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Comparative Evaluation of Transdermal Buprenorphine and Fentanyl Patches on Perioperative Physiological Parameters in Patients Undergoing Laparoscopic Cholecystectomy

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ABSTRACT

Background: Postoperative pain management is an essential part of the recovery process after undergoing laparoscopic cholecystectomy (LC). Use of transdermal opioids like buprenorphine and fentanyl for continuous pain relief provides the patient with a medication that has a good safety and efficacy profile relative to other forms of analgesia.

Objective: Compare the analgesic efficacy, hemodynamic stability, and side effects of transdermal buprenorphine (10 mcg/hr) versus transdermal fentanyl (25 mcg/hr) in patients undergoing LC.

Methods: A double-blinded, prospective, randomized trial was conducted with a total of 160 patients aged 18-65 years with American Society of Anesthesiologists' (ASA) Classification I and II. The duration of the study was twelve months from 01/04/23 to 31/03/24, with a three-month preparatory phase, five-month data collection phase, three-month data analysis phase, and one month for preparation of the report. The patients were divided into two groups of 80 each: Group B received transdermal buprenorphine (10 mcg/hr), and Group F received transdermal fentanyl (25 mcg/hr), 12 hours before surgery. Demographics before surgery, intraoperative heart rate (HR), mean arterial pressure (MAP), and oxygen saturation (SpO2), postoperative visual analogue scale (VAS) for pain, need for rescue analgesia, and adverse events were recorded. Statistical significance was considered significant if $p < 0.05$.

Results: The baseline demographic characteristics, including age, sex, body mass index, and ASA physical status, were comparable between the groups ($p>0.05$). During the intraoperative period, patients in Group F demonstrated significantly higher HR and MAP than Group B at 1, 10, 30, and 60 minutes after induction of anesthesia (all $p<0.05$). Oxygen saturation remained comparable throughout, with a statistically significant but clinically insignificant difference observed only at 30 minutes after induction (99.43±0.74% in Group B vs. 99.08±0.92% in Group F; $p=0.0091$). Postoperative pain intensity, assessed using VAS, did not differ significantly between the groups at any assessment during the first 24 hours (all $p>0.05$). Rescue analgesia was required by significantly fewer patients in Group B than in Group F (7.5% vs. 18.8%; $p=0.0351$), although the mean total rescue analgesic dose among those requiring additional analgesia was comparable between the groups ($p=0.1673$). Postoperative nausea and vomiting occurred significantly more frequently in Group F (71.3% and 85.0%, respectively) than in Group B (8.8% and 23.8%, respectively; $p<0.0001$). Conversely, drowsiness was significantly more common in Group B (82.5% vs. 30.0%; $p<0.0001$). No episodes of respiratory depression were observed in either group, and the incidence of pruritus was low and did not differ significantly between the groups ($p=0.0803$).

Conclusion: Transdermal buprenorphine and fentanyl provide good pain relief after laparoscopic surgery using either of these medications. Patients who received buprenorphine had better hemodynamic stability, with the incidence of nausea and

vomiting being less than that of patients treated with fentanyl, and those who took buprenorphine required fewer rescue medications. There were higher HR and MAP in the fentanyl group, and they had more gastrointestinal side effects than the buprenorphine group. Therefore, patients may benefit from using transdermal buprenorphine due to its improved tolerability and prolonged effect.

