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Magnesium sulfate as an adjuvant in serratus anterior plane block for postoperative pain management in modified radical mastectomy: A randomized controlled trial

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Abstract

Background: Although modified radical mastectomy (MRM) is a frequently performed surgical procedure, patients may experience pain both during and after the operation. Adding magnesium sulfate to a local anesthetic can make its effects last longer. The objective of this research was to find out whether patients having mastectomy could benefit from using magnesium sulfate as an adjuvant in serratus anterior plane blocks (SAPB).

Methods: This randomized, controlled, double-blinded study was performed on 40 women aged 18 to 65 who underwent MRM under general anesthesia. Patients were divided into two equal groups. Both groups received SAPB using bupivacaine 0.5% (28.5ml) plus 1.5 ml of magnesium sulfate (750 mg) Group BM and 1.5 ml of normal saline Group B.

Results: The two groups did not differ significantly in terms of the need for intraoperative fentanyl consumption. The time it took for group BM to experience their initial rescue analgesia was significantly longer than in group B ($p < 0.001$). The total morphine consumed by group BM was significantly less than that of group B ($p < 0.001$). The visual analog scale was significantly lower at 4h, 8 h, and 12 h in group BM than in group B ($p < 0.05$).

Conclusion: By combining magnesium sulfate with bupivacaine in SAPB, postoperative pain and the requirement for postoperative analgesics were decreased with minimum adverse effects.

Keywords: Magnesium sulfate, adjuvant, serratus anterior plane block, pain, mastectomy

Introduction

Cancer of the breast is the most prevalent malignancy among women [1]. It is crucial to effectively treat the perioperative pain that comes with a mastectomy. Inadequate pain control leads to an increase in the incidence of postoperative complications and chronic pain syndrome [2]. Patients report more pleasure and earlier mobilization after surgery when they receive enough postoperative analgesia [3].

Various regional anesthetic methods can be used for perioperative pain control, which in turn reduces the need for opiates and their common side effects. Local wound infiltration, paravertebral block, and thoracic epidural block are examples of such regional methods [4, 5].

A number of thoracic surgeries have found success with multimodal analgesic regimens that include the serratus anterior plane block (SAPB) [6, 7]. SAPB's principal function is to completely analgesia the lateral chest by blocking the thoracic intercostal nerves. Due to its lower risk of side effects, it could be a suitable substitute for paravertebral block and thoracic epidural analgesia. A high success rate and low complication rate are hallmarks of this simple procedure [8]. Alternative methods, such as thoracic paravertebral blocks, intrapleural blocks, or intercostal blocks, necessitate more local anesthetic volume and concentration to achieve a similar, protracted, multi-dermatomal thoracic analgesia [9].

In order to enhance the quality of regional blocks during breast surgeries, various medications, including fentanyl, morphine, and dexmedetomidine, may be employed as adjuvants to local anesthesia. On the other hand, there are a lot of potential side effects with these adjuvants, such as hypotension, nausea, and vomiting [10].

Researchers have discovered that adding magnesium sulfate to local injections or nerve blocks makes the effects of local anesthetics last longer. The analgesic effects of adenosine are due to its impact on mediators in both the peripheral and central nervous systems, as well

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as its role in neuron regeneration [11, 12].

The objective of this research was to find out whether patients having modified radical mastectomy (MRM) could benefit from using magnesium sulfate as an adjuvant in SAPB.

Patients and Methods

This randomized, controlled, double-blinded study was performed on 40 women aged from 18 to 65, belonging to the American Society of Anesthesiology (ASA) physical status I-II, and underwent MRM under general anesthesia. The study was conducted at Cairo University Hospital from July 2023 to June 2024. The patient's signed informed consent was acquired.

Exclusion criteria included medical conditions that could not be treated with regional blocks, such as coagulopathy or infection at the injection site. Other exclusion criteria included known drug allergies, chronic pain therapy, anatomical abnormalities, bleeding disorders, liver or renal dysfunction, body mass index ≥ 35 kg/m², patients who could tolerate opioids, previous surgeries, or plastic surgery.

Randomization and blindness

A random list was generated using an online randomization application (<http://www.randomizer.org>), and the codes for each patient were stored in an opaque sealed envelope. Using a 1:1 allocation ratio, the patients were divided into two equal groups: Both groups received SAPB using bupivacaine 0.5% (28.5ml) plus 1.5 ml of magnesium sulfate (750 mg) Group BM and 1.5 ml of normal saline Group B.

