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Comparative Evaluation of Transdermal Fentanyl and Buprenorphine Patches for Postoperative Analgesia in Total Knee Replacement Patients

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KEYWORDS

Transdermal fentanyl, Buprenorphine patch, Postoperative analgesia.

ABSTRACT:

Background: Effective postoperative analgesia is essential for early mobilization and functional recovery following Total Knee Replacement (TKR). Transdermal opioid patches such as fentanyl and buprenorphine provide sustained analgesic effects and offer a non-invasive alternative to systemic opioids. This study aimed to compare the analgesic efficacy, sedation levels, rescue analgesic requirements, and safety profiles of transdermal fentanyl and buprenorphine patches in patients undergoing TKR.

Materials and Methods: A prospective comparative study was conducted on 200 patients, randomized into two groups: Fentanyl (25 µg/hr, n = 100) and Buprenorphine (10 µg/hr, n = 100). Patches were applied 6 hours before surgery. Postoperative pain was assessed using the Visual Analogue Scale (VAS) at regular intervals for 72 hours. Sedation was assessed using the Brussels Sedation Scale. Rescue analgesia with intravenous tramadol was provided if VAS ≥5. Adverse effects were recorded. Statistical analysis was performed using t-tests, chi-square tests, and 95% confidence intervals, with $p < 0.05$ considered significant.

Results: Baseline demographic characteristics were comparable across groups. Fentanyl showed significantly lower VAS scores at all time intervals ($p < 0.05$), indicating superior analgesia, especially during the first 24 hours. Sedation scores were slightly higher with fentanyl but remained within safe limits. Rescue analgesic requirement was significantly lower in the fentanyl group (21% vs. 34%, $p = 0.039$). Side-effect incidence-including nausea, vomiting, dizziness, pruritus, and skin irritation-was similar between groups, and no major complications were observed.

Conclusion: Transdermal fentanyl provides superior postoperative analgesia with fewer rescue analgesic requirements compared to transdermal buprenorphine in TKR patients, while maintaining a comparable safety profile. It represents an effective and well-tolerated option for postoperative pain management in major orthopedic surgeries.

INTRODUCTION

Effective postoperative pain control is a cornerstone of enhanced recovery following major orthopedic procedures such as Total Knee Replacement (TKR). TKR is commonly performed to improve mobility and quality of life in patients with severe osteoarthritis or rheumatoid arthritis; however, it is frequently associated with moderate to severe postoperative pain, which can impede early mobilization, rehabilitation, and overall surgical outcomes. Inadequately controlled pain may also predispose patients to chronic postoperative pain, delayed functional recovery, and increased healthcare utilization.[1] Postoperative pain is a multifactorial physiological response involving peripheral nociceptor activation, central sensitization, and inflammatory mediator release, making its management challenging for both anesthesiologists and surgeons.[2]

Journal of Chemical Health Risks

www.jchr.org

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Traditionally, systemic opioids-particularly intravenous formulations-have been the mainstay for moderate to severe postoperative pain management. While opioids provide potent analgesia, their adverse effects, including respiratory depression, sedation, nausea, vomiting, constipation, urinary retention, and risk of dependence, may limit their use in the postoperative period. These limitations have prompted exploration of alternative delivery systems that can provide more stable plasma concentrations with fewer side effects.[3] Transdermal drug delivery systems (TDDS) have gained prominence as a non-invasive and patient-friendly method for postoperative analgesia. By bypassing first-pass metabolism and maintaining prolonged therapeutic levels, transdermal patches ensure consistent pain relief with improved patient compliance.[4]

Transdermal fentanyl and buprenorphine patches are two commonly utilized opioid-based systems in perioperative pain management. Fentanyl, a highly lipid-soluble synthetic opioid, provides potent μ-opioid receptor agonism and rapid transdermal absorption, making it suitable for sustained postoperative analgesia. The 25 μg/hr transdermal fentanyl patch delivers a controlled release of drug over several hours, reducing fluctuations in plasma concentrations and minimizing breakthrough pain.[5] Buprenorphine, a semi-synthetic opioid, acts as a partial μ-opioid receptor agonist with high receptor affinity and a ceiling effect on respiratory depression, contributing to a favorable safety profile. Buprenorphine patches (10 μg/hr) offer extended analgesia lasting up to seven days, but comparative performance in acute postoperative settings such as TKR continues to be an area of clinical research.

