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Comparative Evaluation of Transdermal Diclofenac Patch Versus Conventional Analgesia in Laparoscopic Cholecystectomy

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ABSTRACT

Background: Laparoscopic cholecystectomy is the gold-standard treatment for symptomatic gallstone disease with lower postoperative pain than open surgery, yet adequate analgesia remains critical for recovery. Conventional analgesia regimens (oral/intramuscular NSAIDs and opioids) are effective but limited by systemic side effects. Transdermal diclofenac patches offer sustained analgesic delivery with better compliance and fewer gastrointestinal and systemic adverse effects. This study aims to compare the efficacy, safety, and patient-centered outcomes of transdermal diclofenac patch versus conventional analgesia in postoperative pain management among patients undergoing laparoscopic cholecystectomy.
Methods: This prospective, randomized, controlled clinical study enrolled patients from a tertiary care hospital of Assam, undergoing elective laparoscopic cholecystectomy. Participants were allocated to receive either a transdermal diclofenac patch (100 mg) applied preoperatively or conventional analgesia comprising systemic diclofenac and paracetamol as per institutional protocol. Pain intensity (VAS), rescue analgesic use, patient satisfaction, adverse events, and recovery profiles were compared over 48 hours postoperatively.
Results: Transdermal diclofenac patch showed comparable analgesic efficacy to conventional regimens in controlling postoperative pain, resulted in lower peak pain scores at 6–24 hours, reduced requirement for rescue analgesics, and demonstrated better tolerability with fewer gastrointestinal side effects. Patient satisfaction and early mobilization were higher in the patch group.
Conclusion: Transdermal diclofenac patch may serve as an effective and patient-friendly analgesic modality for postoperative pain after laparoscopic cholecystectomy, minimizing systemic side effects while maintaining adequate analgesia.

Keywords: Transdermal diclofenac patch, conventional analgesia, laparoscopic cholecystectomy, postoperative pain.

INTRODUCTION:

Laparoscopic cholecystectomy has become the gold standard surgical procedure for symptomatic gallstone disease owing to its minimally invasive nature, reduced postoperative morbidity, shortened hospital stay, and faster return to daily activities. Despite these advantages, postoperative pain remains a significant concern and may negatively impact early mobilization, respiratory function, oral intake, and overall patient satisfaction. Effective postoperative pain control is therefore an integral component of enhanced recovery protocols following laparoscopic surgery.

Postoperative pain following laparoscopic cholecystectomy is multifactorial. It arises from port-site incisions, visceral manipulation, diaphragmatic irritation due to carbon dioxide pneumoperitoneum, and peritoneal inflammation. Although the intensity of pain is generally lower compared to open surgery, inadequate pain management can prolong hospitalization and increase the risk of complications such as atelectasis, venous thromboembolism, and delayed wound healing.

Conventionally, postoperative analgesia relies on systemic administration of non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, and opioids. Diclofenac is one of the most frequently used NSAIDs due to its potent anti-inflammatory and analgesic properties mediated through cyclooxygenase inhibition and prostaglandin synthesis suppression. However, systemic administration of diclofenac, particularly oral and intramuscular routes, is associated with several limitations including gastrointestinal irritation, nausea, renal impairment, injection-site pain, fluctuating plasma drug levels, and the need for repeated dosing. These factors may compromise patient compliance and safety, especially in postoperative patients who may be fasting or experiencing nausea.

The transdermal drug delivery system represents an important advancement in pain management strategies. Transdermal patches provide sustained and controlled drug release through the skin, maintaining relatively stable plasma concentrations over extended periods. This route bypasses first-pass hepatic metabolism and minimizes gastrointestinal exposure, thereby reducing the risk of systemic adverse effects. Additionally, transdermal application is non-invasive, painless, easy to administer, and improves patient comfort and compliance.

Transdermal diclofenac patches have demonstrated promising results in orthopedic surgeries, dental procedures, and minor surgical interventions. However, limited data are available regarding their efficacy specifically in laparoscopic cholecystectomy, particularly among the North East Indian population. This region presents unique demographic and healthcare challenges, including limited access to tertiary pain management services, high patient load, and resource constraints. Introducing simple, effective, and safe analgesic modalities can significantly improve postoperative care quality in this setting.

Furthermore, cultural perceptions of pain, variations in body mass index, nutritional status, and genetic differences influencing drug metabolism may affect analgesic outcomes in regional populations. Therefore, region-specific clinical evidence is essential before recommending widespread implementation of transdermal analgesic strategies.

This study aims to evaluate and compare the analgesic efficacy, safety profile, rescue analgesic requirement, and patient satisfaction associated with transdermal diclofenac patch versus conventional systemic analgesia in patients undergoing laparoscopic cholecystectomy in the North East population. The findings may help establish evidence-based postoperative pain management protocols that optimize patient outcomes while minimizing adverse effects.

