



Usg Guided Erector Epinae Plane Block Using Dexmedetomidine as an Adjuvant with Ropivacaine in Patients Coming for Elective Laparoscopic Cholecystectomy: A Prospective Randomised Double Blind Controlled Study

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ABSTRACT

The USG guided erector spinae plane (ESP) block is a novel truncal intrafascial block administered at the level of T7 transverse process resulting spread of drug cranially and caudally from the site of injection. The aim of study is to compare the efficacy of USG guided ESP block using ropivacaine alone and ropivacaine with dexmedetomidine in prolonging postoperative analgesia and also in reducing rescue analgesics in first 24 hrs after laparoscopic cholecystectomy, along with comparing intraoperative hemodynamic changes. Sixty American Society of Anaesthesiology (ASA) grade I and II patients undergoing elective laparoscopic cholecystectomy surgery under general anesthesia were randomly assigned into two groups of 30 each. USG guided ESP block was given bilaterally using either 0.375% ropivacaine plus 50mcg of dexmedetomidine (16mL each side) in group RD or 0.375% ropivacaine alone (16mL each side) in group R before induction of anesthesia. Hemodynamic monitoring like SBP, DBP, HR, MAP, SpO₂ were assessed before intubation, immediately after intubation, 5th min, 10th min, 15th min, 30th min, 60th min, 90th min and at the end of surgery. Pain was monitored postoperatively using visual analogue score for 24 hrs. The time at which first rescue analgesia was given were noted along with total analgesic consumption in 24 hrs. The demographic parameters like age, sex and BMI were not statistically significant. The total duration of analgesia was 5.42±0.54 hours in group R and 7.71±0.57 in group RD which was statistically significant (p = 0.000). The total duration of postoperative analgesia was 3.58±0.57 hours in group R and 5.71±0.8 in group RD which was statistically highly significant (p = 0.000). Total analgesic consumption in first 24 hrs after surgery was significantly high in group R when compared to group RD (p<0.05). Paracetamol 1gm was given intravenously whenever the VAS score was ≥4 followed by 100mg tramadol intravenously if VAS score had not come down after 30 min. We have also observed the adverse effects like nausea, vomiting, shivering, sedation and shoulder pain which were statistically not significant. USG guided ESP block improves postoperative analgesia in patients undergoing laparoscopic cholecystectomy with minimal hemodynamic changes and adverse effects.

INTRODUCTION

The gold standard for surgical treatment of cholelithiasis is laparoscopic cholecystectomy, which is minimally invasive. It has got the advantage of early ambulation, shorter hospital stay, faster recovery and less pain while comparing with open surgical technique^[1,2]. It also avoids big incision which prevents many postoperative complications such as wound infection, pulmonary complications and incisional hernia^[3,4]. Prolonged postoperative pain is the most common complaint which could be due to somatic and visceral pain. Somatic pain is due to trocar entry. Peritoneal distension with diaphragmatic irritation and pain from gall bladder resection are the causes of visceral^[5] and referred shoulder pain^[6,7]. Several techniques have been tried such as neuraxial opioids, intra peritoneal instillation of local anaesthetics^[8-10] with adjuvants and oblique subcostal transverse abdominis plane block. These techniques have successfully reduced postoperative pain and opioid consumption postoperatively^[11-14].

The USG guided ESP block is a novel truncal interfascial block. The injection site is either at the level of T5 transverse process or at the level of T7 to T9 transverse process depending upon either thoracic or abdominal procedures. ESP block at the level of T5 results in spread of local anaesthetic between C7 and T8 segments. ESP block at the level of T7 to T9 transverse process results in spread of local anaesthetics between T6 and T12^[15-20]. ESP block facilitates early recovery with lesser complications and early ambulation while providing good analgesia^[21,22]. Local anaesthetics penetrates anteriorly through the costo-transverse foramina to the paravertebral space, hence it is described as an indirect paravertebral block^[19]. Analgesia in ESP block is mediated by immunomodulatory effect of local anaesthetics and this effect is mediated through mechanosensory properties of thoracolumbar fascia. Based on the evidence the most probable primary mechanism is a direct effect of local anaesthetic via physical spread and diffusion to the neural structure in fasciae plane deep to erector spinae muscles and adjacent tissue compartments. The spread of the injectant to the ventral rami of the spinal nerves is quite variable, but there is a consistent involvement of dorsal rami. Systemic effect of local anaesthetics contribution is less in analgesic efficacy.

