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Original Article

Anaesthesia Section

Efficacy of Erector Spinae Plane Block in Modified Radical Mastectomy for Postoperative Analgesia: A Randomised Controlled Study

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ABSTRACT

Introduction: The Erector Spinae Plane Block (ESPB) is a recently introduced Ultrasound (US)-guided interfascial plane block commonly used for treating thoracic neuropathic pain. Although ESPB has been used for pain control after Modified Radical Mastectomy (MRM), which is a frequently performed operation nowadays, its efficacy compared to other methods of pain control is yet to be established.

Aim: To evaluate the effectiveness of ESPB in controlling acute postoperative pain after MRM surgery.

Materials and Methods: A total of 64 adult females aged between 18-60 years, with American Society of Anaesthesiologists (ASA) physical status I and II, scheduled to undergo elective MRM, were enrolled in the present randomised, double-blinded, controlled study conducted at Department of Anaesthesiology and Critical Care, Nil Ratan Sircar Medical College, Kolkata, West Bengal, India over a period of nine months (from March 2021 to November 2021). They were randomly assigned to two groups, with 32 patients in each group. Group A (n=32) received general anaesthesia only, while Group B (n=32) received US-guided ESPB in addition to general anaesthesia. Postoperative Visual Analogue Scale (VAS) scores, total intra and postoperative analgesic requirements for the first 24 hours, and duration of postoperative analgesia were recorded for each patient. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 24.0 software. Mean and Standard Deviation (SD) were used to express data for numerical variables, while count and percentages were used for categorical variables.

Results: Demographic characteristics (age, weight), ASA status, and mean duration of surgery were similar between the groups. The duration of postoperative analgesia was significantly ($p<0.05$) prolonged in Group B patients (584.1±89.1 minutes) compared to Group A patients (78.0±53.1 minutes). Intra and postoperative analgesic requirements were significantly lower in Group B (fentanyl 87.0±16.8 mcg, tramadol 68.3±35.9 mg) compared to Group A patients (fentanyl 94.5±26.7 mcg, tramadol 158.3±32.3 mg). The postoperative VAS score was more favourable in Group B than in Group A (1.1±0.4 vs. 4.1±0.8 at rest).

Conclusion: The US-guided ESPB is a simple and easy procedure that provides prolonged duration of postoperative analgesia with reduced overall analgesic requirement in the postoperative period after MRM surgery. Therefore, it can be concluded that ESPB is an effective method for controlling acute postoperative pain after MRM surgery.

Keywords: Anaesthetic, Fentanyl, Regional, Ultrasound

INTRODUCTION

Breast cancer is now the most common cancer and the leading cause of mortality from cancer-related causes among females worldwide [1]. In India, it ranks first amongst Indian females with an incidence rate of 25.8 per 100,000 population [2]. Surgery, specifically MRM, is the mainstay of treatment, and general anaesthesia with opioids is conventionally used as the anaesthetic technique for this surgery [3,4]. Acute postoperative pain following breast surgeries is severe, leading to increased opioid use, morbidity, and hospital stay duration. The incidence of postoperative chronic pain after breast surgeries is also high (25-60%) [5]. Both acute postoperative and chronic pain after MRM are difficult to treat due to the complex and widespread innervation of the breast. Conventionally, postoperative pain following breast surgery is managed using parenteral opioids, which are associated with multiple side-effects such as nausea, vomiting, sedation, respiratory depression, and constipation. Nowadays, various regional blocks are being used to manage this postoperative pain. Among the various techniques, thoracic epidural analgesia, thoracic paravertebral block, pectoral and serratus anterior plane blocks (PEC1 and PEC2) are frequently used to provide postoperative analgesia after breast surgery [6,7]. Each of these techniques has its own advantages and disadvantages. The new ESPB is a simple and easy alternative analgesic method for the management of acute postoperative pain. ESPB is a recently developed technique of Ultrasound (US)-guided interfascial plane block, first described by Forero M et al., which is now being used to treat thoracic neuropathic pain [8,9]. It is a simple, easier, and effective regional analgesic technique for various surgical procedures, including rib fractures, back surgeries, and chest wall surgeries. The main advantage of the ESP block is that the site of the block is distant from the surgical field, minimising the risk of microbial contamination [10]. Additionally, there is a minimal risk of major vessel or pleural injury by the block needle in the immediate vicinity during the procedure. ESPB can sufficiently anaesthetise unilateral dermatomal sensation from T1 to L3 when administered at T5. It anaesthetises the innervation of the paraspinal muscle by blocking the dorsal rami of spinal nerves [8]. As a novel technique, ESPB is being utilised in different types of surgical procedures in trials, and a number of prospective studies with this block are ongoing [11]. To date, no study has concluded regarding the optimal dose and level of ESPB for postoperative analgesia in MRM. Some authors have used this block at the T5 level for postoperative analgesia in total mastectomy patients. One study used ropivacaine 0.5% 0.4 mL/kg as the local anaesthetic, and another study used bupivacaine 0.5% 20 mL with similar results [12,13]. The present study aimed to assess the effectiveness of thoracic ESPB at the T3 level using a lower concentration and higher volume of local anaesthetic (0.2% 30 mL ropivacaine) as part of a multimodal approach for postoperative pain relief in breast surgery.

