

A CLINICAL COMPARATIVE STUDY BETWEEN TRANSDERMAL FENTANYL PATCH AND TRANSDERMAL BUPRENORPHINE PATCH FOR POST-OPERATIVE OPEN CHOLECYSTECTOMY

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ABSTRACT

Background: Postoperative pain is one of the most common and challenging clinical problems faced by patients undergoing surgical procedures. Transdermal drug delivery systems have gained increasing attention as an alternative method for postoperative analgesia. Opioids such as fentanyl and buprenorphine are particularly suited for transdermal delivery due to their high potency, lipophilicity, and relatively low molecular weight, which allow effective absorption through the skin. Despite the widespread use of these transdermal opioids, there is limited comparative evidence regarding their efficacy and safety in patients undergoing open cholecystectomy. **Objectives:** The primary purpose of the study was to evaluate the efficacy and hemodynamic effects of transdermal fentanyl patch compared to transdermal Buprenorphine patch for post operative open cholecystectomy in respect of VAS score, Ramsay sedation score and hemodynamic effects. **Materials and Methods:** A double-blinded, randomized controlled trial was done during the period of Mar 2024 – Feb 2026 at JN Institute of Medical Sciences, Imphal, Manipur. Adult patients undergoing elective open cholecystectomy surgeries under general anaesthesia were the study participants. Following all institutional pre-anesthetic check-up and medication, Patients were randomly assigned into two equal groups: Group A received a transdermal fentanyl patch delivering 25 µg/hour, and Group B received a transdermal buprenorphine patch delivering 10 µg/hour. The assigned patch was applied 6–12 hours prior to surgery. Intra-operative and post-operative assessments were done for up-to 72 hours. **Results:** A total of 54 patients (27 in each group) participated in the study. The SBP and DBP remained comparable in the two groups, throughout. The mean respiratory rate was also comparable between the two groups at the different points of observation except that, at 18 hours, a statistically significant difference was observed, with a higher mean respiratory rate in the fentanyl group (13.43 ± 1.23) compared to the buprenorphine group (12.78 ± 0.80) ($p = 0.024$). The mean SpO₂ between the two groups at baseline was comparable ($p=0.350$). It remained comparable on subsequent measurements. At induction and at follow-up, the mean VAS score was comparable. But, at 24 hours, a statistically significant difference in VAS scores was observed, with higher pain scores in the fentanyl group (2.93 ± 1.49) compared to the buprenorphine group (1.89 ± 1.25) ($p = 0.008$). At 30 hours and afterwards, there was no significant difference between the two groups. In the immediate post-operative period, none of the participants in either the fentanyl or buprenorphine patch groups required rescue analgesia. At 6 hours, rescue analgesia was required in 5 participants (18.5%) in the fentanyl group and 3 participants (11.1%) in the buprenorphine group; however, this difference was not statistically significant ($p = 0.330$). At induction, the mean sedation score was significantly higher in the fentanyl patch group (1.63 ± 0.49) compared with the buprenorphine patch group (1.30 ± 0.47), and this difference was statistically significant ($p = 0.014$). In the immediate post-operative period and at all subsequent time points (6, 12,

18, 24, 30, 36, 42, 48, 54, 60, 66, and 72 hours), both groups demonstrated a uniform sedation score of 1.00 with no variability. Adverse effects like nausea and vomiting occurred more in fentanyl group ($p=0.036$). **Conclusion:** Buprenorphine demonstrated better analgesic efficacy at select postoperative intervals and was associated with a lower incidence of gastrointestinal adverse effects. While fentanyl showed higher sedation at induction, both drugs were safe and well tolerated in the postoperative period. Overall, transdermal buprenorphine appears to be an effective and safer alternative to transdermal fentanyl for postoperative pain management.