Keywords*: adverse effects, hemodynamic stability, laparoscopic cholecystectomy, post operative analgesia, transdermal buprenorphine, transdermal fentanyl.*

INTRODUCTION

Laparoscopic cholecystectomy (LC) is one of the most popular minimally invasive surgical techniques. It allows for earlier hospital discharge and a speedier recovery than open cholecystectomy. It is associated with moderate to severe discomfort and hemodynamic instability during surgery, which is mostly caused by alterations caused by pneumoperitoneum [1-4]. Postoperative pain is one of the most common concerns for patients after major surgery. Satisfactory perioperative analgesia improves surgical outcomes by lowering morbidity and organ dysfunction. This aids in faster healing and discharge from the hospital, lowering costs and increasing patient satisfaction [5,6]. Effective postoperative pain control poses a significant problem for both treating surgeons and anesthesiologists. A variety of therapy options for postoperative pain have been proposed, including intravenous injection, epidural infusion, patient-controlled analgesia, peripheral nerve block, and continuous intra-articular infusion. All of the treatments listed above are aggressive and invasive, with the possibility of causing bleeding, infection, and nerve damage [7-9].

Parenteral administration of opioids and nonsteroidal anti-inflammatory medications necessitates experienced personnel and vigilance. Transdermal patches can counteract the side effects of oral and parenteral opioids. They are becoming increasingly popular for pain therapy because of their non-invasive drug delivery, improved absorption, extended duration of action, lack of first-pass metabolism, and low side effects [10,11]. The approach of using transdermal delivery systems was used in this study, considering its simplicity, non-invasiveness, cost-effectiveness, and longer duration of action. Fentanyl and buprenorphine were chosen for intra- and postoperative analgesia. Fentanyl is 75 to 125 times more potent than morphine as an analgesic and can lessen the severity of postoperative pain [12,13]. Buprenorphine, a semi-synthetic agonist-antagonist opioid, has been demonstrated to have a favourable analgesic effect and lessen the requirement for additional analgesics for pain following surgery [10,14,15].

This research aimed at examining the efficacy of transdermal buprenorphine and fentanyl patches in providing perioperative analgesia in LC. The objectives were to examine and compare the efficacy of transdermal buprenorphine and fentanyl patches in LC in providing analgesia over 24 hours as determined by visual analogue scale (VAS), and to compare the hemodynamic effects [heart rate (HR), mean arterial pressure (MAP) and oxygen saturation (SpO2)], and to document any side effects associated with the study drugs.

MATERIALS AND METHODS

The Department of Anesthesiology at IQ City Medical College and Hospital undertook this double blinded, prospective, randomized trial following approval from the Institutional Ethics Committee (IQMS/IEC-10/LTR/10(08)/22) and Clinical Trials Registry - India (CTRI/2023/07/055819). The total duration of the study was twelve months from 01/04/23 to 31/03/24, with a three-month preparatory phase, followed by five months for data collection, three months for data analysis, and one month for preparation of the report.

The study included adult patients, 18-65 years old, of either sex, classified by the American Society of Anaesthesiologists (ASA) as ASA I or II, who were scheduled for an elective LC under general anesthesia, expected to take up to sixty minutes [16]. Any patient with a body mass index (BMI) greater than 30 kg/m², ASA III or IV, immunocompromised, had an infection in the area of the surgery, had a history of substance abuse/addiction, chronic pain, had a known allergy to opioids or transdermal patches, or refused to provide consent, was excluded from the study.

Based on the study by Arshad et al., which examined the differences between transdermal buprenorphine and transdermal fentanyl for postoperative analgesia and measured different hemodynamic parameters, sample size calculations were made using an α error rate of 0.05, a power of 80% (calculated using $Z\alpha = 1.96$ and $Z1 - \beta = 0.84$), and the effect size as the means of systolic blood pressure [17]. The minimum number of patients required per group would be 69. After adding 10% for attrition, the final number of patients was determined to be 80 per group. Patients were sampled consecutively and randomly assigned to one of two groups using a lottery method of assignment with sealed envelopes marked B or F. Participants assigned to Group B (n = 80) were given a transdermal buprenorphine patch (10 mcg/hr). Those assigned to Group F (n = 80) were given a transdermal fentanyl patch (25 mcg/hr).

