Original Research Paper

Volume - 16 | Issue - 09 | September - 2026 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Anaesthesiology

A STUDY OF POSTOPERATIVE ANALGESIA AFTER PREOPERATIVE APPLICATION OF TRANSDERMAL FENTANYL PATCH IN CASES OPERATED FOR TOTAL KNEE REPLACEMENT UNDER SPINAL ANAESTHESIA: A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT **Background:** Total Knee Replacement (TKR) improves mobility and quality of life, particularly in geriatric patients; however, postoperative pain in the first 24–72 hours can delay recovery. Transdermal fentanyl patch (TFP) provides continuous, non-invasive analgesia. **Objective:** To evaluate postoperative analgesia in TKR patients using preoperative TFP by comparing Numeric Rating Scale (NRS) scores, time to first rescue analgesia, total analgesic consumption, and cost over 48 hours. **Methods:** This prospective randomized study included 40 patients (ASA I–III) undergoing TKR under spinal anaesthesia. Group F received TFP 25 mcg/hr 12 hours prior to surgery, while Group C did not. Pain was assessed using NRS. Rescue analgesia was administered when NRS ≥4. Statistical analysis was performed using an independent sample t-test. **Results:** NRS scores at rest (p=0.018), knee movement (p=0.007), and ankle movement (p=0.002) were significantly lower in Group F. Time to first rescue analgesia was prolonged (8.7 vs. 2.6 hours). Total analgesic consumption and cost were lower in Group F. **Conclusion:** Preoperative TFP significantly improves postoperative analgesia and reduces analgesic requirement and cost in TKR patients.

KEYWORDS : total knee replacement, transdermal fentanyl patch, postoperative analgesia, spinal anaesthesia, rescue analgesia

INTRODUCTION

Total Knee Replacement (TKR) is a commonly performed orthopedic procedure aimed at improving mobility and quality of life, particularly in elderly patients. Despite its benefits, postoperative pain in the first 24–72 hours remains a significant challenge and can delay rehabilitation.[1]

Inadequate pain control may lead to complications such as deep vein thrombosis, myocardial ischemia, infection, and prolonged hospital stay.[1]

Conventional analgesic modalities including oral and intravenous drugs often provide inconsistent analgesia and are associated with systemic side effects.[2]

Regional techniques such as epidural analgesia, femoral nerve block, and adductor canal block provide effective analgesia but are invasive, require expertise, and may not be suitable in anticoagulated patients.[3]

Transdermal Drug Delivery Systems (TDDS) provide continuous, non-invasive drug delivery and maintain stable plasma concentrations.[4] Fentanyl, due to its high lipid solubility and potency, is particularly suitable for transdermal use.[5]

Preoperative application of transdermal fentanyl patch ensures adequate plasma concentration during the postoperative period despite its delayed onset of action.[6]

This study aims to evaluate the efficacy of preoperative TFP in TKR patients.

METHODS

This prospective randomized controlled study was conducted at Bhaikaka University, Karamsad, Gujarat, between December 2023 and August 2024 after obtaining Institutional Ethics Committee approval. Written informed consent was obtained from all participants. A total of 40 patients aged 18–80 years, belonging to ASA physical status I–III, undergoing elective TKR under spinal anaesthesia were included and randomized into two groups (n=20 each).

- **Group F (Fentanyl group):** Received transdermal fentanyl patch 25 mcg/hr applied 12 hours prior to surgery.
- **Group C (Control group):** Did not receive fentanyl patch.
- **Exclusion criteria:** contraindications to spinal anaesthesia, local skin infection, pregnancy, opioid allergy, neurological deficits, opioid dependence, severe pulmonary disease, and conversion to general anaesthesia.

Spinal anaesthesia was administered using 3.6 ml of 0.5% hyperbaric Levobupivacaine. Standard monitoring was applied.

Pain assessment was done using Numeric Rating Scale (NRS) at rest and during knee and ankle movement at regular intervals up to 48 hours.

Rescue analgesia protocol:

- IV Paracetamol (10–15 mg/kg) when NRS ≥4
- IV Diclofenac (1.5 mg/kg) if pain persisted
- Statistical analysis was performed using STATA version 14.2. Independent sample t-test was used, with $p < 0.05$ considered statistically significant.

RESULTS

A total of 40 patients were analyzed, with comparable demographic characteristics between groups.

NRS scores at rest, knee movement, and ankle movement were significantly lower in the fentanyl group throughout the 48-hour postoperative period ($p < 0.05$).