Aim

To compare the postoperative analgesic efficacy of transdermal fentanyl and buprenorphine patches in patients undergoing total knee replacement under spinal anesthesia.

Objectives

1. To compare postoperative analgesia provided by transdermal fentanyl and buprenorphine patches.
2. To assess and compare the sedation levels associated with both transdermal opioids.
3. To evaluate the requirement of rescue analgesics and the incidence of opioid-related side effects in both groups.

MATERIAL AND METHODOLOGY

Source of Data

Data were obtained from patients undergoing elective Total Knee Replacement (TKR) surgery under spinal anesthesia at the orthopedics and anesthesiology departments of the study center.

Study Design

A hospital-based, prospective, comparative observational study.

Study Location

The study was conducted in the Department of Anaesthesiology and Critical Care at a tertiary-care teaching hospital.

Study Duration

The study was carried out over an 18-month period.

Sample Size

A total of **200 patients** posted for elective TKR surgery were included and divided into two groups of 100 each.

Inclusion Criteria

- Adults aged 40-80 years.
- ASA physical status I or II.
- Patients scheduled for unilateral TKR under spinal anesthesia.
- Willingness to provide written informed consent for participation and patch application.

Exclusion Criteria

- Known hypersensitivity to fentanyl or buprenorphine.
- Chronic opioid use or substance abuse.
- Severe hepatic, renal, or respiratory disease.
- Skin infections or dermatological conditions at patch application site.
- Pregnant or lactating women.

Journal of Chemical Health Risks

www.jchr.org

JCHR (2025) 15(6), 2186-2193 | ISSN:2251-6727

- Refusal to participate.

Procedure and Methodology

All patients underwent routine preoperative evaluation. Eligible patients were randomly allocated into two equal groups:

- **Group F (n = 100):** Received a transdermal fentanyl patch (25 µg/hr).
- **Group B (n = 100):** Received a transdermal buprenorphine patch (10 µg/hr).

The assigned patch was applied to a clean, dry, non-hairy area on the upper arm or chest approximately **6 hours prior to surgery** to ensure adequate transdermal absorption. All patients received standardized spinal anesthesia with 0.5% hyperbaric bupivacaine.

Intraoperative monitoring included heart rate, non-invasive blood pressure, ECG, and SpO_2. Postoperatively, pain intensity was assessed using the Visual Analogue Scale (VAS) at 0, 4, 8, 12, 18, 24, 36, 48, 60, and 72 hours. Sedation was assessed using the Brussels Sedation Scale at the same intervals. If the VAS score was ≥5, intravenous tramadol (1 mg/kg) was administered as rescue analgesia. Side effects such as nausea, vomiting, dizziness, pruritus, respiratory depression, and skin reactions were recorded.

Sample Processing

All observations-including VAS scores, sedation scores, rescue analgesic timing and dosage, and adverse events-were documented in predesigned data collection sheets and verified by the supervising anesthesiologist.

Statistical Methods

Data were compiled and analyzed using SPSS software.

- Continuous variables (e.g., VAS scores) were expressed as mean ± SD and compared using Student's t-test.
- Categorical variables (e.g., side effects) were compared using Chi-square or Fisher's exact test.
- A p-value <0.05 was considered statistically significant.

Data Collection

Data were collected prospectively from preoperative evaluation to 72 hours postoperatively. All entries were cross-checked for accuracy, completeness, and consistency before statistical processing.

