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ANALGESIC EFFICACY AND HEMODYNAMIC STABILITY OF TRANSDERMAL BUPRENORPHINE PATCHES IN ABDOMINAL SURGERIES: A PROSPECTIVE RANDOMIZED STUDY

Anaesthesiology

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ABSTRACT

Background: Effective postoperative pain control enhances recovery and patient satisfaction. Buprenorphine, a partial μ-opioid receptor agonist, is known for its potent analgesia and favorable safety profile. **Aim:** To evaluate the analgesic efficacy, sedation, hemodynamic impact, and safety of transdermal buprenorphine patches in abdominal surgery patients. **Methods:** A prospective randomized study included patients undergoing abdominal surgeries who received 10 mcg/hr or 20 mcg/hr transdermal buprenorphine patches applied 6 hours preoperatively. Parameters recorded included heart rate, blood pressure, respiratory rate, SpO_2, VAS, Ramsay sedation scores, and rescue analgesic requirements. Results: Buprenorphine patches provided effective analgesia with stable hemodynamics and minimal adverse effects. The 20 mcg/hr group had significantly lower VAS scores and required fewer rescue analgesics. **Conclusion:** Transdermal buprenorphine offers a safe, effective alternative for managing postoperative pain in abdominal surgeries.

KEYWORDS

Buprenorphine, transdermal patches & analgesic efficacy

INTRODUCTION

Effective postoperative pain management is a cornerstone of optimal surgical care. Poorly controlled postoperative pain impairs functional recovery, increases the risk of complications such as deep vein thrombosis, pulmonary morbidity, and chronic pain, and negatively impacts overall patient satisfaction.1,2,3 The initial postoperative days are particularly critical, as acute pain can contribute to central sensitization, setting the stage for persistent postsurgical pain syndromes.4,5

Despite advances in multimodal analgesia, opioids remain a mainstay for managing moderate to severe postoperative pain. However, their use is tempered by well-known adverse effects such as nausea, vomiting, ileus, sedation, respiratory depression, and the growing concern of opioid dependence and abuse.6,7 This has led to increasing interest in opioid-sparing and alternative opioid delivery strategies.

Buprenorphine, a semi-synthetic derivative of thebaine, is a partial agonist at the μ-opioid receptor and an antagonist at κ-receptors. 8 It offers several pharmacological advantages, including potent analgesia, a ceiling effect for respiratory depression (but not for analgesia), and a lower potential for tolerance and dependence.9 The transdermal formulation provides stable plasma concentrations over several days, enhancing both efficacy and compliance, particularly in the perioperative setting where oral intake may be limited.10

Previous studies have established the utility of transdermal buprenorphine in chronic and cancer-related pain. Its application in acute postoperative pain is a more recent development, with emerging data supporting its effectiveness and safety.11,12 However, evidence remains limited, particularly regarding its hemodynamic impact and comparative performance across dosing regimens. This study evaluates the analgesic efficacy, sedation profile, hemodynamic effects, and overall tolerability of two dosing strengths (10 mcg/hr and 20 mcg/hr) of transdermal buprenorphine in patients undergoing abdominal surgeries

METHODS

Study Design And Setting

This prospective, randomized, controlled, single-center study was conducted in a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee (IEC) and informed written consent from all participants. The study adhered to the principles of the Declaration of Helsinki and followed the CONSORT guidelines for randomized trials.

Study Population

A total of 60 adult patients (aged 18–65 years) scheduled for elective lower abdominal surgery under general anaesthesia were enrolled. All patients were classified as American Society of Anesthesiologists (ASA) physical status I or II. Exclusion criteria included:

- Known allergy or hypersensitivity to opioids
- Chronic opioid use or history of substance abuse
- Hepatic or renal impairment
- Severe cardiorespiratory disease
- Cognitive impairment precluding informed consent or pain scoring

Randomization And Group Allocation

Patients were randomly allocated into two equal groups (n = 30 per group) using computer-generated random numbers and sealed opaque envelopes:

- **Group A**: Received transdermal buprenorphine 10 mcg/hr patch
- **Group B**: Received transdermal buprenorphine 20 mcg/hr patch

Patches were applied to a hairless area on the upper outer arm or chest 6 hours prior to surgery to ensure preoperative drug absorption and establishment of therapeutic plasma levels.

