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An Investigation Into The Effects of Modulated Frequency and Low Frequency Transcutaneous Electrical Nerve Stimulation in Relief of Pain Following Abdominal Surgery- A Randomized Controlled Trial

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ABSTRACT

Purpose: This study intended to evaluate the efficacy of transcutaneous electrical nerve stimulation (TENS) for the treatment of postoperative agony in patients who experienced stomach surgery.
Methodology: A randomized study with 45 patients with a pain score > 3 on the visual analogue scale (VAS) were haphazardly allocated in three groups to receive modulated TENS, low TENS and placebo TENS 20 minutes for every session for 5 days postoperatively. Every day the patients got treatment 4 and 8 hourly. Pain was evaluated using a standard 11 point VAS before the application of TENS and followed by 24, 48, 72, 96 and 120 post operative hours.
Results: Modulated TENS group when compared with low TENS group shows that both the groups are equally effective in reducing pain (p=0.836). Whereas when modulated TENS and low TENS groups were compared to the placebo TENS group it was found that both the groups had a noteworthy lessening in postoperative pain (p=0.01).
Conclusions: This study uncovered that modulated TENS as well as low TENS are a significant method of treatment to mitigate postoperative torment.

KEYWORDS Transcutaneous electrical nerve stimulation (TENS), Visual analog scale (VAS), abdominal surgery, Postoperative pain

INTRODUCTION

Viable postoperative pain help is a significant variable for an effective recuperation process after surgery. Around 23 million surgeries are performed in the United States every year. These techniques cause tissue injury and release of powerful mediators of inflammation and pain. In spite of critical advancement in comprehension the pathophysiology of pain, the improvement of remedial alternatives, and the distribution and spread of rules, patients are frequently under-medicated and once in a while get treatment for pain past pharmacologic strategies.[1]

Pain is an essential negative impact in the postoperative advancement of stomach surgeries, particularly those in the upper belly, notwithstanding utilizing pain relieving drugs.

Pain has been described as "an unpleasant experience which we associate with tissue damage or express in terms of tissue damage, or both" (Merskey, 1978).[2] Transcutaneous electrical nerve stimulation (TENS) is a seemingly simple therapeutic apparatus that is increasingly being used in the control and management of pain. [3] Pain has a subjective and socio-emotional element. Hence, it is significant to search for full and humanized care and also non-pharmacological behaviors to handle pain that can minimize conceivable dangers to wellbeing [4], considering the unfriendly impacts that can be brought on by drug. Transcutaneous electrical stimulation is a physical therapy instrument broadly used to relieve pain. [5] It stimulates nerve fibers that send signals to the brain, which the thalamus interprets as pain. Transcutaneous electrical stimulation can be used in the postoperative hospital routine as adjuvant to conventional analgesia. Transcutaneous electrical nerve stimulation (TENS) is a nonpharmacologic methodology that is utilized to treat postoperative pain amid cholecystectomy [6, 7], Laparoscopic sterilization, myomectomy, hysterectomy and surgical abortion. Further, in systematic reviews, Bjordal et al [8] demonstrated decrease in pain relieving utilization in patients utilizing TENS postoperatively. In past studies, low and high frequencies of stimulation amid the same treatment have been appeared to increment postoperative agony help and diminish postoperative pain relieving necessities and symptoms more viably than the different use of low-frequency or high-frequency TENS. A few TENS and TENS-like devices incorporate frequency modulated and frequency alternating settings in their outline. Modulated currents are methodical variations in a specific parameter. Frequency-modulated TENS includes the change of pulse frequency (rate) between preset limits over a settled timeframe (e.g., from 50 pulses for each second [pps] to 100 pps and back to 50 pps at 1 pps steps over a 10-second duration). Frequency-alternating TENS switches pulse frequency between 2 preset values (e.g., 2 pps for 6 seconds took after by 110 pps for 6 seconds.