OBSERVATION AND RESULTS

Table 1: Baseline Comparison Between Groups (N = 200)

Variable	Fentanyl (n=100)	Buprenorphine (n=100)	Test Statistic	95% CI of Difference	p-value
Age (years), Mean ± SD	64.3 ± 7.8	63.1 ± 8.1	t = 1.04	-0.93 to 3.33	0.299
Male, n (%)	56 (56%)	59 (59%)	$\chi^2 = 0.18$	-	0.673
Female, n (%)	44 (44%)	41 (41%)	$\chi^2 = 0.18$	-	0.673
BMI (kg/m²), Mean ± SD	28.7 ± 3.9	29.2 ± 4.1	t = -0.80	-1.72 to 0.62	0.423
ASA I, n (%)	38 (38%)	36 (36%)	$\chi^2 = 0.09$	-	0.765
ASA II, n (%)	62 (62%)	64 (64%)	$\chi^2 = 0.09$	-	0.765
Duration of surgery (min), Mean ± SD	94.6 ± 11.3	96.1 ± 10.7	t = -0.96	-4.97 to 1.27	0.338

Table 1 presents the baseline demographic and perioperative characteristics of the 200 patients included in the study, with 100 each in the fentanyl and buprenorphine groups. Both groups were comparable

Journal of Chemical Health Risks

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JCHR (2025) 15(6), 2186-2193 | ISSN:2251-6727

across all assessed variables, indicating successful randomization and the absence of selection bias. The mean age of participants was similar between the fentanyl (64.3 ± 7.8 years) and buprenorphine (63.1 ± 8.1 years) groups, with no statistically significant difference (t = 1.04, p = 0.299; 95% CI: -0.93 to 3.33). Gender distribution was also balanced, with males comprising 56% in the fentanyl group and 59% in the buprenorphine group ($\chi^2 = 0.18$, p = 0.673). Females accounted for 44% and 41%, respectively, with identical non-significant differences.

Similarly, the mean BMI was comparable between the groups (28.7 ± 3.9 vs. 29.2 ± 4.1 kg/m²; t = -0.80, p = 0.423), indicating minimal anthropometric variation. ASA physical status distribution (ASA I/II) demonstrated no meaningful difference (ASA I: 38% vs. 36%; ASA II: 62% vs. 64%; p = 0.765 for both), suggesting equal baseline comorbidity profiles. The duration of surgery was also statistically similar between fentanyl (94.6 ± 11.3 minutes) and buprenorphine (96.1 ± 10.7 minutes) groups (t = -0.96, p = 0.338; CI: -4.97 to 1.27).

Table 2: Comparison of Postoperative Analgesia (VAS Scores) (N = 200)

Time Interval	Fentanyl Mean ± SD	Buprenorphine Mean ± SD	Test Statistic	95% CI of Difference	p-value
VAS at 4 hrs	2.9 ± 0.8	3.4 ± 0.9	t = -3.98	-0.74 to -0.28	<0.001*
VAS at 8 hrs	3.3 ± 0.9	4.1 ± 1.0	t = -5.63	-1.08 to -0.53	<0.001*
VAS at 12 hrs	3.6 ± 1.0	4.3 ± 1.1	t = -4.45	-1.02 to -0.36	<0.001*
VAS at 24 hrs	2.7 ± 0.7	3.1 ± 0.8	t = -3.62	-0.62 to -0.18	<0.001*
VAS at 48 hrs	1.9 ± 0.6	2.2 ± 0.7	t = -3.38	-0.47 to -0.12	0.001*
VAS at 72 hrs	1.5 ± 0.5	1.7 ± 0.6	t = -2.53	-0.41 to -0.05	0.012*

Table 2 compares trends in postoperative pain intensity between fentanyl and buprenorphine groups using VAS scores across multiple time intervals. Fentanyl consistently demonstrated superior analgesic efficacy during the early and intermediate postoperative periods. At 4 hours postoperatively, mean VAS scores were significantly lower in the fentanyl group (2.9 ± 0.8) compared to the buprenorphine group (3.4 ± 0.9), with a highly significant difference (t = -3.98, p < 0.001; 95% CI: -0.74 to -0.28). This trend continued at 8 hours (3.3 ± 0.9 vs. 4.1 ± 1.0; p < 0.001) and 12 hours (3.6 ± 1.0 vs. 4.3 ± 1.1; p < 0.001), demonstrating fentanyl's stronger analgesic performance during the immediate postoperative phase.

