

# Effects of Modulated Transcutaneous Electrical Nerve Stimulation on Incisional Pain Post Cardiac Surgery: A Randomized Controlled Trial

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## Abstract

**Purpose:** To evaluate effects of modulated transcutaneous nerve stimulation on incisional pain post cardiac surgery.

**Methods/design:** 40 patients undergoing cardiac surgery were randomized into 2 groups (20 in each) by single blinded envelope sealed method. Experimental group has been given Modulated TENS following normal cardiac rehabilitation while Control Group has been given Placebo TENS Following normal cardiac rehabilitation respectively. TENS was given for 30 minutes once in a day after the removal of pacing wire till the day of discharge. Pre intervention outcome measure for pain (VAS) and Anxiety (BAI) was evaluated on the first and last day of the treatment.

**Results:** Between the group analysis is done using Mann Whitney U Test. The results showed there is significant difference between the groups in pre and post values VAS, where as for BAI there is no significant difference between the groups in pre and post values. Within the group analysis was done by Wilcoxon Sign Rank Test. The results indicated a significant difference in the pre and post values of VAS and BAI.

**Conclusion:** From the study conducted, we came to a conclusion that transcutaneous electrical nerve stimulation was found to be effective in reducing incisional pain post cardiac surgery.

**Keywords:** Median sternotomy, Coronary artery bypass graft, Stenotic Valves.

## INTRODUCTION

Seven million heart surgeries worldwide are conducted in a year<sup>[1]</sup>. And in India, evidence shows 60,000 heart surgeries performed in one year. Among the various hospitals per year nearly 1000 to 2000 cardiac surgery is performed collectively, particularly in Karnataka. Cardiovascular disease is the leading killer in the world, accounting for 16.7 million or 29.2 percent of global total deaths. Victims of heart attack are just the first wave of death now happening in nations comprising most Asian Countries. The major cause to be the genetic predisposition and acquisition of conventional risk factors at a speedy rate as a result of Urbanization.

Coronary artery bypass graft surgery (CABG) is done to correct the myocardial ischemia or coronary artery blockage. Valvular surgery is another type of cardiac surgery which is performed to repair the valve defects. The main cause of valve problems is rheumatic heart disease, Ageing can cause valve weaken and harden; Certain disease can scar or destroy a valve. Stenotic valves are too tight and restrict the blood flow. Leaking of valves or damage to valves can also lead to myocardial ischemia or heart attack.

In the patients undergoing cardiac surgery the main route of surgery is median sternotomy<sup>[2]</sup>. Median sternotomy is type of surgical procedure in which vertical midline incision is made along the sternum, after which the sternum itself is divided. Incisional pain is usually described as a type of post-operative pain caused by presence of inflammatory substances due to the structural damage to the skin over sternum, fascia and sternum itself. The incisional pain also contribute to the anxiety and depression, breathing difficulty, reduced chest wall mobility, secretion retention etc

TENS is a type of electro-therapeutic modality where rectangular shape electrical impulses are delivered transcutaneous root primarily to reduce pain and related dysfunction<sup>[3]</sup>. TENS has been increasingly used in physical therapy for the relief of acute and chronic pain. TENS is particularly suited for the treatment of neurogenic pain, orthopedic pain and incisional pain.

There are five types of TENS, they are Acupuncture TENS, Burst TENS, Brief Intense TENS, Modulated TENS and Placebo TENS.

**Acupuncture TENS** having high intensity and low frequency which stimulates high threshold A delta and C fibres which leads to release of endogenous opioids and provides further sensory input from muscle spindle afferents and is commonly used in longstanding, deep aching pain.

**Burst TENS** is low frequency trains consisting of high frequency, high intensity and short duration pulses and therefore provides pain relief by both routes.

**Brief Intense TENS** is high frequency, long pulse duration, maximum tolerable intensity applied for limited (<15 min) periods.

**Modulated TENS**, there is variation in frequency, amplitude, and pulse duration in a cyclical fashion. Sometimes some units have modulation in two or all three of these parameters. If the output is set for amplitude modulation, a cyclical modulation in amplitude is produced which increases from zero to preset level then back to zero again. With this, we can overcome the nerve accommodation and provides more comfort to the patient. The frequency is low (less than 10Hz) variable, intensity should be set according to the patient comfortable and variable. The duration should be 20 to 30 minutes. The mechanism of pain relief is opioid mediated. It is used for both acute and chronic pain.