MATERIALS AND METHODS

The present study was a randomised, double-blinded, controlled trial conducted over a period of nine months (from March 2021 to November 2021) at Department of Anaesthesiology and Critical Care, Nil Ratan Sircar Medical College, Kolkata, West Bengal, India. Ethical clearance was obtained from the Institutional Ethical Committee (No. NMC/480 dated 03/02/2021), and written informed consent was obtained from every patient. The study was registered with the Clinical Trials Registry of India, with the registration number CTRI/2021/03/031731 (Registered on: 05/03/2021).

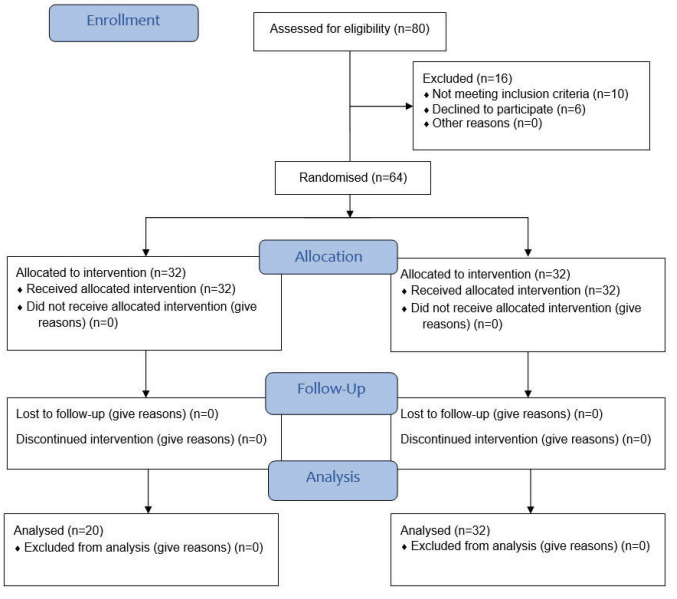
The primary outcome measure was to compare the duration of postoperative analgesia between the two groups. The secondary outcome measures were to compare VAS scores, total intra and postoperative analgesic consumption over 24 hours, and to observe any complications.

Inclusion and Exclusion criteria: For the present study, 64 female patients between the ages of 18-60 years, with ASA physical status I and II, scheduled to undergo planned MRM, were selected. Exclusion criteria included patients' refusal, uncooperative patients, Body Mass Index (BMI) more than 35 kg/m^2, known allergy to local anaesthetic, patients on anticoagulants, a history of any bleeding disorder, patients with sepsis and/or local site infection, patients with known cardiovascular or respiratory diseases, hepatic or renal disorders, psychiatric disorders, spinal deformity, patients on chronic opioid therapy during the last one month, and opioid addiction.

Sample size calculation: The sample size was calculated to be 64 using Epi Info (TM) 3.5.3., which is a trademark of the Centres for Disease Control and Prevention (CDC).

Study Procedure

Patients were randomly allocated into two groups using the sealed opaque envelope technique. A Consolidated Standards of reporting Trials (CONSORT) diagram is given [Table/Fig-1].



[Table/Fig-1]: CONSORT flow chart.

Group A: Patients in this group were scheduled to receive general anaesthesia without any intervention (control group, n=32).

