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COMPARISON BETWEEN TRANSDERMAL BUPRENORPHINE VERSUS INTRAVENOUS DICLOFENAC FOR POST OPERATIVE ANALGESIA IN LAPAROSCOPIC CHOLECYSTECTOMY SURGERY

Anaesthesiology

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC) is the gold standard for treating symptomatic gallstone disease due to its minimally invasive approach, faster recovery, and reduced hospital stay. However, effective postoperative pain management remains a challenge. **Aim:** This study compares the analgesic efficacy and safety of transdermal buprenorphine versus intravenous diclofenac in patients undergoing LC. **Methods:** A randomized controlled trial was conducted at the Department of Anaesthesiology, Pacific Institute of Medical Sciences, Udaipur, from June 2023 to November 2024. Sixty patients, aged 18–65 years (ASA Grade I or II), scheduled for elective LC, were randomly allocated into two groups (n=30 each). Group A received a transdermal buprenorphine patch (20 µg/hour) 12 hours before surgery, while Group B received IV diclofenac sodium (75 mg) post-extubation and every 8 hours for 48 hours. Postoperative pain was assessed using the Visual Analogue Scale (VAS). Secondary outcomes included Ramsay Sedation Score (RSS), rescue analgesia requirements, and cardiorespiratory parameters. **Results:** Group A demonstrated significantly lower VAS scores in the later postoperative hours, deeper sedation (higher RSS at all intervals), and reduced rescue analgesia need (mean doses: 0.6 ± 0.67 vs. 2 ± 0.83; $P < 0.001$). Heart rate and MAP showed transient variations but remained within stable ranges. SpO_2 and respiratory rates were comparable across both groups with no significant differences. **Conclusion:** Transdermal buprenorphine provided superior postoperative analgesia with sustained sedation and less need for additional analgesics, without compromising cardiorespiratory stability. It represents a safe and effective alternative to intravenous diclofenac for pain management following LC.

KEYWORDS

Laparoscopic cholecystectomy, postoperative analgesia, transdermal buprenorphine, intravenous diclofenac, Visual Analogue Scale, Ramsay Sedation Score, pain management.

INTRODUCTION

Laparoscopic cholecystectomy (LC), introduced by Dr. Erich Mühe in 1985, is the gold standard for managing symptomatic gallstone disease due to its minimally invasive nature, faster recovery, reduced postoperative pain, and shorter hospital stays compared to open surgery. Although LC has numerous benefits, postoperative pain remains a significant concern.[1] Pain originates from port-site incisions, visceral manipulation, and diaphragmatic irritation due to pneumoperitoneum or bile/blood spillage. Despite technological advances, managing postoperative pain effectively remains a challenge. Optimal pain control is essential to enhance patient satisfaction, promote early ambulation, and reduce complications.[2]

Conventional analgesics like NSAIDs and opioids are commonly used but are associated with adverse effects such as GI irritation, renal impairment, and respiratory depression. This has driven interest in alternative approaches like transdermal drug delivery systems, which offer sustained analgesia with minimal systemic side effects. Buprenorphine, a semi-synthetic opioid with high µ-opioid receptor affinity and κ-receptor antagonism, has emerged as a promising option.[3] It provides potent analgesia—75–100 times stronger than morphine—while reducing respiratory depression and dependency risks. It is primarily metabolized in the liver, making it safer for patients with renal dysfunction. The transdermal formulation releases buprenorphine at 20 µg/hour, achieving effective plasma levels in 12–24 hours and providing analgesia for up to seven days.[4]

Although buprenorphine is well-established for chronic and cancer pain, its role in acute postoperative pain, especially in short-stay surgeries like LC, is underexplored. Meanwhile, diclofenac, a widely used NSAID, offers anti-inflammatory and analgesic effects by inhibiting COX enzymes. Intravenous diclofenac provides rapid pain relief but may cause GI issues, renal dysfunction, and cardiovascular risks. Its transdermal form offers localized pain relief with fewer systemic effects.[5]

Both agents have unique advantages: buprenorphine offers prolonged, potent analgesia with minimal side effects and low abuse potential,while diclofenac is effective but limited by systemic risks and administration requirements. Given the lack of comparative evidence, this study aims to evaluate the analgesic efficacy and safety of transdermal buprenorphine versus intravenous diclofenac following LC.[6]

MATERIALS AND METHODS

Study Setting: The study was conducted in the Department of Anaesthesiology at Pacific Institute of Medical Sciences, Umarda, Udaipur. It was a comparative randomized controlled study carried out over 18 months, from June 2023 to November 2024. A total of 60 patients were enrolled and randomly divided into two groups of 30. The sample size was calculated with α error 0.25, 90% power, mean difference 0.5, and SD 0.8.

