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A Prospective Comparative Study Between Tumescent With Local Anaesthesia of Calot's Triangle Versus Placebo on Post-Operative Pain after Laparoscopic Cholecystectomy at A Tertiary Care Hospital in Sikkim.

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Abstract

Background:

Postoperative pain remains a significant concern after laparoscopic cholecystectomy. Subserosal tumescence with local anesthetics may reduce pain, but evidence is limited.

Methods:

A prospective comparative study was conducted on 60 patients undergoing laparoscopic cholecystectomy. Patients were divided into two groups: lidocaine tumescence and placebo (normal saline). Postoperative pain was assessed using the Visual Analog Scale (VAS) at multiple intervals. Secondary outcomes included postoperative nausea and vomiting (PONV), shoulder tip pain, and hemodynamic parameters.

Results:

The mean age was comparable between groups (37.13±11.34 vs 39.43±12.32 years; p=0.455). The lidocaine group demonstrated significantly lower VAS scores at all postoperative time points ($p<0.05$), with the greatest difference at 2 hours (5.37±2.31 vs 7.13±2.51; p=0.006). No significant differences were observed in PONV or shoulder tip pain ($p>0.05$). Hemodynamic parameters remained stable in both groups.

Conclusion:

Subserosal tumescence of Calot's triangle with lidocaine significantly reduces postoperative pain following laparoscopic cholecystectomy without affecting PONV or shoulder tip pain.

Keywords: *laparoscopic cholecystectomy, postoperative pain, lidocaine, tumescence, VAS.*
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Introduction

Laparoscopic cholecystectomy offers a safe, effective, and relatively less painful treatment for patients with symptomatic biliary tract disease and has been the standard of care since its introduction in 1985. The advantages include smaller incisions, reduced postoperative pain, shorter hospital stays, and quicker recovery times (1). Although postoperative pain following laparoscopic cholecystectomy tends to be less intense compared to that of open cholecystectomy, early discomfort from the operation after laparoscopy can be similar or more intense than after open surgery in the initial hours post-surgery and requires more analgesia (2).

The commonest post-operative problems associated with laparoscopic cholecystectomy are post-operative pain and post-operative nausea and vomiting. These factors not only affect the patient's overall experience but also put a strain on the healthcare resources. The post-operative pain, peritoneal irritation, and anaesthetic agents can provide a potent synergy to induce significant post-operative nausea and vomiting. In the past, various techniques have been used, whether pharmacological or mechanical, to reduce this effect, but none of them alone or in combination have been successful in mitigating it. Therefore, 2Kapur et al in their study have mentioned it as "The Big Little Problem."(3).

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This problem led to multiple studies in which efforts were made to reduce pain and post-operative nausea and vomiting after cholecystectomy. Pharmacological methods include the use of opioid based drugs, but due to increased cases of drug abuse and addiction related to opioids, it is now only used in severe post-operative pain. Moreover, the use of opioids also delays the time to first flatus postoperatively. A study used Esketamine as an opioid free analgesia showed significant improvement in post-operative nausea and vomiting. (4).

Pain post-laparoscopic cholecystectomy is multifactorial, including the somatic pain from the trocar insertion site, abdominal stretching, and visceral pain from the gall bladder dissection. One such component adding to the cause of pain is CO2 insufflation and creation of pneumoperitoneum, which causes an acidic environment of the peritoneum post-surgery, which in turn irritates and damages the phrenic nerve and causes right shoulder tip pain. In one such study, sodium bicarbonate was instilled into the peritoneal cavity post-surgery to wash out excess CO2, and there was a significant reduction in right shoulder tip pain. (5). Creation of pneumoperitoneum also stretches the abdominal cavity and adds to the somatic component of the pain, which can be reduced by the use of port site local anaesthesia post-surgery. Pneumoperitoneum also adds to increased vagal stimulation, which in turn leadsincreased post operative nausea and vomiting. Patients under the ERAS1 protocol also showed a significant decline in postoperative pain, postoperative nausea, and vomiting after elective laparoscopic cholecystectomy. But this is unsuitable for emergency laparoscopic cholecystectomies since elective cases have controlled perioperative settings and fewer unforeseen events. (6).

The purported advantage of this technique is that the anaesthetic agent can be used in limited quantities and the site of its application and resultant action can be controlled, which is not possible as accurately if intraperitoneal instillation is done. The current study was planned to confirm or refute the effectiveness of subserosal tumescence of Calot's triangle with lidocaine by comparing it to a placebo (normal saline) instillation in the same site.

