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Original Article

Outcome of Transcutaneous Electrical Nerve Stimulation (TENS) device for patients with chronic non-specific low back pain

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Abstract:

Background : *Transcutaneous electrical nerve stimulation (TENS) was introduced more than 30 years ago as an adjunct to the pharmacological management of pain.*

Objective : *This controlled trial examined the benefit of TENS on patients with chronic non-specific low back pain.*

Methods : *This randomized controlled clinical trial was conducted in the department of Physical Medicine and Rehabilitation of Bangabandhu Sheikh Mujib Medical University, Dhaka over a period of 6 months from March,2013 to August,2013. One hundred and ten (n=110) participants were treated. 55 patients were treated with NSAID+ADL, consider as Group-A (treatment as usual control group) and 55 patients were treated with NSAID+ADL+TENS, consider as Group-B (experimental group).*

Result : *The mean age was found 39.1 ± 1.34 years in Group-A and 41.3 ± 2.80 years in Group-B.. Mean duration of pain was found 23.20 ± 2.34 months in Group-A and 21.00 ± 1.50 months in Group-B. Subjective pain intensity, Visual analogue score, tenderness index improved in both groups after at the end of 3rd week and at the end of 6th week, which was statistically significant but in between two groups there is no statistically significant difference.*

Conclusion :*These results suggested that TENS specifically could not have an effect in reducing pain and improving quality of life in chronic non specific low back pain patients but as number of patients were small no firm conclusion could be drawn.*

Key Words: *Transcutaneous Electrical Nerve Stimulation (TENS), Chronic Non specific low-back pain.*

Introduction

Low back pain is defined as an uncomfortable sensation in the lumbar and buttock region originating from neurons near or around the spinal canal that are injured or irritated by one or more pathologic processes[1]. Patients of chronic low back pain are frequently found in our day to day practice. Low back pain (LBP) affects approximately 60–85% of adults during some point in their lives. Fortunately, for the large majority of individuals, symptoms are mild and transient, with 90% subsiding within 6 weeks. For the minority with intractable symptoms, the impacts on quality of life and economic implications are considerable[2]. Low back pain that continues for at least three months is known as chronic low back pain[3]. The management of LBP encompasses a diverse range of possible interventions including drug therapy, surgery, exercise, patient education, physiotherapy, cognitive-behavioral therapy and various other non-pharmacological therapies. A multidisciplinary approach founded on the bio-psychosocial model has been advocated for some patients.[4] Acute and chronic LBP warrant separate consideration as they may respond differently to the same interventions.[5] Transcutaneous electrical nerve stimulation (TENS) is appropriate treatment for acute and chronic low back pain which cannot be treated less expensively, more safely or more effectively by other means.[6] TENS is widely used as a therapeutic adjunct in the management of low back pain. It is 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. TENS units deliver electrical stimulation to underlying peripheral nerves via electrodes placed over the intact skin surface, near the source of maximal pain.[7] The development and application of TENS was based on the Gate Control Theory conceptualized by Melzack and Wall.[8] According to

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this theory, the stimulation of large diameter, (A-beta) primary sensory afferents activates inhibitory interneurons in the sunbstantia gelatinosa of the spinal cord dorsal horn and, thereby, attenuates the transmission of nociceptive signals from small diameter A-delta and C fibers.[8] Supraspinal mechanisms involving the endogenous opioid system have also been described.[9] The postulated effect of TENS is to " close the gate" and dampen the perception of pain.[8] Adverse reaction reported with TENS include skin irritation at the site of electrode placement.[10] TENS is contraindicated in patients with cardiac pacemakers due to the potential of interfering with pacemaker activity.[8] The purpose of the study was conducted to evaluate the effects of Transcutaneous electrical nerve130 stimulation on patients with chronic nonspecific low back pain to decrease patients suffering thereby increasing working capacity. Few studies on chronic non specific low back pain were previously done in Bangladesh. But from those studies, easy and cost-effective treatment option could not be evaluated. So the research dates are needed to evaluate the cost-effective treatment option. Therefore, the present study has conducted to evaluate the effects of TENS on the patients of chronic non specific low back pain to make the treatment easy and cost-effective and to make the disabled patients in to working ones.