Patients and outcome assessors were unaware of which group they were in. The interventional drugs were produced by a pharmacist who was not engaged with the study.

The patients' medical and surgical histories were documented, along with their clinical examinations and laboratory tests, such as complete blood counts and coagulation studies. Postoperative pain assessment using the visual analog scale (VAS) was taught to every patient. On the VAS scale, 0 represents no pain, and 10 describes the most excruciating agony a person might experience [13].

Standard monitoring, including electrocardiography, non-invasive arterial blood pressure, pulse oximetry, capnography, and temperature probes, was linked to all patients as soon as they entered the operating room.

Intravenous (IV) propofol and fentanyl were used to induce general anesthesia at doses of 2-2.5 mg/kg and 1-2 μ g/kg, respectively. The endotracheal tube was implanted subsequent to the administration of 0.15 mg/kg of IV cis-atracurium.

Isoflurane (1-1.5%) was given in conjunction with 50-100% oxygen to maintain anesthesia. IV cis-atracurium doses of 0.03 mg/kg were administered in increments. Afterward, patients were mechanically ventilated to ensure that their end-tidal carbon dioxide levels remained within the range of 35 to 45 mmHg.

Further, 1 μ g/kg bolus concentrations of fentanyl were administered if the heart rate (HR) or mean arterial blood pressure (MAP) increased by more than 20% from the baseline, after all potential causes other than pain had been ruled out.

Serratus anterior plane block technique

Each patient received the SAPB block guided by a linear

ultrasound (US) transducer operating within the 6-13 MHz frequency range. The pectoral region was surgically disinfected. The procedure was carried out while the patient was lying supine, with the patient's right upper limb bent at a 90-degree angle in abduction. In order to distinguish the serratus anterior from other muscles, the investigator used the sagittal plane linear probe to find the fifth rib in the mid-axillary line. The US made it possible to identify the superficial and posterior latissimus dorsi, superior teres major, and deep and inferior serratus muscles. To administer the anesthetic mixture, the researcher inserted a 25 GA needle perpendicular to the US probe and worked his way down into the serratus anterior muscle, moving from the superior to the inferior aspect of the muscle. Both groups received SAPB using bupivacaine 0.5% (28.5ml) plus 1.5 ml of magnesium sulfate (750 mg) Group BM and 1.5 ml of normal saline Group B, which was confirmed visually by the US. Extubation was performed when the anesthetic was withdrawn, and any remaining neuromuscular blockade was treated with neostigmine (0.08 mg/kg) and atropine (0.02 mg/kg). Upon regaining consciousness, patients were moved to the post-anesthesia care unit (PACU).

Postoperative:

During the following surgery, a regular pain medication schedule was given. Paracetamol 1 gm every six hours is the standard analgesic for all patients. The patient was administered a 3-milligram bolus of morphine as a rescue analgesic if the VAS was greater than 3, and if the pain persisted for more than 30 mins, the injection was repeated until the VAS became below 4.

In order to evaluate the adverse effects, the following were administered: IV ephedrine 5-10 mg for hypotension (a 20% decrease in basal MAP), IV atropine 0.02 mg/kg for bradycardia (a 20% decrease in basal HR), oxygen supplementation was needed for respiratory depression (a SpO₂ < 95%), and IV ondansetron 0.1 mg/kg for postoperative nausea and vomiting (PONV).

The patients' level of satisfaction was measured using a 5-point Likert scale: 1, extremely dissatisfied; 2, unsatisfied; 3, neutral; 4, satisfied; 5, extremely satisfied [14].

The primary outcome was the time to the 1st rescue analgesia. The secondary outcomes were total morphine consumption in the 1st 24hours, pain intensity, intraoperative fentanyl consumption, intraoperative hemodynamics, patient satisfaction, and adverse events.

Sample Size Calculation:

Using G*Power 3.1.9.2 (Universitat Kiel, Germany), we were able to estimate the sample size. Based on our pilot investigation, which included five cases in each group, we observed that the mean (\pm SD) time to the 1st rescue analgesia was 10.80 \pm 2.68 in group BM and 8.40 \pm 2.07 in group B. Twenty patients were enrolled in each group based on a 95% confidence limit, 80% power, an allocation ratio of 1:1, and an effect size of 1.002 in the study and three cases to surpass dropout.

