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Original Article

Anaesthesia Section

Efficacy of Bilateral Erector Spinae Plane Block using Bupivacaine and Ropivacaine for Postoperative Analgesia following Lumbar Spine Surgeries- A Randomised Clinical Study

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ABSTRACT

Introduction: Erector Spinae Plane Block (ESPB) is a safe and simple technique that provides favourable pain relief and reduced postoperative analgesia consumption. Both bupivacaine and ropivacaine have been used in ESPB and have been found to provide good postoperative analgesia.

Aim: To compare the efficacy of bupivacaine and ropivacaine in bilateral ESPB for postoperative pain relief in lumbar spine surgeries.

Materials and Methods: The randomised clinical trial was conducted from July 2019 to June 2020. The study included 60 patients posted for lumbar spine surgeries which were divided randomly into two groups. Group A patients (n=30) received ESPB using 0.25% bupivacaine and group B patients (n=30) received ESPB with 0.2% ropivacaine after induction of GA with endotracheal intubation. Visual Analog Scale (VAS) score, time to first rescue analgesic, haemodynamic changes and any complications were monitored at regular time intervals in the postoperative period. For quantitative data, a parametric test (Student's t-test) and a non parametric test (Mann-Whitney U test) were used. The Chi-square test was used for parametric analysis of qualitative data.

Results: The mean age (in years) in Group A was 36.93±9.47 and Group B was 38.00±8.43. There was significant difference in mean VAS scores between bupivacaine and ropivacaine groups at 4 hours (4.03±0.93 vs 4.57±0.94; p-value=0.033) and at 6 hours (5.63±0.55 vs 5.26±0.64; p-value=0.021), postoperatively. The mean time to first rescue analgesic requirement was significantly higher in bupivacaine group than ropivacaine group (6.33±1.3 vs 5.27±0.97 hours: p-value=0.001). Patients in both the groups remained haemodynamically stable throughout the study period. No significant change in saturation, Electrocardiogram (ECG) changes, postoperative nausea and vomiting was observed in any of the two groups.

Conclusion: The ESPB with bupivacaine 0.25% provides better and prolonged analgesic effect postoperatively as compared to ropivacaine 0.2% with acceptable haemodynamic stability.

Keywords: Postoperative pain, Postoperative opioid consumption, Ultrasound-guided block, Visual analogue scale score

INTRODUCTION

According to the Global burden of disease study in 2010, the incidence of low back pain (due to degenerative spine diseases or trauma) among world population is around 60-70%. The incidence is increasing every year and many of these patients have to undergo surgery [1]. Severe postoperative pain following spine surgery is the most important cause of morbidity, extended length of hospital stay and marked opioid usage. Control of postoperative pain following spine surgery remains a challenge for the anaesthesiologist. Different modalities of acute postoperative pain relief have been mentioned previously in many studies. In spine surgeries, this has been primarily confined to neuraxial techniques, namely epidural analgesia and intrathecal opioids [2]. These have side effects and limitations.

The Erector Spinae Plane Block (ESPB) has been recently described as an effective method of postoperative analgesia. It is a para spinal block targeting the ventral rami, dorsal rami, and rami communicates of spinal nerves [3]. It stands out for its effectiveness, simplicity and safety [4,5]. Potential benefits of the lumbar ESPB include the ease of performance with clear landmarks for ultrasound anatomy. The block spreads craniocaudally which allows the block to be performed at a distance from the surgical field [6]. Another notable benefit is the possible reduction in perioperative and postoperative opioid consumption. This technique is safe, because it is injected in a muscular plane with no risk for mechanical nerve contact [7].

ESPB facilitates recovery and is associated with lesser complications while providing good analgesia [8]. Patients report lower pain, require limited postoperative opioid, have fewer medication side effects and achieved earlier ambulation [7].