Objectives: Comparing the efficacy of USG guided ESP block by using ropivacaine alone and ropivacaine with dexmedetomidine in prolonging the postoperative analgesia and also in reducing the analgesics consumption in first 24 hrs after laparoscopic cholecystectomy.

Primary objectives:

- Total duration of post operative analgesia and total analgesic consumption in first 24 hrs
- Changes in the hemodynamic parameters, heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and oxygen saturation (SpO₂) at various intervals following general anaesthesia

Secondary objectives:

- Post operative visual analogue scale (VAS) score in first 24 hrs
- Adverse effects like post operative nausea, vomiting, shivering, sedation and shoulder pain

MATERIALS AND METHODS

Source of data: The study was conducted on 60 subjects aged between 20 and 60 years, in ASA grade 1 and 2 who were undergoing elective laparoscopic cholecystectomy under general anaesthesia in a tertiary care hospital during 2020 to 2022.

Inclusion criteria:

- Subjects aged 20-60 years of either gender
- Subjects belonging to ASA grade I and II

Exclusion criteria:

- Subjects with cardiac, renal, hepatic, cerebral diseases and peripheral vascular disease
- Subjects with heart rate less than 60 bpm
- Presence of 1st, 2nd or 3rd degree heart block
- Subjects with difficult airway, cervical spine injuries and obesity (BMI >30 kg m⁻²)
- Subjects with endocrinological diseases like hyperthyroidism, hypothyroidism, hypertension and diabetes mellitus
- Subjects with known allergies to ropivacaine and dexmedetomidine
- Pregnant and lactating subjects
- Active dermatological lesions over the site of needle insertion
- Patient refusal

After obtaining clearance from ethical and scientific committee the study population was randomly divided into 2 groups with 30 subjects in each group using shuffled opaque sealed envelopes containing the name of the group and patients were asked to choose an envelope. Envelopes were opened by a senior anesthesiologist not involved with the study who was also assigned to prepare the test drugs.

Group RD: ESP block with 0.375% ropivacaine (30mL) plus 50mcg dexmedetomidine in 2mL normal saline (total 32mL, 16mL each side).

Group R: ESP block with 0.375% ropivacaine (30mL) plus 2mL of normal saline (32mL total, 16mL each side).

Pre anaesthesia evaluation was done in the evening before the surgery. Detailed written informed anaesthesia consents were obtained from all the subjects volunteering for the study. All those subjects who were being included in the study with their informed consent were given tablet alprazolam 0.5mg and tablet pantoprazole 40mg orally at bed time the night prior to surgery as per institutional protocol. The following morning, after transferring the subjects into the operation theatre (OT), an intravenous line was secured using 18G cannula on the non-dominant hand and an infusion of ringer lactate started. All the subjects were connected to non-invasive monitoring such as pulse oximetry, noninvasive blood pressure (NIBP) and electrocardiogram (ECG) using multiparameter monitor EDAN iM80. The SBP, DBP, MAP, HR and SpO₂ were recorded. The patients were made lying down in lateral position with the support of assistants. A preliminary scan was done to define and mark the required level (T7). At first, T12 vertebra was identified by identifying the 12th rib and thereafter the probe was guided to T7 vertebra by counting the thoracic vertebrae. After identifying T7 spinous process, the probe was moved laterally till the transverse process was identified (2-3cm away from the midline). The parts were painted and draped. Under aseptic precautions the linear probe was used for the scanning. The anatomical landmarks were identified by the USG machine. The T7 transverse process and other 3 layers of muscle from posterior to anterior (trapezius, rhomboid, erector spinae) were identified. A 10cm, 23G needle, with the needle tip aiming towards the T7 transverse process was inserted under USG guidance by in-plane technique after giving local infiltration at entry site, After the needle tip touching the transverse process, a total of 15mL 0.375% ropivacaine plus 25mcg dexmedetomidine (1mL) was given in incremental dose with careful repetitive aspiration to avoid intravascular injection in group RD. Similarly 16ml 0.375% ropivacaine was given in group R. The same process was repeated on the other side also. All necessary precautions for the safe administration of local anesthetics were taken. A good spread (caudal and cephalic) of the drug anterior to ES plane was noted. Following ESP block, patients were turned to supine position and preoxygenated for 3mins with 100% oxygen. After premedication with intravenous doses of 0.01mg/kg of glycopyrrolate, 1mg