At 24 hours, pain scores were still significantly lower with fentanyl (2.7 ± 0.7) than buprenorphine (3.1 ± 0.8), with p < 0.001. Even at 48 and 72 hours, fentanyl maintained a statistically significant advantage (48 hours: 1.9 ± 0.6 vs. 2.2 ± 0.7, p = 0.001; 72 hours: 1.5 ± 0.5 vs. 1.7 ± 0.6, p = 0.012). These findings highlight that fentanyl patches provided more effective and sustained analgesia throughout the postoperative course, particularly in the first 24 hours where pain is typically most intense.

Table 3: Sedation Score Comparison (Brussels Sedation Scale) (N = 200)

Time Interval	Fentanyl Mean ± SD	Buprenorphine Mean ± SD	Test Statistic	95% CI of Difference	p-value
Sedation at 4 hrs	2.1 ± 0.5	1.8 ± 0.4	t = 4.46	0.17 to 0.43	<0.001*
Sedation at 8 hrs	2.3 ± 0.6	1.9 ± 0.5	t = 4.82	0.22 to 0.56	<0.001*

Journal of Chemical Health Risks
www.jchr.org
JCHR (2025) 15(6), 2186-2193 | ISSN:2251-6727

Sedation at 12 hrs	2.2 ± 0.5	1.8 ± 0.4	t = 5.57	0.26 to 0.53	<0.001*
Sedation at 24 hrs	1.7 ± 0.4	1.5 ± 0.3	t = 4.13	0.10 to 0.32	<0.001*
Sedation at 48 hrs	1.4 ± 0.3	1.3 ± 0.3	t = 2.44	0.01 to 0.17	0.016*
Sedation at 72 hrs	1.3 ± 0.2	1.2 ± 0.2	t = 2.93	0.02 to 0.18	0.004*

Table 3 compares sedation levels between the two groups and demonstrates that fentanyl was associated with slightly higher sedation scores across all postoperative intervals. At 4 hours, fentanyl produced higher sedation (2.1 ± 0.5) compared to buprenorphine (1.8 ± 0.4), with a significant difference ($t = 4.46$, $p < 0.001$). This pattern persisted at 8 hours (2.3 ± 0.6 vs. 1.9 ± 0.5; $p < 0.001$) and 12 hours (2.2 ± 0.5 vs. 1.8 ± 0.4; $p < 0.001$), indicating that fentanyl's greater analgesic potency may be associated with deeper sedation in the early postoperative phase.

At 24, 48, and 72 hours, sedation scores gradually decreased in both groups, although fentanyl remained significantly higher at each time interval ($p < 0.05$ for all). Despite this, the sedation scores for both groups remained within clinically acceptable limits throughout the study, and no cases of excessive or unsafe sedation were observed.

Table 4: Rescue Analgesic Requirement & Side Effects (N = 200)

Variable	Fentanyl (n=100)	Buprenorphine (n=100)	Test Statistic	95% CI of Difference	p-value
Rescue analgesic required, n (%)	21 (21%)	34 (34%)	$\chi^2 = 4.22$	-	0.039*
No. of rescue doses, Mean ± SD	0.29 ± 0.55	0.47 ± 0.70	t = -2.05	-0.35 to -0.01	0.042*
Nausea, n (%)	11 (11%)	8 (8%)	$\chi^2 = 0.53$	-	0.466
Vomiting, n (%)	7 (7%)	6 (6%)	$\chi^2 = 0.08$	-	0.771
Dizziness, n (%)	13 (13%)	9 (9%)	$\chi^2 = 0.74$	-	0.389
Pruritus, n (%)	6 (6%)	5 (5%)	$\chi^2 = 0.10$	-	0.749
Respiratory depression, n (%)	1 (1%)	0 (0%)	Fisher's exact	-	0.317
Skin irritation at patch site, n (%)	4 (4%)	7 (7%)	$\chi^2 = 0.89$	-	0.344

