Clinical Investigations
ISSN (Print): 2394-6954
ISSN (Online) : 2394-9775
Karnataka Anaesthesia Journal *Vol 17(1&2), January-June 2019, p. 13-21* *DOI: 10.4103/kaj/2019/v17i1-2/158805*

Efficacy of Ultrasound Guided Bilateral Erector Spinae Block for Postoperative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy under General Anaesthesia – A Randomised Control Study

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Abstract

Background: The Ultrasound guided Erector spinae plane block is a novel paraspinal plane block, first described in 2016 for thoracic analgesia at T5 level. Currently there are only a few case reports/ studies on ultrasound guided erector spinae block with inconsistent results, hence this study was undertaken to assess the post-operative analgesic efficacy in patients undergoing laparoscopic cholecystectomy under general anaesthesia. **Material and Methods:** Thirty patients aged between 20 to 60 yrs of American Society of Anaesthesiologists (ASA) grade 1 and 2, undergoing laparoscopic cholecystectomy under general anaesthesia were randomly allocated into two groups of 15 each. Group C–Laparoscopic cholecystectomy under general anaesthesia without erector spinae block and Group E–Laparoscopic cholecystectomy under general anaesthesia with erector spinae block at T7 level using 20ml of 0.25% plain bupivacaine bilaterally. Intraoperative vitals, isoflurane consumption, duration of postoperative analgesia, postoperative paracetamol requirement and visual analogue scores were noted. **Results:** The demographic parameters were comparable. Pain scores were lower in group E. Post-operative duration of analgesia was prolonged in group E (group C-100.00±34.49 mins, group E-513.00±121.30 mins with p value <0.001). 24hrs paracetamol requirement (group C-3930±260 mg, group E-1733±960 mg with p value <0.001) and isoflurane consumption (at 30mins: Group C-6.87±1.41 ml, group E-4.40±1.18 ml with p value <0.001, at 60mins: group C-13.93±4.64, group E-10.87±3.56 with p value 0.052) were lower in group E. **Conclusion:** Ultrasound guided bilateral erector spinae plane block provides longer duration of postoperative analgesia with reduced requirement of rescue analgesia in patients undergoing laparoscopic cholecystectomy.

Keywords: Bupivacaine, Erector Spinae Block, Postoperative Analgesia, Ultrasound

1. Introduction

The Ultrasound guided Erector spinae plane block is a novel paraspinal plane block, first described in 2016 for thoracic analgesia at the T5 level[1]. Emerging research shows that erector spinae block can be employed as a simple and safe alternative analgesic technique for acute postsurgical pain instead of using multimodal regimes[2]. More recently case reports have shown erector spinae block to be effective in providing extensive somatic and visceral abdominal analgesia in laparoscopic abdominal surgeries by injection at lower thoracic level of T7-T9 level[1].

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We only have limited evidence for the clinical utility of Erector spinae block, but it has good advantages that includes its simplicity, easily identifiable ultrasonographic landmarks and an end point for injection, as well as low risk for serious complications because the injection is into a tissue plane that is distant from the pleura, major blood vessels and discrete nerves[3].

In laparoscopic cholecystectomy, visceral pain is more intense for the first 24 hours than other components like parietal and shoulder pain, therefore erector spinae block can be used as a safe alternative for early postoperative analgesia[1].

Currently there are only a few case reports with inconsistent results but no randomized studies on ultrasound guided erector spine block at T7 level for laparoscopic cholecystectomy, hence this study was undertaken to assess the post-operative analgesic efficacy in patients undergoing laparoscopic cholecystectomy under general anaesthesia. The primary objective of this study was to assess the postoperative analgesic efficacy of bilateral ultrasound guided Erector spinae block at T7 level in patients undergoing laparoscopic cholecystectomy under general anaesthesia.

2. Methodology

This prospective randomized case control study was conducted from June 2019 to August 2019. After obtaining institutional ethical clearance, the study was registered at ctri.nic.in (CTRI/2019/06/019690).