Both bupivacaine and ropivacaine belong to amide group of local anaesthetics, and are capable of producing prolonged anaesthesia by percutaneous infiltration, peripheral nerve block(s) and central neural block. Due to reduced potential for cardiotoxicity and neurotoxicity, ropivacaine is safer than the racemic mixture, bupivacaine [9]. Ropivacaine has lower lipid solubility as compared to bupivacaine, which is responsible for its lower penetration into myelinated motor fibers and thus lesser motor blockade with greater sensory- motor differentiation [9]. Previous studies by Ghamry MR et al., and Singh S and Chaudhary NK. in Ultrasound (USG) guided ESPB have found bupivacaine to be very effective in providing postoperative analgesia [10,11]. Similarly previous studies done by Gonzalez S et al., Jin Y et al. and Yao Y et al., in ESPB have found ropivacaine to be very effective in postoperative pain control [12-14]. However, to the best of our knowledge, no previous study has ever compared bupivacaine and ropivacaine for their efficacy in ESPB in patients undergoing lumbar spine surgeries.

Aim of this study was to compare the efficacy of bupivacaine and ropivacaine in bilateral erector spine block for postoperative pain relief following lumbar spine surgeries. Primary objective was to compare the Visual Analogue Scale (VAS) scores at different time

points postoperatively between the groups. Secondary objectives were to compare the times at which first rescue analgesic was required in the two groups as well as haemodynamic stability and complications if any.

MATERIALS AND METHODS

The randomised double blind study was conducted from July 2019 to June 2020 at King George's Medical University (KGMU), Lucknow, Uttar Pradesh, India. Clearance was obtained from Institutional Ethics Committee (ECR/262/Inst/UP/2013/RR-16).

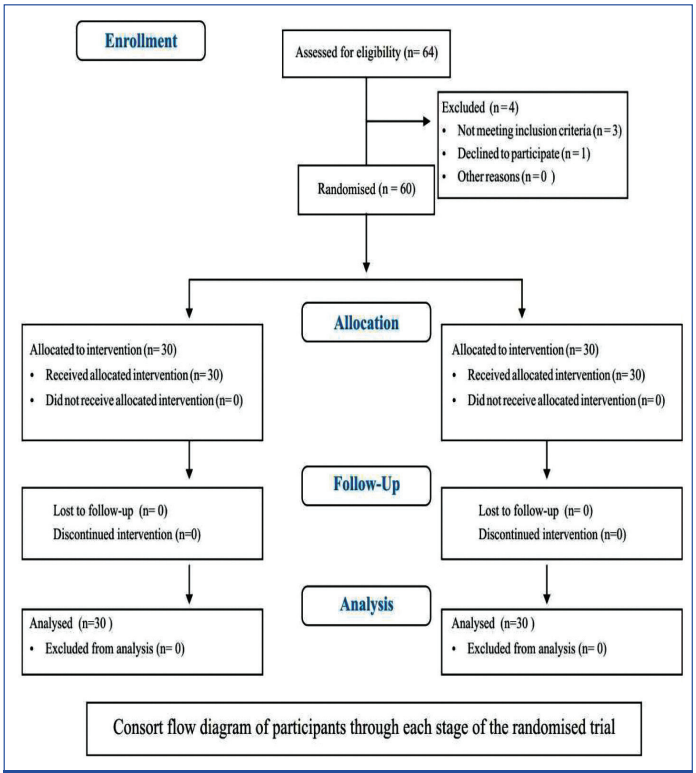
Inclusion and Exclusion criteria: Patients of either sex in the age group of 18-65 years admitted for lumbar spine surgeries and belonging to American Society of Anaesthesiologists physiologic state I-II were included in the study. Patients not giving consent, having known allergy to local anaesthetics, having bleeding disorders, a history of drug abuse or dependent on opioid drugs were excluded from the study.

Sample size calculation: Sample size was calculated on the basis of maximum variation in VAS during the postoperative period among the study groups using the formula:

$$n=\frac{(Z_\alpha+Z_\beta)^2(\sigma_1^2+\sigma_2^2)}{d^2}$$

based on a previous study by Nagaraja PS et al., keeping the confidence level at 95% and power of study at 90% [15]. The required sample size came out to be n=30 each group.