Randomization: Patients were randomly assigned using a computer-generated random number list. Group A received a transdermal buprenorphine patch (20 mcg/hour), and Group B received intravenous diclofenac sodium 75 mg.

Drugs And Equipment Used: The study utilized IV diclofenac sodium (75 mg) and transdermal buprenorphine patches (20 mcg/hour).

Inclusion Criteria: Patients aged 18–65 years of either sex, ASA Grade I or II, scheduled for elective laparoscopic cholecystectomy.

Exclusion Criteria: Excluded were pregnant/breastfeeding women, patients with drug hypersensitivity or severe systemic disorders.

Methodology: All patients underwent a pre-anesthetic evaluation, were given premedication, and consented after being educated about the study. Group A received the patch 12 hours before surgery, while Group B was administered IV diclofenac after extubation and every 8 hours for 48 hours. Standard anesthetic protocols and intraoperative monitoring were followed. Pain, sedation, rescue analgesia, and adverse events were recorded postoperatively at specific intervals.

Outcomes: The primary outcome was postoperative pain assessed using the VAS scale. Secondary outcomes included sedation levels (RSS), episodes of rescue analgesia, nausea/vomiting, and other adverse events within 48 hours post-surgery.

RESULT AND OBSERVATION

Table No- 1 Distribution Of Patients According To VAS Score.

Visual Analogue Score	Group A		Group B		P-value
	Mean	SD	Mean	SD	
0 Hr	5.03	0.8	5.16	0.46	0.44
4 Hr	4.66	1.12	5.1	0.66	0.06
8 Hr	4.43	0.89	7.86	0.68	<0.0001
12 Hr	4.06	0.98	5.2	0.66	<0.0001
24 Hr	3	1.17	5.8	0.71	<0.0001
36 Hr	2.23	0.81	3.66	0.92	<0.0001
48 Hr	0.46	0.5	2.43	0.5	<0.0001

The age of 18 holds major medico-legal importance in India, marking eligibility for marriage, voting, driving, and legal responsibility. After 16 years, dental and secondary sexual characteristics are less reliable, making radiological methods essential for age estimation. A 1964 Government of India committee recommended zone-wise studies to account for regional variation. However, Rajasthan still lacks sufficient data for individuals aged 16–21 years, highlighting the need for region-specific studies to support accurate age determination in legal and forensic settings.

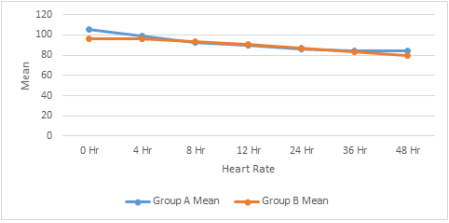

Figure No- 1 Distribution Of Patients According To Heart Rate.

The table compares mean heart rates between Group A and Group B at multiple postoperative intervals. Group A had a significantly higher heart rate at 0 hours ($P < 0.0001$) and a slight but significant difference at 4 hours ($P = 0.02$). From 8 to 36 hours, no significant differences were observed ($P > 0.05$). At 48 hours, Group A again showed a significantly higher heart rate ($P < 0.0001$).

Table No- 2 Distribution of Patients According To Ramsay Sedation Score.