Thirty patients aged between 20 to 60 yrs of American Society of Anaesthesiologists (ASA) grade 1 and 2, who were undergoing laparoscopic cholecystectomy under general anaesthesia were randomly allocated into two groups of 15 each using a computer generated randomisation sequence (www.random.org). Group C – Laparoscopic cholecystectomy under general anaesthesia without erector spinae block. Group E – Laparoscopic cholecystectomy under general anaesthesia with erector spinae block at T7 level using 20ml of 0.25% plain bupivacaine on each side.

Patients who refused to give written informed consent for Erector spinae block, those who were hypersensitive to the drugs used, patients with systemic illness such as uncontrolled diabetes mellitus, neuromuscular disorder and bleeding diathesis were excluded from the study.

After obtaining a written informed consent, adequate preanaesthetic evaluation was done and patients were trained about the use of Visual Analogue Scale (VAS). Preoperative investigations were performed as per the institution's protocol. All patients were kept nil orally for 8hrs and were premedicated with tab ranitidine 150mg and tab alprazolam 0.5mg on the previous night of surgery.

On the day of surgery, patient's basal parameters like heart rate, Non-Invasive Blood Pressure (NIBP) and peripheral oxygen saturation were recorded. Based on the computer generated random list, patients were allocated randomly into group C and group E. The allocation based on the randomisation sequence was concealed using sequentially numbered opaque sealed envelopes.

In the preoperative room an 18G intravenous cannula was inserted and patients were preloaded with 10ml/kg ringer lactate fluid. Under aseptic precautions, the T7 spinous process was identified. Ultrasound linear probe was placed in a transverse orientation and the tip of the T7 transverse process was identified. The tip of the transverse process was centred on the ultrasound screen and the probe was rotated into a longitudinal orientation to produce a parasagittal view. The layers visible superficial to the acoustic shadows of the transverse processes were skin, subcutaneous tissue, trapezius and erector spinae muscle as shown in Image 1[4]. Following local anaesthetic infiltration of the superficial tissues, an echogenic 23-G spinal needle (Quincke's) was inserted in-plane to the ultrasound beam in a cranial-to-caudal direction until contact was made with the T7 transverse process. Needle tip was confirmed by injecting 0.5–1 ml saline. A total of 20ml study drug was injected into the erector spinae plane (below the erector spinae muscle) as shown in Image 2. The procedure was repeated on the contralateral side. Vital parameters were recorded every 5mins till 20mins. After 20 mins of administering the drug, spread of the block was assessed with cold swab from clavicular level till inguinal ligament anteriorly, from spine of scapula till posterior superior iliac spine posteriorly and the dermatomal spread was recorded on both sides.

In the operation theatre, monitors like Electro-Cardio-Gram (ECG), NIBP and oxygen saturation (SPO2) were connected and basal parameters recorded. Patients were premedicated with intravenous glycopyrrolate 0.004mg/kg, midazolam 0.015mg/kg, fentanyl 2mcg/kg and

preoxygenated for 3 minutes with 100% oxygen at 6L/min. Then induced with inj. propofol 2mg/kg, inj. vecuronium 0.1 mg/kg was used as muscle relaxant and trachea was intubated with appropriate sized cuffed endotracheal tube. Anaesthesia was maintained with 50% oxygen, air and isoflurane. Vital parameters were recorded before induction, after induction, after intubation and every 5mins thereafter till the end of surgery. Initial flows were kept at 4L/min till equilibrium between inspired isoflurane and end tidal isoflurane (ET isoflurane) was achieved. Then the flows were reduced to 2L/min. Inhaled concentration of isoflurane was titrated depending upon the clinical signs of light planes of anaesthesia i.e. {tachycardia (HR>100/min), hypertension (20% increase from baseline)}. Isoflurane consumption was recorded every 30mins from the agent gas module of the anaesthesia workstation (Datex Ohmeda Avance S5™). The depth of neuromuscular blockade was monitored using Train Of Four (TOF), which was connected after the patient was induced but before the administration of muscle relaxant. TOF was maintained below a count of 2 with incremental doses of vecuronium.