of midazolam, 2 mcg kg⁻¹ of fentanyl, 8mg of dexamethasone and 4mg of ondansetron, general anaesthesia was induced with intravenous doses of 2mg kg⁻¹ of propofol and 0.1mg kg⁻¹ of vecuronium. Patients were ventilated with bag and mask for 3mins with 33% oxygen, 66% nitrous oxide and 0.5-1% isoflurane.

After securing the airway with appropriately sized cuffed endotracheal tube, anaesthesia was maintained with 33% oxygen, 66% N₂O, 0.5%-1% of isoflurane and intravenous vecuronium. Since lower umbilical part was not covered by the block (based on existing literature) we requested surgeon to infiltrate the area with 5mL of 0.5% ropivacaine. Once the surgery was over, patients were extubated after meeting the extubation criteria. Pain was assessed using visual analogue scale (VAS) score from 0 point of time. The 0 point of time was the moment the patient recovered from general anaesthesia and responded to verbal commands. The rescue analgesic medication like intravenous paracetamol 1gm was given when VAS score reached 4 and if VAS score did not come down less than 4 within 30min, then intravenous tramadol 100mg slow was given subsequently as second analgesic. Time of rescue analgesia (that is the time duration from the point of administration of block to the point of patient's request for analgesic) was noted which was defined as total duration of analgesia. Whereas the duration of 0 point of time till the time of rescue analgesia was defined as total duration of postoperative analgesia. Hemodynamic monitoring like SBP, DBP, HR, MAP, SpO₂ were assessed at the baseline, immediately after intubation, 5th, 10th, 15th, 30th, 60th, 90th min and at the end of surgery. Patients were also monitored for hypotension and bradycardia intraoperatively. Hypotension was defined as a reduction in SBP of more than 20% below the baseline or fall in SBP less than 90mm of Hg. Hypotension was treated with increased rate of intravenous fluids and graded dosage of Inj mephentermine if needed. Bradycardia was defined as a heart rate of less than 50 beats per minute and it was treated by 0.6mg of atropine intravenously. Postoperatively pain was assessed using VAS score at 1st, 2nd, 4th, 6th, 12th, 16th, 20th, 24th hrs. Patients were also monitored for any adverse effect like nausea, vomiting, sedation, respiratory depression and shoulder pain.

Statistical methods: Data was captured in MS Excel and analysed using Statistical Package for Social Sciences (SPSS) version 20.0. Data was represented in the form of mean, median, proportions, standard deviation and inter quartile range. Chi square test, one way ANOVA, Mann Whitney Test and Student t-test were used to analyse the data and a p-value less than

0.05 was considered statistically significant. Sample size was calculated using estimation technique ($S = Z^2pq/d^2$). The estimated sample size was 60.

RESULTS

Table 1 showing the total postoperative analgesia from the time of recovery of general anaesthesia (0 point of time), which was maximum in group RD (5.71+0.8) hours when compared to group R (3.58+0.57) hours, which was statistically highly significant ($p = 0.000$). Table 2 showing total duration of analgesia from the time of block, group RD showing a result of 7.71+0.57 hrs which was higher than group R (5.42+0.54 hrs) which was statistically highly significant ($p = 0.000$). Tables 3 and 4 show total analgesic consumption in first 24 hrs of postoperative period which includes intravenous Paracetamol and Tramadol.