Ramsay Sedation Score	Group A		Group B		P- value
	Mean	SD	Mean	SD	
0 Hr	3.1	0.3	2	0	<0.001
4 Hr	2.13	0.34	2	0	0.04
8 Hr	2	0	1.6	0.49	0.0001
12 Hr	2	0	1.4	0.49	0.0001
24 Hr	1.73	0.44	1.83	0.37	0.34
36 Hr	1.5	0.5	1	0	<0.001
48 Hr	1.46	0.5	1.16	0.37	0.01

The Ramsay Sedation Score (RSS) comparison showed that Group A had significantly higher sedation levels than Group B at all measured intervals. At 0 hours, Group A's RSS was 3.1 vs. 2 in Group B ($P<0.001$). This trend continued, with significant differences at 4, 8, 12, 36, and 48 hours (P values ranging from <0.0001 to 0.01). Group A showed a gradual decline in sedation, while Group B returned to baseline levels faster, indicating prolonged sedation in Group A.

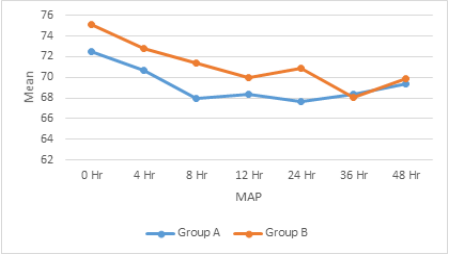

Figure No- 2 Distribution of Patients According To MAP.

This table presents the mean MAP values (in mmHg) of patients in Group A and Group B at various postoperative time points. Group B consistently showed higher MAP readings compared to Group A from 0 to 24 hours, with statistically significant differences observed at all these intervals ($P \leq 0.02$). At 36 and 48 hours, the MAP values between the groups were comparable, with no statistically significant difference ($P = 0.4$ and 0.12, respectively). These findings suggest a more pronounced reduction in MAP in Group A during the early postoperative period.

Table No- 3 Distribution Of Patients According To Rescue Analgesia.

Rescue Analgesia	Group A		Group B	
	No. of Patients	Percentage	No. of Patients	Percentage
Zero	15	50.00	0	0.00
One	12	40.00	10	33.33
Two	3	10.00	10	33.33
Three	0	0.00	10	33.33
Total	30	100.00	30	100.00
Mean ± SD	0.6± 0.67		2 ± 0.83	
P-value	<0.001			

This table shows the number and percentage of patients in each group based on the frequency of rescue analgesia required postoperatively. In Group A, 50% of patients did not require any rescue analgesia, while none in Group B were analgesia-free. A greater proportion of patients in Group B required multiple doses, with 33.33% needing up to three doses compared to none in Group A. The mean number of rescue analgesia doses was significantly lower in Group A (0.6 ± 0.67) compared to Group B (2 ± 0.83), and the difference was statistically significant ($P < 0.001$).

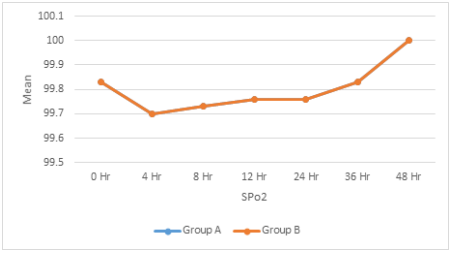

Figure No- 3 Distribution of Patients According to Spo2.

The postoperative monitoring of SpO_2 levels and respiratory rates over 48 hours revealed consistent and stable values in both Group A and Group B. Oxygen saturation remained high in both groups, while respiratory rates showed a gradual decline over time. No statistically significant differences were observed between the groups at any time point, with all P-values equal to 1. These findings indicate comparable oxygenation and respiratory patterns, reflecting similar postoperative respiratory stability in both groups throughout the observation period.

DISCUSSION

Postoperative pain management is crucial for recovery after laparoscopic cholecystectomy. Transdermal buprenorphine, an opioid, offers steady, long-lasting analgesia with fewer dosing needs but requires preoperative application and may cause sedation. Intravenous diclofenac, an NSAID, provides rapid pain relief, particularly effective in the immediate postoperative period. This study compares the efficacy of transdermal buprenorphine and intravenous diclofenac for postoperative analgesia in laparoscopic cholecystectomy.[7]

VAS score comparison showed similar baseline pain levels in both groups, but Group A demonstrated significantly greater pain reduction from 8 hours onward ($P < 0.0001$), with a notably lower mean score at 48 hours (0.46 vs. 2.43), indicating superior analgesic efficacy**. Kumar S** et **al**[8] reported significantly higher postoperative pain in Group A than in Groups B and C ($p < 0.001$), with mean VAS scores of 4.93 ± 0.98, 1.73 ± 0.64, and 1.40 ± 0.50, respectively. **Shrestha B et al**[9] noted a steady decline in pain from 12 to 48 hours. **Talnia S et al** [10] found better outcomes in the patch group, with fewer severe pain cases on Day 1 and more pain-free patients by Day 2, showing significant pain reduction over time ($p < 0.001$).

