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Feasibility of combined ultrasound guided interscalene and erector spinae plane block for regional anesthesia in modified radical mastectomy with axillary lymph node dissection: A pilot study

Mona Raafat Elghamry, Mohamed Samir AbdElghafar and Mohamed Elsayed Afandy

Anesthesia, Surgical ICU, and Pain Medicine department, Tanta University, Tanta, Egypt

ABSTRACT

Background: In patients at high risk, regional anesthesia (RA) is a viable substitute for general anesthesia (GA). For a modified radical mastectomy that included axillary lymph node dissection (MRM-ALND), we assumed that a combination erector spinae plane block (ESPB) and interscalene block (IBPB) could offer a sufficient anesthesia.
Methods: After clinical trial registration (No. NCT04239716), this pilot study included thirteen consecutive female, 40–85 years old, and scheduled for MRM-ALND. Patients received ESPB at T4 level (5 ml of 2% lidocaine, 10 ml of 0.5% bupivacaine, and 5 ml of normal saline), IBPB (5 ml each of 2% lidocaine and 0.5% bupivacaine), and sedation with dexmedetomidine. The primary aim was to assess the success rate of our technique as a sole anesthesia for MRM-ALND in high-risk patients. Secondary outcomes included intraoperative vital signs measurements. Postoperative measurements were numeric rating scale (NRS) score, analgesic duration, the consumption of morphine, patients' satisfaction, and adverse effects.
Results: Our technique succeeded in 11 out of 13 patients. In whom RA were succeeded, the analgesia lasted 360–720 minutes, they received morphine 3–9 mg and had low NRS scores. The two failure cases received GA, the analgesia lasted 60–120 minutes postoperative, they received morphine 9 mg and had high NRS scores. The reduction of hemodynamic parameters intraoperative responded to reduce dexmedetomidine infusion rate. Two patients had post-operative vomiting treated with ondansetrone.
Conclusions: The combined ESPB and IBPB could be utilized as an alternative to GA for MRM-ALND, which reduced the potential risks of GA in high-risk patients; furthermore, it provides satisfactory postoperative analgesia with limited opioid consumption.

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1. Introduction

Anesthesia for modified radical mastectomy (MRM) includes general anesthesia (GA), or GA combined with regional anesthesia (RA). The RA provides an alternative to avoid complications that faced with GA particularly in those at high risk. Added benefits to cancer patients are reduction of the response to surgical stress and opioid consumption, it is thought to be responsible for immunosuppression and recurrence of cancer. Besides, control of acute postoperative pain, which is among the risk factors that is associated with post mastectomy pain (PMP) syndrome [1–3].

Even though the paravertebral block(PVB) and thoracic epidural anesthesia (TEA) represent the gold standard RA in breast surgery [4,5]; they are invasive techniques, techniqually challanging and have potential serious complications e.g., pneumothorax [6].

Depending on the volume of local anesthetic (LA), the interscalene brachial plexus block (IBPB) targets the brachial plexus and T1-T2 distribution. Yet, it cannot block the intercostal nerves (INs) [7].

When TEA or PVB are contraindicated, the erector spinae plane block (ESPB) is a safe and easy intervention that may be used. Moreover, it may effectively be used as an alternative for GA in high-risk patients. The multisegment spread of local anesthetic (LA) by a single injection that diffuses into paravertebral and intercostal space results in analgesia of chest wall by acting at ventral and dorsal rami [8].

We supposed that combination of ESPB and IBPB could provide a satisfactory anesthesia for (MRM-ALND).

Our research was to assess the feasibility of combined ultrasound guided (UG) ESPB and IBPB with dexmedetomidine sedation as a sole anesthesia for MRM with ALND in high-risk patients.

CONTACT Mona Raafat Elghamry drmonagh19802000@gmail.com Anesthesia, Surgical ICU, and Pain Medicine department, Tanta University, El-Geish Street, Tanta, Egypt

2. Materials and methods

This prospective pilot research was conducted out in Tanta University Hospitals from January 2022 to October 2022 after the institutional Ethics Committee approval, clinical trial registration(at ClinicalTrials.gov, No. NCT04239716), and obtaining an informed written consent from all participants.

