

A Study on Efficacy of 5% Lidocaine Patch for Postoperative Pain Management in Patient Undergoing Laparoscopic Cholecystectomy

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Abstract

Introduction: Postoperative pain, including referred shoulder pain, remains a common concern following laparoscopic cholecystectomy. The 5% lidocaine patch may provide local analgesia with minimal systemic effects. This study evaluated the efficacy and safety of a 5% lidocaine patch for postoperative pain management in patients undergoing laparoscopic cholecystectomy.

Materials and Methods: This hospital-based, single-blinded, randomized controlled study was conducted at a tertiary care hospital in Jaipur from March 2024 to August 2025. Eighty patients aged 18–65 years, with American Society of Anesthesiologists physical status I or II, undergoing elective laparoscopic cholecystectomy under general anaesthesia were randomly allocated into two groups of 40 each. In the patch group, a 5% lidocaine patch was applied over the left shoulder before surgery, while the control group received dressing tape at the same site. Postoperative pain was assessed using the Visual Analogue Scale (VAS) for 24 hours. Time to first rescue analgesia, total analgesic consumption, incidence of shoulder pain, haemodynamic parameters, and adverse effects were recorded.

Results: Baseline demographic, clinical, operative, and anaesthetic characteristics were comparable between the groups. VAS scores were significantly lower in the patch group from 1 to 24 hours postoperatively. The mean time to first rescue analgesia was longer in the patch group than in the control group (148 ± 41 versus 92 ± 34 minutes; $p < 0.001$). Total analgesic consumption was also lower in the patch group (96 ± 32 versus 134 ± 38 mg; $p < 0.001$). Postoperative shoulder pain occurred in 35.0% of patients in the patch group compared with 67.5% in the control group ($p = 0.006$). Haemodynamic parameters remained stable, and the frequency of nausea, vomiting, and skin irritation did not differ significantly between the groups.

Conclusion: The 5% lidocaine patch improved postoperative pain control following laparoscopic cholecystectomy. It reduced pain scores, analgesic consumption, and postoperative shoulder pain while delaying the need for rescue analgesia, without a significant increase in adverse effects. It may be used as a simple and safe adjunct to multimodal postoperative analgesia.

Keywords: Analgesia; Laparoscopic cholecystectomy; Lidocaine patch; Postoperative pain; Visual Analogue Scale.

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Introduction

Laparoscopic cholecystectomy is the the gold standard surgical treatment for symptomatic gallbladder disease. Over the past three decades, advancements in laparoscopic techniques, anaesthetic management, and peri operative care have substantially improved surgical safety and patient outcomes. [1] Despite these benefits,

postoperative pain continues to remain a clinically significant challenge following laparoscopic cholecystectomy and represents one of the principal determinants of delayed recovery, prolonged hospitalization, impaired respiratory function, and reduced patient satisfaction. [2]

Therefore, optimal postoperative analgesia is an essential component of enhanced recovery pathways and quality peri operative care. [3] Traditionally, systemic opioids have formed the cornerstone of postoperative pain management following abdominal surgery. [4] The concept of multimodal analgesia has gained widespread acceptance. [5] Multimodal analgesia involves the use of multiple pharmacological and non-pharmacological interventions targeting different pain pathways to achieve superior analgesia while minimizing opioid consumption and associated adverse effects. [5]

Although many of these techniques demonstrate clinical efficacy, several limitations exist. Regional blocks require technical expertise, additional procedural time, and may carry risks such as bleeding, organ injury, or local anaesthetic systemic toxicity. [6] Intra peritoneal and infiltrative techniques may provide only short-lived analgesia. [7] Furthermore, resource constraints and variability in practitioner skill may limit the routine applicability of these interventions in many clinical settings. These challenges underscore the need for simple, safe, non-invasive, and cost-effective analgesic adjuncts that can be easily incorporated into routine peri operative care.

In this context, the 5% transdermal lidocaine patch has emerged as a promising modality for localised postoperative pain control. Lidocaine is a well-established amide-type local anaesthetic that exerts its primary action through reversible blockade of voltage-gated sodium channels in neuronal membranes, thereby inhibiting initiation and propagation of nerve impulses. [8] When administered via a transdermal patch, lidocaine provides targeted analgesia to superficial peripheral nerves in the area of application with minimal systemic absorption. [9] In addition, lidocaine has been shown to possess anti-inflammatory and antihyperalgesic properties, potentially reducing postoperative pain. [10]

Although preliminary evidence indicates that the 5% lidocaine patch may reduce postoperative pain and opioid requirement after laparoscopic surgery, definitive evidence in laparoscopic cholecystectomy remains insufficient. Therefore, the present study has been designed to evaluate the efficacy of a 5% lidocaine patch in postoperative pain management among patients undergoing laparoscopic cholecystectomy, with assessment of pain scores, rescue analgesic requirement, and haemodynamic parameters during the early postoperative period.

