Section: Anaesthesiology

Original Research Article

A STUDY OF EFFICACY OF IITV-GUIDED ERECTOR SPINAE PLANE (ESP) BLOCK AS NOVEL MULTIMODAL ANALGESIA TECHNIQUE FOR POSTOPERATIVE ANALGESIA IN MODIFIED RADICAL MASTECTOMY(MRM).

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Abstract

Background: MRM is a commonly performed surgery for breast cancer and is associated with severe postoperative pain. Erector Spinae Plane Block (ESP) for pain management has many advantages in such patients like adequate analgesia, reduced need for opioids, early ambulation and decreased postoperative nausea & vomiting. **Materials and Methods:** 60 female patients in a prospective, randomised, controlled study with American Society of Anaesthesiologist (ASA) physical status I, II or III and aged 20 to 65 years scheduled for an elective unilateral MRM surgery under general anaesthesia were included in the study. 30 patients were taken in each group. Patients in Group S (Study Group) received IITV guided unilateral ESP Block in prone position at T4 level with 30 mL of Inj.Bupivacaine (0.25%) before general anaesthesia, while patients in Group C (Control Group) received general anaesthesia only. The primary objective was to compare the total tramadol consumption in the first 24 h postoperatively and secondary objectives were to compare the duration of analgesia, VAS score, haemodynamic changes and postoperative complications. **Result:** The demographic data of all the patients included in the study were comparable. Statistically significant difference ($P < 0.05$) in HR, SBP, DBP, MBP was seen between two groups. The 24 h tramadol consumption was less and mean duration of analgesia was more in Group S who received ESP block as compared to control group. The postoperative VAS scores were higher in Group C in comparison to Group S. The incidence of nausea and vomiting in both the groups were statistically insignificant. **Conclusion:** We conclude from our study that patients who were given pre-incisional IITV-guided ESP block before administering general anaesthesia have less postoperative rescue analgesic requirement, longer duration of analgesia, lower pain scores and also provides significant intraoperative haemodynamic stability with no significant adverse effects compared to the control group.

INTRODUCTION

MRM is a commonly performed surgery for breast cancer and is associated with moderate-to-severe postoperative pain. Poor postoperative pain management can lead to increased chances of recurrence of malignancy and the development of chronic pain.[1] Therefore, adequate postoperative pain management after breast cancer surgery is essential.

Regional block for pain management has many advantages in such patients including provision of adequate analgesia, reduced need for opioids, decreased postoperative nausea & vomiting and postoperative pulmonary complications. It also facilitates early ambulation.[1] Thoracic Epidural (TE), interscalene brachial plexus block, paravertebral block (PVB), pectoral nerve I & pectoral nerve II blocks, serratus anterior plane block

and Erector Spinae Plane (ESP) block have been used with good results.

In ESP block, local anaesthetic is deposited deep to the erector spinae muscle which results in blocking of the ventral and dorsal rami of multiple spinal nerves. The LA diffuses into the paravertebral space and cephalo-caudally and blocks the pain by action on dorsal rami, ventral rami, and lateral cutaneous branches of intercostal nerves.[2] ESP block was more commonly performed in thoracic surgeries to provide postoperative analgesia; but nowadays, it is being successfully given for abdominal surgeries, cardiac surgeries, total hip arthroplasty and chronic back pain as well.

The aim of our study was to measure the average duration of analgesia, the average time duration to administer first postoperative analgesia (rescue analgesia), the average total dose requirement of analgesic in the first 24 h after surgery and the severity of postoperative pain via visual analogue scale (VAS) score. We also compared the hemodynamic changes and adverse effects between study and control groups.

MATERIALS AND METHODS

After the approval of the Institutional Ethics Committee (Humans) and registered with the Clinical Trial Registry of India with Reg. No. CTRI/2022/05/042371,a prospective, randomised controlled study was conducted in a tertiary care hospital on 60 female patients, American Society of Anaesthesiologist (ASA) physical status I, II or III and aged 20 to 65 years, who were scheduled for an elective unilateral MRM surgery under general anaesthesia were included in the study between February 2021 and August 2022. A pregnant or lactating mother, patients with known allergy to LA agent, infection at the block site, opioid abuse, coagulopathy, major cardiac disorders, decreased pulmonary reserve, renal dysfunction, preexisting neurological deficits, or psychiatric illness were excluded.

30 patients were taken in each group. Patients in Group S (Study Group) received unilateral Erector Spinae Plane (ESP) Block with 30 mL of Inj.Bupivacaine (0.25%) before general anaesthesia, while patients in Group C (Control Group) received general anaesthesia only.