INTRODUCTION

Postoperative pain is one of the most common and challenging clinical problems faced by patients undergoing surgical procedures.^[1,2] Studies suggest that 50–80% of patients experience inadequate pain relief after surgery, which can lead to delayed rehabilitation, impaired respiratory function, hemodynamic instability, psychological distress, and in some cases, the development of chronic postsurgical pain.^[1,3,4] Effective management of postoperative pain is therefore a critical component of perioperative care, as it improves patient comfort, accelerates recovery, reduces hospital stay, and enhances overall satisfaction.^[5,6]

Traditionally, postoperative pain has been managed using systemic opioids such as morphine and fentanyl, or non-steroidal anti-inflammatory drugs (NSAIDs) like diclofenac.^[7] While intravenous or oral administration provides rapid analgesia, these routes are associated with fluctuations in plasma drug concentration, risk of adverse effects, and the need for frequent dosing, which can complicate patient care and prolong hospital monitoring.^[8] Multimodal analgesia, combining different drug classes or delivery methods, has emerged as a superior approach for achieving effective pain control while minimizing side effects.^[8,9]

Transdermal drug delivery systems (TDDS) have gained increasing attention as an alternative method for postoperative analgesia.^[10] TDDS offers several advantages, including non-invasive administration, avoidance of gastrointestinal absorption and first-pass metabolism, sustained and predictable plasma drug concentrations, reduced dosing frequency, and improved patient compliance.^[11] Opioids such as fentanyl and buprenorphine are particularly suited for transdermal delivery due to their high potency, lipophilicity, and relatively low molecular weight, which allow effective absorption through the skin.^[12,13]

Buprenorphine is a semi-synthetic opioid that acts as a partial μ -opioid receptor agonist and κ -receptor antagonist, with weak δ -receptor activity. It is 75–100 times more potent than morphine and associated with less respiratory depression. The transdermal formulation provides continuous drug release over seven days, maintaining stable plasma concentrations and allowing pre-emptive analgesia.^[8] Fentanyl, a pure μ -opioid receptor agonist, is highly potent, rapidly absorbed transdermally, and provides

consistent analgesia for up to 72 hours. Both opioids have been successfully used in various postoperative settings, including orthopedic, abdominal, and cardiac surgeries, demonstrating effective analgesia and acceptable safety profiles.^[12]

Despite the widespread use of these transdermal opioids, there is limited comparative evidence regarding their efficacy and safety in patients undergoing open cholecystectomy. Moreover, differences in analgesic onset, duration, rescue medication requirements, and side effect profiles between buprenorphine and fentanyl remain underexplored in this population. This study is therefore designed to compare the postoperative analgesic efficacy, hemodynamic stability, and adverse effect profile of transdermal fentanyl and buprenorphine patches in patients undergoing open cholecystectomy, with the aim of identifying the optimal strategy for pain management in this setting.

Objectives

The primary purpose of the study was to evaluate the efficacy and hemodynamic effects of transdermal fentanyl patch compared to transdermal Buprenorphine patch for post operative open cholecystectomy in respect of VAS score, Ramsay sedation score and hemodynamic effects.

MATERIALS AND METHODS

A double-blinded, randomized controlled trial was done during the period of Mar 2024 – Feb 2026 at JN Institute of Medical Sciences, Imphal, Manipur. Adult patients undergoing elective open cholecystectomy surgeries under general anaesthesia were the study participants. Only patients who are categorised under ASA I and II were included. Patients with history of allergy/ hypersensitivity to study drugs, pregnancy, bradycardia, atrioventricular blocks, use of psychoactive medications, substance abuse, alcohol abuse, obesity, hepatic failure or serious medical conditions were excluded.

Based on a study done by Arshad Z et al[9], where the mean (SD) VAS Scores across the study groups were Buprenorphine patch (4.37; 0.58) and Fentanyl patch (3.91; 0.51) and considering an effect size of 0.84 and a probable attrition rate of 10%, a sample size of 27 in each of the two intervention groups was calculated. All eligible participants were consecutively recruited until the calculated sample size was achieved. Prior to the start of the study, a randomization schedule was generated by using a

computer-generated random number table. Allocation concealment was ensured through the use of sequentially numbered, opaque, sealed envelopes, each containing a unique randomization code and labelled according to the order of patient enrolment. At the time of recruitment, eligible participants were allotted a unique identification number, and the corresponding envelope was opened to determine group allocation. Patients were randomly assigned into two equal groups: Group A received a transdermal fentanyl patch delivering 25 µg/hour, and Group B received a transdermal buprenorphine patch delivering 10 µg/hour. The assigned patch was applied 6–12 hours prior to surgery. Group allocation was carried out by the investigator, who was not blinded to the assignment; however, both the patients and the statistician were blinded, as data were recorded and analyzed using coded identification numbers. The group allocation was disclosed only after completion of the statistical analysis to minimize bias.