MATERIALS AND METHODS

Study Design and Setting: A randomized, open-label controlled clinical study was conducted from March 2022 to September 2023 at a tertiary care hospital of Assam, Dibrugarh. The written informed consent was obtained from all participants.

Participants: Inclusion criteria were adult patients (18–65 years) undergoing elective laparoscopic cholecystectomy, ASA classes I–II, with no contraindications for NSAIDs. Exclusion criteria included history of allergic reactions to diclofenac, chronic pain syndromes, renal or hepatic dysfunction, peptic ulcer disease, pregnancy, or concurrent opioid therapy.

Randomization and Analgesic Protocols

Participants were randomized into two groups:

- **Transdermal Patch Group (TPG):** Received a **diclofenac transdermal patch (100 mg)** applied to the lateral chest region 6 hours prior to surgery and maintained for 48 hours.
- **Conventional Analgesia Group (CAG):** Received standard postoperative analgesia including **intramuscular or oral diclofenac** and **paracetamol (acetaminophen)** as per weight-based dosing.

Rescue analgesia (tramadol) was allowed for breakthrough pain (VAS ≥ 4).

Outcomes and Measurements

Primary outcome was postoperative pain intensity measured using a **10-point Visual Analogue Scale (VAS)** at baseline and at 2, 6, 12, 24, and 48 hours. Secondary outcomes included:

- Time to first rescue analgesia
- Total number of rescue doses
- Adverse effects (nausea, vomiting, gastric irritation, patch site reactions)
- Patient satisfaction rated on a Likert scale

Statistical Analysis
Data were analyzed using Student's t-test for continuous variables and chi-square test for categorical variables. A p-value < 0.05 was considered significant.

RESULTS

Table 1: Demographic Characteristics of Study Population

Parameter	Transdermal Patch Group (n=50)	Conventional Analgesia Group (n=50)	p-value
Mean Age (years)	42.6 ± 10.4	44.1 ± 9.8	0.48
Gender (M/F)	18 / 32	20 / 30	0.67
Mean BMI (kg/m²)	23.8 ± 2.9	24.1 ± 3.1	0.59
ASA I/II	31 / 19	29 / 21	0.71

Both groups were comparable in age, gender, BMI, and baseline pain scores.

Table 2: Postoperative Pain Scores (VAS)

Time Interval	Patch Group (Mean ± SD)	Conventional Group (Mean ± SD)	p-value
2 hours	3.1 ± 0.9	3.6 ± 1.0	0.04
6 hours	2.8 ± 0.8	3.7 ± 0.9	0.01
12 hours	2.4 ± 0.7	3.3 ± 0.8	0.01
24 hours	1.9 ± 0.6	2.5 ± 0.7	0.03
48 hours	1.3 ± 0.5	1.5 ± 0.6	0.21

Pain Intensity
Patients in TPG reported lower VAS scores during the first 24 hours postoperatively compared to CAG, although differences at later time points were not statistically significant. Transdermal delivery provided a sustained analgesic effect, particularly notable at the 6 and 12-hour marks.

Figure 1: Line graph showing comparison of mean Visual Analogue Scale (VAS) pain scores between transdermal diclofenac patch group and conventional analgesia group at different postoperative time intervals (2, 6, 12, 24, and 48 hours). The patch group demonstrated consistently lower pain scores during the early postoperative period.