A total of 64 patients were assessed for eligibility, of which three didn't meet the inclusion criteria and one patient declined to participate. Sixty patients were finally included in the study [Table/Fig-1]. All enrolled patients were randomly allocated into one of two groups using computer generated random number table and sealed envelope method:



[Table/Fig-1]: CONSORT flow diagram.

Group A (n=30): received ESPB with 15 mL of 0.25% Bupivacaine on each side.

Group B (n=30): received ESPB with 15 mL of 0.2% Ropivacaine on each side.

A preanaesthetic check-up was done. All patients were given tablet alprazolam 0.25 mg on the night before surgery for anxiolysis. Bilateral ESPB technique was fully explained. Written informed consent was taken from all the patients. In the operating room, all the standard anaesthesia monitors were attached and induction of general anaesthesia was done using standard anaesthesia technique.

After placing the patients in prone position and ensuring haemodynamic stability, the skin was disinfected and blocks performed at L1 or L2 level. High frequency linear array ultrasound transducer, covered with a sterile sleeve was placed at the mid vertebral line in a longitudinal parasagittal plane. The transducer was shifted from the midline 3 cm laterally to visualise the tip of the transverse process. Superficial to hyperechoic lumbar process, the erector spinae muscles were identified. A 22G/80 mm block needle (Stimuplex A, B Braun, Melsungen, Germany) was advanced in-plane with the ultrasound beam in cranial to caudal direction to gently contact the transverse process where 0.5-1 mL of the prepared Local anaesthesia (LA) solution was administered leading to hydrodissection (upward displacement of erector spinae muscle) to confirm correct location. The needle was repositioned by pulling back a few millimetres if resistance occurred while administering local anaesthesia. All LA was administered at this location between the transverse process and the ESM in the interfascial plane. The same procedure was performed on opposite side.

Continuous monitoring of Heart Rate (HR), Blood Pressure (BP), Oxygen Saturation (SpO_2) and Electrocardiography (ECG) were done intraoperatively. At the end of surgery, tracheal extubation was performed after reversal of neuromuscular blockade. The postoperative pain assessment was performed using 10 cm VAS. The VAS score was recorded at zero hour (being immediate postextubation), 1, 2, 4, 6, 12 and 24 hours. Postoperative haemodynamic parameters were recorded at regular intervals. Any complication related to method or drugs was noted. Injection tramadol 50 mg intravenous (i.v.) was given as rescue analgesic when patient complained of pain and VAS score was ≥5. Time to first rescue analgesia was also noted. Until first rescue analgesia, no other analgesics were administered. The patient as well as the anaesthetist assessing pain in the postoperative period was unaware of group allocation.

STATISTICAL ANALYSIS

The statistical analysis was done using Statistical Package for Social Sciences (SPSS) Version 21.0 Inc Chicago, IL, USA statistical Analysis Software. Data were presented as mean±Standard Deviation (SD), or frequency (percentage). For quantitative data, a parametric test with normal distribution was performed using the Student's t-test and a non parametric test with abnormal distribution was performed using the Mann-Whitney U test. For qualitative data, the Chi-square test was used for parametric analysis. The p-value <0.05 was considered as statistically significant for all tests.

RESULTS

Both the groups were comparable with respect to demographic profile (age, sex, weight, height) and duration of surgery [Table/Fig-2]. The mean HR and BP at baseline were comparable between the groups.

