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USE OF TENS FOR POSTOPERATIVE PAIN CONTROL IN CABG PATIENTS: A RANDOMIZED CONTROLLED STUDY

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Abstract

Background: Managing postoperative pain after Coronary Artery Bypass Graft (CABG) surgery remains challenging, with limited evidence on effective interventions. This trial evaluated the impact of Transcutaneous Electrical Nerve Stimulation (TENS) on post-CABG pain. Methodology: A single-blind, two-arm randomized controlled trial was conducted with 68 CABG patients aged 40–70 years. Patients with serious cardiac or pulmonary conditions were excluded. Participants were randomly assigned to Group A (TENS + standard care, n=34) or Group B (standard care only, n=34). TENS was applied twice daily for 30 minutes over 5 days. Pain was measured using the Visual Analogue Scale (VAS) before and after intervention. Data were analyzed with SPSS 25, and chi-square tests determined significance ($p \leq 0.05$). Results: Group A showed a significant reduction in pain compared to Group B ($p < 0.001$). Notably, 61.8% of Group A reported no pain post-treatment, while 44.1% of Group B experienced moderate pain. Conclusion: TENS combined with standard care significantly reduces postoperative pain after CABG and offers a cost-effective, efficient pain management option.

INTRODUCTION

The management of postoperative pain associated with Coronary Artery Bypass Graft (CABG) is a significant global health challenge. Each year, more than one million open heart surgeries are performed in low and middle-income countries worldwide (1). Unfortunately, around 30% of patients experience serious problems such as sternal pain, incisional pain, pneumonia, wound infection, stroke, graft occlusion, etc (2). The literature highlighted the dire need to provide early cardiac surgery facilities and quality post-operative care to improve patient recovery, surgery-related issues and overall patient health (3).

According to the latest evidence cardiac issues in Pakistan have been increasing steadily for the last few years. The cases of coronary artery disease which require surgery, have also been raised (4). After heart surgery, one of the main issues is pain experienced by patients (5). The most painful condition is post-thoracotomy pain which causes impaired recovery, increased cardiovascular stress, psychological consequences, and increased dependency on Opioids (6). Studies documented that increased consumption of Opioids for pain management has various adverse effects including delayed recovery (7, 8).

Literature documented Transcutaneous Electrical Nerve Stimulation (TENS), a non-invasive analgesic modality as effective in pain management. Since 1970 TENS has been used for pain management (9). It's like an adjunct therapy added to other treatments which reduces pain and makes patients feel better (10). Additionally, this therapy is delivered by placing electrodes over the skin with no metabolic side effects as in any pharmacological intervention (11). It doesn't involve any medicine, and won't make anyone get

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addicted to it. This means it's a safe option (12). TENS has been used for a long time and patients feel more comfortable with it after their surgery (13).

Evidence reported TENS, as an effective modality in the management of pain for various cardiac and other health conditions. However, there is a scarcity of up-to-date evidence on CABG surgery-associated pain. Therefore this trial aimed to evaluate the effect of TENS on postoperative pain associated with CABG surgery using the Visual Analogue Scale (VAS) pre and post-5 days of intervention in cardiac care unity of tertiary care PNS Shifa Hospital, Karachi, Pakistan. The findings of this study significantly contribute to enhancing pain management strategies and improving the overall postoperative experience for CABG patients.

METHODOLOGY:

A single-blinded, two-arm, parallel-group design Randomized-Controlled Trial was conducted following the CONSORT guidelines. The Trial was carried out at the cardiac unit of Pakistan Navy Station Shifa Hospital Karachi, Pakistan, after obtaining ethical approval from the Ethical Review Committee of PNS Shifa. The study was completed in between June 2023 to January 2024.

Patients who underwent CABG surgery with a median sternotomy, aged 40 to 70 years and gave written informed consent were included in the study. However, patients affected by a neuromuscular blockade due to general anesthesia, had pacemaker implants, skin infections or wounds at the suture site, patients that were narcotic and drug-addicted had diabetic neuropathic condition and other neuromuscular disorders or suffering from any serious pathology involving the lungs or heart were excluded from the study. The trial adhered to the ethical principles outlined in the Declaration of Helsinki. The details of the patients' recruitment and random assignment are briefly illustrated in Figure # 1.

