

A randomised prospective single-blind pilot study to compare the analgesic efficacy of thoracic epidural block and erector spinae plane block in breast cancer surgery

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Submitted: 09-Nov-2021

Revised: 18-Apr-2022

Accepted: 21-Apr-2022

Published: 17-May-2022

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ABSTRACT

Background and Aims: Thoracic epidural analgesia (TEA) is an effective analgesic technique for breast surgery, although it has many associated complications. Ultrasound (US)-guided erector spinae plane (ESP) block requires less technical expertise, is safe and may be an alternative to TEA. We aimed to compare the efficacy of TEA with US-guided continuous ESP block for post-operative analgesia in patients undergoing modified radical mastectomy (MRM) surgeries. **Methods:** Sixty-six female patients of age group 18–65 years, and American Society of Anesthesiologists (ASA) physical status I and II, undergoing MRM surgeries were recruited. Patients received TEA in Group Ep and US-guided ESP block in Group Er, before induction of general anaesthesia. Both the groups received 0.2% ropivacaine 15 mL, followed by 5 mL.h⁻¹ infusion for 24 h. The primary outcome was the duration of analgesia. Secondary outcomes were total doses of rescue analgesics in 24 hours and visual analogue scale (VAS) scores at 0 h, 1 h, 2 h, 4 h, 8 h, 12 h, and 24 h. **Results:** The mean duration of analgesia was 21.72 ± 4.73 hours in Ep group and 20.60 ± 5.77 hours in Er group ($P = 0.39$). The total dose of rescue analgesics in the postoperative period was comparable between both the groups. There was no significant difference in VAS scores between the groups over 24 h. **Conclusion:** US-guided ESP block can be used as safe and easy to perform alternative analgesic technique over thoracic epidural analgesia for peri-operative pain management in breast cancer surgeries.

Key words: Breast neoplasms, epidural analgesia, modified radical mastectomy, nerve block

Access this article online
Website: www.ijaweb.org
DOI: 10.4103/ija.ija_982_21
Quick response code


INTRODUCTION

Breast cancer is the most commonly reported malignancy in females worldwide.^[1] Approximately 55% of patients who undergo breast surgery experience significant chronic pain persisting for months to years if adequate analgesia is not provided post-operatively, causing anxiety, depression and decreased quality of life.^[2]

Various regional anaesthesia techniques like thoracic epidural analgesia (TEA), paravertebral block, intercostal nerve block, pectoral nerve block and erector spinae plane (ESP) block have been used for postoperative analgesia. Before the era of ultrasound

and interfascial plane blocks, TEA has been the standard regional analgesic technique in breast cancer surgery, as it provides excellent pain relief.^[3]

The ultrasound (US)-guided ESP block technique, described by Forero *et al.*,^[4] involves the administration

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How to cite this article: Karoo K, Kumar M, Sinha M, Nilima N. A randomised prospective single-blind pilot study to compare the analgesic efficacy of thoracic epidural block and erector spinae plane block in breast cancer surgery. *Indian J Anaesth* 2022;66:S148-53.

of local anaesthetic injection beneath the erector spinae muscle just above the transverse process of vertebrae. US-guided ESP block is technically easy to perform, can be learnt quickly and has minimal complications.

Continuous ESP block has been used recently to provide post-operative analgesia after cardiac and thoracic surgeries.^[5,6] The purpose of this randomised controlled trial was to compare the efficacy of TEA with US-guided continuous ESP block for post-operative analgesia in patients scheduled for elective unilateral modified radical mastectomy (MRM).

We hypothesised that continuous ESP block could reduce analgesic consumption and provide adequate postoperative analgesia for breast surgeries similar to continuous TEA.

METHODS

This prospective, randomised, single-blinded parallel-group controlled clinical study was conducted in the operating room of a tertiary care referral centre from November 2019 to July 2020. The study was registered in the Clinical Trial Registry, India (CTRI/2019/11/022118) prospectively after approval by the Institutional Ethics Committee (488/IEC-AIIMS RPR/2018). The study followed all the principles of the declaration of Helsinki.

