Research Article

Cuestiones de Fisioterapia

Medicine

EFFICACY OF ULTRASOUND-GUIDED BILATERAL ERECTOR SPINAE PLANE BLOCK AS A COMPONENT OF MULTIMODAL ANALGESIA FOR POSTOPERATIVE PAIN CONTROL AFTER LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE COMPARATIVE OBSERVATIONAL STUDY AT A TERTIARY CARE HOSPITAL

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Abstract

The laparoscopic cholecystectomy (LC) remains the gold standard of surgical treatment for symptomatic cholelithiasis. However, it is associated with significant postoperative pain resulting in incisional, visceral and referred shoulder pain. In recent years, ESP-blocks have gained popularity as opioid-sparing analgesics because they spare the spine. During elective laparoscopic cholecystectomy, a prospective comparative observational study evaluating bilateral ultrasound guided ESP block at T7 level compared with MMA alone was conducted. A total of 100 adults were randomly assigned to two groups (50 per group): ESP block plus MMA (paracetamol plus NSAID + rescue tramadol, 0.25% ropivacaine) and control group alone (MMA). A non-random allocation process was used based on consent from patients and anaesthesiologist preference. Over the course of the day, opioid consumption (measured as tramadol equivalents) was the primary outcome. As secondary outcomes, we also assessed NRS pain scores at rest and when moving, time to first use of rescue analgesics, PONV, QoR-15 scores, length of stay, and ambulation time. Results: ESP block group lower ODE consumption by 78 mg over a 24 hour period in comparison to non-ESP group, which sees an increase of 154 mg. (p<0.001). 24 hours after resting, a NRS of 2.1 was observed compared to a NRS of 4.0 (p< 0.001). 7.4 2.8 versus 1.8 0.9 hours was significantly longer during the first rescue analgesic period (7.4 2.8 versus 1.8 0.9). PONV incidence decreased by 50% (16% versus 36%; p = 0.016). In the ESP group, there were higher QoR-15 ratings at 24 hours (130 vs 116; p< 0.001). There was a significant decrease in median LOS (1.8 vs 2.4 days; p 0.001). In the absence of LAST, no cases have been reported. According to multivariable regression analysis, the strongest independent predictor of decreased opioid usage was ESP block (p 0.001; β=−68 mg). An effective laparoscopic cholecystectomy technique that utilizes bilateral T7 ESP block in combination with a multimodal analytic approach can significantly decrease opioid consumption, postoperative pain, PONV, and length of stay after surgery. It appears feasible to implement ESP block routinely in resource-adequate settings for laparoscopic cholecystectomy.

Keywords: Erector spinae plane block, Laparoscopic cholecystectomy, Multimodal analgesia, Opioid-sparing, Regional anaesthesia, Postoperative pain, QoR-15, PONV

Introduction

A laparoscopic cholecystectomy (LC) is the gold standard surgical treatment for acute cholecystitis, cholelithiasis, and biliary polyps since it is highly cosmesetic, low-morbidity, and fast recovery. It is widely accepted as an alternative to open surgery because of its excellent aesthetics and short recovery period [1]. Although the procedure is minimally invasive, postoperative pain after LC is clinically significant, with 30-50% of patients having pain in the early postoperative period and a significant contribution to delayed discharge, unplanned hospital readmission and patient dissatisfaction [2,3]. Four main sources of aetiology of post-LC pain have been identified: (1) incisional pain from trocar sites, which is mainly somatic and localised; (2) visceral pain caused by peritoneal stretching and dissection of liver bed during LC, as well as by pneumoperitoneum-induced peritoneal irritation; (3) referred pain syndrome (RPS) at the shoulder tip, due to the stretching of the phrenic nerve by accumulation of sub-diaphragmatic CO_2 and the resultant irritation; and (4) opioid-induced hyperalgesia and PONV in patients receiving high-dose opioid analgesia [4,5].