MATERIALS AND METHODS

Study site

The study was conducted in the department of General Surgery, Central Referral Hospital, which is a 500-bedded hospital associated with Sikkim Manipal Institute of Medical Sciences, Gangtok, Sikkim. This is the only teaching hospital in the north-eastern state of Sikkim.

Study design

A prospective comparative observational study.

Study duration

1 year 6 months

Study population

All the patients who underwent laparoscopic cholecystectomy between May 2023 and April 2024 were invited to participate in the study. All the patients who consented to be part of the study were included and randomized as stated below.

Selection criteria

All the patients who will undergo laparoscopic cholecystectomy between May 2023 and April 2024 were invited to participate in the study. All the patients who consented to be part of the study were included and randomized as stated above.

Inclusion Criteria

1. Patients who underwent elective laparoscopic cholecystectomy.

Exclusion Criteria

1. Patients who do not provide consent for participation in the study.
2. Any deviation from the planned procedure
3. Patients with jaundice
4. Difficult cholecystectomy (Cuschieri scale Grade 3,4 and Nassar scale grade 4)
5. Tumescence was deemed hazardous by the operating surgeon.
6. Patients with gall bladder malignancy.
7. Pregnant patient

Sample size

The sample size was calculated based on previous study findings (Mundra et al., 2018), using the formula:

$n = 2 \times (Z\alpha + Z\beta)^2 \times \sigma^2 / d^2$

Where $Z\alpha = 1.96$, $Z\beta = 0.84$, σ = standard deviation, and d = expected difference. A minimum of 30 patients per group was required.

Bias:

To minimize bias, patients with difficult cholecystectomies, comorbid conditions affecting pain perception, and

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intraoperative complications were excluded. Standardized anesthesia and surgical techniques were followed.

Data analysis

Data was entered using Microsoft Excel/ Google Sheets and was analysed using SPSS® version 27. Graphical presentation of data was done wherever applicable. Appropriate techniques were used for analysis. Numerical parameters were compared by using Student's T test and/or ANOVA. Nominal data were compared using non-parametric tests like the chi-square. The continuous variables were presented as mean and standard deviation, and the categorical variables were presented as frequency and percent. The cut-off p-value for significance was ≤0.05 for all statistical tests.

Ethical consideration

The study was approved by the Institutional Ethics Committee of Sikkim Manipal Institute of Medical Sciences. Written informed consent was obtained from all participants prior to inclusion.

RESULTS

Patient flow

A total of 75 patients were assessed for eligibility during the study period, of which 60 patients met the inclusion criteria and were enrolled. These participants were divided equally into two groups: the lidocaine tumescence group (n=30) and the normal saline group (n=30). All enrolled patients completed the study and were included in the final analysis.

Baseline Characteristics

The demographic characteristics of both groups were comparable. The mean age in the lidocaine group was 37.13±11.34 years, while in the normal saline group it was 39.43±12.32 years (p=0.455). Females predominated in both groups (80% overall), with no statistically significant difference in gender distribution (p>0.05).

Similarly, the mean BMI was comparable between the lidocaine group (26.86±3.43 kg/m²) and the saline group (25.52±3.40 kg/m²), with no statistically significant difference (p=0.136).

The distribution of comorbidities such as hypertension, diabetes mellitus, and hypothyroidism was similar in both groups (p=0.498), indicating baseline comparability.

Table 1: Baseline Demographic Characteristics

Variable	Lidocaine Group (n=30)	Normal Saline Group (n=30)	p-value
Age (years, mean ± SD)	37.13 ± 11.34	39.43 ± 12.32	0.455
Male	6 (20%)	5 (16.7%)	>0.05
Female	24 (80%)	25 (83.3%)	
BMI (kg/m², mean ± SD)	26.86 ± 3.43	25.52 ± 3.40	0.136

Preoperative and Ultrasonographic Findings

The most common diagnosis in both groups was uncomplicated cholelithiasis. There were no statistically significant differences between the groups in terms of diagnosis (p=0.157), gallbladder wall thickness (p=0.161), or mean wall thickness values (p=0.442).

Common bile duct (CBD) diameter was within normal limits in both groups, although a statistically significant difference in mean values was observed (3.33±0.83 mm vs 3.83±0.91 mm; p=0.032), which was not clinically significant.

Gallbladder sludge was significantly more common in the saline group compared to the lidocaine group (p=0.023). The number and type of gallstones were comparable between the groups (p=0.595).