Demographic variable	Group A (n=30)	Group B (n=30)	t*	p-value
Age (years)	36.93±9.47	38.00±8.43	-0.46	0.647
Weight (kg)	58.7 7±6.77	58.00±5.94	0.223	0.824
Height (cm)	162.23±6.28	162.57±5.80	-0.214	0.832
Duration of surgery (min)	167.83±4.54	166.50±5.04	1.08	0.286
Gender	**n (%)**	**n (%)**	**χ^{2}†**	**p-value**
Female (n=21)	12 (40.0)	9 (30.0)	0.659	0.417
Male (n=39)	18 (60.0)	21 (70.0)		

[Table/Fig-2]: Demographic profile and duration of surgery.
*Independent t-test used; †Parametric chi-square test used; p-value <0.05 was significant

The mean time to first rescue analgesia requirement was significantly later in group A than group B [Table/Fig-3]. No patients required rescue analgesia till three hours after surgery. Requirement of rescue

analgesia was earlier in more patients in group B as compared to group A [Table/Fig-4]. On intergroup comparison, significant difference was observed in proportion of patients requiring first rescue analgesia at different time periods (p-value=0.026).

VAS (Postoperative)	Group A (n=30) Mean±SD	Group B (n=30) Mean±SD	t*	p-value
Baseline (Before induction)	0.70±0.47	0.80±0.41	-0.89	0.375
0 hr	1.13±0.43	1.23±0.43	-0.86	0.391
1 hr	1.70±0.65	1.63±0.56	-0.30	0.764
2 hr	2.87±0.82	3.30±0.65	-1.12	0.261
4 hr	4.03±0.93	4.57±0.94	-2.13	0.033
6 hr	5.63±0.55	5.26±0.64	2.37	0.021
12 hr	4.70±0.54	4.5±0.51	1.48	0.143
24 hr	4.40±0.50	4.5±0.51	-1.03	0.309

[Table/Fig-3]: Intergroup comparison of Visual Analog Scale (VAS) score at various time points.
*Independent t-test used; p-value <0.05 was significant

Group	N	Time of first rescue analgesia Mean±SD	t*	p-value
Group A	30	6.33±1.3	3.69	0.001
Group B	30	5.27±0.91		

[Table/Fig-4]: Intergroup comparison of mean time to first rescue analgesia dose requirement.
*Independent t-test used; p-value <0.05 was significant

In both the groups, there was a progressive increase in VAS scores till 6 hours postoperative after which there was a decreasing trend [Table/Fig-5]. Between the groups a significant difference in mean VAS score was found at 4 hours and 6 hours postoperative, being lesser in group A at 4 hours and in group B at 6 hours.

Time to first rescue analgesia (hrs)	Group A (n=30) No. (%)	Group B (n=30) No. (%)	χ^{2*}	p-value
0-3	0	0	7.28	0.026
3-6	3 (10.0)	13 (43.33)		
6-9	26 (86.7)	17 (56.67)		
9-12	1 (3.3)	0 (0.0)		
Total	30 (100.0)	30 (100.0)		

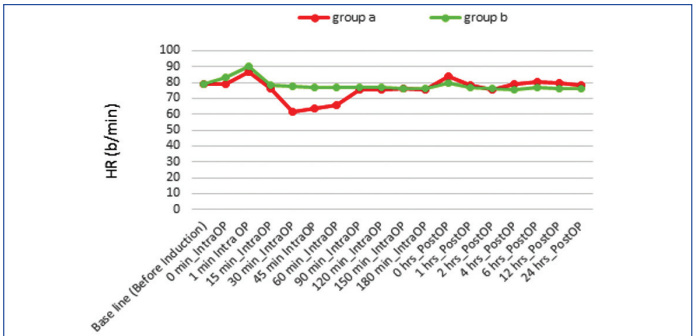
[Table/Fig-5]: Intergroup comparison of number of patients requiring first rescue analgesia at different time intervals.
*Parametric chi-square test used; p-value <0.05 was significant

Patients in both the groups remained haemodynamically stable throughout the study period. There was no significant difference in the mean HR between the groups at baseline and at other time points throughout the study except at 30 minutes, 45 minutes and 60 minutes intraoperative when the HR was significantly lesser (p-value<0.001) in group A as compared to group B. However, HR was never below 60/min and no medical intervention was required at any point of time [Table/Fig-6].