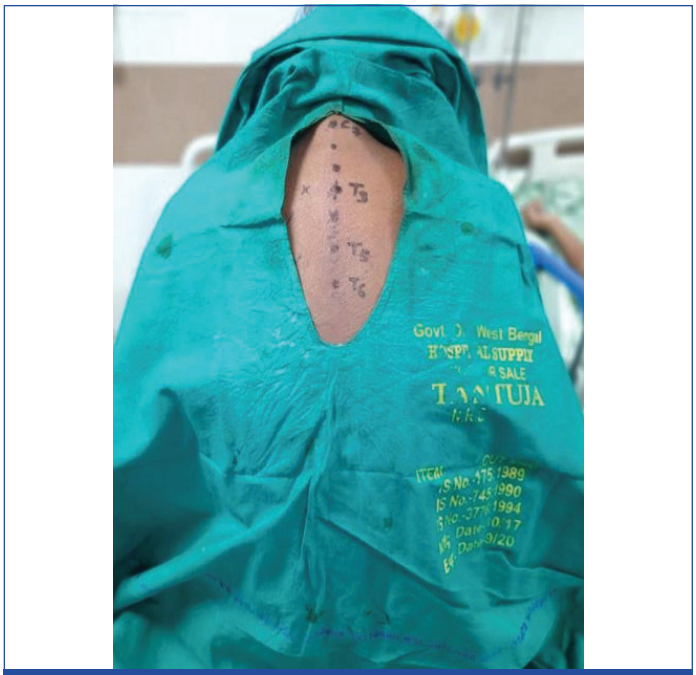
Group B: Patients in this group were scheduled to receive US-guided ESPB at the T3 level in addition to general anaesthesia (n=32).

All the patients were blinded to the group they were allocated to, and the anaesthesiologist who collected all the data from the patients was also blinded.

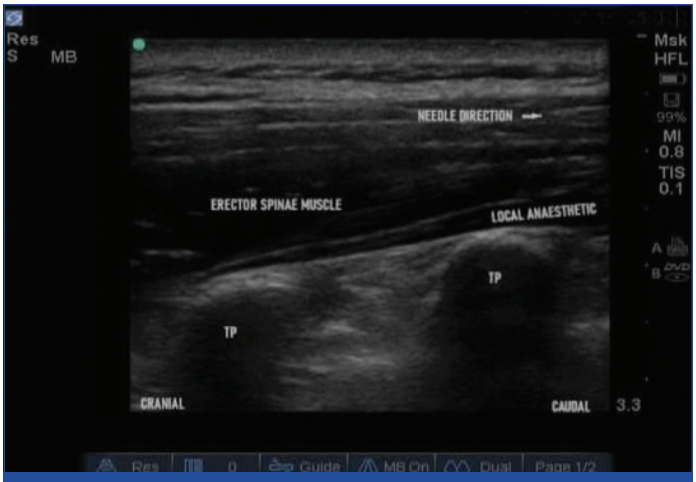
Before the surgery, a detailed history was taken, and a thorough physical examination, including the airway and back, was conducted for every patient. Baseline and special investigations were also performed as required. A written informed consent was obtained from each patient. A six-hour preoperative fasting guideline was followed in every case.

On the day of surgery, each patient was taken to the operating room, and a multichannel monitor {Non Invasive Blood Pressure (NIBP), Oxygen Saturation (SpO_2), HR, continous Electrocardiogram (ECG) and End-tidal Carbon Dioxide ($EtCO_2$)} was attached, and baseline parameters were recorded. Intravenous access was established with an 18 G cannula.

Before general anaesthesia, all patients in Group B received US-guided ESPB. For this, the patient was placed in a sitting position, and the T3 spinous process was identified and marked, starting from the C7 spinous process and counting downwards [Table/Fig-2,3]. A linear high-frequency ultrasound probe (Sonosite M-Turbo Inc., USA) was used. The probe was placed in a craniocaudal orientation in the midline at the T3 spine. The probe was then moved laterally to identify the T3 transverse process, usually at a distance of 2.5-3 cm laterally from the spinous process. The erector spinae muscle, rhomboids major, and trapezius muscle were also identified. After infiltrating the skin with 2% lidocaine, a 10 cm block needle (Stimuplex® Ultra 360® 22 G, B Braun) was inserted in-plane in a craniocaudal direction until the transverse process of the T3 vertebra was encountered. After hydrodissection with 2 mL of normal saline to confirm separation of the erector spinae muscle from the transverse process, 30 mL of 0.2% ropivacaine was injected slowly, and the spread of the drug was observed in real-time in the erector spinae plane craniocaudally.



[Table/Fig-2]: Position of the patient.



[Table/Fig-3]: Local anaesthetic deposition in erector spinae plane.