The preoperative assessment took place the day before surgery. Blood counts, electrolytes, 12-lead electrocardiogram, and echocardiogram were performed before surgery as per our institution's guidelines. All subjects received education about this study and how the patch will be applied, along with a briefing about pain assessment using VAS [18]. Informed consent was provided by all subjects prior to receiving a patch. An anesthesiologist placed a patch 12 hours prior to the surgery on dry, non-hair-bearing skin on the anterior chest wall, after cleaning with an alcohol swab. The anesthesiologist and the

patient were blinded to the intervention. Subjects were instructed to fast overnight before surgery and were premedicated with oral alprazolam 0.25 mg the night before surgery and ranitidine 150 mg orally the morning of surgery.

In the operating room, baseline hemodynamic parameters were taken with a multiparameter monitor. An 18-gauge IV cannula was placed for access to an IV line. All subjects were preloaded with Ringer's lactate solution at a rate of 5-6 ml/kg. All subjects received glycopyrrolate 0.2 mg IV and midazolam 0.1 mg/kg IV prior to being induced. Induction of anesthesia was accomplished with propofol 2 mg/kg IV, lignocaine 1.5 mg/kg IV, and vecuronium 0.1 mg/kg IV to facilitate intubation. Anesthesia was maintained with 50% oxygen, 50% room air, and isoflurane 1%-1.5% with the ventilator settings adjusted to maintain end-tidal carbon dioxide between 35 mmHg and 40 mmHg. Prior to insufflation of carbon dioxide, paracetamol 20 mg/kg IV was given.

HR, MAP, and SpO2 were continuously measured and recorded for all patients at 1, 10, 30, and 60-minute intervals during the procedure. Intraoperative rescue analgesia (IV tramadol 50 mg) was given to patients exhibiting hemodynamic instability, specifically defined as increased HR greater than 20% above baseline HR and/or increased MAP (greater than 20% baseline MAP), demonstrated by three consecutive readings (with hypoxia, hypercarbia, and inadequate depth of anesthesia excluded). Exclusion from the study was applied to all patients receiving rescue analgesia during surgery. Residual neuromuscular blockade was reversed at the end of surgery with neostigmine (0.05 mg/kg IV) and glycopyrrolate (0.01 mg/kg IV) to provide adequate recovery before extubation and transferring patients to the post-anesthesia care unit (PACU).

The following parameters by were recorded by the same anesthesiologist at various intervals following surgery - VAS score at T0 (arrival to PACU), T1 (1 hour), T2 (2 hour), T4 (4 hour), T8 (8 hour), T12 (12 hour), T16 (16 hour) and T24 (24 hour) postoperatively, the time to first rescue analgesic and total amount of tramadol consumed was recorded. Adverse events were recorded, including nausea, vomiting, respiratory depression, drowsiness, and pruritus. IV Tramadol (50 mg) was administered when the VAS score was ≥ 3.

Data were analyzed using Microsoft Excel and SPSS v. 27.0 (SPSS Inc, Chicago, IL, USA). Quantitative variables are expressed as Mean ± Standard deviation (SD). Independent t-tests were used to compare continuous variables between independent groups following verification of normality. Categorical variables were analyzed using the Pearson Chi-Square or Fischer's exact test as deemed appropriate. A p-value of less than 0.05 was considered statistically significant. CONSORT flow diagram of the study is seen in Figure *1*.