A sample size of 68 (n=38 in each group) was calculated via the OpenEpi Version 3.0 software, using methods by Kelsey et al. and Fleiss. Parameters included a two-sided significance level of 95% (alpha = 0.05), a power of 80%, an exposure ratio of 1:1and the risk/prevalence difference was 30. Participants were randomly divided into Group A (TENS+ standard care) and Group B (standard care) using a simple random sampling technique. Both groups received the same standard care however the experimental group received an additional TENS application. TENS was applied to both sides of the sternal incision i.e. 3 centimeters apart, proximal and distal to the sternotomy incision (see figure# 2). TENS was applied for 5 days, twice daily for 30 minutes, with a 6-hour break (i.e. morning and afternoon sessions). Pain was measured using a Visual Analog Scale (VAS) before and after the application of TENS. VAS is an interval scale demonstrating excellent test-retest reliability with an ICC value of 0.97 and moderate to strong validity ranging from 0.62–0.91 for measuring pain.

Statistical analysis was carried out through SPSS version 25.0. Continuous variables were presented as mean and standard deviation. Categorical variables were presented as frequencies and percentages. The normality of data was checked through Kolmogorov Simrnov test. All variables were found to be non-normally distributed except age. The Chi-square test was run to evaluate the difference between the groups. The p-value ≤ 0.05 was considered statistically significant at 95% CI.

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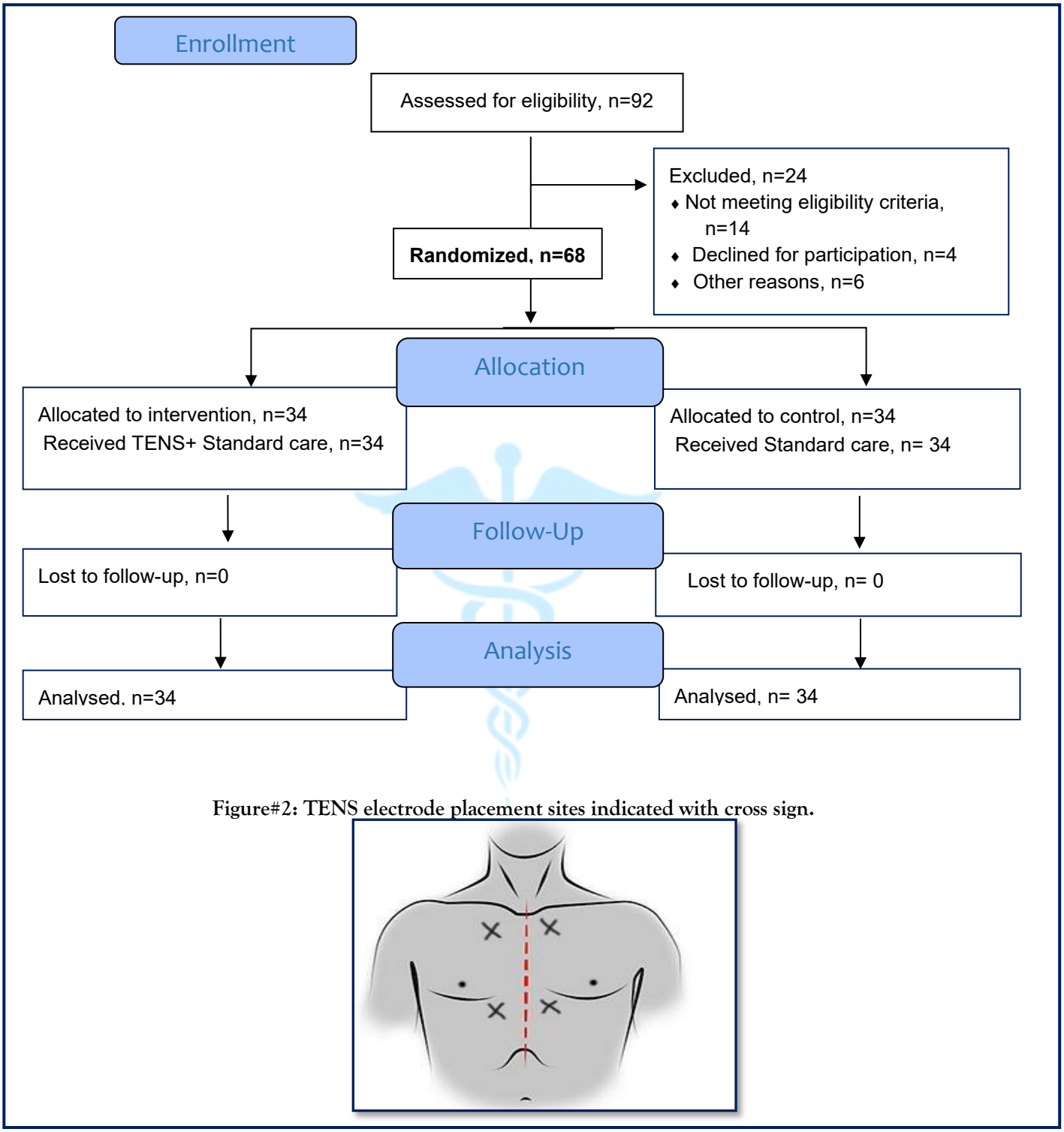
Figure#1: CONSORT flow diagram