At the end of surgery, isoflurane was discontinued and muscle relaxation was reversed with Inj neostigmine 0.05mg/kg and glycopyrrolate 0.008mg/kg and trachea extubated when the TOF >0.9 with sustained head lift and hand grip.

Duration of postoperative analgesia {from the time of block to demand for first rescue analgesia postoperatively (VAS≥3)} was noted. Paracetamol was used as the rescue analgesic and was given when the VAS≥3. Paracetamol requirement postoperatively for the first 24hrs was recorded. Visual analogue scores were noted at the end of surgery, 2hrs, 4hrs, 8hrs, 12hrs and 24hrs postoperatively.

Sample size was calculated based on a pilot study involving 12 cases, 6 cases were given ESP and 6 cases were taken as control. Duration of analgesia observed was 180±90 mins in control group and 300±150 mins in those given ESP block. To achieve similar results, at a power of 90%, considering α error at 0.05, a minimum of 13 patients were required in each group. To compensate for a drop out of 10%, we have taken 15 patients in each group.

Descriptive and inferential statistical analysis was done. Continuous measurements are presented on Mean ± SD (Min-Max). Categorical measurements are presented in Number (%). Student t test (two tailed, independent) was used for study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Fisher Exact test was used to find the significance of study parameters on categorical scale between two or more groups and non-parametric setting for Qualitative data analysis. P value of ≤ 0.05 was considered statistically significant. Box and Whiskers plot was used for the duration of analgesia and isoflurane consumption. The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data.

3. Results

A total of 30 patients were enrolled and randomly allocated into two groups (group C n=15 and group E n=15) (Figure 1). No patients were excluded from the study and a total of 15 patients in each group were included for the final analysis.

Table 1. Demographic parameters

DATA	GROUP C	GROUP E
Age in years	46.47±10.76	43.93±10.38
Gender distribution	male(8) female(7)	male(6) female(9)
Duration of surgery in minutes (number of patients)	<45 (2) 45-75 (10) <75 (3)	<45 (1) 45-75 (10) <75 (4)

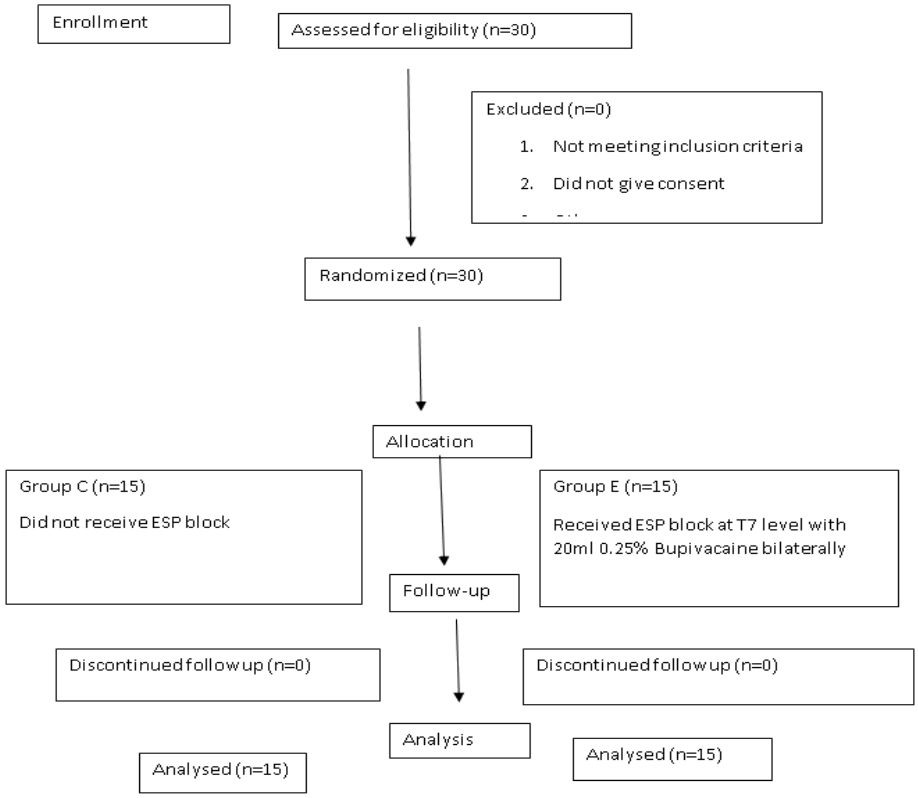

Figure 1. Consort Flow Diagram.