Patients were randomized into two equal groups (30 each) by computer-generated random number table (Group S - Study group, Group C - Control group) by a researcher who was not involved in the study. An anaesthesiologist took the corresponding sealed envelope indicating the treatment assigned to the patient which was opened just before the block performed. All blocks were performed by an experienced anaesthesiologist.

Written informed consent, detailed preoperative anaesthesia evaluation and education of the block procedure & visual analogue scale (VAS) were done on day before the surgical procedure. All patients were kept nil per oral as per the institutional protocol. A 20 G intravenous (i.v.) cannula was secured in the forearm opposite to the surgical side and all the patients were premedicated with glycopyrrolate 0.2 mg, ondansetron 4 mg and pantoprazole 40 mg 2 hrs before the surgery.

In the procedure room, standard ASA monitors like electrocardiography (ECG), non-invasive blood pressure (NIBP), and pulse oximetry (SpO2) were applied in all the patients, and baseline data were recorded.

In Group S, IITV-guided ESP block was performed before general anaesthesia in prone position with 18 Gauge Touhy needle at T4 level on the operative side. The block was given with 30 mL of bupivacaine (0.25%) after local infiltration with lignocaine 2% and negative aspirations under all aseptic & antiseptic precautions. The patient's ECG and SpO2 were monitored continuously. For all the patients, a blinded observer used an alcohol-soaked cotton ball to assess the dermatome of the sensory blockade every 5 min for the first 30 min after block performance, from T1 to T8 dermatome on the anterior chest wall. The sensation to cold touch was compared to the opposite side. If the cold sensation does not decrease even after 30 min in any segment, it was labelled as block failure, and these patients were excluded from the study. After 30 min of the block, the patients were shifted to the operating room (OR). In Group C, only general anaesthesia was administered. Thus, all the patients belonging to Group C were directly shifted to the operation room. The observer who collected perioperative data was blinded to the technique of analgesia used.

Anaesthesia was induced with sodium thiopentone 3-5 mg/kg and fentanyl 1.5µg /kg in both the groups. Tracheal intubation was facilitated by succinylcholine 1.5 mg/kg and the neuromuscular blockade was maintained with vecuronium. Anaesthesia was maintained by isoflurane (1-2%) and 50% nitrous oxide in oxygen. Intraoperative monitoring included heart rate, electrocardiogram, non-invasive blood pressure (NIBP), oxygen saturation and capnography (EtCO2). After the completion of surgery, neuromuscular blockade was reversed with glycopyrrolate 8 µg/ kg and neostigmine 0.05 mg /kg. and extubated. All patients were shifted to post-anaesthesia care unit (PACU) for monitoring and then to the surgical ward. The duration of surgical procedure was noted.

Postoperative pain was assessed using Visual Analogue Scale (VAS) which is graded from 0 to 10 (0 signified no pain and 10 signified severe pain). Pain score was assessed postoperatively at the time of arrival in PACU and then after 2, 4, 6, 8,12, and 24 h after surgery. Patients in both the groups were given rescue analgesia with tramadol 100 mg i.v., when the VAS Score was more than 4. Other parameters recorded were the onset time of sensory block, intraoperative haemodynamic changes (HR, SBP, DBP and MBP), duration of analgesia and total

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tramadol consumption in 24 h postoperatively. All the parameters recorded and compiled in Microsoft Excel file-2019.The duration of analgesia was defined as the time interval from completion of the block procedure to the first rescue analgesic requested. Throughout the perioperative period, patients were observed for any adverse effects like nausea & vomiting, any block related complications such as local anaesthesia (LA) toxicity, hypotension, bradycardia, vascular puncture etc. and were treated accordingly.

The primary objective was to compare the total tramadol consumption in the first 24 h postoperative period and secondary objectives were to compare the duration of analgesia, VAS score, haemodynamic changes and postoperative complications.

The sample size is calculated based on the pilot study, which indicated that the Mean ± SD 24
h consumption of tramadol following MRM surgery under general anaesthesia is 50±64.33 mg. We considered that achieving a 50% reduction in tramadol consumption 24 h in postoperative period in Group S (Study group) with a statistical power of 0.9 and a type 1 error rate of 0.05, a sample size calculation determined that 26 patients per group was required to demonstrate this difference using a two-tailed unpaired student's t-test. Assuming a 5% drop out rate, the final sample size will be set at 30 patients in each group. Differences between the two groups were analysed using the two-tailed Student's t-test (normally distributed continuous data). Categorical data were analysed using the Chi-square test. A P value of <0.05 was considered statistically significant for all comparison between the groups.

RESULTS

A total of 60 patients were included in the study out of which 30 patients were included in each group in the final analysis as shown in the consort diagram [Figure 1]. The demographic data of all the patients included in the study were comparable (P > 0.05) [Table 1].