**Placebo TENS** - It is a technique in which very low intensity electrical impulses are delivered into the tissue transcutaneously in order to reduce the pain perception among the patients with any painful clinical condition.

#### **OBJECTIVE OF THE STUDY:**

To find out the clinically meaningful group difference between the pain score among the patients with post cardiac surgery through median sternotomy.

To find out the clinically meaningful group differences between the hospital induced anxiety among the patients with post cardiac surgery through median sternotomy.

**HYPOTHESIS:**

**NULL HYPOTHESIS:** There will not be significant group differences between the primary and secondary outcome measures among the patients with post cardiac surgery through median sternotomy.

**ALTERNATE HYPOTHESIS:** There will be significant group differences between the primary and secondary outcome measures among the patients with post cardiac surgery through median sternotomy.

**METHODOLOGY**

**SOURCE OF DATA**

Department of CTVS, Cardiac Intensive Care Unit, Justice K.S Hegde Charitable Hospital, Deralakatte, Mangalore

**METHOD OF DATA COLLECTION**

**Study Design:** Single Blinded Randomized Controlled Trial

**Study Type:** Intervention Study

**Target Population:** Patients undergoing cardiac surgeries through median sternotomy (Acute Phase)

**Study Duration:** 12 Months

**Study Enrolment:** February 2019- February 2020

**Sampling Design:** Simple Random Sampling

**Sampling Method:** Concealment Method

**Randomization:** Envelope sealed method

**Sample Size:** 40

**CTRI registration no:** CTRI/2019/09/021150

**SELECTION CRITERIA:**

**INCLUSION CRITERIA:**

- Both the gender with 30 to 70 years of age.
- On and Off pump cardiac surgery with median sternotomy.
- Patients willing to participate.
- Post-operative (Acute Phase).

**EXCLUSION CRITERIA:**

- Patient with hemodynamic instability.
- Patients unconscious/ coma patients (GCS<10)
- Patient with post-operative complications like post-operative bleeding, bloodstream infection, pericarditis
- Patients having cardiac pacemaker and metal implants other than prosthetic heart valves.
- Subjects with impaired sensations, broken or damaged skin and infection at the suture.

