ORIGINAL RESEARCH PAPER
Volume - 14 | Issue - 05 | May - 2025 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

TRANSDERMAL BUPRENORPHINE VERSUS FENTANYL FOR POSTOPERATIVE ANALGESIA IN LOWER ABDOMINAL SURGERY: A RANDOMIZED DOUBLE-BLIND COMPARATIVE STUDY

Anaesthesiology

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ABSTRACT

Background: Despite advancements in pain management, postoperative analgesia remains suboptimal in 30-50% of surgical patients. This study compares the efficacy and safety of transdermal buprenorphine and fentanyl patches in lower abdominal surgery. Methods: Sixty ASA I-II patients undergoing elective lower abdominal procedures were randomized to receive either buprenorphine (10 mcg/hr) or fentanyl (25 mcg/hr) patches applied 6 hours preoperatively. Primary outcomes included duration of analgesia and visual analog scale (VAS) pain scores. Secondary outcomes encompassed rescue analgesia requirements, Ramsay sedation scores, and adverse effects over 72 hours. Results: The buprenorphine group demonstrated significantly longer analgesia duration (46.0±8.49 vs 34.84±9.23 hours; p=0.001) and lower rescue analgesia needs (10% vs 50%; p=0.0007). Fentanyl showed higher sedation scores at 24-48 hours ($p<0.001$) and increased heart rate variability postoperatively. Both groups maintained hemodynamic stability with comparable adverse effect profiles. Conclusion: Transdermal buprenorphine provides superior prolonged analgesia with less sedation compared to fentanyl, making it a preferable option for postoperative pain management in abdominal surgery.

KEYWORDS

Postoperative Pain, Transdermal Analgesia, Opioid Patches, Buprenorphine, Fentanyl

INTRODUCTION

Effective postoperative pain management is a critical component of surgical care, directly influencing patient recovery, morbidity, and overall outcomes. Despite significant advances in analgesic techniques, a substantial number of patients continue to experience inadequate pain relief following surgery [1]. Poorly managed postoperative pain may result in a range of complications including hemodynamic instability, impaired respiratory function, psychological distress, delayed mobilization, and an increased risk of developing chronic postsurgical pain [2].

Recent years have witnessed a resurgence in the use of medications traditionally employed for chronic pain to address acute postoperative discomfort. Among these, transdermal drug systems (TDS) have emerged as an innovative and effective modality for pain management. TDS provides a non-invasive, reliable, and sustained method of drug delivery, maintaining stable plasma concentrations and minimizing the pharmacokinetic limitations of oral or parenteral routes[3]. Although costlier than conventional analgesics, TDS may reduce the requirement for supplemental opioids, thereby mitigating opioid-related adverse effects [4].

Fentanyl and buprenorphine are the most commonly used opioids in transdermal formulations for perioperative analgesia. Fentanyl is a potent synthetic mu-opioid receptor agonist known for its rapid onset and efficacy, whereas buprenorphine, a partial mu-opioid agonist and kappa antagonist, is recognized for its long duration of action and lower incidence of respiratory depression and dependence [5, 6].

Buprenorphine's pharmacological profile—characterized by high lipid solubility, low molecular weight, and slow release kinetics—makes it particularly suitable for transdermal administration. Several studies have shown its effectiveness in reducing postoperative pain, opioid consumption, and improving patient satisfaction after various surgical procedures [7, 8].

AIMS AND OBJECTIVES

Aim: To compare the potency of transdermal buprenorphine and transdermal fentanyl for postoperative pain relief in lower abdominal surgery.

Objective: The objective of this study was to evaluate and compare the onset of action, analgesic efficacy, and duration of analgesia between two randomly assigned groups: Group 1, receiving a transdermal buprenorphine patch, and Group 2, receiving a transdermal fentanyl patch.

MATERIALS AND METHODS

Study Design: This prospective, randomized, double-blind, comparative study was conducted over a period of 18–24 months at Mayo Institute of Medical Sciences, Barabanki, following approval from the Institutional Ethics Committee. The primary aim was to compare the efficacy and safety of transdermal buprenorphine (10 mcg/hr) and transdermal fentanyl (25 mcg/hr) for postoperative analgesia in patients undergoing lower abdominal surgeries.

Sample Size: The sample size was calculated using the formula

$$n = \frac{z^2 p(1-p)}{d^2}$$

There are 60 patients in all, split into two groups of 30 each, for this study.