Materials and Methods

This was a randomized controlled clinical trial conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka since March, 2013 to August, 2013 a total 118 patients were enrolled in random sapling method. Study population was selected in the Department of Physical Medicine and Rehabilitation (PMAR), BSMMU who was referred from different departments of the hospital and from the general practitioners outside the hospital. Subjects were selected purposively according to the availability of the patients who were fulfill the inclusion criteria and then randomly allocated in two groups (Group A and group B) by lottery. The patients were treated in the department of PM&R with TENS (low frequency 0.5 to 10Hz, high intensity, electrodes placed in paravertebral position) in low back region for 30 minutes 6 times/week for 6 weeks in Group-B and Non-steroidal anti-inflammatory drug (NSAID) & activities of daily living (ADL) are advised in both Group-A and B. NSAID is prescribed in form of Naproxen 250 mg twice daily orally along with ADL advice to both the groups. The therapeutic procedures were executed by the same physiotherapist in the department and advice to continue at home.

Inclusion criteria are a) Patients of both sexes from 18-65 years, b) Individuals who had low back pain for >3months. c) Patients able to complete questionnaire, d) Preferably residents of Dhaka City who are able to attend for follow-up.

Exclusion criteria are the following.

- Duration of Pain < 3moths.
- Individuals who were receiving treatment for their pain with another method at the same time, except for medicine.
- Pregnant women.
- Patients who had undergone vertebral column surgery (less than 3 months before the time of this study).
- Individuals with contraindication against electro therapy, such as skin lesion, abnormal sensitivity, infections & blood diseases, heart pacemakers or inability to answer questionnaire.
- Patients with fibromyalgia.
- Individuals with psychiatric problems.
- Individuals who refused to participate or were unwilling to follow a protocol lasting for two weeks.

Main outcome variables include demographic variables like Age, Sex, Marital Status, Occupation, Socio Economic Condition, baseline clinical and laboratory parameters in first visit.

Out Come measure variables also include, Subjective pain intensity score, Visual

Analogue Scale [11], Tenderness index, Disability due to pain, Spinal mobility index,

Oswestry disability Index[12] .

Statistical analysis:-

Data were processed and analyzed using computer software SPSS (Statistical Package for Social Science). The test statistics used were descriptive statistics, Chi-square (X^2) and F-test (Analysis of variance) Test Level of significance was set at 0.05 and $P<0.05$ was considered significant.

Results

Figure 1 and 2 respectively show the age and sex distribution of groups A & B of the study population.

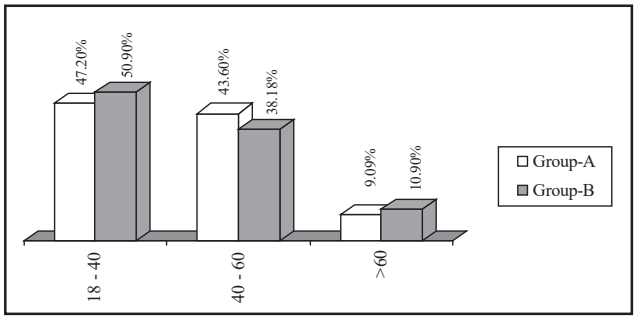

Fig 1

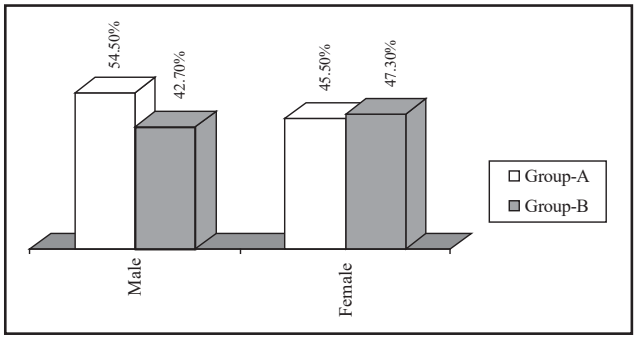

Fig 2

Figure 3 and Fig 4 respectively show distribution of marital status of the patients and socio economic condition of Group-A and Group-B:

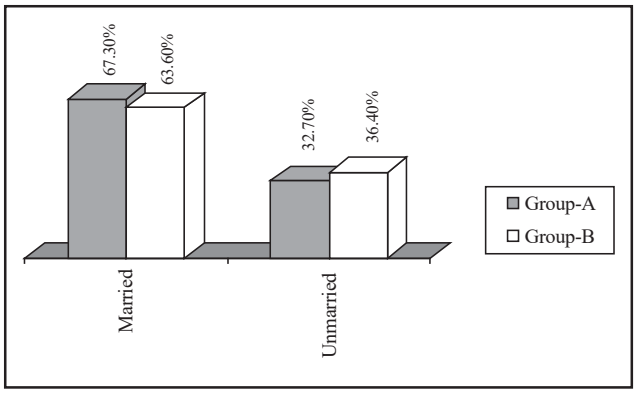

Fig 3

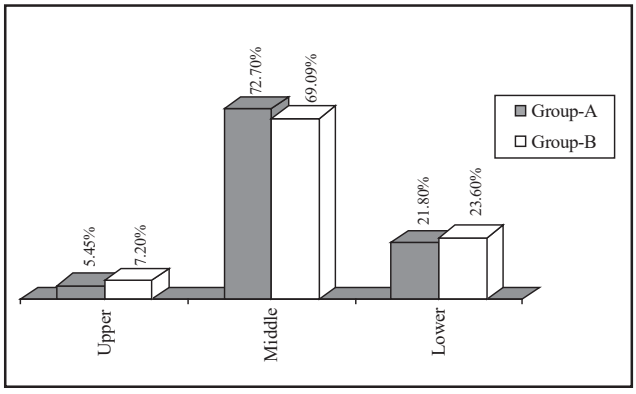

Fig 4

Figure 5 shows distribution of the occupation of the patients of Group-A and Group-B:

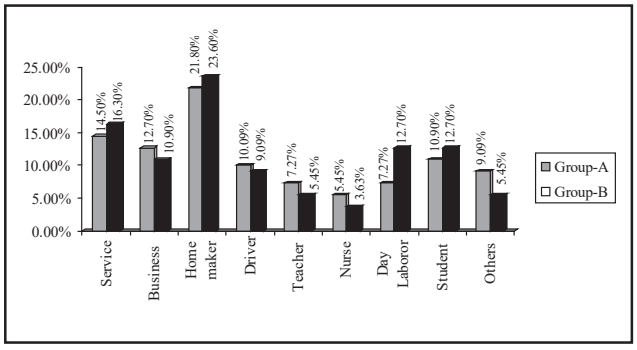

Fig 5

Table: 1 shows baseline clinical criteria during the first attendance of the subjects

Table 1

Parameters	**Group A (n=55)**	**Group B (n=55)**
Duration of pain days	23.2 ± 2.34	21.0 ± 1.50
Height (inch)	62.22 ± 2.55	63.24 ± 3.15
Weight (kg)	57.20 ± 10.32	58.58 ± 10.75
Pulse/min	73.25 ± 4.73	74.56 ± 4.64
Systolic blood pressure (mmHg)	122.35 ± 9.13	117.10 ± 10.09
Diastolic blood pressure (mmHg)	77.91 ± 6.23	74.43 ± 4.50
Hemoglobin (g/dL)	11.12 ± 1.65	12.05 ± 1.42
ESR mm1st hr	17.23 ± 7.55	19.35 ± 9.42
Schober's test	4.22 ± 0.35	4.67 ± 0.73

Table 2 shows treatment response in Group-A (n=55) at different time points:

Table 2

	Mean ± SD	95% confidence interval	Significance (2-tailed)
(a) Subjective pain intensity			
W_0 vs W_3	2.24 ± 0.543 vs 1.53 ± 0.504	0.55 to 0.87	0.000
W_0 vs W_6	2.24 ± 0.543 vs 1.07 ± 0.634	0.99 to 1.33	0.000
(b) Pain Scale (VAS)			
W_0 vs W_3	7.82 ± 0.696 vs 5.62 ± 0.757	1.93 to 2.47	0.000
W_0 vs W_6	7.82 ± 0.696 vs 4.02 ± 0.805	3.52 to 4.08	0.000
(c) Tenderness index			
W_0 vs W_3	1.42 ± 0.599 vs 0.95 ± 0.524	0.33 to 0.62	0.000
W_0 vs W_6	1.42 ± 0.599 vs 0.69 ± 0.573	0.58 to 0.88	0.000
(d) Disability due to pain			
W_0 vs W_3	0.93 ± 0.262 vs 0.56 ± 0.501	0.23 to 0.49	0.000
W_0 vs W_6	0.93 ± 0.262 vs 0.33 ± 0.474	0.47 to 0.73	0.000
(e) Spinal mobility index			
W_0 vs W_3	6.09 ± 0.290 vs 6.53 ± 0.504	0.57 to 0.30	0.000
W_0 vs W_6	6.09 ± 0.290 vs 6.80 ± 0.404	0.84 to 0.57	0.000
(f) Oswestry disability index			
W_0 vs W_3	29.96 ± 4.082 vs 25.33 ± 4.155	3.92 to 5.35	0.000
W_0 vs W_6	29.96 ± 4.1082 vs 22.60 ± 4.605	6.51 to 8.21	0.000

W^0 means before start of first week of treatment, W^1 to W^6 means post treatment week 1 to 6 respectively.

Fifty Five patients were included in Group-A and all of them regularly took the treatment allocated to them. Based on subjective pain intensity, visual analogous scale, tenderness index for chronic non specific low back pain pretreatment and post treatment data were compared statistically. There was significant improvement after treatment in Group-A. In respect to time point improvement, marked improvement started to occur after 3rd week i.e. visual analogue scale at pretreatment score vs. at the end of 3rd week score (W_3) was 7.82 ± 0.696 vs 5.62 ± 0.757 (P=0, 95% CI= 1.93 to 2.47). Based on disability due to pain, spinal mobility index, Oswestry disability index for chronic non specific low back pain pretreatment and post treatment data were compared statistically. There was significant improvement after treatment in Group-A. In respect to time point improvement, marked improvement started to occur after 3rd week i.e. Oswestry disability index at pretreatment score vs. at the end of 3rd week score (W_3) was 29.96 ± 4.082 vs. 25.33 ± 4.155 (P=0, 95% CI=3.92 to 5.35). The improvement gradually increased day by day and after the end of treatment significant improvement was found in our study.

Table 3 shows treatment response in Group-B (n=55) at different time points:

Table 3

	Mean ± SD	95% confidence interval	Significance (2-tailed)
(a) Subjective pain intensity			
W_0 vs W_3	2.27 ± 0.592 vs 1.42 ± 0.534	0.69 to 1.01	0.000
W_0 vs W_6	2.27 ± 0.592 vs 1.15 ± 0.678	0.95 to 1.30	0.000
(b) Pain Scale (VAS)			
W_0 vs W_3	8.02 ± 0.707 vs 5.56 ± 0.714	2.23 to 2.67	0.000
W_0 vs W_6	8.02 ± 0.707 vs 3.95 ± 0.731	3.85 to 4.29	0.000
(c) Tenderness index			
W_0 vs W_3	1.51 ± 0.690 vs 0.96 ± 0.429	0.39 to 0.70	0.000
W_0 vs W_6	1.51 ± 0.690 vs 0.78 ± 0.567	0.57 to 0.89	0.000
(d) Disability due to pain			
W_0 vs W_3	0.93 ± 0.262 vs 0.44 ± 0.501	0.35 to 0.63	0.000
W_0 vs W_6	0.93 ± 0.262 vs 0.25 ± 0.440	0.54 to 0.80	0.000
(e) Spinal mobility index			
W_0 vs W_3	6.11 ± 0.315 vs 6.65 ± 0.480	0.68 to 0.41	0.000