**OUTCOME MEASURES:**

**Visual Analog Scale (VAS):**

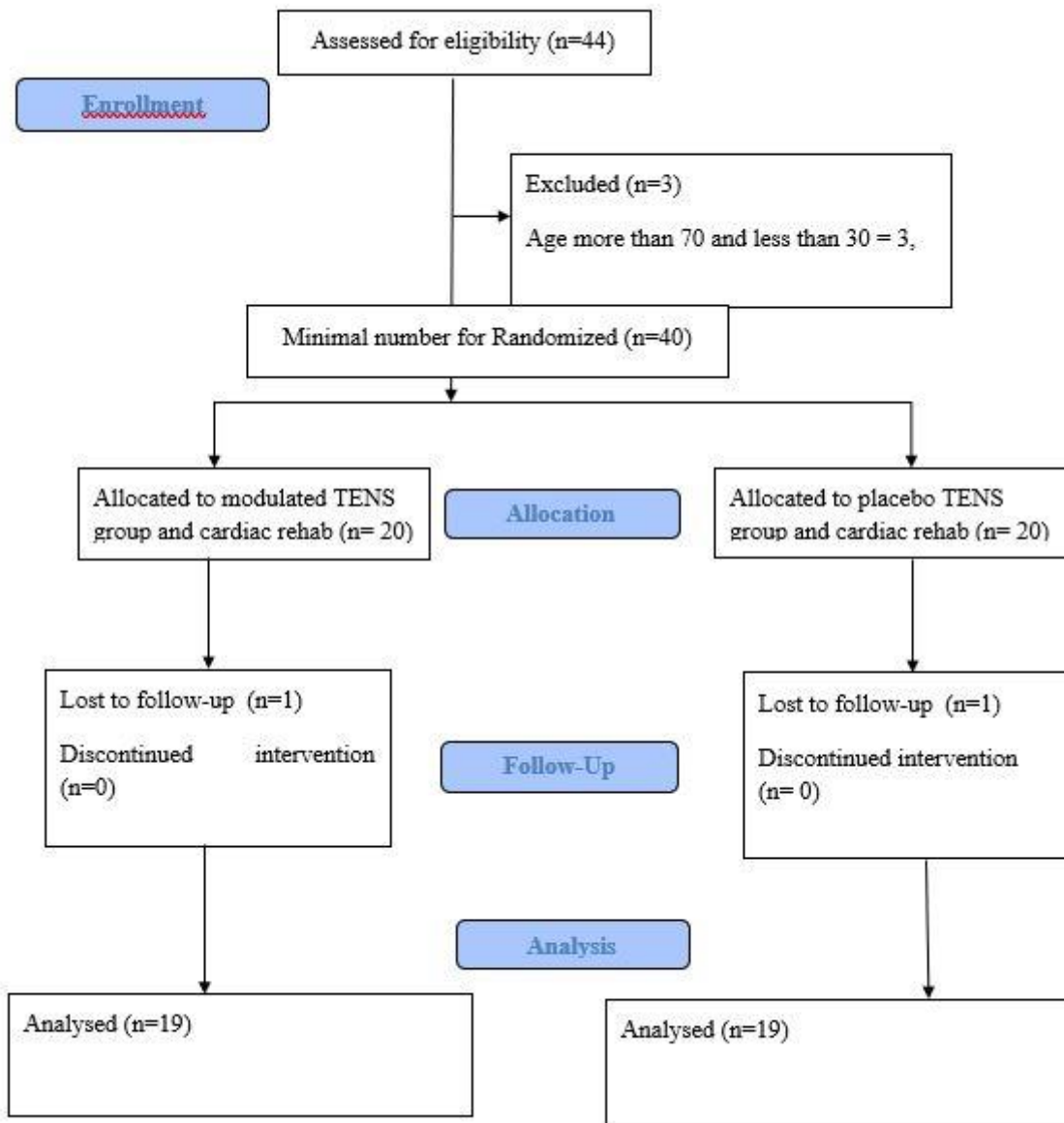
It is a pain rating scale which is used to know about severity of the pain a patient perceives.

**Beck Anxiety Inventory (BAI):**

It is a brief measure of anxiety which focus on somatic symptoms of anxiety. It includes the assessment of symptoms such as nervousness, dizziness and inability to relax etc. It has total 21 items which indicate how much they have been bothered by each symptom over past week. The BAI is used in effort

to obtain a purer measure of anxiety that is relatively independent of depression. The total scoring is from 0-63. According to scoring it is classified as low, moderate and potentially concerning level of anxiety.

