Original Article

Efficacy of erector spinae plane block for postoperative analgesia in total mastectomy and axillary clearance: A randomized controlled trial

ABSTRACT

Background: The erector spinae plane block is a newer technique of analgesia to the chest wall.

Objective: The study was carried out to establish the efficacy and safety of this block in patients undergoing total mastectomy and axillary clearance.

Design: Prospective randomized controlled study.

Setting: Single tertiary care center, the study was conducted over a period of 1 year.

Patients: 65 patients were included; final analysis was done for 60 female patients undergoing total mastectomy and axillary clearance under general anesthesia were randomly allocated to two groups.

Intervention: Group B (block group) received ultrasound-guided erector spinae plane block at T5 level with ropivacaine (0.5%, 0.4 mL/kg) while the control group did not receive any intervention. Postoperatively, patients in both groups received morphine via intravenous patient-controlled analgesia device. Patients were followed up for 24 h postoperatively.

Main Outcome Measures: The 24-hour morphine consumption was considered as the primary outcome and secondary outcomes included time to first rescue analgesia, pain scores at 0, ½, 1, 2, 4, 6, 8, 12, and 24 h and characteristics and complications associated with block procedure.

Results: The 24-hour morphine consumption was 42% lower in block group compared to control group [mean (SD), 2.9 (2.5) mg vs 5.0 (2.1) mg in group B and group C, respectively, $P = 0.01$]. The postoperative pain score was lower in group B vs group C at 0, 1/2, 1, 2, 4, 6, 12, and 24 h ($P < 0.05$). 26 patients in group C against 14 in group B used rescue analgesia within 1 h of surgery ($P = 0.01$).

Conclusion: Erector spinae block may prove to be a safe and reliable technique of analgesia for breast surgery. Further studies comparing this technique with other regional techniques are required to identify the most appropriate technique.

Key words: Acute postoperative pain; analgesia; breast surgery; erector spinae plane block; pain score; patient-controlled; regional anesthesia; ropivacaine; total mastectomy and axillary clearance; ultrasound-guided

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Shashikant Sharma, Suman Arora, Anudeep Jafra, Gurpreet Singh[1]

Departments of Anaesthesia and Intensive Care and [1]Surgery, Post Graduate Institute of Medical Education and Research, Sector-12, Chandigarh, India

Address for correspondence: Dr. Anudeep Jafra, Department of Anaesthesia and Intensive Care, 4th Floor B Block, Nehru Hospital, Post Graduate Institute of Medical Education and Research, Sector-12, Chandigarh - 160 012, India. E-mail: anu_gmch@yahoo.co.in

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Introduction

Acute postoperative pain is common after breast surgery,[1] and despite adequate pain management, 20% of patients respond poorly to analgesics.[2] Thoracic epidural,[3] thoracic paravertebral block,[4] pectoral block,[5] and serratus plane block[6] are commonly used techniques of regional anesthesia for breast surgery. All these techniques have their merits and demerits. Erector spinae plane block is a newer technique of regional anesthesia to the chest wall,[7-11] where local anesthetic is deposited between the transverse process and erector spinae muscle resulting in analgesia and anesthesia to hemithorax. This study was conducted to assess the efficacy of erector spinae plane block for postoperative analgesia in patients undergoing total mastectomy and axillary clearance.

Methods

This study was carried out after getting approval from the institute's ethics committee (PGIMER Institutional ethics committee), reference no. NK/3870/MD/339 dated September 21, 2016, the study was conducted over a period of 1 year from July 2017 to December 2018. This study adheres to the applicable CONSORT guidelines. Written informed consent was obtained from 60 female patients of ASA I or II class, aged 18–60, who were scheduled to undergo total mastectomy and axillary clearance under general anesthesia. Patients with infection at the local site, coagulopathy, morbid obesity (BMI >40 kg/m^2), uncontrolled hypertension or ischemic heart disease, renal dysfunction, allergy to local anesthetics, preexisting neurological deficits, and psychiatric illness were excluded from the study. The patients were kept fasting overnight and premedication was given with alprazolam 0.25 mg and ranitidine 150 mg orally the night before and 2 h prior to surgery.

Patients were allocated to either block group (group B) or control group (group C) using computer-generated random numbers. Random numbers were concealed using opaque envelopes and were opened just prior to the administration of block. Patients in the block group received ultrasound-guided erector spinae plane block at T5 level with ropivacaine (0.5%, 0.4 mL/kg) while those in the control group did not receive any intervention.

