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Efficacy of Ultrasound-Guided Erector Spinae Plane Block for Postoperative Analgesia in Modified Radical Mastectomy: A Prospective, Randomized, Clinical Study

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ABSTRACT

Breast surgeries are very painful and effective pain relief helps in deep breathing, coughing and remobilization. ESPB is a novel, attractive alternative technique of analgesia and we aim to compare analgesic efficacy of USG-guided ESPB with conventional analgesic technique in patients undergoing MRM surgery. Total 72 patients of ASA I-III were randomly divided in two groups to receive USG guided ESP block (Group E, n = 36) and Multi-modal IV analgesics (Group C, n = 36). USG guided ESP block using Inj. Ropivacaine 0.375% was given with 23 G spinal needle (cephalo-caudal trajectory) in the plane between Erector Spinae muscle and T5 transverse process, whereas multi-modal IV analgesics were used for the control group. Post operative pain relief using VAS scores at predetermined time intervals, time for first rescue analgesia, total number of analgesics, vital parameters, patient satisfaction score and complications were observed, if any. Patients were evaluated for postoperative pain from Time "0" (30 min after extubation) up-to 24 hrs at predetermined time intervals. In present study, we used Inj. Tramadol 2 mg kg^{-1} in 100 mL normal saline as rescue analgesic drug. Time for first rescue analgesia in Group E was 15±4.18 hrs while in Group C it was 1.22±0.9. It was significantly prolonged in Group E than Group C ($p<0.0001$). The median time to first recue analgesic in Group E versus Group C was 12 hrs (12-18) versus 1 hr (1-2) respectively, with p-value of 0.00001. Better satisfaction scores were achieved without any noted side effects in the ESP group. We concluded from our study that USG-guided erector spinae plane block with general anaesthesia provided a safe and effective postoperative analgesia modality with decreased opioid requirements and better patient satisfaction scores, without complications in patients undergoing MRM surgery.

INTRODUCTION

Breast cancer is the most common cancer type in Indian women with an age-adjusted incidence rate of 25.8 per 1,00,000 women where surgeries like Modified Radical Mastectomy (MRM), simple mastectomy and lumpectomy are routinely performed[1,2]. General anaesthesia with opioids and inhalational agents is the most preferred technique of anaesthesia for breast surgeries. Acute postoperative pain after MRM is due to the dissection of both thoracic and axillary regions which leads to more opioid consumption causing nausea, vomiting, sedation, respiratory depression, constipation and delayed patient mobilization[3].

Various techniques available for pain relief include multimodal analgesia and regional techniques like Thoracic epidural analgesia (TEA), thoracic para-vertebral block (TPVB), Serratus Anterior plane block, Pectoral nerve block and Intercostal nerve block which provide opioid-sparing analgesia.

The Erector spinae plane (ESP) block, originally described by Forero *et al*.[4], is a relatively newer fascial plane block used for analgesia. ESP block is simple, safer and superior as compared to other regional blocks and it appears to be providing both somatic and visceral analgesia, which makes it an attractive alternative as no anatomical proximity to vital structures like pleura, vessels and central neuraxial system, more volume of LA can be given and can be implemented easily in peri-operative period when performed at T 4-5 level for breast and thoracic surgeries[4-6].

The purpose of this randomized study was to examine the effectiveness of US-guided ESP block in postoperative analgesia in the first 24 hrs after surgery. The primary outcome was Postoperative VAS (visual analogue score) scores up to 24 hrs and Time to first rescue analgesia.

MATERIALS AND METHODS

After obtaining approval of Institutional Human Ethics Committee, this prospective, randomized study protocol was registered in CTRI (Clinical Trail Registry-India, CTRI/2023/05/053288). Written informed consent was obtained from each patient willing to participate in study. This study included 72 females aged 18-65 years with ASA II and III scheduled for elective modified radical mastectomy (MRM). on the day before surgery. Patients with Body mass index (BMI) <18 or >40 kg m^{-2}, history of known allergy to any of the study drugs, infection at the injection site, coagulopathies/bleeding disorders or any spine deformities were excluded from the study.