- Comparison of NRS at rest in both group:
- Comparison of NRS at Knee movement in both groups:
- Comparison of NRS at Ankle movement in both group:
- Time to First Rescue Analgesia in both group:
- Time to first rescue analgesia was significantly prolonged in the fentanyl group (8.7 ± 4.11 hours) compared to the control group (2.6 ± 0.94 hours) ($p = 0.001$).
- Total analgesic consumption was significantly lower in the fentanyl group, with reduced requirements of both Paracetamol and Diclofenac.
- Total cost of analgesia was also significantly lower in the fentanyl group ($p = 0.001$).
- No significant adverse effects such as nausea, vomiting, constipation, or respiratory depression were observed.

Table 1. Comparison of NRS at rest in both groups

Time (h)	Control NRS at rest	Fentanyl NRS at rest	p
0	0.35±0.58	0.01±0.01	0.01
2	2.5±0.51	0.85±0.81	0.001
4	2.6±0.59	1.9±0.44	0.02
6	2.3±0.47	2.01±0.44	0.04
8	2.3±0.47	2±0.64	0.04
10	2.4±0.50	1.8±0.69	0.003
12	2.25±0.44	1.7±0.65	0.003
18	2.4±0.59	1.9±0.71	0.02
24	2.3±0.47	1.9±0.55	0.01
30	2.3±0.47	1..85±0.74	0.02
36	2.35±0.48	1.9±0.55	0.009
42	2.4±0.50	1.55±0.51	0.001
48	2.3±0.47	1.55±0.51	0.001

Table 2. Comparison of NRS at knee movement in both groups

Time (h)	Control knee movement	Fentanyl knee movement	p
0	0.65±1.03	0.01±0.01	0.001
2	3.65±0.48	1.2±1.05	0.001
4	3.75±0.44	2.75±0.55	0.001
6	3.75±0.44	3.3±0.47	0.003
8	3.4±0.50	3.15±0.67	0.019
10	3.85±0.366	2.9±0.78	0.001
12	3.55±0.51	2.55±0.75	0.001
18	3.65±0.48	3±0.85	0.005
24	3.65±0.48	2.9±0.68	0.007
30	3.64±0.52	2.85±0.74	0.003
36	3.66±0.33	3.05±0.68	0.002
42	2.4±0.50	1.55±0.51	0.001
48	3.75±0.44	2.6±0.50	0.001

Table 3. Comparison of NRS at ankle movement in both groups

Time (h)	Control ankle movement	Fentanyl ankle movement	p
0	0.65±1.03	0.01±0.1	0.008
2	3.5±0.51	1.2±1.05	0.001
4	3.4±0.52	2.7±0.47	0.001
6	3.3±0.47	3.05±0.39	0.04
8	3.3±0.47	3±0.64	0.03
10	3.6±0.50	2.8±0.83	0.007
12	3.3±0.47	2.5±0.68	0.001
18	3.35±0.48	2.9±0.78	0.036
24	3.25±0.44	2.65±0.48	0.002
30	3.3±0.47	4.3±0.01	0.05
36	3.3±0.47	2.8±0.69	0.01
42	3.3±0.47	2.6±0.48	0.001
48	3.35±0.48	2.65±0.48	0.001

Table 4. Time to first rescue analgesia in both groups

Measure	Control	Fentanyl	p
Time to first rescue analgesia (h)	2.6 ± 0.94	8.7 ± 4.11	0.001

DISCUSSION

- The present study demonstrates that preoperative application of transdermal fentanyl patch significantly improves postoperative analgesia in TKR patients.
- Fentanyl acts as a potent μ-opioid receptor agonist and provides sustained analgesia through continuous transdermal delivery, maintaining stable plasma levels.[7]
- The prolonged duration before first rescue analgesia observed in this study is consistent with previous studies.[8–10]
- Reduced analgesic consumption and improved pain scores observed in this study are also supported by earlier research.[11–14]
- Transdermal fentanyl offers advantages such as non-invasive administration, improved compliance, and reduced need for repeated dosing.[15]
- Spinal anaesthesia itself has been associated with improved postoperative outcomes and fewer complications compared to general anaesthesia, which may further enhance analgesic effectiveness.[16–17]
- Pharmacokinetic studies have demonstrated stable plasma drug levels with transdermal fentanyl, supporting its role in sustained analgesia.[18–19]
- Limitations of this study include small sample size, single-center design, and short follow-up duration.

CONCLUSION

Preoperative application of transdermal fentanyl patch significantly improves postoperative pain control, delays rescue analgesia, reduces total analgesic consumption, and lowers treatment cost in patients undergoing total knee replacement under spinal anaesthesia.

Acknowledgments

The authors acknowledge the Department of Anaesthesiology, Pramukh Swami Medical College, Karamsad, and all patients who participated in the study.

Conflict Of Interest: None

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