General Anaesthesia (GA) was administered to all patients in both Group A and B. Each patient was premedicated with Inj. glycopyrrolate (10 mcg/kg body weight) and fentanyl (1.5 mcg/kg body weight) intravenously. After induction with Inj. Propofol (1%) (2 mg/kg body weight) intravenously, endotracheal tube insertion was facilitated with Inj. Succinylcholine (2 mg/kg body weight) intravenously. Anaesthesia was maintained with a mixture of oxygen and nitrous oxide (30%+70%), intermittent administration of isoflurane (0.8-1%), top-up dosage of Inj. Atracurium (0.1 mg/kg body weight), and intermittent positive pressure ventilation via a Drager anaesthesia workstation. The target $EtCO_2$ was kept between 35-40 mmHg.

Intraoperatively, any increase in Heart Rate (HR) or blood pressure 20% above baseline, and any incidence of hypotension defined as a fall of Systolic Blood Pressure (SBP) 20% below the baseline for two consecutive readings, were treated with Inj. Fentanyl citrate 0.5 mcg/kg intravenously and boluses of normal saline and mefentermine 3-5 mg, respectively. Intraoperative blood loss was replaced if required. HR, SBP, DBP, MAP, and SpO_2 were recorded at baseline, at incision, 15, 30, 45, 60, 90, and 120 minutes.

After the surgery, all patients were shifted to the Postoperative Care Unit (PACU). An independent anaesthesiologist who was not involved in the anaesthesia procedures assessed the patients in the PACU and collected data from them. The pain intensity was assessed at 0, 0.5, 2, 4, 6, 8, 12, and 24 hours using a Visual Analog Scale (VAS) at rest and on movement in both groups. Intravenous tramadol hydrochloride (50 mg) was used as rescue analgesia in both groups when the VAS score became >3. The duration of postoperative analgesia (time from the first dose of rescue analgesic since the last bite of skin suture) was recorded for each patient.

Any incidence of Postoperative Nausea and Vomiting (PONV) was noted. Total intraoperative opioid (fentanyl) consumption and postoperative analgesic consumption for the first 24 hours were recorded. PONV was assessed using a 4-point PONV scale (0-no nausea, 1-mild nausea, 2-severe nausea, 4-vomiting). Intravenous ondansetron 4 mg was given if the score was >1. The duration of surgery for all cases was about two hours. The data obtained were recorded for statistical analysis.

STATISTICAL ANALYSIS

All the data were tabulated in Microsoft Excel and analysed using SPSS version 24.0 software. The data were expressed as mean and standard deviation for numerical variables and count and percentages for categorical variables. Chi-square test or Fischer's-exact test were used for the comparison of unpaired proportions, and an independent t-test was used for comparisons between the groups. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 80 patients undergoing MRM were assessed as eligible for the study. Sixteen patients were excluded from the study, 10 for not meeting the inclusion criteria and six for declining to participate. Finally, data from 64 patients were analysed.

Demographic characteristics such as age, weight, ASA status, and mean duration of surgery were similar between the groups [Table/Fig-4]. Baseline haemodynamic parameters such as HR, SBP, DBP, and MAP were also similar between the groups. There were no significant differences in intraoperative and postoperative haemodynamic characteristics, except for intraoperative HR changes, which were higher in Group A (84.2±6.5) compared to Group B (75.2±8.8), and this difference was statistically significant (p<0.001) [Table/Fig-5].

[Table/Fig-6] showed that patients in Group A required significantly more intraoperative fentanyl (94.5±26.7 vs. 87.0±16.8 mcg). The duration of postoperative analgesia (time from the first request of rescue analgesia at VAS >3) was significantly longer in Group B (584.1±89.1 min) compared to Group A (78.0±53.1 min). VAS score was significantly lower both at rest (1.1±0.4 vs 4.1±0.8) and during movement (2.0±0.4 vs 5.3±0.8) in Group B patients compared to Group A patients, as recorded at various intervals in the 24 hours postoperatively [Table/Fig-7]. Patients in Group A required significantly more analgesics (tramadol) than Group B (158.3±32.3 mg vs. 68.3±35.9 mg) in the postoperative period. The incidence of PONV was higher in Group A (12/37.5%) than in Group B (8/25%), but the difference was not statistically significant.

