

Effectiveness of ultrasound-guided Continuous Unilateral Erector Spinae Plane Block for Postoperative Analgesia in Modified Radical Mastectomy: A Randomised Clinical Study

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ABSTRACT

Introduction: Modified Radical Mastectomy (MRM) can cause postoperative pain, which is often difficult to relieve due to the complex innervation of the breast. This may lead to chronic pain syndrome if not managed adequately. Continuous Erector Spinae Plane (ESP) block could be useful as it provides analgesia over a wide range of dermatomes and avoids opioid-related adverse events.

Aim: To evaluate the effectiveness of unilateral continuous ESP block in providing postoperative analgesia in MRM.

Materials and Methods: A prospective randomised clinical study was conducted involving 56 females scheduled for MRM in Government Medical College, Kozhikode, Kerala, India. They were divided into two groups. Group E (n=28) received an ultrasound-guided ESP block using inj. Ropivacaine 0.5% 20 mL and an indwelling catheter was inserted in the plane. Group I (n=28) received local infiltration around the incision with 20 mL of 0.2% Ropivacaine. Postoperatively, patients in Group E received an infusion of Inj. Ropivacaine 0.2% at 5 mL/hr for 24 hours through the catheter. Postoperative pain was assessed

using the Numerical Rating Scale (NRS). The time to the first rescue analgesic and the cumulative dose of rescue analgesic over 24 hours were recorded. The incidence of nausea or vomiting and haemodynamic parameters were also recorded. The Student's t-test was used to determine the significance of parameters on a continuous scale, while the Fisher's exact test/ Chi-square test was employed for categorical variables.

Results: The mean NRS pain scores were significantly lower in Group E (p-value <0.001) at all time intervals. Group I required rescue analgesia earlier than Group E (p-value <0.001). The mean cumulative dose of rescue analgesics in 24 hours was significantly lower in Group E (p-value <0.001). The incidence of postoperative nausea or vomiting at six hours and 12 hours was significantly lower in Group E.

Conclusion: Unilateral continuous ESP block is an effective technique for providing postoperative analgesia for patients undergoing MRM. It offers a longer duration of analgesia, a lesser requirement for postoperative rescue analgesics and a reduced incidence of nausea and vomiting.

Keywords: Breast surgery, Postoperative pain, Ropivacaine

INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and accounts for the greatest number of cancer deaths among them [1]. MRM, the commonly performed surgery for breast cancer, involves the removal of breast tissue along with axillary dissection. Sensory innervation of the breast is derived from the anterolateral and anteromedial branches of the thoracic intercostal nerves T3-T5. Supraclavicular nerves from the lower fibres of the cervical plexus also innervate the upper and lateral parts of the breast [2]. Due to the complex nature of this innervation, inadequately managed acute postoperative pain may lead to chronic pain syndrome, which includes paraesthesia, phantom breast pain and intercostobrachial neuralgia [3]. Every surgical episode places the patient at risk for transitioning to persistent postoperative opioid use. Opioid-associated adverse effects, such as nausea, vomiting, sedation and respiratory depression, are not uncommon [4]. This can result in delayed return to normal activities of daily living and reduced patient satisfaction.

The Erector Spinae Plane Block (ESPB) was first described by Forero M et al., for the treatment of chronic thoracic neuropathic pain and postoperative pain in thoracic surgery [5]. The erector spinae muscle group consists of the spinalis muscle, longissimus muscle and iliocostalis muscle [6]. The ESPB is an interfascial plane block performed by depositing a local anaesthetic solution

between the transverse processes of the vertebrae and the erector spinae muscles, resulting in a blockade of the dorsal and ventral rami of thoracic and lumbar spinal nerves. The local anaesthetic solution also diffuses into the paravertebral and epidural spaces [6-8]. The spread of the anaesthesia effectively blocks both somatic and visceral pain [9,10]. The advantages of ESPB include ease of performance and safety compared to paravertebral block, as the site of drug deposition is away from the pleura and neuraxis. The ESPB minimises the risk of microbial contamination of the surgical site which is a significant concern as it allows to be performed at a distance from the site [11]. Furthermore, ESPB does not interfere with surgical dissection at the site, which may be a concern with pectoralis plane block [12].