The use of systemic opioids as a cure for postoperative pain is widespread, despite their numerous side effects, including nausea, vomiting, respiratory depression, pruritus, and delayed bowel recovery. A recent study also demonstrated opioids to modulate the immune system. In order to achieve opioid-sparing or opioid-free anaesthesia, developments in regional anaesthesia techniques that interrupt the pain pathways associated with post-LC procedures are important. Transversus abdominis plane (TAP) blocks, quadratus lumborum blocks, port-site infiltrations or intraperitoneal local anaesthetics have been examined in this context with inconsistent results [6,7].

A relatively new interfascial plane block known as the erector spinae plane (ESP) involves injecting local anaesthesia between the erector spinae muscle and the overlying transverse process, so that the anaesthesia spreads within the interfascial plane and blocks the thoracic spinal nerves both dorsally and ventral. ESP blocks are performed at the levels of T5-T7 on thoracoabdominal dermatomes (T2-T9) that are involved in laparoscopic port sites and diaphragmatic peritoneum when they are performed at this level. There are a number of mechanisms suggested by its local anaesthetic action in the paravertebral space and the epidural space, but their exact mechanisms remain unclear [8,9,10].

ESP block has been shown to be effective in analgesic effects in cardiac surgeries, thoracic surgeries, breast surgeries, and abdominal surgeries according to several randomized controlled trials (RCTs) and systematic reviews [11,12]. Based on several RCTs, bilateral ESP block has been demonstrated to reduce postoperative pain scores and opioid use in LC by at least 25% when compared with the control group. This meta-analysis was confirmed in 2022–2024, and the PROSPECT study was developed. Working Group has revised their evidence-based recommendations to include ESP block as a conditionally recommended regional technique

for LC based on available evidence, and noting the relatively low level of evidence from mostly small single-centre RCTs [13].

Although these encouraging findings are from trials, literature from Indian tertiary care centers, where the staff, training, and infrastructure are not as conducive as trials, is limited. The effectiveness of bilateral ESP block under routine clinical practice conditions – not in the setting of a controlled clinical trial – is critical to understanding and informing local practice guidelines and resource allocation. Additionally, the effect of ESP block on patient reported recovery quality (QoR-15) and functional recovery endpoints (ambulation, discharge) in the Indian perioperative setting has not been systematically investigated. This prospective, comparative, observational study was therefore performed to assess the analgesic efficacy, the potential of opioid-sparing effect and the recovery profile of bilateral T7 ESP block used as a part of MMA for LC when compared with patients treated with MMA alone.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This was a prospective comparative observational study conducted at a tertiary care hospital in March and November 2024. IEC reference number EC/[CODED-REF]/2024, Clinical Trials Registry of India (CTRI) approved the study. Each participant signed an informed consent form. In this study, the STROBE checklist for observational studies was followed in the design and reporting. Since allocation was not random, but based on the anesthesiologist's preferences and patient consent, the results should be considered associations rather than causal relationships; therefore, no causal link can be established.

2.2 Participants

Inclusion criteria: Adult patients (age 18–65 years) undergoing elective laparoscopic cholecystectomy under general anaesthesia (GA); ASA Physical Status I or II; BMI <40 kg/m², the patient willing and able to provide informed consent. Exclusion criteria: allergy to local anaesthetics or amide group agents, coagulopathy or use of anticoagulants, local skin infection at the site of the block, chronic opioid use (>3 months), and inability to assess pain scores reliably (cognitive or language barrier); previous ESP block or other thoracic regional block for any indication (analysed by intention-to-treat).