Statistical analysis

SPSS v27 (IBM©, Armonk, NY, USA) was implemented to conduct statistical analysis. The data was examined for normality of distribution using histograms and the Shapiro-Wilks test. The unpaired Student t-test was employed to explore the quantitative parametric data, described as mean

and standard deviation (SD). The Mann-Whitney test was executed to analyze the quantitative non-parametric data, expressed as the median and interquartile range (IQR). Qualitative variables, which were expressed as percentages and frequencies, were evaluated using either Fisher's exact test or the Chi-square test. A two-tailed P value below 0.05 was used to assess statistical significance.

Results

Of the 51 patients that were considered for this trial, seven were found to be ineligible, and four chose not to take part. The other forty patients were divided into two groups, with twenty patients in each. The follow-up and statistical analysis of all allocated patients were conducted. Figure 1.

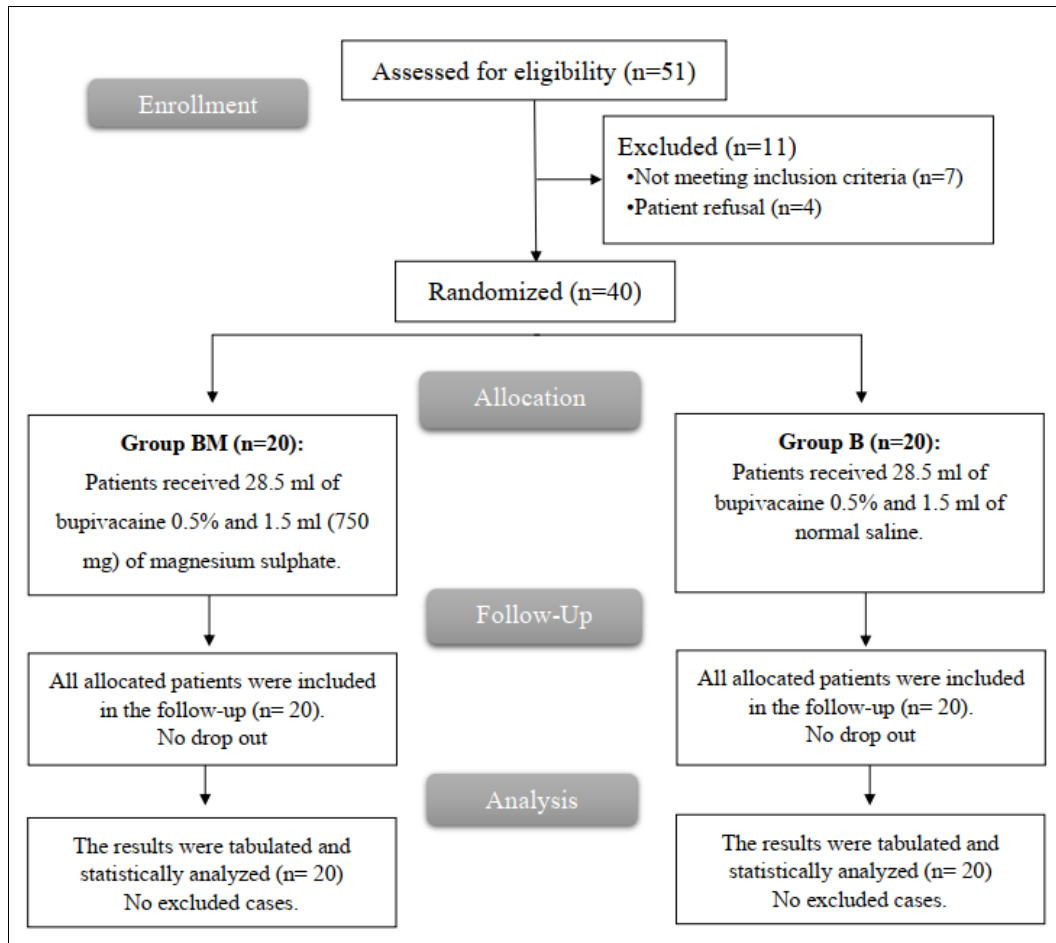


Fig 1: CONSORT flowchart of the enrolled patients

When comparing the groups according to age, weight, height, BMI, ASA physical status, or operation duration, no

significant differences were found. Table 1.

