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"COMPARISON OF POST-OPERATIVE PAIN STATUS IN TENS AND PLACEBO GROUPS ON VAS SCALE AT DAY 1 AND 6 WEEKS IN TKR"

Orthopaedics

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ABSTRACT

Background: Total knee replacement (TKR) is a leading treatment for end-stage knee osteoarthritis. Effective postoperative pain management is crucial for recovery and patient satisfaction. Traditional pain relief methods like opioids have significant side effects. Transcutaneous electrical nerve stimulation (TENS) is a non-invasive pain management method that delivers electrical currents through skin electrodes to block pain signals. This study compares postoperative pain levels in TENS and placebo groups, measured on the Visual Analog Scale (VAS) at Day 1 and six weeks post-surgery, to evaluate the efficacy of TENS in pain relief and rehabilitation after TKR. **Methodology:** A randomized controlled trial was conducted at SRMS-IMS, Bareilly, from August 2022 to January 2024. Patients aged 55 and above undergoing unilateral or bilateral TKR were included, excluding those with contraindications to TENS. Participants were randomly assigned to four groups: Unilateral TENS, Unilateral Placebo, Bilateral TENS, and Bilateral Placebo. TENS was administered from Day 1 to Week 6. Pain was measured using the VAS at various intervals. Data were analyzed using IBM SPSS Statistics. **Results:** Baseline characteristics showed no significant differences between groups. VAS scores indicated significant pain reduction in TENS groups compared to placebo groups at all follow-up points. TENS groups showed higher absolute reductions in VAS scores with statistical significance ($p<0.05$). Adverse effects were comparable across all groups. **Conclusion:** TENS significantly reduces postoperative pain in TKR patients compared to placebo and has a comparable safety profile. These findings support the use of TENS as an effective adjunctive therapy for pain management and rehabilitation following TKR, enhancing patient outcomes and quality of life.

KEYWORDS

Total knee replacement, TKR, pain management, TENS, transcutaneous electrical nerve stimulation, Visual Analog Scale, postoperative rehabilitation, multimodal analgesia.

INTRODUCTION

Total knee replacement (TKR), or total knee arthroplasty (TKA), is a leading treatment for end-stage knee osteoarthritis, replacing damaged joint areas with metal and plastic parts to restore function.[1] Effective postoperative pain management is essential for swift recovery, patient satisfaction, and positive outcomes.[2] Traditional pain relief methods like opioids, despite their effectiveness, have significant side effects such as nausea and respiratory issues. Multimodal analgesia, which includes various pain control techniques, aims to reduce opioid use and improve pain management.[3-8]

Transcutaneous electrical nerve stimulation (TENS) is a non-invasive pain management method gaining attention. TENS uses a battery-operated device to deliver electrical currents through skin electrodes, stimulating nerve fibers and blocking pain signals.[9-11] This technique not only manages pain effectively but also preserves motor function, aiding faster rehabilitation. In contrast, placebo treatments, which have no therapeutic effect, are often used in clinical studies to assess the true efficacy of interventions like TENS.[12-18]

This study compares the postoperative pain levels of TENS therapy versus a placebo, measured on the Visual Analog Scale (VAS) at Day 1 and six weeks post-surgery. The goal is to determine if TENS offers effective pain relief without compromising mobility, ultimately enhancing recovery and patient satisfaction. By evaluating the difference in pain management between TENS and placebo groups, this research aims to provide valuable insights into improved pain control

MATERIAL & METHODS

This randomized controlled trial was conducted in the Department of Orthopaedics at SRMS-IMS, Bareilly, from August 1, 2022, to January 31, 2024, to compare postoperative pain status in TENS and placebo groups. Participants included patients aged 55 and above undergoing unilateral or bilateral total knee replacements (TKR) who consented to TENS therapy and had a history of knee osteoarthritis. Patients with prior neurological disorders, tactile weakness, contraindications to TENS, permanent wheelchair use, or prior TENS use within the last five years were excluded. All patients meeting these criteria during the study period were included.

Participants were randomly assigned to four groups: Group 1 (TENS with unilateral TKR), Group 2 (placebo with unilateral TKR), Group 3 (TENS with bilateral TKR), and Group 4 (placebo with bilateral TKR). TENS therapy involved a battery-operated device delivering electrical currents through electrodes placed on the skin over the distal vastus medialis and proximal vastus lateralis muscles, administered from postoperative Day 1 to Week 6. Each TENS session lasted 15-20 minutes before rehabilitation exercises, which included quadriceps sets, straight leg raises, ankle pumps, knee straightening exercises, walking, and standing knee bends. Patients also used a Pocket TENS device at home. Placebo groups had electrodes attached without electrical stimulation, followed by the same rehabilitation exercises.

Pain intensity during rehabilitation was assessed using the Visual Analog Scale (VAS) on postoperative Day 1, Day 5, Week 4, and Week 6. Data were collected on demographic information, clinical history, and investigations, and entered into Microsoft Excel. Statistical analysis was conducted using IBM SPSS Statistics, employing frequency distribution and chi-square tests to examine relationships between variables. Key findings were presented in tables and graphs to highlight trends and relationships.