Demographic parameters such as age, sex and duration of surgery were comparable in both the groups as shown in (Table 1).

After erector spinae block 5 patients in group E had a sensory block of T4-L1, 5 patients had T6-L1, 2 patients had T4-T12, 2 patients had T6-T12 and 1 patient had

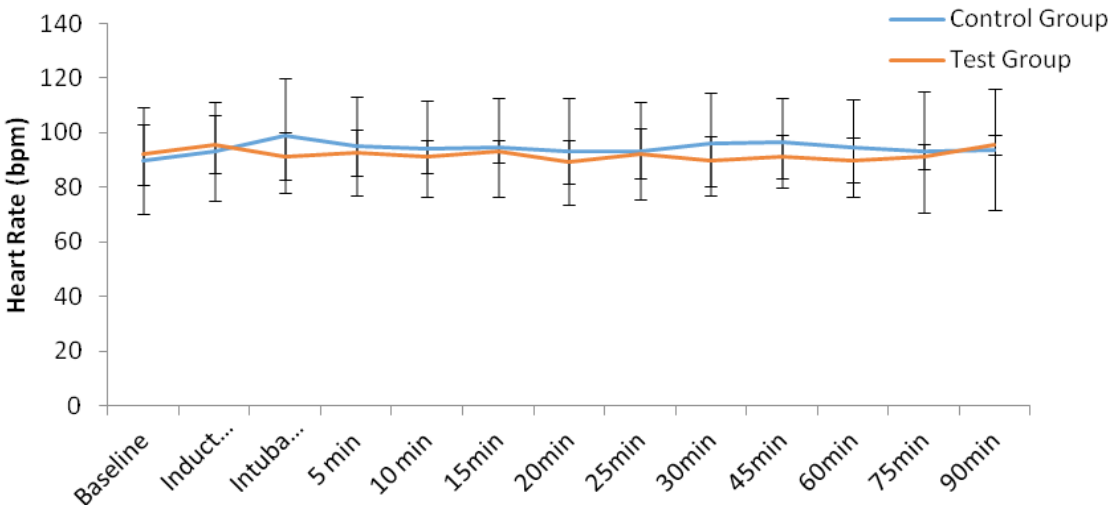

Figure 2. Comparison of heart rate between the two groups.

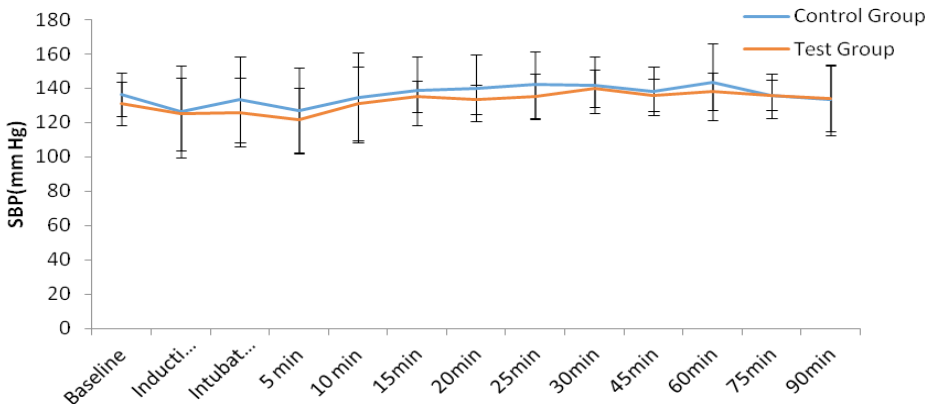

Figure 3. Comparison of MAP between group C and group E.

