. 2016;28:296-302.

22. Chandran P, Sluka KA. Development of opioid tolerance with repeated transcutaneous electrical nerve stimulation administration. Pain. 2003 ;102(1-2):195-201.

23. Liebano RE, Rakel B, Vance CG, Walsh DM, Sluka KA. An investigation of the development of analgesic tolerance to TENS in humans. PAIN®. 2011;152(2):335-342.

24. Bergeron-Vezina K, Leonard G. On "What makes transcutaneous electrical nerve stimulation work?" Sluka KA, Bjordal JM, Marchand S, Rakel BA. Phys Ther. 2013; 93: 1397–1402. Physical therapy. 2013;93(10):1426-1427.