All patients were randomly allocated into two groups of 36 each by computer generated random numbers. After a thorough pre anaesthetic check-up, they were kept nil per oral (NPO) for 8 hrs. Group of the patient was revealed in the pre-anaesthetic room. Group C patients received GA only, whereas Group E patients received US-guided ESPB along with GA. On arrival of the patient in the operating room, multipara monitor with ECG was attached and baseline vital parameters (Pulse rate, Non-Invasive Blood Pressure (NIBP) and SpO_2) were recorded and Large bore intravenous cannula was inserted, for administration of fluids and other anaesthetic drugs.

Group E patients were given the block in sitting position, under aseptic precautions, with the high frequency linear ultrasound probe placed longitudinally 3 cm lateral to the T5 spinous process of the surgical side. The three muscle layers from outward were recognised as Trapezius, Rhomboids major and Erector Spinae muscle at T5 Transverse Process (TP). Inj. Lignocaine (2%) 1.5-2 mL injected with 24G disposable needle directed towards T5 for pain free experience of the block. A 23-gauge Quincke spinal needle was inserted in-plane, cephalo-caudal approach to place the tip of the needle into fascial plane between erector spinae muscle and TP (preferably over the lateral edge of TP to avoid intramuscular injection). The location of the needle tip was confirmed by visible fluid spread (hydro dissection with 1-2 mL saline) below erector spinae muscle off the bony shadow of the TP. Total 25 mL of Inj. Ropivacaine 0.375% was injected in small incremental doses after frequent negative aspirations. Any block related complications like Hypotension and vascular puncture were recorded.

All patients were pre-medicated with Inj. Glycopyrrolate 4 µg kg^{-1} IV, Inj. Midazolam 0.05 mg kg^{-1} IV, Inj. Ondansetron 0.08 mg kg^{-1} IV, Inj. Fentanyl 2 µg kg^{-1} IV. After preoxygenation with 100% O_2 for 3 min, titrated dose of Inj. Propofol 2 mg kg^{-1} IV was given till loss of eye lash reflex. Tracheal intubation was facilitated by Inj. Suxamethonium chloride 1.5-2 mg kg^{-1} IV. Anaesthesia was maintained with Sevoflurane (1.5-2%), Nitrous oxide and Oxygen (60:40) and Inj. Atracurium (0.5 mg kg^{-1} followed by 0.1 mg kg^{-1} every 25 min) using closed circuit of Fabius Drager anaesthesia workstation to maintain end-tidal CO_2 at 35-40 mmHg. Intraoperative rise in heart rate and systolic blood pressure ≥ 20% from pre induction value was managed by giving Inj. Fentanyl 0.25 µg kg^{-1} IV. Fluid requirement and blood loss was calculated and replaced accordingly. Inj. Paracetamol 1000 mg IV infusion was given 15 min before skin incision.

Hemodynamic parameters were monitored and recorded intraoperatively such as heart Rate by ECG (lead II and V_5), Non-invasive arterial blood pressure, $EtCO_2$ and SpO_2 at specific time intervals before induction, after induction, 15, 30 and 60 min, 2 and 3 hrs till the end of surgery. At the end of surgery, all patients were reversed by Inj. Neostigmine (0.04 mg kg^{-1}) and Inj. Glycopyrrolate (0.04 mg kg^{-1}), then extubated and transferred to the postanesthetic care unit (PACU).