**STUDY PROFILE:**



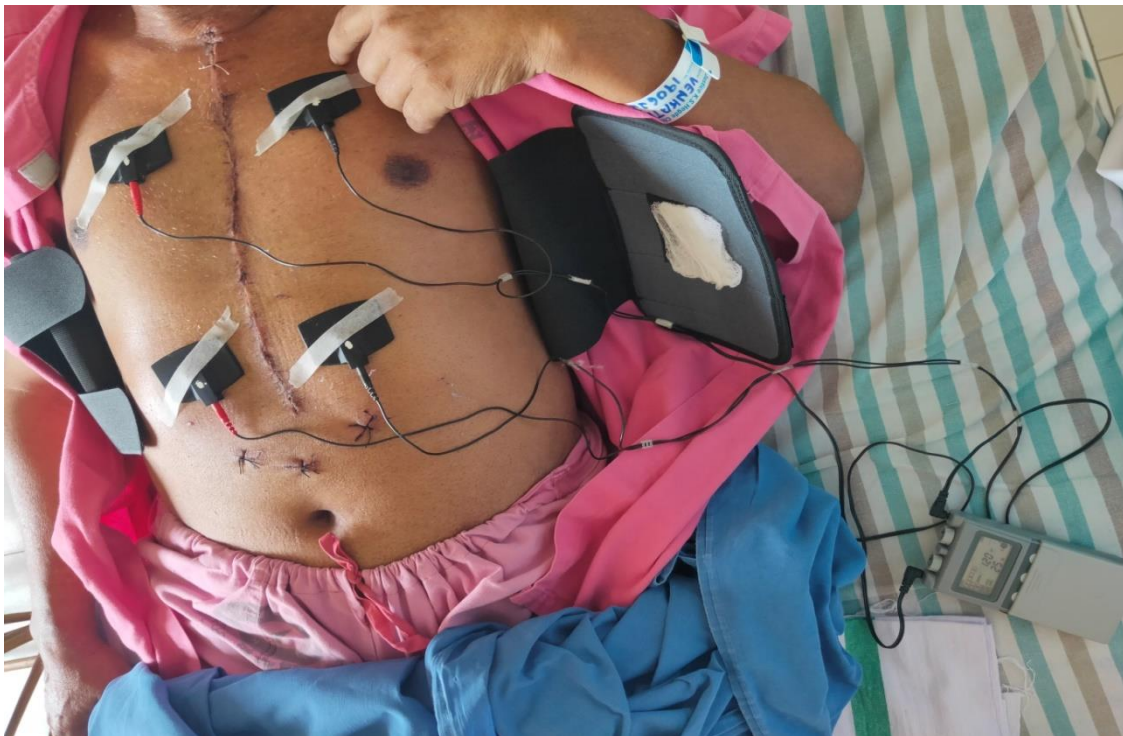
**Method**

Patients who were approached with On and off pump cardiac surgery were recruited for the study. Patients were explained about the purpose of the study and an informed consent was taken from them before surgery. Patients were screened according to the inclusion and exclusion criteria and were allocated single blinded into 2 groups (1) Experimental group (2) control group. In experimental group Modulated TENS was given by physiotherapist and Analgesic drug is given by the medical professionals followed by cardiac rehabilitation and in control group Placebo TENS was given by physiotherapist and Analgesic drug is given by the medical professionals followed by cardiac rehabilitation. The treatment was started on the day of removal of pacing wire till the day of discharge. Patient position is supine.

TENS with 2 channel output with four rubber pad electrodes are used and is kept 2 to 3 cm away from the incision <sup>[10]</sup>. The TENS was given for 30 minutes once in a day<sup>[16]</sup> After the TENS the normal exercise protocol was followed according to the cardiac rehabilitation in both the groups. The Primary outcome measure used was Visual Analogue Scale (VAS) which shows the intensity of pain which patient perceives <sup>[5]</sup>. Secondary outcome measure was Beck anxiety Inventory scale to check anxiety level of the patients which is admitted in ICU <sup>[8]</sup>. Both the outcome measures was taken after the removal of pacing wire till the day of discharge.

### Procedure

Patient was asked to lie down in supine position. Electrodes of TENS were placed 2 to 3 cm away from the incision with applying gel, to reduce skin resistance. On the machine, set the parameters as mentioned above. Increase the intensity according to the patient tolerable capacity and leave it for 30 minutes.



**Application of TENS**

### Interventions

#### **Group A: Modulated TENS:**

Patient was asked to lie down in supine position. Electrodes of TENS were placed 2 to 3 cm away from the incision with applying gel, to reduce skin resistance. On the machine, Set as modulated TENS and its parameters as mentioned in the study. Increase the intensity according to the patient's tolerable capacity and leave it for 30 minutes once in a day.

#### **Group B: Placebo TENS:**

Patient was asked to lie down in supine position. Electrodes of TENS were placed 2 to 3 cm away from the incision with applying gel, to reduce skin resistance. On the machine, Set as Placebo TENS and its

parameters as mentioned in the study. Increase the intensity according to the patient’s tolerable capacity and leave it for 30 minutes once in a day.

**Duration of Treatment:** 30 minutes once in a day, after removal of pacing wire till the day of discharge.

**RESULTS**

**Statistical Analysis:**

The collected data was taken from the patient and was summarized by using frequency, Mean, standard deviation, percentage and inter quartile range (IQR) (descriptive statistics).

All statistical analysis was done using SPSS version 21.