MATERIALA AND METHODS

Forty five patients, who were enrolled in the department of Surgery, were enlisted in this trial. Patients were selected from the population group satisfying the inclusion criteria from the patients of the department of surgery of K.S Hegde Charitable hospital, Mangalore. Ethical approval was granted by the ethical committee of Nitte University, Mangalore. At first; all the patients underwent an evaluation. The principle target was to gather the information on general and medical history, pain intensity by visual analogue scale score. The targets of doing as such were disclosed to the patient and were educated about the treatment. They were advised that the treatment would not preclude with their different methods of treatment.

Inclusion criteria were patients with abdominal surgery, Patients age 25 – 50 years during the study trial, patients with post abdominal incision pain score > 3 considered by the visual analogic scale (VAS) on the principal postoperative day, both sex, Patient ability to take an interest and the patients which were excluded were Cardio respiratory ailments, patients matured more than 50 Years, Hemoptysis, abnormal skin sensation, Psychiatric illness. The following were the three different groups of treatment:

Modulated TENS Group: In this group, 15 patients were given modulated frequency (4 -150 Hz) TENS. Injectable Tramadol drug 50 mg i.v 8 hourly was given for 5 days post surgery.

Low TENS Group: In this group, 15 patients were given low frequency (4 Hz) TENS. Injectable Tramadol drug 50 mg i.v 8

hourly was given for 5 days post surgery.

Placebo TENS Group: In this group, 15 patients were given injectable Tramadol drug 50 mg i.v. 8 hourly for 5 days without intervention of TENS. [9]

Patients with post-operative incision pain were selected after obtaining surgeon's permission. Two sterile electrodes (first unit channel) were placed on one side of the incision and two other electrodes (second unit channel), on the other side. The electrodes were positioned 1 cm away from the suture line. TENS was given using Gem Stim combo apparatus; model GM320TE, which is a battery-operated TENS. To apply TENS, the type of incision was not taken into consideration.

Based on subject's tolerance, the intensity of the amplitude was adjusted individually generating a perceptible tingling sensation without significant muscle contraction for 20 minutes twice 4 and 8 hourly after surgery. All patients received 50 mg of Tramadol every 8 hours as requested to control pain after surgery. Pain was assessed by a VAS score before the application of TENS on the first post-operative day, and after application of TENS on the 1st, 2nd, 3rd, 4th and 5th postoperative days. [9]

ANALYSIS AND RESULTS:

This study selected and evaluated 64 patients for qualification, where 19 patients were excluded from this study. 12 patients were not ready to satisfy the inclusion criteria, 5 patients declined to take an interest and 2 patients gave different reasons. 64 patients were haphazardly assigned to 3 distinctive groups (15 in each) by method for PC created programming. All the patients were treated with respect to their groups and analyzed. A stream outline of the procedure is as follows:

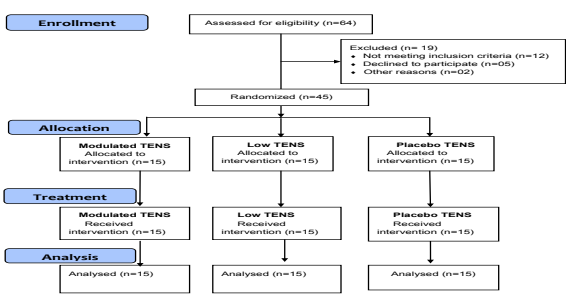


Figure 1: Study flow diagram according to CONSORT guidelines.

Statistical analysis was performed using IBM SPSS 21. For this study, 45 abdominal surgery patients were recruited in the study in which 34 were male and 11 were female. From each subject, pain was measured 6 times. All recorded data were taken for analysis including those of patients who were discharged.

The difference in these variables between and within group was analyzed using repeated measures of analysis of variance (ANOVA). Bonferroni test was used for Pairwise comparisons. The level of significance was set at $P<0.05$. Details are presented in the following tables.