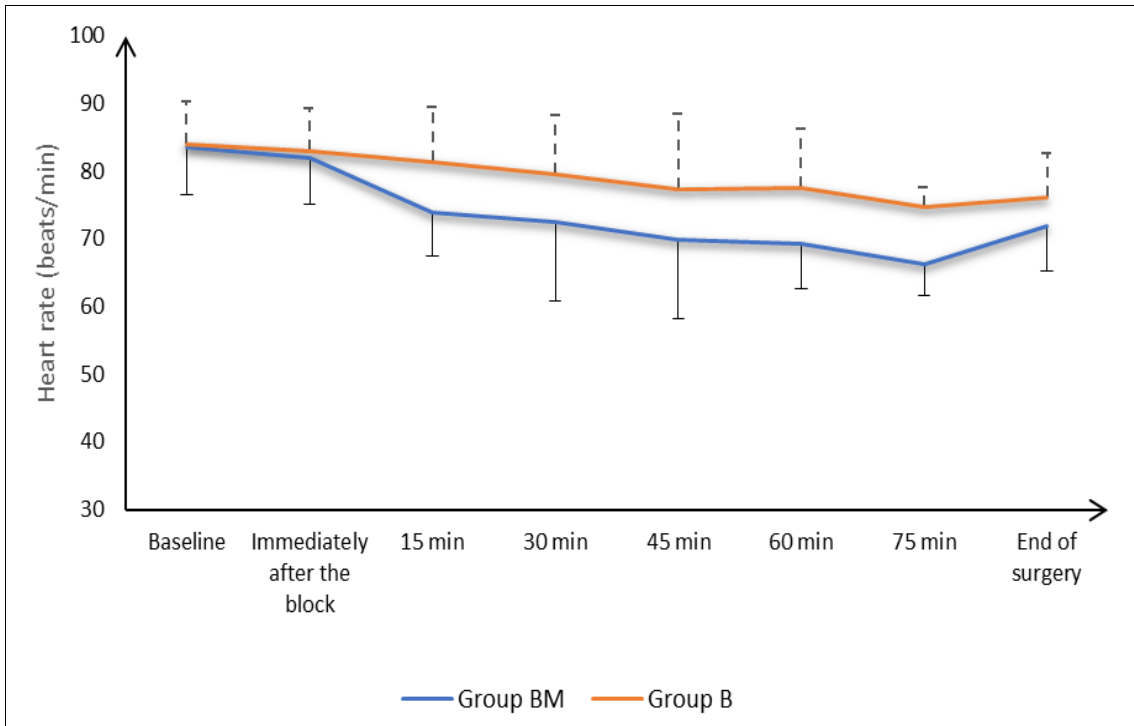
Table 1: Demographic data and duration of surgery of the studied groups

	Group BM (n=20)	Group B (n=20)	P value
Age (years)	48.15±12.96	45.1±10.59	0.420
Weight (kg)	81.75±8.72	83.45±13.84	0.645
Height (cm)	171.15±5.83	168.75±7.39	0.261
BMI (kg/m ²)	27.95±3.11	29.28±4.43	0.277
ASA physical status	I	11 (55%)	0.519
	II	9 (45%)	
Duration of surgery (min)	73.5±7.63	76.75±9.07	0.228

