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Opioid Free Anesthesia for Laparoscopic Cholecystectomy; A Randomized Control Trial at a Tertiary Care Hospital

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Abstract

Objectives: This study evaluated the role of Erector Spinae Plane Block as a non-opioid analgesic regimen for Laparoscopic Cholecystectomy in terms of intraoperative and postoperative analgesia.

Methods: This double-blind randomized control trial included patients aged 16-80 years, ASA-PS I, II who underwent elective laparoscopic cholecystectomy of less than 1h. The participants were randomly divided into Group E vs Group O. The primary outcome measures were adequacy of intra-operative and post-operative analgesia in terms of intra-operative hemodynamics and post-operative Visual Analog Scale. The secondary outcome measures were the amount of intra-operative rescue IV fentanyl and total analgesics consumed in 6 hours postoperatively.

Results: 72 participants were enrolled. Intraoperatively DBP, MAP, and HR upon skin incision and pneumoperitoneum along with MAP and HR at the end of surgery were significantly lower in group E vs group O. The median intra-operative rescue opioid consumption in group O was 57.5 Mcg while group E was 0.00 (p-value < 0.001). Postoperatively pain scores were significantly lower in group E vs group O. Postoperatively IV Tramadol was given to 4 patients in group O vs 0 in group E. Post-operative consumption of IV Paracetamol was 2.0 in group O vs 1.0 in group E (p-value of <0.001). Post-operative IV Ketorolac consumption in group O was 15.0 mg vs 0.0 in group E (p-value <0.001).

Conclusions: Pre-incisional ESPB in laparoscopic cholecystectomy is an effective regional anaesthetic technique which greatly reduces analgesic consumption and enhances the quality of post-operative recovery.

Keywords: Laparoscopic Cholecystectomy, Non Opioid Analgesic, Nerve Block, Acute Post-operative Pain

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Introduction

Daycare surgical procedures utilize the principles of Enhanced Recovery After Surgery (ERAS) to accelerate post-operative recovery resulting in early discharge. Among many components of ERAS minimal invasive surgery, multi-modal pain management, minimal use of opioids and early mobilization were found to be most effective in decreasing length of hospital stay and readmission rates.[1] One of the most commonly performed minimally invasive daycare surgeries is Laparoscopic Cholecystectomy. However, early pain after laparoscopic cholecystectomy is multi-factorial in origin which is similar or even more intense than open cholecystectomy.[2] The different pain management options include IV lidocaine infusion, intra-peritoneal instillation of local anaesthetics, Neuraxial block, Transversus Abdominis plane block, incisional infiltration of local anaesthetics, opioids, NSAIDS and Paracetamol. Each technique or class of drug is associated
with several side effects. Opioids effectively treat surgical pain but cause sedation, nausea, vomiting, pruritis, constipation and respiratory depression.[3]

This can delay recovery and discharge from hospital settings. IV Lignocaine infusion for effective pain relief has to be administered for 24 hours in a strictly monitored environment as it is a high-risk medicine with its administration should be done on risk to benefit ratio.[2,4] Routine use of Neuraxial blocks and Transversus Abdominis plane block to manage pain is not recommended[2]. Recently Erector Spinae Plane Block (ESPB) has been utilized for pain management in Laparoscopic Cholecystectomy so that opioid consumption can be minimized and ERAS goals can be achieved. In a randomized control trial, pre-incisional ESPB along with IV Lignocaine, Magnesium, Paracetamol and NSAIDs resulted in better post-operative pain control while intraoperative hemodynamics were similar to the patients treated with a conventional opioid-based regimen.[5] ESPB is a novel regional anaesthetic technique which was labelled as one of the seven plan A blocks by Regional Anaesthesia UK and is effective in providing analgesia for thoracoabdominal surgeries.[6] The block is relatively easy to perform with relatively few side effects as the site of injection is far from the pleura, blood vessels and spinal cord.[7] Literature has shown that ESPB is an effective alternative to single shot epidural and was found to be effective in managing pain and improving pulmonary function among patients of chest trauma.[8] Furthermore, it has been shown that ESPB provided longer post-operative analgesia, less opioid consumption and better hemodynamic stability as compared to single-shot epidural among patients undergoing lumbar spine surgery.[9] Thus, ESPB which is a safer alternative to single-shot epidural anesthesia, can be utilized to provide effective peri-operative analgesia to patients undergoing laparoscopic cholecystectomy. This study compared the effectiveness of single-shot ESPB versus conventional opioid base analgesia in terms of intra-operative and post-operative analgesia.

