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Comparison of Erector Spinae Plane Block and Serratus Anterior Plane Block for Modified Radical Mastectomy: A Prospective Randomised Study

Modifiye Radikal Mastektomi Hastalarında Erektör Spina Plan Bloğu ve Serratus Anterior Plan Bloğunun Karşılaştırılması: Prospektif Randomize Çalışma

Saurabh Sagar[1], Sandeep Loha[1], Anil Paswan[1], Arvind Pratap[2], Shashi Prakash[1], Amrita Rath[1]

[1]Banaras Hindu University, Institute of Medical Sciences, Department of Anaesthesiology, Varanasi, India
[2]Banaras Hindu University, Institute of Medical Sciences, Department of General Surgery, Varanasi, India

ABSTRACT

Objective: Breast cancer is one of the most commonly diagnosed malignancies among females. In this study, we compared the analgesic efficacy of ultrasound-guided (USG) erector spinae plane block (ESPB) with serratus anterior plane block (SAPB) after modified radical mastectomy (MRM) for unilateral breast cancer.

Methods: After obtaining clearance from the institute's ethical committee, this prospective double-blinded clinical study was conducted from August 2021 to April 2022. Females aged between 18 and 65 years with body mass index ≤30 kg m^{-2} and ASA I and II who were scheduled for MRM for breast cancer were included in this study. Forty patients were randomly divided into two groups: Group E (USG-ESPB was administered) and Group S (USG-SAPB was administered). Both the groups received 0.4 mL kg^{-1} of 0.25% bupivacaine. Duration of analgesia of the patients, intra-operative and post-operative hemodynamic changes, intra-operative opioid & post-operative analgesic consumption, Numerical Rating Scale (NRS) pain scores and adverse effects like vascular puncture, hypotension, pleural puncture or pneumothorax or local anaesthetic toxicity were recorded.

Results: The mean duration of analgesia was significantly prolonged in Group E as compared to Group S and was statistically significant (p<0.001). The mean NRS score was found to be significantly lower in Group E as compared to Group S at 2,4,8 and 12 hours which was statistically significant (p<0.005). Though the intraoperative opioid requirement was comparable among both groups, the postoperative analgesic consumption was significantly lower in the Group E compared to the Group S (p<0.05).

Conclusion: In our study, we concluded that USG-ESPB is superior to USG-SAPB in the post-operative period in patients undergoing unilateral MRM.

Keywords: Breast cancer, nerve block, ultrasonography

ÖZ

Amaç: Meme kanseri, kadınlar arasında en sık teşhis edilen malignitelerden biridir. Bu çalışmada, tek taraflı meme kanseri için modifiye radikal mastektomi (MRM) sonrası ultrason eşliğinde (USG) erektör spina plan bloğu (ESPB) ile serratus anterior plan bloğunun (SAPB) analjezik etkinliğini karşılaştırdık.

Yöntem: Enstitünün etik kurulundan izin alındıktan sonra, bu prospektif, çift kör klinik çalışma, Ağustos 2021'den Nisan 2022'ye kadar yürütülmüştür. Meme kanseri nedeniyle MRM planlanan 18-65 yaş arasında, vücut kitle indeksi ≤30 kg m^{-2} ASA I-II kadınlar çalışmaya dahil edildi. Kırk hasta rastgele iki gruba ayrıldı: Grup E (USG-ESPB uygulandı) ve Grup S (USG-SAPB uygulandı). Her iki gruba da 0,4 mL kg^{-1} %0,25 bupivakain verildi. Hastaların analjezi süresi, intraoperatif ve postoperatif hemodinamik değişiklikler, intraoperatif opioid ve postoperatif analjezik tüketimi, Sayısal Derecelendirme Ölçeği (NRS) ağrı skorları ve vasküler ponksiyon, hipotansiyon, plevral ponksiyon veya pnömotoraks gibi yan etkiler veya lokal anestezik toksisitesi kaydedildi.