**INFERENTIAL STATISTICS:**

Chi square test and independent sample “t” test was used to find the homogeneity of baseline characteristics and groups.

To compare the outcome measures (VAS, BAI) between Group 1 and Group 2, Mann Whitney U test was used.

To compare the difference in pre and post values of outcome measures Wilcoxon sign rank test was used.

The P-value <0.05 was considered significant.

**Table 1 – Testing of homogeneity of Gender according to groups**

	Group A		Group B		Chi Square	p value	
	n	%	n	%			
Gender	Male	13	65	12	60	0.107	0.744
	Female	7	35	8			

Chi square test was used to test homogeneity of gender according to groups. The obtained p value was 0.744 and hence gender was distributed equally according to groups.

**Table 2 – Testing of homogeneity of Age and VAS (Pre test) according to groups**

	Mean	S.D	"t"	p value	
Age	Group A	54.25	10.16	0.462	0.647
	Group B	52.70	11.05		
VAS	Group A	5.24	1.53	3.09	0.004*
	Group B	3.68	1.65		

(\* Significant)

Independent sample “t” test was used to test homogeneity of Age and VAS (Pre test) according to groups. Obtained p value for age was 0.647, which is more than 0.05 and hence age was distributed equally according to groups. For VAS the p value is 0.004 and hence pretest measurements of VAS not distributed equally according to groups.

**Table 3 – Testing of homogeneity BAI (Pre test) according to groups**

	Median	IQR	"Z"	p value	
BAI	Group A	3	2.25 to 4	0.938	0.368
	Group B	2.5	0 to 4		

Mann Whitney U test was used for Testing of homogeneity BAI (Pre test) according to groups and obtained p value is 0.368. Thus, pre test BAI was distributed equally according to groups.

**Table 4 – Comparison of VAS irrespective of groups**

	Median	IQR	"Z"	p value	
VAS	Pre	4.3	3.43 to 5.8	-5.414	< 0.001
	Post	2.15	1.43 to 3.5		

(\* Significant)

Wilcoxon sign rank test was used to compare VAS before and after interventions irrespective of groups.

**VAS:** Pre-value for median 4.3 and IQR 3.43 to 5.8, Post-value for median 2.15 and IQR 1.43 to 3.5, p-value is less than 0.001 hence it was statistically significant.

The calculated p value was less than 0.001. Hence, there was a difference in VAS score.

**Table 5 – Comparison of VAS according to each group**

VAS	Median	IQR	"Z"	p value	
Group A	Pre	4.85	4.25 to 6.18	-3.928	< 0.001
	Post	2	1.5 to 3.05		
Group B	Pre	3.8	2.43 to 4.55	-3.648	< 0.001
	Post	2.95	1.05 to 4.08		

(\* Significant)

Within group comparison of VAS according to groups was analyzed by using Wilcoxon sign rank test and the obtained p values are less than 0.001 for all comparison. Hence there was a difference in VAS before and after interventions for each group.

**Table 6 – Comparison of BAI irrespective of groups**

	Median	IQR	"Z"	p value	
BAI	Pre	3	0.25 to 4	-3.799	< 0.001*
	Post	1.5	0 to 2		

(\* Significant)

Wilcoxon sign rank test was used to compare BAI before and after interventions irrespective of groups.

**BAI:** Pre-value for median is 3 and IQR 0.25 to 4, Post-value for median 1.5 and IQR is 0 to 2, hence the p-value is less than 0.001 which shows statistically significance in pre and post values of BAI.

As, p value was less than 0.001 there was a difference in BAI score.

**Table 7 – Comparison of BAI according to each group**

BAI	Median	IQR	"Z"	p value	
Group A	Pre	3	2.25 to 4	-3.173	0.002*
	Post	2	0.25 to 2		
Group B	Pre	2.5	0 to 4	-2.172	0.030*
	Post	1	0 to 3		

(\* Significant)