In the preoperating room, the block was performed 30 min prior to the induction of anesthesia using a linear probe (5–10 MHz) of ultrasound (SonoSite, Inc., Bothell, WA, USA). The anesthetist who performed the block was not blinded to group allocation.

In the sitting position, the spinous process from C7 to T7 was marked with a permanent skin marker and the paravertebral area (C7 to T7) on the side of the surgery was cleaned with 5% povidone-iodine and draped. Ultrasound probe with sterile cover was put in the midline in craniocaudal orientation at the T5 level and was moved laterally about 2.5–3 cm to identify the tip of the transverse process. At this location, the anatomy was identified as the tip of the transverse process with muscles laying above it namely erector spinae, rhomboid major, and the trapezius (from deep to superficial). The skin was infiltrated with 3–5 mL of 2% lignocaine and, a Quincke's needle (20G, 9 cm) was inserted in caudocephalad direction till the tip lay between the transverse process and the erector spinae muscle. The erector spinae plane was confirmed as lift up of erector spinae muscle from the transverse process after injection of 3–5 mL of normal saline. After the confirmation of the plane, 0.4 mL/kg of 0.5% ropivacaine was injected in the erector spinae plane.

The block effect was assessed every 5 min with the loss of sensation to pinprick in the dermatome T1–T8. The dermatomes showing less pain to pinprick compared to the opposite side were noted. Block failure was considered if no dermatome showed decreased sensation to pinprick up to 20 min of the block.

The patient's heart rate (HR), noninvasive blood pressure (NIBP), and oxygen saturation (SPO_2) were recorded at baseline, at the time of block and every 5 min up to 30 min after the block. Any block-related complications such as hypotension, vascular puncture, and Horner's syndrome were also recorded.

All patients underwent a total mastectomy and axillary clearance under general anesthesia. Analgesia was provided with injection fentanyl 1 μg/kg and induction with injection propofol 2–3 mg/kg with the loss of response to verbal command as an endpoint. Injection atracurium 0.5 mg/kg was used to facilitate tracheal intubation. Anesthesia was maintained with 60% nitrous oxide in a mixture of oxygen and isoflurane (MAC-1-1.3). Positive pressure ventilation was used to maintain end-tidal carbon dioxide between 4.2 and 4.6 kpa. Monitoring with heart rate, NIBP, and SPO_2 and the nasopharyngeal temperature was continued throughout the surgical procedure. HR and blood pressure were recorded at preinduction, at the time of induction, after intubation, and every 5 min till the end of the surgery. Normal saline at the rate of 8–10 mL/kg/hr was given throughout the surgical procedure. The rise in mean arterial blood pressure (20% above baseline) for two consecutive readings was treated with injection fentanyl 0.5 μg/kg while

the hypotension (20% below baseline) for two consecutive readings was treated with boluses of normal saline and injection mephentermine 3–6 mg if required. Atropine 0.6 mg was used to treat bradycardia (HR <40 beats/min). Toward the end of the surgery, injection diclofenac 1.5 mg/kg was provided for analgesia and injection ondansetron 0.1 mg/kg for postoperative nausea and vomiting (PONV). All patients were successfully reversed and shifted to the postoperative anesthesia care unit and monitored for 24 h postoperatively.

An intravenous patient-controlled analgesia (PCA) pump was used to provide morphine for rescue analgesia in all the patients [bolus-1.5 mg, lockout interval-20 min, no baseline infusion]. The pain score on a numeric rating scale (NRS) was recorded at 0, ½, 1, 2, 4, 6, 8, 12, and 24 h by an investigator blinded to the study. Patients with VAS >3 despite morphine bolus received injection paracetamol 1 g as a rescue to morphine. PONV was assessed by a 4-point PONV scale (0: no nausea; 1: mild nausea; 2: severe nausea; 4: vomiting),[12] and injection metoclopramide 0.2 mg/kg was used if score >1.