Inclusion Criteria

- ASA physical status I or II
- Age 20–60 years
- Elective lower abdominal or lower limb orthopedic surgery

Exclusion Criteria

- Patient refusal
- Comorbidities: diabetes, chronic lung, hepatic, renal, or cardiovascular diseases
- Neuromuscular disorders, active infection, bleeding disorders
- Obesity (BMI > 30 kg/m²)
- Known allergy to study drugs

A randomized study was conducted on 60 adult patients (ASA I & II), aged 20–60 years, divided into two equal groups (n=30).

- Group I received a transdermal buprenorphine patch (10 mcg/hr), and
- Group II received a transdermal fentanyl patch (25 mcg/hr), applied to a hairless area (chest, back, flank, or upper arm) 6 hours preoperatively.

Preoperative Preparation: All patients underwent pre-anesthetic evaluation and provided written informed consent. Baseline hemodynamic parameters (BP, SpO_2, pulse rate, ECG) were recorded. Patients were kept nil per oral overnight, and IV access was secured.

Anesthesia Protocol: Premedication included IV midazolam (1 mg), fentanyl (2 mcg/kg), and ondansetron (4 mg). Induction was done with propofol (2 mg/kg), and intubation with vecuronium (0.1 mg/kg). Anesthesia was maintained with isoflurane, N_2O:O_2 (60:40), and vecuronium. Extubation was performed after reversal with glycopyrrolate (0.01 mg/kg) and neostigmine (0.05 mg/kg).

Postoperative Monitoring: Sedation (Ramsay Sedation Scale) and pain (VAS) were assessed at 12-hour intervals for 3 days. Hemodynamics and adverse effects were noted. Pain was managed with rescue IV diclofenac (75 mg) or 0.25% bupivacaine (10 ml) when VAS >4. The time to first analgesic request and total rescue doses over 24 hours were recorded.

Statistical Analysis: Data were analyzed using SPSS v10. Quantitative data were expressed as mean ± SD; qualitative data as frequency (%). Student's t-test and Chi-square test were used. A p-value <0.05 was considered statistically significant.

Ethical Considerations: The study received ethical clearance. Informed consent was obtained. Participation was voluntary, and patient care was not affected by refusal. All ethical principles, including confidentiality and non-maleficence, were strictly followed.

RESULTS

A total of 60 patients undergoing lower abdominal surgeries were randomly allocated into two groups of 30 each to receive either transdermal buprenorphine (Group I) or transdermal fentanyl (Group II) patches for postoperative analgesia. The mean age of patients in Group I was 39 ± 8.6 years, while in Group II it was 41.87 ± 7.61 years. Majority of patients (53.3%) in both groups belonged to the 41–50 years age group. Female predominance was noted, with females comprising 70% in Group I and 60% in Group II.

Most patients in both groups were classified as ASA Grade I (80% in Group I and 93.3% in Group II), indicating a generally healthy study population. The average body weight was comparable between groups, being 62.5 ± 8.33 kg in Group I and 63.7 ± 8.03 kg in Group II, with no statistically significant difference ($p = 0.572$). Clinical diagnoses leading to surgery varied, but most common were uterine pathologies grouped as 'others' (60%), followed by hernia (25%), appendicitis (11.7%), and cholecystitis (3.3%). Similar trends were seen in the types of surgeries performed, with uterine surgeries being the most frequent (51.7%), followed by hernia and appendectomy procedures.

The mean duration of surgery was also comparable between the two groups: 87 ± 17.8 minutes in Group I and 91.16 ± 25.9 minutes in Group II ($p = 0.471$). Intraoperative hemodynamic parameters—including heart rate (HR), systolic and diastolic blood pressure (SBP, DBP), mean arterial pressure (MAP), and oxygen saturation (SpO_2)—remained stable and statistically similar across both groups at all time intervals measured (baseline, 15, 30, and 45 minutes), indicating intraoperative hemodynamic stability with both analgesic modalities.

In the postoperative period, heart rate measurements between groups were mostly comparable, except at 12 hours ($p = 0.002$) and 24 hours ($p < 0.001$), where Group II showed a significantly higher HR. Systolic blood pressure was significantly lower in the fentanyl group at 1, 4, 8, and 20 hours postoperatively ($p = 0.036$), although the clinical significance of this modest drop remains to be interpreted cautiously. Diastolic blood pressure and mean arterial pressure did not show any statistically significant differences between the two groups throughout the 24-hour monitoring period. SpO_2 levels were stable and within normal limits in both groups during intraoperative and postoperative monitoring.