Gürkan Y et al., in a randomised controlled study conducted in 2018, demonstrated that ESPB is effective for postoperative analgesia in patients undergoing MRM under general anaesthesia [13]. Clinicians have utilised the technique of retaining a catheter in the ESP, enabling the administration of local anaesthetic solution in the postoperative period for patients undergoing major abdominal surgeries and thoracotomy [14,15]. This technique could also be applied for providing postoperative analgesia in breast surgeries. A literature search revealed no studies using continuous ESP block for analgesia in MRM and comparing it with infiltration of local

anaesthetics. Therefore, this study was conducted to evaluate the efficacy of continuous unilateral ESP block using a catheter inserted and retained in the ESP, aiming to extend analgesic coverage postoperatively and improve patient outcomes.

MATERIALS AND METHODS

This prospective randomised clinical study was conducted in the general surgery operation theatre at Government Medical College Hospital, Kozhikode, Kerala, India, from February 2020 to April 2021. The study commenced after receiving clearance from the Institutional Ethics Committee (Ref. no. GMCKKD/RP 2020/IEC/334). Written informed consent was obtained from all participants.

Inclusion criteria: Female patients aged between 20 and 65 years, posted for unilateral MRM, who were classified as American Society of Anaesthesiologists (ASA) physical status 1 or 2, were included in the study.

Exclusion criteria: Patients with a BMI greater than 35 kg/m², ASA physical status 3 and above, those with local infection over the back near the site of the block procedure, any known drug allergies, coagulopathy and those with a history of recent opioid use were excluded from the study.

Sample size calculation: Gürkan Y et al., conducted a randomised study involving 50 patients undergoing mastectomy under general anaesthesia. They investigated the effectiveness of ultrasound-guided ESP block in reducing postoperative opioid consumption [13]. Based on this study, the sample size was calculated assuming a power of 80% using the formula:

$$n = \frac{2(Z\alpha + Z\beta)^2 \cdot SD^2}{d^2}$$

Where, $Z\alpha=1.96$ and $Z\beta=0.84$ and d is the effect size. Mean SD of morphine consumption at postoperative 24 hour from SD1 and SD2 is 5.36. For $d=4$, sample size in each group is 28.

A total of 56 patients were randomly allocated into two groups of 28 participants each, using a computer-generated random number table. Patients in Group E received general anaesthesia followed by a USG-guided unilateral erector spinae block using 0.5% Ropivacaine. A catheter was placed in the fascial plane and they received postoperative analgesia via infusion of 0.2% Ropivacaine through an elastomeric infusion pump, which delivers at a fixed rate of 5 mL/hr [16,17]. Group I received general anaesthesia along with local infiltration of 20 mL 0.2% Ropivacaine at the end of the surgery.

Study Procedure

All the patients underwent a preanaesthetic check-up, which included a thorough history, physical examination and laboratory investigations. Written informed consent was obtained from all participants, who were educated on how to use the Numerical Rating Scale (NRS) for assessing pain. All patients were kept nil per os before surgery (eight hours for solids, six hours for semi-solids and two hours for clear fluids). After being shifted to the operating room, monitors were attached, including a pulse oximeter, ECG and Non Invasive Blood Pressure (NIBP). Venous access was established using an 18 G cannula in the arm opposite to the side of the surgery. All patients were premedicated with Inj. Midazolam 0.03 mg/kg intravenously (i.v.) and Inj. Morphine 0.1 mg/kg i.v. General anaesthesia was induced using Inj. Propofol 2 mg/kg i.v., followed by Inj. Succinylcholine 1.5 mg/kg for endotracheal intubation. The airway was secured with a cuffed oral endotracheal tube and general anaesthesia was maintained using oxygen, nitrous oxide and isoflurane. Neuromuscular blockade was maintained with Inj. Vecuronium after an initial bolus dose of 0.08 mg/kg.

Patients in Group E were positioned laterally and the skin at the block site was prepared with 10% povidone iodine solution. A linear probe of the ultrasound machine was used to locate the T4 transverse process.

An 18 G Touhy needle was introduced from a cranial to caudal direction in the plane and advanced deep to the muscle, just touching the T4 transverse process. After hydrodissection, an indwelling catheter was introduced through the needle and fixed at a sufficient length, followed by the injection of 20 mL of 0.5% Ropivacaine. This procedure was performed each time by an anaesthesiologist with adequate experience in conducting ultrasound-guided blocks. Successful block was assumed based on the visualisation of the spread of the drug in the erector spinae plane, lifting the muscle from the transverse process. Sensory effects of the block were not objectively assessed, as it was administered after the administration of general anaesthesia. Both the participants and the investigators were not blinded to the study procedure.