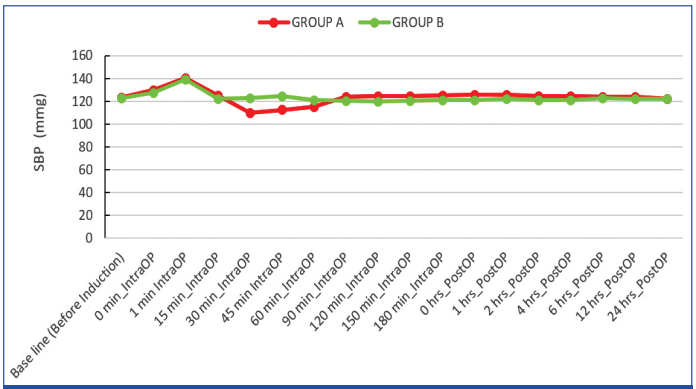
HR (Heart rate (beats/min))	Group A Mean±SD	Group B Mean±SD	t*	p-value
Base line (Before induction)	79.00±7.87	78.87±8.81	0.06	0.951
0 min intraoperative	79.33±7.40	82.90±9.00	-1.68	0.099
1 min intraoperative	87.00±7.39	90.47±9.14	-1.62	0.112
15 min intraoperative	76.40±7.06	78.57±9.17	-1.03	0.309
30 min intraoperative	61.67±6.77	77.80±8.82	-8.05	<0.001
45 min intraoperative	63.57±6.72	76.97±8.60	-6.73	<0.001
60 min intraoperative	65.60±6.64	77.10±8.47	-5.75	<0.001
90 min intraoperative	75.67±4.52	76.63±8.51	-0.55	0.585
120 min intraoperative	75.77±4.26	76.97±8.03	-0.72	0.473
150 min intraoperative	76.27±5.22	75.93±8.30	0.19	0.853
180 min intraoperative	75.53±4.83	76.43±7.63	-0.55	0.587
0 hr postoperative	83.83±6.75	80.07±8.34	1.92	0.059
1 hr postoperative	78.53±6.93	77.23±7.73	0.69	0.496

[Table/Fig-6]: Intergroup comparison of Heart Rates (HR) at various time points.
*Independent t-test used; p-value <0.05 was significant

Similarly, BP was stable with only minor fluctuations throughout the study in both the groups. There was no significant difference in systolic and diastolic BP between the two groups except at 30, 45 and 60 minutes intraoperative when it was lesser in group A however the change in SBP and DBP was never more than 20% from the baseline values and it never necessitated any medical intervention [Table/Fig-7 and 8].



[Table/Fig-7]: Intergroup comparison of SBP at various time points.



[Table/Fig-8]: Intergroup comparison of DBP at various time points.

In the present study, there was no significant difference observed in peripheral capillary SpO_2 between the two groups during intraoperative and postoperative periods [Table/Fig-9]. There were no episode of airway compromise.

SpO_2 (%)	Group A Mean±SD	Group B Mean±SD	t*	p-value
Baseline (Before induction)	98.67±1.12	98.23±1.19	1.45	0.153
0 min intraoperative	99.60±2.41	98.77±2.33	1.75	0.083
15 min intraoperative	100.00±0.00	99.97±0.18	1.00	0.321
30 min intraoperative	100.00±0.00	99.97±0.18	1.00	0.321
60 min intraoperative	99.60±0.62	99.53±0.73	0.38	0.705
90 min intraoperative	99.50±0.68	99.53±0.63	-0.20	0.845
120 min intraoperative	99.63±0.62	99.73±0.52	-0.68	0.500
150 min intraoperative	99.70±0.59	99.63±0.56	0.45	0.656
180 min intraoperative	99.73±0.58	99.67±0.57	-0.44	0.662
0 hr postoperative	98.67±0.99	98.83±1.21	-0.58	0.561
1 hr postoperative	99.40±0.67	99.03±1.03	1.63	0.109
2 hr postoperative	99.60±0.92	99.17±1.33	1.90	0.061
4 hr postoperative	99.53±0.83	98.93±2.09	1.89	0.062
6 hr postoperative	99.30±1.02	98.83±1.35	1.95	0.054
12 hr postoperative	99.07±0.91	98.97±0.85	0.44	0.661
24 hr postoperative	99.37±0.72	99.37±0.67	0.00	1.000

