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Ultrasound-guided serratus anterior block versus instillation of local anaesthetic through surgical drain in modified radical mastectomy: A randomized controlled study

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ABSTRACT

Background: The primary outcome measure of this study was to compare ultrasound-guided serratus anterior block versus instillation of local anesthetic through the surgical drain in modified radical mastectomy patients as regards the duration of analgesia between the two techniques.

Material and methods: This prospective, randomized, double-blinded study was conducted on 162 female patients aged 25–50 years, ASA 1, ASA 2, selected for elective unilateral modified radical mastectomy in the Main University Hospital. Group SABP (n = 81) received 20 ml bupivacaine 0.5% in the plan between serratus anterior and latissimus dorsi muscles. Group LA (n = 81) received 40 ml bupivacaine 0.25%, 20 ml in each surgical drain (axillary and chest wall drain).

Results: The results of the study revealed that the duration of analgesia lasted for 20.8 hr in the SAPB group, while it was 8.14 hourshr in the LA group (P-value ˂0.001). In most postoperative periods, the SAPB group had lower VAS scores at rest and with movement of the ipsilateral arm compared to the LA group. The overall dose and frequency of the consumed rescue analgesic over the first 24 hr in the postoperative period were significantly lower in the SAPB group than in the second group (P-value <0.001). The SAPB group had higher satisfaction scores than the LA group (P-value <0.001).

Conclusion: It was concluded that the SAPB technique showed superiority over the anesthetic instillation method in controlling acute post-mastectomy pain with a longer duration of analgesia, more patient satisfaction, and less rescue analgesics were consumed.

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Mastectomy; postoperative pain; local anesthetic; instillation; surgical drain; serratus anterior; regional block

1. Introduction

Breast cancer is one of the most diagnosed cancer worldwide. [1] This resulted in improvements in screening techniques for early detection and management. Surgery, chemotherapy, radiation, and hormonal therapy are used to treat it. [2] In most cases, a combination of these approaches yields the best results, allowing for the early and complete eradication of tumor cells while also improving both quality of life and survival. Modified radical mastectomy (MRM), either with or without axillary lymph node clearance, is one of the surgical options for treating breast cancer. [3] This procedure results in a significant surgical scar and intense pain after surgery. It is imperative that this pain be effectively handled so that no negative outcomes result.

Adverse effects of postoperative pain affect almost all of the body systems. It is associated with anxiety, depression, and psychological disturbance. It causes hemodynamic changes and affects the lungs with atelectasis and respiratory depression as a result of the excessive use of narcotic painkillers. Along with possible occurrence of limb edema, it results in delayed upper limb mobility as well leading to an increase in hospital costs and a delay of the hospital discharge. This acute pain can develop into the chronic illness known as post-mastectomy pain syndrome [4], a kind of nociceptive pain characterized by burning, itching, paresthesia, or numbness sensations. [5]

Multimodal analgesia is a rising technique that permits the use of different modes of analgesia with different mechanisms of action and different methods of administration. It avoids dependence on opioids and their side effects [6]. Under this technique, small amounts of multiple drugs are used to avoid getting the side effects of the large concentration of a single agent. Managing acute postmastectomy pain includes pharmacological methods (opioids, paracetamol, NSAIDS, lidocaine, dexmedetomidine, clonidine, gabapentin, corticosteroid, NMDA receptor antagonists) [7]. The non-pharmacological methods include thoracic epidural anesthesia (TEA), paravertebral block (PVB), peripheral nerve blocks like erector spinae plan block (ESPB), pectoral nerve block (PECS I, PECS II), and

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serratus anterior plane block (SAPB), and lastly, wound infiltration or local anaesthetic instillation via the surgical drain. The aim of this study was to compare the analgesic effect of ultrasound guided SAPB versus local anaesthetic instillation through surgical drains in modified radical mastectomy. The primary outcome of this study was to compare the duration of analgesia between those offered by both techniques, while the secondary objectives were to compare the analgesic profile of the two techniques by using visual analogue score (VAS) score at rest and with the movement of the ipsilateral arm in addition to the total postoperative doses and frequency of opiates and patient satisfaction.