Time "0" was defined as 30 min post extubation. The pain scores were evaluated by Visual Analog Scale (handwritten mark on a 10 cm line that represents a continuum between "no pain" and "worst pain") at the time of arrival in PACU (Time 0 and then after 1, 2, 4, 6,12, 18 and 24 hrs after surgery. Rescue analgesia was given in the form of Inj. Tramadol 2 mg kg^{-1} IV diluted in 10 mL of Normal Saline after Inj. Ondansetron 0.08 mg kg^{-1} IV when VAS score was $\geq$4. Time at which 1st rescue analgesic required was noted. Total number of doses of rescue analgesics given in first 24 hrs were noted. Patients were monitored in the postoperative ward for any complications including nausea, vomiting, bradycardia, hypotension, respiratory depression etc. during the first 24 hrs following surgery and were managed accordingly. Intravenous Metoclopramide 10 mg was given for severe nausea or vomiting. Patient satisfaction score was assessed at 24 hrs after operation as Poor, Good and Excellent.

Sample size: was calculated from the pilot study using Mean±SD value of "Time to first rescue analgesia" parameter, which was 4±2 hr after ESP block following MRM surgery in which a sample size of 25 patients in each group was obtained at significance level of 0.05 alpha error and 0.2 beta error with 80 % power. Hence, we included 36 patients in each group to account for errors, possible dropouts or failed blocks.

Statistical analysis: Data analysis was done with the help of medCalc 12.5 software version 2021. Continuous data were reported as Mean±standard deviation (SD) or median (quartiles) and analyzed using the Students t test or Mann-Whitney U test as per data distribution. Qualitative (non-parametric) data were presented as frequency (%) using Chi-square test. The significance of statistical analysis was judged by p-value ($p<0.05$ considered as significant).

RESULTS

A total of 72 consecutive patients were randomized and all patients were placed in two groups as per the allocated intervention. No patients were excluded; hence 36 patients per group were enrolled and analysed. All demographic data like age, weight, height, BMI and ASA grading were statistically comparable between the two groups (Table 1).

From baseline till extubation at specific regular time intervals like before induction, after induction, 15, 30 and 60 min, 2 and 3 hrs, before extubation, after extubation. Basal and before induction HR (Mean±SD) was 84.14±10.68 per minute in Group E and 87.89±8.78 per minute in Group C (Table 2). This difference was statistically non-significant ($p>0.05$). Basal and before induction SBP (Mean±SD) was 124.06±8.81 mmHg in Group E and 124.17±11.24 mmHg in Group C with p-value of 0.9 (Table 3). This difference was statistically non-significant ($p>0.05$). Basal and before induction DBP (Mean±SD) was 79.25±9.38 mmHg in Group E and 81.89±6.08 mmHg in Group C (Table 4). This difference was statistically non-significant ($p>0.05$). Basal MAP (mmHg) and before induction (Mean±SD) was 94.42±8.84 in Group E and 95.47±6.89 in Group C (Table 5). This difference was statistically non-significant ($p>0.05$). At all other intervals, in perioperative period p-value of SpO_2 among both groups were not applicable. from induction to extubation, values of $EtCO_2$ among both the study groups were comparable ($p>0.05$).

While comparing the VAS score for postoperative pain assessment, we observed that VAS score was <4 up to 12 hrs in the majority of patients in Group E whereas, VAS score was >4 in the majority of patients in Group C which required rescue analgesia much earlier than Group E.

VAS was significantly higher in Group C as compared with Group E, at time intervals of 0, 1, 2, 4, 6, 12 hrs post-surgery with a $p<0.05$. At the 18th and

Table 1: Demographic data of both the study groups

Parameters	Group E (n = 36) GA+ESPB	Group C (n = 36) GA	p-value
Age (years)	49.92±8.66	53.33±8.7	0.10
Weight (kg)	56.14±7.86	56.78±6.95	0.7
Height (cm)	160.11±6.42	160.44±6.64	0.83
BMI (kg m^{-2})	21.66±2.97	22.08±2.65	0.5
ASA grading N (%)			
I	1 (2.78%)	0 (0%)	0.6 (χ^2 test)
II	30 (83.33%)	31 (86.11%)	
III	5 (13.89%)	5 (13.89%)	