Intraoperatively, all patients received Inj. Paracetamol 10 mg/kg intravenously (i.v.) [18]. Vital signs were monitored throughout the procedure. At the end of the surgery, local infiltration with 20 mL of 0.2% Ropivacaine around the skin incision site was administered to Group I. Patients were extubated and transferred to the recovery room, while patients in Group E were connected to a portable silastic infusion pump, which delivered Inj. Ropivacaine 0.2% at a rate of 5 mL/hr for 24 hours through the indwelling catheter. The catheter was removed shortly after this period. Both groups received Inj. Paracetamol 10 mg/kg every six hours.

Postoperative pain was assessed using the NRS in both groups. Patients were asked to circle a whole number between 0 and 10, where zero denotes no pain at all and 10 denotes the most severe pain [19,20]. NRS scores were recorded upon arrival in the recovery room at zero hours, one hour, six hours, 12 hours and 24 hours postoperatively.

The duration of analgesia was defined as the time until the first request for rescue analgesia in the postoperative period. When the NRS score was greater than 4, Inj. Tramadol 1 mg/kg was administered as an intravenous bolus to both groups as the first rescue analgesic. Inj. Meperidine 1 mg/kg intramuscularly was used as the second rescue analgesic, known for providing pain relief in MRM [21,22]. It was given if the NRS remained above 4, half an hour after the administration of the first rescue analgesic. The cumulative doses of Tramadol and Meperidine in the first 24 hours were recorded.

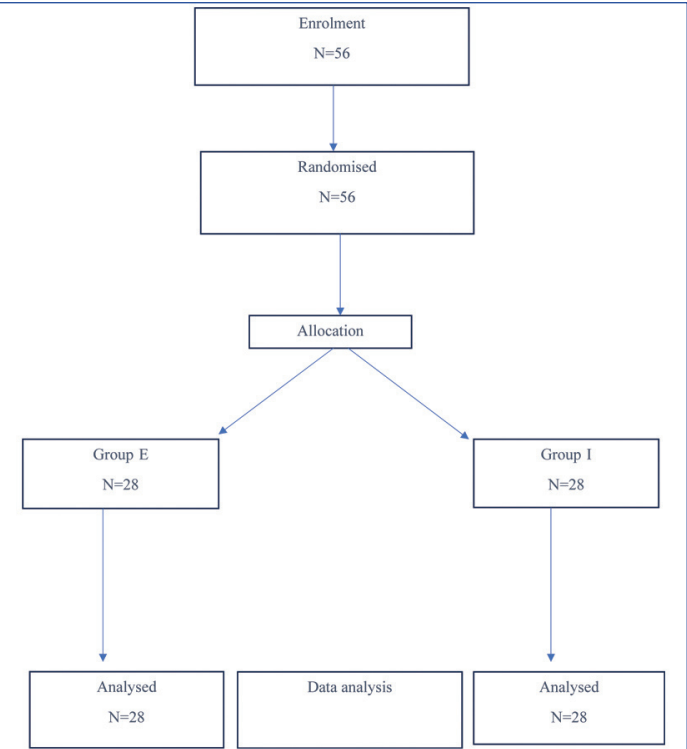
The incidence of nausea and vomiting in the postoperative period during the first 24 hours was documented in both groups at one hour, six hours, 12 hours and 24 hours. Additionally, heart rate and blood pressure were recorded at one hour postoperatively in both groups.

STATISTICAL ANALYSIS

Microsoft Word and Excel were used to generate graphs and tables. Statistical software Statistical Package for the Social Sciences (SPSS) version 22.0 and R environment version 3.2.2 were used for data analysis. Results for continuous measurements were presented as Mean \pm SD, while results for categorical measurements were presented as number (%). Significance was assessed at a 5% level. The Student's t-test (two-tailed, independent) was used to determine the significance of study parameters on a continuous scale between the two groups (intergroup analysis) for metric parameters. Levene's test for homogeneity of variance was performed to assess the homogeneity of variance. The Chi-square or Fisher's exact test was used to determine the significance of study parameters on a categorical scale between the two groups. The Fisher's exact test was employed when cell counts were very small.

RESULTS

In this study, 28 participants who received erector spinae block with continuous postoperative infusion of 0.2% Ropivacaine were categorised into Group E, while 28 participants who received local infiltration of 0.2% Ropivacaine were categorised into Group I [Table/ Fig-1]. The mean age, mean BMI, ASA status, mean height and the average duration of surgery were comparable between both groups [Table/ Fig-2].