Figure#2: TENS electrode placement sites indicated with cross sign.

RESULTS:

This RCT entailed 68 post-CABG surgery patients, randomly divided into Group A (received TENS+ standard care) and Group B (received standard care). The mean age of the participants was 53.94 ±7.65, ranging from 41-70 years. A total of 38 females and 30 males who underwent CABG surgery participated in the trial (See Figure# 3).

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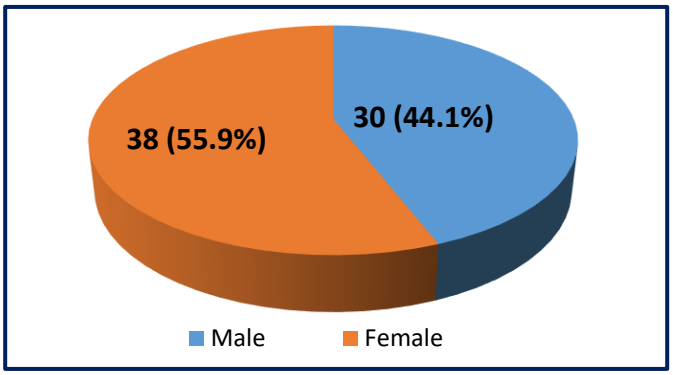

Figure# 3: Gender of the study participants

The baseline post-operative pain associated with CABG in group A showed that most of the patients 58.8% (n=20) had severe pain, while 11.8% (n=4) experienced the worst possible pain. However, in group B, 52.9% (n=18) experienced severe pain, while 5.9% (n=2) reported worst possible pain. Both the groups were comparable at the baseline and there was no statistically significant difference in the distribution of pain between the groups (See Table #1).

Table #1: Baseline post-operative pain intensity associated with CABG, before the application of TENS

			Group A	Group B	
Pain Intensity before the application of TENS	Moderate	Frequency	10	14	24
		Percentage	29.4%	41.2%	35.3%
	Severe	Frequency	20	18	38
		Percentage	58.8%	52.9%	55.9%
	Worst Possible	Frequency	4	2	6
		Percentage	11.8%	5.9%	8.8%
Total		Frequency	34	34	68
		Percentage	100.0%	100.0%	100.0%
Chi-Square Tests					
	Value	df	Asymptotic Significance (2-sided)		
Pearson Chi-Square	1.439[a]	2	0.487		
Likelihood Ratio	1.455	2	0.483		
Linear-by-Linear Association	1.406	1	0.236		
N of Valid Cases	68				
a. 2 cells (33.3%) have an expected count of less than 5. The minimum expected count is 3.00.					

The pain intensity associated with CABG, after the application of TENS on the 5th day of intervention showed a statistically significant reduction in pain intensity in the experimental group i.e. Group A compared to the control group i.e. group B. In group A, a high proportion of the patients 61.8% (n=21) reported no pain, while 38.2% (n=13) experienced mild pain only. However, in group B, most of the patients still experienced moderate pain 44.1% (n=15), while 26.5% (n=9) reported mild pain. (See Table #2).

Table #2: Post-operative pain intensity associated with CABG, after the application of TENS on the 5th day

			Group A	Group B	
	No Pain	Frequency	21	10	31

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Pain Intensity on the 5th day after the application of TENS		Percentage	61.8%	29.4%	45.6%
	Mild	Frequency	13	9	22
		Percentage	38.2%	26.5%	32.4%
	Moderate	Frequency	0	15	15
		Percentage	0.0%	44.1%	22.1%
Total		Frequency	34	34	68
		Percentage	100.0%	100.0%	100.0%
Chi-Square Tests					
	Value	df	Asymptotic Significance (2-sided)		
Pearson Chi-Square	19.630[a]	2	< 0.001		
Likelihood Ratio	25.515	2	< 0.001		
Linear-by-Linear Association	15.770	1	< 0.001		
N of Valid Cases	68				
a. 0 cells (0.0%) have an expected count of less than 5. The minimum expected count is 7.50.					