2. Methods and materials

This is a prospective, double-blinded, randomized clinical trial conducted after the approval of the Local Ethics Committee (Reg. No. 0106538) dated 17/9/2020, and PACTR Reg. No PACTR202108765231210. PACTR registration was applied in February 2021.

The study started in October 2020 till December 2021. The present study was carried out in Alexandria Main University Hospital, Egypt, on 162 female patients aged 25–50 years old, ASA class I or II scheduled for elective unilateral MRM after obtaining written informed consent from all patients. Exclusion criteria were refusal to participate, local infection at the injection site, morbid obesity, psychological problem, contraindication to any researched medicine, history of bleeding diathesis, and persistent narcotics abusers. Patients were randomized by a computer-based software program, and then the randomization sequence was concealed by using a sealed opaque envelope technique into two equal groups. Group SAPB (n = 81) received US-guided serratus anterior block by using 20 ml bupivacaine 0.5%. Group LA (n = 81) received instillation of 40 ml bupivacaine 0.25% through surgical drains (20 ml in chest wall drain, 20 ml in axillary drain). Each technique was done after the end of the surgery and before extubation, while the patients were in the supine position. In the preoperative interview, full medical, surgical, and anaesthetic history was taken. Physical examination and evaluation of the airway were done. Routine laboratory investigations were reviewed.

All patients were taught how to interpret the visual analogue scale (VAS) of 0 to 10 with 0 experiencing no pain and 10 being the worst pain imaginable. Patients kept fasting for 8 hr before the operation.

On the day of surgery, a peripheral cannula was inserted on the contralateral limb. Basic monitors were attached to the patients (NIBP, ECG, pulse oximetry, ETCO2). All patients were premedicated with midazolam (0.03 mg/kg), and preload fluids were given.

Induction of general anesthesia was done by propofol until loss of verbal response, atracurium (0.5 mg/kg), fentanyl (1mic/kg). Intubation of trachea was done. Maintenance of anesthesia by using isoflurane (MAC1.2–1.5), mechanical ventilation (to keep ETCO2 35–40 mm. Hg), and atracurium top-up doses according to the train of four (TOF). All patients were given fluids according to the standardized guidelines. An appropriate type of antibiotics and paracetamol (15 mg/kg) were given at the start of surgery. Ondansetron IV (4–8 mg) and ketorolac IV (30 mg) were given at the end of surgery. Then, either technique was performed.

In group SAPB (n = 81), under aseptic technique, a linear ultrasound transducer (10–12 MHz) attached to a Sonosite M Turbo (Sonosite Inc, Bothell, WA, USA) was put in a sagittal plane over the second intercostal space in the midclavicular region, while the patient was lying supine. After that, the probe was moved downward and laterally to count the ribs till the fifth rib was detected in the midaxillary line. The following muscles were delineated overlying the fifth rib: the latissimus dorsi (superficial and posterior), teres major (superior), and serratus muscle (deep and inferior). Targeting the plane between the latissimus dorsi and serratus anterior muscles, the needle (20 G Tuohy needle) was inserted in plane with the ultrasound probe. A total of 20 ml of 0.5% bupivacaine were administered under continuous ultrasound guidance [8] (Figure 1).

In group LA (n = 81), while the patients were in the supine position, after insertion the two surgical drains (one in axillary bed and the second in the chest wall) and wound closure was done. Patients received 40 ml of 0.25% bupivacaine, 20 ml through each of the drains, then the drains were clamped for 20 min then the clamp was released to allow the negative pressure through suction drains under complete aseptic technique [9].

Reversal of muscle relaxant was done by using neostigmine (0.07 mg/kg) and atropine (0.01 mg/kg) and extubated the patient when having the criteria of extubation. Patients then were transferred to the post-anesthesia care unit (PACU) for 2 hr for observation of any complications and early assessment of pain then transferred to the ward.