Patients belonging to group RD consumed intravenous paracetamol (1.03+0.18) gm and intravenous tramadol (126.67+52.08)mgs in first 24 hrs which was significantly lesser than group R. Patients belonging to group R consumed intravenous paracetamol (1.3+0.47) gm and intravenous tramadol (183.33+37.9)mgs respectively, which was statistically highly significant ($p = 0.005$), ($p = 0.000$).

Table 5 showing HR at various time intervals intraoperatively. None of the patients in either group showed any significant HR variation in first 30 mins. 30th min onwards it was decreased in group RD which was statistically significant ($p < 0.05$). Table 6 showing MAP distribution of either group at various time intervals. group RD showing statistically significant decrease in MAP from 15th min onwards when compared to group R ($p < 0.05$) Table 7 showing the median postoperative VAS score among the group R and group RD the differences between the distribution was statistically significant from 2nd hrs to 16th hrs ($p < 0.05$) (Mann Whitney U-Test).

Adverse effects: One patient in group R (3.33%) and none of the patient in group RD (0%) had nausea which was statistically not significant. None of the patient from group R had vomiting, only one patient (3.33%) in group RD had vomiting which was statistically not significant. 3 (10%) patients in group R and 3(10%) patients in group RD had shivering which was not statistically significant. Almost all patients from either group had arousable sleep. None of the patients from either group had shoulder pain.

DISCUSSIONS

The most commonly used surgical technique for cholelithiasis in recent time is laparoscopic cholecystectomy in comparison to open cholecystectomy due to its advantages like less post-

operative pain, shorter hospitalisation and faster functional recovery^[23]. In laparoscopic cholecystectomy early postoperative pain is a major obstacle for early ambulation leading to increased risk of deep vein thrombosis, pulmonary complications and prolonged hospital stay^[24]. The causes for pain following laparoscopic cholecystectomy may be somatic due to skin incisions and trocar insertion or visceral due to the gall bladder dissection, peritoneal exposure to CO₂ and peritoneal stretching due to insufflation. All these limits the early ambulation^[24].

The pneumoperitoneum by CO₂ insufflation, required for laparoscopic surgeries leads to increase in plasma norepinephrine, epinephrine levels and plasma renin activity^[25,26]. This sympathetic stimulation leads to tachycardia, hypertension, increase in systemic and pulmonary vascular resistance. The reverse trendelenburg position in laparoscopic cholecystectomy surgery leads to diminished venous return and thereby decreasing the cardiac output^[27]. These hemodynamic changes predispose the myocardium to ischemia in vulnerable patients. The main goal of anaesthesia practice is to reduce the sympathetic stimulation resulting either from intubation or from pneumoperitoneum and provide good hemodynamic stability perioperatively. For this purpose, multimodal analgesic regimen such as parenteral opioids, non-steroidal anti-inflammatory drugs or local wound infiltration with local anaesthetics have been tried to reduce pain and postoperative complications of patients undergoing laparoscopic surgeries^[28]. Despite their efficacy, all parenteral medications are associated with some or the other adverse effects. The ESP block can be a novel regional anaesthesia technique without any major adverse effects to provide analgesia for laparoscopic surgeries. The advantage of ESP block are, ease of administration, minimal or no sedation and ease of administration even in outside settings such as in ICU.

It can be done either as a single injection on single side or on both sides, or as a continuous infusion through catheter. The ESP block is performed by injecting the local anesthetic between the erector spinae muscle and transverse process. The local anesthetic diffuses into the paravertebral space, through the space adjacent to vertebra and blocks both dorsal and ventral branches of the thoracic spinal nerves^[29,30]. In our study, we evaluated the efficacy of ESP block by using 0.375% ropivacaine with or without dexmedetomidine on either side at T7 level using USG guidance in patients undergoing laparoscopic cholecystectomy under general anaesthesia. Based on the existing literature, we believed that the lower umbilical trocar incision would not be covered by the block. So we have given 5mL of 0.5% ropivacaine to surgeons to infiltrate at lower trocar site at the time of