[Table/Fig-1]: CONSORT flow diagram, N=56.

| Parameters | Group E | Group I | p-value |
|--|-------------|-------------|---------|
| Age (mean±SD) in years | 50.67±8.20 | 52.50±7.54 | 0.391 |
| Weight (mean±SD) in kg | 60.43±2.97 | 61.29±4.19 | 0.381 |
| Height (mean±SD) in cm | 156.5±4.32 | 155.11±6.78 | 0.364 |
| Body mass index (kg/m ²) | 24.83±1.73 | 25.53±1.59 | 0.122 |
| ASA 1 (number) | 14 | 15 | 1 |
| ASA 2 (number) | 14 | 13 | 1 |
| Duration of surgery in minutes (mean±SD) | 109.64±8.34 | 107±18.66 | 0.497 |

[Table/Fig-2]: Demographic data.

It was found that the mean NRS scores were significantly lower in Group E at zero hours, one hour, six hours, 12 hours and 24 hours [Table/Fig-3]. In Group E, two patients required rescue analgesia within six hours; only one patient required it from seven to 12 hours and no patients required it from 13 to 24 hours. In Group I, six patients required rescue analgesia within six hours, eight patients required it from seven to 12 hours and seven patients required it from 13 to 24 hours. Group I required rescue analgesics earlier than Group E (p-value <0.001) [Table/Fig-4].

| NRS | Group E | Group I | p-value |
|----------|-----------|-----------|---------|
| 0 hour | 0.86±1.15 | 2.18±1.52 | <0.001 |
| 1 hour | 1.71±1.61 | 3.14±1.53 | <0.001 |
| 6 hours | 2.07±1.59 | 4.11±1.47 | <0.001 |
| 12 hours | 2.5±1.04 | 4.57±1.29 | <0.001 |
| 24 hours | 2.64±0.95 | 4.79±1.45 | <0.001 |

[Table/Fig-3]: Mean postoperative NRS scores.
Fisher's exact test

| Time of rescue analgesic (hours) | Group E | Group I |
|----------------------------------|------------|-------------|
| 1-6 | 2 (7.1%) | 6 (21.4%) |
| 7-12 | 1 (3.6%) | 8 (28.6%) |
| 13-24 | 0 | 7 (25%) |
| No rescue analgesia requirement | 25 (89.3%) | 10* (35.7%) |
| Total | 28 (100%) | 28 (100%) |

[Table/Fig-4]: Time of rescue analgesia in numbers (percentage).
*Three patients of I group required rescue analgesia at more than one time interval; Fisher's exact test

The mean cumulative dose of Tramadol as the first rescue analgesic was significantly lower in Group E compared to Group I (p-value <0.001) using the Student's t-test. The mean cumulative dose of Meperidine as the second rescue analgesic in Group I was 16.21±28.62 mg, while none of the patients in Group E required it [Table/Fig-5].

| Variables | Group E | Group I | p-value |
|------------------------------------|------------|-------------|---------|
| Cumulative dose of Tramadol (mg) | 5.36±20.81 | 60.71±62.89 | <0.001 |
| Cumulative dose of Meperidine (mg) | 00.00±0.00 | 16.21±28.62 | <0.001 |

[Table/Fig-5]: Rescue analgesic consumption in milligram over 24 hours.

The incidence of postoperative nausea or vomiting was lower in Group E at six hours and 12 hours, with statistical significance (p < 0.001). The difference in this parameter at one hour and 24 hours was not significant [Table/Fig-6].

| Variables | | Group E | Group I | p-value |
|-----------------------------|-----|------------|------------|---------|
| Nausea/vomiting in 1 h | No | 28 (100%) | 26 (92.9%) | 0.490 |
| | Yes | 0 | 2 (7.1%) | |
| Nausea/vomiting in 6 hours | No | 25 (89.3%) | 12 (42.9%) | <0.001 |
| | Yes | 3 (10.7%) | 16 (57.1%) | |
| Nausea/vomiting in 12 hours | No | 26 (92.9%) | 15 (53.6%) | <0.001 |
| | Yes | 2 (7.1%) | 13 (46.4%) | |
| Nausea/vomiting in 24 hours | No | 25 (89.3%) | 21 (75%) | 0.295 |
| | Yes | 3 (10.7%) | 7 (25%) | |

[Table/Fig-6]: Incidence of postoperative nausea/vomiting in number (percentage).