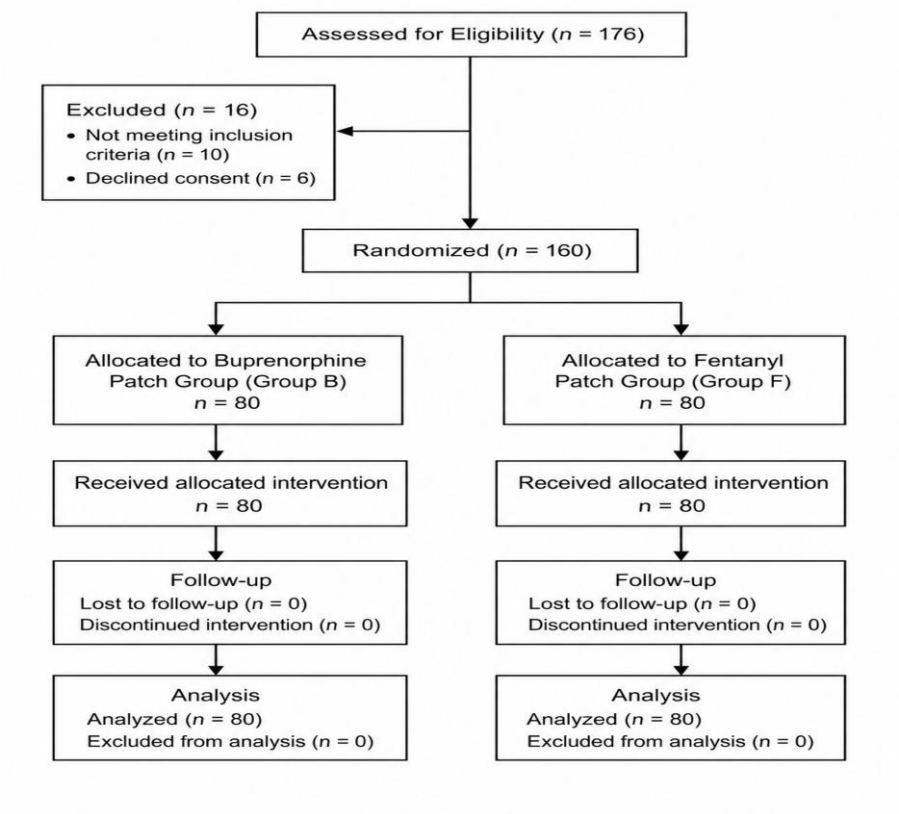

FIGURE 1: CONSORT flow diagram

RESULTS

The mean age of participants in Group B was 36.85 ± 12.23 years, while the mean age in Group F was 39.07 ± 12.71 years; these means were not statistically different (p=0.2610). The mean BMI of participants in Group B was 23.36 ± 3.10 kg/m² and the mean BMI of participants in Group F was 23.76 ± 3.18 kg/m²; these means were also not different statistically

(p=0.4221). The gender distribution was also fairly similar, with 52 patients (65.0%) being female and 28 patients (35.0%) being male in Group B, while Group F included 50 female patients (62.5%) and 30 male patients (37.5%). No statistical association was found between sex and group, as assessed with a χ^2 of 0.1082 (p=0.7422); odds ratio of 1.1143; 95% confidence interval of 0.58472.1237. ASA class had similar distributions across both groups; no significant differences between groups were found (assessed with a χ^2=0.0255; p=0.8731; odds ratio of 1.0523; 95% confidence interval of 0.56281.9675). In Group B, 42 patients (52.5%) belonged to ASA I and 38 patients (47.5%) belonged to ASA II, whereas in Group F, 40 patients (50.0%) each belonged to ASA I and ASA II categories. Demographic statistics are shown in Table *1*.

TABLE 1: Demographic parameters

Parameter	Group B	Group F	P-value
Age (years) (Mean	36.85 ± 12.23	39.07 ± 12.71	0.2610
BMI (kg/m²)	23.36 ± 3.10	23.76 ± 3.18	0.4221
Gender (Male/Female)	28 (35.0%) / 52 (65.0%)	30 (37.5%) / 50 (62.5%)	0.7422
ASA Physical Status (I/II)	42 (52.5%) / 38 (47.5%)	40 (50.0%) / 40 (50.0%)	0.8731

* - p<0.05 is statistically significant

Values are expressed as Mean ± SD or n(%).