[Table/Fig-9]: Intergroup comparison of SpO_2 at various time points.
*Independent t-test used; p-value <0.05 was significant

DISCUSSION

The ESPB is a novel interfascial paraspinal plane technique, which was first proposed by Mannion AF et al., and further developed by Forero M et al., for analgesia in thoracic neuropathic pain [3,16]. Since then, the block has been reported to have been used successfully in a multitude of procedures and is still in numerous trials with many different types of surgical procedures, and various prospective studies are ongoing.

The standard practice for performing an ESPB now-a-days uses an ultrasound guidance to inject local anaesthetic between the erector spinae muscle and the transverse process of the lumbar vertebra. This leads to spread of LA cephalad, caudally and through the paravertebral space between the adjacent vertebrae thereby blocking the dorsal and ventral rami of spinal nerves [17]. This blockage helps to achieve a multi-dermatomal sensory block of the anterior, posterior and lateral lumbar and abdominal walls [6].

Both bupivacaine and ropivacaine have been used in ESPB in many previous studies and both these local anaesthetics have been found to provide good analgesia resulting in minimal opioid consumption in the postoperative period. However, no previous studies could be found comparing these two drugs for their efficacy in ESPB in patients undergoing lumbar spine surgeries.

In this randomised double blind study, USG-guided ESPB was given to a total of 60 patients who underwent lumbar spine surgeries over a period of one year. It was found that ultrasound guided ESPB with bupivacaine 0.25% provided better and prolonged analgesic effect postoperatively as compared to ropivacaine 0.2% with acceptable haemodynamic stability.

The concentration of bupivacaine used in this study was based on a previous study done by Ghamry MR et al., in USG guided ESPB for acute pain management in patients undergoing posterior lumbar interbody fusion surgery under general anaesthesia [10]. They used 0.25% bupivacaine for ESPB and found it to be very effective in providing postoperative analgesia and decreased intraoperative and postoperative opioid consumption. Similarly, Singh S and Chaudhary NK, in their study on bilateral. The ESPB with 0.25% bupivacaine in lumbar spine surgery cases reported the prolonged postoperative analgesic effect [11]. Likewise the concentration of ropivacaine used in this study was based on a previous study done by Gonzalez S et al., in ESPB with 0.2% ropivacaine in patients undergoing lumbar spine fusion surgery and found it to be very effective in postoperative pain control [12].

In this study, the mean VAS score of the patients in bupivacaine group increased progressively in the postoperative period till 6 hours and later on decreased after receiving rescue analgesia. Ghamry MR et al., conducted a randomised study in USG guided ESPB for acute pain management in patients undergoing posterior lumbar interbody fusion surgery [10]. In their study, 30 patients received bilateral ESPB with 0.25% bupivacaine and another 30 patients using normal saline. They observed that the mean VAS score began to increase (VAS score ≥5) in bupivacaine group at 12 hour and 8 hours postoperative (static and dynamic VAS respectively), but they were lower than in control group. Prolonged duration of postoperative analgesia obtained in their study might be due to use of intraoperative opioid analgesic (Inj. fentanyl 75.5±5.99 mcg) in their study.

Mean VAS score of the ropivacaine group patients in the present study also increased progressively to reach a maximum value at 6 hours postoperative. Gonzalez S et al., in a case series performed bilateral ESPB using 0.2% ropivacaine in patients undergoing lumbar spine fusion surgery [12]. They recorded patient-reported pain intensity during the first 48 postoperative hours using VAS score and rescue analgesic requirements. Pain at rest was controlled in all patients (VAS 0-3) and pain on movement ranged from mild to severe (VAS 0-8).