Thirteen consecutive female patients, aged 40–85 years, physical status ASA III and IV, planned for MRM with ALND under RA were recruited.

Exclusion criteria were coagulopathy, psychiatric or neurological disorders, injection site infection, alcoholic or opioid addiction, allergy, contraindication to any of the study drugs, chest wall or spine deformity, chronic pain of any cause and uncooperative patients.

Preoperative visit was conducted for clinical evaluation and explanation of IBPB and ESPB with the possible complications. Also, they were trained how to use 11-point (NRS) used to express pain (0= no pain, 10= maximal imaginable pain).

On arrival to the operating theatre, the patients were administered midazolam 0.02 mg/kg IV. Monitoring including electrocardiogram (ECG), pulse oximetry and non-invasive blood pressure (NIBP) were applied. Baseline measurements of mean arterial pressure (MAP), heart rate (HR), and pulse arterial saturation of oxygen (Sp_aO_2) were obtained. Nasal cannula was used to provide oxygen (4 L/min) then UG-IBPB and ESPB were performed.

2.1. Technique of UG-ESPB

A linear ultrasound transducer (Philips® c× 50extreme edition, USA) with high frequency was positioned in a longitudinal parasagittal orientation 3 cm laterally to the ipsilateral T4 spinous process in order to carry out the ESPB while the patient was sitting. A 22 gauge, 100-mm, blunt needle (B. Braun Medical Inc., Bethlehem, PA) was inserted using an in-plane cranio-caudal direction to place the tip of needle into the fascial plane deep to erector spinae muscle. The location of the needle tip was confirmed by LA spread lifting the muscle off the bony shadow of the transverse process. Total volume of 20 ml solution (10 ml 0.5% bupivacaine, 5 ml 2% lidocaine, and 5 ml normal saline) was injected.

2.2. Technique of UG-IBPB

The UG-IBPB was carried out in the supine position with the patient's neck rotated to the contralateral side. A pencil-point 22 gauge cannula (22 G/50 mm Sprotte®, Pajunk™, Geisingen, Germany) was inserted. At the sixth cervical vertebral level, using cross-sectional view, the cannula's tip was inserted between the three brachial plexus cords. The proper cannula placement was determined by the perineural distribution of 1 to 2 ml of LA, followed by a gradual infusion of the remaining LA. Ten ml solution (5 ml each of 2% lidocaine and 0.5% bupivacaine) was used.

The success of the block was tested by absence the sensation of the cold all over four quadrants of the breast (T2-T8 dermatomes) and at the axilla. If loss of sensation was not achieved within 30 minutes, the block was deemed to have failed, and at this time, GA was induced.

Dexmedetomidine 0.5 µg/kg intravenous infusion in 20 min before surgery then 0.2–0.4 µg/kg/h was utilized for sedation throughout the operation.

Ten minutes before the surgery ends 1 g of paracetamol, 4 mg dexamethasone and 4 mg of ondansetron were administered. All patients were sent to the post-anesthesia care unit (PACU) after the operation.

Our primary outcome was the success rate of combined UG- IBPB and ESPB as RA for MRM with ALND. That was defined as completion of the surgery without supplementary GA.

Secondary outcomes were measurement of HR, MAP, and oxygen saturation. They were recorded before RA (baseline values) then every 5,10,20 min after the blocks, at the skin incision, every 15 min till 60 min, then every 30 minutes till the surgery is ended.

Pain was assessed by 11-point NRS on arrival to PACU then after 1,2,4,6,8,12,24 hours postoperative. It was assessed at rest and on movement (90° arm abduction). Patients were received morphine 3 mg IV if NRS score>three and repeated if needed. Morphine was not repeated if morphine-related complications were met e.g., respiratory depression, pruritus.

The time between blockade and first dose of morphine postoperative besides total 24-hours postoperative morphine consumption was recorded.

Patients' satisfaction about analgesia intra and postoperative was evaluated by 4-points scale (4:very satisfied,3: satisfied, 2: dissatisfied, 1:very dissatisfied). Adverse events intraoperative and within 24-hours postoperative e.g., LA systemic toxicity (LAST), oxygen desaturation had been noted.