Data are expressed as Mean±SD and $p<0.05$ by using an unpaired t-test

Table 2: Comparison of mean heart rate (HR) in between two study groups

Pulse	Group E	Group C	p-value
Baseline	84.14±10.68	87.89±8.78	0.1081
Before induction	84.08±10.22	87.61±9.18	0.1276
After induction	84.06±9.19	98.22±9.87	<0.0001
15 min	79.50±8.22	91.61±9.65	<0.0001
30 min	79.42±7.52	89.11±8.55	<0.0001
60 min	79.47±8.17	90.69±7.72	<0.0001
2 hrs	79.19±6.67	90.56±6.37	<0.0001
3 hrs	78.54±6.55	91.19±9.21	<0.0001
Before extubation	80.22±6.95	85.06±7.00	0.0044
After extubation	84.86±7.22	95.56±6.66	<0.0001

Data are expressed as Mean±SD and $p<0.05$ by using an unpaired t-test

Table 3: Comparison of mean Systolic Blood Pressure (SBP) in between two study groups

SBP	Group E	Group C	p-value
Baseline	124.06±8.81	124.17±11.24	0.9633
Before Induction	124.06±8.9	124.17±11.24	0.9634
After Induction	122.00±8.02	135.22±10.3	<0.0001
15 Minutes	118.97±8.84	127.81±7.94	<0.0001
30 Minutes	119.56±6.55	128.67±6.79	<0.0001
60 Minutes	119.94±6.05	130.56±4.67	<0.0001
2 Hours	119.36±7.77	128.86±4.75	<0.0001
3 Hours	120.23±7.32	127.47±7.53	0.0001
Before Extubation	122.25±6.9	127.78±4.94	0.0002
After Extubation	126.89±6.63	133.44±7.98	0.0003

Data are expressed as Mean±SD and p<0.05 by using an unpaired t-test

Table 4: Comparison of mean diastolic blood pressure (DBP) in between two study groups

DBP	Group E	Group C	p-value
Baseline	79.25±9.38	81.89±6.08	0.1609
Before Induction	79.17±9.12	81.89±6.08	0.1410
After Induction	76.97±6.05	87.47±6.47	<0.0001
15 min	74.00±4.69	80.44±4.27	<0.0001
30 min	73.14±4.17	82.00±3.66	<0.0001
60 min	75.47±3.84	83.89±3.59	<0.0001
2 hrs	73.83±5.8	80.42±4.69	<0.0001
3 hrs	76.11±4.25	80.44±4.27	0.0001
Before extubation	76.08±4.59	80.92±3.68	<0.0001
After extubation	80.14±5.92	85.67±8.35	0.0018

Data are expressed as Mean±SD and p<0.05 by using an unpaired t-test

Table 5: Comparison of Mean Arterial Pressure (MAP) in between two study groups

MAP	Group E	Group C	p-value
Baseline	94.42±8.84	95.47±6.89	0.5758
Before induction	94.36±8.87	95.75±7.27	0.4695
After induction	92.06±6.48	103.11±7.03	<0.0001
15 min	89.28±5.72	95.92±4.74	<0.0001
30 min	88.22±4.43	97.25±4.51	<0.0001
60 min	90.03±4.12	99.08±3.38	<0.0001
2 hrs	88.78±6.07	96.31±4.36	<0.0001
3 hrs	90.51±4.97	95.75±4.66	<0.0001
Before extubation	91.11±4.9	96.31±3.21	<0.0001
After extubation	95.44±5.78	101.28±7.15	0.0003

Data are expressed as Mean±SD and p<0.05 by using an unpaired t-test

Table 6: Comparison of pain in both groups by VAS Score

Time	Group E	Group C	p-value
Time 0	1.03±0.84	2.83±0.77	<0.0001
1 hr	1.36±0.76	3.25±0.69	<0.0001
2 hr	1.83±0.65	3.25±0.65	<0.0001
4 hr	2.39±0.49	3.22±0.59	<0.0001
6 hr	2.81±0.47	3.53±0.7	<0.0001
12 hr	3.28±0.61	3.61±0.69	0.0350
18 hr	3.39±0.64	3.67±0.72	0.0856
24 hr	3.44±0.77	3.75±0.81	0.1005