This study outlines the average heart rate measurements at various postoperative intervals for Group A and Group B. At 0 hour, Group A showed a significantly higher heart rate than Group B ($P < 0.0001$), with a mild but significant difference at 4 hours ($P = 0.02$). From 8 to 36 hours, no significant differences were noted ($P > 0.05$), but at 48 hours, Group A again exhibited a significantly elevated heart rate ($P < 0.0001$). **Kumar S et al**[8] found that Group A consistently had higher heart rates than others, with significant differences at intubation, 15, 20, 40, and 60 minutes post-intubation, and extubation. **Angom C**

L et al[11] observed both groups began near 85 bpm; Group B peaked at ~95 bpm in the first hour, while Group A remained stable, converging around 75 bpm by 48 hours. **Singh H et al**[12] reported higher heart rates in Group I (96.03 ± 14.81 at 4h, 112.77 ± 9.21 at 6h), significantly more than Groups II and III ($P < 0.001$).

The comparison of Ramsay Sedation Scores (RSS) between Groups A and B revealed significantly deeper sedation in Group A, especially in the early postoperative period. At 0 hours, Group A had a mean RSS of 3.1 versus 2.0 in Group B ($P < 0.001$), with this trend persisting at 4, 8, and 12 hours ($P \leq 0.04$). Although sedation gradually decreased in both groups, Group A consistently showed higher scores even at 36 and 48 hours ($P < 0.001$ and $P = 0.01$, respectively). **Arshad Z et al**[13] observed consistently higher sedation in Group A over three days, with mean RSS scores of 1.86, 1.78, and 1.87 compared to Group B's 1.40, 1.45, and 1.43 ($p < 0.01$), indicating significantly greater sedation in Group A**.** In contrast, **Angom C L et al**[11] found no significant sedation differences between Group A (buprenorphine) and Group B (fentanyl). Although Group B showed a slightly higher score at surgery end (2.58 ± 0.59 vs. 2.35 ± 0.48; $p = 0.067$), sedation scores remained similar throughout the postoperative period.

This study displays the mean arterial pressure (MAP) values of patients in Group A and Group B measured at various postoperative intervals. During the first 24 hours, Group B consistently had significantly higher MAP levels than Group A ($P \leq 0.02$). By 36 and 48 hours, the MAP values between the groups were comparable, with no significant differences ($P = 0.4$ and 0.12), indicating a more marked early postoperative decline in MAP in Group A. In a similar study, **Angom C L et al** [11] reported higher MAP values in Group A than Group B over 48 hours, peaking at 89 mm Hg at 2 hours. Group B showed milder fluctuations. Similarly, **Helmy N et al** [14] found Group I had elevated MAP at 4 and 6 hours (93.07 ± 5.15 and 93.07 ± 6.48) versus lower values in Groups II and III, with a significant difference at 6 hours ($P < 0.001$).

The study observed consistently high mean SpO_2 levels in both Group A and Group B over 48 hours postoperatively. No significant fluctuations or differences were found at any time point, with identical P-values of 1, indicating stable and comparable oxygen saturation across both groups throughout the observation period. **Dhamankar S et al** [15] observed minimal difference in SpO_2 between transdermal and injectable groups, with means of 99.60 ± 0.54% and 99.64 ± 0.53% ($P = 0.6941$). Similarly, **Qutubuddin S S et al** [16] reported nearly identical values between Group A (99.59 ± 0.77%) and Group B (99.56 ± 0.78%), with a non-significant P-value of 0.771, indicating comparable oxygen saturation levels across all groups.

