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Original Research Article

A Randomized Controlled Trial to Compare the Efficacy of Ultrasound Guided PECS II Block & SAP Block in Unilateral Modified Radical Mastectomy for Post-Operative Analgesia

Shaista Tabassum[1], Suryabrata Chattopadhyay[2], Chandan Kumar Pal[3], Samir Basak[4], Satish Kumar[5], Shahbaz Ahmad[6]

[1]Senior Consultant, Department of Anesthesiology, Central Hospital, South Eastern Railway, Kolkata, West Bengal, India

[2]Senior Consultant, Department of Anesthesiology, Central Hospital, South Eastern Railway, Kolkata, West Bengal, India

[3]Senior Consultant, Department of Anesthesiology, Central Hospital, South Eastern Railway, Kolkata, West Bengal, India

[4]Senior Consultant, Department of Anesthesiology, Central Hospital, South Eastern Railway, Kolkata, West Bengal, India

[5]Professor, Department of Anesthesiology, BRD Medical College, Gorakhpur, U.P., India

[6]Assistant Professor, Department of Anesthesiology, BRD Medical College, Gorakhpur, U.P., India

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Corresponding Author: Dr. Shaista Tabassum

Conflict of interest: Nil

Abstract

Background and Aims: Effective postoperative analgesia following modified radical mastectomy (MRM) facilitates early recovery and improves patient comfort. Ultrasound-guided Pectoral Nerve (PECS II) block and Serratus Anterior Plane (SAP) block are novel regional analgesic techniques for breast surgery. This study compared the analgesic efficacy of PECS II block and SAP block in patients undergoing unilateral MRM. Secondary objectives included comparison of onset and duration of sensory block, postoperative tramadol consumption, hemodynamic changes, and adverse effects.

Material and Methods: After institutional ethics committee approval, 50 ASA I–II female patients undergoing elective unilateral MRM under general anesthesia were randomized into two equal groups. Group P received ultrasound-guided PECS II block, while Group S received ultrasound-guided SAP block. Postoperative pain was assessed using the Visual Analogue Scale (VAS) at rest and during arm abduction over 24 hours. Time to first rescue analgesia, 24-hour tramadol consumption, hemodynamic parameters, and block-related complications were recorded.

Results: Baseline demographic characteristics, ASA status, and duration of surgery were comparable between groups. SAP block demonstrated a faster onset of sensory blockade and significantly lower VAS scores at 24 hours. Pain scores during arm abduction were significantly lower after 12 hours in the SAP group. Time to first rescue analgesia was longer and 24-hour tramadol consumption was significantly lower with SAP block. Intraoperative hemodynamic parameters were comparable, while postoperative pulse rate and mean arterial pressure were significantly lower in the SAP group at later time points. No complications were observed either related to block or not.

Conclusion: Ultrasound-guided SAP block provided superior and longer-lasting postoperative analgesia with reduced opioid consumption compared with PECS II block after unilateral modified radical mastectomy. More Larger randomized studies are needed to confirm these findings.

Keywords: PECS block, serratus anterior plane block, modified radical mastectomy, postoperative analgesia.

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Introduction

Breast cancer is the most common type of cancer in Indian women and has recently surpassed cervical cancer in prevalence, with an incidence rate of around 31%. It is the second major cause of cancer-related death in women. Surgery is the main treatment for breast cancer, and about 60% of women who can undergo surgery have a mastectomy. Post-surgical pain is a major issue that affects healing and overall quality of life. Patients may experience both short-term injury-related pain and long-term nerve-related pain. The worst pain usually occurs within the first 24 hours after the operation. This pain is often caused by removal of lymph nodes under the arm and can be worsened by moving the shoulder or arm. About 50% of women who have a mastectomy, with or without breast reconstruction, develop pain after surgery. If acute postoperative pain is not properly managed, it can affect breathing and gas exchange in the lungs. It also strongly predicts the development of ongoing pain after surgery. Effective pain management during and around surgery can reduce the body's stress response, lower the use of pain medications, and help maintain a well-functioning immune system.