2.3. Statistical analysis

The IBM SPSS software programme version 20.0 (IBM Corporation, Armonk, New York) was used to do the analysis once the data were entered into the computer. The categorical data were shown via the use of numbers and percentages. The Shapiro-Wilk test was used to determine whether the continuous data exhibited normality. Quantitative information was presented in the following formats: range (minimum – maximum), mean, standard deviation, median, and interquartile range (IQR). To compare various eras for normally distributed quantitative variables, an ANOVA with repeated measurements was utilized, followed by a Post Hoc test (modified Bonferroni) for pairwise comparison. On the other hand, the Friedman test was used in order to compare various periods for quantitative variables that were not normally distributed, and this was then followed by the Post Hoc test (Dunn's) in comparing the periods pairwise. At the 5% level, the significance of the findings that were obtained was evaluated.

3. Results

For 10 months, 72 individuals were evaluated for eligibility, but only 13 were included in the trial. In 11 individuals (84.6%), combined UG- ESPB and IBPB were satisfactory as a sole RA for MRM with ALND. Two patients (15.4%) needed supplementary GA (Figure 1).

Demographic data and other clinical parameters of participants are shown in Table 1.

For patients in whom RA has succeeded, analgesia (as indicated by the time of first analgesic request postoperative) lasted from 360 to 720 minutes. They received one to three doses of morphine (3 to 9 mg) as postoperative rescue analgesia. While in the two failure cases, analgesia lasted 60 and 120 minutes postoperative and they received three doses of morphine (9 mg) postoperative (Table 1).

For patients in whom RA has succeeded, pain score began to increase (NRS >3) at 6,8,12,24 hours postoperative. While, in the two failure cases NRS>three at first and second hours postoperative (Table 2).

There were significant decrease in MAP and HR compared to baseline measurement at different time points intraoperative and only four patients suffered from bradycardia (HR < 50) that responded to decrease rate of dexmedetomidine infusion. However, comparing with baseline values, there were no major differences in SpaO2 (Table 3).

Seven patients were satisfied and four were very satisfied about analgesia. Two patients had postoperative vomiting and they were treated with ondansetron. No local or systemic complications (Table 1).

4. Discussion

This is the initial pilot study (as far as we are aware) to evaluate the probability of combined IBPB and ESPB using UG as a primary anesthesia for MRM with ALND.

Our study showed that UG-IBPB and ESPB could provide a satisfactory anesthesia for MRM with