Bulgular: Ortalama analjezi süresi Grup E'de Grup S'ye göre daha uzun ve istatistiksel olarak anlamlıydı (p<0,001). Ortalama NRS skoru Grup E'de grup S'ye göre 2,4,8 ve 12. saatlerde istatistiksel olarak anlamlı (p<0,005) şekilde daha düşük bulundu. Her iki grup arasında intraoperatif opioid gereksinimi benzer olmasına rağmen, postoperatif analjezik tüketimi Grup E'de Grup S'ye kıyasla anlamlı olarak daha düşüktü (p<0,05).

Sonuç: Çalışmamızda tek taraflı MRM uygulanan hastalarda postoperatif dönemde USG-ESPB'nin USG-SAPB'den üstün olduğu sonucuna vardık.

Anahtar sözcükler: Meme kanseri, sinir bloğu, ultrasonografi

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***Corresponding author:** Amrita Rath • amritambbs08@gmail.com

Saurabh Sagar 0000-0003-0089-000X / Sandeep Loha 0000-0001-6759-8359
Anıl Paswan 0000-0003-4786-9769 / Arvind Pratap 0000-0001-6954-2236
Shashi Prakash 0000-0002-3854-5124 / Amrita Rath 0000-0002-1990-2667

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INTRODUCTION

Modified radical mastectomy (MRM) is one of the most commonly performed surgeries for breast cancer (1). Previous studies found that perioperative pain may affect the oncological outcome in major tumour resection surgeries (2). Also, pain following a mastectomy may persist chronically in the form of postmastectomy pain syndrome (phantom breast pain, paraesthesia, and intercostobrachial neuralgia) (3). Inadequate pain management has both psychological and physiological repercussions (4). It is difficult to provide analgesia following MRM due to the complex innervation of the breast and the extensive nature of the surgery (5).

Various local or regional nerve blocks like thoracic epidural, interscalene brachial plexus, paravertebral, pectoral nerve blocks, and erector spinae plane blocks are performed in MRM to provide analgesia (6-11). Ultrasound-guided erector spinae plane block (USG-ESPB) is one of the novel and effective regional techniques where local anaesthetic is deposited deep into the erector spinae muscle, blocking the ventral and dorsal rami of multiple spinal nerves, and is technically simple, with fewer hemodynamic side effects and with minimal complications (12-14).

Recently, a newer block, i.e, ultrasound-guided serratus anterior plane block (USG-SAPB), targets the plane above or below the serratus anterior muscle in the midaxillary line and blocks the lateral branches of the intercostal nerves (15). It has the advantage of easier identification and a relatively shallow needle angle that allows for easy block administration while using ultrasound with minimal complications. However, there are very few randomized controlled trials that evaluated the analgesic efficacy of USG-ESPB and USG-SAPB in MRM. Hence, the purpose of this randomized controlled trial was to compare the analgesic efficacy of USG-ESPB and USG-SAPB in patients undergoing unilateral MRM.

MATERIAL and METHODS

The study was a prospective, single-centre, randomized, double-blind study approved by the institute's ethical committee. After obtaining written informed consent from the participants, the study was conducted in the Department of Anaesthesiology from August 2021 to April 2022. The study followed the Consolidated Standards of Reporting Trials (CONSORT) statement and principles of the Declaration of Helsinki (Figure 1). A total of 40 female patients aged 18–65 years with a body mass index ≤ 30 kg m^{-2} and American Society of Anesthesiologists (ASA) I and II who were scheduled for MRM for breast cancer were included in this study. Patient's refusal, patients with a known history of allergies to the study drugs, infection at the puncture site of the proposed block, patients with coagulopathy (International normalized ratio >1.5), patients on anticoagulant therapy, pregnant or lactating mothers, patients with cognitive or communication impairment, and patients having a history of chronic opioid consumption were excluded from the study.