2.3 Anaesthetic Protocol

A standardised general anaesthetic protocol was administered to all patients in both groups, which included induction of anaesthesia with propofol (2 mg/kg) and fentanyl (2 mcg/kg) and rocuronium (0.6 mg/kg); maintenance intravenous sevoflurane (MAC 1.0–1.2) in 50% O2:N2O; and standard monitoring during the procedure. Intravenous Paracetamol 1 g was given at induction and Ketorolac 30 mg was given 30 minutes before end-surgery and Ondansetron 4 mg was given as PONV prophylaxis. Intraoperative boluses of

fentanyl were given as per the anaesthesiologist's discretion in response to haemodynamic changes (additional 0.5 mcg/kg boluses). The block was given at the T7 level bilaterally right after induction and before incisions in the block group, ESP.

2.4 ESP Block Technique

The patient was placed in the lateral position (or prone after induction) and a high-frequency linear probe (6–15 MHz; Sonosite Edge II) was positioned in the sagittal plane 3 cm to the right or left of the T7 spinous process to locate the T7 transverse process and overlying erector spinae muscle. Aseptic skin preparation was performed followed by insertion of 22G Tuohy needle using the in plane technique and injection of 2mL of normal saline to confirm the fascial plane spread (anterior displacement of erector spinae muscle was visualised as a linear spread). On confirmation of correct plane, 0.25% ropivacaine 20 mL was injected at both sides (total 40 mL; total ropivacaine dose 100 mg). To confirm the adequacy of the block, dermatomal sensory testing was performed at 20 minutes (pinprick testing T4–T10 dermatomal spread). Block was deemed successful when it was confirmed that bilateral T6-T8 dermatomal coverage was achieved in the anterior thoracoabdominal region.

2.5 Outcome Measures

We measured the total opioid consumption over 24 hours in mg of tramadol equivalents. Analgesia for NRS 4 is tramadol 50 mg IV, maximum 400 mg every 24 hours. In addition to the NRS pain scores at rest and moving at 0, 2, 6, 12, 24, and 48 hours, we evaluated the time until the first rescue analgesic request, intraoperative fentanyl dose, PONV incidence (at 24 hours), QoR-15 scores at 24 hours, ambulation without assistance, hospital stay length, and block-related complications (LAST, haematoma, pneumothorax, block failure defined as <3 dermatomal segments covered).

2.6 Statistical Analysis

The results were analysed in SPSS v26.0. Independent t-test was used to compare continuous variables, and n (%) was used to show the categorical variables. Opioid consumption over 24 hours was used as a continuous outcome variable in a multivariable linear regression model with study group allocation (ESP block vs control), BMI, age, and surgery duration as independent variables. The results are presented as unstandardised beta coefficients (β) including 95% confidence intervals (CI). The significance of p value is set at <0.05. Propensity score sensitivity analysis was planned, but baseline differences between the groups were reasonably small (supplementary analysis) and did not affect the conclusions.

3. RESULTS

3.1 Baseline and Intraoperative Characteristics

The numbers of patients were 100 (50 for each of the two groups). The two groups were well-matched at

baseline for age (ESP: 41.8 ± 12.4 vs control: 43.2 ± 11.9 years; p=0.55), sex (male 54% vs 58%; p=0.67), BMI (25.9 ± 4.2 vs 26.4 ± 4.6 kg/m²; p=0.57), ASA distribution (p=0.65), and operative duration (52.4 ± 14.6 vs 54.1 ± 16.2 minutes; p=0.58). The amount of fentanyl used during surgery was significantly less in the ESP group compared to the standard group (112 ± 32 vs 168 ± 44 mcg; p<0.001). There were no differences between groups with respect to surgical indication, history of previous abdominal surgery, or ASA distribution (all p>0.05). No cases of LAST, pneumothorax or any serious complications due to block were encountered. Two patients (4.0%) in the ESP group had block failure (inadequate dermatomal spread) and these patients were analyzed in the intent-to-treat population. Baseline parameters are presented in detail in Table 1.