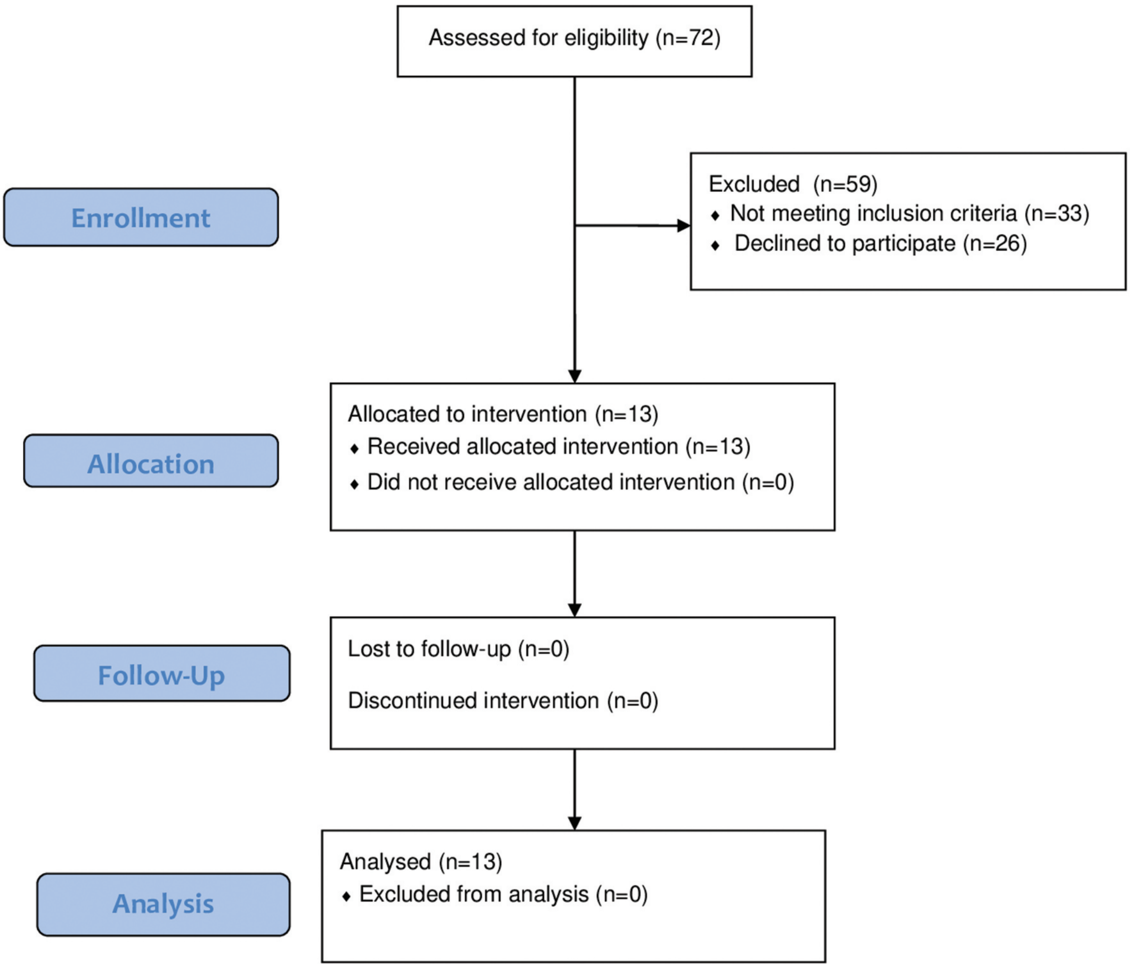

Figure 1. Flow chart of participants.

Table 1. Demographic data and other clinical parameters of the participants.

Variables	Number = 13
Age (years)	
Mean ± SD.	63.6 ± 11.8
BMI (kg/m2)	
Mean ± SD.	34.4 ± 3.26
ASA	
III	10 (76.9%)
IV	3 (23.1%)
Comorbidities	
CKD	7 (53.8%)
CKD with HD	3 (23.1%)
CHF	2 (15.4%)
Critical AS	1 (7.7%)
Duration of surgery (minutes)	
Mean ± SD.	127 ± 19.2
Success rate	
Success	11 (84.6%)
Failure	2 (15.4%)
Time to first analgesic request postoperative (min)	
Mean ± SD.	475 ± 217
Total postoperative morphine consumption (mg)	
3	4 (30.8%)
6	5 (38.5%)
9	4 (30.8%)
Mean ± SD.	6.0 ± 2.45
Patients satisfaction	
1	1 (7.7%)
2	1 (7.7%)
3	7 (53.8%)
4	4 (30.8%)
Adverse effects	
No	7 (53.8%)
POV	2 (15.4%)
Bradycardia	4 (30.8%)

Values are expressed as mean ± standard deviation (SD) or Number (%).
BMI: body mass index, **ASA**: American Society of Anesthesiologists, **CKD**: chronic kidney disease, **HD**: hemodialysis, **CHF**: congestive heart failure, **AS**: aortic stenosis, **POV**: postoperative vomiting.

Table 2. Comparison of Visual analogue scale (VAS) score at different time points postoperative at rest and on movement.

	VAS score			
	At Rest		On movement	
	Median (IQR)	p_0	Median (IQR)	p_0
PACU	1 [1,2]		2 [1,2]	
1	2 [1,2]	0.401	2 [2]	0.262
2	2 [2]	0.150	2 [2,3]	0.037*
4	2 [2]	0.078	3 [3]	0.008*
6	3 [2,3]	<0.001*	3 [3]	<0.001*
8	3 [3,4]	<0.001*	4 [3–5]	<0.001*
12	3 [2–5]	<0.001*	3 [3–6]	<0.001*
24	4 [3,4]	<0.001*	4 [3–5]	<0.001*

Values are expressed as median and inter quartile range (IQR). **VAS**: visual analogue scale, **IQR**: Inter quartile range, PACU: postanesthesia care unit p_0:p value for Post Hoc test (Dunn's) for Friedman test for comparison between VAS at PACU and each other periods.
* denotes statistically significant difference at *P* value ≤ 0.05.