Statistical analysis

The analysis of the data of this study was done using IBM SPSS version 17 (Chicago, IL) and Microsoft Excel (Microsoft company) 2010. Quantitative data like age, weight, height, duration of surgery, and intraoperative fentanyl dose were expressed as median (range) and a cumulative 24-hour dose of morphine was presented as mean ± SD. The pain score on the NRS scale was expressed as a median and interquartile range. The normality of quantitative data was checked by Kolmogorov-Smirnov tests of normality. Unpaired t-tests were applied to compare means for normally distributed data, and the Mann-Whitney test was used for skewed data. Categorical variables like ASA as numbers. Chi-square test or Fischer's exact tests were applied to analyze the association between categorical variables. A comparison of intraoperative and postoperative hemodynamic variables was made using an independent *t*-test. All calculations were two-sided with the confidence interval of 95%. A *P* value of less than 0.05 was considered to indicate statistical significance. Based on a study by Kulhari *et al*.[13] to detect a difference of 30% in 24-hour morphine consumption, a minimum of 22 patients were needed in each group at an alpha error of 0.05 and power of 0.8. To allow dropouts, 30 patients were included in each group. A *P* value < 0.05 was considered as statistically significant.

Results

65 patients undergoing total mastectomy and axillary clearance were assessed for eligibility, out of 5 were excluded and 60 patients were randomized into two groups [Figure 1]. Both the groups were comparable in terms of demographic variables, ASA physical status, duration of surgery, and intraoperative fentanyl dose [Table 1]. However, the mean age was significantly different between two groups [mean (SD), 46.4 (9.7) VS 52.6 (9.0) year in group B and group C respectively, $P = 0.01$].

The 24-hour morphine consumption was 42% lower in block group vs control [mean (SD), 2.9 (2.5) vs 5.0 (2.1) group B and group C, respectively, $P = 0.01$], [Table 2].

Fourteen patients in the block group versus 26 in the control group used rescue analgesia within 1st hour of surgery. The pain score on NRS was lower in the block group compared to the control group at all-time intervals except at 8 h after surgery [Table 3]. The two groups were alike in terms of intraoperative HR and blood pressure.

Four patients in the block group against eight in the control group experienced nausea and vomiting in the postoperative period and were treated with injection metoclopramide but this difference was not significant ($P > 0.05$). The majority of the patients had sensory spread in the dermatome T3-T6 while 19, 16, 4 and 1 patients had sensory spread in T2, T7, T8, and T1 respectively [Figure 2]. No block-related complications such as hypotension, vascular puncture, and Horner's syndrome were recorded. The majority of the patients had sensory spread in the dermatome T3–T6 while 23, 16, 4 and, 1 patient had sensory spread in T6, T7, T8, and T1, respectively.

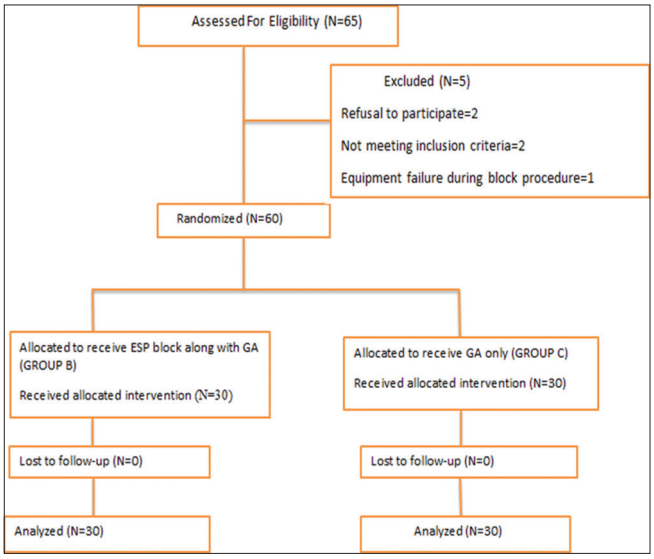

Figure 1: Consort diagram

Table 1: Patient characteristics

Variable	Group B (*n*=30)	Group C (*n*=30)	*P*
Age (year)	46.4 (25–60)	52.6 (24–60)	0.01
Weight (kg)	62.8 (39–88)	67.7 (44–95)	0.16
Height (cm)	158.3 (149–170)	158.1 (144–167)	0.89
ASA (I: II)*	24:6	18:12	0.09
Duration of surgery (min)	78.3 (45–120)	80.0 (45–120)	0.74
Intraoperative fentanyl dose (μg)	69.3 (40–100)	73.3 (50–120)	0.30