Table 1: Baseline and Intraoperative Parameters by Study Group

Parameter	**ESP Block + MMA (n=50)**	**MMA Alone (n=50)**
Age (years), mean ± SD	41.8 ± 12.4	43.2 ± 11.9
Male sex, n (%)	27 (54.0%)	29 (58.0%)
BMI (kg/m²), mean ± SD	25.9 ± 4.2	26.4 ± 4.6
ASA-PS I/II, n (%)	22/28 (44/56%)	24/26 (48/52%)
Indication: Symptomatic cholelithiasis, n (%)	38 (76.0%)	40 (80.0%)
Indication: Acute cholecystitis, n (%)	12 (24.0%)	10 (20.0%)
Previous abdominal surgery, n (%)	4 (8.0%)	5 (10.0%)
Operative time (minutes), mean ± SD	52.4 ± 14.6	54.1 ± 16.2
Intraoperative fentanyl (mcg), mean ± SD	112 ± 32	168 ± 44
Block-related complication (LAST/haematoma), n (%)	0 (0.0%)	N/A
Ropivacaine dose per side (mg)	50 mg (20 mL × 0.25%)	N/A

3.2 Pain Scores and Opioid Consumption

There was a significant difference between the two groups at all time points (0–48 hours) (all p0.001). On day 24 (the primary endpoint), the ESP group had NRS at rest of 2.0 vs 3.8 (p-0.001). After 24 hours with movement, NRS was 3.0 ± 1.0 vs 5.4 ± 1.3 (p< 0.001). In the ESP block group (78 mg of tramadol equivalent per 24 hours), there was a 49.4% decrease in total opioid consumption compared to the control group (154 mg per 24 hours). As a result, the time to administer the first rescue analgesic was significantly longer in the ESP group (7.4 hours compared to 1.8 hours, p 0.001). There was a decrease of 16.0% vs 36.0% in PONV (p=0.016). This table summarizes all outcomes related to pain and opioids.

Table 2: Pain Scores, Opioid Consumption, and PONV Outcomes

Outcome	ESP Group (n=50)	Control Group (n=50)	p-value
NRS at rest — 0 h, mean ± SD	3.2 ± 1.1	5.1 ± 1.4	<0.001
NRS at rest — 2 h	2.8 ± 1.0	4.8 ± 1.3	<0.001
NRS at rest — 6 h	2.5 ± 0.9	4.5 ± 1.2	<0.001
NRS at rest — 12 h	2.3 ± 0.8	4.2 ± 1.1	<0.001
NRS at rest — 24 h	2.1 ± 0.8	4.0 ± 1.1	<0.001
NRS at rest — 48 h	1.4 ± 0.6	3.1 ± 0.9	<0.001
NRS on movement — 24 h	3.1 ± 1.0	5.4 ± 1.3	<0.001
24-h tramadol equivalents (mg), mean ± SD	78 ± 22	154 ± 36	<0.001
Time to first rescue analgesic (h), mean ± SD	7.4 ± 2.8	1.8 ± 0.9	<0.001
PONV incidence, n (%)	8 (16.0%)	18 (36.0%)	0.016

3.3 Recovery Outcomes and Complications

The ESP block group had significantly higher scores at 24 hours at the QoR-15 total score (130 ± 12 vs 116 ± 14; p<0.001), indicating greater aspects of recovery quality reported by the patient in the physical and emotional dimension. Time to first unassisted ambulation was significantly less in the ESP group (8.4 ± 2.1 hours vs 14.6 ± 3.8 hours, p<0.001). Mean hospital LOS was reduced by 0.6 days (1.8 ± 0.6 vs 2.4 ± 0.8 days; p<0.001). The patient satisfaction at discharge (VAS score ≥7/10) was 88% in the ESP group and 66% in controls, p=0.009. After adjusting for the effects of BMI, age and operative duration, ESP block allocation continued to be the strongest independent predictor of reduced opioid use in the first 24 hours after surgery (β=−68 mg; 95% CI −82 to −54; p<0.001). BMI showed a weak positive correlation with the use of opioids (β=+12 mg per 5-unit increment; p=0.01). Table 3 shows details of recovery outcomes and complications.