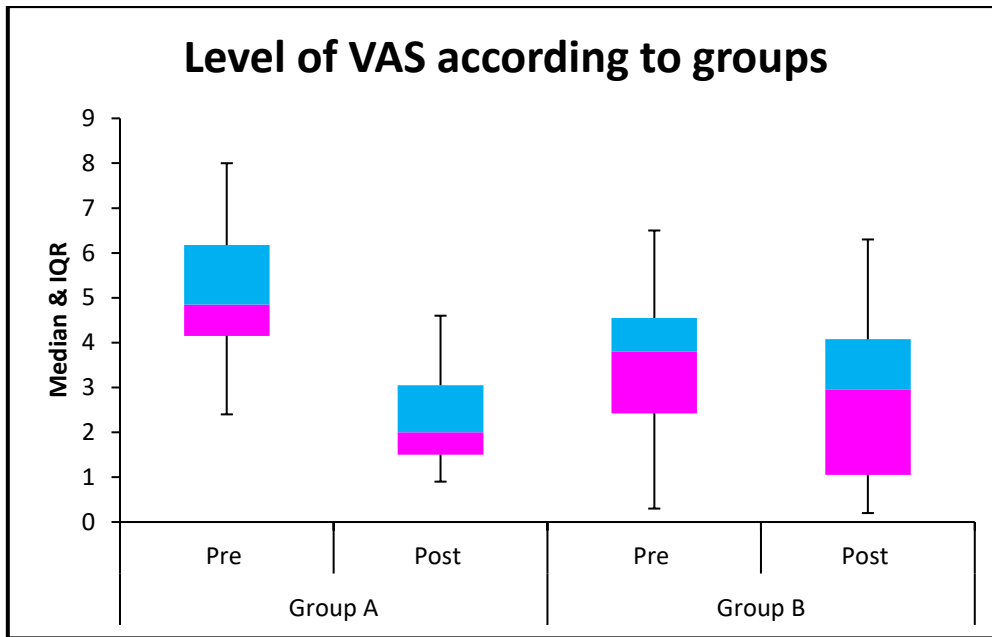
Within group comparison of BAI according to groups was analyzed by using Wilcoxon sign rank test and the obtained p values are 0.002 and 0.030 for all comparison. Hence there was a difference in BAI before and after interventions for each group.

**Table 8 – Comparison of effectiveness (Pre – Post) of VAS and BAI between the groups by using Mann Whitney U test**

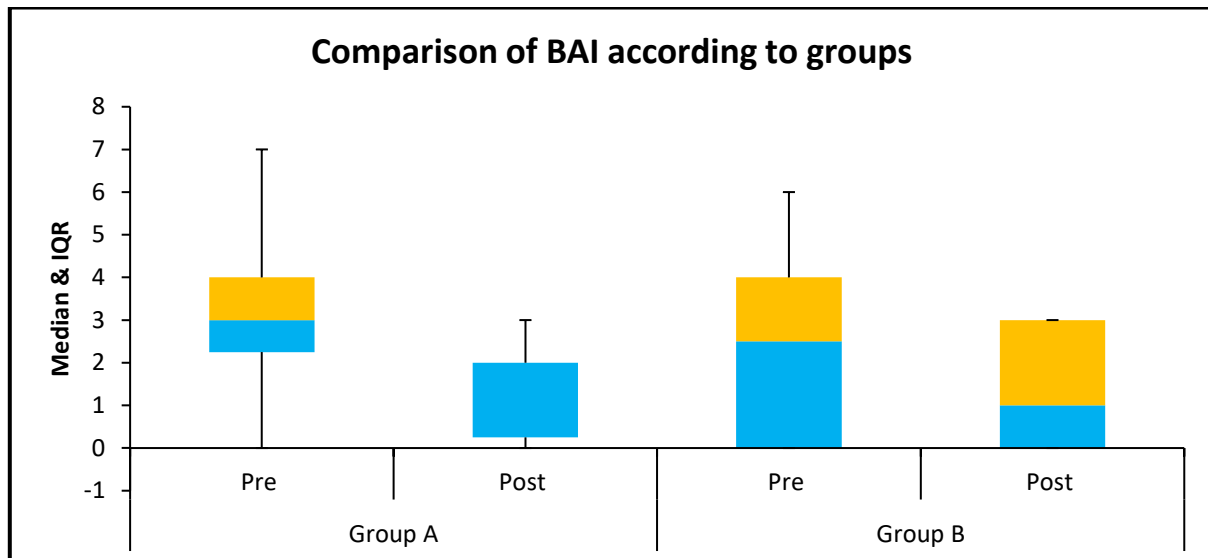
BAI	Median	IQR	"Z"	p value	
VAS	Group A	2.8	2.6 to 3.38	-4.815	< 0.001*
	Group B	2	0.25 to 3		
BAI	Group A	0.45	0.13 to 1.43	-1.281	0.211
	Group B	1	0 to 3		