Materials And Methods

This double-blind randomized control trial was carried out from 15th January 2024 to 31st August 2024 at the Department of Anesthesia and Critical Care Medicine, Pakistan Institute of Medical Sciences, Islamabad after approval from the Institutional Ethics Review Board (Approval no. F.3-2/2022(ERRB)/PIMS; dated: 2-11-22). The trial was registered at ClinicalTrials.gov (NCT06202664). Written informed consent was obtained before enrolling participants in the study. Respect for patient privacy, confidentiality and autonomy was observed. The sample size was calculated using the Open Epi calculator; the confidence interval was kept at 95%, the power of the test was 80%, and the Mean MAP for group 1 was 92.53(8.10) while for group 2 was 87.22(7.76) 5. The total sample size was 72 (36 in each group). Patients were enrolled according to inclusion criteria i.e. age 16-80 years, ASA class I, II and elective laparoscopic cholecystectomy of less than 1h duration. Patients who have neuromuscular disease, body mass index >35 kgm^{-2}, known allergy to local anaesthetics, history of Ischemic Heart disease, Cardiac Failure, and Liver and Renal insufficiency were excluded from the study. None of the participants were lost or dropped out during follow-up. The enrolled participants were divided into two groups (Group O vs Group E) using computer-generated random numbers with a ratio of 1:1. Allocation concealment was achieved by enclosing the assignments in sealed, opaque and sequentially numbered envelopes, which were opened only after the arrival of the patient in the operating theatre. Anaesthetic induction and intervention were administered by an experienced anaesthetist who was not involved in outcome assessment. Both participant and outcome assessor were kept blinded during the period of assessment or till any signs of local anaesthetic toxicity became evident. All the participants were brought into the OR after 8 hours of fasting for solid food and 2 hours for clear water. Upon arrival in the OR standard ASA monitoring was attached, 18G IV line maintained and infusion Ringer Lactate started. All patients were induced with IV Midazolam 1mg, IV Propofol 2mg/kg, and IV Atracurium 0.5 mg/kg. The airway was secured with a cuffed endotracheal tube. Group O patients received conventional opioid base anaesthesia at the time of induction. IV Fentanyl 1 Mcg/kg was administered to group O patients. Group E patients received an Erector Spinae plane block after induction of anaesthesia. They were placed in a lateral position and the Ultrasound probe was placed in the longitudinal axis, The transverse process of T6 vertebrae and overlying erector spinae muscle were identified. The needle was introduced by in-plane technique from the cranio-caudad direction and hydro dissection was done using sterile water which lifted off the erector spinae muscle indicating correct needle placement. After negative aspiration 30ml Bupivacaine 0.25% and 10ml Lignocaine 1% were administered bilaterally. The skin incision is given 15 minutes after ESPB administration. A balanced anaesthesia technique was used to maintain anaesthesia. The primary study outcome was the adequacy of intra-operative and postoperative analgesia among the two groups as determined by a comparison of intraoperative hemodynamics and postoperative VAS scores. VAS scores were determined at rest and on cough at 1 hourly interval from the time of arrival in PACU to 6 h postoperatively. The secondary outcome measures were the total amount of intra-operative rescue IV Fentanyl consumed and total IV analgesics consumed in the first 6 hours following surgery. The administration of rescue analgesia was dictated by intraoperative hemodynamics and post-operative VAS score. Intraoperatively a rise in heart rate ± blood pressure by more than 20% from baseline particularly upon skin incision and at generation of pneumoperitoneum indicated ineffective analgesia provided other causes were ruled out. Analgesia was then supplemented with IV Fentanyl 1 Mcg/kg, IV Paracetamol 1g and IV Ketorolac 30 mg. Posts operatively if VAS score was > 4 then IV Paracetamol 1g was given and if VAS > 6 then IV Ketorolac 15mg along with IV Paracetamol 1g was given. The dosing interval between two successive doses of Paracetamol and Ketorolac was kept for 4 hours. IV Tramadol 50 mg was given if the VAS> 8. Incidence of PONV, different types of post-operative complaints and time till mobilization were noted.