At the ward, patients were given paracetamol (15 mg/kg) IV every 8 hr. Rescue analgesia in form of nalbuphine IV (6 mg/dose) when VAS score ≥4 at any time postoperatively during the first 24 hr. The following parameters were collected, demographic data, duration of surgery. Hemodynamics were recorded (HR, MAP) throughout the first 24 hr at 30 min, 2 hr, 4 hr, 6 hr, 12 hr, 18 hr, and 24 hr together with pain assessment by using VAS score at rest and with the movement of the ipsilateral arm, time to first rescue analgesic (min), the total dose of rescue analgesia (mg) and frequency of

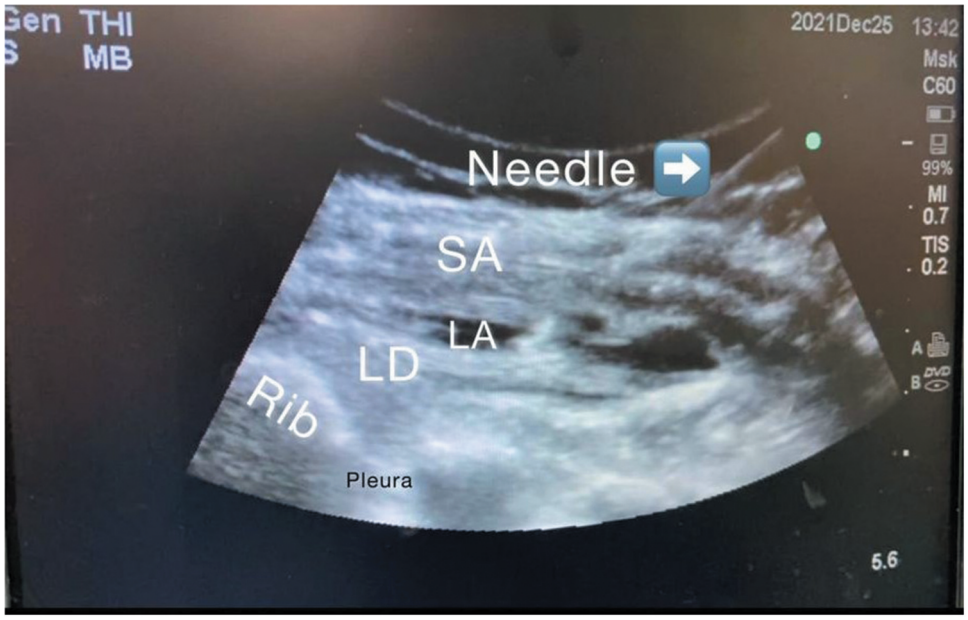

Figure 1. Ultrasound-guided serratus anterior block (SAPB), identifying the serratus anterior muscle (SA) and the latissimus dorsi muscle (LD) introducing the needle and injecting 20 ml bupivacaine 0.5% (LA) in the plan between serratus anterior and latissimus dorsi muscles.

consumption. Any technique-related complications were detected and managed accordingly. Patients' satisfactions were taken by using the verbal rating scale (from 1 to 5). Patients then were discharged home when they are eligible and ready.

3. Sample size determination

The minimal hypothesized total sample size of 162 female patients aged 25–50 years old, ASA class I or II scheduled for elective unilateral MRM (81 per group) is needed to determine the mean difference in the duration of analgesia between serratus anterior block and instillation of local anesthetic through the surgical drain in MRM between Group (SAPB) and Group (LA) with common estimated group standard deviations of 6 and with 95% confidence level and 95% power and 5% probability of type 1 error using independent t-test. [10]

4. Statistical analysis

After data were extracted, revised, coded, and delivered to the computer and analyzed using IBM SPSS software package version 20.0 (Armonk, NY: IBM Corp). The Kolmogorov–Smirnov test was used to prove the normality of the distribution of variables. Comparisons between groups for categorical variables were calculated using the Chi-square test (Fisher or Monte Carlo). Differences in the study parameters among the study groups were assessed by independent t-test for normally distributed variables, and by Mann Whitney for abnormally distributed quantitative variables. All statistical analysis was done using two tailed tests. P value less than 0.05 was statistically significant.

5. Results

The whole data were collected by the PACU nurse and the ward nurse who were blinded to the intervention received.