A thorough medical history and clinical examination was done for all the participants. Routine laboratory investigations such as hemoglobin concentration, differential leukocyte count, bleeding time, clotting time, fasting blood sugar, serum urea and creatinine, serum electrolytes, liver function tests, and cardiological evaluation were performed as indicated.

Pre-operatively, patients were educated regarding postoperative pain management and the use of the transdermal analgesic patch. The Visual Analogue Scale (VAS), a 10-cm pain assessment scale, was explained in detail to all participants prior to surgery. A pre-tested, semi-open clinical proforma was used to collect data. Baseline demographic data including age, sex, and American Society of Anesthesiologists (ASA) physical status were recorded for all study participants. Anthropometric parameters including height, weight, and body mass index (BMI) were also recorded. Further, Hemodynamic stability was assessed by monitoring heart rate, systolic and diastolic blood pressure, mean arterial pressure (MAP), oxygen saturation (SpO₂), and respiratory rate. Postoperative analgesia was evaluated using the Visual Analogue Scale (VAS) for pain intensity and a standardized sedation score. The requirement of rescue analgesic doses administered were also documented.

Pre-operatively, all patients were kept nil per oral for at least 8 hours for solids and 2 hours for clear fluids prior to surgery. Premedication included oral alprazolam 0.5 mg and oral pantoprazole 40 mg administered on the night before surgery. Upon arrival in the operating room, an intravenous line was secured using an 18G cannula. Baseline vital parameters including pulse rate, blood pressure, oxygen saturation (SpO₂), and respiratory rate were recorded. Patients received intravenous ondansetron 0.1 mg/kg and glycopyrrolate 0.2 mg either intramuscularly or intravenously. All transdermal patches were covered to maintain blinding.

Preoxygenation with 100% oxygen was administered for 3–5 minutes. Intravenous fentanyl (2–20 µg/kg) was administered for intraoperative analgesia. Induction of anaesthesia was achieved using intravenous propofol (1–2.5 mg/kg), followed by succinylcholine (1–2 mg/kg) to facilitate endotracheal intubation. After confirmation of bilateral air entry, patients were connected to a ventilator in volume-controlled mode. Injection Vecuronium 0.1mg/kg IV loading dose given. Maintained with oxygen, air, Sevoflurane 1 MAC and intermittent Vecuronium bolus.

Intraoperative monitoring included heart rate, non-invasive blood pressure, electrocardiogram, SpO₂, respiratory rate, end-tidal CO₂, and mean arterial pressure (MAP), recorded at 15-minute intervals. Depth of anesthesia was monitored using bispectral index (BIS).

Intraoperative complications were managed as per institutional guidelines. At the end of surgery, before skin closure Sevoflurane was stopped and residual neuromuscular blockade was reversed using neostigmine (50–70 µg/kg) and glycopyrrolate (10 µg/kg). Patients were extubated after adequate recovery of spontaneous respiration and transferred to the postoperative ward for monitoring.

Postoperatively, pain intensity was assessed using the Visual Analogue Scale (VAS) and sedation was evaluated using the Ramsay Sedation Score. Assessments were carried out at regular intervals for up-to 72 hours postoperatively. IV Diclofenac 75mg was administered as rescue analgesia in patients reporting inadequate pain relief or VAS score >5.

Hemodynamic parameters and respiratory variables were monitored, and any adverse effects were recorded. Intravenous diclofenac 75 mg was administered as rescue analgesia in patients reporting inadequate pain relief. Opioid-related side effects such as nausea, vomiting, and pruritus were specifically observed and documented.

The statistical analysis was carried out using IBM SPSSv20. The analysis includes frequency table, bar, pie chart, association of variables based on Chi-square test and if any cell frequency is <5. All quantitative variables were estimated using measures of central location (mean and median) and measures of dispersion (standard deviation). Normality of data was checked by Kolmogorov–Smirnov tests of normality. Data was found to be distributed normally and mean was compared using Independent t test (for two groups). All statistical tests were seen at two-tailed level of significance ($p \leq 0.05$).