ALND in high-risk patients in whom GA can be life threatening. Moreover, this technique provides good quality postoperative analgesia with limited opioid consumption. Encountered adverse effects were bradycardia that reversed by reduction in dexmedetomidine infusion rate. Furthermore, two patients had postoperative vomiting.

Sedation by dexmedetomidine may be beneficial due to its sedative, analgesic, sympatholytic and anxiolytic properties additionally It could extend the period that RA's sensory block lasts [9].

This technique failed in two out of 13 patients. One patient complained of pain during lymph node (LN) dissection and the other complained during

Table 3. Comparison of heart rate (HR), mean arterial pressure (MAP), and O_2 saturation at different time points intraoperative.

		HR		MAP		O_2 saturation	
	N	Mean ± SD.	p_0	Mean ± SD.	p_0	Mean ± SD.	p_0
Baseline	13	75.62 ± 6.19		94.54 ± 9.96		95.23 ± 1.09	
5 min after block	13	77.92 ± 5.75	<0.001*	94.23 ± 9.84	1.000	95.15 ± 0.90	>0.05
10 min after block	13	75.77 ± 5.63	1.000	93.0 ± 9.87	1.000	95.31 ± 0.95	>0.05
20 min after block	13	75.0 ± 5.28	1.000	92.46 ± 9.62	1.000	95.38 ± 0.77	>0.05
Skin incision	13	72.62 ± 5.30	1.000	91.08 ± 10.44	0.742	95.46 ± 0.88	>0.05
After 15 min	13	69.38 ± 9.10	0.664	90.23 ± 11.84	1.000	95.38 ± 1.04	>0.05
After 30 min	13	65.92 ± 9.59	0.501	87.15 ± 9.67	0.006*	95.54 ± 0.78	>0.05
After 45 min	13	67.54 ± 5.06	0.029*	84.15 ± 8.81	<0.001*	95.46 ± 0.52	>0.05
After 60 min	13	66.38 ± 8.23	0.231	86.0 ± 7.56	0.006*	95.69 ± 0.85	>0.05
After 90 min	13	67.46 ± 3.45	0.083	83.77 ± 7.11	0.001*	95.77 ± 0.83	>0.05
After 120 min	13	66.23 ± 5.39	0.040*	83.69 ± 7.23	0.002*	95.62 ± 0.87	>0.05
After 150 min	7	66.43 ± 3.69	0.014*	84.86 ± 6.52	<0.001*	95.43 ± 0.53	>0.05

Values are expressed as mean ± standard deviation (SD).
p0: *p* value for Post Hoc test (adjusted Bonferroni) for ANOVA with repeated measures for comparison between baseline and each other periods.
*denotes statistically significant difference at *P* value ≤ 0.05.
HR: heart rate, MAP: mean arterial pressure.

mastectomy at upper inner and outer quadrants. Both cases received GA.

Comprehensive understanding of breast and axilla innervation is essential to attain appropriate sensory block to entire breast tissue for breast cancer surgery.

The breast is innervated by branches of the supraclavicular nerves (C4-C5) and the anterior and lateral cutaneous branches of the second to sixth INs (T2-T6). Moreover, the brachial plexus (C5-T1), which contributes to the long thoracic (C5-C7), medial pectoral (C8-T1), lateral pectoral (C5-C6), and thoracodorsal (C6-C8) nerves, is necessary for the innervation of the axilla. Moreover, the innervation of the axilla is aided by the lateral cutaneous branches of the intercostal nerves (LCINs) from T2 to T7. During ALND, the intercostobrachial nerve (T2) is usually injured. As a result, the majority of patients report postoperative pain in the upper limb and axilla [2,5,10].