In the demographic data (Figure 2) (Table 1) (Age, ASA, BMI) there was no statistically significant difference between both groups. No statistically significant difference was detected between the median duration of surgery (Table 1) in both groups (*P*-value 0.069). The same was recorded for the hemodynamic values (HR, MAP) with no statistical significance difference between both groups.

Pain score (Table 2) by using VAS at rest (VAS_R) and with moving the ipsilateral arm (VAS_M) was obtained at the same intervals. Statistically significant lower VAS scores were showed at most intervals in the SAPB group (*p*-value <0.001).

The duration of analgesia was evaluated as the time to initial rescue analgesia (Table 3). The SAPB group had a median duration of 1370 min, while the LA group had a median duration of 450 min (p-value <0.001).

The overall dose of rescue analgesia administered to the LA group was greater (Table 3) than the SAPB group (p-value 0.001). Whereas the total dose of rescue analgesia in the group (SAPB) was ranged from [6–18] mg with a median value of 6 mg, while in the group (LA) the total dose ranged from (6–30) mg with a median value of 18 mg.

As regards the frequency of rescue analgesic (nalbuphine Hcl) (Table 3) in the group (SAPB) it was found

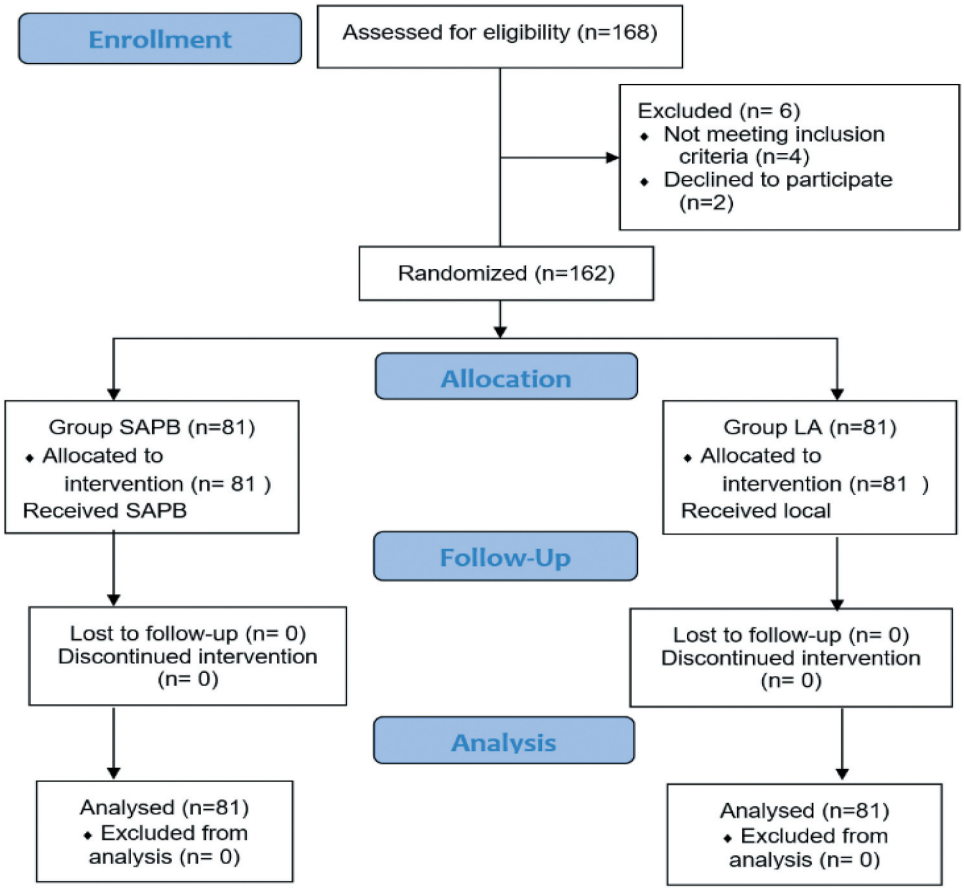

Figure 2. Consort flow chart. Group SAPB: General anesthesia and serratus block, Group LA: General anesthesia and local instillation.