We observed a statistically significant difference (P < 0.05) in HR between two groups just after induction till 2 h post-induction [Figure 2]. A statistically significant difference was also observed in SBP, DBP and MBP from induction till 2 h post-induction [Figure 3].

The postoperative VAS scores were higher in Group C in comparison to Group S [Table 2]. The postoperative VAS were statistically significant till 12 h postoperatively (P < 0.05). The mean sensory block onset time was 28.83 mins[Table 3]. The mean duration of analgesia was significantly longer in Group S compared to Group C (18.23±1.67 h and 9.10±3.23 h; P = 0.00001) [Table 3]. The 24 h tramadol consumption was less in Group S who received ESP block when compared with the control group and it was statistically significant (116.67±37.90 mg vs 163.34±49.01mg, P = 0.0001) [Table 3]. In Group C, 3 out of 30 patients whereas in Group S, 5 out of 30 patients developed nausea; which is statistically not significant. In Group C, 1 out of 30 patients whereas in Group S, 1 out of 30 patients had vomiting; which is statistically not significant [Table 4]. Block-related complications, such as pneumothorax, vascular puncture, or LA toxicity was not seen in any of the groups.

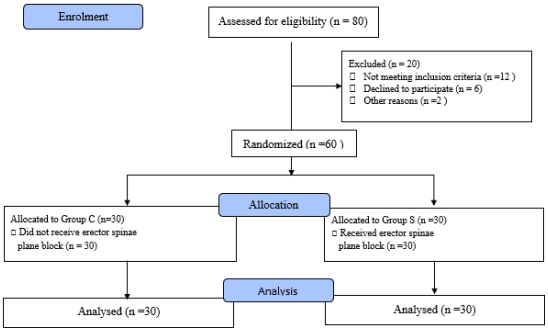

Figure 1: CONSORT flowchart of the study

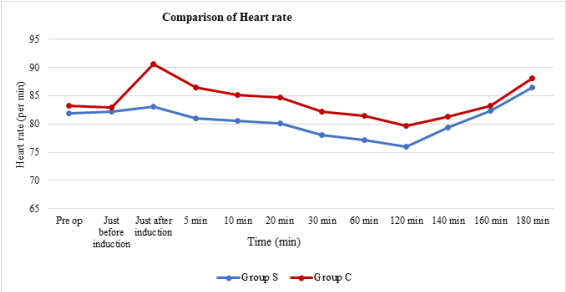

Figure 2: Heart rate changes

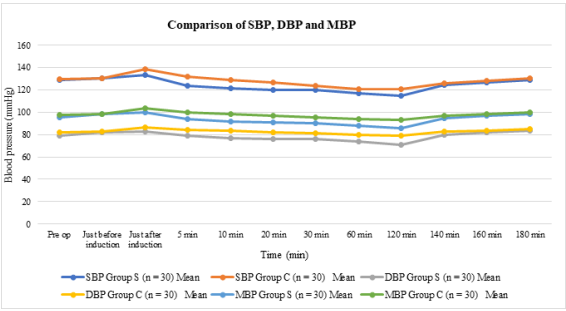

Figure 3: Blood pressure changes

* SBP: Systolic blood pressure, DBP: Diastolic blood pressure, MBP: Mean blood pressure.

Table 1: Demographic data and duration of surgery*

Variables	Group S (n = 30)	Group C (n = 30)	P
Age (years)	47.83±10.91	49.6±8.50	0.487
Weight (in kg)	57.1±7.15	56.6±5.77	0.766
ASA Grade (I/II/III)	10/11/9	11/12/7	0.843
Duration of surgery (min)	122.67±35.12	124±31.68	0.877

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*Student's t-test: P<0.05 was considered statistically significant. Data are presented as mean±SD and patient numbers. SD: Standard deviation, ASA: American Society of Anesthesiologist

Table 2: Postoperative VAS score

Time periods (h)	Group S (n=30)	Group C (n=30)	P
Immediate postoperative	0.33±0.47	1.16±0.79	0.0003
1	0.76±0.56	1.60±0.72	0.0006
2	1.36±0.66	2.26±1.04	0.017
4	1.63±0.61	3.00±1.46	0.004
8	2.33±0.84	3.47±0.68	0.0001
12	2.40±0.77	3.83±1.46	0.0007
24	3.06±1.35	3.76±0.97	0.37

*Data are presented as mean±SD; Chi square test used: P<0.05 was considered statistically significant.

Table 3: Onset of sensory block (min), duration of analgesia (h) and total consumption of tramadol (mg) in 24 h postoperatively*

	Group S (n=30)	Group C (n=30)	P
Onset of sensory block (min)	28.83±4.48	Not Applicable	Not Applicable
Duration of Analgesia (h)	18.23±1.67	9.10±3.23	0.00001
Total consumption of tramadol (mg) in 24 h postoperatively	116.67±37.90	163.34±49.01	0.00012

* Student's t-test used: P<0.05 was considered statistically significant. Data are presented as mean±SD

Table 4: Adverse effects in both groups*

	Group S (n=30)	Group C (n=30)	P
Nausea	3	5	0.746
Vomiting	1	1	
Other	0	0	-

*Chi square test used: P<0.05 was considered statistically significant. Data are presented as patient numbers.