Table 1: Total postoperative analgesia (hrs)

	Group R	Group RD	p-value
Primary Objectives	3.58±0.57	5.71±0.8	0.000

Table 2: Total duration of analgesia from the time of block (hrs)

	Group R	Group RD	p-value
Total duration of analgesia	5.42±0.54	7.71±0.57	0.000

Table 3: Total Paracetamol consumption in first 24 hrs of postoperative period

	Group R	Group RD	p-value
Paracetamol consumption(gm)	1.3(±0.47)	1.03(±0.18)	0.005

Table 4: Total Tramadol consumption in first 24 hours of postoperative period

	Group R	Group RD	p-value
Tramadol consumption (mg)	183.33(±37.9)	126.67(±52.08)	0.000

Table 5: HR at various time intervals intraoperatively (baseline, after intubation, 5, 10, 15, 30, 60, 90 mins and at the end of the surgery)

Groups	Group R (n = 30)	Group RD (n = 30)	p-value
HR-Baseline	85.37±14.13	86.97±14.43	0.666
HR-after intubation	88.2±13.65	85.63±11.65	0.437
HR-5mins	86.27±13.05	82.47±10.77	0.224
HR-10mins	85.73±11.51	81.73±10.02	0.156
HR-15mins	86.83±16.03	80.87±9.35	0.084
HR-30mins	87.47±15.29	71.77±7.45	0.000
HR-60mins	86.9±14.83	79.97±8.98	0.033
HR-90mins	86.87±13.44	68.33±7.68	0.000
HR-at the end of Sx	93.1±12.64	65.8±7.03	0.000

Table 6: MAP distribution of either groups at various time intervals intraoperatively

Groups	Group R (n = 30)	Group RD (n = 30)	p-value Student t-test
MAP-Baseline	99.8±12.44	97.6±11.35	0.477
MAP-after intubation	101.43±11.25	97.73±11.07	0.204
MAP-5mins	93.4±11.44	90.23±10.47	0.268
MAP-10mins	91.87±10.34	89.1±9.83	0.293
MAP-15mins	96.63±10.01	89.77±8.18	0.005
MAP-30mins	96.17±10.63	88.2±8.29	0.002
MAP-60mins	97.07±11.22	89.4±7.98	0.003
MAP-90mins	96.67±12.19	88.63±7.75	0.003
MAP-at the end of Sx	100.07±11.09	89.53±10.13	0

Table 7: VAS Score at various time intervals from 0 point of time

Groups	Group R (n = 30)	Group RD (n = 30)	p-value
PO VAS 1st hrs	1	1	0.154
PO VAS 2nd hrs	2	2	0.009
PO VAS 4th hrs	4	2	0.000
PO VAS 6th hrs	3	3.5	0.001
PO VAS 8th hrs	3	2	0.000
PO VAS 12th hrs	2.5	1.5	0.000
PO VAS 16th hrs	2	2	0.033
PO VAS 20th hrs	2	4	0.113
PO VAS 24th hrs	2	2	0.861

introduction of trocar. We have observed duration of post-operative analgesia, intensity of pain using VAS score, time to request for first rescue analgesic, total rescue analgesic consumption in first 24 hrs, hemodynamic changes following ESP block, adverse effects and complications. The demographic data like age, sex, Mallampatti Class, ASA grades and diagnosis were not statistically significant ($p>0.05$).

In our study, hemodynamic parameters like HR, SBP, DBP, MAP, SpO₂ were observed. HR in our study in group RD significantly reduced from 30th min onwards till the end of surgery when compared to group R ($p<0.05$). Though it was significantly reduced in group RD, none of the patients had bradycardia requiring treatment. This is comparable with study conducted by Basak Altiparmak *et al.*^[31] where they

have noticed significant reduction in heart rate from 30th min onwards without any additional intervention. In their study they used 0.25% bupivacaine 40 mL (20 mL injection each side). In our study, the group R results regarding heart rate are comparable with the study of Veena *et al.* who had also used 0.25% ropivacaine 15mL on each side without any additives. They also noticed no changes in heart rate like our group R results.