RESULTS

Table 1: Baseline Characteristics of the Study Population by Treatment Groups

Characteristics	Group 1 (Unilateral TENS)	Group 2 (Unilateral Placebo)	Group 3 (Bilateral TENS)	Group 4 (Bilateral Placebo)	P-value
Age (years) a	65.8 ± 5.7	64.7 ± 7.5	67.1 ± 9.8	64.1 ± 7.7	0.137
Gender Distribution b					0.06
- Male	8 (53.3%)	10 (66.7%)	8 (53.3%)	9 (60%)	
- Female	7 (46.7%)	5 (33.3%)	7 (46.7%)	6 (40%)	
Average Weight (kg) a	62.0 ± 10.8	62.0 ± 8.8	60.9 ± 12.0	57.0 ± 10.9	0.314
Average Height (cm)	159.4 ± 10.2	159.6 ± 12.1	159.9 ± 8.4	160.7 ± 12.4	0.967
No. of patients with diabetes a	2 (13.3%)	5 (33.3%)	7 (46.7%)	5 (33.3%)	0.261

Table 1 presents the baseline characteristics of the study population across four treatment groups: Unilateral TENS, Unilateral Placebo, Bilateral TENS, and Bilateral Placebo. The groups showed no significant differences in age, gender distribution, average weight, average height, or the number of patients with diabetes, with P-values of 0.137, 0.06, 0.314, 0.967, and 0.261 respectively. This indicates a

comparable baseline across all groups.

Table 2: VAS Scores in the Study Participants at Baseline and 6 Weeks Follow-Up

Follow-up	Group	N	Mean (M)	Std. Deviation (SD)
Day 1	Group 1 (TENS)	15	5.76	1.14
	Group 2 (Placebo)	15	6.06	1.35
	Group 3 (TENS Bilateral)	15	6.61	1.23
	Group 4 (Placebo Bilateral)	15	6.87	1.12
Day 5	Group 1 (TENS)	15	4.76	1.19
	Group 2 (Placebo)	15	5.78	1.10
	Group 3 (TENS Bilateral)	15	5.01	1.16
	Group 4 (Placebo Bilateral)	15	5.87	1.10
Week 4	Group 1 (TENS)	15	2.82	1.14
	Group 2 (Placebo)	15	3.88	1.38
	Group 3 (TENS Bilateral)	15	2.12	1.23
	Group 4 (Placebo Bilateral)	15	3.36	1.17
Week 6	Group 1 (TENS)	15	1.80	1.19
	Group 2 (Placebo)	15	2.43	1.10
	Group 3 (TENS Bilateral)	15	1.81	1.16
	Group 4 (Placebo Bilateral)	15	2.26	1.18

Table 2 shows VAS scores for pain at baseline and follow-up (Day 5, Week 4, Week 6) in four groups: Unilateral TENS, Unilateral Placebo, Bilateral TENS, and Bilateral Placebo. TENS groups consistently demonstrated greater pain reduction compared to placebo groups over time.

Table 3: Absolute Reduction in VAS Scores Across the Groups at Various Time Points

Variable (VAS)	Group 1 (TENS Unilateral)	Group 2 (Placebo Unilateral)	p-value	Group 3 (TENS Bilateral)	Group 4 (Placebo Bilateral)	p-value
At Day 1	5.7 ± 1.2	6.06 ± 1.4		6.6 ± 1.3	6.8 ± 1.2	
At Day 5	4.7 ± 1.3	5.7 ± 1.8		5.0 ± 1.1	5.8 ± 1.6	
Score Reduction (Day 1 to Day 5)	1.0	0.3	0.0128	1.6	1.0	0.0145
At Week 4	2.82 ± 1.1	3.98 ± 1.67		2.12 ± 0.32	3.36 ± 1.4	
Score Reduction (Day 5 to Week 4)	1.88	1.92	0.0125	2.88	2.44	0.026
At Week 6	1.8 ± 0.8	2.4 ± 1.0		1.8 ± 0.7	2.2 ± 1.1	
Score Reduction (Week 4 to Week 6)	1.02	1.48	0.0256	0.32	1.16	0.032

Table 3 presents the absolute reduction in VAS scores across four groups (Unilateral TENS, Unilateral Placebo, Bilateral TENS, Bilateral Placebo) at various time points. Significant pain reduction was observed in the TENS groups compared to placebo groups from Day 1 to Day 5, Day 5 to Week 4, and Week 4 to Week 6, with p-values indicating statistical significance.