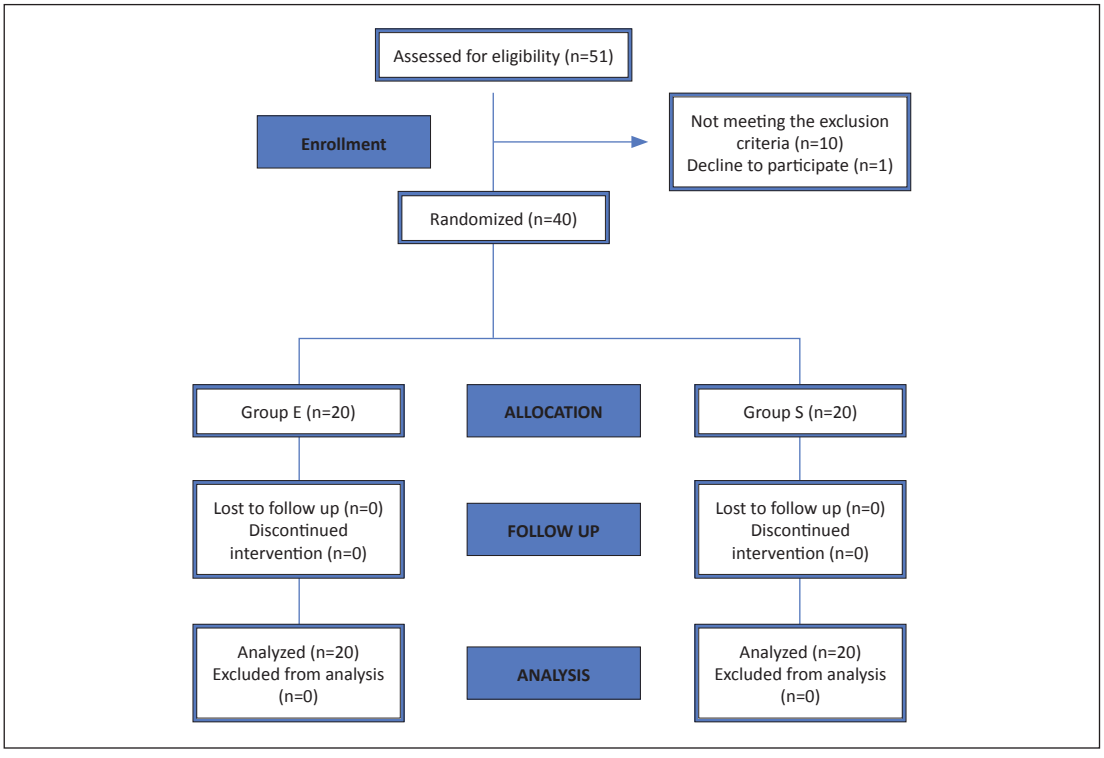

Figure 1. CONSORT (Consolidated Standards of Reporting Trials) flowchart.

The study participants were randomized into two groups using a computer-generated list of random numbers sealed in an opaque envelope and were randomly allotted into two groups on a scale of 1:1.

Group E: Received USG-ESPB with 0.4 mL kg^{-1} of 0.25% bupivacaine (16) with 22 Gauge Quincke spinal needle.

Group S: Received USG-SAPB with 0.4 mL kg^{-1} of 0.25% bupivacaine with 22 Gauge Quincke spinal needle (16).

At the preoperative visit, all patients were instructed on how to evaluate their pain by using the 11-point Numerical Rating Scale (NRS), which ranges from 0 (meaning no pain) to 10 (meaning worst pain imaginable) and details of nerve block procedures. All the patients received ranitidine 150 mg, Tablet metoclopramide 10 mg and alprazolam 0.25 mg peroral on the night before and the day of the scheduled surgery as premedication.

General anaesthesia was administered as per the institute protocol. The patients were premedicated with IV midazolam 30 µg kg^{-1} and fentanyl 2 µg kg^{-1} and were induced with propofol 2.5 mg kg^{-1} and the trachea was intubated after administering vecuronium bromide 0.1 mg kg^{-1} IV for muscle relaxation. The lungs were ventilated to maintain an end-tidal carbon dioxide of 30-35 mmHg. Anaesthesia was maintained with oxygen and isoflurane to maintain a minimal alveolar concentration of 1.0. At the end of the surgery, ondansetron 0.1 mg kg^{-1} was administered IV and muscle relaxation was reversed with IV neostigmine 50 µg kg^{-1} and glycopyrrolate 10 µg kg^{-1}. The trachea was extubated, and the patients were transferred to the post-anaesthetic care unit (PACU) for follow-up.