Table 1: Descriptive of patients with VAS scores

Descriptive Statistics				
	Groups	Mean	Std. Deviation	N
POD1B	Modulated TENS	7.6667	.61721	15
	Low TENS	7.4667	.63994	15
	Placebo TENS	7.4000	.50709	15
	Total	7.5111	.58861	45
POD1	Modulated TENS	5.8000	.94112	15
	Low TENS	6.0000	.92582	15
	Placebo TENS	6.2000	.67612	15
	Total	6.0000	.85870	45
POD2	Modulated TENS	4.2667	.79881	15
	Low TENS	4.5333	1.06010	15
	Placebo TENS	5.3333	.81650	15
	Total	4.7111	.99138	45
POD3	Modulated TENS	3.0667	.79881	15
	Low TENS	3.3333	.89974	15
	Placebo TENS	4.4667	.74322	15
	Total	3.6222	1.00654	45
POD4	Modulated TENS	1.8667	.83381	15
	Low TENS	2.4667	.99043	15
	Placebo TENS	3.5333	.83381	15
	Total	2.6222	1.11373	45
POD5	Modulated TENS	1.2667	.59362	15
	Low TENS	1.6667	.61721	15
	Placebo TENS	2.8667	.74322	15
	Total	1.9333	.93905	45

Table 1 demonstrates the mean and standard deviation of VAS scores. It was observed that the VAS score reduced from day three until the fifth post operative day in all the groups but modulated TENS group exhibits a faster pain reduction as compared to the other two groups.

Table 2: Tests of Within-Patients Effects

Measure: VAS							
Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
POD[S]	Sphericity Assumed	998.356	5	199.671	746.693	.000	.947
	Greenhouse- Geisser	998.356	4.082	244.561	746.693	.000	.947
	Huynh- Feldt	998.356	4.792	208.340	746.693	.000	.947
	Lower- bound	998.356	1.000	998.356	746.693	.000	.947
Error(-POD[S])	Sphericity Assumed	56.156	210	.267			
	Greenhouse- Geisser	56.156	171.454	.328			
	Huynh- Feldt	56.156	201.262	.279			
	Lower- bound	56.156	42.000	1.337			

From table 2 we can find the F value for the "POD[S]" factor, its related significance level and impact size ("Partial Eta Squared"). As our information debased the assumption of sphericity, we take a look at the values in the "Greenhouse-Geisser" column (as showed in yellow). We can report that when utilizing an ANOVA with repeated measures with a Greenhouse-Geisser correction, the mean scores for VAS focus were measurably altogether distinctive ($F(998.35, 56.15) = 746.693$, $p < 0.0005$).

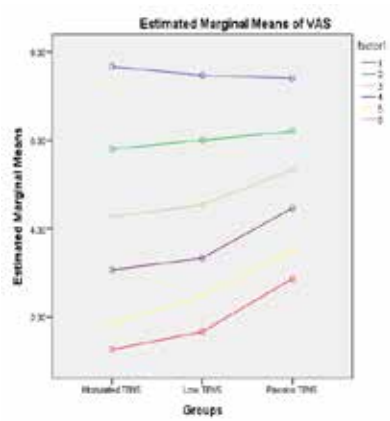
Table 3: Pairwise Comparisons between the groups

Measure: VAS						
(I) Groups	(J) Groups	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Modulated TENS	Low TENS	-.256	.233	.836	-.836	.325
	Placebo TENS	-.978*	.233	.000	-1.559	-.397

Measure: VAS						
(I) Groups	(J) Groups	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
Low TENS	Modulated TENS	.256	.233	.836	-.325	.836
	Placebo TENS	-.722*	.233	.010	-1.303	-.141
Placebo TENS	Modulated TENS	.978*	.233	.000	.397	1.559
	Low TENS	.722*	.233	.010	.141	1.303
Based on estimated marginal means						
*. The mean difference is significant at the .05 level.						
b. Adjustment for multiple comparisons: Bonferroni.						