Data are expressed as Mean±SD and p<0.05 by using an unpaired t-test

Table 7: Comparison of rescue analgesia, patient satisfaction and postoperative complications in both groups

Parameters	Group E	Group C	p-value
Time to 1st rescue analgesia	15±4.18	1.22±0.9	<0.0001
The mean of total no. of rescue analgesia	1.53±0.51	3.28±0.51	<0.0001
Patients satisfaction score			
Good	29 (80.56%)	27 (75%)	= 0.0003 (χ^2 test)
Poor	0 (0%)	9 (25%)	
Excellent	7 (19.44%)	0 (0%)	
Complication			
Nausea	0 (0%)	3 (8.33%)	= 0.0514 (χ^2 test)
Vomiting	0 (0%)	3 (8.33%)	
Nausea, vomiting	0 (0%)	1 (2.78%)	
Nil	36 (100%)	29 (80.56%)	

Data are expressed as Mean±SD and p<0.05 by using an unpaired t-test

24th hrs post-surgery, VAS was comparable in both groups with a p>0.05 (Table 6). In the present study, we have used Inj. Tramadol 2 mg kg^{-1} in 100 mL normal saline as a rescue analgesic drug. The mean time to first rescue analgesia in Group E was 15±4.18 hrs while in Group C it was 1.22±0.9. It was significantly prolonged in Group E than Group C (p<0.0001). The median time to first recue analgesic in Group E versus Group C was 12 hrs (12-18) versus 1h (1-2) respectively, with p value of 0.00001 (Table 7).

A total number of rescue analgesic doses (Mean±SD) in Group E (1.53±0.51) was lower compared to Group C (3.28±0.51) up to 24 hrs and this difference was statistically significant (p<0.0001). More

than 80% of patients in Group E had good satisfactory score compared to 75% in Group C. None of the patients in Group E had experienced any of the complications like nausea or vomiting (Table 7).

DISCUSSIONS

The study was conducted on 72 female patients with ASA grade I, II and III scheduled for Modified Radical Mastectomy under general anaesthesia. Patients were randomly divided into two groups (36 in each group). Group E received USG-guided ESPB before induction with Inj. Ropivacaine 0.375% 20 mL Group C received General Anaesthesia.

Numerous research investigations have substantiated the analgesic effectiveness of Erector Spinae Plane Block (ESPB) across a spectrum of surgical contexts. For instance, Sobhy *et al*.[7] demonstrated its efficacy in thoracotomy procedures, while Tulgar *et al*.[8], Chin *et al*.[9] and Luis-Navarro *et al*.[10] found it to be beneficial in abdominal surgeries. Additionally, Qiu *et al*.[11] established its utility in lumbar spinal surgeries, Altinpulluk *et al*.[12] in caesarean sections and Macaire *et al*.[13] in cardiac surgery. Furthermore, Singh *et al*.[14], Thiagarajan *et al*.[15] and Gürkan *et al*.[16] have reported its advantages in breast surgeries. In this particular investigation, our focus was on patients undergoing modified radical mastectomy, a procedure for which the Erector Spinae Plane Block has been well-documented to provide effective visceral and somatic analgesia in the context of breast oncological interventions.

Various studies have compared ESPB to alternative techniques or analgesics: Aksu *et al*.[17] assessed ESPB vs. USG quadratus lumborum block in paediatric lower abdominal surgeries, Altiparmak *et al*.[18] evaluated ESPB vs. PECS block for unilateral modified radical mastectomy, Gürkan *et al*.[16] compared ESPB to conventional analgesics in breast surgery, Singh *et al*.[14] investigated ESPB for postoperative analgesia in modified radical mastectomy and our study focuses on ESPB compared to conventional general anaesthesia.