CONCLUSION

This study compares transdermal buprenorphine and intravenous diclofenac for postoperative analgesia after laparoscopic cholecystectomy. Both groups were comparable in age and gender. Transdermal buprenorphine offered superior pain relief in the later postoperative period, with deeper sedation and reduced need for rescue analgesia, indicating higher analgesic efficacy. Although heart rate and MAP varied at some intervals, overall hemodynamic parameters remained stable. Oxygen saturation and respiratory rates were consistently maintained across both groups. Overall, transdermal buprenorphine proved more effective without compromising cardiorespiratory function, making it a reliable option for postoperative pain management.

REFERENCES

1. Barazanchi AW, MacFater WS, Rahiri JL, Tutone S, Hill AG, Joshi GP, Kehlet H, Schug S, Van de Velde M, Vercauteren M, Lirk P. Evidence-based management of pain after laparoscopic cholecystectomy: a PROSPECT review update. British Journal of Anaesthesia. 2018;121(4):787-803.
2. Londhe S, Patwardhan M, Shah R, Oak M. Efficacy and Safety of Buprenorphine Transdermal Patch for Immediate Postoperative Analgesia After Total Knee Arthroplasty Surgery. J Arthroplasty. 2020;35(6S): S178-S181
3. Max MB, Marilee D and Christine AM. Quality improvement guidelines for the treatment of acute pain and cancer pain. American pain society quality of care committee. JAMA. 1995;274(23):1874-1880.
4. Gupta H, Babu RJ. Transdermal delivery: product and patent update. Recent Pat Drug DelivFormul. 2013;7:184-205
5. Mitchell RWD, Smith G. The control of Acute postoperative pain. Br J Anaesth 1989;63:147-58
6. Likar R. Transdermal buprenorphine in the management of persistent pain-safety aspects. Ther Clin Risk Manag. 2006;2(1):115-25.
7. Kress HG. Clinical update on the pharmacology, efficacy and safety of transdermal buprenorphine. Eur J Pain. 2009;13(3):219-30.
8. Kumar S, Chaudhary AK, Singh PK, Reetu R, Chandra G, Bhatia VK, et al. Transdermal buprenorphin patches for postoperative pain control in abdominal surgery. J Clin Diagn Res 2016;10(6):UC05-UC08.
9. Shrestha BB, Lakhe G, Ghimire P. Postoperative Pain after Laparoscopic Cholecystectomy in a Tertiary Care Center: A Descriptive Cross-sectional Study. J Nepal Med Assoc 2024;62(276):502-6.
10. Talnia S, Fry RR, Sharma A, Patidar DC, Goyal S, Gandhi G. Efficacy of Transdermal Diclofenac Patch as an Analgesic Following Premolar Extractions in Orthodontic Patients. Ann Maxillofac Surg 2020;10:37-41.
11. Angom CL, Singh KM, Roy LS, Kobing S, Sudarshan A, Thangaraj G. Comparative study of transdermal buprenorphine and fentanyl patch for post-operative analgesia in abdominal surgery under general anaesthesia: a randomised single blinded study. Int J Res Med Sci 2024;12:2455-60.
12. Singh H, Kundra S, Singh RM, Grewal A, Kaul TK and Sood D. Preemptive analgesia with ketamine for laparoscopic cholecystectomy. J Anaesthesiol Clin Pharmacol. 2013;29(4): 478-484
13. Arshad Z, Prakash R, Gautam S, Kumar S. Comparison between transdermal buprenorphine and transdermal fentanyl for postoperative pain relief after major abdominal surgeries. J Clin Diagn Res. 2015;9(12):UC01-UC04
14. Helmy N, Badawy AA, Hussein M and Reda H. Comparison of the preemptive analgesia of low dose ketamine versus magnesium sulfate on parturient undergoing cesarean section under general anesthesia. Egypt J Anaesth. 2015;31(1):53-58.
15. Dhamankar S, Javali SB, Sunkad M. Efficacy of diclofenac transdermal patch versus injection as post-cesarean analgesia: A clinical, comparative, single-blind randomized control trial. Wadia J Women Child Health. 2024;3:61-7.
16. Qutubuddin SS, Agarwal SB, Parashar D, Singh VL, Gupta G. Comparative evaluation of analgesic efficacy of buprenorphine transdermal patch and fentanyl trandermal patch in management of postoperative pain after lower limb surgery. Int J Clin Pharmacol 2024;13:838-42.