RESULTS

The mean age in the fentanyl patch group was 41.82 ± 17.72 years, while that in the buprenorphine patch group was 38.74 ± 10.99 years. Statistical analysis using the independent t-test showed no significant difference in age between the two groups ($p = 0.444$). The gender distribution ($p=0.74$), ASA status

distribution ($p=0.186$), mean weight ($p=0.362$), mean weight (0.541), BMI ($p=0.824$) also were found to be comparable in the two groups.

Table 1: SBP among study participants

Time	Fentanyl patch		Buprenorphine patch		P-Value
	Mean	SD	Mean	SD	
Baseline	122.50	28.204	123.78	11.991	0.587
After Induction	123.18	28.455	126.70	17.944	0.539
Post OP	133.68	29.454	129.81	13.868	0.262
6 Hours	128.43	18.558	122.93	17.393	0.537
12 Hours	126.86	15.089	124.33	15.026	0.507
18 Hours	127.79	28.959	123.67	13.892	0.009
24 Hours	128.11	11.683	120.37	13.644	0.029
30 Hours	126.78	14.677	117.67	13.669	0.022
36 Hours	125.64	13.801	116.30	11.632	0.173
42 Hours	120.93	10.839	116.70	11.838	0.244
48 Hours	121.54	9.566	117.93	12.955	0.310
54 Hours	120.29	9.809	117.33	11.503	0.278
60 Hours	120.00	10.887	116.44	13.119	0.796
66 Hours	119.64	9.206	118.89	12.208	0.798
72 Hours	121.07	10.147	120.30	12.098	0.798

Table 1 presents the comparison of systolic blood pressure between the fentanyl patch and buprenorphine patch groups at various time intervals. Baseline and induction SBP values were comparable between the two groups, with no statistically significant difference observed ($p = 0.587$ and $p = 0.539$, respectively). Postoperative SBP and values at 6, 12, and 36 hours also showed no significant intergroup differences ($p > 0.05$). However, a statistically significant difference in SBP was observed at 18 hours ($p = 0.009$), 24 hours ($p = 0.029$), and 30 hours ($p = 0.022$), with higher mean SBP values noted in the fentanyl patch group compared to the buprenorphine patch group. Beyond 36 hours and up to 72 hours postoperatively, SBP values remained comparable between the two groups, with no statistically significant differences observed, indicating similar long-term hemodynamic profiles. The diastolic blood pressure trends were largely similar between the two groups throughout the study period. Also, the MAP trends remained largely similar between the fentanyl and buprenorphine patch groups throughout the study period, except for a transient difference at 36 hours. (Fig. 1) The mean heart rate in the two groups were also comparable at

the various periods of time. The mean respiratory rate was also comparable between the two groups at the different points of observation except that, at 18 hours, a statistically significant difference was observed, with a higher mean respiratory rate in the fentanyl group (13.43 ± 1.23) compared to the buprenorphine group (12.78 ± 0.80) ($p = 0.024$).

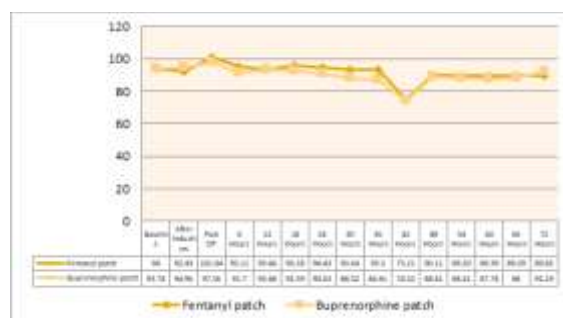


Figure 1: Line-graph showing mean arterial pressure (MAP among study participants)

The mean SpO₂ between the two groups at baseline was comparable ($p=0.350$). It remained comparable on subsequent measurements.