After obtaining written informed consent, 66 female patients aged 18–65 years of American Society of Anesthesiologists (ASA) physical status I and II who underwent unilateral MRM were included.

Patients with ASA grade III and above, obesity (body mass index [BMI] >30 kg.m⁻²), infection of the skin at the site of the needle puncture, known allergies to any of the study drugs, coagulopathy, psychiatric disorder or pre-existing neurological disease were excluded from the study.

Patients were randomly allocated to two groups (group Ep and group Er) of 33 each. Group Ep patients received TEA; Group Er patients received US-guided continuous ESP block. In both the groups, patients received 15 mL of 0.2% ropivacaine as a bolus, and thereafter 5 mL.hr⁻¹ infusion of 0.2% ropivacaine intraoperatively and postoperatively.

Randomisation was achieved using computer-generated random numbers [online from www.researchrandomiser.com].

The group allocation random numbers were concealed in sequentially numbered opaque sealed envelopes that were opened after the enrolment of the patients, and the intervention was done according to the number in the envelope.

In the operation room, after securing an intravenous line, patients were placed in the sitting position with standard ASA monitors (pulse oximeter, electrocardiogram and noninvasive blood pressure). In Ep group, an epidural catheter was inserted through an 18-gauge Tuohy needle at T3-T4 or T4-T5 level after identifying the epidural space by loss of resistance technique. Epidural catheter was fixed at skin at 9-10 cm. Patient was made supine immediately after epidural catheter placement and 15 mL of 0.2% ropivacaine was administered in aliquots of 5 mL over 5 minutes.

In the Er group, the ipsilateral ESP block was given at the level of T3 or T4 using an 18-gauge Tuohy epidural needle using a linear probe (7–12 MHz) of ultrasound (SonoSite, Inc., Bothell, WA, USA) in-plane parasagittal approach. ESP block was given by investigators of the study who were well trained and regularly performing ESP block. The needle was inserted in a craniocaudal direction deep to the erector spinae muscle. Normal saline (1-2 mL) was injected to observe the lifting up of the fascia above the transverse process [Figure 1]. Thereafter, a catheter was inserted beneath the erector spinae muscle just above the transverse process of vertebrae, fixed at 8–10 cm at skin and 15 mL of 0.2% ropivacaine was injected

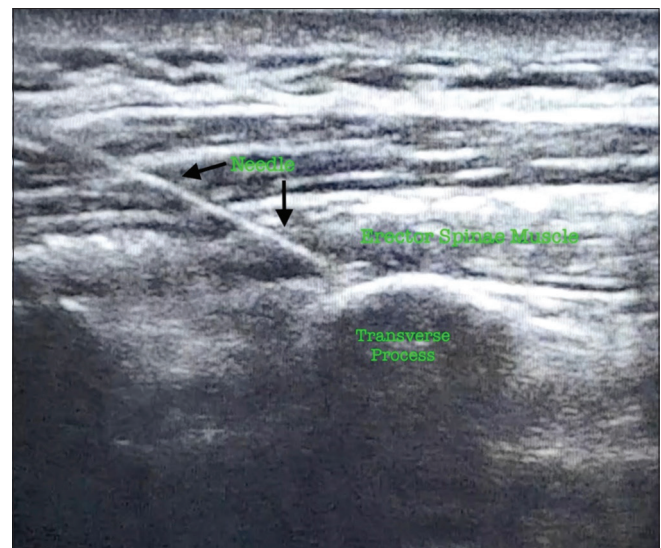


Figure 1: Ultrasound image showing needle tip over the transverse process

slowly in aliquots of 5 mL. The spread of the drug was observed by lifting the erector spinae muscle off the underlying transverse process.