DISCUSSION

Effective postoperative pain management is pivotal in enhancing recovery, minimizing complications, and improving patient satisfaction following surgery. This study compared the safety and efficacy of transdermal buprenorphine patches (Group I) and fentanyl patches (Group II) in providing postoperative analgesia. The findings revealed several key differences and similarities between the two interventions, which are discussed below in the context of existing literature.

1. Demographic and Clinical Characteristics

The majority of patients in this study were middle-aged (41–50 years), with a higher proportion of females (65%). Both groups were comparable in terms of age, weight, and ASA physical status classification. These characteristics align with findings from earlier studies that reported similar demographic distributions in patients undergoing postoperative pain management interventions [9]. Moreover, it has been suggested that the efficacy of transdermal analgesics is not significantly affected by factors such as gender or body weight, supporting the generalizability of our results [10].

2. Pain Control and Rescue Analgesia

Group I demonstrated superior analgesic efficacy compared to Group II, with only 10% of patients requiring rescue analgesia versus 50% in Group II, a difference that was statistically significant ($p = 0.0007$). This observation is supported by previous research indicating that buprenorphine, a partial μ-opioid receptor agonist and κ-opioid receptor antagonist, provides sustained analgesia with fewer rescue requirements [11]. In contrast, while fentanyl is a full μ-opioid agonist known for its potency, its relatively shorter duration of action often necessitates more frequent supplemental analgesia [12].

3. Duration of Analgesia

Patients in Group I experienced a significantly longer duration of analgesia (46 ± 8.49 hours) compared to Group II (34.84 ± 9.23 hours; $p = 0.001$). This is consistent with the known pharmacokinetics of buprenorphine, which includes a prolonged half-life and sustained release from transdermal formulations [13]. Conversely, fentanyl, despite its rapid onset, is associated with a shorter duration of action, contributing to the need for earlier rescue doses [12].

4. Sedation Levels

Group II exhibited higher sedation scores at 24, 36, and 48 hours postoperatively ($p < 0.001$). This can be attributed to the strong sedative properties of fentanyl, which may persist even after its analgesic effects diminish, potentially delaying recovery and increasing the risk of complications such as respiratory depression [14]. Buprenorphine, due to its partial agonist profile, is associated with less sedation, offering a safer alternative in the postoperative setting.

5. Pain Scores

Pain intensity, assessed using the Visual Analog Scale (VAS), was significantly lower in Group I at 24, 36, and 48 hours ($p < 0.05$ or < 0.001), indicating superior pain control. These findings are consistent with those of Lee et al., who reported greater patient satisfaction and better pain control with transdermal buprenorphine compared to fentanyl in postoperative patients [11].

6. Adverse Effects

Both groups tolerated their respective analgesic regimens well, with no statistically significant differences in the incidence of nausea, vomiting, or dizziness. However, a slightly higher incidence of nausea and vomiting was noted in Group II (4%) compared to Group I (1%), consistent with the known adverse effect profile of fentanyl [15, 16]. The low overall incidence of adverse effects in both groups underscores the safety of transdermal opioid analgesics in post-operative care.

7. Hemodynamic Stability

There were no significant differences in hemodynamic parameters (HR, SBP, DBP, MAP, SpO_2) between the two groups at most time intervals. However, a statistically significant increase in heart rate was observed in Group II at 12 and 24 hours ($p < 0.05$). This may reflect a sympathetic stress response due to inadequate pain control, a phenomenon also reported in previous studies [17].

8. Comparison with Previous Studies

Our findings align with several prior investigations comparing buprenorphine and fentanyl in postoperative pain management. For instance, [18] found that buprenorphine offered prolonged analgesia and reduced need for rescue medication. Similarly, a meta-analysis by [19] concluded that buprenorphine was associated with better pain control and fewer side effects. However, some studies have reported conflicting results, favoring fentanyl for acute pain due to its rapid onset [20]. Such discrepancies may be explained by variations in study design, surgical procedures, patient populations, and opioid dosing strategies.

CONCLUSION

The effectiveness, safety, and clinical results of the Fentanyl Patch (Group II) and Buprenorphine Patch (Group I) for postoperative pain management in patients having different surgical procedures were compared in this study. According to the results, the Buprenorphine Patch has a number of benefits over the Fentanyl Patch, such as better pain management, an extended period of analgesia, and a decreased requirement for rescue analgesia. Buprenorphine is a safer and more

efficient choice for postoperative pain treatment because it has also been linked to reduced sedation levels, improved hemodynamic stability, and fewer side effects.

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