Table 2: VAS score among study participants

Time	Fentanyl patch		Buprenorphine patch		P-Value
	Mean	SD	Mean	SD	
Induction	6.57	17.929	2.96	0.437	0.301
Post OP	3.14	1.145	3.00	0.877	0.607
6 Hours	2.75	0.752	2.89	0.934	0.545
12 Hours	3.04	1.427	2.74	1.196	0.411
18 Hours	2.68	0.983	2.19	1.178	0.097
24 Hours	2.93	1.492	1.89	1.251	0.008
30 Hours	2.18	1.188	1.56	0.934	0.036
36 Hours	1.46	0.637	1.19	0.483	0.074
42 Hours	1.36	0.559	1.11	0.320	0.051
48 Hours	1.11	0.315	1.00	0.000	0.083
54 Hours	1.04	0.189	1.00	0.000	0.331
60 Hours	1.00	0.000	1.00	0.000	-
66 Hours	1.00	0.000	1.00	0.000	-
72 Hours	1.00	0.000	1.00	0.000	-

P value - Independent t test

Table 2 presents the comparison of pain intensity as assessed by the Visual Analogue Scale (VAS) between participants receiving the fentanyl patch and those receiving the buprenorphine patch at various peri-operative and postoperative time intervals up to 72 hours. At induction and at follow-up, the mean VAS score was comparable. But, at 24 hours, a statistically significant difference in VAS scores was observed, with higher pain scores in the fentanyl group (2.93 ± 1.49) compared to the buprenorphine group (1.89 ± 1.25) ($p = 0.008$). At 30 hours and afterwards, there was no significant difference between the two groups.

In the immediate post-operative period, none of the participants in either the fentanyl or buprenorphine patch groups required rescue analgesia. At 6 hours, rescue analgesia was required in 5 participants (18.5%) in the fentanyl group and 3 participants (11.1%) in the buprenorphine group; however, this difference was not statistically significant ($p = 0.330$). Afterwards, a few more participants needed rescue analgesia which was more in the fentanyl which was not statistically significant.

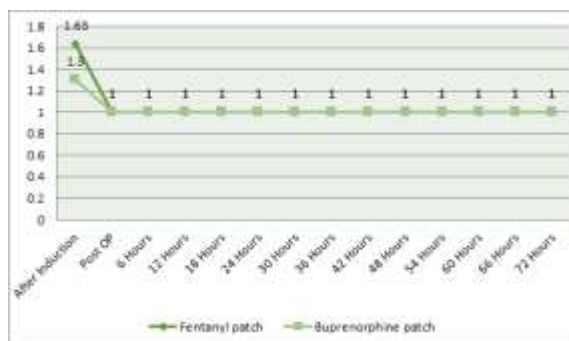


Figure 2: Sedation score among study participants

At induction, the mean sedation score was significantly higher in the fentanyl patch group (1.63 ± 0.49) compared with the buprenorphine patch group (1.30 ± 0.47), and this difference was statistically significant ($p = 0.014$).

In the immediate post-operative period and at all subsequent time points (6, 12, 18, 24, 30, 36, 42, 48, 54, 60, 66, and 72 hours), both groups demonstrated a uniform sedation score of 1.00 with no variability. (Fig. 2)

Regarding adverse effects, nausea and vomiting were the most commonly reported adverse effects in the study. These occurred in 8 participants (29.6%) in the fentanyl patch group compared with 2 participants (7.4%) in the buprenorphine patch group. This difference was statistically significant ($p = 0.038$), indicating a higher incidence of nausea and vomiting in the fentanyl group. No cases of pruritus, constipation, or respiratory depression were reported in either the fentanyl or buprenorphine patch groups during the study period; therefore, statistical comparison was not applicable for these adverse effects.

DISCUSSION

In the present study, SBP and DBP, MAP at baseline and during induction was comparable between the fentanyl and buprenorphine patch groups, with no statistically significant differences observed. Statistically significant differences were noted at 18 hours, 24 hours and 30 hours during which high SBP observed in fentanyl group compared with buprenorphine patch group. DBP value at 6, 12, 18, 24 and 30 hours postoperatively did not differ significantly. A statistically significant difference was observed at 36 hours postoperatively with high DBP value noted in fentanyl patch group. In MAP statistically significant difference was noted at 36 hours postoperatively with higher mean MAP value observed in fentanyl patch group.

MAP trends were largely similar throughout the study period, with only a transient and isolated difference observed at 36 hours, which was not sustained. These findings are consistent with those reported by Angom CL et al., who demonstrated no statistically significant differences in postoperative MAP between fentanyl and buprenorphine patch groups across various time intervals ($p > 0.05$), thereby supporting the hemodynamic stability of both transdermal opioid formulations.