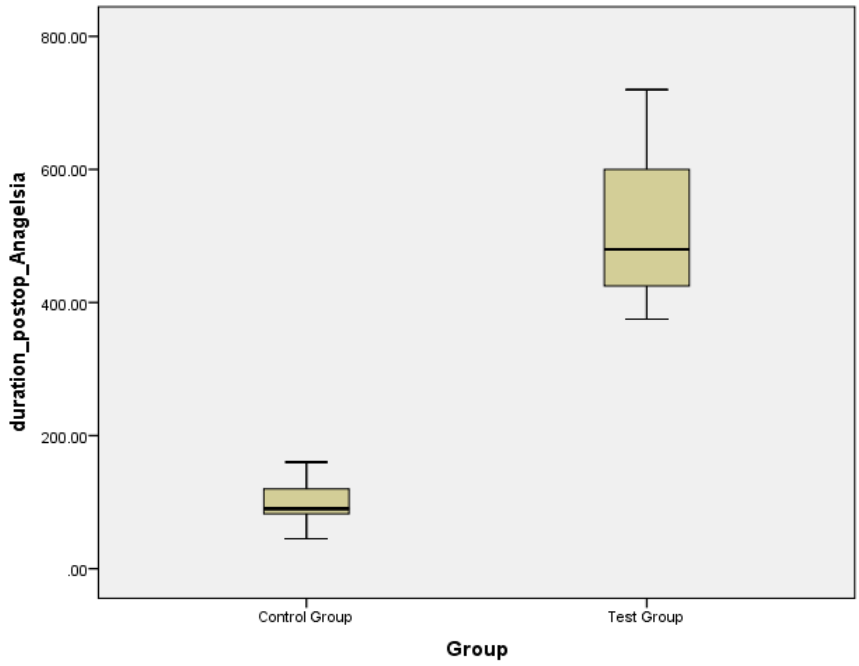

Figure 3. Box and whiskers plot for the duration of postoperative analgesia between group C and group E.

T2-L1 anteriorly. Posteriorly 12 patients had sensory block between T6-L2 and 3 patients between T6-L1.

We did not observe any significant change in heart rate between group C and group E as shown in Figure 2. There was also no significant change in HR from the baseline within the groups.

The MAP was comparable between group C and group E as shown in Figure 3. There was no significant change in MAP from the baseline within the groups.

The pain scores in group E was significantly lower than in group C for the first 6hrs postoperatively. After 6hrs and up to 24hrs pain scores were less in group E than in group C, though it was not statistically significant.