Materials and Methods

This hospital based single blinded, randomized controlled study was conducted in tertiary care

hospital of Jaipur. The study population was patients scheduled for elective laparoscopic cholecystectomy under general anaesthesia during the study period from March 2024 to August 2025. The sample size was calculated as 34 in each group, at alpha error of 0.05 & 80% power, using incidence of shoulder pain as 69% & 35% respectively in control & patch group. [11] So, to study efficacy of 5% Lidocaine patch for postoperative pain management in patient undergoing Laparoscopic cholecystectomy a minimum total sample size was estimated to be 80 (40 in each group).

Patients aged 18–65 years of either gender, belonging to American Society of Anesthesiologists (ASA) physical status I or II, and scheduled for elective laparoscopic cholecystectomy under general anaesthesia were included in the study. Patients with known psychiatric disorders, coagulopathy, a history of cerebrovascular disease, pregnancy or lactation, and those unable to understand the Visual Analogue Scale (VAS) scoring system were excluded from the study.

All patients underwent a detailed pre-anaesthetic evaluation, including history and physical examination, Airway assessment & Routine laboratory investigations. Written and informed consents were obtained. Patients were explained about the VAS scoring system, where 0 represents no pain and 10 represents worst imaginable pain. On the day of surgery, patients were shifted to the pre-operative area. Two groups of 40 patients each were formed with the help of computer-generated random numbers-

Group A (Lidocaine Patch Group): A 5% lidocaine patch was applied over the left shoulder before surgery & it was covered with dressing tape to maintain blinding.

Group B (Control Group): A dressing tape was applied at the same site to serve as placebo.

Randomly one of the two groups was assigned to each patient. All patients were explained about the anaesthesia technique. The VAS scores were further assessed at 0 hour, 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, 24 hours. Rescue analgesia was provided to all the patients of VAS score ≥ 4 with inj. Tramadol i.v. (@1mg/kg/dose, max 400mg in 24 hours). In case, if the pain was persistent (VAS ≥ 4) even after 30 minutes of tramadol administration, then second line analgesic; inj. Paracetamol i.v. (@15mg/kg/dose, max dose 1 gram) was given. Repeat dose of inj. Tramadol (@1mg/kg/dose, max 400mg in 24 hours) and inj. Paracetamol (@15mg/kg/dose, max dose 1 gram) were considered, if VAS score was ≥ 4 after six hours of the previous dose.

Total number of patients requiring rescue analgesia & total consumption of analgesics were recorded, during first twenty-four hours after surgery. Adverse events like decrease in blood pressure and heart rate from the base line, dizziness, diplopia, dry mouth, nausea, and vomiting were also noticed for after administration of analgesics. Hemodynamic parameters were recorded at baseline and postoperatively at predefined intervals.

Results

[Table-1] The baseline demographic and clinical characteristics were comparable between the two groups. The mean age was 44.8 ± 11.2 years in the control group and 43.9 ± 10.6 years in the patch group ($p = 0.710$). Gender distribution was similar ($p = 0.810$). The mean BMI was 25.9 ± 3.1 kg/m² in the control group and 25.4 ± 3.3 kg/m² in the patch group ($p = 0.530$). Likewise, the distribution of ASA physical status did not differ significantly between the groups ($p = 0.820$).

[Table-2] The mean duration of surgery was 64.7 ± 13.6 minutes in the control group and 62.9 ± 14.1 minutes in the patch group, with no significant difference between the groups ($p = 0.570$). Similarly, the mean duration of anaesthesia was 88.4 ± 15.3 minutes in the control group and 86.1 ± 16.0 minutes in the patch group ($p = 0.480$).

[Table-3] Baseline heart rate and mean arterial pressure were similar in both groups. Heart rate was significantly lower in the patch group at 2 hours ($p = 0.040$) and 4 hours ($p = 0.030$) after

surgery. Likewise, mean arterial pressure was significantly lower in the patch group at 2 hours ($p = 0.040$) and 4 hours ($p = 0.030$). At all other time points, the differences between the groups were not statistically significant.

[Table-4] The VAS scores were comparable immediately after surgery (0 hour, $p = 0.150$). From 1 hour onwards, the patch group had significantly lower pain scores than the control group. The difference was significant at 1 hour ($p = 0.002$), 2 hours, 4 hours, and 6 hours ($p < 0.001$ for each), and remained significant at 12 hours ($p = 0.004$) and 24 hours ($p = 0.010$).