Preoperative laboratory parameters, including hemoglobin, total leukocyte count, bilirubin, and alkaline phosphatase, showed no statistically significant differences (p>0.05).

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Table 2: Distribution of Comorbidities

Comorbidity	Lidocaine Group (n=30)	Normal Saline Group (n=30)
Hypertension	6	2
Hypothyroidism	2	1
Diabetes Mellitus (± HTN)	1	1
Others	4	8
None	17	18

Intraoperative Findings

Intraoperative parameters were comparable between the two groups. Gallbladder adhesions were observed in 35% of patients, with no statistically significant difference between groups (p=0.058).

Intraoperative gallbladder perforation occurred in 13.33% of cases, with similar distribution between the groups (p=0.448). Likewise, intraoperative spillage and drain placement did not differ significantly (p>0.05).

The mean duration of surgery was 69.50±20.44 minutes in the lidocaine group and 66.50±26.10 minutes in the saline group, with no statistically significant difference (p=0.622).

Table 3: Preoperative and Ultrasonographic Findings

Parameter	Lidocaine Group	Normal Saline Group	p-value
Gallbladder wall thickness (mm)	2.56 ± 0.66	2.44 ± 0.45	0.442
CBD diameter (mm)	3.33 ± 0.83	3.83 ± 0.91	0.032
Gallbladder sludge present	1 (3.3%)	7 (23.3%)	0.023
Multiple stones	16 (53.3%)	16 (53.3%)	0.595

Table 4: Intraoperative Findings

Parameter	Lidocaine Group	Normal Saline Group	p-value
Adhesions present	14 (46.7%)	7 (23.3%)	0.058
Gallbladder perforation	3 (10%)	5 (16.7%)	0.448
Intraoperative spillage	4	9	>0.05
Drain placement	0	1	0.313
Duration of surgery (min)	69.50 ± 20.44	66.50 ± 26.10	0.622

Postoperative Pain

Postoperative pain was assessed using the Visual Analog Scale (VAS) at multiple time intervals. The lidocaine group demonstrated significantly lower pain scores at all postoperative time points compared to the saline group (p<0.05).

The maximum difference in pain scores was observed at 2 hours postoperatively (5.37±2.31 vs 7.13±2.51; p=0.006). Pain scores gradually decreased over time in both groups, but remained consistently lower in the lidocaine group up to 24 hours.

Table 5: Postoperative Pain (VAS Score)

Time Interval	Lidocaine Group (Mean ± SD)	Normal Saline Group (Mean ± SD)	p-value
1 hour	5.93 ± 2.08	8.03 ± 1.40	<0.001
2 hours	5.37 ± 2.31	7.13 ± 2.51	0.006
4 hours	4.83 ± 2.10	6.37 ± 1.49	0.001

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6 hours	4.67 ± 1.86	6.03 ± 1.29	0.001
12 hours	3.73 ± 1.61	5.17 ± 1.17	<0.001
24 hours	3.10 ± 1.29	4.67 ± 1.32	<0.001

Postoperative Nausea and Vomiting (PONV)

The incidence of postoperative nausea and vomiting was comparable between the two groups at all time intervals, with no statistically significant differences (p>0.05). No cases of nausea or vomiting were reported after 12 hours postoperatively.

Table 6: Postoperative Nausea

Time	Lidocaine Group	Normal Saline Group	p-value
1 hour	8	5	0.347
2 hours	8	8	1.000
4 hours	18	13	0.196
6 hours	17	13	0.302
12 hours	4	6	0.488
24 hours	0	0	—

Table 7: Postoperative Vomiting

Time	Lidocaine Group	Normal Saline Group	p-value
1 hour	1	1	1.000
2 hours	2	4	0.389
4 hours	6	5	0.739
6 hours	5	2	0.228
12 hours	0	2	0.150
24 hours	0	0	—

Postoperative Shoulder Tip Pain

Shoulder tip pain was observed in both groups, peaking between 4 and 12 hours postoperatively. There was no statistically significant difference between the groups at most time intervals (p>0.05), except at 24 hours, where a higher incidence was noted in the saline group (p=0.044).