In Table *2*, there is a comparison of HR in both Group B and Group F. Prior to surgery, HR values were similar between the two groups, with no statistically significant difference between the two groups (Group B: 80.95 ± 10.89 bpm and Group F: 83.84 ± 9.18 bpm; p=0.0717). At 1 minute after induction of anesthesia, there was a significant difference between Group B and Group F (84.70 ± 11.07 bpm in Group B versus 92.51 ± 8.36 bpm in Group F; p<0.0001). There was a significant difference between the two groups at 10 minutes (80.94 ± 9.51 bpm in Group B versus 87.53 ± 6.91 bpm in Group F; p<0.0001), 30 minutes (79.73 ± 8.47 bpm in Group B versus 83.04 ± 9.00 bpm in Group F; p=0.0177), and 60 minutes (79.96 ± 9.73 bpm in Group B versus 85.20 ± 8.42 bpm in Group F; p=0.0004) after induction of anesthesia; Group B had significantly lower HR than Group F.

TABLE 2: Comparison of HR

Time Point	Group	N	Mean HR (bpm)	SD	Minimum	Maximum	Median	p-value	t-value
Preoperative	Group B	80	80.95	10.89	58	100	80.5	0.0717	1.8131
	Group F	80	83.84	9.18	67	99	84.5		
Intraoperative (1 minute after induction)	Group B	80	84.70	11.07	61	112	84	<0.0001*	5.0365
	Group F	80	92.51	8.36	64	111	94		
Intraoperative (10 minutes after induction)	Group B	80	80.94	9.51	63	99	82	<0.0001*	5.0109
	Group F	80	87.53	6.91	70	101	88.5		
Intraoperative (30 minutes after induction)	Group B	80	79.73	8.47	58	96	80.5	0.0177*	2.3971
	Group F	80	83.04	9.00	65	101	84		
Intraoperative (60 minutes after induction)	Group B	80	79.96	9.73	55	99	80	0.0004*	3.6396
	Group F	80	85.20	8.42	65	100	85		

* - p<0.05 is statistically significant

No significant change was observed between the groups' MAP values for their preoperative measurements (p=0.3337). Analysis of MAP values measured during surgery further confirmed that Group B's MAP was significantly lower than that of Group F at each of the four measured time points. At 1 minute after induction, Group B had a MAP of 73.08 ± 5.84 mmHg compared to 75.04 ± 6.57 mmHg in Group F (p=0.0476). At 10 minutes, MAP values were 70.80 ± 5.70 mmHg in Group B and 73.03 ± 7.07 mmHg in Group F (p=0.0298). At 30 minutes, Group B demonstrated significantly lower MAP values (70.41 ± 6.50 mmHg) than Group F (76.54 ± 6.40 mmHg; p<0.0001). Similarly, at 60 minutes, MAP values were 68.69 ± 5.47 mmHg in Group B and 72.43 ± 6.62 mmHg in Group F (p<0.0001). The data show that Group B maintained a more stable hemodynamic balance during all surgical time periods, as shown in Table *3*.

TABLE 3: Comparison of MAP

Time Point	Group	N	Mean MAP (mmHg)	SD	Minimum	Maximum	Median	p-value	t-value
Preoperative	Group B	80	69.94	5.95	60	88	69.5	0.3337	0.9697
	Group F	80	70.94	7.05	59	87	70.0		
Intraoperative (1 minute after induction)	Group B	80	73.08	5.84	62	98	74.0	0.0476*	1.9962
	Group F	80	75.04	6.57	64	89	75.0		
Intraoperative (10 minutes after induction)	Group B	80	70.80	5.70	59	90	71.0	0.0298*	2.1922
	Group F	80	73.03	7.07	60	90	73.5		
Intraoperative (30 minutes after induction)	Group B	80	70.41	6.50	58	86	69.5	<0.0001*	6.0095
	Group F	80	76.54	6.40	64	89	76.5		
Intraoperative (60 minutes after induction)	Group B	80	68.69	5.47	60	85	69.0	<0.0001*	3.8925
	Group F	80	72.43	6.62	58	89	73.0		

