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ORIGINAL RESEARCH

Comparative analgesic efficacy of adding magnesium sulphate to bupivacaine in serratus anterior plane block to reduce pain after mastectomy

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Background: Magnesium sulphate has been used as an adjuvant to anaesthetic mixtures in peripheral nerve blocks. This study aimed to assess the efficacy of magnesium sulphate as an adjuvant to bupivacaine in ultrasound-guided serratus anterior plane (SAP) block for postoperative analgesia in patients undergoing modified radical mastectomy.

Methods: This randomised, double-blinded, controlled trial included adult female patients undergoing modified radical mastectomy under general anaesthesia. The patients were randomised into two groups that underwent ultrasound-guided SAP block. The control group received 28.5 ml of plain bupivacaine 0.5% and 1.5 ml of 0.9% normal saline, while the study group received 28.5 ml of bupivacaine 0.5% and 1.5 ml (750 mg) of magnesium sulphate. All patients were hospitalised postoperatively for at least 24 hours. Both the time to first request for analgesia and the postoperative pain score using the visual analogue scale (VAS) were recorded.

Results: Compared to the control group, the magnesium sulphate group had a significantly longer mean time to first analgesic request (666 vs 462 minutes, $p < 0.001$), as well as lower VAS at rest (at 4 and 8 hours postoperatively) and VAS at movement (at 2, 4 and 8 hours postoperatively). However, analgesic consumption was comparable between the two groups ($p > 0.05$). The percentage of satisfied surgeons was significantly higher in the magnesium sulphate group (95% vs 65%, $p = 0.018$), but patients' satisfaction did not differ significantly ($p = 0.292$).

Conclusion: Adding magnesium sulphate during SAP blockade can enhance the analgesic effect and prolong the time to first analgesic request in patients undergoing radical mastectomy.

Keywords: analgesia, magnesium sulphate, mastectomy, serratus anterior plane block

Introduction

Breast cancer is the most common cause of death due to cancer among women worldwide, and it is the most common cancer affecting women in Egypt; representing about one-fifth of the total cancer cases.[1] Most breast cancer patients require breast surgery to remove the primary tumor and perform axillary staging or dissection.[2] Approximately 40% of those patients experience clinically-significant, acute, postoperative pain, which is also an important risk factor for the development of persistent, chronic, postoperative pain.[3,4]

Effective treatment modalities are used to reduce postoperative pain in mastectomy patients and these include patient-controlled analgesia, thoracic epidural and paravertebral blocks, besides the newer pectoral blocks.[5]

The serratus anterior plane (SAP) block has proven to be an effective component of multimodal analgesia regimens for a variety of thoracic procedures.[6] It is primarily designed to block the thoracic intercostal nerves and provide complete analgesia of the lateral part of the thorax. It may be a good alternative to paravertebral block and thoracic epidural analgesia as it is associated with fewer adverse effects. The technique is easy to perform with a high success rate and minimal incidence of complications.[5] Alternative techniques, such as intercostal, intrapleural or thoracic paravertebral blocks require relatively higher concentrations and volumes of local anaesthetics to produce similar, prolonged, multi-dermatomal thoracic analgesia.[6,7]

Evidence supporting the presence of peripheral N-methyl-D-aspartate (NMDA) receptors in the skin and muscles[8] has led to the use of magnesium sulphate, an antagonist of NMDA, as an analgesic. Furthermore, magnesium sulphate could be used as an adjuvant for brachial plexus block[9] and via the neuraxial route.[10] There is a paucity of studies that evaluate the role of magnesium sulphate as an adjuvant in SAP block. Hence, this study was carried out to assess the efficacy of magnesium sulphate as an adjuvant to bupivacaine in ultrasound-guided SAP block for postoperative analgesia in patients scheduled for modified radical mastectomy.

Methods

This randomised, double-blinded, controlled trial was conducted at the Suez Canal University Hospital's operating theatres (Ismailia, Egypt) between December 2017 and December 2018.