Authors didn't come across any prior study comparing bupivacaine and ropivacaine for their efficacy in ESPB in patients undergoing lumbar spine surgeries. In the present study comparing bupivacaine and ropivacaine in ESPB, at 4 hours postoperative the mean VAS score increased to ≥5 only in 10% cases in bupivacaine group against the 43% cases in ropivacaine group. The mean VAS score of ≥5 was reached in 86.7% of cases in bupivacaine 0.25% group only at 6 hours postoperative, making it quite evident that the bupivacaine provides prolonged analgesia when compared to ropivacaine. A significantly lower mean VAS score was found in bupivacaine group at 4 hours. However, at 6 hours postoperative, the mean VAS score reported was lesser in ropivacaine group. This could be because of the fact that significantly higher number of patients in group B than group A had already received their first rescue analgesia dose by 6 hours postoperative.

The duration of ESPB is related to the type and dose of local anaesthetics used. The dose and concentration can be increased appropriately to prolong the analgesia time and help the patients to get through the most painful stage after surgery.

Ghamry MR et al., in their USG-guided ESPB using bupivacaine 0.25% in patients undergoing posterior lumbar interfusion surgery found the mean requirement of first rescue analgesic was at 461.33±58.82 min (7.68±0.98 hrs) which is slightly prolonged as compared to the present study (6.33±1.3 hrs) [10].

Takahashi H and Suzuki T, in a case report mentioned the duration of pain relief obtained by bilateral ESPB using 0.1875% ropivacaine for low back pain in failed back surgery syndrome [18]. Pain relief lasted for approximately 10 hrs after the initial block and the patient's daily baseline level of low back pain had diminished to <40% of its original severity. Krishna SN et al., in their randomised controlled trial in bilateral ESPB using 0.375% ropivacaine in 106 patients undergoing cardiac surgery, reported that the mean duration of analgesia was 8.98 hrs in ropivacaine group compared to control group using normal saline [19]. Lower time to requirement of first rescue analgesia in ropivacaine group in the present study compared to the above mentioned study might be due to differences in concentrations of ropivacaine used and types of surgeries studied.

All the patients in both the groups in this study were haemodynamically stable throughout the study. In ropivacaine group none of the patients had BP and HR fall. Though there was fall in mean HR and BP intraoperatively in considerable number of patients in bupivacaine group, but the fall was less than 20% from baseline and didn't require any medical interventions. This observation is in line with the study of Ayoubi SE et al., in ESPB using 0.25% bupivacaine in radical mastectomy patients [20].

They noted a fall in SBP, DBP and HR from the baseline during incision and dissection time (variations were less than 20% from the baseline). In view of above observations, it can be said that both bupivacaine 0.25% and ropivacaine 0.2% used in ESPB for postoperative analgesia offers acceptable haemodynamic stability.

Compared with other regional techniques, ESPB is a safe and simple technique. The USG guidance improves the ease of performing the procedure, increases the success rate, reduce complications and onset time of blocks. Bilateral ESPB provides favourable pain relief and reduced postoperative analgesia consumption and complications related to opioid use. Also, ESPB helps in early recovery and early mobilisation of patients.

Limitation(s)

This study was from a single centre with limited number of participants. Multicentric studies with larger numbers of patients should be done in future to verify the effects. The VAS score was used for assessing pain which is a subjective parameter for evaluating outcomes and varies from person to person. This might have caused some bias in assessment of postoperative analgesia.

The dose of local anaesthetic was not determined as per the height and weight of the patient.

CONCLUSION(S)

It was concluded that USG-guided guided ESPB with bupivacaine 0.25% provides better and prolonged analgesic effect postoperatively as compared to ropivacaine 0.2% with acceptable haemodynamic stability.

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