[Table-5] The mean time to first rescue analgesia was significantly longer in the patch group (148 ± 41 minutes) than in the control group (92 ± 34 minutes) ($p < 0.001$). Total postoperative analgesic consumption was also significantly lower in the patch group (96 ± 32 mg) compared with the control group (134 ± 38 mg) ($p < 0.001$). Postoperative shoulder pain occurred in 67.5% of patients in the control group and 35.0% in the patch group, representing a significant reduction in the patch group ($p = 0.006$).

The incidence of postoperative adverse effects was low in both groups. Nausea was reported in 15.0% of patients in the control group and 12.5% in the patch group, while vomiting occurred in 10.0% and 7.5% of patients, respectively. Mild skin irritation was observed in 5.0% of patients receiving the lidocaine patch and in none of the control patients. None of these adverse effects showed a statistically significant difference between the groups.

Table 1: Comparison of Baseline Demographic and Clinical Characteristics between the Study Groups

Variable	Control Group (n=40)	Patch Group (n=40)	p-value
Age (years)	44.8 ± 11.2	43.9 ± 10.6	0.710
Gender			
Male	14 (35.0%)	13 (32.5%)	0.810
Female	26 (65.0%)	27 (67.5%)	
BMI (kg/m ²)	25.9 ± 3.1	25.4 ± 3.3	0.530
ASA Physical Status			
ASA I	18 (45.0%)	19 (47.5%)	0.820
ASA II	22 (55.0%)	21 (52.5%)	

Table 2: Comparison of Intraoperative Characteristics between the Study Groups

Parameter	Control Group (n=40)	Patch Group (n=40)	p-value
Duration of surgery (minutes)	64.7 ± 13.6	62.9 ± 14.1	0.570
Duration of anaesthesia (minutes)	88.4 ± 15.3	86.1 ± 16.0	0.480

Table 3: Comparison of Hemodynamic Parameters between the Study Groups

Time	Heart Rate (beats/min)		Mean Arterial Pressure (mmHg)	
	Control	Patch	Control	Patch
Baseline	78.2 ± 8.6	77.9 ± 7.9	92.3 ± 9.4	91.8 ± 8.7
0 hour	82.4 ± 9.1	80.6 ± 8.3	96.1 ± 9.8	93.4 ± 9.1
1 hour	83.7 ± 8.4	80.9 ± 7.8	95.7 ± 9.5	92.6 ± 8.7
2 hours	84.1 ± 8.7*	80.1 ± 7.6	95.9 ± 9.2*	91.7 ± 8.3
4 hours	82.3 ± 7.9*	78.5 ± 7.3	94.8 ± 8.6*	90.5 ± 7.9
6 hours	80.2 ± 7.4	77.4 ± 6.9	93.7 ± 8.1	90.8 ± 7.5
12 hours	79.5 ± 6.8	77.8 ± 6.4	92.9 ± 7.9	90.4 ± 7.3
24 hours	78.6 ± 6.1	77.2 ± 6.3	92.1 ± 7.3	90.2 ± 6.9

* p < 0.05 between the two groups at the respective time point.

Table 4: Comparison of VAS Scores

Time	Control	Patch	p-value
0 hr	4.8 ± 1.3	4.4 ± 1.2	0.15
1 hr	5.2 ± 1.4	4.1 ± 1.3	0.002
2 hr	5.0 ± 1.5	3.8 ± 1.2	<0.001
4 hr	4.7 ± 1.4	3.5 ± 1.1	<0.001
6 hr	4.3 ± 1.3	3.2 ± 1.0	<0.001
12 hr	3.7 ± 1.2	2.9 ± 1.0	0.004
24 hr	2.9 ± 1.1	2.3 ± 0.9	0.01

Table 5: Comparison of Postoperative Analgesic Outcomes and Adverse Effects between the Study Groups

Groups			
Parameter	Control Group (n=40)	Patch Group (n=40)	p-value
Time to first rescue analgesia (minutes)	92 ± 34	148 ± 41	<0.001
Total analgesic consumption (mg)	134 ± 38	96 ± 32	<0.001
Postoperative shoulder pain			
Present	27 (67.5%)	14 (35.0%)	0.006
Absent	13 (32.5%)	26 (65.0%)	
Adverse effects			
Nausea	6 (15.0%)	5 (12.5%)	1.000
Vomiting	4 (10.0%)	3 (7.5%)	1.000
Skin irritation	0 (0.0%)	2 (5.0%)	0.474

Discussion

The present randomized controlled study evaluated the efficacy of a 5% lidocaine patch as an adjunct for postoperative pain management following laparoscopic cholecystectomy. Patients receiving the lidocaine patch had lower postoperative pain scores, delayed requirement for rescue analgesia, reduced analgesic consumption, and a lower incidence of postoperative shoulder pain without an increase in adverse effects.