Table 3 above, gives us the significance level for differences between the groups. We can see that there was a significant difference in VAS application when all the three groups were compared. When modulated TENS group was compared with low TENS and placebo TENS group it was documented that there was no significant difference with the low TENS group (p=0.836), which justifies that both the groups were equally effective in managing pain. Whereas when modulated TENS and low TENS groups were compared with the placebo groups, there was significant difference (p=0.001, 0.10 respectively), indicating that both the modulated TENS and low TENS groups were equally effective when compared with placebo TENS group. From the **"**Mean Difference (I-J)**"** column we can see that VAS concentration was significantly reduced at this time point.

Graph 1: Between-group comparison of mean VAS score



In the above graphs when comparing the three experimental groups (Modulated TENS, Low TENS and Placebo TENS) the differences before treatment of TENS on the 1st post operative day is compared to the 5th post operative day, there was a pain reduction on all the 5 post operative days for all the groups, but Modulated TENS showed clinically more effective in reduction of pain.

DISCUSSION: In the current study, most of the patients informed about their pain intensities after surgical incision immediately in the post operative period. The routine analgesics or post operative drug for pain was maintained in each patient in this study. Statistical analysis demonstrates that in each of the three groups the pain relieving medicine did not impact a large portion of the methodology. For post-operative absence of pain, the part of TENS is uncertain. There is limited systemic review on effectiveness of TENS for post-operative analgesia. A systemic review on TENS concluded TENS to be ineffective; be that as it may, the trials incorporated into these surveys did not mull over the viable parameters of TENS and the result measures were not standardized. Bennet et al**.** found that low loyalty in studies might be in charge of uncertain discoveries. They discovered many areas of concern such as lack of information given to patients regarding the sensations, lack of instruction on how to self-administer TENS devices and assessment of compliance, improper use of TENS in regards to duration and pattern, and failure to standardise or report concurrent analgesia and to assess comparability between groups. Notwithstanding, the principle region of concern was the ampleness of the TENS mediation and poor appraisal of results.

In this study, TENS was effective in calming pain brought about by post surgical. The consequence of this study demonstrates that all the modes of TENS altogether decreased abdominal incision pain when contrasted with the control group. This information is like that got by Ali et al [10], who likewise exhibited the adequacy of TENS in alleviating postoperative pain.

Post operative pain along the incision is one of the major hindering factor which leads to difficulty in performing activities of daily living caused due to pain after abdominal surgery. Various physical therapy means such as abdominal binders were used in past to overcome pain during movement. The most common method used was the pharmacological interventions but with a compromise of side effects. Transcutaneous electrical nerve stimulation with conventional or acupuncture type of TENS with or without modulation was effectively used in past to relieve pain. There are several studies documenting the positive effects of low as well as high TENS for relieving pain. The modulated frequency TENS has the properties to produce the non-painful regulated sensory-motor stimulation which may make a patient comfortable in receiving electrical mode of intervention.

The strong evidence of modulated TENS for pain reduction in post surgical pain suggesting that even modulated frequency TENS is a successful option treatment strategy The aftereffects of various examinations of this study confirming that modulated frequency is a superior helpful device like low frequency TENS. In addition, these outcomes likewise firmly relate with past study aftereffects of Rakel B, et al. [11] who has done a study on modulated TENS in the administration of post stomach surgical pain. This present study results have shown the further evidence for the therapeutic effectiveness of low Frequency TENS in reducing pain.

Hansson and Ekblom, found no distinction between low (2-Hz) and high frequency (100-Hz) electrical stimulation. Nonetheless, the alternating example of low-and high-frequency stimulation might offer favorable position over either frequency alone. Moreover, a study by Gary J Ordog and this study demonstrate the effectiveness of TENS in the management of pain and may be indicated for patients who cannot be given medicines.

CONCLUSION: The current RCT results show that modulated TENS is effective in reducing post-abdominal incision pain and pulmonary dysfunction as compared to the high TENS and control group. This study shows that frequency-modulated TENS and low TENS significantly reduces post-operative incision pain as compared with the placebo group following abdominal surgery. Due to the absence of complications and adverse effects of TENS compared to conventional opioids and non-opioid analgesics, it is suggested that TENS is safe and may be a reliable therapeutic procedure that can be used as an adjunctive to relieve postoperative pain.

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