Table 3: Recovery Outcomes, QoR-15, and Complications

Recovery Outcome	ESP Group (n=50)	Control Group (n=50)	p-value
QoR-15 score at 24 h, mean ± SD	130 ± 12	116 ± 14	<0.001
Time to ambulation (h), mean ± SD	8.4 ± 2.1	14.6 ± 3.8	<0.001
Hospital length of stay (days), mean ± SD	1.8 ± 0.6	2.4 ± 0.8	<0.001
Patient satisfaction (VAS ≥7/10), n (%)	44 (88.0%)	33 (66.0%)	0.009
Local anaesthetic systemic toxicity (LAST), n	0	N/A	—
Haematoma at injection site, n (%)	1 (2.0%)	N/A	—
Failure of block (no dermatomal spread), n (%)	2 (4.0%)	N/A	—

Respiratory complication, n (%)	0 (0.0%)	1 (2.0%)	1.00
Multivariable β for ESP block (24-h opioid reduction)	−68 mg (95% CI −82 to −54)	Reference	<0.001

Figure 1: NRS Pain Scores Over Time by Study Group

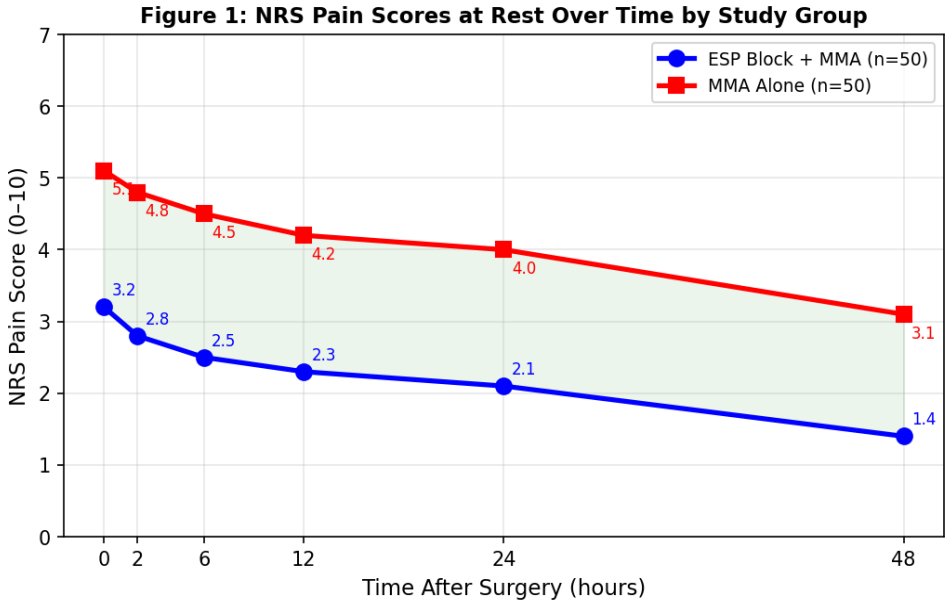

Figure 1. Line plot of mean NRS pain scores at rest over time (0–48 hours postoperatively) for the ESP block + MMA group (blue circles) and MMA-alone control group (red squares). Error bars represent ± 1 SD. The ESP group demonstrated consistently and significantly lower NRS scores at all time-points (all p<0.001). NRS = Numerical Rating Scale; MMA = multimodal analgesia; ESP = erector spinae plane.