Different RA succeeded to provide analgesia and anesthesia in different types of breast surgery. However, because of technical difficulties, insufficient sensory block, and the associated complications e.g., pneumothorax, their application is not preferred for extensive breast surgeries [4].

Despite PVB is the gold standard RA in breast surgeries. There is a chance that there will not be enough anesthesia especially in breast surgeries involving ALND. The PVB is unable to block lateral and medial pectoral nerves (LPN and MPN), long thoracic (LTN), and thoracodorsal nerves [11,12].

after the era of ultrasound, TEA and PVB have been replaced by thoracic interfascial plane blocks (TIFPB) e.g., pectoral nerve block (PNB) [13].

The TIFPB have several advantages. They may be used as an alternative to PVB e.g., coagulopathy, can be applied in segmental or unilateral surgery. Several dermatomes and the axilla are covered with a single injection, are simple and easy, do not affect surgical time, can be combined with neuroaxial or GA, and are safely applied in the outpatient setting [11].

Owing to multiple innervations of the breast and axilla, it is essential to combine RA techniques to covers the whole breast and axilla for more extensive surgical interventions especially with ALND [10]. This is evident in some researches [14–18].

The PECS I block targets MPN and LPN. Meanwhile, the PECS II block targets MPN, LPN, and LCINs (T2–6). While, the serratus anterior plane block (SAPB) targets LCINs (T2–9), LTN, and thoracodorsal nerve. The limitation of these three blocks is sparing anterior cutaneous branches of the intercostal nerves (ACINs) and supraclavicular nerves. Thus, they cannot provide enough analgesia to the whole breast tissue [19]. Further, Bakshi S *et al* [20]. reported that when LA is injected close to the surgical site e.g., PNB, this may cause tissue edema and impede the effect of electrocautery. In addition, the blocks may fail in altered sonoanatomy of the chest wall e.g., post-mastectomy chest wall contractures [21].

Moreover, Kim D-H *et al* [22]. demonstrated that PNB; combined PECS I and II cannot cover the entire nerve supply of breast tissue although PECS II block was efficient in reducing axillary pain than breast pain.

Likewise, SAPB does not produce complete anesthesia of the chest wall. Furthermore, it may not provide a block in the axillary region [12] and this is evident in a study by Hetta DF *et al* [23]. who concluded that SAPB was inferior to PVB. Consequently, these techniques (PECS II and SAPB) may be suitable for axillary surgery, not for mastectomy [14].

Recently, many researches show efficiency of ESPB to provide an excellent postoperative analgesia with great patients' satisfaction. It can be a valuable alternative to PVB [24,25].

Radiological studies by Schwartzmann *et al* [26,27]. illustrated the analgesic effect of ESPB which is related to the spread of LA into the transforaminal, epidural and intercostal spaces. This spread is variable and unpredictable (2.5–6.6 ml to cover 1 dermatome) [28]. Accordingly, the epidural spread is a potential during ESPB especially when using large LA volume.

In a case report, De Cassai A *et al* [29]. used ESPB combined with PECS II block to provide anesthesia for MRM with ALND. This combination was an effective technique where PECS II block spares ACINs and here is the role of ESPB. Nevertheless, the drawbacks of this combination are an overlapping effect on INs. Furthermore, the injection of large LA volume could trigger LAST.

The combination of PVB with IBPB has been proved to provide adequate anesthesia for MRM in 10 high risk patients [30]. Similarly, Nirmal CP *et al* [31]. applied combination of PVB, IBPB, and Superficial Cervical Plexus block in one high-risk patient. Their results showed that the technique provides satisfactory postoperative analgesia safely.

Du H *et al* [1]. performed IBPB, INs block, and block of supraclavicular nerves for MRM. It is efficient but complex technique with multiple injections that needs high proficiency of anesthesiologists. Moreover, it consumes large LA volume that may trigger LAST especially in high-risk patients.

Based on mentioned studies and as anesthesia in MRM with ALND could not be achieved by ESPB alone, we combined ESPB with IBPB instead of other invasive and complex techniques.