The mean postoperative heart rate at one hour was significantly lower in Group E (80.46±7.96) compared to Group I (p-value <0.001). The mean systolic and diastolic blood pressure at this time was significantly lower in Group E compared to Group I (p-value=0.020 and p-value=0.004, respectively) [Table/Fig-7]. There were no incidences of hypotension, respiratory depression, or any catheter site complications in the subjects.

| Variables | Group E | Group I | p-value |
|-------------------------------------|--------------|--------------|---------|
| Heart rate (bpm) | 80.46±7.96 | 88.89±10.45 | <0.001 |
| Systolic blood pressure (mm of Hg) | 120.43±12.01 | 130.93±19.84 | 0.020 |
| Diastolic blood pressure (mm of Hg) | 75.21±8.51 | 82.71±10.29 | 0.004 |

[Table/Fig-7]: Postoperative heart rate and blood pressure at one hour.

DISCUSSION

Effective pain control is essential for the optimal care of surgical patients. Postoperative pain can significantly impede the return of normal pulmonary function, promote immobility and subsequently lead to the development of deep vein thrombosis [23]. Acute postoperative pain usually results from a combination of nociceptive, inflammatory and neuropathic elements. Opioids, which are widely used for postoperative pain management, are known to cause adverse effects such as nausea, vomiting, respiratory depression, sedation and constipation. Excessive opioid use carries the risk of opioid abuse [24].

The ultrasound-guided ESP is a simple technique involving the injection of local anaesthetic into a paraspinal tissue plane that is distant from the pleura and neuraxis, thereby minimising the risk of complications associated with injury to these structures. The injectate spreads readily in this tissue plane and a single injection of 20-30 mL in adults produces predictable and extensive cephalo-caudal spread and anaesthesia of several dermatomes [5].

In the present study, the demographic profiles and the average duration of surgery were comparable between both groups. It was found that patients who received a continuous unilateral ESP block for MRM had significantly lower postoperative pain perception, as indicated by significantly lower NRS pain scores at all time points

during a 24-hour follow-up period. Comparable results were obtained by Elyazed MM et al., who performed bilateral ultrasound-guided ESP blocks in patients undergoing open epigastric hernia repair using 20 mL of 0.25% bupivacaine and compared it with a control group that received normal saline in the ESP block [25]. In that study, at two hours postoperatively, the Visual Analogue Scale (VAS) pain score was significantly lower in the ESP block group compared to the control group (p -value <0.001) and remained lower until 12 hours. However, at 18 and 24 hours, VAS pain scores were not significantly different between both groups, possibly because it was a single-shot technique. In the present study, retaining an indwelling catheter in the ESP with continuous infusion of local anaesthetic may have contributed to extending analgesia for up to 24 hours.

Saxena V et al., conducted a case series on continuous erector spinae block in paediatric Video-Assisted Thoracoscopic Surgery (VATS) using bupivacaine and fentanyl infusion for 48 hours [26]. They found that all patients achieved excellent postoperative analgesia beyond 48 hours. Moorthy A et al., compared the infusion of levobupivacaine 0.15% through an ESP catheter versus a paravertebral catheter and found that the quality of recovery at 24 and 48 hours was better with the ESP catheter [27].

The results observed in the present study regarding postoperative NRS scores are in line with the RCT conducted by Bajpai S et al., [28]. They studied 50 patients undergoing mastectomy for breast cancer, in which one group received an ultrasound-guided continuous ESP block using a fine catheter, while the other group received no block. Postoperative NRS scores were found to be significantly lower in the block group at 0, 1, 2, 6, 12 and 24 hours (p -value <0.05).

Nagaraja PS et al., compared continuous thoracic epidural anaesthesia with bilateral continuous ESP block in cardiac surgery among 50 patients. The NRS scores were significantly lower in the ESP group at 24 hours, 36 hours and 48 hours and were comparable to the thoracic epidural group at 0, 3, 6 and 12 hours. This indicates that continuous ESPB is comparable to continuous thoracic epidural anaesthesia during the first 12 hours and superior to it in the subsequent 36 hours [29]. The present study also showed comparable results in terms of lower postoperative NRS scores at 0 hours, 1 hour, 6 hours, 12 hours and 24 hours.