Similar to our investigation, Sobhy *et al*.[7], Aksu *et al*.[17] and Singh *et al*.[14] conducted studies examining the efficacy of ESPB in various surgical contexts and found no statistically significant differences in demographic profiles ($p>0.05$).

In our study, significant differences ($p<0.05$) were observed in mean variables of HR, SBP, DBP and MAP at all time intervals, except for baseline and pre-induction parameters in both groups. No pharmacological intervention was required for any patients. Mean SPO2 and ETCO2 values were comparable between both groups ($p>0.05$). Contrary to our findings, Altıparmak *et al*.[18] assessed mean HR and MAP but found no significant differences between the two groups.

In our study, Group E exhibited a VAS score of <4 for up to 18 hrs post-surgery, while Group C had a VAS score of >4 within the first 2 hrs, necessitating rescue analgesia earlier in Group C. VAS was significantly higher in Group C compared to Group E at time intervals 0, 1, 2-, 4-, 6- and 12 hrs post-surgery ($p<0.05$). At 18- and 24 hrs post-surgery, VAS scores were similar in both groups ($p>0.05$). This aligns with the findings of Oksuz *et al*.[19] who observed significantly lower pain scores (NRS) in the ESPB group at various time points (1, 2, 4, 6, 12 and 24 hrs) compared to Tumescent anesthesia ($p<0.001$). Similarly, Sobhy *et al*.[7] found statistically significant differences in VAS scores at rest (6, 12, 18 and 24 hrs) in favour of USG-guided ESP compared to conventional systemic analgesics ($p<0.04$). Singh *et al*.[14] reported highly significant differences in postoperative pain (Numerical Rating Scale-NRS) at 0, 2 and 4 hrs ($p<0.05$) when comparing ESPB for postoperative analgesia. Thota *et al*.[15] observed lower NRS pain scores in the ESPB group at rest, with statistical significance at 0 and 1 hr postoperatively and NRS scores with movement were also lower in the ESPB group at 0, 1, 6 and 24 hrs postoperatively.

In our study, the mean time for the first rescue analgesia was significantly longer in Group E compared to Group C ($p<0.0001$). Thota *et al*.[15] reported a similar outcome with a median time to first rescue analgesia of 8 hours in the ESP group compared to 1 hr in the control group. Tulgar *et al*.[8] found reduced tramadol consumption in that ESPB group during the first 12 hrs, requiring less rescue analgesia. Kwon *et al*.[20] observed that patients of ESPB required their first dose of Fentanyl between 12-15 hours after surgery, consistent with our findings. Shweta *et al*.[21] found comparable times to first rescue analgesia in groups receiving modified pectoralis and ESP blocks, with our study.

Our findings align with Thota *et al*.[15] study, where none of the patients receiving ESP block were dissatisfied, compared to 12% dissatisfaction in the control group (Group A). Shweta *et al*.[21] noted high satisfaction in both Group P (Modified Pectoralis) and Group ESP, with only 2 patients reporting discomfort during needle insertion. Singh *et al*.[14] reported better patient satisfaction in the ESP group without postoperative nausea and vomiting complications requiring medications.

Sobhy *et al*.[7] found fewer cases of nausea and vomiting in the ESP group, consistent with our study, where opioid use contributed to this difference. However, our results differ from Thota *et al*.[15] and

Gürkan *et al*.[16] who reported no significant difference in postoperative nausea and vomiting (PONV) scores between the ESP group and General Anaesthesia group.

LIMITATIONS OF STUDY

Sensory levels could not be tested properly in PACU by ice test/needle prick test, as patients were either sedated or drowsy post-extubation and the surgical dressing interfered with the examination.

Bi-level ESP block could have been performed to cover more cephalic and caudal dermatomes for analgesia in MRM patients.

Further studies between comparison of other LA and adjuvant/regional blocks like PEC can be conducted to broaden our knowledge of this novel block.

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