Data expressed as mean (range) or number* of patients in each group

Table 2: 24- hour morphine consumption

Variable	Group B (*n*=30)	Group C (*n*=30)	Mean difference, 95% CI	*P*
24- hour morphine consumption (mg)*	2.9 (2.5)	5.0 (2.1)	2.1 (2.0–2.2)	0.01

*mean (SD), CI: confidence interval

Table 3: Postoperative pain score on NRS (numeric rating scale)

Time (hours)	Group B	Group C	*P*
0	0.5 (0–2)	4.5 (0–7)	0.017
0.5	1 (0–4)	4 (2–2.6)	0.001
1	1 (1–2.7)	2 (2–4)	0.010
2	1 (1–2)	2 (2–3)	0.002
4	1 (1–2)	1.5 (1–3)	0.012
6	1 (0–1)	2.5 (1–5)	0.000
8	1 (0–1.7)	1 (1–2)	0.137
12	1 (0–1)	1 (1–2.7)	0.009
24	0 (0–1)	1 (1–1)	0.006

Data are expressed as the median (interquartile range)

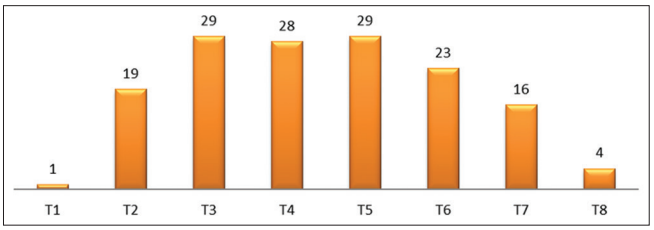

Figure 2: Dermatomal spread in the Erector spinae block group

Discussion

The increasing incidence of breast cancer has led to an increased number of patients getting operated for breast surgery. This group of patients experiences significant pain not only in the acute postoperative period but the majority of them also develop chronic persistent pain during follow-up. Erector spinae plane block, a newer technique of regional anesthesia provides anesthesia and analgesia to the chest wall.[7-11,14] Literature also suggests the role of erector spinae plane block for the management of myofascial pain syndromes.[15] The erector spinae plane block has been used in combination with other blocks for performing breast surgery without the need for general anesthesia. Piraccini *et al*. reported a combination of a rhomboid intercoastal nerve block (local anesthetic injection between intercostal and rhomboid muscle), parasternal block (local anesthetic between major pectoral muscle and superficial to internal intercostal muscles) and erector spinae block for breast surgery under regional anesthesia.[16] Similarly, thoracic transverse muscle plane block is a recently described fascial plane block that anesthetizes anterior branches of intercostal nerves from T2 to T6 and has been used in breast surgery, can be used in combination to ESP block.[17]

This study was conducted to evaluate the efficacy of this block in patients undergoing total mastectomy and axillary clearance.

Erector spinae muscle consists of spinalis, longissimus thoracic, and iliocostalis. It runs in the paraspinal gutter on either side of the vertebral column and extends between the base of the skull and sacrum. It is covered by thoracolumbar fascia in the thoracic and lumbar region and by a nuchal ligament in the cervical region.[8]

Injection of the drug at costotransverse foramen near the tip of transverse process and encasement of erector spinae muscle by thoracolumbar fascia and nuchal ligament explains the anatomical basis of the spread of drug anteriorly to anesthetize spinal nerves along with craniocaudal spread leading to extensive anesthesia of thoracic wall. ESP block anesthetize not only the ventral and dorsal rami of spinal nerve roots but also the rami communicantes which contain fibers connecting sympathetic ganglion with spinal nerve leading to somatic as well as visceral analgesia. The relatively superficial location of ESP block, distant from any neurovascular structure, minimizes concerns regarding anticoagulation and development of a significant hematoma.[10]

We found 42% decrease in 24-hour morphine consumption in block group B compared to the control group C [mean