* - p<0.05 is statistically significant

SpO_2 was compared preoperatively between both groups and found to be statistically similar (p=0.9318). During the intraoperative period, at one minute, SpO_2 in Group B was slightly higher than in Group F but did not achieve statistical significance (99.48 ± 0.73% versus 99.24 ± 0.80%; p=0.0513). At ten minutes, no statistically significant difference could be demonstrated between the groups (99.45 ± 0.61% in Group B versus 99.36 ± 0.64% in Group F; p=0.3794). A statistically significantly higher SpO_2 was measured in Group B as compared to Group F at thirty minutes (99.43 ± 0.74% versus 99.08 ± 0.92%; p=0.0091). At sixty minutes, no statistically significant difference was observed between the groups (99.28 ± 0.84% in Group B versus 99.25 ± 0.74% in Group F; p=0.8419), indicating that overall SpO_2 remained comparable for both study groups, with the exception of a transient significant difference at thirty minutes after induction, as shown in Table *4*.

TABLE 4: Comparison of SpO2

Time Point	Group	N	Mean SpO_2 (%)	SD	Minimum	Maximum	Median	p-value	t-value
Preoperative	Group B	80	98.87	0.97	97	100	99	0.9318	0.0858
	Group F	80	98.86	0.89	97	100	99		

Intraoperative (1 minute after induction)	Group B	80	99.48	0.73	97	100	100	0.0513	1.9638
	Group F	80	99.24	0.80	97	100	99		
Intraoperative (10 minutes after induction)	Group B	80	99.45	0.61	98	100	100	0.3794	0.8814
	Group F	80	99.36	0.64	98	100	99		
Intraoperative (30 minutes after induction)	Group B	80	99.43	0.74	97	100	100	0.0091*	2.6398
	Group F	80	99.08	0.92	97	100	99		
Intraoperative (60 minutes after induction)	Group B	80	99.28	0.84	97	100	99	0.8419	0.1998
	Group F	80	99.25	0.74	98	100	99		

* - $p<0.05$ is statistically significant

The postoperative VAS scores from both groups had no statistically significant differences at any given time over the 24-hour postoperative period. The average VAS score for Group B was 2.44 ± 0.82 at T0 and 2.58 ± 0.98 for Group F (p=0.3378). The VAS scores at T1, T2, T4, T8, T12, T16, and T24 were also not statistically significantly different between the groups (p>0.05). At T1, the mean VAS score was 2.24 ± 1.01 in Group B and 2.41 ± 0.92 in Group F (p=0.2543). At T2, values were 2.35 ± 0.70 and 2.41 ± 0.74, respectively (p=0.5830). At T4, Group B and Group F had mean VAS scores of 2.30 ± 0.85 and 2.36 ± 0.83, respectively (p=0.6383). At T8, scores were 2.14 ± 0.79 in Group B and 2.29 ± 0.75 in Group F (p=0.2202). At T12, values were 2.21 ± 0.76 and 2.31 ± 0.94, respectively (p=0.4588). At T16, Group B and Group F had mean VAS scores of 2.21 ± 0.79 and 2.24 ± 0.78, respectively (p=0.8410). At T24, the scores were 2.16 ± 0.97 in Group B and 2.28 ± 1.06 in Group F (p=0.4844). The results of both groups are depicted in Table 5, with pain scores remaining similar across the 24-hour postoperative interval.