W_0 vs W_6	6.11 ± 0.315 vs 6.75 ± 0.440	0.77 to 0.51	0.000
(f) Oswestry disability index			
W_0 vs W_3	30.84 ± 3.299 vs 26.36 ± 3.822	3.68 to 5.26	0.000
W_0 vs W_6	30.84 ± 3.299 vs 23.55 ± 3.971	6.44 to 8.14	0.000

Fifty Five patients were included in Group-B and all of them regularly took the treatment allocated to them. Based on subjective pain intensity, visual analogous scale, tenderness index for chronic non specific low back pain pretreatment and post treatment data were compared statistically. In respect to time point improvement, marked improvement started to occur after 3rd week i.e. visual analogue scale at pretreatment score vs. at the end of 3rd week score (W_3) was 8.02 ± 0.707 vs 5.56 ± 0.714 (P=0, 95% CI= 2.23 to 2.67). Based on disability due to pain, spinal mobility index, Oswestry disability index for chronic non specific low back pain pretreatment and post treatment data were compared statistically. There was significant improvement after treatment in Group-B. In respect to time point improvement, marked improvement started to occur after 3rd week i.e. Oswestry disability index at pretreatment score vs. at the end of 3rd week score (W_3) was 30.84 ± 3.299 vs 26.36 ± 3.822 (P=0, 95% CI=3.68 to 5.26). The improvement gradually increased day by day and after the end of treatment significant improvement was found in our study.

Table 4 shows comparison of outcome variables between Group-A & Group-B in different time points:

Table 4

	Mean ± SD	**95% confidence interval**	**Significance (2-tailed)**
(a) Subjective pain intensity			
W_0 A vs W_0 B	2.24 ± 0.543 vs 2.27 ± 0.592	0.23 to 0.16	0.709
W_3 A vs W_3 B	1.53 ± 0.504 vs 1.42 ± 0.534	0.08 to 0.29	0.243
W_6 A vs W_6 B	1.07 ± 0.634 vs 1.15 ± 0.678	0.34 to 0.20	0.591
(b) Pain Scale (VAS)			
W_0 A vs W_0 B	7.82 ± 0.696 vs 8.02 ± 0.707	0.46 to 0.06	0.132
W_3 A vs W_3 B	5.62 ± 0.757 vs 5.56 ± 0.714	0.20 to 0.31	0.672
W_6 A vs W_6 B	4.02 ± 0.805 vs 3.95 ± 0.731	0.18 to 0.32	0.560
(c) Tenderness index			
W_0 A vs W_0 B	1.42 ± 0.599 vs 1.51 ± 0.690	0.30 to 0.12	0.389
W_3 A vs W_3 B	0.95 ± 0.524 vs 0.96 ± 0.429	0.20 to 0.17	0.0844
W_6 A vs W_6 B	0.69 ± 0.573 vs 0.78 ± 0.567	0.33 to 0.15	0.451
(d) Disability due to pain			
W_0 A vs W_0 B	0.93 ± 0.262 vs 0.93 ± 0.262	0.09 to 0.09	1.000
W_3 A vs W_3 B	0.56 ± 0.501 vs 0.44 ± 0.501	0.05 to 0.30	0.146
W_6 A vs W_6 B	0.33 ± 0.474 vs 0.25 ± 0.440	0.08 to 0.23	0.350
(e) Spinal mobility index			
W_0 A vs W_0 B	6.09 ± 0.290 vs 6.11 ± 0.315	0.13 to 0.09	0.742
W_3 A vs W_3 B	6.53 ± 0.504 vs 6.65 ± 0.480	0.31 to 0.05	0.164
W_6 A vs W_6 B	6.80 ± 0.404 vs 6.75 ± 0.440	0.77 to 0.21	0.472
(f) Oswestry disability index			
W_0 A vs W_0 B	29.96 ± 4.082 vs 30.84 ± 3.299	2.40 to 0.65	0.257
W_3 A vs W_3 B	25.33 ± 4.155 vs 26.36 ± 3.822	2.69 to 0.62	0.214
W_6 A vs W_6 B	22.60 ± 4.605 vs 23.55 ± 3.971	2.82 to 0.93	0.316

Though highly significant improvement (P<0.005) were observed throughout the whole treatment period in individual group (Table 2 and Table 3), the difference of improvement between the groups were not found to be significant (Table 4).