The study block in either group was performed under complete aseptic conditions after the induction of anaesthesia. Consultant anaesthesiologists with experience in regional anaesthesia and familiarity with USG-ESPB and USG-SAPB performed or supervised all blocks and were not involved in the study. Following the onset of general anaesthesia, envelopes were opened to reveal the group assignment. Blocks were performed under full aseptic conditions according to the randomisation before the commencement of surgery. All patients received bupivacaine 0.25%, whichever block they received. All blocks were performed with a 22-gauge echogenic Quincke spinal needle (BD spinal needle, 22G, New Delhi, India) using the linear transducer (8-13 MHz) of the ultrasound machine (HFL38x; FUJIFILM SonoSite, Bothell, Washington) in an in-plane technique.

In Group E, patients were placed in lateral decubitus position with the operation site up. The probe was placed vertically 3 cm lateral to the T5 spinous process and the transverse process was identified. The needle was introduced in an in-plane fashion until the tip lay deep in the erector spinae muscle. 0.5 mL of normal saline was injected to confirm the correct needle tip position by visualizing the spread under the erector spinae muscle. A total of 0.4 mL kg^{-1} of 0.25% bupivacaine was injected.

In group S, patients were placed in a supine position with the arm abducted. The probe was placed in the mid-axillary line around the 4^{th} and 5^{th} ribs and the three muscles were identified: latissimus dorsi (superficial and posterior), teres major (superior) and serratus muscles (deep and inferior). The thoracic dorsal artery was also identified as an additional landmark to identify the superficial plane of the serratus anterior muscle. The needle was inserted in an in-plane approach and 0.5 mL of normal saline was injected to confirm the correct needle tip position by visualizing spread over the serratus anterior muscles. Then half of 0.4 mL kg^{-1} of 0.25% bupivacaine was injected and then the needle was advanced with an in-plane technique and the other half of 0.25% bupivacaine was injected deep to the serratus anterior muscle.

Heart rate (HR) and mean arterial pressure (MAP) were recorded immediately before induction of anaesthesia, 15 min after performing the block, and then every 30 minutes intraoperatively and then hourly for the next 4 hours (hr) postoperatively. If HR or MAP increased > 20% from baseline (at the time just before induction), the anaesthesia plane was deepened by inhalation anaesthesia. If it didn't settle after deepening the plane of anaesthesia, and the patient was believed to have pain, a bolus of fentanyl 0.5-1 µg kg^{-1} was given intravenously as rescue analgesia. The total requirement of intraoperative rescue analgesia was also recorded. Investigators involved in data collection were absent during the block administration and were masked to the patient's group allocation.

Post-operative pain was assessed and recorded at 1^{st}, 2^{nd}, 4^{th}, 8^{th}, 12^{th}, 18^{th}, and 24^{th} hr by NRS. If the NRS was ≥ 4, rescue analgesics were administered. Tramadol 1-2 mg kg^{-1} was given IV as a first-line drug. If the pain persisted, paracetamol 15 mg kg^{-1} was administered IV. Intraoeprative analgesia was maintained with iv fentanyl and paraceramol (1 g) in all patients. Postoperatively, all the patients received analgesia in the ward in the form of paracetamol (15 mg kg^{-1} 4/day) and ketorolac (0.5 mg kg^{-1} 3/day).

The duration of analgesia was defined as the time from the administration of the block to the first use of rescue analgesic. The time when the first dose of rescue analgesia was administered, as well as the total dose of rescue analgesic required in the first 24 hours, were recorded.

The primary outcome of this study was to determine the difference in the duration of analgesia between the two blocks. The secondary outcomes were to compare the intra-operative and post-operative haemodynamic changes, intra-operative opioid and post-operative analgesic consumption, pain scores using NRS, and adverse effects like vascular puncture, hypotension, pleural puncture or pneumothorax, or local anaesthetic toxicity of the two blocks.