The study enrolled 40 adult female patients (≥ 18 years old) scheduled for modified radical mastectomy under general anaesthesia who had American Society of Anesthesiologists (ASA) physical status I, II or III. Patients with known allergy to the study drugs, anatomical abnormalities, infections in the serratus region, bleeding disorders, or impaired liver or kidney functions

were excluded from the study. Patients with a body mass index (BMI) of more than 35 were also excluded.

Patients were randomised into two groups using the table of random characters. Group 1 (control group) underwent ultrasound-guided SAP block with bupivacaine and Group 2 (magnesium sulphate group) underwent ultrasound-guided SAP block with bupivacaine in addition to magnesium sulphate. The randomisation sequence was concealed in opaque, numbered, closed envelopes that were opened on the day of surgery by one member of the anaesthesia team (not involved in the study) to prepare the local anaesthetic solution and give it to the investigator who performed the block.

At the preoperative visit, patients were informed how to use the visual analogue scale (VAS), marked from 0 (no pain) to 10 (the worst pain imaginable). The serratus area was examined for any abnormalities such as skin infection, spine deformity or scars from previous operations. Upon arrival to the operating room, standard intraoperative monitors (ECG, pulse oximeter and non-invasive blood pressure) were attached. Peripheral venous lines were established on the contralateral side of the operation. General anaesthesia was administered with propofol (2 mg/kg) and fentanyl (1 µg/kg), followed by cisatracurium (0.15 mg/kg) to facilitate endotracheal intubation. Anaesthesia was maintained with isoflurane at end-tidal concentration of 1.3% (1.2 minimum alveolar concentration [MAC]) in 50% oxygen in the air by controlled mechanical ventilation, keeping the end-tidal CO_2 at 35–40 mmHg. The mean blood pressure and heart rate were maintained within 20% of the preoperative baseline values (incremental boluses of fentanyl were given in some patients). The same technique of the SAP block was used in all patients under ultrasound (SonoSite, FUJIFILM) guidance, with a linear ultrasound transducer of 6–13 MHz frequency. Surgical disinfection of the pectoral region was done. It was performed in the supine position placing the ipsilateral upper limb in abduction at 90 degrees position. To distinguish the serratus anterior muscle, the investigator identified the fifth rib in the mid-axillary line by the linear probe in the sagittal plane. The latissimus dorsi muscle (superficial and posterior), teres major muscle (superior) and serratus muscle (deep and inferior) were detected using ultrasound. The investigator penetrated the serratus anterior muscle by a 25 GA, 90 mm sonoplex needle in-plane concerning the ultrasound probe from superoanterior to posteroinferior to inject the anaesthetic mixture deep into it. Participants of the control group were injected with 28.5 ml of bupivacaine 0.5% and 1.5 ml of normal saline (a total volume of 30 ml), which was confirmed visually by the ultrasound. Participants of the magnesium sulphate group, were injected with 28.5 ml of bupivacaine 0.5% and 1.5 ml (750 mg) of magnesium sulphate (a total volume of 30 ml), which was confirmed visually by the ultrasound. At the end of the surgery, isoflurane was turned off, and the residual neuromuscular block was reversed with neostigmine and atropine. When patients were awake, they were transferred to the postanaesthesia care unit. The first request of analgesia was recorded (defined as the time from the completion of the block to the time of the first request of analgesia). Postoperative pain was evaluated using the VAS both at rest and with arm movement of 90 degrees at intervals of 0 (immediately postoperative in the recovery room), 2, 4, 8, 16 and 24 hours by the anaesthesia resident who was blinded to the performed technique. All patients were hospitalised postoperatively for at least 24 hours. During the study period, the pain score was recorded. Whenever the VAS was ≥ 4, 1 g of paracetamol (maximum daily dose of 4 g) was administered intravenously as a rescue analgesic. If the pain persisted more than 20 minutes, tramadol (1 mg/kg) was administered intravenously. The total analgesic consumption was recorded for the first 24 hours postoperatively. The patients were asked if they experienced nausea or vomiting, with 0 (not having nausea or vomiting) or 1 (having nausea with or without vomiting) as possible scores. Other postoperative complications were also recorded (e.g. pruritus and hypotension). After 24 hours postoperatively, the patient satisfaction score was recorded as 0 (not satisfied) or 1 (satisfied). Surgeons' satisfaction with the quality of the block was also recorded by phone as 0 (not satisfied) or 1 (satisfied). Criteria for their final conclusion were not discussed with them.