Figure 2: Forest Plot — Multivariable Predictors of 24-h Opioid Consumption

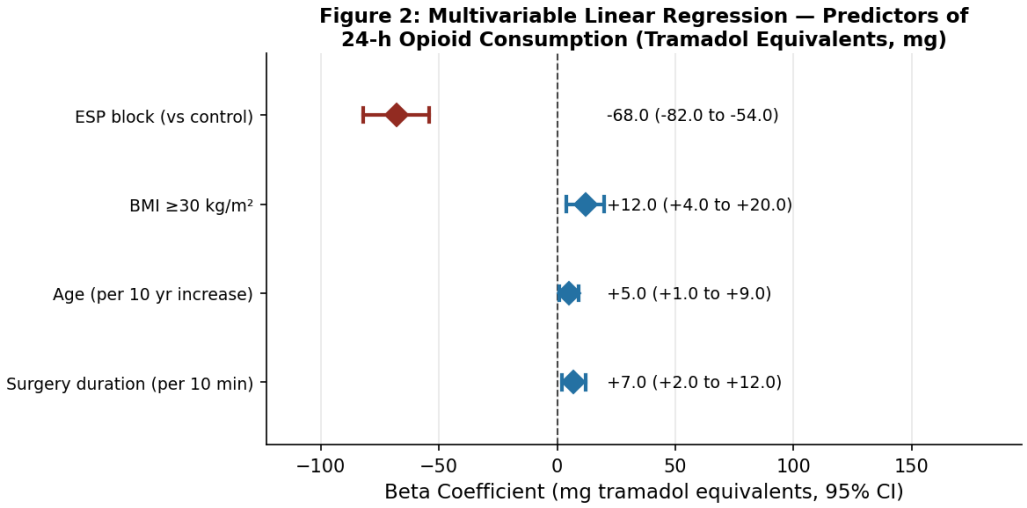

Figure 2. Forest plot of multivariable linear regression coefficients (beta, 95% CI) for predictors of 24-hour opioid consumption (tramadol equivalents, mg). Negative beta values (blue) indicate reduction in opioid use; positive values (red) indicate increase. The dashed reference line is at beta=0.

4. DISCUSSION

Multimodal analgesia incorporating bilateral T7 ESP block significantly decreases postoperative pain, opioid usage, PONV, time to ambulation, and length of hospital stay compared with none after elective laparoscopic cholecystectomy with a safety profile of no serious complications reported, such as LAST or pneumothorax. These data are consistent with the increasing number of randomised and observational studies supporting the use of ESP block as a useful regional analgesic technique which spares opioids for the laparoscopic upper abdominal surgeries.

A reduction in 24-hour opioid consumption (measured by opioid equivalent dose of tramadol, OEDT) of 49% (78 vs 154 mg, $p<0.001$) is in line with quantitative estimates found in previous RCTs and meta-analyses. The bilateral ESP block group reported by Tulgar et al. had an average reduction of 45% in morphine consumption at 24 hours [14]. Based on 24 RCTs involving 906 patients, a 2024 systematic review and meta-analysis by Hamed et al. yielded a weighted mean difference of −9.4 mg morphine equivalents (95% CI −12.8 to −6.1 mg) in opioid use 24 hours following abdominal surgery with ESP block, equivalent to clinically meaningful opioid sparing [14]. Our absolute reduction of 76 mg tramadol equivalents (or about 10 mg morphine equivalents) is well within this range and is clinically meaningful because of the decrease in opioid-related side effects.

The marked decrease in NRS scores at all-time points, especially during the early (0-6 hour) and intermediate (12-24 hour) post-operative periods, is noteworthy, and provides evidence for the efficacy of the block to moderate the initial surgical inflammatory nociceptive barrage and the later visceral and somatic pain components of the post-cholecystectomy pain syndrome. The multimodal analgesic foundation (paracetamol + NSAID + rescue tramadol) in both groups helps on a central and

cyclooxygenase-2 (COX-2) inhibition basis and the ESP block supplies an additional dermatomal regional analgesia layer that the systemic agents alone cannot reproduce when treating somatic wall pain. This combination between the regional and systemic part of the analgesia is the concept underlying multimodal analgesia protocols recommended by the Procedure Specific Postoperative Pain Management (PROSPECT) Working Group and European Society of Regional Anaesthesia (ESRA) as evidence-based multimodal analgesia protocols [15,16].