Data collected was then analyzed using Statistical Packages for Social Sciences (SPSS) version 26.0. Qualitative variables such as sex, ASA class, and different types of post-operative complaints were calculated in terms of frequency and percentage. Quantitative variables such as age, intra-operative hemodynamics, postoperative VAS score, number of episodes of PONV, and time till mobilization were assessed for normality using the Shapiro-Wilk test. Parametric data were described in terms of mean scores, standard deviation and independent t-test. Non-parametric data was described in terms of median, Interquartile range and Mann-Whitney U test. A p-value less than 0.05 was considered to be significant. Confidence interval (CI) was kept at 95%

Results

Out of 72 participants, 63(87.5%) were female while 9(12.5%) were male having similar distribution across groups. The distribution of ASA-PS was similar across groups with 25 (69.4%) participants in group O labelled ASA-I and in group E 24(66.7%) participants were labelled ASA-I. The mean age of presentation was similar across the two groups (38.77 ± 12.4 vs 40.06 ±12.07 years). The distribution of weight was also similar across the two groups (67.22 ± 6.45 vs 65.83 ± 5.43 kg). The baseline hemodynamics are shown in Table 1.

Table 1: Comparison of baseline parameters

	Group O (n=36)	Group E (n=36)	p-value
Baseline SBP	128.75 ± 12.33	130.50 ± 8.54	0.466
Baseline DBP	81.28 ± 8.38	82.05 ± 9.22	0.709
Baseline MAP	96.19 ± 11.37	94.25 ± 10.67	0.457
Baseline HR	86.02 ± 11.55	90.14 ± 12.73	0.156

Data presented as Mean ± Standard deviation

SBP= Systolic Blood Pressure, **DBP=** Diastolic Blood Pressure, **MAP**= Mean Arterial Pressure, **HR**= Heart Rate

Table 2: Comparison of Parametric Intraoperative Hemodynamic variables

Hemodynamic variable	Group O (n=36)	Group E (n=36)	p-value
SBP upon skin incision	118.42 ± 10.78	115.83 ± 9.37	0.281
DBP upon skin incision	75.08 ± 8.62	69.78 ± 7.28	0.006*
MAP upon skin incision	84.63 ± 11.73	79.08 ± 7.56	0.020*
HR upon skin incision	84.50 ± 11.21	76.28 ± 8.74	0.001*
SBP at the end of surgery	125.14 ± 11.95	121.42 ± 8.11	0.126
DBP at end of surgery	78.25 ± 8.97	75.53 ± 8.02	0.179

Table 3: Comparison of Non-parametric Intraoperative Hemodynamic variables

	Group O (n=36)	Group E (n=36)	p-value
SBP at pneumoperitoneum	125.00 (109.0-137.5)	117.00 (113.0-120.0)	0.118
DBP at pneumoperitoneum	78.50 (70.5-91.0)	71.00 (67.0-78.0)	0.004*
MAP at pneumoperitoneum	89.00 (81.75-104.5)	81.00 (70.25-88.0)	0.001*
HR at pneumoperitoneum	86.50 (71.25-106.0)	68.50 (64.25-78.75)	0.000*
MAP at end of surgery	88.00 (81.25-97.5)	83.00 (68.75-88.75)	0.019*
HR at end of surgery	85.50 (79.0-90.75)	69.50 (67.0-77.75)	0.001*

Data presented as median (IQR); p-value <0.05 considered as significant

SBP= Systolic Blood Pressure, DBP= Diastolic Blood Pressure, MAP= Mean Arterial Pressure, HR= Heart Rate

Intra-operatively only 2 patients (5.55%) in group E required rescue analgesia. While in group O, 20 patients (55.55%) required rescue analgesia (p-value of 0.000). The median intra-operative rescue opioid consumption in group O was 57.5 Mcg (IQR=65) while in group E was 0.00 Mcg (IQR=0).