Variables	Group B (n=32)	Group A (n=32)	p-value
Age (years) Mean±SD	51.7±5.6	48.8±7.4	0.098
Weight (kg)	54.6±9.6	55.3±5.6	0.708
ASA I/II (N and %)	18/14 56.2%/43.7%	21/11 65.6%/34.3%	0.442
Duration of surgery (min)	93.8±25.0	100.5±16.9	0.230

[Table/Fig-4]: Demographic data.
Independent-t test and Chi-square test used
p-value >0.05 non significant

Variables	Group B (n=32)	Group A (n=32)	p-value
Baseline Heart Rate (HR) bpm	80.9±6.6	83.7±6.3	0.106
Baseline Mean SBP (mean SD) mm Hg	128.6±13.1	126.6±8.1	0.489
Baseline Mean DBP (mean SD) mm Hg	75.3±7.8	72.6±7.3	0.186
Baseline mean arterial pressure (MAP)	93.0±9.7	88.0±5.3	0.323
Intraoperative mean HR	75.2±8.8	84.2±6.5	<0.001**
Intraoperative mean SBP	121.4±10.3	125.6±9.1	0.157
Intraoperative mean DBP	71.4±8.9	72.0±9.4	0.392
Intraoperative mean MAP	88.6±8.5	90.2±8.3	0.256
Postoperative mean HR	76.5±16.5	94.7±9.3	0.115
Postoperative mean SBP	134.1±11.3	137.6±7.0	0.152
Postoperative mean DBP	76.1±10.4	79.4±9.2	0.205
Postoperative mean MAP	95.3±9.9	98.1±9.6	0.274

[Table/Fig-5]: Baseline intra and postoperative haemodynamic parameters.
Independent t-test used
p-value >0.05 non significant
p-value <0.001** statistically highly significant

Variables	Group B	Group A	p-value
Intraoperative fentanyl (mcg)	87.0±16.8	94.5±26.7	<0.001**
Duration of postop erative analgesia (min)	584.1±89.1	78.0±53.1	<0.001**
Postoperative mean VAS at rest	1.1±0.4	4.1±0.8	<0.001**
Postoperative mean VAS at movement	2.0±0.4	5.3±0.8	<0.001**
Postoperative total analgesic (tramadol) consumption (mg)	68.3±35.9	158.3±32.3	<0.001**
Post operative nausea vomiting: Present n%/Absent n%	8 (25%)/24 (75%)	12 (37.5%)/20 (62.5%)	0.280

[Table/Fig-6]: Other intra and postoperative parameters.
Independent-t test used
p-value >0.05=non significant
**:Highly significant (p-value <0.001)

Time	Group	Rest		Movement	
		Mean±SD	p-value	Mean±SD	p-value
0 h	B	0.2±0.4	<0.001**	1.2±0.4	<0.001**
	A	2.0±0.6		3.3±0.5	
0.5 h	B	0.2±0.4	<0.001**	1.2±0.4	<0.001**
	A	2.7±1.2		4.3±0.9	
2 h	B	0.4±0.5	<0.001**	1.3±0.4	<0.001**
	A	4.8±1.3		5.9±1.3	

4 h	B	0.4±0.5	<0.001**	1.4±0.5	<0.001**
	A	5.8±0.8		6.8±0.8	
6 h	B	1.0±0.0	<0.001**	2.0±0.0	<0.001**
	A	5.3±1.0		6.3±1.0	
8 h	B	1.5±0.5	<0.001**	2.2±0.6	<0.001**
	A	5.0±0.8		6.0±0.8	
12 h	B	3.3±0.7	0.772	4.2±0.5	0.491
	A	4.2±0.7		5.2±0.7	
24 h	B	1.8±0.6	0.601	2.5±1.0	0.827
	A	3.7±0.7		4.7±0.7	

[Table/Fig-7]: Postoperative VAS at rest and at movement.
Independent-t test used
p-value >0.05=non significant
p-value <0.001** statistically highly significant

DISCUSSION

Traditionally, systemic opioids have been the primary choice for perioperative analgesia. However, high opioid doses are associated with significant adverse effects such as sedation, respiratory depression, cognitive impairment, constipation, and the risk of long-term habituation and dependence [14-16]. Opioids can suppress the immune system by interfering with natural killer cell activity and may also promote cancer recurrence [17,18].

Other methods, such as local anaesthetic wound infiltration and regional analgesia techniques (thoracic epidural and thoracic paravertebral blocks), have also been used with varying success for postoperative pain management. ESPB (erector spinae plane block) was first published in 2016. It is an easy procedure that can be performed in the preoperative holding area with minimal or no sedation and can be used to provide postoperative analgesia.