A combination of different types of medicines and techniques, known as multimodal analgesia, is now recommended for managing short-term postoperative pain. This includes non-steroidal anti-inflammatory drugs, opioids, local anaesthetics injected into the wound, and blocks of specific nerves. However, even with these methods, 20–40% of patients who have breast surgery still experience poor pain control. General anaesthesia, although commonly used in cancer surgery, does not provide long-lasting pain relief or fully control the body's stress response. While opioids are often used, they can lead to side effects such as nausea, vomiting, drowsiness, and breathing difficulties. Thoracic epidural anaesthesia and paravertebral blocks are effective but can be complex to perform and carry risks such as pneumothorax, neurological issues, and, rarely, complete spinal anaesthesia. The use of ultrasound-guided blocks in the inter-fascial plane has offered safer and easier options for managing pain after breast surgery. In 2011, Blanco introduced the PECS I block and later improved it to the PECS II block, which allows for better pain coverage by placing the anaesthetic between two muscles. These blocks target several nerves in the chest and arm area. Blanco and others later developed the serratus anterior plane (SAP) block, which provides effective pain relief for the front and side of the chest by blocking specific nerves. Both the PECS II and SAP blocks are effective and safe for use in breast surgery and other chest procedures. Despite these benefits, there is not much evidence comparing the effectiveness of the PECS II block and the SAP block in patients who undergo a unilateral modified radical mastectomy.

Therefore, this study aims to compare the effectiveness of these two ultrasound-guided blocks for postoperative pain relief in such patients, with the main goal of assessing the duration and quality of pain control provided by each technique.

Materials and Methods

Study Design: This prospective, parallel-group, randomized controlled trial was conducted in the Department of Anaesthesiology, Central Hospital, Garden Reach, Kolkata, India, between June 2020 and May 2021. Institutional Ethics Committee approval and Clinical Trials Registry–India (CTRI) registration were obtained before participant enrollment. Written informed consent was obtained from all participants, and the study adhered to the ethical principles of the Declaration of Helsinki.

During the recruitment period, 65 patients scheduled for elective unilateral modified radical mastectomy were assessed for eligibility. Fifteen patients were excluded (five did not meet the inclusion criteria and ten fulfilled the exclusion criteria). Fifty eligible patients were randomized equally into two groups and completed the study without loss to follow-up (Figure 1).

CONSORT 2010 Flow Diagram

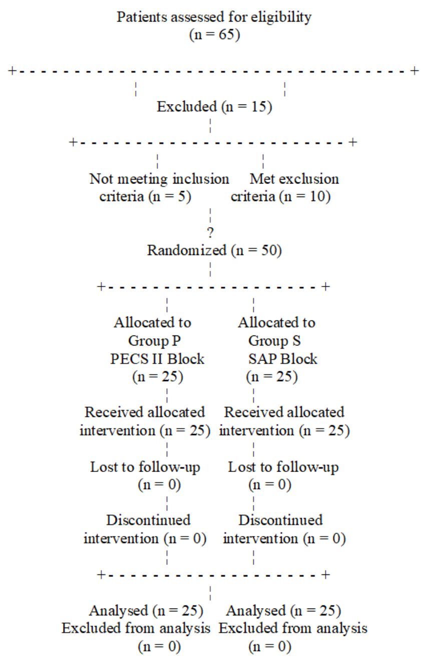

Figure 1: Consort flow diagram

The flow of participants through each stage of the trial is illustrated in the CONSORT 2010 flow diagram (Figure 1).

Patient Selection: Female patients aged 30–65 years with ASA physical status I or II undergoing elective unilateral modified radical mastectomy under general anaesthesia were included. Patients were excluded if they declined consent, had hypersensitivity to local anaesthetics or opioids, contraindications to regional anaesthesia (coagulopathy, anticoagulant therapy, local infection, or chest wall abnormalities), BMI >35 kg/m², chronic pain requiring daily analgesics for >4 weeks, psychiatric illness, pregnancy, previous breast surgery other than diagnostic biopsy, ASA physical status III or higher, or bilateral breast cancer. Patients were followed during hospitalization and for one month postoperatively.