Table 1. Comparison between the two studied groups according to demographic data.

Demographic data	Serratus (n = 81)	Local(n = 81)	Test of sig.	p
Age (years)	43.84 ± 5.33	45.20 ± 4.31	t = 1.783	0.076
Weight (kg)	95.70 ± 6.48	94.48 ± 6.13	t = 1.234	0.219
BMI (kg/m^2)	31.46 ± 2.56	31.33 ± 2.03	t = 0.340	0.735
ASA 1	35 (43.2%)	39 (48.14%)		
ASA 2	46 (56.79%)	42 (51.85%)		
Duration of surgery (min)	110 (90–130)	105 (85–130)	U = 2741.5	0.069

Data was expressed by using **Mean ± SD**. if data was normally distributed, **Median (Min. – Max.)** if data was not normally distributed
t: Student t-test, U: Mann Whitney test
p: p value for comparing between the two studied groups

that 83% of the patients who required nalbuphine Hcl consumed it once during the postoperative period, while in the group (LA) around 48% of the patients who required nalbuphine HCl consumed it three times during the first 24 hr postoperative (P-value <0.001).

Regarding complications in our study, four patients in the SAPB group developed hematomas, which were treated with cold compresses for 20 to 30 min every 4 hr until the hematoma subsided. Six patients in the SAPB group experienced postoperative nausea and vomiting (PONV), compared to 12 participants in the LA group. Each patient was administered 4 mg of IV ondansetron. There were no additional issues observed in either group.

As regard patient satisfaction (Figure 3), patients in the SAPB group were significantly more satisfied with the procedure than the patient in the second group where (*P*-value <0.001)

6. Discussion

Mastectomy is a widely accepted and common procedure for breast cancer management worldwide. Many patients are complaining of side effects from such surgical intervention. Postmastectomy pain is one of the most common complaints during the postoperative time and can be complicated by postmastectomy pain syndrome in an insignificant number of patients if not adequately controlled. The primary objective of our study was to compare the duration of analgesia between both techniques. In the SAPB group, the duration lasted for 1370 min (around 22 hr) while in the local instillation group lasted for 450 min (around 7.5 hr) that could be explained by using ultrasound allows delivery of the precise amount of LA in the exact plan without escaping into the undesired site and also explained by a higher dose of bupivacaine 0.5% used which has a longer duration of action than other types of LA used in other studies. On the other hand, escape of local anesthetic by the effect of gravity and drain

Table 2. Comparison between the two studied groups according to VAS score.

VAS		Serratus(n = 81)	Local(n = 81)	U	p
Rest	30 min	2 (0–3)	1 (0–2)	2324.5*	0.001*
	2 hr	1 (0–3)	2 (0–3)	1741.5*	<0.001*
	4 hr	1 (0–3)	3 (0–4)	1053.0*	<0.001*
	6 hr	1 (0–3)	3 (1–4)	234.0*	<0.001*
	12 hr	2 (0–3)	3 (2–4)	766.5*	<0.001*
	18 hr	2 (0–4)	3 (2–4)	803.0*	<0.001*
	24 hr	2 (0–4)	3 (1–4)	1045.5*	<0.001*
Movement	30 min	2 (0–3)	2 (0–3)	2564.5*	0.009*
	2 hr	2 (1–3)	3 (1–3)	1572.5*	<0.001*
	4 hr	2 (0–3)	3 (2–4)	841.0*	<0.001*
	6 hr	2 (0–3)	4 (2–4)	371.0*	<0.001*
	12 hr	2 (0–4)	4 (3,4)	527.50*	<0.001*
	18 hr	3 (0–4)	4 (3,4)	1236.0*	<0.001*
	24 hr	3 (0–4)	3 (3,4)	1448.5*	<0.001*

Data was expressed by using **Median (Min. – Max.)**
U: Mann Whitney test
p: p value for comparing between the two studied groups
*: Statistically significant at p ≤ 0.05

Table 3. Comparison between the two studied groups according to rescue analgesia.