Sample size

According to Shokri and Kasem,[11] it is predicted that 20 patients per group were required to give 80% power of independent populations at a confidence level of 90% for a one-sided test. This is based on the assumption that the time to first analgesic dosage following breast surgery for the SAP block group (527.4 minutes) and the control group (580.14 minutes) had a detectable difference of 52.74 minutes, and the highest within-group standard deviation was 57 minutes.

Statistical analysis

The statistical analysis was performed using IBM SPSS Statistics® 22 for Windows (IBM Corp., USA). Descriptive data were expressed as mean and standard deviation (SD) for continuous parametric variables, and count/total and percentages (%) for categorical and dichotomous variables. The student t-test was used to analyse the continuous variables between the two studied groups and the chi-square test for categorical and dichotomous variables. The level of statistical significance was adopted at $p < 0.05$.

Results

In total, 52 female patients scheduled for modified radical mastectomy under general anaesthesia were assessed. Of these, 40 patients met the eligibility criteria and were randomly allocated to receive serratus anterior plane block either with bupivacaine and placebo (normal saline) ($n = 20$) or bupivacaine and magnesium sulphate ($n = 20$) (Figure 1).

The current study found that both groups were matched regarding their age and clinical characteristics (i.e. the presence of chronic illnesses including hypertension, diabetes mellitus,