TABLE 5: Comparison of VAS

Time Point	Group	N	Mean VAS	SD	Minimum	Maximum	Median	p-value	t-value
T0	Group B	80	2.44	0.82	1	6	3	0.3378	0.9615
	Group F	80	2.58	0.98	1	7	3		
T1	Group B	80	2.24	1.01	1	8	2	0.2543	1.1441
	Group F	80	2.41	0.92	1	6	2		
T2	Group B	80	2.35	0.70	1	3	2	0.5830	0.5501
	Group F	80	2.41	0.74	1	5	2.5		
T4	Group B	80	2.30	0.85	1	5	2	0.6383	0.4710
	Group F	80	2.36	0.83	1	5	2.5		
T8	Group B	80	2.14	0.79	1	3	2	0.2202	1.2308
	Group F	80	2.29	0.75	1	3	2		
T12	Group B	80	2.21	0.76	1	3	2	0.4588	0.7427
	Group F	80	2.31	0.94	1	5	2		
T16	Group B	80	2.21	0.79	1	3	2	0.8410	0.2009
	Group F	80	2.24	0.78	1	4	2		
	Group B	80	2.16	0.97	1	4	2		

T24	Group F	80	2.28	1.06	1	5	2	0.4844	0.7009

* - p<0.05 is statistically significant

The comparison of requirement and total dose of rescue analgesia between the two groups is shown in Table 6. Rescue analgesia was required in 6 patients (7.5%) in Group B compared to 15 patients (18.8%) in Group F, whereas 74 patients (92.5%) in Group B and 65 patients (81.3%) in Group F did not require rescue analgesia. This difference was statistically significant (p=0.0351). There was no statistically significant difference in the mean total dose of rescue analgesic required, with Group B requiring a mean total dose of 58.33 ± 20.41 mg and Group F requiring 60.00 ± 20.70 mg (p=0.1673).

TABLE 6: Association Between Requirement and Total Dose of Rescue Analgesic Between Groups

Parameter	Group	N	No. of Patients	Mean Total Dose (mg)	SD	p-value
Rescue Analgesic Required	Group B	80	6 (7.5%)	58.33	20.41	0.0351*
	Group F	80	15 (18.8%)	60.00	20.70	
Rescue Analgesic Not Required	Group B	80	74 (92.5%)	—	—	-
	Group F	80	65 (81.3%)	—	—	

* - p<0.05 is statistically significant Values are expressed as n(%).

Table 7 compares adverse effect outcomes across both groups. Nausea was the most frequently reported adverse effect in Group F, occurring in 57 patients (71.3%) compared to 7 patients (8.8%) in Group B, with an extremely statistically significant difference (p<0.0001). Similarly, vomiting occurred in 68 patients (85.0%) in Group F compared to 19 patients (23.8%) in Group B (p<0.0001). Drowsiness was more commonly experienced by patients in Group B, affecting 66 patients (82.5%) compared to 24 patients (30.0%) in Group F, which was also statistically significant (p<0.0001). No episodes of respiratory depression were observed in either group. Pruritus was observed in 3 patients (3.8%) in Group F, whereas no patients in Group B experienced pruritus; however, this difference was not statistically significant (p=0.0803).

TABLE 7: Adverse Effects

Adverse Effect	Response	Group B	Group F	Total	p-value
Nausea	No	73 (91.3%)	23 (28.8%)	96 (60.0%)	<0.0001*
	Yes	7 (8.8%)	57 (71.3%)	64 (40.0%)	
Vomiting	No	61 (76.3%)	12 (15.0%)	73 (45.6%)	<0.0001*
	Yes	19 (23.8%)	68 (85.0%)	87 (54.4%)	
Drowsiness	No	14 (17.5%)	56 (70.0%)	70 (43.8%)	<0.0001*
	Yes	66 (82.5%)	24 (30.0%)	90 (56.3%)	
Respiratory Depression	No	80 (100.0%)	80 (100.0%)	160 (100.0%)	—
	Yes	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Pruritus	No	80 (100.0%)	77 (96.3%)	157 (98.1%)	0.0803
	Yes	0 (0.0%)	3 (3.8%)	3 (1.9%)	

* - p<0.05 is statistically significant Values are expressed as n(%).