Anaesthesia And Intraoperative Management

All patients received standardized general anaesthesia with:

- **Induction:** Inj. propofol (2 mg/kg), fentanyl (2 mcg/kg), and vecuronium (0.1 mg/kg)
- **Maintenance:** Isoflurane (1 MAC) in oxygen–nitrous oxide (50:50), intermittent boluses of vecuronium
- **Monitoring:** ECG, NIBP, SpO_2, $EtCO_2$, and temperature

No additional long-acting opioids were used intraoperatively to eliminate confounding effects.

Postoperative Assessment And Follow-Up

Patients were evaluated postoperatively for the next 72 hours at 6-hour intervals by a blinded observer. The following parameters were recorded:

- **Hemodynamic Variables:** Heart rate (HR), systolic and diastolic blood pressure (SBP, DBP), mean arterial pressure (MAP), respiratory rate (RR), and peripheral oxygen saturation (SpO_2)
- **Pain Intensity:** Assessed using the Visual Analog Scale (VAS, 0 = no pain; 10 = worst pain)
- **Sedation**: Graded using the Ramsay Sedation Scale (RSS)
- **Rescue Analgesic**: IV tramadol 50 mg was administered when VAS ≥ 4; total consumption was recorded
- **Adverse Effects**: Nausea, vomiting, pruritus, respiratory depression, dizziness, or skin reactions were noted

- **Patient Satisfaction**: Assessed on day 3 using a 5-point Likert scale (1 = very dissatisfied, 5 = very satisfied)

Statistical Analysis

Data were compiled and analyzed using SPSS software version 22.0 (IBM Corp, Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation (SD) and compared using Student's unpaired t-test. Categorical data, including frequency of rescue analgesia and adverse effects, were compared using the Chi-square test or Fisher's exact test as appropriate. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 60 patients were enrolled and completed the study, with 30 patients in each group. Demographic characteristics such as age, sex, body mass index (BMI), ASA status, and duration of surgery were comparable between the two groups, with no statistically significant differences ($p > 0.05$), as shown in Table 1.

Table 1. Baseline Demographic And Surgical Characteristics

Parameter	Group A (10 mcg/hr)	Group B (20 mcg/hr)	p-value
Age (years)	43.5 ± 10.1	45.2 ± 9.8	0.448
Sex (M/F)	16/14	17/13	0.795
BMI (kg/m²)	24.6 ± 2.3	24.1 ± 2.1	0.392
ASA I/II	18/12	19/11	0.793
Duration of surgery (min)	97.4 ± 14.6	100.2 ± 13.9	0.412

Hemodynamic Stability

Both groups demonstrated stable intraoperative and postoperative hemodynamic profiles with no episodes of bradycardia, hypotension, or respiratory depression. Intergroup differences in heart rate, blood pressure, respiratory rate, and oxygen saturation were not statistically significant throughout the observation period ($p > 0.05$) (Table 2).