The success of the block was confirmed by observing and evaluating the patient for 20 min after performing the block. The sensory level of block was assessed with pin-prick sensation every 5 min in each dermatomal distribution from T1 to T8. The block was considered as failed if loss of sensation was not attained within 20 min. Intraoperative analgesia was maintained with 5 mL of 0.2% ropivacaine infusion per hour in both groups.

Intravenous induction of anaesthesia was done with fentanyl $2 \mu\text{g.kg}^{-1}$, propofol $2\text{-}3 \text{ mg.kg}^{-1}$ and vecuronium 0.1 mg.kg^{-1} . The trachea was intubated with an appropriately sized endotracheal tube. Anaesthesia was maintained with 50% oxygen with nitrous oxide and isoflurane 1-1.5% (minimum alveolar concentration of 0.8-1.0). Heart rate (HR) more than 20% of baseline was treated with fentanyl $0.5 \mu\text{g.kg}^{-1}$. Ondansetron 4 mg was administered 30 minutes before completion of surgery.

At the end of the surgery, neuromuscular reversal was provided with 0.05 mg.kg^{-1} of neostigmine and 0.01 mg.kg^{-1} of glycopyrrolate. The infusion of 0.2% ropivacaine 5 mL.hr^{-1} was continued in the postoperative period and patients were monitored for 24 h after surgery in the postoperative ward.

The primary outcome measure of the study was the duration of analgesia (time to demand of first rescue analgesia after administration of block). The secondary outcome measures were total analgesic consumption in the 24 h after surgery, visual analogue scale (VAS) scores at 0 h, 1 h, 2 h, 4 h, 8 h, 12 h, and 24 h and the presence of any adverse effects such as hypotension, respiratory depression, shivering, and urinary retention. Post-operative pain was assessed using VAS scores ranging between 0 (no pain) and 10 (worst imaginable pain). Significant pain requiring analgesia was considered only if VAS was more than 4. The readings were recorded in the data collecting sheet. The time of first request of rescue analgesia was noted. Rescue analgesia was given as intravenous paracetamol (PCM) 15 mg.kg^{-1} if VAS >4 and additional tramadol 2 mg.kg^{-1} was administered if the patient continued to complain of pain [VAS >4]. The total dose of PCM and tramadol administered was noted. If a patient requested analgesia between

the assessment period, VAS scores were assessed and recorded at that particular time.

Due to the unavailability of literature on continuous ESP block in MRM, the present study was conducted as a pilot study with a minimum sample size of 30 in each group. Furthermore, after considering 10% dropout rate throughout the study, a total of 33 subjects were enrolled in each group.

Continuous variables were expressed as mean \pm standard deviation and median (25th, 75th percentiles), and categorical variables as counts (percentages). The Kolmogorov–Smirnov test was used to investigate if the distribution was normal. Normally distributed continuous variables were compared across the groups using unpaired Student's *t*-test, whereas non-normally distributed continuous variables and ordinal variables were compared using the Wilcoxon rank sum test. Associations between categorical variables were investigated using Fisher's Exact test or Chi-square test, as applicable. Friedman's analysis of variance (ANOVA) was used to compare the VAS scores across groups Ep and Er over time. The data were analysed using R version 3.0.1 and Stata version 15 (StataCorp, College Station, Texas, USA) software. A *P* value <0.05 was considered statistically significant.

RESULTS

Sixty-six patients were randomised into two groups and analysed [Figure 2]. No patient was excluded from the final analysis. Demographic data, ASA physical status and durations of surgeries were comparable between the two groups [Table 1].