Postoperatively 4 patients in group O required opioid analgesic while none required it in group E. All of the patients in group O required IV Paracetamol in the first 6 hours following surgery while 28 patients (77.7%) required IV Paracetamol in group E. In group O, 33 patients (91.67%) required IV Ketorolac postoperatively while only 1 patient required it in group E (p-value of 0.000). The median post-operative IV Paracetamol consumption in group O was 2.0 (IQR=0) while in group E it was 1.0 (IQR=0) with a p-value of 0.000. The median IV Ketorolac consumption in group O was 15.0 (IQR=O) vs 0.0 (IQR=O) in group E with a p-value of 0.001.

The median time to post-operative mobilization was 5.5 (IQR=1) in group O vs 4.0 (IQR=1) in group E with a p-value of 0.000. The incidence of PONV was 52.78% in group O vs 16.66% in group E. The difference was statistically significant (p-value 0.001). Apart from PONV other types of post-operative discomfort such as Shoulder pain, Generalized Abdominal pain, Epigastric pain, and Abdominal numbness were more common among patients of group O as compared to group E. Their combined incidence was 24(66.67%) in group O as compared to 4(11.1%) in group E. The difference is statistically significant (p-value 0.000). No harm such as Local Anesthetic toxicity, or hemodynamic instability was observed.

Table 4: Comparison of Postoperative pain scores

	Group O (n=36)	Group E (n=36)	p-value
VAS 0h at rest	3 (2-4)	0 (0-0)	<0.001*
VAS 0h at cough	4 (4-4)	0 (0-0)	<0.001*
VAS 1h at rest	4 (3-4)	0 (0-0)	<0.001*
VAS 1h at cough	5 (4-6)	0 (0-1)	<0.001*
VAS 2h at rest	4 (3-4)	1 (0-1)	<0.001*
VAS 2h at cough	4.5 (4-6)	2 (1-2)	<0.001*
VAS 3h at rest	4 (2.25-4)	1 (1-1)	<0.001*
VAS 3h at cough	4 (4-4)	2 (2-3)	<0.001*
VAS 4h at rest	3 (2-4)	2 (1-2)	<0.001*
VAS 4h at cough	4 (4-5)	3 (2-5)	0.009*
VAS 5h at rest	3 (2-4)	1 (0.25-2)	<0.001*
VAS 5h at cough	4 (4-5)	3 (2-3)	<0.001*
VAS 6h at rest	3 (2-3)	0 (0-1.75)	<0.001*
VAS 6h at cough	4 (4-4)	2 (1.25-3.0)	<0.001*

Data presented as median (IQR); p-value <0.05 considered as significant
VAS= Visual Analog Score

Discussion

This study adds important information to the literature on Opioid anaesthesia for daycare surgery. Baseline characteristics were similar across the two groups. After the intervention, upon skin incision and generation of pneumoperitoneum DBP, MAP and HR and at the end of surgery MAP and HR were significantly lower in the opioid-free group as compared to the conventional group. SBP was similar across the two groups. This is contrary to the observations made by Ragupathy et al. which showed that the conventional group had lower intraoperative systolic and mean blood pressure.5 The difference can be due to the expertise of ESPB administration as well as the different populations studied. Furthermore, we observed that pre-incisional ESPB significantly reduces pain scores up to 6 hours following surgery resulting in significantly lower post-operative analgesic consumption. Limited literature is available regarding the pre-incisional administration of ESPB and its effects on postoperative analgesic consumption.