The sample size was calculated using a universal sample size calculator. Assuming a two-tailed alpha threshold of 0.05 and a power (1-beta) of 90% and a mean difference of 30% between the groups based on an initial pilot study, 18 participants were required in each group. We did a pilot study on 10 patients in which we found that the mean duration of analgesia in minutes in group E was 401.05 ± 39.43, whereas it was 308.02 ± 38.90 in group S. Assuming a 10% withdrawal rate and a loss for follow-up, we eventually recruited 40 patients for this study.

The statistical analysis of the data was done by using the statistical software SPSS for Windows version (23.0). The chi-square test was used for categorical variables. Normal distribution test was performed for quantitative data and parametric test was used. An independent Student's test was used to compare two groups of mean values. For paired samples, a paired t-test was applied for statistical analysis. For comparison, the critical value of p, which indicates the probability of a significant difference, was set to 0.05.

RESULTS

The Consolidated Standards of Reporting Trials (CONSORT) flow diagram for this trial is shown in Figure 1. Fifty-one patients were initially screened for suitability, with 40 patients meeting the inclusion criteria. All patients enrolled were followed successfully, with no patients lost to follow-up.

Baseline characteristics were comparable among both the groups (Table I).

Our primary outcome, i.e., the mean duration of analgesia, was significantly prolonged in Group E as compared to Group S and was statistically significant ($p<0.001$) (Table II). The mean NRS pain score was found to be significantly lower in group E as compared to Group S at 2, 4, 8, and 12 hrs which was statistically significant ($p<0.005$) (Table III). However, it was comparable at 1 hr, 18 hrs and 24 hrs. The mean intra-operative period fentanyl consumption was comparable between the two groups ($p>0.05$). However, the total dose of rescue analgesia required by the patients during the 24 hour postoperative period was significantly less in group E compared to Group S ($p<0.005$) (Table IV).

The mean HR of the patients was comparable between both groups throughout the perioperative period (Figure 2).

The MAP of the patients was comparable among both groups throughout the perioperative period (Figure 3).

DISCUSSION

There are various analgesic modalities for managing post-operative pain in MRM surgery. It can range from local wound infiltration to more invasive thoracic epidural techniques. However, with the advancement of ultrasound and newer blocks like ESPB and SAPB, the focus has changed to a more precise block that can provide effective and prolonged analgesia with minimal side effects.

In this prospective, randomized, double-blind controlled trial, we evaluated the superiority of EPSB over SAPB. In our study,

Table I. Demographic Information for the Two Groups

	Group E (N=20)	Group S (N=20)	p
Age (years)	53.95±4.796	53.90±4.064	0.972
Weight (kg)	58.55±6.947	58.75±7.697	0.932
Height (cm)	156.70±6.242	157.85±5.824	0.550
BMI (kg m^{-2})	25.53±2.54	24.89± 3.21	0.488
Surgery time (minutes)	120±30	124±28	0.881

Values are in Mean±Standard deviation (SD), **N=** numbers, **BMI=** Body mass index.

Table II. Comparison of the Mean Duration of Analgesia

Parameter	Group E (N=20)	Group S (N=20)	p
Time of the first rescue analgesia (minutes)	412.50±42.411	313.00±42.439	<0.001*

*p<0.001 is statistically significant.

we found that the duration of analgesia was significantly prolonged in Group E compared to Group S. Our finding is similar to the previous study where they compared USG-ESPB and USG-SAPB in minimally invasive thoracic surgery and found time to the first rescue analgesia was greater in group E than in group S (17).