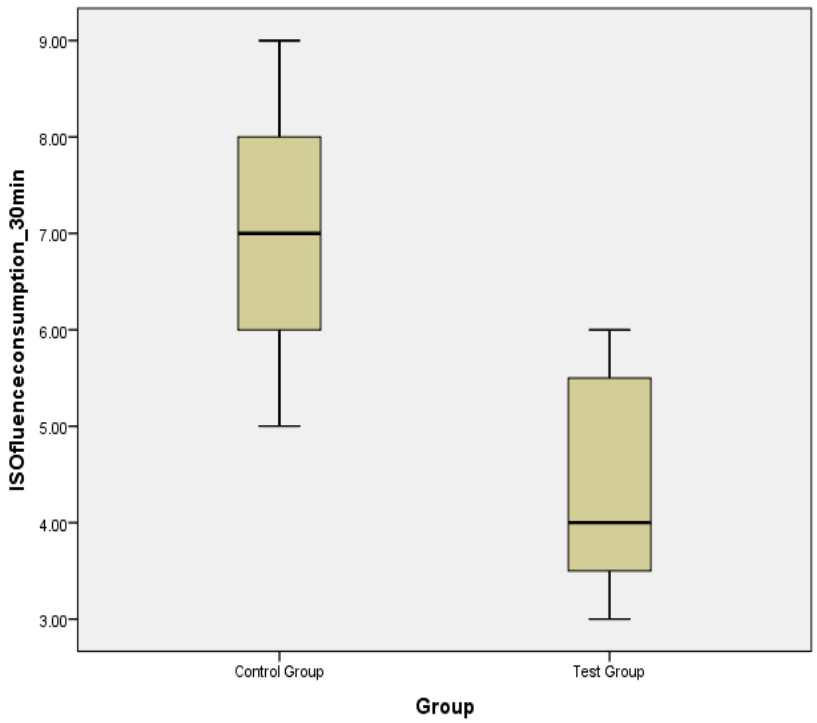

Figure 5. Box and whiskers plot for isoflurane consumption at the end of 30mins between group C and group E.

Table 2. Comparison of VAS scores, postoperative analgesia and dosage of rescue analgesic and isoflurane consumption between group C and group E

	GROUP C	GROUP E	P VALUE
VAS SCORES At end of surgery 2hrs 4hrs 6hrs 12hrs 24hrs	 7.53±1. 13 7.60±0. 83 6.27±1. 16 5.80±1. 15 4.73±0. 96 3.93±0. 80	 0.40±1. 06 0.87±1. 36 2.13±2. 26 4.00±2. 42 3.93±1. 67 3.20±1. 15	 <0.001* <0.001* <0.001* 0.015 0.119 0.052
Duration of postoperative analgesia in minutes	100.00±34.49 (45.0-160.0) #	513.00±121.30 (375-720)#	< 0.001*
Dosage of rescue analgesic (paracetamol) in mg in 24hrs	3930±260 (3.0-4.0)#	1733±960 (0-3.0)#	<0.001*
Isoflurane consumption in ml At 30mins At 60mins	 6.87±1.41 (5.0-9.0)# 13.93±4.64 (6.0-21.0)#	 4.40±1.18 (3.0-6.0)# 10.87±3.56 (6.0-18.0)#	 <0.001* 0.052

Group E had significantly prolonged duration of postoperative analgesia compared with Group C as shown in Table 2 and Figure 4.

The postoperative requirements of paracetamol in group E was significantly less when compared with group C. Isoflurane consumption was significantly less in group E at the end of 30mins as shown in Table 2 and Figure 5. At the end of 60mins isoflurane consumption was lesser in group E compared to group C, though it was not statistically significant as shown in Table 2.

We observed bradycardia in 2 patients out of 15 patients in group E soon after giving the block which was adequately treated with 2 doses of atropine 0.6mg IV in one patient and with one dose of atropine 0.6mg IV in the other patient. We also observed mild itching in one patient who received ESP block which did not require any treatment.

4. Discussion

In the present study, it was observed that ultrasound guided bilateral erector spinae plane block provides longer duration of postoperative analgesia with reduced requirement of rescue analgesia in patients undergoing laparoscopic cholecystectomy.

Postoperative analgesia can be treated with systemic opioids, Non- Steroidal Anti-Inflammatory Drugs (NSAIDs), neuraxial and peripheral nerve blocks[5]. Paravertebral blockade is a useful analgesic method but it is technically challenging and also associated with complications like pneumothorax or subarachnoid injection[6].

Erector Spinae Plane (ESP) block was firstly reported in 2016, a relatively simple regional anaesthesia technique, it blocks both supra-umbilical and infra-umbilical dermatomes with a single level injection[1,2]. ESP block is usually given between T5-T7 level. ESP block at T5 level is given for thoracic surgeries and modified radical mastectomies[7]. Ultrasound-guided erector spinae plane block at the level of T7 relieves visceral abdominal pain. Local anesthetic injected into the fascial plane deep to erector spinae muscle spreads craniocaudally through the inter-transverse connective tissue, thoracic paravertebral space, ventral rami, dorsal rami of spinal nerves and the rami communicantes[1].