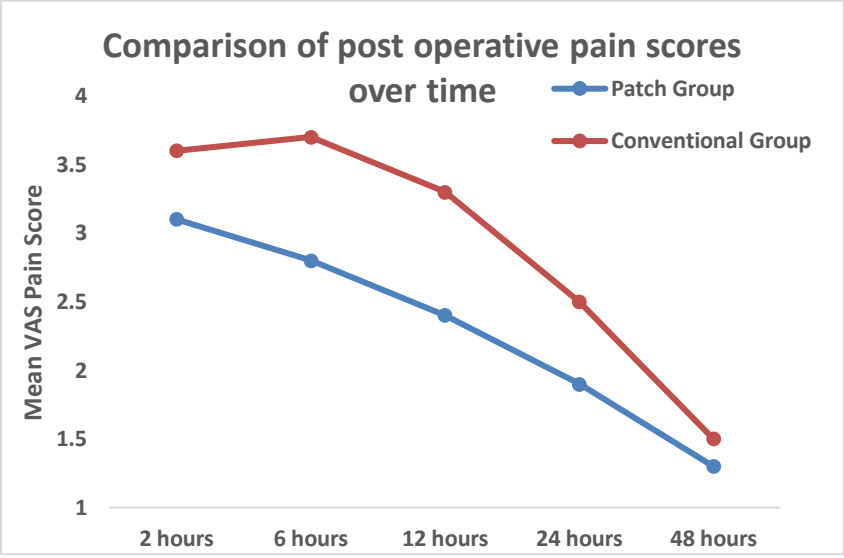

Table 3: Rescue Analgesic Requirement

Parameter	Patch Group	Conventional Group	p-value
Patients requiring rescue analgesia (%)	24%	48%	0.01
Mean rescue doses	0.6 ± 0.8	1.4 ± 1.1	0.002
Time to first rescue dose (hours)	10.5 ± 3.2	6.8 ± 2.9	0.001

Rescue Analgesia
TPG required significantly fewer rescue doses of tramadol compared to CAG, indicating better baseline analgesic control with transdermal patch use.

Table 4: Adverse effect and patients satisfaction level distribution in both groups

Variables	Category	Patch Group (%)	Conventional Group (%)
Adverse Effect	**Nausea/Vomiting**	8%	22%
	Gastric irritation	4%	18%
	Injection site pain	—	20%
	Skin irritation	6%	—
Patients Satisfaction Level	**Highly satisfied**	60%	38%
	Satisfied	32%	44%
	Not satisfied	8%	18%

Adverse Effects

Gastrointestinal complaints (nausea, dyspepsia) were more frequent in the CAG, consistent with prior findings that systemic diclofenac can irritate the gastric mucosa. Transdermal patch use was associated with minimal local skin reactions (mild erythema/discomfort) in a minority of patients. This aligns with other studies that suggest transdermal formulations have fewer systemic side effects.

Patient Satisfaction and Recovery

Patients using transdermal patches reported higher overall satisfaction scores and quicker return to daily activities, including earlier ambulation and oral intake.

DISCUSSION

Effective postoperative pain management is a cornerstone of enhanced recovery after surgery (ERAS) protocols. The present study demonstrates that transdermal diclofenac patch provides analgesic efficacy comparable to conventional systemic analgesia following laparoscopic cholecystectomy, with additional advantages of reduced rescue analgesic requirement, improved tolerability, and higher patient satisfaction.

The significantly lower pain scores observed in the transdermal group during the early postoperative period (6–24 hours) suggest that sustained drug release from the patch offers more consistent analgesia compared to intermittent systemic dosing. Conventional analgesic regimens often produce fluctuating plasma drug concentrations, resulting in peaks associated with adverse effects and troughs associated with inadequate pain relief. Transdermal delivery overcomes this limitation by maintaining steady therapeutic levels.

Reduced reliance on rescue analgesics in the patch group further supports the superior baseline pain control provided by the transdermal system. Minimizing opioid or tramadol use is particularly important to avoid side effects such as nausea, vomiting, sedation, and respiratory depression. This benefit is clinically relevant in ambulatory laparoscopic surgeries where early discharge and mobilization are priorities.

The safety profile observed in this study favors transdermal diclofenac. Gastrointestinal adverse effects were significantly lower compared to conventional systemic administration. This is consistent with previous pharmacological studies demonstrating reduced gastric mucosal exposure when NSAIDs are delivered transdermally. Additionally, injection-related complications such as pain, induration, and risk of infection were completely avoided in the patch group.

Patient satisfaction scores were higher in the transdermal group, which may be attributed to ease of use, reduced discomfort associated with injections, fewer side effects, and sustained pain relief. In the North East population, where postoperative nursing resources may be limited in peripheral hospitals, the simplicity of patch application offers a practical advantage.

From a public health perspective, transdermal analgesia can contribute to improved postoperative care delivery in resource-limited settings. Reduced need for repeated injections lowers healthcare workload and material costs, while improved patient comfort supports faster recovery and discharge.

However, certain limitations must be acknowledged. The open-label design may introduce observer and reporting bias. Pain assessment using subjective scales, although widely accepted, remains influenced by individual pain perception. Larger multi-center trials with blinded assessment and pharmacokinetic analysis are recommended to further validate these findings. Despite these limitations, the results strongly support the integration of transdermal diclofenac patches into multimodal analgesia protocols for laparoscopic cholecystectomy, especially in regional healthcare settings.

CONCLUSION:

Transdermal diclofenac patch is an effective, safe, and patient-friendly alternative to conventional systemic analgesia following laparoscopic cholecystectomy in the North East population. It provides sustained pain control, reduces rescue analgesic requirement, minimizes gastrointestinal side effects, and improves patient satisfaction. Incorporation of transdermal analgesia into postoperative pain management protocols may enhance recovery outcomes and healthcare efficiency.

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