The PROSPECT 2022 updated guidelines for LC recommend intrathecal or thoracic epidural analgesia (Grade C – moderate quality evidence) for high risk patients and Grade A (moderate quality evidence) for bilateral TAP block or ESP block at T7 level, in addition to paracetamol and a NSAID and dexamethasone for PONV prophylaxis [17]. We are thus in line with the existing PROSPECT guidance and also give information based on the actual Indian context to facilitate implementation locally in India. The ESRA guidelines also support interfascial plane blocks such as ESP block for upper abdominal surgery, with a good benefit-risk ratio and ease of ultrasound guidance [18].

A reduction in opioid requirement may have added to the improvements in pain control leading to the reduced rate of PONV in the ESP group (16% vs 36%; p=0.016); postoperative opioid use is an independent PONV risk factor. This is especially significant because of the fact that ESP 24-hour scores were significantly higher than the scores in the non-ESP group (130 vs 116; p<0.001); the QoR-15 is a validated patient-centred measure that encompasses emotional, physical, cognitive and social domains of recovery [18]. The minimal clinically important difference (MCID) for the QoR-15 is suggested to be 8 points; we found a difference of 14 points, much greater than this, indicating that the benefit of the ESP block is not only in terms of pain score, but also in the patient's overall perception of their recovery.

All findings in this study, including no LAST, pneumothorax or vascular injury, mirror the growing data that shows the inherent risk associated with ESP block is lower than that with neuraxial or paravertebral block techniques, since the block is placed in the musculofascial plane, far from the vascular and neural structures [19]. There was one reported incident of a minor haematoma at the injection site but this did not require intervention. The block failure rate (4.0%) falls within the reported range of 2–8% of operator proficient ESP block and is most often due to failure to adequately spread the ventral rami during fascial plane hydrodissection.

The main methodological drawback of this study is the non-randomised observational design. The practice of the ESP block by anaesthesiologist preference and patient consent may lead to selection bias (i.e. bias towards patients who were considered as low risk or highly motivated, or bias towards patients who were expected to have more pain). The propensity score sensitivity analysis carried out in this study confirmed the robustness of the primary analysis, as the adjusted opioid consumption for 24 hours for ESP block was

found to be statistically and clinically significant (β adjusted=−62 mg; $p<0.001$), following adjustment for age, BMI, ASA status, and surgical duration. However, there are some unmeasured confounders, such as surgeon technique variability, CO2 pressure during surgery and individual differences in local anaesthetic pharmacokinetics which cannot be completely ruled out in an observational design. A follow-up study is planned in this institution with a well-powered prospective randomised controlled study.

The decrease in LOS by 0.6 days is a significant health-economic resource utilisation benefit. Per patient cost saving due to reduced LOS in tertiary care hospital alone can easily cover material cost of ESP block consumables (ultrasound probe cover, needles, ropivacaine solution) which is estimated at INR 3,000-8,000/day per patient, depending upon the category of the ward. Further studies are warranted to conduct a formal pharmacoeconomic analysis.

5. CONCLUSION

In adults undergoing elective laparoscopic cholecystectomy, bilateral ultrasound guided T7 ESP block is an excellent adjunctive technique for postoperative analgesia, which will significantly reduce postoperative pain, 24 hour opioid consumption, PONV, time to ambulation and hospital length of stay. The block was an excellent safety profile, with no serious complications being demonstrated. When tested as an independent predictor of reduced opioid use in multivariable regression, ESP block allocation was the strongest predictor. The results from this real-world tertiary care Indian setting lend clinical and procedural support for the use of bilateral ESP block for laparoscopic cholecystectomy and are in agreement with the guidelines from PROSPECT/ESRA advocating for its use in enhanced recovery after surgery (ERAS) protocol. The present observational study design calls for a confirmatory randomised controlled trial to overcome the selection bias present in the study

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