The difference in the duration of analgesia was non-significant among the two groups. None of the patients required rescue analgesia in the first

Table 1: Demographic profile of patients and duration of surgery

Parameters	Group Ep (n=33)	Group Er (n=33)
Age (years)	47 \pm 10	49 \pm 9
Height (cm)	154.30 \pm 6.76	154.27 \pm 6.16
Weight (kg)	56.10 \pm 8.40	56.74 \pm 9.80
BMI (kg.m ²)	23.63 \pm 3.71	23.72 \pm 3.87
Duration of Surgery (min)	157.48 \pm 17.6	160.21 \pm 21.4
ASA I	17 (51.5%)	17 (51.5%)
ASA II	16 (48.5%)	16 (48.5%)

BMI : Body Mass Index; ASA: American Society of Anesthesiologists. Data is expressed as Mean \pm standard deviation and frequency (percentage) as applicable

5 hours. The mean duration of analgesia was 20.60 ± 5.77 h in group Er, whereas in group Ep, it was 21.72 ± 4.73 h [$P = 0.39$] [Table 1]. The total dose of PCM [median (25th, 75th percentile)] used among the two groups Er and Ep was 0 (0,735) gm and 0 (0,750) gm, respectively [Table 2]. This difference in the requirement of PCM was not statistically significant ($P = 0.88$). Furthermore, 11 out of 33 patients in Er group and 10 out of 33 patients in Ep group required only a single dose of analgesic (PCM 15 mg.kg⁻¹) in 24 hours.

The postoperative VAS score at rest at 0 h, 1 h, 2 h, 4 h, 8 h, 12 h and 24 h was comparable in both the groups [Table 3]; also the mean VAS score was ≤ 4 at 0, 1, 2, 4, 8, 12 and 24 hours in both the groups.

The haemodynamics were comparable in both groups. However, five patients developed intra-operative hypotension in TEA group as compared to ESP block group, where one patient developed hypotension requiring fluid boluses and mephentermine. None of the patients in any group had technique-related complications such as high spinal, vascular puncture and local anaesthetic toxicity. None of the patients in Ep group or Er group had nausea and vomiting.

DISCUSSION

Our initial hypothesis involved the comparison of the efficacy of continuous ESP block with continuous TEA in MRM surgeries. To the best of our knowledge, this is the first randomised controlled trial comparing the peri-operative analgesia provided by continuous ESP block and TEA during MRM, and our findings support observations from previous case reports.^[7,8]

In our study, the mean duration of analgesia was 21.72 ± 4.73 h and 20.60 ± 5.77 h in the TEA and ESP groups, respectively, similar to studies done by other researchers,^[9,10] who also found that ESP block significantly reduces the postoperative analgesic consumption and time to request of first analgesia.

In our study, the difference between two groups Ep and Er with respect to postoperative pain scores [VAS] at 0, 1, 2, 4, 8, 12 and 24 h was non-significant and comparable [$P > 0.05$]. Also, both groups had a mean VAS ≤ 4 , which signifies optimal pain management and efficacy of both techniques. In a similar study conducted to compare continuous bilateral ESP block with TEA in patients undergoing cardiac surgery, both