In our study SBP, DBP and MAP were recorded at various time intervals in both the groups. In group RD SBP, DBP and MAP were significantly reduced from 15th min onwards till the end of the surgery ($p<0.05$) when compared to group R. But none of the patient required any treatment. Whereas in the study conducted by Basak Altiparmak *et al.* [] it was observed that there were no significant differences in MAP in both group ESP and control group, which could be due to the use of ropivacaine 0.25% without any adjuvants in both groups. Veena *et al.* [] also had similar results as that of Basak Altiparmak *et al.* [] study because they also didn't use any adjuvants.

None of the patients in our study had any respiratory depression which was comparable with the study of Veena *et al.* [] In our study, VAS score from 0 point of time postoperatively was statistically highly significant in group RD up to 16th hrs when compared to group R ($p<0.05$).

In our study, the total duration of analgesia in hours (from the time of ESP block till VAS score was >4) in group RD was 7.71±0.57 which was statistically highly significant when compared to group R (5.42±0.54) ($p = 0.000$). This parameter of our study is comparable with the study of Qiang Wang *et al.* [] where they have conducted USG guided ESP block by using ropivacaine alone in one group and ropivacaine plus dexmedetomidine in the second group to prolong the analgesic duration after thoracotomy surgeries. In their study, group R received 28mL of 0.5% ropivacaine plus 2mL normal saline and group RD received 28mL of 0.5% ropivacaine plus 0.5mcg kg⁻¹ dexmedetomidine in 2mL normal saline. They have noticed the duration of analgesia in group RD to be 505.1±113.9 mins which was statistically highly significant ($p<0.001$) when compared to group R (323.2±73.4mins). These results are almost similar to our results, but the study was in different set of population. Chunfang Jian *et al.*^[32] conducted a randomised controlled study using 3 different doses and concentrations of ropivacaine (0.25%, 0.33%, 0.5%) respectively. The groups with 0.25-0.33% both received 30mL volume of ropivacaine along with 0.5mcg kg⁻¹ of dexmedetomidine where as 0.5% group received 20mL of ropivacaine along with 0.5mcg kg⁻¹ of dexmedetomidine. Here also they noticed a significantly prolonged duration of analgesia

in 0.33-0.5% group when compared to 0.25% group. Since they have used different dosages and different concentrations with different set of patient population, our study cannot be comparable with this study.

In our study, the total duration of postoperative analgesia in group RD is 5.71+0.8 hrs when compared to group R (3.58+0.57) hrs, which was statistically highly significant ($p = 0.000$). In the study of Veena et al.[] even though they have used similar volume (15mL) of drug (0.25% ropivacaine) at similar level (T7) and in similar set of patients (laparoscopic cholecystectomy), the results of our control group cannot be comparable with their group R where the duration of analgesia was 734+64.98 mins which was statistically highly significant when compared to their control group. Even though the methodology and data collection was similar, large disparity in the results between the two studies cannot be explainable.

The total analgesic consumption of intravenous paracetamol in first 24 hrs after surgery was 1.03+0.18 in group RD and 1.3+0.47 in group R which was statistically highly significant ($p = 0.005$). Intravenous tramadol consumption in group RD was 126.67+52.08 when compared to group R (183.33+37.9) which was statistically highly significant ($p = 0.000$). These results of our study cannot be comparable with any other study because different study people have used different drug for rescue analgesia. Most of them have used intravenous morphine, intravenous fentanyl, oral morphine and oral tenoxicam.

The adverse effect like nausea was seen in one patient in group R and none in group RD. One patient in group RD had vomiting and none in group R. Shivering was there in 3 patients in group R and 3 patients in group RD. None of the patients from both groups had shoulder pain. Patients from both the group had arousable sleep. None of the above adverse effects had any statistical significance ($p>0.05$). The adverse effects of our study can be comparable with Veena et al.[] study, where they also got similar results.

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