RR and HR baseline and induction values were comparable between the fentanyl and buprenorphine patch groups with no statistically significant differences observed. There is significant difference observed at 18 hours ($p=0.024$), 30 hours ($p=0.038$) and 36 hours ($P=0.020$) with slightly higher mean respiratory rate in fentanyl patch group. The heart rate trends observed in the present study are consistent with those reported by Gupta and Chopra, Angom CL et al, Arshad et al, Shetty and Solomon, Patil et al and Das et al, all of whom demonstrated no significant differences in heart rate between patients receiving transdermal fentanyl and buprenorphine.^[7-9,12-14]

SpO₂ baseline and induction values were comparable between the fentanyl and buprenorphine group. Postoperatively Spo₂ values assessed time intervals from immediate postoperative period up to 72 hours did not show any statistically significant intergroup differences.

VAS scores recorded in the immediate postoperative period and at 6 and 12 hours were also comparable between the two groups ($p>0.05$). At 18 hours postoperatively fentanyl group reported marginally higher pain score. statistically significant differences observed at 24 hours and 30 hours during which higher VAS score were noted in fentanyl patch group which suggested superior analgesic efficacy with buprenorphine during mid postoperative period. Beyond 36 hours till 72 hours VAS score progressively declined both groups. In present study both transdermal fentanyl patch and transdermal buprenorphine patch provided effective postoperative analgesia following open

cholecystectomy, with buprenorphine demonstrating superior pain control at selected postoperative intervals. Kausar and Singh reported significant differences in early postoperative VAS scores, with lower scores in the buprenorphine group at the fourth hour and in the fentanyl group at the eighth hour. Patil et al. observed comparable early VAS scores between the two groups, followed by statistically significant differences persisting up to 72 hours.^[2]

Mean sedation score was significantly higher in fentanyl patch group (1.63 ± 0.49) compared with buprenorphine patch group (1.30 ± 0.47). Similar finding Observed in Gupta and Chopra et al study reported sedation score higher in fentanyl group during early postoperative period (0-2hours) followed by progressive decline with both groups after 4 hours.^[7]

In present study requirement of rescue analgesia required more in fentanyl patch group patient. At 6- and 18-hours higher proportion of fentanyl group patient required rescue analgesia compare to buprenorphine group (18.5% vs 11.1%). However, these differences were not statistically significant.

In the present study, nausea and vomiting were most frequently observed adverse effects in fentanyl patch group (29.6%) of patient compared to buprenorphine patch group (7.4%) of patient, similar results found in Kausar and Singh et al study.^[2]

Gupta and Chopra also observed a higher incidence of nausea and vomiting in the fentanyl group, although the differences did not reach statistical significance. However, they noted a significantly higher occurrence of headache and blurring of vision among patients receiving fentanyl, suggesting a broader side-effect profile with this agent.^[7]

The present study had certain limitations. The study was conducted at a single tertiary care center, which may limit the generalizability of the findings. The sample size was relatively small, which may not detect rare adverse effects. Again, plasma drug concentrations were not measured, and hence pharmacokinetic correlations could not be established. Further, the study included only patients undergoing open cholecystectomy, limiting applicability to other surgical procedures. Lastly, the intraoperative administration of fentanyl for analgesia may have influenced early postoperative pain scores. Larger multicentric randomized controlled trials are recommended to validate the findings. And also, future studies should include measurement of plasma fentanyl and buprenorphine levels to correlate pharmacokinetics with clinical efficacy.

ONCLUSION

Both transdermal fentanyl and transdermal buprenorphine patches provide effective and sustained postoperative analgesia following open cholecystectomy, with comparable hemodynamic

and respiratory stability. Buprenorphine demonstrated better analgesic efficacy at select postoperative intervals and was associated with a lower incidence of gastrointestinal adverse effects. While fentanyl showed higher sedation at induction, both drugs were safe and well tolerated in the postoperative period. Overall, transdermal buprenorphine appears to be an effective and safer alternative to transdermal fentanyl for postoperative pain management, making it a valuable component of multimodal analgesia following open cholecystectomy.

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