Mann Whitney U test was used to compare the effectiveness between the two groups. Obtained p value was less than 0.001 for VAS and hence there was a difference in the effectiveness VAS between the groups. Since the p value for BAI was 0.211, there was no difference effectiveness between the groups.





**Graph 1: Level of VAS According to groups**



**Graph 2: Comparison of BAI according to groups**

## DISCUSSION

With the increase in present day lifestyle and food habits Coronary Artery Disease is increasing among all populations. Cardiac surgery has become very common, where CABG is one of the most common surgery which is done.

In the early stage of post-surgery, patient mainly complains of pain in the incisional area, and this pain may contribute to Anxiety, depression and breathing difficulty.

Therefore, our current study was designed to evaluate the effects of modulated transcutaneous electrical nerve stimulation on incisional pain, post cardiac surgery and also to evaluate hospital induce anxiety.

40 subjects were recruited for this study where they were randomised into two groups, Group A & B.

Group A received modulated transcutaneous electrical nerve stimulation following normal cardiac rehabilitation and Group B received Placebo transcutaneous electrical nerve stimulation following normal cardiac rehabilitation.

The intervention outcome measures used were VAS and Beck Anxiety Inventory which is a valid and reliable tool. The pre and post treatment outcomes were assessed by the blinded assessor.

Testing of homogeneity of gender was analysed using chi square test and obtained p-value is more than 0.05 indicating that the gender was equally distributed according to group as shown in **Table 1**.

Baseline characteristics were also analyzed using independent sample t-test for age and VAS. For **AGE**, Group A, mean age among 20 patients was  $54.25 \pm 10.16$ , while in Group B, among 20 patients mean age was  $52.70 \pm 11.05$ . The p-value was 0.647, which is more than 0.05 hence there was no significant difference in the mean age between the groups.

**VAS:** Group A, mean was  $5.24 \pm 1.53$ , while in Group B, mean was  $3.68 \pm 1.65$ . p-value was 0.004, which is less than 0.05 hence there was significant difference in VAS mean between the groups.

For **BAI** the homogeneity was analyzed using Mann Whitney U test where Group A, median is 3 and IQR is 2.25 to 4, Group B, median 2.5 and IQR 0 to 4, p-value is 0.368, which is more than 0.05.

**Thus the Baseline characteristics (Age, VAS & BAI) were found to be homogeneous as shown in Table 2 & 3.**

Within group comparison of VAS and BAI was analysed using Wilcoxon sign rank test.

For **VAS**, in Group A, the pre-value for median is 4.85 and IQR is 4.25 to 6.18. The Post-value for median was 2 and IQR 1.5 to 3.05. The calculated p-value was less than 0.05 which shows statistical significance in pre and post values in group A.

In Group B, pre-value for median is 3.8 and IQR 2.43 to 4.55, Post-value for median is 2.95 and IQR 1.05 to 4.08, p-value less than 0.05 which shows statistical significance in pre and post values in group B.

The pre and post intervention outcome for VAS for both the groups and obtained p-value was less than 0.05 indicating that there was a difference in Visual Analog Scale before and after intervention for each group as shown in **Table 5**.

The underlying mechanism can be explained by the Gate Control Theory of pain where the modulation of pain is because of the activation of the descending inhibitory pathways.

For **BAI**, in Group A, Pre-value for median is 3 and IQR is 2.25 to 4, Post-value for median is 2 and IQR is 0.25 to 2, hence p-value is less than 0.05 which shows statistical significance in pre and post values in group A.

In Group B, Pre-value for median is 2.5 and IQR is 0 to 4, Post-value for median is 1 and IQR is 0 to 3, hence p-value is less than 0.05 which shows statistical significance in pre and post values in group B.