DISCUSSION

In this prospective, randomised study; IITV-guided ESP block was given preoperatively to 30 female patients for MRM surgery and compared with the control group. The result was a significant decrease in requirement of postoperative tramadol in patients who received ESP block. Patients who received ESP block were hemodynamically more stable than control group. Duration of postoperative analgesia was longer in ESP group. Postoperative VAS score was better in ESP group with comparable adverse effects.

Postoperative pain after breast cancer surgery is strongly associated with increased morbidity, prolonged hospital stays and hence, higher economic burden and patient's suffering. MRM surgery is associated with moderate-to-severe acute postoperative pain. Failure to provide adequate acute pain control is associated with poor quality of recovery and chronic postsurgical pain.[3,4] The regional techniques obviate the need of parenteral analgesia, hence associated side effects are also minimized. The fascial plane blocks are considered safer alternatives of central neuraxial blocks due to less invasiveness. PECS I, PECS II, SAP block, and ESP block are fascial plane blocks used as postoperative analgesia for breast surgeries.[5] Single fascial plane block has not been sufficient to provide analgesia and so multiple fascial plane blocks have to be supplemented and also posterior part of chest wall is spared. Hence, we have used unilateral ESP Block in our study which is safe, easy to perform and entire posterior part of chest wall is covered, less invasive, and is having all the benefits of thoracic epidural anaesthesia without the risk of pneumothorax, dura puncture and hypotension. We used IITV-guidance to identify the primary landmark that is the TP. Its recognition was easier than ultrasonography (USG) where TP can easily be confused with ribs and block efficacy may be compromised.[2] Moreover, Fluoroscopy or IITV-guided ESP block is a feasible option where USG is not available.

The mechanism of action of ESP Block is local anaesthetic when injected below the covering sheath of ESM and TP, it spreads cephalo-caudally and blocks the pain by action on dorsal rami, ventral rami, and lateral cutaneous branches of intercostal nerves. Local anaesthetic spread has also been observed in paravertebral space. The extent of block is volume-dependent as the local anaesthetic can spread from nuchal line to sacrum depending on the injection volume.[2]

Aman et al,[1] studied USG-guided erector spinae plane block for complete surgical anaesthesia and postoperative analgesia for breast surgeries in 30 cases. They used 25 ml bupivacaine (0.5%) with dexamethasone 8 mg on the operating side to provide complete anaesthesia. The mean sensory block onset time was 31.50 min. They observed all the 30 patients showed significantly lower VAS score, both at rest and on movement of the ipsilateral arm when assessed for severity of postoperative pain at various predetermined time intervals for up to 48 h. The average time to administer rescue analgesia was 41.73 h and average total number of doses (1 dose = 100 mg tramadol) of analgesic requirement in the first 48 h was 1. Although, there were no significant differences among all the patients in terms of intraoperative heart rate and mean blood pressure.

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Swati Singh et al,[6] conducted a study on 40 patients undergoing MRM surgery to evaluate the postoperative analgesic efficacy of USG-guided ESP block for up to 24 h and observed that only 3 out of 20 patients in the ESP block group required supplemental morphine as compared to the control group in which all patients required supplemental morphine; none of the patients in our study group required rescue analgesia in the first 24 h.

Mukesh et al,[7] studied postoperative analgesic efficacy of fluoroscopy-guided erector spinae plane block after percutaneous nephrolithotomy (PCNL). In the two groups - Group I did not receive ESP block while Group II received ESP block (20 ml of 0.375% ropivacaine). Average time for first rescue analgesia in the postoperative period was 17.22 ± 0.97 h in study group compared to 15 ± 3.9 h in control group. Mean consumption of tramadol in 24 h postoperatively in study was significantly lower (100 mg) than the control group (350±57.24

mg). Five patients from control group developed severe nausea and vomiting and required parenteral metoclopramide within 24 h while none of the patients from ESP group developed nausea or vomiting.

However, the use of IITV is associated with radiation hazard. Also, the limitations of our study were that we did not follow-up with patients after discharge; hence, we could not assess the effect of ESP block on chronic pain.

CONCLUSION

We conclude from our study that patients given pre-incisional IITV-guided ESP block before administering general anaesthesia has lower pain scores, has less postoperative rescue analgesic requirement and also provides significant intraoperative haemodynamic stability with no significant adverse effects compared to the control group.

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