	Serratus(n = 81)	Local(n = 81)	Test of sig.	p
Duration of analgesia (min)	1370 (700–1490)	450 (300–690)	U = 0.0*	<0.001*
Need analgesia				
Not need	45 (55.6%)	0 (0%)		
Need	**36 (44.4%)**	**81 (100%)**		
Frequency rescue analgesia#				
1	30 (83.3%)	2 (2.5%)	82.722*	MCp<0.001*
2	4 (11.1%)	27 (33.3%)		
3	2 (5.6%)	39 (48.1%)		
4	0 (0.0%)	11 (13.6%)		
5	0 (0.0%)	2 (2.5%)		
Total dose rescue analgesia mg#	6 [6–18]	18 (6–30)	U = 189.0*	<0.001*

Data was expressed by using **Median (Min. – Max.), or No. (%)**
Chi square test, MC: **Monte Carlo**, U**: Mann Whitney test**
p: p value for comparing between the studied groups
*: Statistically significant at p ≤ 0.05

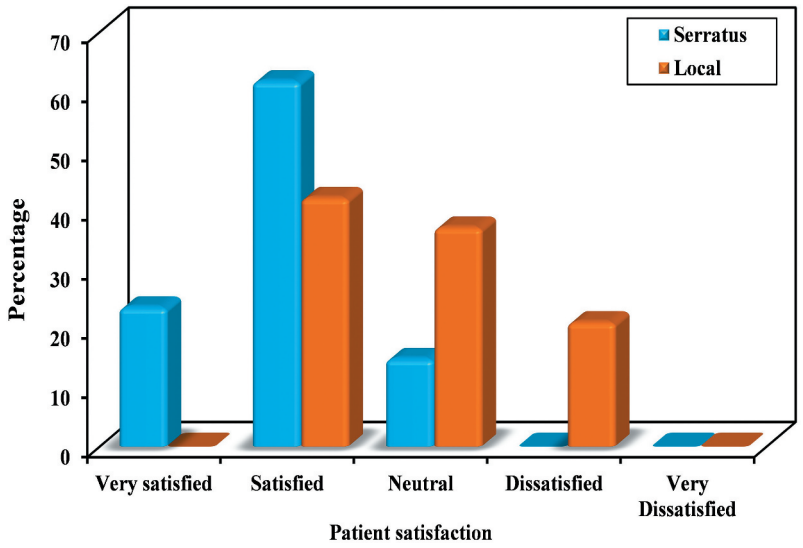

Figure 3. Comparison between the two studied groups according to patient satisfaction.

malposition may add to the shorter duration of analgesia.

Blanco R et al. [11] studied the effect of the injection of 0.4 ml/kg levobupivacaine 0.125% in the serratus plane in healthy volunteers. This study found that paresthesia lasted for (752 ± 21 min) after injection. This finding is not comparable to our results regarding the duration of analgesia of SAPB. This may be due to the different types and doses of LA used and the judgment of the effect of the block by the persistence of paresthesia without the presence of surgical pain.

Ohgoshi Y et al. [12] studied the effect of SAPB by using 30 ml ropivacaine 0.375% on partial mastectomy patients stated that the analgesic effect lasted for 12 to 24 hr postoperative; however, they recommended that it must be combined with another analgesia if surgery combined axillary clearance.

A systemic review was performed by Byager N et al. [13] on the analgesic effect of wound infiltration with LA after breast surgery concluded that the analgesic effect of local infiltration covers only the first few hours postoperative and should not be standardized as an analgesic method but also it should be combined with another non-invasive analgesic method.

Another study done by Meena RK et al. [14] on 90 female patients to study the effect of instillation of different concentrations of bupivacaine through the surgical drain in MRM patients found that the mean duration of analgesia was 5.5 hr when using 40 ml bupivacaine 0.25% compared to 4.65 hr with 40 ml bupivacaine 0.125%, while it lasted for around 2.15 hr in the control group (no instillation).