DISCUSSION

This study consisted a total of 160 patients between 18 and 65 years of age who underwent LC. The two groups were compared based on baseline demographics (age, sex, ASA grade, and BMI), and these variables did not differ significantly

between the two groups (p=0.2610, p=0.7422, p=0.8731, and p=0.4221, respectively), indicating that both groups were homogeneous as far as demographic variables are concerned. Arshad et al. report similar patient demographic distributions when they used transdermal opioids as part of their postoperative management for surgery, where patients were older than those in our study [17].

When measuring intraoperative hemodynamics, there was an increased HR and MAP for patients in the fentanyl group compared to the buprenorphine group. These were statistically different at almost all time points, indicating that buprenorphine provided greater hemodynamic stability than fentanyl. SpO2 values were similar between the two groups at all time points except there was a statistically significant transient difference at the 30-minute mark (p=0.0091), which would have little clinical relevance. Kumar et al. also found that buprenorphine provided greater hemodynamic stability compared to fentanyl in patients receiving major abdominal surgeries [19]. Norozi et al. did not notice any difference in hemodynamic parameters between transdermal opioids, which may be due to differences in the amount of surgical stress and the patient characteristics [20].

All time points for postoperative VAS scores were comparable between groups (p>0.05), suggesting equal effectiveness of both medications. There was a significant difference between Group B and Group F, with more patients in Group F needing rescue medication (18.8% vs 7.5%, p=0.0351). The total amount of rescue medication between groups did not differ significantly. This is also consistent with the data reported by Arshad et al., as both medications produced similar effectiveness, but supplemental analgesic use was lower in patients receiving buprenorphine [17]. Khandelwal et al. had similar findings regarding reductions in supplemental analgesic use when patients received buprenorphine patches as well [21].

The groups experienced different adverse effects. Nausea and vomiting occurred more often with fentanyl (p<0.0001), while drowsiness occurred more often with buprenorphine (p<0.0001). These findings conform to Arshad et al. and the majority of studies comparing opioids that report more gastrointestinal side effects with fentanyl and more sedation with buprenorphine [17]. Neither group had any noted respiratory depression, indicating that both transdermal systems are safe for use. Pruritus was very rare in both groups, not statistically significant, and by itself demonstrates the same outcome for opioid-related dermatological effects noted by Setti et al., who reported very few dermatological adverse effects related to transdermal opioid formulations [22].

The study demonstrates that both fentanyl and buprenorphine can provide adequate postoperative analgesia. Buprenorphine provides superior hemodynamic stability and requires less rescue analgesic use than fentanyl, while fentanyl produces more gastrointestinal side effects. These data extend previously published work and further support the use of buprenorphine when providing an alternative transdermal analgesic option for laparoscopic surgery.

There were several limitations to the study. First, the small sample size reduces the ability to evaluate less common results. Second, all the patients included were only those who underwent LC; therefore, the findings may not be generalized to all surgical patients. Third, there were no objective measures of analgesic use or the use of a measure of plasma drug level. Fourth, the 24-hour follow-up period eliminated the ability to evaluate the longer-term effects of the transdermal drugs and their pharmacokinetics.

CONCLUSIONS

The comparison between transdermal buprenorphine and fentanyl patches in patients undergoing LC reveals nuanced differences in perioperative physiological parameters. Both analgesic methods provide effective pain management, but their impacts on hemodynamic parameters can vary. Buprenorphine patches, though initially used for chronic pain, have been used recently for acute postoperative pain. When applied 12-24 hours prior to the procedure, they offer more stable hemodynamic profiles, contributing to a potentially smoother perioperative course. Fentanyl patches, while equally effective in pain control, might be associated with more pronounced changes in physiological parameters and adverse effects such as nausea and vomiting due to their potent opioid effects. Ultimately, the choice between buprenorphine and fentanyl patches should be considered with respect to individual patient profiles, potential side effects, and specific perioperative goals to optimize patient outcomes.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

Concept and design: Dipshikha Paul, Sumedha Mukherjee, Susmita Dutta

Disclosures

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