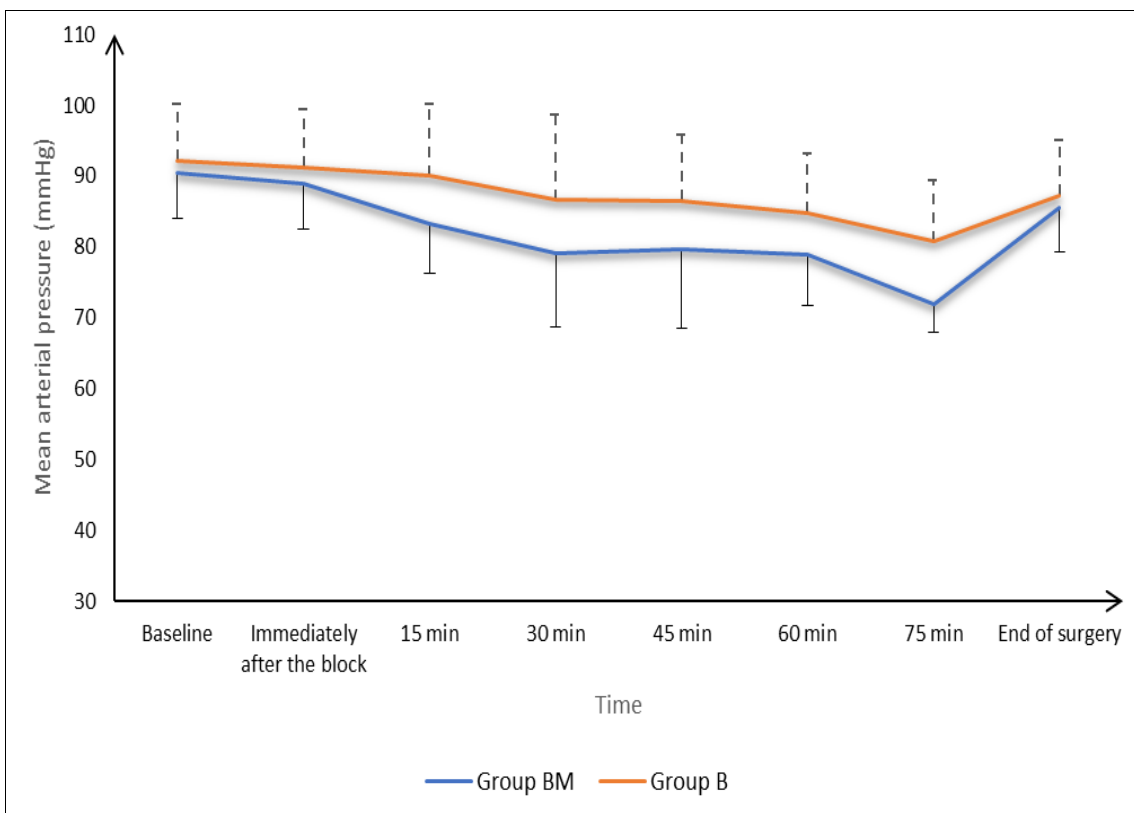
Data are presented as mean ± SD or frequency (%). BMI: Body Mass Index, ASA: American Society of Anesthesiologists

When comparing the two groups' HR and MAP at baseline, immediately after the block, and at the end of the surgery, no statistically significant differences were found. However, the HR and MAP in group BM were significantly lower

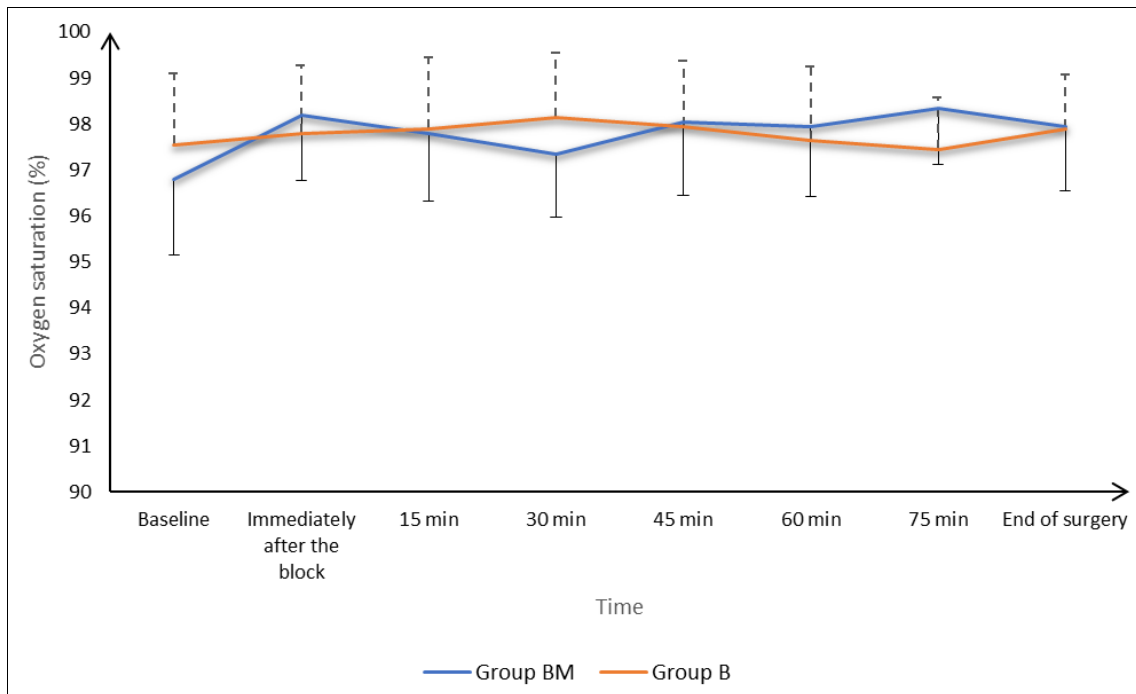
than in group B at 15, 30, 45, 60, and 75 min (P value<0.05). Oxygen saturation was insignificantly different at baseline, immediately after the block, 15, 30, 45, 60, 75 min, and end of surgery between both groups. Figure 2.