In a case series, authors performed ultrasound guided bilateral erector spinae block at T7 level using 20ml 0.5% ropivacaine in three cases posted for laparoscopic cholecystectomy and concluded that it provides effective somatic and visceral pain relief[8]. An another case report demonstrated a dermatomal spread from T6 to T12 following a ultrasound guided ESP block at T7 level using 20ml 0.5% ropivacaine[4] the volume used in our study is similar and most patients had a sensory block of T4-L1 and T6-L1 after erector spinae block at T7 level using 20ml 0.25% bupivacaine.

Ultrasound guided ESP block at T7 level was effective in providing postoperative analgesia in patients who underwent bariatric surgery and found that there was better somatic and visceral analgesia due to extensive dermatomal spread with stable haemodynamics[1]. In our study also, patients had adequate dermatomal spread with stable haemodynamics, though we observed transient bradycardia in two patients which responded to atropine.

Preoperative administration of ultrasound guided ESP block at T7 level was associated with lower pain scores and reduced opioid consumption in a series of four patients undergoing laparoscopic ventral hernia repair under general anaesthesia. In our study, postoperative pain scores were found to be lower (VAS≤3) in those patients given erector spinae block compared with control for the first 6 hours postoperatively. Pain scores after 6hrs and up to 24hrs postoperatively were also lower in those given ESP block though not statistically significant.

Serkan *et al.*, have performed the ultrasound guided bilateral Erector spinae block at T8 level with local anaesthetic mixture (10 ml of 0.5% bupivacaine+5ml of 2% lidocaine and 5ml of serum physiologic) in three patients undergoing laparoscopic cholecystectomy and concluded that ESP block leads to effective analgesia (duration of analgesia between 13hrs to 17hrs)[9]. Swati and associates studied the efficacy of ultrasound guided erector spinae block at T5 level for postoperative analgesia in modified radical mastectomy and concluded that 20ml of 0.5% bupivacaine reduced the postoperative morphine consumption compared to the control group[8]. We have also observed prolonged duration of postoperative analgesia and lower pain scores in those patients undergoing laparoscopic cholecystectomy after giving ESP block with 20 ml of 0.25% bupivacaine bilaterally at T7 level.

Restrepo-Garces et al, have studied the efficacy of continuous bilateral erector spinae block on postoperative analgesia after major open abdominal surgery in one case and reported that ESP at T8 level provided effective perioperative analgesia with reduced opioid (morphine) demands and lesser side effects during the postoperative course[10]. We have used paracetamol as rescue analgesic in our study and observed that the postoperative requirement of paracetamol was significantly lesser in the first 24 hours when compared with the control group.

To the best of our knowledge, there are no case reports or studies that have analysed the isoflurane consumption when ESP block has been given. We observed that the isoflurane consumption was lower in those given erector spinae block though it was statistically significant only at the end of 30mins. Though the isoflurane consumption at the end of 60mins was reduced in those given ESP block when compared to the control, it was not statistically significant.

The potential for drug to spread into the epidural region may result in haemodynamic disturbances in occasional patient. We observed bradycardia in 2 patients out of 15 patients in group E soon after giving the block which was adequately treated with 2 doses of atropine 0.6mg IV in one patient and with one dose of atropine 0.6mg IV in the other patient. We also observed mild itching in one patient who received ESP block which did not require any treatment. This bradycardia could be a vasovagal attack as we have performed ESP block in sitting position, hence we should be cautious while performing the block in sitting position. The ergonomics in the lateral position was not feasible, hence we have given the block in sitting position. We did not observe shoulder pain in any patient.

There are certain limitations in our study, we did not use continuous catheter technique hence we may have a limited duration of analgesia. Further randomised studies are needed in different surgical procedures as the intensity of pain varies and to determine segmental analgesia with different volume and concentration. The postoperative respiratory dynamics of cholecystectomy pain were also not assessed. Further studies may be required to differentiate the effects of ESP block in sitting versus lateral position.

5. Conclusion

To conclude, Ultrasound guided bilateral erector spinae plane block is a simple and effective technique which provides longer duration of postoperative analgesia with reduced requirement of rescue analgesia in patients undergoing laparoscopic cholecystectomy with stable haemodynamics.

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