Table 8: Postoperative Shoulder Tip Pain

Time	Lidocaine Group	Normal Saline Group	p-value
1 hour	2	2	1.000
2 hours	7	8	0.766
4 hours	21	22	0.774
6 hours	25	24	0.739
12 hours	26	22	0.197
24 hours	1	6	0.044

Hemodynamic Parameters

Postoperative pulse rate and mean arterial pressure (MAP) remained stable and comparable between the two groups at all time intervals. No statistically significant differences were observed (p>0.05), indicating hemodynamic safety of the intervention.

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Table 9: Hemodynamic Parameters (Mean Values)

Time	Lidocaine	Saline	p-value
1 hr	79.17	81.73	0.288
24 hr	78.60	78.53	0.971
Time	**Lidocaine**	**Saline**	**p-value**
1 hr	89.84	91.24	0.536
24 hr	89.62	88.82	0.621

Discussion

Between May 2023 and November 2024, a prospective randomized comparative study was carried out to assess how well lidocaine-induced subserosal tumescence reduced postoperative pain after laparoscopic cholecystectomy. Pre-operative, intra-operative, and post-operative data were used to evaluate the 60 patients who were randomized into lidocaine and normal saline groups.

Participants in the lidocaine group were 37.13 years old on average, whereas those in the saline group were 39.43 years old. Both groups were dominated by females, which is consistent with the well-known fact that gallstone disease is more common in women because estrogen causes an increase in biliary cholesterol saturation. The most prevalent comorbidity was hypertension, which was followed by hypothyroidism and diabetes mellitus. These illnesses have been linked to gallstone disease in the past through mechanisms like metabolic syndrome and dyslipidemia. (7). With the exception of gallbladder sludge ($p < 0.05$), other pre-operative measures, including clinical symptoms, laboratory tests, and ultrasonographic features, showed no statistically significant differences between the two groups. The Visual Analog Scale (VAS), which measures postoperative pain, peaked in the first hour following surgery and then progressively decreased over the course of the following day. During every recorded interval, the lidocaine group showed a statistically significant decrease in pain levels, with the biggest difference happening during the second postoperative hour. (8). After the second hour, there was a noticeable decrease in VAS differences, which continued to be comparatively constant from the 4^{th} to the 24^{th} hour. (9).

There was no discernible difference in postoperative nausea and vomiting (PONV) between the two groups. Vomiting and nausea were absent after the twelfth postoperative hour and were most common between the fourth and sixth hours. Likewise, with no discernible intergroup variation, postoperative shoulder tip discomfort peaked between the 4^{th} and 12^{th} hours. (10), (11).

Nebulization or intraperitoneal instillation of local anesthetic drugs has been shown in prior research to improve hemodynamic stability and lessen postoperative discomfort. None, meanwhile, has assessed local anesthetic drugs' subserosal infiltration in Calot's triangle. (12). Thus, the current study emphasizes the technique's potential advantages and uniqueness in lowering postoperative pain after laparoscopic cholecystectomy.

Generalizability

"Findings of this study can be generalized to patients undergoing elective laparoscopic cholecystectomy in similar tertiary care settings. However, applicability may be limited in emergency cases or patients with complex comorbidities."

Add Limitations

"This study has certain limitations. The sample size was relatively small and was conducted at a single center, limiting external validity. The study design was not randomized, which may introduce selection bias. Pain perception is subjective and may vary among individuals."

Recommendations

"Further multicentric randomized controlled trials with larger sample sizes are recommended to validate these findings and assess long-term outcomes."

Conclusion

In comparison to a placebo (normal saline), the current study shows that the tumescence of Calot's triangle with lidocaine considerably lowers postoperative pain following laparoscopic cholecystectomy. The analgesic effect was less noticeable in instances with recent acute cholecystitis or longer surgical duration, although it was more noticeable in females, younger patients, and those with higher BMI. Shoulder tip pain and postoperative nausea and vomiting (PONV), which usually went away within 24 hours, were not significantly affected by tumescence with lidocaine. Lidocaine infiltration is a safe and efficient method for managing postoperative pain, as evidenced by the study's

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stable hemodynamic parameters and lack of adverse responses.

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Conflict of Interest
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Informed Consent
"Written informed consent was obtained from all participants."

Data Availability
"Data supporting the findings of this study are available from the corresponding author upon reasonable request."

Author Contribution
"Priyanka: Study design, data collection
Babita Chettri: Analysis, manuscript writing
Shashank Aswal: Data interpretation
Kumar Nishant: Supervision and final approval."

List of Abbreviations
- VAS – Visual Analog Scale
- PONV – Postoperative Nausea and Vomiting
- BMI – Body Mass Index
- CBD – Common Bile Duct

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