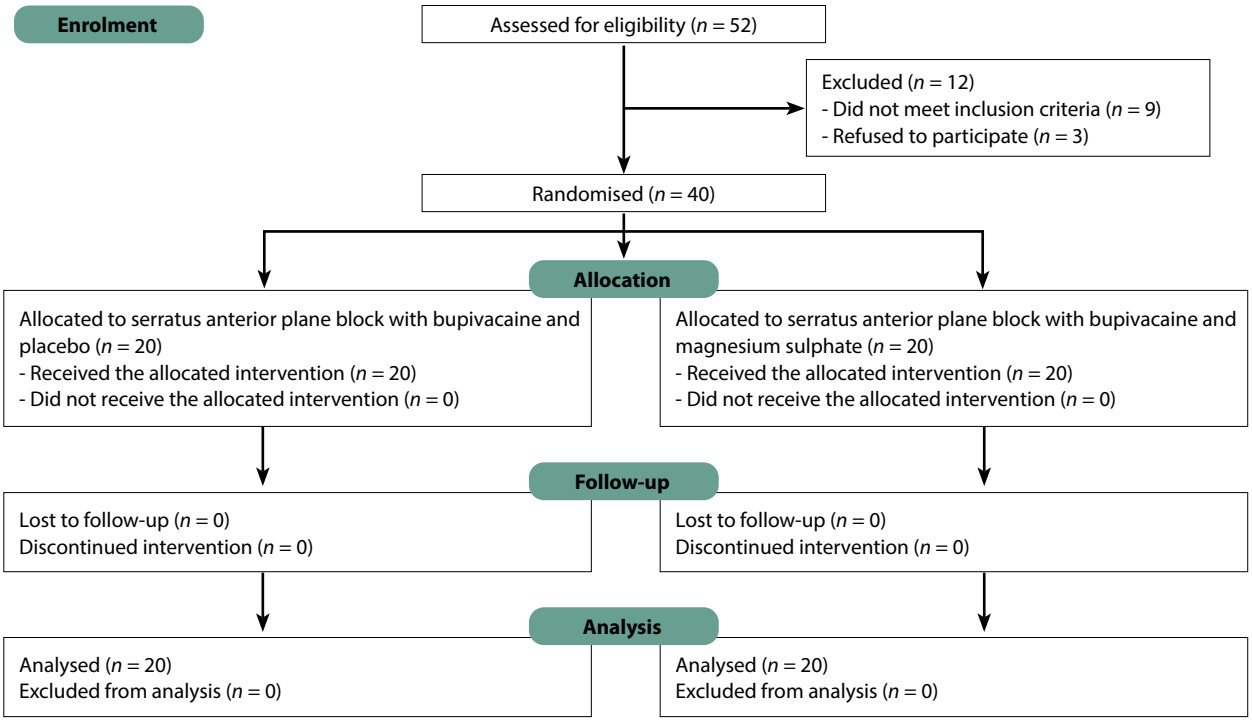

Figure 1: Patient selection flow chart

bronchial asthma, ischaemic heart disease and renal impairment) (Table I).

Table II indicates that the time to the first analgesic request postoperatively was significantly longer in the magnesium sulphate group than the control group (666 vs 462 minutes, $p < 0.001$*). However, although the total analgesic consumption in the magnesium sulphate group was reduced, it did not reach statistical significance ($p > 0.05$). A significantly higher percentage of surgeons were satisfied with the quality of pain control in the magnesium sulphate group compared to the control group (95 vs 65%, $p = 0.018$). Meanwhile, the percentage of patients who were satisfied with pain control were comparable in both groups, with no statistically significant difference ($p = 0.292$). Nausea and vomiting were reported in 10% of patients in the control group probably because of acute pain, but in none of the patients in the magnesium sulphate group, with no statistically significant difference between the two studied groups ($p = 0.147$).

Table I: Patients' demographics and clinical characteristics

Variable		Control group (*n* = 20)	Mg group (*n* = 20)	*p*-value
Age	Mean ± SD	51.58 ± 6.915	52.7 ± 4.52	0.648
BMI (kg/m²)	Mean ± SD	26.13 ± 3.91	25.71 ± 4.77	0.762
Hypertension	*n* (%)	6 (30%)	7 (35%)	0.144
Diabetes mellitus	*n* (%)	3 (15%)	7 (35%)	0.137
Bronchial asthma	*n* (%)	2 (10%)	1 (5%)	0.548
Ischaemic heart disease	*n* (%)	1 (5%)	0 (0%)	0.311
Renal impairment	*n* (%)	1 (5%)	0 (0%)	0.311

Mg – magnesium, SD – standard deviation, BMI – body mass index

Table II: The study outcomes

Variable		Control group (*n* = 20)	Mg group (*n* = 20)	*p*-value
First analgesic request (minutes)	Mean ± SD	462.0 ± 91.514	666.0 ± 113.342	< 0.001*
Paracetamol consumption (g)	Mean ± SD	1.45 ± 0.68	1.15 ± 0.36	0.093
Tramadol consumption (mg)	Mean ± SD	19.0 ± 50.8	5.0 ± 22.3	0.267
Need for opioid	*n* (%)	3 (15%)	1 (5%)	0.292
Surgeon satisfaction	*n* (%)	13 (65%)	19 (95%)	0.018*
Patient satisfaction	*n* (%)	17 (85%)	19 (95%)	0.292
Nausea and vomiting	*n* (%)	2 (10%)	0 (0%)	0.147