This is evident in a case report [32] where ESPB at T1 level was insufficient for anesthesia in accessory breast surgery. In addition, a radiological study [33] demonstrated that small proportion of LA extended to the cervical nerve roots when ESPB was performed at T2–3 level. Moreover, according to a cadaver research, 20 mL of LA was distributed between three and seven levels [34].

Tulgar S *et al* [35]. validated the expectation that ESPB does not affect the axillary innervation originating from cervical plexus branches. Patients having mastectomy and ALND had axillary pain.

Nevertheless, Kimachi *et al* [6], described the success of UG-ESPB at T5 level to provide adequate anesthesia for MRM with ALND in high-risk cardiovascular patient. The LA spread to the brachial plexus is unlikely at T5 level however; the success of the block was related to the surgery that preserved the pectoralis muscles and fascia. The TEA and PVB could be used in this type of surgery, but they are invasive with potential serious complications in such high-risk patient on contrary to ESPB. Furthermore, Malawat A *et al* [36]. proved the efficacy of ESPB to provide adequate anesthesia in 30 patients but the surgeries were MRM without ALND. They performed ESPB at T4 level and sensory loss was attained at T1-T8 chest wall dermatomes.

On the contrary, Talawar P *et al* [37]. performed ESPB under GA in breast surgery. They observed raised hemodynamics during cauterization in the infraclavicular area and in the vicinity of pectoral nerves, which is most likely to be spared. Postoperative, six patients complained of pain on movement.

Thus, it is essential to combine ESPB with other blocks in order to achieve a satisfactory anesthesia in breast and axilla.

De Cassai A *et al* [38]. in a case report, explained that combination of ESPB and selective brachial plexus block (SBPB) is effective for MRM with ALND in a successful attempt to avoid GA. The SBPB targets MPN, LPN, LTN, and thoracodorsal nerve.

This technique consumed small LA volume (36 ml). However, SBPB needs high experience in order to identify the mentioned nerves and the surrounding landmarks which may be difficult in some cases e.g., obesity. In addition, it needs multiple injections, which is uncomfortable to the patients.

The evidence presented in the case report [38] supports the idea of our research. We performed IBPB instead of SBPB, which is easy with single injection. Besides, we consumed small LA volume (30 ml).

The IBPB is commonly associated with hemi diaphragmatic paresis which may be avoided by injection of small LA dose with UG as demonstrated by Renes SH *et al* [39]. MoreoverESPB is reported to cause multiple complications e.g., Pneumothorax [35] and LAST [40]. Pneumothorax is not expected following UG- ESPB but it may be a result of hand-eye de-synchronization or depth miscalculation. Similarly, the LAST is a rare but fatal complication after ESPB especially if it is performed bilaterally. In our study, no complications were related to RA.

5. Limitations of the study

First, it was a pilot study of small sample size to evaluate the possibility of new RA technique for MRM with ALND as an alternative to GA. We did not want to use this new technique that has not been tried before, in a large number of patients where the potential complications and its success were completely unknown especially we selected high-risk patients. Therefore, well-structured randomized studies are needed to confirm or disprove our results.

Second, spread of LA in ESPB is highly variable and unpredictable with interindividual variability thus, further radiological and cadaveric studies are needed to understand the level of the block, volume, and the extent of LA to the brachial plexus to determine whether its combination with IBPB is necessary or not.

Third, we did not evaluate the effect on diaphragmatic function. Pulmonary function test e.g., bedside spirometry, ultrasound evaluation will be beneficial for the study.

Fourth, our study focused on short-term outcomes, further studies should be carried out to assess long-term effects of this technique.

6. Conclusions

The combined ESPB and IBPB with sedation may be used as a substitute for GA for MRM with ALND, which eliminates possible risks of GA in high-risk patients; in addition, it provides satisfactory postoperative analgesia with limited opioid consumption.

Disclosure statement

No potential conflict of interest was reported by the author(s).

ORCID

Mona Raafat Elghamry http://orcid.org/0000-0002-7087-864X
Mohamed Samir AbdElghafar http://orcid.org/0000-0003-2004-9410
Mohamed Elsayed Afandy http://orcid.org/0000-0003-3662-9137

Data availability statement

The data that support the findings of this study are available from the corresponding author, [M R E], upon reasonable request.

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