The sensory supply of the breast is by anterior and lateral cutaneous branches from the 2nd to 6th thoracic intercostal nerve and supraclavicular nerve (18). The anterior cutaneous branches of the thoracic intercostal nerve supply the parasternal areas of the breast, whereas the upper and lateral quadrants are partly supplied by the supraclavicular nerve. Therefore, serratus anterior plane block alone can't provide

Table III. Comparison of the Mean Numerical Rating Scale (NRS) Pain Score Post-Operatively Between the Groups at Different Time Intervals

Time at	Group E (N=20)	Group S (N=20)	p
NRS 1st Hour	0.35±0.489	0.55±0.510	0.214
NRS 2nd Hour	0.75±0.444	1.20±0.616	0.012*
NRS 4th Hour	1.60±0.598	2.50±0.688	<0.001*
NRS 8th Hour	1.70±0.657	2.35±0.745	0.005*
NRS 12th Hour	1.60±0.681	2.25±0.550	0.002*
NRS 18th Hour	2.75±0.851	2.90±0.852	0.581
NRS 24th Hour	2.70±0.733	2.65±0.745	0.832

Values are in Mean±Standard deviation (SD), **N=** numbers, **NRS=** Numerical Rating Scale.

Table IV. Comparison of the Mean Intra-Operative Period Fentanyl Consumption and Total Dose of Rescue Analgesia Required by the Patients in the 24 Hours Postoperative Period Among Groups

Parameters	Group E (N=20)	Group S (N=20)	p
Intra-operative fentanyl consumption (μg)	101.25±13.463	106.75±12.489	0.188
Total dose of rescue analgesia required in 24 hours post-operative period (mg)	185.00±36.635	227.50±47.226	0.003*

Values are in Mean ± Standard deviation (SD), **N=** numbers.

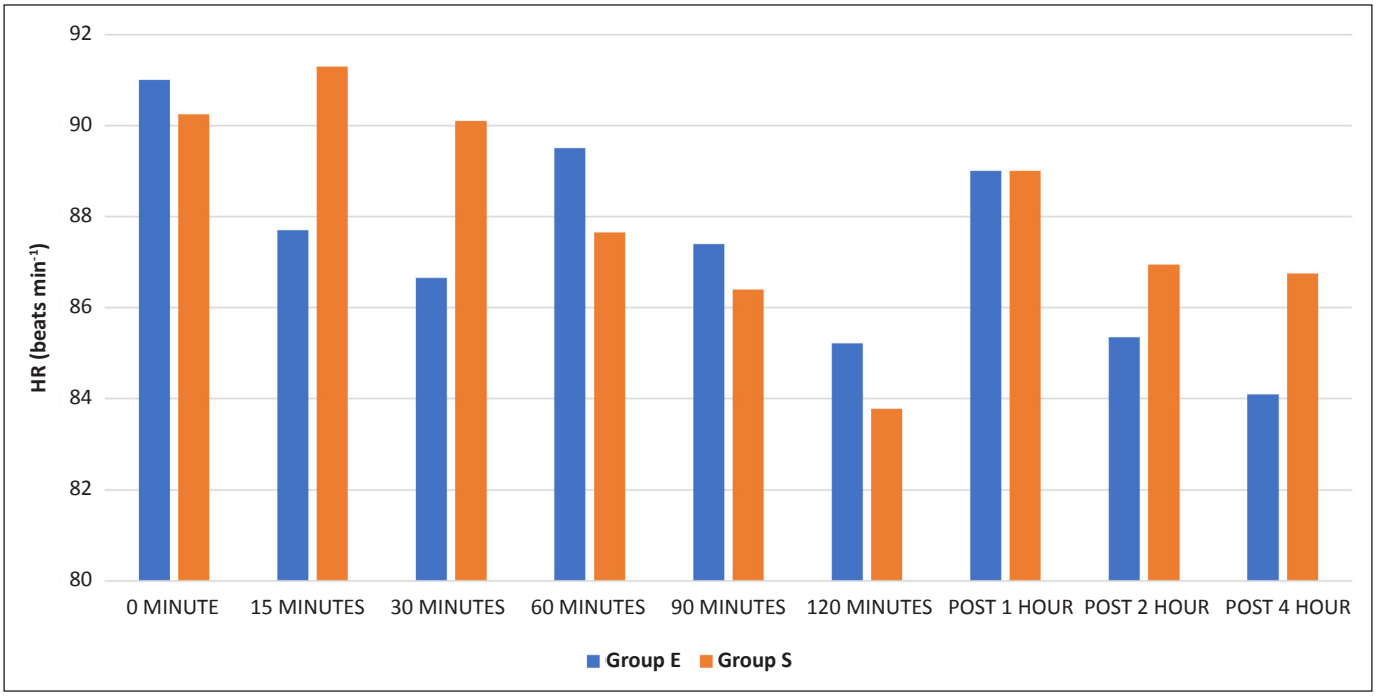

Figure 2. Comparison of mean heart rate (HR) between the two groups perioperatively.