Mg – magnesium, SD – standard deviation, * significant at $p < 0.05$

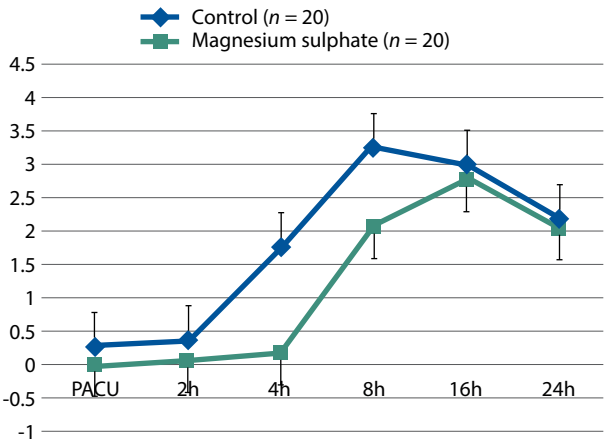

Figure 2: Postoperative visual analogue scale at rest in both groups

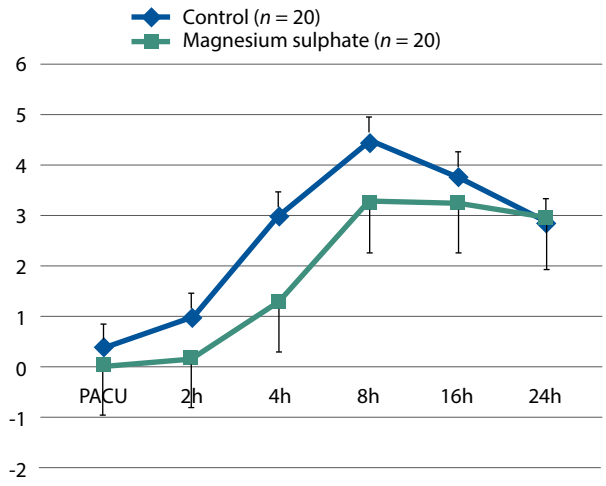

Figure 3: Postoperative visual analogue scale at movement in both groups

Postoperative assessment of the VAS score at rest showed a significantly lower score in the magnesium sulphate group than in the control group at 4 and 8 hours. The postoperative VAS score at movement in the magnesium sulphate group was significantly lower than in the control group at 2, 4 and 8 hours (Figures 2 and 3).

Discussion

The SAP block has emerged as a convenient alternative to other techniques of thoracic regional anaesthesia, including paravertebral, intercostal and intrapleural blocks.[12] The SAP block is relatively safer compared to the other techniques as it is performed in the superficial plane.[13]

The present study aimed to evaluate the role of magnesium sulphate as an adjuvant to bupivacaine in ultrasound-guided SAP block for achieving postoperative analgesia in patients undergoing modified radical mastectomy. While several earlier studies have investigated pain management following mastectomy, the addition of magnesium sulphate to bupivacaine in SAP block was only tested in one experiment that compared its usage to the addition of nalbuphine to bupivacaine for the same block.[14]

We found that magnesium sulphate enhanced the analgesic effect of SAP block as evidenced by the significant prolongation of the average time to the first analgesic request postoperatively and the lower VAS scores at 4 and 8 hours while at rest, as well as at 2, 4 and 8 hours during arm movement. Although the frequency of analgesic consumption and the administered doses were considerably lower in the magnesium sulphate group, these differences did not reach statistical significance ($p > 0.05$).

The observed analgesic effect of magnesium sulphate could be attributed to its effect as an antagonist to NMDA receptors and calcium channels.[15] Magnesium blocks NMDA receptors, resulting in the inhibition of calcium influx into the cells. This effect of magnesium on NMDA receptors can prevent the hypersensitivity caused by central sensitisation. Central sensitisation occurs due to peripheral tissue injury which initiates repeated nociceptive afferent inputs. This results in a decrease of the pain threshold, leading to pain hypersensitivity, which manifests as pain even after cessation of the triggering initial stimulus.[16,17]

Several studies reported the improvement of pain control with the use of magnesium sulphate in patients scheduled for modified radical mastectomy as an adjuvant to paravertebral block[18] and pectoral nerve block.[19-21] However, only one study[14] assessed the addition of magnesium sulphate to local anaesthetics for SAP block in mastectomy patients.

Hassan and Mahran[18] assessed the addition of magnesium sulphate to bupivacaine for an ultrasound-guided paravertebral block in 90 women undergoing modified radical mastectomy. They reported that magnesium sulphate was associated with significantly lower VAS scores for up to 24 hours postoperative, with prolongation of the time to the first analgesic request as well as lower postoperative opioid consumption.