(A)



(B)



(C)

Fig 2: Intraoperative (A) heart rate, (B) mean arterial pressure, and (C) Oxygen saturation changes of the studied groups

In terms of intraoperative fentanyl need and consumption, neither group differed significantly from the other. The time it took for Group BM to experience their initial rescue

analgesia was significantly longer than Group B ($P < 0.001$). Group BM had a significantly lower total dose of morphine consumption compared to group B ($P < 0.001$). **Table 2**

Table 2: Time to first rescue analgesia, postoperative morphine consumption, and intraoperative fentanyl of the studied groups

	Group BM (n=20)	Group B (n=20)	P value
Time to first rescue analgesia (h)	12.8±2.19	6.15±1.35	<0.001*
Total dose of morphine consumption (mg)	5.4±1.57	7.65±1.81	<0.001*
Need for intraoperative fentanyl	2 (10%) (n=2)	4 (20%) (n=4)	0.661
Intraoperative fentanyl consumption (µg)	75±7.07	87.5±5	0.061

Data are presented as mean ± SD or frequency (%), *: Significant as P value ≤ 0.05

There was no significant difference in VAS scores between the two groups at 0,16, and 24 hours. The VAS was

significantly lower in group BM compared to group B at 4, 8, and 12 hours ($P \text{ value} < 0.05$). **Table 3.**

Table 3: VAS of the studied groups

	Group BM (n=20)	Group B (n=20)	P value
0 h	0 (0 - 0)	0 (0 - 0)	0.799
4 h	1 (1 - 2)	2.5 (2 - 3)	0.001*
8 h	1.5 (1 - 2)	2.5 (2 - 3)	0.01*
12 h	2 (1 - 3)	3 (2.75 - 4)	0.002*
16 h	3 (2 - 4)	3 (3 - 4)	0.659
24 h	4 (2 - 4)	4 (3 - 4)	0.414

Data presented as median (IQR). *: Significant as P value ≤ 0.05. VAS, Visual analog scale

Neither group significantly differed from the other in terms of hypotension, bradycardia, PONV, or patients'

satisfaction. Neither group had any patients who experienced respiratory depression. **Table 4.**

Table 4: Complications and patients' satisfaction of the studied groups

		Group BM (n=20)	Group B (n=20)	P value
Hypotension		3 (15%)	2 (10%)	1
Bradycardia		2 (10%)	1 (5%)	1
PONV		1 (5%)	3 (15%)	0.605
Respiratory depression		0 (0%)	0 (0%)	---
Patients' satisfaction	Extremely dissatisfied	0 (0%)	3 (15%)	0.082
	Unsatisfied	1 (5%)	2 (10%)	
	Neutral	4 (20%)	6 (30%)	
	Satisfied	6 (30%)	7 (35%)	
	Extremely satisfied	9 (45%)	2 (10%)	

Data are presented as frequency (%), PONV: Postoperative nausea and vomiting

Discussion

There are a number of advantages to regional blocks, including a decrease in the need for analgesics, maintenance of hemodynamic stability, the ability to walk about sooner, and a shorter hospital stay [15]. SAPB has become a popular substitute for paravertebral, intercostal, and intrapleural blocks, three additional methods of thoracic regional anesthesia. Since the SAPB is carried out on the surface, it is less invasive and more secure than other methods [16].