Ragupathy et al. showed that post-operative VAS scores at 0h,2h,4h and 6h were significantly lower among patients who received ESPB. The comparison of VAS at rest revealed a score of 2 vs 4 at 0h,2h,4h and 6h while comparing the opioid-free group with the conventional opioid group.5 While VAS scores upon coughing were 3 vs 5 at 0h,2h,4h and 2 vs 3 at 6h intervals.5 Our study revealed even a lower resting pain score in the opioid-free group with pain scores of 0 vs 3 at 0h, 1 vs 4 at 2h, 1.5 vs 3 at 4h and 0 vs 3 at 6h and on coughing VAS scores were 0 vs 4 at 0h, 2 vs 4.5 at 2h, 3 vs 4 at 4h and 2 vs 4 at 6h. The lower pain scores observed in our study can be due to lesser surgical duration i.e. <1h. In a study done by Ragupathy et al., the mean duration of laparoscopic cholecystectomy was > 1h.5 As ESPB is a single-shot block, the quality of the block decreases with time leading to increased pain scores and the need for rescue analgesia. Similarly, administration of 20ml Bupivacaine 0.375% bilaterally at the level of T7 vertebra resulted in a significant reduction of post-operative with the majority of the patients having VAS scores between 0-3.10 However, these patients were also given IV Fentanyl 2 Mcg/kg, IV Diclofenac 75 mg and IV Paracetamol 1g at the time of induction of anesthesia.10 Therefore Joshi et al. failed to evaluate the operative opioid sparing effect of ESPB.10 The post-operative fentanyl consumption was considerably higher at 99.14(33.02) Mcg with the majority of this IV Fentanyl consumed during the first 6 hours following surgery.10 Contrary to this, in our study IV Fentanyl was given if dictated by intra-operative hemodynamics and only 2 out of 36 patients required it in the intraoperative period while none in the ESPB group required Opioids in the post-operative period. Similarly, administration of 20ml Bupivacaine 0.375% or 20ml Bupivacaine 0.25% in ESPB bilaterally at T7 or T8 levels resulted in higher intra-operative and post-operative opioid consumption as compared to our study.11,12 Similarly, ESPB given at the end of surgery significantly reduces post-operative pain scores and opioid consumption.13-16 However, contrary to the above-mentioned studies, of the patients who received ESPB in our study, only 2 of them required IV Fentanyl intraoperatively while none required opioids in the postoperative period. The difference can be due to a higher volume of local anaesthetics administered in ESPB i.e. 30 ml Bupivacaine 0.25% and 10ml Lignocaine 1% bilaterally at the level of T6 vertebra which could have resulted in a greater number of dermatomes being covered thereby significantly reducing peri-operative opioids and analgesic consumption.

Furthermore, the quality of postoperative recovery was found to be better among patients who received ESPB with significantly lower incidence of PONV, epigastric pain, abdominal discomfort, and shoulder pain and they showed early mobilization. The previously reported incidence of postoperative nausea was 3.2% among patients who received right-sided ESPB in PACU as compared to the 9.7% incidence of nausea in the control group.14 In our study patients who received ESPB had a considerably lower incidence of PONV i.e. 16.7% while the conventional opioid group had a higher incidence that was 52.8%. Contrary, to our

study the lower incidence of PONV among both groups as observed by Rahimzadeh P et al. can be due to Total Intravenous Anesthesia employed for the maintenance of anaesthesia.14 On the other hand, our study employed a balanced anaesthesia technique for the maintenance of anaesthesia which increases the risk of PONV. Nevertheless, ESPB had an opioid-sparing effect which greatly reduces the incidence of PONV. Our findings are supported by Joshi et al. who showed that ESPB effectively reduces the incidence of PONV among patients who underwent laparoscopic cholecystectomy with balanced anesthesia.10 Other studies have contradicting results as they show no significant difference between the incidence of PONV among patients who received ESPB and those who received conventional opioid anaesthesia.12,15,17 However, the insignificance could be due to the administration of opioids to participants of both groups at the time of induction of anaesthesia.12,15,17

Furthermore, we found the incidence of shoulder pain, abdominal discomfort and epigastric pain was lower among patients who received ESPB. In previously available literature no significant differences regarding the incidence of shoulder pain were found among the two groups.14 The exact mechanism of referred shoulder pain is not known.18 Therefore, we cannot deduce the factors responsible for the reduced incidence of shoulder pain as observed in our study. The lower incidence of epigastric and abdominal discomfort observed can be due to better visceral analgesia offered by ESPB. Postoperatively early mobilization was achieved among patients who received ESPB (4.0 hours vs 5.5 hours) indicating block spares motor neurons. Further studies are required to validate these findings by administering appropriate doses of local anaesthetics in pre-incisional ESPB. No block-related complication was noted in our study apart from block failure in 2 patients.

Conclusions

Pre-incisional ESPB in laparoscopic cholecystectomy is an effective regional anaesthetic technique which greatly reduces peri-operative analgesic consumption and enhances the quality of postoperative recovery.

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All authors approved the final version to be published & agreed to be accountable for all aspects of the work.