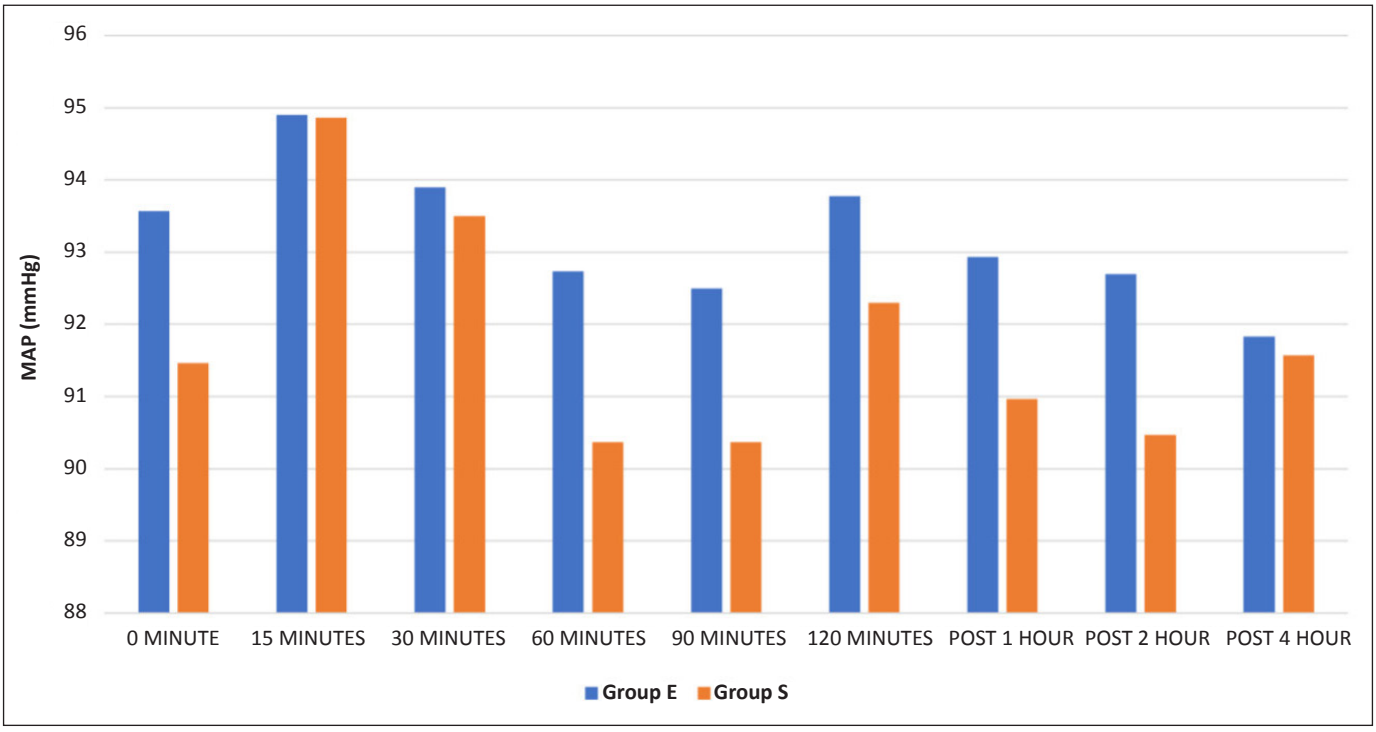

Figure 3. Comparison of Mean arterial pressure (MAP) between the two groups perioperatively.