The baseline characteristics were comparable between the control and patch groups. There were no significant differences in age (44.8 ± 11.2 vs. 43.9 ± 10.6 years; p = 0.710), gender distribution (p = 0.810), BMI (25.9 ± 3.1 vs. 25.4 ± 3.3 kg/m²; p = 0.530), or ASA physical status (p = 0.820). Comparable baseline demographic and clinical characteristics have also been reported in previous randomized controlled trials evaluating 5% lidocaine patches for postoperative pain management, including studies by Kim HY et al

[11], Vrooman BM et al [12], Saber Alan A et al [13], Chiu WK et al [14], Swenson JD et al [15], and Lee WS et al [16]. The similarity in baseline characteristics indicates that the two groups were well matched, minimizing the influence of potential confounding factors on postoperative outcomes.

The mean duration of surgery (64.7 ± 13.6 vs. 62.9 ± 14.1 minutes; p = 0.57) and duration of anaesthesia (88.4 ± 15.3 vs. 86.1 ± 16.0 minutes; p = 0.48) were comparable between the control and patch groups. Similar findings have been reported by Kim HY et al [11], Lee WS et al [16], and Saber Alan A et al [13], who also observed no significant differences in perioperative variables between study groups. The comparable operative and anaesthetic durations suggest that these factors were unlikely to have influenced the postoperative analgesic outcomes.

Baseline heart rate and mean arterial pressure were comparable between the two groups. Although heart rate and MAP were significantly lower in the

patch group at 2 and 4 hours postoperatively, no significant differences were observed at the remaining time points.

The lower hemodynamic parameters during the early postoperative period may reflect better pain control and reduced sympathetic response in patients receiving the lidocaine patch. Similar findings have been reported by Vrooman BM et al [12], Gordon DB et al [17], White PF et al [18], and Habib AS et al [19], who demonstrated effective postoperative analgesia with topical lidocaine without clinically significant hemodynamic instability. Patients receiving the 5% lidocaine patch experienced significantly lower postoperative pain scores than the control group. Although VAS scores were comparable immediately after surgery (4.8 ± 1.3 vs. 4.4 ± 1.2 ; $p = 0.15$), significantly lower scores were observed in the patch group from 1 to 24 hours postoperatively. These findings are consistent with those of Kim HY et al [11] and Chiu WK et al [14], who also reported improved postoperative pain control with topical lidocaine patches. Similarly, a meta-analysis by Koo CH et al [20] demonstrated that lidocaine patches significantly reduced postoperative pain following various surgical procedures.

Patients in the patch group had a significantly longer time to first rescue analgesia (148 ± 41 vs. 92 ± 34 minutes; $p < 0.001$) and lower total analgesic consumption (96 ± 32 vs. 134 ± 38 mg; $p < 0.001$) than the control group. These findings are in agreement with Habib AS et al [19] and Vrooman BM et al [12], who reported reduced postoperative analgesic requirements with topical lidocaine. Although previous reviews have shown variability in opioid-sparing effects across different surgical procedures, our findings support the analgesic benefit of the 5% lidocaine patch. [21]

Postoperative shoulder pain was significantly less frequent in the patch group than in the control group (35.0% vs. 67.5%; $p = 0.006$). A similar reduction in postoperative shoulder pain after laparoscopic cholecystectomy has been reported by Kim HY et al [11], supporting the role of topical lidocaine as an effective adjunct for managing referred shoulder pain.

The incidence of postoperative adverse effects was low and comparable between the two groups. Mild skin irritation occurred in two patients in the patch group, while the incidences of nausea and vomiting were similar. These findings are consistent with previous reports demonstrating the favorable safety profile of topical lidocaine patches. [22,23]

Conclusion

The use of a 5% lidocaine patch as an adjunct to multimodal analgesia effectively improved

postoperative pain management following laparoscopic cholecystectomy. Compared with standard postoperative care alone, the lidocaine patch was associated with lower postoperative pain scores, delayed requirement for rescue analgesia, reduced overall analgesic consumption, and a lower incidence of postoperative shoulder pain. Hemodynamic parameters remained stable, and no increase in adverse effects was observed, indicating a favorable safety profile. These findings suggest that the 5% lidocaine patch is a simple, safe, and effective adjunct for postoperative analgesia and may be considered as part of multimodal pain management protocols in patients undergoing laparoscopic cholecystectomy.

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