Table 2. Hemodynamic Parameters (Mean ± SD over 72 hours)

Parameter	Group A	Group B	p-value
HR (beats/min)	82.3 ± 6.1	80.4 ± 5.9	0.121
SBP (mmHg)	122.7 ± 8.2	121.2 ± 9.1	0.435
DBP (mmHg)	76.5 ± 6.8	75.1 ± 6.3	0.287
MAP (mmHg)	91.9 ± 7.1	90.4 ± 7.6	0.418
RR (breaths/min)	16.4 ± 1.2	16.1 ± 1.4	0.279
SpO_2 (%)	97.6 ± 1.1	97.4 ± 1.3	0.522

Analgesic Efficacy

Pain scores assessed using the Visual Analog Scale (VAS) were significantly lower in Group B (20 mcg/hr) at all measured postoperative intervals. The mean VAS over 72 hours was 4.2 ± 1.1 in Group A and 2.9 ± 1.0 in Group B ($p < 0.001$). The requirement for rescue analgesia was significantly lower in Group B, with only 7 patients (23.3%) needing tramadol versus 18 patients (60%) in Group A ($p = 0.003$). Ramsay Sedation Scores were higher in Group B but remained within safe clinical limits (Table 3).

Table 3. Analgesia, Sedation, and Rescue Medication

Parameter	Group A (10 mcg/hr)	Group B (20 mcg/hr)	p-value
Mean VAS Score (0–10)	4.2 ± 1.1	2.9 ± 1.0	<0.001 *
Ramsay Sedation Score	2.3 ± 0.5	2.8 ± 0.6	0.020 *
Rescue Analgesic Required (n)	18 (60%)	7 (23.3%)	0.003 *
Time to first rescue (hours)	4.5 ± 1.2	7.6 ± 2.1	0.002 *
Total rescue tramadol dose (mg)	87.5 ± 15.2	42.3 ± 9.8	<0.001 *

*Significant at $p < 0.05$.

Adverse Effects And Patient Satisfaction

Adverse events were mild and infrequent. Nausea and vomiting occurred in both groups but did not differ significantly ($p > 0.05$). No patient experienced respiratory depression or pruritus. Local skin irritation was noted in two patients in Group B. Patient satisfaction scores were significantly higher in Group B, with 83% of patients rating their experience as "very satisfied" compared to 60% in Group A ($p = 0.028$).

DISCUSSION

This study supports the efficacy and tolerability of transdermal buprenorphine in managing postoperative pain following abdominal surgeries. The findings reveal that both 10 mcg/hr and 20 mcg/hr dosages of buprenorphine provided effective analgesia with minimal adverse effects. However, the higher-dose group (20 mcg/hr) demonstrated significantly superior outcomes in terms of pain control, sedation adequacy, and reduced reliance on rescue analgesia.

Our findings are in agreement with previous research by Machado et al., who reported effective analgesia and reduced postoperative opioid consumption with transdermal buprenorphine without increasing adverse effects.11 Additionally, the observed stable hemodynamic profile reaffirms buprenorphine's safety, aligning with pharmacodynamic evidence suggesting minimal cardiovascular disturbance compared to full μ-agonists like morphine or fentanyl.13,14

The use of transdermal buprenorphine has practical perioperative advantages. Application prior to surgery allows for a sustained analgesic effect postoperatively, obviating the need for intravenous access or frequent dosing adjustments. Its consistent plasma concentration avoids peaks and troughs that can precipitate side effects like sedation or hypoventilation. 15 Moreover, the transdermal route enhances compliance and is particularly advantageous in settings where oral or intravenous access is limited or contraindicated.

Concerns about delayed onset are mitigated by applying the patch preemptively, 6–12 hours before surgery, allowing therapeutic levels to be reached intraoperatively. Importantly, no significant respiratory depression or major adverse events were noted, consistent with the known ceiling effect of buprenorphine on respiratory suppression.9,12 While this study provides compelling evidence for the use of transdermal buprenorphine, limitations include the relatively small sample size and short duration of follow-up. Future multicenter trials with extended monitoring would be beneficial to confirm these findings and further explore the utility of this modality across various surgical populations.

CONCLUSION

Transdermal buprenorphine, especially the 20 mcg/hr patch, is a safe and effective modality for postoperative pain control in abdominal surgeries. It provides good analgesia with minimal side effects, stable hemodynamics, and high patient satisfaction. It should be considered a viable component of multimodal postoperative analgesia strategies.

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