complete somatic and sympathetic blockade in the axillary area as compared to the thoracic paravertebral block (19-21). In USG-ESPB, the drug percolates into the paravertebral space and blocks both dorsal and ventral rami of the thoracic spinal nerves and elicits some degree of sympathetic blockade as opposed to USG-SAP block, which targets only branches of the intercostal nerve (22). Also, once it enters the paravertebral space, the drug may extravasate medially into the epidural space. Hence, providing a longer duration of blockade. The erector spinae plane is safe as there are no major vessels or vital structures that can get punctured by a needle. Therefore, the chance of inadvertent haematoma is less. Also, the transverse process acts as an anteromedial barrier to the pleura. Thus, the chance of injuring the pleura is less.

In our study, we found that the postoperative NRS pain scores were better in Group E at 2nd, 4th, 8th and 12th hr as compared to group S. In an another study, authors compared the three blocks; ultrasound-guided rhomboid intercostal block (RIB), ESPB, and SAPB. They found that the NRS scores in ESP block and RIB groups at 0.5, 1, 3, 6, 12, 18 and 24 were significantly lower than those in SAPB group ($p<0.05$) (23).

Though the intraoperative opioid requirement was comparable among both groups, the postoperative analgesic consumption was significantly lower in Group E. This can be explained as a result of the prolonged and more effective block that was achieved in Group E. Thus, the need for rescue analgesia was less in Group E as compared to Group S. Our study was supported by another study where they found that USG-EPSP and thoracic paravertebral blocks minimize post-operative pain scores, prolong the duration of analgesia and diminish the requirements for assigning analgesics in the first 24 hr of the postoperative period compared to ultrasound-guided serratus anterior plane block (24). The first analgesic dose requirement was significantly longer in ESB (416±68 min) as compared to SAPB (343.5±54.7 min), which is similar to our study. The mean duration of analgesia was significantly longer in ESB compared with SAPB ($p<0.001$). For the first 24 hr, the total morphine consumption as rescue analgesia was significantly lower in ESPB as compared to the SAPB group. In contrast to our finding, another study found that USG SAPB and ESPB provided effective postoperative analgesia in patients undergoing modified radical mastectomy with lower pain scores, less perioperative analgesic consumption, and longer duration of analgesia in SAPB compared to ESPB (25). In their result, VAS scores were nearly similar in SAPB and ESPB groups, but the amount of total rescue morphine was higher in ESPB than in the SAPB group. The difference in their results might be due to the difference in the volume of drug used in both the blocks; 20 mL for ESPB and 30 mL for SAPB. Since SAPB is a fascial block, a larger volume of local anaesthetic is expected to enhance its spread in this technique. They also gave paracetamol (1 g) IV to the patients just after they reached the PACU and this was repeated every 6 hour.

In our study, we didn't encounter any block failures. Also, there were no complications related to the block, such as vascular puncture, hypotension, pleural puncture, pneumothorax, or local anaesthetic toxicity.

Our study also has a few limitations. First, since the procedure was performed after the induction of general anaesthesia, it was not possible to elicit the onset time of block and the level of dermatome blocked. Secondly, we didn't put a continuous catheter in our study for continuous analgesia. Further studies are needed to comment on the efficacy of the block with a continuous catheter technique. Thirdly, we didn't keep a track of the follow-up for the long-term implications of the development of chronic pain.

CONCLUSION

We concluded that USG-ESP block provides prolonged analgesia, lower pain scores, and decreased postoperative analgesic requirements as compared to USG-SAP block in patients undergoing unilateral MRM surgery. However, no definite opinion can be given due to the relatively small number of patients studied. Our sample size is small, so a further large multi-centric study is required, which may usher in a new era of ultrasound-guided interfascial blocks for breast cancer patients undergoing MRM.

AUTHOR CONTRIBUTIONS

Conception or design of the work: SL

Data collection: SS

Data analysis and interpretation: AKP

Drafting the article: AR

Critical revision of the article: AP

Other (study supervision, fundings, materials, etc): SP

All authors (SL, SS, AP, AP, SP, AR) reviewed the results and approved the final version of the manuscript.

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