It was found that patients in Group E consumed a significantly lesser amount of rescue analgesics compared to Group I. The mean cumulative dose of tramadol in Group E was 5.36 ± 20.81 mg, while that of Group I was 60.71 ± 62.89 mg over 24 hours, demonstrating statistical significance (p -value <0.001). The mean cumulative dose of intramuscular meperidine in 24 hours was 16.21 ± 28.62 mg in Group I, while none of the patients in Group E required it as a rescue analgesic (p -value <0.01). This finding was consistent with the randomised controlled study conducted by Gürkan Y et al., who studied 50 female patients undergoing breast cancer surgery, wherein they found that 24-hour morphine consumption was significantly lower in patients who received a preoperative ESP block [13].

Another RCT by Gürkan Y et al., involving 75 patients undergoing unilateral breast cancer surgery revealed comparable results. They divided the participants into three groups: one group received a unilateral single-shot paravertebral block with 20 mL of 0.25% bupivacaine, another group received a single-shot ESP block with the same drug and the third group was the control group [30]. They found a statistically significant difference between the ESP and control groups (p -value <0.001) and between the PVB and control groups (p -value <0.001), with no significant differences observed between the ESP and PVB groups (p -value >0.05) for 24-hour morphine consumption. Both PVB and ESP group had significantly lower post operative morphine consumption at 6, 12 and 24 hours (p -value <0.001) compared to the control group.

The time of demand for rescue analgesia was compared between the two groups. Two patients from Group E required rescue analgesia within six hours postoperatively, while six patients from Group I required the same (p -value <0.001). This indicates a significantly earlier demand for rescue analgesia among patients who received local infiltration compared to those who received continuous ESP block. Comparable results were obtained in a study conducted by Sharma L et al., who conducted a non inferiority trial comparing continuous erector spinae block with continuous paravertebral block in patients undergoing MRM [31]. They administered 0.2% ropivacaine with fentanyl 2 mcg/mL as postoperative infusion in two groups, one with a paravertebral catheter and the other with an ESP catheter. They concluded that the time to first rescue analgesia and the total rescue analgesic dose in the continuous erector spinae group were comparable to the paravertebral group (p -value >0.05). Thus, the continuous ESP block was not inferior to the continuous paravertebral block for pain relief following MRM.

The incidence of postoperative nausea and vomiting was significantly lower in patients who received the ultrasound-guided continuous ESP block at 6 hours and 12 hours. This could be attributed to the significantly lower consumption of opioids as rescue analgesics by these patients. No statistically significant difference was observed at one hour and 24 hours. Comparable results were found in a systematic review and meta-analysis by Bhushan S et al., on randomised comparative studies of ultrasound-guided ESP block for postoperative analgesia in patients undergoing liver surgeries [32]. Their study demonstrated that ESP block reduces postoperative nausea and vomiting along with lower 48-hour rest pain scores, but no significant reduction in rest pain scores at eight hours or cumulative opioid consumption in the first 24 hours.

Postoperative heart rate and blood pressure at one hour were significantly lower in the ESP block group. This could be due to sufficient pain relief that helps reduce anxiety and discomfort.

To summarise, the ESP block group experienced a significantly longer duration of analgesia, a decreased requirement for rescue analgesics and reduced postoperative pain. Additionally, there was a significantly decreased incidence of postoperative side-effects, namely nausea, vomiting, tachycardia and hypertension.

Limitation(s)

The study has certain limitations. It was a single-centre study and only patients belonging to ASA I and ASA II were included. The catheter could have been kept in place for a longer period to assess the effects on late postoperative pain, patient satisfaction and duration of hospital stay. Additionally, both participants and investigators were not blinded, as this was difficult due to the presence of visible catheters and the infusion device. Furthermore, the success of the ESP block was not assessed by checking skin sensations soon after the administration of the block, as the patients were already anaesthetised.

CONCLUSION(S)

In patients undergoing MRM, ultrasound-guided continuous ESP block provides better postoperative analgesia compared to infiltration of local anaesthetics. It results in a longer duration of analgesia, a lesser requirement for postoperative opioid analgesics and reduced pain. These patients also experienced fewer postoperative side-effects in terms of nausea and vomiting. This study highlights that continuous ESP block should be considered as part of a multimodal analgesia approach for MRM. Further studies utilising blinding techniques, incorporating adjuvants alongside the local anaesthetic solution and conducting multicentre trials will help to extend its clinical benefits.

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