(SD), 2.9 (2.5) vs 5.0 (2.1), respectively, $P = 0.01$]. Similarly, in a randomized controlled trial by Gurkan *et al*.,[18] authors found 65% reduction in 24-hour morphine consumption in ESP group compared to control [mean (SD), 5.6 (3.8) mg 16.6 (6.9) ESP group and control, respectively, $P < 0.001$]. The difference in 24-hour morphine consumption in our study as opposed to that in Gurkan *et al*.[18] (42% vs 65%) could be due to the different analgesic regimen. In our study, we used morphine through patient-controlled analgesia [bolus-1.5 mg, lockout interval-20 min] device in the postoperative period while Gurkan *et al*.[18] used morphine through PCA device [bolus- 1 mg, lockout interval- 8 min, maximum-6mg/hr] after surgery. According to Stoelting's (2015 edition),[19] the time to peak effect of morphine after intravenous administration is 15–30 min. So, it is likely that patients in the control group in the study by Gurkan *et al*.[18] used morphine boluses more frequently in order to get pain relief before the peak effect of morphine could be achieved. Aksu *et al.* also reported, 75% decrease in 24-hour morphine consumption in ESP group compared to placebo group. Morphine consumption was 3.02 ± 2.06 mg in block group and 13.2 ± 4.98 mg in the control group, this could be explained as patients received bi-level block, at T2 and T4 levels which resulted in lower postoperative NRS score at 12 and 24 h postoperatively and lower morphine consumption.[20] Similar results have been reported by Gurkan *et al.* while comparing ESP block and paravertebral block with the control group respectively (24-hour morphine consumption 5.6 ± 3.43 mg, 5.64 ± 4.15 mg and 14.92 ± 7.44).[21]

The pain score on the NRS scale in our study was found to be significantly lower in the ESP group as compared to control at 0, ½, 1, 2, 4, 6, 12, and 24 h ($P < 0.05$) of surgery. This finding of our study is also supported by Nair *et al*.[22] who also found a lower pain score (VAS = 1) at 1, 3, and 6 h of surgery in five patients who underwent a mastectomy. Bonvicini *et al*.[23] also reported a pain score of <3 on NRS up to 24 h of surgery in a patient who underwent breast cancer surgery with reconstruction.

We found a cephalocaudal spread of drug after injection of the drug at the T5 level as evident from the sensory spread in dermatomes T3–T6 (in the majority of the patients). Similar to our study, various authors,[7-11,24,25] also reported the cephalocaudal spread of drug following a single-site ESP in their study. The erector spinae muscle, with its origin from lumbosacral vertebrae and insertion at thoracocervical vertebrae, is encased by thoracolumbar fascia and nuchal ligament in its entire length. This plane permits extensive craniocaudal spread of local anaesthetic and coverage of multiple dermatomes.[22]

In our study, four patients in the ESP group vs eight in the control group experienced nausea and vomiting, but there was no difference between the two groups ($P > 0.05$). Likewise, Gurkan *et al*.[18] reported nausea and vomiting in 8 patients in the ESP group vs 10 in the control group, however, both the groups were comparable ($P > 0.05$).

In our study, no complications such as hypotension, pneumothorax and Horner's syndrome were reported in any of the patients undergoing block procedure.

In our study, we recorded hemodynamic parameters including HR, NIBP (systolic/diastolic/mean), and SPO2 at various time intervals beginning from preinduction till the completion of surgery. We found comparable results in both groups.

The erector spinae block is not without complications, Cassai *et al.* reported the development of motor blockade following bilateral ESP block in a patient.[26] Which authors described resulted due to the spread of drug to paravertebral space via contact between the bevel and costotransverse foramen. The approach authors followed was with the probe placed in axial plane and needle directed in-plane lateral to the medial direction so as to reduce the risk of pneumothorax and prevents injury to a neural axis that gets protected by vertebral lamina using this technique. But the approach has limitations; the drug spread cannot be appreciated well. Hence, Piraccini *et al.* reported using the sagittal plane technique over the transverse process; this technique improves the visualization for the spread of drugs and reduces the possibility of spread to paravertebral space and epidural space.[27,28]

Tulgar *et al.* reported a novel approach to prevent both the complications and simultaneously improving the visibility of drug spread, by using both axial and sagittal imaging techniques while giving the block.[29]

Limitations

Our study had few limitations, all the patients were ASA grade 1 or 2, and how effective is the block in patients with multiple comorbidities needs to be evaluated. Second, the patient and the anesthetist performing the block were not blinded to the group assignment.

Conclusion

Erector spinae block may prove to be a safe and reliable technique of analgesia for breast surgery. Further studies comparing this technique with other regional techniques are required to identify the most appropriate technique in this group of patients.

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Conflicts of interest
There are no conflicts of interest.

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