The post-operative pain intensity associated with CABG surgery after the application of TENS significantly reduced in group A compared to group B over the five days intervention period. Each day a significant difference was found between the groups (p-value=<0.05) (See Table #3).

Table #3: Post-operative pain intensity associated with CABG after the application of TENS from day 1 to day 5

Pain intensity	Day 1		Day 2		Day 3		Day 4		Day 5	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
No Pain	14	3	0	0	29	5	29	5	15	2
	41.2%	8.8%	0.0%	0.0%	85.3%	14.7%	85.3%	14.7%	44.1%	5.9%
Mild	15	2	14	3	0	0	0	0	14	14
	44.1%	5.9%	41.2%	8.8%	0.0%	0.0%	0.0%	0.0%	41.2%	41.2%
Moderate	0	11	15	19	5	29	5	29	5	18
	0.0%	32.4%	44.1%	55.9%	14.7%	85.3%	14.7%	85.3%	14.7%	52.9%
Severe	5	18	5	12	0	0	0	0	0	0
	14.7%	52.9%	14.7%	35.3%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
p-value	< 0.001		0.005		< 0.001		< 0.001		< 0.001	

DISCUSSION:

This RCT demonstrated that TENS along with routine care significantly reduced postoperative pain associated with CABG surgery and was also found to be a safe and effective non-invasive analgesic modality for CABG surgery patients.

The findings of this trial are in line with the study conducted by Johnson et al., 2022 which concluded that pain decreases during or immediately after TENS application in the experimental group compared to placebo (14). Additionally, another study also claimed the positive effect of TENS on pain control (15). An experimental study revealed that TENS effectively reduced pain and improved inspiratory capacity and coughing in patients who had undergone median sternotomy surgery; the experimental group showed better results compared to the placebo group (16). Additionally, the latest study claimed a significant effect of preoperative in-person patient education in alleviating pain associated with CABG surgery (17). Therefore TENS should be used for acute and chronic pain relief instead of opioids that may result in side effects.

In 2022, Cho et al., conducted a study and found no appreciable changes in myocardial infarct pain between pre and post-aortic valve replacement treatment indicating TENS didn't show a cardio-protective effect on patients (18). In contrast, this trial claimed significant effects of TENS. Therefore highlighting the need for more quality researches to clarify the effect.

A Meta-analysis conducted by Cardinali et al.,2021 (19) concluded that adding TENS therapy to multimodal analgesia can effectively decrease pain, enhance pulmonary function recovery, and reduce the need for analgesics. This trial supported this meta-analysis finding that TENS can be used as an alternative pain management method which has no side effects as compared to pharmaceutical analgesics. Evidence reported that TENS had better results for pain management after CABG (20). Furthermore, an integrative review observed the same effect of TENS in pain management (21). In 2021, Rajandekar et al., conducted a descriptive study that also supported the fact that TENS is useful in reducing postoperative pain and improving functional capacity (22). The finding of the plethora of evidence aligns with the results of this trial. Therefore make the TENS as an effective pain management tool for CABG surgery patients.

As per the knowledge of the authors, this trial is the first of its type with a large sample size and methodological rigor. However, the study had some limitations, such as not exploring various TENS modes and their effectiveness. Future research should explore the long-term benefits of TENS on post-CABG recovery. Larger multicenter trials with diverse patient populations are needed to enhance the generalizability of the results.

CONCLUSION

This trial concluded the significant effects of TENS application along with standard care on pain associated with postoperative CABG surgery. The results highlighted the potential role of TENS as a cost-effective, patient-friendly and safe adjunct therapy for pain management of patients with cardiac surgery. Future high-quality trials are the need of time to explore the optimal TENS parameters and the long-term effect on other cardiac surgeries.

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Authors Contribution:

ST: Conceptualized the research idea, provided research supervision and Drafted manuscript.

KA and HAS: Drafted manuscript, collected data and ensured methodological rigor.

A, SR, ML, and SA: Drafted manuscript, collected and analyzed data.

All authors approved the final version.

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