In contrast to our study, Jonnavithula N et al. [9] conducted a RCT on 60 patients undergoing MRM to study the role of instillation of LA (bupivacaine) into the surgical drain by using the same volume and concentration of LA used in our study. They divided the patients into three equal groups where group C (control group that received no instillation), group S (received 40 ml normal saline), and group B (received 40 ml 0.25% bupivacaine, 20 ml in each drain), it was found that LA lasted for 14.6 hr in group B, while it lasted for 10.3 hr in group S and 4.3 hr in the control group.

The secondary objectives of our study were to compare the analgesic profile of the two techniques by using visual analogue score (VAS) score at rest (VAS_R) and with the movement of the ipsilateral arm (VAS_M), and we found a statistically significant difference between both groups at different intervals (*P*-value <0.001) with lower VAS scores observed in the serratus group at most of the intervals.

In agreement with our results, Hards M et al. [15] conducted a retrospective study on 27 female patients to compare the analgesic effect of SABP under direct vision versus wound infiltration alone in mastectomy patients and found similar pain scores in both groups during the early recovery period; however, 81% of patients in the SABP group suffer no or mild pain in the first 24 hr postoperative, while 27% of the patients in the infiltration group suffered severe pain.

Another study conducted by Arora S. et al. [16] that examined the effect of SAPB versus PVB by injecting 0.4 ml/kg 0 f 0.5% ropivacaine on 40 female patients selected for radical mastectomy found superiority of the SAPB group over the latter in terms of pain score during the first 24 hr postoperative with a longer analgesic profile that lasted for (255.3 ± 47.8 min), while it lasted for (146.8 ± 30.4 min) in the PVB group.

Shokri H et al. [10] when conducted a study to compare SAPB and infiltration of local anesthetic in MRM patients recorded statistically significant lower VAS scores at 6 h, 10 hr, and 12 hr postoperative for the SAPB group with (*P*-value <0.001).

In contrast to our results, a RCT study conducted by Saad FS et al. [17] on 90 lung cancer patients scheduled for thoracotomy to compare the analgesic effect of SAPB versus PVB showed a comparable VAS score during the postoperative periods up to 9 hr, then after the PVB group showed a statistically significant lower VAS score that could be explained that thoracotomy incision extends to the back of chest wall that is not covered by SAPB alone. On the other hand, thoracotomy is associated with pain that is more severe than in mastectomy.

This study showed a significant difference (*P*-value <0.001) in frequency and total dose of rescue analgesia (nalbuphine Hcl) given. In the SAPB group, the median dose was 6 mg, and 83% of the patients who required nalbuphine Hcl needed only one dose during the first 24 hr postoperative while in the LA group the median dose was 18 mg, and 48% of the patients who required nalbuphine Hcl consumed only three doses. In terms of patient satisfaction, patients in the SAPB group were significantly more satisfied with the procedure than the patients in the LA group, where (P-value 0.001).

According to Shokri H et al. [10], the SAPB group received significantly less rescue analgesia than the infiltration group. Using 30 ml of bupivacaine 0.25%, Bakeer AH et al. [18] studied 180 female patients undergoing MRM to compare PECS II block to SAPB and found no significant difference in the two procedures but both groups showed a significant reduction in these measures when compared to the control group (received general anesthesia alone).

Arora S et al. [16] showed the superiority of SAPB over PVB in MRM in terms of the total dose of rescue analgesia needed by the patient postoperative.

In contrast to our study, Albi-Feldzer A et al. [19] conducted a RCT on 236 patients undergoing mastectomy to study the role of wound infiltration by ropivacaine 0.375% (3 mg/kg) versus placebo (0.8 ml/kg of normal saline) on the acute and chronic postoperative pain. They showed no significant difference in the

overall consumption of rescue analgesics between the saline group and the ropivacaine group.

The limitation of the study is that the serratus anterior block was performed after completion of the surgery, so the patients could have benefited from the intraoperative analgesic effect of the technique.

7. Conclusion

Serratus anterior block and instillation of LA through drain are effective and safe methods for controlling postoperative pain. Serratus anterior block shows superiority over the LA instillation in terms of duration of analgesia with less rescue analgesia being consumed.

Disclosure statement

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

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