Table 4: Reduction in Pain Scores Among Patients Across Groups by Gender, Diabetes Mellitus Status, and BMI Between 1st POD and Last Follow-Up

Category	Outcome Measure	TENS Unilateral	Placebo Unilateral	TENS Bilateral	Placebo Bilateral	P-valu
Gender						
Male	VAS Score Reduction	3.9 ± 1.1	3.5 ± 0.9	4.1 ± 1.2	3.2 ± 1.1	>0.05
Female	VAS Score Reduction	3.7 ± 1.2	3.1 ± 1.0	3.8 ± 1.3	3.0 ± 1.2	
Diabetes Mellitus						
With Diabetes	VAS Score Reduction	4.6 ± 1.2	3.6 ± 1.1	4.6 ± 1.3	3.4 ± 1.2	>0.05
Without Diabetes	VAS Score Reduction	4.1 ± 1.1	3.3 ± 0.9	4.2 ± 1.2	3.5 ± 1.1	
BMI						
Overweight (BMI ≥ 25)	VAS Score Reduction	4.4 ± 1.2	4.2 ± 1.0	3.9 ± 1.3	4.0 ± 1.1	>0.05
Normal (BMI < 25)	VAS Score Reduction	4.7 ± 1.0	3.2 ± 0.8	4.3 ± 1.2	3.8 ± 0.9	

Table 4 shows the reduction in VAS pain scores across groups by gender, diabetes status, and BMI from the 1st post-operative day to the last follow-up. TENS groups generally exhibited greater pain reduction compared to placebo groups, with no significant differences based on these categories ($P > 0.05$).

Table 5: Comparison of Adverse Effects Among Study Participants in Each Group

Event	TENS Group (Unilateral, n=15)	Placebo Group (Unilateral, n=15)	TENS Group (Bilateral, n=15)	Placebo Group (Bilateral, n=15)	P-value (Unilateral)	P-value (Bilateral)
Skin Irritation	2 (13%)	1 (7%)	1 (7%)	0 (0%)	0.35	0.22
Device-related Issue	1 (7%)	0 (0%)	1 (7%)	0 (0%)	0.50	0.50
Infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1.00	1.00
Discomfort at Electrode Site	2 (13%)	1 (7%)	2 (13%)	1 (7%)	0.29	0.32

Table 5 compares adverse effects among the study groups, showing no significant differences in skin irritation, device-related issues, infection, or discomfort at the electrode site between TENS and placebo groups ($P > 0.05$). This indicates comparable safety profiles across all groups.

DISCUSSION

Optimizing pain management and rehabilitation techniques following total knee replacement (TKR) is crucial due to the rising prevalence of osteoarthritis and the aging population. Effective postoperative pain management significantly enhances patient outcomes and quality of life. The results indicate that TENS significantly reduces pain levels compared to placebo, underscoring its potential role as an adjuvant therapy in this setting.

The study found no significant differences in age, gender distribution, average weight, or height among the four groups, ensuring a comparable baseline. The prevalence of diabetes also showed no significant variation, further supporting the reliability of the results. These consistent baseline characteristics confirm that the observed differences in pain outcomes are attributable to the interventions rather than demographic factors.

Our findings revealed that TENS therapy led to a significant reduction in pain levels from Day 1 to Week 6 postoperatively. Group 1 (Unilateral TENS) experienced a pain score decrease from 5.76 ± 1.14 to 1.8 ± 1.19, while Group 2 (Unilateral Placebo) showed a lesser reduction from 6.06 ± 1.4 to 2.4 ± 1.0. Similarly, Group 3 (Bilateral TENS) reduced pain from 6.61 ± 1.3 to 1.8 ± 1.16, compared to Group 4 (Bilateral Placebo), which reduced from 6.87 ± 1.12 to 2.2 ± 1.18. These results suggest that TENS is more effective than placebo in managing postoperative pain, aligning with previous studies by Sluka et al. and Stiff et al. [19]

Furthermore, the study highlights the consistent effectiveness of TENS therapy across different demographics, including gender, diabetes status, and BMI. Both male and female patients showed significant pain reduction with TENS compared to placebo, corroborating findings by Zimmerman et al.[20] Additionally, TENS was effective in patients with and without diabetes, and across various BMI categories, as noted in studies by Caplan et al.[22] and Audette et al.[21] This consistency underscores the broad applicability of TENS for pain management in diverse patient populations undergoing TKR.

In terms of adverse effects, the incidence of skin irritation and discomfort at the electrode site was slightly higher in the TENS groups compared to placebo, but these differences were not statistically

significant. No significant device-related issues or infections were reported, indicating that TENS is a safe intervention. These findings are consistent with the safety profile reported in previous studies by **Higgins et al.**[23] Overall, this study supports the use of TENS as an effective and safe method for pain management and rehabilitation following total knee replacement.

CONCLUSION

This study demonstrates that transcutaneous electrical nerve stimulation (TENS) significantly reduces postoperative pain in patients undergoing total knee replacement (TKR) compared to placebo, as measured by VAS scores from Day 1 to Week 6. The reduction in pain was consistent across various subgroups, including gender, diabetes status, and BMI, indicating TENS's broad efficacy. Additionally, TENS was found to have a comparable safety profile to placebo, with no significant differences in adverse effects.

Overall, TENS appears to be an effective and safe adjunctive therapy for pain management and rehabilitation following TKR, potentially enhancing patient outcomes and quality of life. These findings support the incorporation of TENS into multimodal pain management strategies for postoperative care in TKR patients.

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