According to Blanco *et al.* [17], who studied SAPB, the target plane has limited vascularity, which means that local anesthetic medications are not absorbed as much, resulting in a lower level of toxicity and a dependable and extensive block. Diéguez García *et al.* [18] and Ohgoshi *et al.* [19] revealed that SAPB alleviated postoperative pain in patients undergoing breast and axillary operations in a safe and effective manner.

The mechanism of action of this compound is the competition with an excitatory amino acid receptor, specifically the N-methyl-D-aspartate receptor antagonist (NMDA). A number of excitatory neurotransmitters, including glutamate and aspartate, activate these receptors in reaction to painful stimuli [20].

Magnesium blocks the entry of calcium into cells via activating NMDA receptors [21]. Postoperative pain can be better managed with the help of calcium influx, which triggers a series of effects on the central nervous system. These include hyperalgesia, wind-up pain, and sustained potentiating action. Consequently, magnesium reduces surgical pain by preventing these chains of reactions [22].

Our findings showed that in terms of intraoperative fentanyl need and consumption, neither group differed significantly from the other. Compared to group B, group BM had a much longer delay before receiving their first rescue analgesic. Group BM consumed a significantly lower total dose of morphine compared to group B. Neither group showed a statistically significant difference in VAS at 0, 16, and 24 hours. At 4, 8, and 12 hours, group BM had a significantly lower VAS than group B. Hypotension, bradycardia, PONV and patients' satisfaction were insignificantly different between both groups. Neither group had a single patient experience respiratory depression.

Abd El-Aziz *et al.* [22] found that between four and twenty-four hours after surgery, the VAS decreased significantly in the magnesium sulfate group as compared to the control group. The mean time to initial rescue analgesia was much longer in the magnesium sulfate group than the control group. The magnesium sulfate group required a substantially lower average total dose of nalbuphine than the control group. The two groups' problem-frequency distributions were not significantly different.

The analgesic effect of SAPB was enhanced by magnesium sulfate, according to Alshawadfy *et al.* [9]. The patients' longer intervals between their first analgesic requests following surgery and their lower VAS ratings at 4 and 8 hours when resting and two, four, and eight hours when using their arms are indicators of this. In regard to the dosages and frequency of analgesic consumption, there was no significant difference between the control and magnesium sulfate groups. The magnesium sulfate group did not experience nausea or vomiting, in contrast to the control group, which had 10% of patients do so. However, there was no statistical significance between the two.

The combination was found to be successful in US-guided pectoral nerve blocks I and II by El-Khattab *et al.* [23]. Shorter durations of analgesics, lower VAS scores for MRM, and significantly less opioid intake were observed after surgery.

A clinical trial was conducted by Megalla *et al.* [24] on female patients who were scheduled for MRM. Opioid intake and pain scores at rest and during arm raising were reduced following radical mastectomy with magnesium sulfate infiltration into the pectoralis major muscle as compared to bupivacaine wound infiltration alone. Less discomfort while elevating the arm and a longer period between the first need for analgesics were two additional advantages.

In clinical research with 90 patients having MRM and pectoral nerve block, Ibrahim and Sultan [25] showed that the group given magnesium sulfate had dramatically reduced total perioperative morphine levels, a longer duration of effect, and substantially lower VAS scores than control group.

In women having MRM, Hassan, and Mahran [26] looked at the utilization of magnesium sulfate in conjunction with bupivacaine for paravertebral block. Their results showed that within the first 24 hours following surgery, patients who took magnesium sulfate had significantly lower VAS scores, less opioid consumption, and a longer wait to the first analgesic request.

This study has a few limitations, such as a limited sample size, a brief follow-up period for patients, and the fact that it only involved one center. Therefore, we suggested conducting more prospective multicenter studies to determine the effectiveness of magnesium sulfate at greater concentrations with more extensive follow-up periods and a larger sample size.

Conclusion

By combining magnesium sulfate with bupivacaine in SAPB, postoperative pain and the requirement for postoperative analgesics were decreased with minimum

adverse effects.

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Conflict of Interest: Nil.

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