Ibrahim and Sultan[19] conducted a clinical trial comparing the effects of magnesium sulphate and adenosine as additives to bupivacaine in 90 patients undergoing modified radical mastectomy and pectoral nerve block. They found that the magnesium sulphate group had significantly lower VAS scores and longer duration of action, while both magnesium sulphate and adenosine groups had significantly lower total perioperative morphine than the control group.

Rashwan et al.[14] compared the efficacy of SAP block using bupivacaine and magnesium sulphate to that of bupivacaine and nalbuphine in mastectomy patients. They found that nalbuphine had a superior effect relative to magnesium sulphate as an adjuvant in SAP block, as evidenced by the significantly higher sensory block, the longer time to the first analgesic request, and the lower VAS scores in the nalbuphine group.

El-Khattab et al.[21] evaluated the efficacy of combined ultrasound-guided pectoral nerve blocks I and II in 50 patients undergoing modified radical mastectomy. They compared bupivacaine alone to bupivacaine with 200 mg of magnesium sulphate. They reported a significant reduction in postoperative opioid

consumption, prolongation of the duration of the analgesia, and lowering of the VAS scores.

Megalla et al.[20] conducted a randomised, controlled clinical trial on 75 female patients scheduled for modified radical mastectomy. They found that when compared to bupivacaine wound infiltration alone, magnesium sulphate infiltration in pectoralis major muscle following radical mastectomy was associated with significantly lower pain scores at rest and during arm elevation as well as a longer time to first analgesic request and reduced postoperative opioid consumption ($p < 0.001$).

Opioids are commonly used to achieve control of acute postoperative pain. However, several disadvantages are associated with the use of opioids. Adverse events related to opioid use may develop, which prolong the hospital stay and predispose the patients to increased risk of 30-day hospital readmissions and mortality.[22] In the current study, magnesium sulphate was associated with a reduction in opioid consumption, though the results did not reach statistical significance. As opioid consumption was reportedly decreased with the performance of SAP block,[23] it seems that the effect size caused by the addition of magnesium sulphate is relatively small, warranting the use of larger sample sizes to confirm or refute its statistical significance. Whether this small effect size is of clinical significance or not requires the measurement of other variables, including hospital stay and total management costs.

The study results showed that none of the patients in the magnesium sulphate group had nausea and vomiting, while these were reported in 10% of the control group, but the difference did not reach statistical significance ($p = 0.147$). Previous studies for thoracic and thoracoscopic surgeries have reported that the rate of incidence of nausea and vomiting in patients undergoing SAP block was comparatively lower than that of standard analgesia using parenteral drugs, ranging between 3.8% and 13%.[24-26] The lower rates of nausea and vomiting with SAP block could be attributed to the lower use of parenteral opioids for postoperative analgesia due to the achieved control of pain by the SAP block. In the current study, it seems that the prolongation of the analgesic effect observed with magnesium sulphate and the reduced parenteral analgesic consumption further lowered the rate of nausea and vomiting. However, as the rate of nausea and vomiting is low, a larger sample size is required to find the potential statistically significant difference in these patients.

The present study was one of the first studies to assess the potential beneficial effect of using magnesium sulphate as an adjuvant to local anaesthetics during SAP block in mastectomy patients. Meanwhile, our results are limited by the relatively low sample size and the single-centre nature of this clinical trial. Although we investigated pain in detail, the satisfaction of patients and surgeons was assessed subjectively and not in detail, and we recommend the use of a structured questionnaire form to measure satisfaction.

Conclusion

The present study demonstrated that adding magnesium sulphate to SAP block can enhance the analgesic effects and prolong the time to first analgesic request in patients undergoing modified radical mastectomy. Future clinical trials should investigate the efficacy and safety of higher concentrations of magnesium sulphate. Also, larger sample sizes should be considered.

Conflict of interest

The authors declare no conflict of interest.

Funding source

No funding was required.

Ethical approval

The researchers obtained ethical approval from the Suez Canal University Faculty of Medicine Research Ethics Committee (Research#3208, 14/1/2019) and informed consent from the study participants. The trial was registered at the ClinicalTrials.gov (NCT03810209).

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