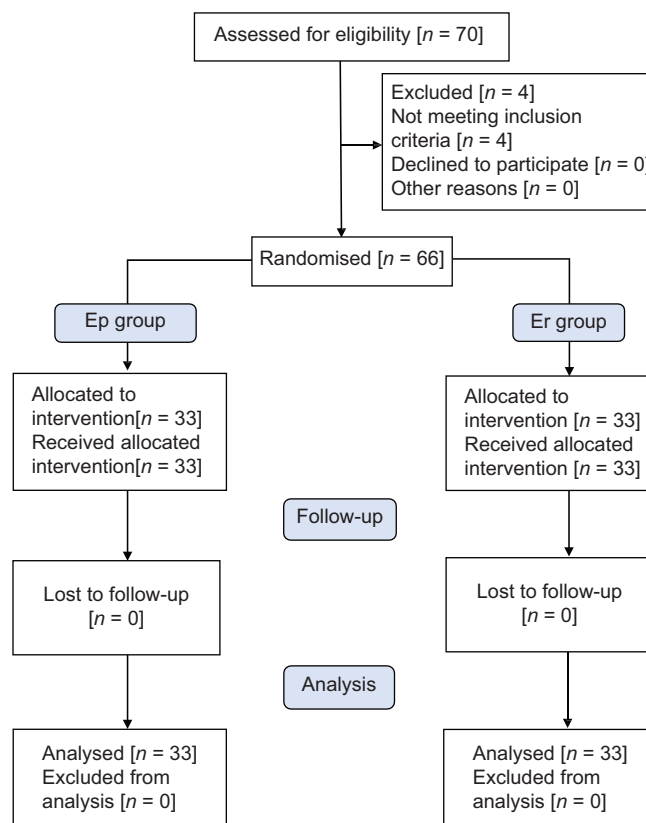


Figure 2: Consolidated Standards of Reporting Trials (CONSORT) diagram for the enrolment of cases

Parameters	Group Ep (n=33)	Group Er (n=33)	P
Duration of analgesia (hours) Mean±SD	21.72±4.73	20.60±5.77	0.39
Total dose of paracetamol (mg) median (25 th , 75 th percentile)	0 (0,735)	0 (0,750)	0.88

SD: Standard deviation

Time (in hours)	Group Er (n=33)	Group Ep (n=33)	P
0	3 (2,4)	3 (2,4)	0.669
1	3 (2,4)	3 (2,4)	0.710
2	3 (2,4)	3 (2,3)	0.639
4	3 (2,3)	3 (2,4)	0.581
8	2 (2,3)	3 (1,3)	0.884
12	2 (2,4)	2 (1,4)	0.462
24	2 (1,3)	2 (1,4)	0.853

Data are expressed as median (25th, 75th percentile). VAS: Visual analogue scale

the groups were comparable for VAS scores at 0 h, 3 h, 6 h, and 12 h [$P > 0.05$].^[5]

ESP block has been compared to other fascial block techniques by various other researchers. Gurkan *et al.*^[11] concluded that both ESP block and paravertebral block

provided better postoperative analgesia compared to intravenous morphine after breast surgeries.

Thiagarajan *et al.*^[12] assessed the efficacy of ESP block in breast cancer surgeries and found it to be effective in post-operative pain control. The mean duration for time to rescue analgesia was 8 h in ESP group, and also patients had lower pain scores and better satisfaction scores.

In our study, a continuous infusion of local anaesthetic was administered through the ESP catheter, which provided more uniform analgesia and led to a reduced requirement of rescue analgesic in the postoperative period for 24 hours.

TEA is technically challenging and associated with complications like intra-operative hypotension, dural puncture, haematoma, abscess and total spinal, which can be easily avoided in ESP block. In our study too, five patients in TEA group developed intraoperative hypotension, whereas in ESP group none of the patients developed hypotension. Thus, ESP block can be an effective modality for postoperative pain management and subsequent prevention of chronic pain syndromes, which are quite prevalent in patients undergoing breast cancer surgery.

Extensive anaesthesia and prolonged analgesia provided by ESP block can be due to the widespread craniocaudal spread of local anaesthetic to the epidural and neural foramina and intercostal spaces. This leads to the blocking of both the ventral and dorsal branches of the spinal nerves^[13] and their communicating branches, augmenting the sympathetic chain.^[14]

Many other advantages of ESP block make it a rather safe and easy block. Firstly, the ease of performing the block as the ultrasonographic target is a bony structure, i.e., the transverse process. Secondly, the block's safety as there are no adjoining critical structures, i.e., pleura, neuraxis and large vascular structures.^[15]

The limitations of the study are that this was a single-blinded study and the investigators were aware of the group allocation. Moreover, the patients were not followed up for a long term to observe the effects of these blocks on persistent post-mastectomy pain.

CONCLUSION

We conclude that continuous US-guided ESP block reduces postoperative analgesic requirement and

provides comparable postoperative analgesia as TEA in breast cancer surgeries. Continuous ESP block is an easy to perform, yet safe and effective alternative to TEA. Further studies of continuous ESP block in breast cancer surgeries are needed to identify its effects on short and long-term outcome measures like chronic pain and the quality of life.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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