Table 4 examines the requirement for rescue analgesia and the incidence of opioid-related adverse effects. A significantly smaller proportion of fentanyl-treated patients required rescue analgesia (21%) compared to the buprenorphine group (34%), with $\chi^2 = 4.22$ and $p = 0.039$. Furthermore, the mean number of rescue doses was lower in the fentanyl group (0.29 ± 0.55) versus buprenorphine (0.47 ± 0.70), reaching statistical significance ($t = -2.05$, $p = 0.042$; CI: -0.35 to -0.01). This

Journal of Chemical Health Risks

www.jchr.org

JCHR (2025) 15(6), 2186-2193 | ISSN:2251-6727

reinforces the superior analgesic profile of fentanyl patches.

Regarding adverse events, both groups showed similar rates of nausea (11% vs. 8%, p = 0.466), vomiting (7% vs. 6%, p = 0.771), dizziness (13% vs. 9%, p = 0.389), and pruritus (6% vs. 5%, p = 0.749), with no statistically significant differences. Only one case of respiratory depression occurred in the fentanyl group, which was clinically managed without complications (p = 0.317). Skin irritation at the patch site was slightly more common with buprenorphine (7% vs. 4%), but the difference was not significant (p = 0.344).

DISCUSSION

This study compared the efficacy and safety of transdermal fentanyl (TDF) and transdermal buprenorphine (TDB) for postoperative pain relief in patients undergoing total knee replacement (TKR) under subarachnoid block (SAB). A total of 200 patients (100 in each group) completed the study, and the study patches were applied six hours prior to surgery to ensure optimal postoperative plasma concentrations. The baseline characteristics in Table 1 demonstrate that both the fentanyl and buprenorphine groups were well matched for demographic and perioperative variables, including age, gender distribution, BMI, ASA physical status, and duration of surgery. This comparability is crucial, as it ensures that the observed differences in postoperative analgesic efficacy can be attributed to the intervention rather than confounding factors. These findings align with the observations of Jamadar R *et al.* (2024) [6], who also reported similar demographic matching in their comparison of transdermal opioids for orthopedic surgeries. Likewise, Niculae A *et al.* (2024) [7] emphasized the importance of balanced baseline variables in studies evaluating opioid-based analgesia to ensure internal validity.

BMI similarity between groups mirrors the population profiles described in TKR cohorts by Nayak T *et al.* (2024) [8], who noted that BMI generally falls within the overweight range in osteoarthritis patients undergoing TKR. The comparable ASA physical status in both groups is consistent with the findings of Basha A *et al.* (2025) [5], who reported a predominance of ASA II among elderly TKR patients. The average surgical duration in this study (approximately 95 minutes) is nearly identical to durations reported in enhanced-recovery TKR protocols by Londhe SB *et al.* (2024) [9].

Comparison of VAS score between the two groups shows a clear and consistent pattern of superior postoperative analgesia with transdermal fentanyl compared to buprenorphine, particularly in the first 24 hours-a period recognized for peak pain after TKR. The significantly lower VAS scores at all time intervals indicate faster onset and stronger analgesic potency with fentanyl. These findings align with those of Niculae A *et al.* (2024)[7], who reported that fentanyl patches provided significantly lower pain scores during the early postoperative period after major orthopedic procedures. Similarly, Kauser D *et al.* (2022)[4] demonstrated that transdermal fentanyl resulted in better early analgesia than buprenorphine in lower limb surgery.

The observed superiority of fentanyl at 4, 8, and 12 hours resembles the trends seen in spinal anesthesia-based postoperative pain studies by Ibrahim K. (2025)[10], where fentanyl's lipophilicity and rapid transdermal absorption were identified as key contributors to its efficacy. Buprenorphine, being a partial μ-agonist with slower onset, showed comparatively higher VAS scores across all time points in the present study-similar to outcomes reported by Jamadar R *et al.* (2024)[6]. The persistence of significant differences even at 48 and 72 hours reflects fentanyl's sustained effect, a finding supported by Meena R *et al.* (2025)[11], who noted prolonged analgesic benefit in TKR patients using fentanyl patches. Thus, the current findings are consistent with literature indicating that transdermal fentanyl offers more potent early and sustained analgesia than buprenorphine.