The within group analysis of Beck Anxiety Inventory was also analysed by Wilcoxon Sign Rank Test whose p-value was also less than 0.05, Hence there was significant difference before and after intervention for each group as shown in **Table 7**.

Our results in comparing the effectiveness of modulated transcutaneous electrical nerve stimulation over placebo transcutaneous electrical nerve stimulation was analysed using the Mann Whitney U Test. The obtained p-value for visual analog scale was found to be less than 0.05 which indicates that there was a significant difference in the effectiveness between the group.

Between groups comparison was done using Mann Whitney U test to compare the effectiveness between the two groups as shown in table 8.

**VAS:** In Group A, calculated median is 2.8 and IQR 2.6 to 3.38. In group B, Median is 2 and IQR 0.25 to 3. Hence p-value is less than 0.05 it shows statistically significance in values of VAS in both the groups.

**BAI:** In Group A, the calculated median is 0.45 and IQR is 0.13 to 1.43. In Group B, median is 1 and IQR 0 to 3. Hence p-value which is more than 0.05 there is no significant difference in values of BAI in both the groups.

Thus, there was no statistically significant difference between the groups in Beck Anxiety Inventory as the obtained p-value was more than 0.05.

Our results in improvement of VAS were supported by the previous study findings by Gerson Cipriano jr et.al, (2008), who conducted a study to evaluate the pain after cardiac surgery, results shows that there was reduction of pain after using TENS in post-operative patients. [6].

Many studies have shown that transcutaneous electrical nerve stimulation can reduce pain in post cardiac surgery. The underlying mechanism can be explained by the Gate Control Theory of pain where the modulation of pain is because of the activation of the descending inhibitory pathways.

Our present study findings were also contradicted by a study done by Alireza Jahangirifard et.al (2017). In his study, TENS was given and the pain intensity and respiratory function was assessed using VAS and a calibrated spirometer device. The results of his study indicated that TENS may be helpful to alleviate post-operative pain and also has a positive effect on pulmonary function test [1].

Alfonso Fiorelli et.al (2011), did a study to assess the efficacy of TENS in controlling post thoracotomy by enrolling patients in a placebo group and TENS group. The study concluded that TENS can be used for decreasing the post thoracotomy pain as it does not have any side effects and treatment with TENS is safe and inexpensive. [11].

Nilgun Kavrut Ozturk et.al (2015), conducted a clinical study, to evaluate the efficacy of TENS over parasternal block on post-operative pain after median sternotomy for CABG but concluded that TENS was not as effective as parasternal block. So according to this study, TENS was not helping in reducing pain, which is contradicting to present study [4].

E. Lucy forster et.al (2017), study on efficacy of TENS as adjunct for the management of post-operative pain in addition to medication showed that the pain at rest was reduced although there was no significant difference in between TENS and Placebo groups [5].

Based on all the literature reviews and current study findings modulated transcutaneous electrical nerve stimulation was found to be effective in reducing pain as compared to placebo TENS.

The likelihood in reducing hospital induced anxiety and depression with the reduction in pain was assessed using the Beck Anxiety Inventory but was found to be insignificant indicating there was no difference in the pre and post outcome. Thus the objective of the study which is finding out the clinically meaningful group difference in in pain score among the patients with post cardiac surgery through median sternotomy has been justified and proven to be effective. However the Hospital induced Anxiety did not show any superiority among the groups.

Therefore, we are rejecting the null hypothesis and accepting the alternate hypothesis for the primary objective which is finding out the meaningful difference in the pain score.

#### **LIMITATIONS:**

1. The size of the group was smaller.
2. Long term effect was beyond the scope of study.

#### **STRENGTH:**

- The baseline data was found to be homogeneous.
- Hospital induced anxiety was assessed using Beck Anxiety Inventory.
- Easy to use in clinical practice.

#### **CONCLUSION**

From the study conducted, we came to a conclusion that transcutaneous electrical nerve stimulation was found to be effective in reducing incisional pain post cardiac surgery. However, it does not play any role in reducing the Hospital induced Anxiety.

#### **FUTURE RECOMMENDATIONS:**

- More study can be done for larger sample size.
- A similar study can also be conducted to evaluate the respiratory function with addition to TENS.

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