In ESPB, a local anaesthetic is injected deep to the erector spinae muscle at the level of the transverse process. The drug spreads within the multifascial plane and acts on the dorsal rami of the spinal nerves at multiple levels, depending on the amount of drug injected. Evidence indicates that with 20 mL of drug injected, the spread of the drug can extend 3-4 vertebral segments or more from the site of injection in a craniocaudal direction [8,9,18,19]. When ESPB is performed at the level of T2 or T3, it blocks the nerve roots of C5 and C6, thereby blocking the suprascapular, axillary, and lateral pectoral nerves [20]. In the present study, the target was the T3 transverse process in all cases. Additionally, a total of 30 mL of local anaesthetic was used, which may explain the blockade of the lateral pectoral nerve and the ventral and dorsal branches of the spinal nerves, resulting in the prolonged analgesia achieved in our study.

The study found that the total amount of fentanyl administered in the ESPB group (87 mcg) over 24 hours was much lower than in the control group (94.5 mcg). Therefore, it can be concluded that ESPB provided effective analgesia and reduced total analgesic consumption.

Kwon WJ et al., studied three patients undergoing total mastectomy with sentinel/axillary lymph node dissection by continuously administering ESPB via a catheter. They observed effective pain relief in the first 24 hours postoperatively, as assessed by resting and dynamic (coughing, deep breathing) pain scores using the Visual Analog Scale (VAS) score [21]. Similarly, Park S et al., studied the efficacy of ultrasound-guided ESPB after mastectomy and immediate breast reconstruction. They observed that the total opioid requirement was lower in the ESPB group than in the control group, and this difference was statistically significant [22].

The duration of postoperative analgesia, measured as the time of the first request for rescue analgesia, was longer after ESPB (584.1±89.1 minutes). This indicates that the duration of analgesia in the ESPB block group was prolonged compared to general anaesthesia alone. A previous study by He W et al., showed that 55% of the ESP group patients and 5% of the control group patients did not require analgesics within 48 hours after surgery ($p<0.05$). Postoperative analgesia was significantly prolonged in the ESP group (48.0±38.75 hours) compared to the control group (4.5±7.5 hours, $p<0.001$) [23].

In the present study, the intergroup comparison showed that the VAS score in the ESPB group was significantly lower up to eight hours postoperatively compared to the control group. At 12 and 24 hours, VAS scores were lower in the ESPB group compared to the control group, but the difference was not statistically significant. Similarly, Yao Y et al., showed that ESPB using 0.5% ropivacaine before surgery lowered VAS scores both at rest and during the first eight postoperative hours, and there was no significant difference at 24 hours postoperatively at rest or during movement [24]. Thiagarajan P et al., also reported similar results, with the mean VAS score at rest and during movement being lower in the ESPB group compared to the general anaesthesia only group [25]. The mean VAS at rest was statistically significant at two hours, and the mean VAS during movement of the arm was statistically significant at 0, 1, 6, and 24 hours. In a similar study by Malawat A et al., where erector spinae block was administered for complete surgical anaesthesia and postoperative analgesia for breast surgeries, VAS scores were significantly lower both at rest and during movement [20].

In the present study, the amount of tramadol hydrochloride consumption in the first 24 hours in the ESPB group (68.3 mg) was lower than in Group A (158.3 mg) and was found to be statistically significant ($p<0.001$).

In a similar previous study by Puthenveettil N et al., the number of patients requiring rescue analgesia and the total amount of tramadol consumption in the first 24 hours after surgery were lower in the ESPB group than in the control group [26]. Thus, the results of the present study corroborate with previous studies. The present study showed that the incidence of PONV was low in patients with ESPB compared to the control group, but this difference was not statistically significant. There were no block-related complications in any of the patients in the present study. In a similar study by Wensheng HE et al., 2 patients (10%) in the ESP group and 6 patients (30%) in the control group ($p>0.05$) experienced PONV [23]. The probable explanation for this is that the use of the ESP block may have reduced postoperative pain and the need for intraoperative opioids, thereby reducing the incidence of PONV. In a similar study by Seelam S et al., there was no statistically significant difference in the PONV score in both groups [27]. Thus, the results of the present study are consistent with previous studies.

Limitation(s)

The present study has certain limitations. Only ASA I and II patients were selected for the study. Patients with multiple co-morbidities (ASA 3 and 4) need to be evaluated to assess the effectiveness of this block in them. Moreover, the present study focused on the first 24 hours after surgery. Longer-term follow-up is required to evaluate the effectiveness of this block in reducing chronic pain.

CONCLUSION(S)

The ESPB is an effective method for controlling acute postoperative pain in patients undergoing MRM. It is technically easy and safe, with no significant side-effects. Mean postoperative VAS scores at rest and during movement are significantly lower with this block. It also reduces intra and postoperative opioid requirements and associated complications.

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