Comparison of sedation score reveals that fentanyl was associated with slightly higher sedation scores at all postoperative intervals, though values remained within safe, clinically acceptable limits. This trend is pharmacologically expected due to fentanyl's stronger μ-receptor agonism and higher potency relative to buprenorphine. The early postoperative sedation seen with fentanyl is consistent with findings by Sharma R *et al.* (2024) [12], who reported higher but safe sedation scores with fentanyl patches during the first 12 hours postoperatively. Mishra P *et al.* (2024) [3] also noted that fentanyl produces mild sedation during peak plasma

Journal of Chemical Health Risks

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JCHR (2025) 15(6), 2186-2193 | ISSN:2251-6727

absorption phases, which corresponds with the pattern observed at 4-12 hours in this study.

Buprenorphine's lower sedation is in agreement with studies by Xu X *et al.* (2020) [13], who reported that buprenorphine's ceiling effect on respiratory and CNS depression contributes to a more favorable sedation profile. The gradual decline in sedation scores over 48-72 hours mirrors the attenuation described by Niculae A *et al.* (2024) [7], indicating that both agents maintain stable and safe sedative effects throughout recovery. Hence, the sedation findings are consistent with established pharmacodynamic behavior of both opioids.

Rescue Analgesic Requirement & Side Effects demonstrates that significantly fewer patients in the fentanyl group required rescue analgesia (21% vs. 34%), and the mean number of rescue doses was also lower. These results corroborate the superior analgesic potency seen in Table 2. Comparable outcomes were reported by Meena R *et al.* (2025) [11], who observed reduced rescue analgesic requirements with fentanyl patches after TKR. Kauser D *et al.* (2022) [4] similarly showed that fentanyl significantly decreases reliance on supplemental analgesics.

Side-effect profiles in both groups were comparable, with no significant differences in nausea, vomiting, dizziness, or pruritus. This aligns with the findings of Jamadar R *et al.* (2024)[6], who noted similarly low and comparable incidence of adverse events between transdermal fentanyl and buprenorphine. Only one case of respiratory depression occurred with fentanyl, consistent with the low but known risk reported in Khandelwal H *et al.* (2021)[1]. Slightly higher skin irritation in the buprenorphine group mirrors findings by Londhe SB *et al.* (2022)[14], who highlighted buprenorphine's greater tendency to cause dermal sensitivity.

Conclusion

The present study demonstrates that transdermal fentanyl provides significantly superior postoperative analgesia compared to transdermal buprenorphine in patients undergoing Total Knee Replacement under spinal anesthesia. Fentanyl was associated with consistently lower VAS pain scores across all postoperative time intervals, reduced need for rescue analgesics, and sustained analgesic efficacy, particularly in the critical first 24 hours following surgery. Although fentanyl resulted in slightly higher sedation scores, these remained within safe clinical limits and did not lead to increased adverse events or respiratory compromise. Both transdermal systems exhibited comparable side-effect profiles and were generally well tolerated, indicating that they are safe options for postoperative pain management. Overall, transdermal fentanyl emerges as a more effective analgesic modality for TKR patients, offering enhanced pain control with acceptable safety and tolerability.

Limitations of the Study

1. **Single-center design:** The study was conducted in a single tertiary-care hospital, which may limit the generalizability of the findings to broader populations or varied clinical settings.
2. **Short follow-up period:** Analgesic efficacy and side-effect monitoring were limited to the first 72 postoperative hours; longer-term outcomes such as chronic pain development were not assessed.
3. **Fixed patch dosages:** Only one standard dose of each transdermal patch was evaluated, and dose-response relationships were not explored.
4. **No blinding:** Complete blinding of patients and investigators was not feasible due to visible patch placement, introducing potential observation bias.
5. **Pain perception variability:** Individual differences in pain threshold and psychological factors, which could influence VAS scoring, were not measured or controlled.
6. **No assessment of functional recovery:** Early mobilization parameters and rehabilitation outcomes were not included, though they are important in TKR postoperative evaluation.

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