Discussion

In our study mean age in Group-A was 39.1±1.34 and 41.3±2.8 in Group-B. The mean age difference was all most similar between two groups. Internationally chronic non specific low back pain can begin in person as young as twenty years and increases as age advances[13]. The mean age was found 42.2 years by Shakoor MA et al[14] and it was almost similar to our study.

In our study it was observed that male was predominant in both groups, which was 54.4% percent in Group-A and 52.7% in Group-B the difference was not significant (P>0.05) between two groups. Similarly Mathur et al[15] found male predominance where the author found male to female ratio was 1.1 = 1 in another study Borman, Keskin and Bodur[11] found male to female ratio was 1=1.6 and 1=2.5 in Group-A and Group-B respectively. But in large epidemiological studies no statistically significant difference exists between male and female. The above findings are consistent with the study.

In our study it was observed that most of the patients were mostly house wives (21.8% and 40.0%) in both groups. Bormin, Keskin and Bodur[13] showed 38.1% and 61.9% patients in Group-A and Group-B respectively were employed. Home maker was 43.1% in Group-A and 14.35 in Group-B.

Moyeenuzzaman et al[16] found 15% housewives, 24% students, 19% service holders, 13% farmers, 11% Workers. Sakoor et al[14] in a study conducted with 102 patients in BSMMU found that most of the patients were housewives (58.8%). This findings are consistent with the present study because the in our country, the housewives perform nearly repetitive, lifting and bending[17] In furnishing their household activities like washing, floor moping, cooking, cutting things in an uncomfortable squatting position. These may lead to recurrent rotational strain causing low back pain.

In our study, it was observed that majority patients came from middle class followed by poor family. Poor people in our country have to do heavy works which includes repetitive twisting, bending, heavy weight lifting etc. In addition they do not have enough money to manage balanced diet and proper medication in early stage of disease which increase the incidence of chronic illness. Interestingly few patients were attended from each group. This is due to our public heath service with recent notable improvement still count reach the satisfactory label. Rich people usually take treatment from private clinic and from private doctors but the poor and middle class people do not have enough money to take treatment from private sector and these two groups comprise most of study population. Shakoor et al[14] in as study with patients with chronic low back pain that maximum patients were from middle socio-economic group. So the above findings are consistent with the present study.

In this study, mean duration of pain was found 23.2±2.34 months in Group-A and 21.0±1.5 moths in Group-B the different were not statistically significant (P>0.05) between two groups Borman, Keskin and Bodur[13] showed the mean duration of low back pain 34.09±14.1 months and 27±19.5 months in Group-A and Group-B respectively. Almost similar observations were also made by shimada et al[18] ,Emery et al[19] and Kraamer[20].

In our study it was observed that all the variable individually improved in Group-A and Group-B but these are not statistically significant in between two groups VAS were better in patient who took TENS than in those who did not but these difference was not statistically significant. The VAS of the patients according to the status of Deyo et al[10]. Subjective pain intensity, tenderness index improved in both the groups and statistically significant but in between the groups these are not statistically significant. These two scores were according to the status of continuing with Deyo et al[10]. Disability due to pain and spinal mobility index - both the variables improved at the end of week 3 and week 6 and statistically significant (P<0.05) Deyo et al[10] showed all most similar observation.

The measurement of disability is an important component of the management of patients with chronic low back pain, as the physical performance of patients with low back pain is obviously different from that in patients with other clinical pain syndromes[21]. No statistically significant difference was observed between two groups regarding the Oswestry disability questionnaire score[12].

Conclusion

The number of the patients was small and there were some limitations of the trial. Therefore, no firm conclusion could be drawn. The information collected need verification by large long-term follow up studies. Considering the information gathered from this study, In treating the patients in Group-A and Group-B there is significant improvement individually in both the groups and that is statistically significant but when comparison is done between Group-A and Group-B there is no statistical significant difference is found.

The study was not without limitation. Study time was short. Sample size was small. The study involved one center only. Larger number of study subjects involving several centers would give more credible results.

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