Sample Size Calculation: Sample size was calculated using G*Power software. Assuming a clinically significant difference of 2 points in the Visual Analogue Scale (VAS), a two-sided α error of 0.05, and 80% power, 40 patients (20 per group) were required. To compensate for potential dropouts, 50 patients were enrolled.

Randomization, Allocation Concealment and Blinding: Participants were randomized in a 1:1 ratio using a computer-generated randomization sequence. The allocation sequence was maintained by an independent consultant anaesthesiologist not involved in patient recruitment, perioperative management, outcome assessment, or statistical analysis. Allocation was revealed only after enrollment, ensuring allocation concealment. Participants and the anaesthesiologist responsible for postoperative outcome assessment were blinded to group allocation. Ultrasound-guided PECS II and SAP blocks were performed by a separate experienced consultant anaesthesiologist who had previously performed at least 20 such blocks and was not involved in postoperative assessment or data analysis.

Block Technique and Perioperative Management: Ultrasound-guided regional blocks were performed pre-operatively under strict aseptic precautions by an experienced consultant anaesthesiologist using a 6–13 MHz linear transducer (Sonosite Micromax, Washington, USA) with an imaging depth of 4 to 6 cm and a 21-G, 100-mm insulated needle. PECS II block was performed with the patient in supine position and the ipsilateral upper limb was placed in abducted position.

After all aseptic precautions, the probe was placed below the lateral third of the clavicle and moved laterally to locate the axillary vessels and pectoralis major and pectoralis minor muscles directly above the 1st rib (Fig. 1). The USG probe was further moved towards the axilla till the lateral border of the pectoralis minor and serratus anterior muscles was identified above the 2nd, 3rd and 4th ribs (Fig. 2). The skin puncture point was infiltrated with 3 mL of 2% lignocaine. A 21 G, 100 mm nerve stimulator needle (Stimuplex A, B. Braun, Germany) was inserted in-plane to the US probe. The fascial plane between pectoralis minor muscle and serratus anterior muscle was identified at the 3rd rib level and 20 mL of 0.25% bupivacaine was injected in 5 mL increments after aspiration (PECS II). The needle was then withdrawn into the fascial plane between pectoralis major and minor muscles and another 10 mL of 0.25% bupivacaine was injected (PECS I) (Fig. 3).

For SAP block, the US probe was moved to the mid-axillary line and kept in cephalo-caudal direction to visualize the 4th and 5th ribs, serratus anterior muscle and pleura. Using an in-plane approach, the needle was inserted below the serratus anterior muscle at the 4th rib. After negative aspiration, 30 mL of 0.25% bupivacaine solution was injected and visualized in real time. In the PECS II group, 20 mL of 0.25% bupivacaine was injected between the pectoralis minor and serratus anterior muscles, followed by 10 mL between the pectoralis major and minor muscles. In the SAP group, 30 mL of 0.25% bupivacaine was deposited beneath the serratus anterior muscle at the level of the fourth rib under real-time ultrasound guidance (Fig 4, Fig 5).

Sensory block onset was assessed using the pin-prick test, and patients were observed for 15 minutes before surgery.

Standard monitoring included five-lead electrocardiography, pulse oximetry, noninvasive blood pressure monitoring, and capnography. General anaesthesia was induced with intravenous glycopyrrolate (0.01 mg/kg), Fentanyl (2 microgram per kg), propofol (1.5–2 mg/kg), and vecuronium (0.1–0.2 mg/kg) to facilitate tracheal intubation. Anaesthesia was maintained with oxygen, nitrous oxide, isoflurane (0.8–1%), and intermittent vecuronium. Neuromuscular blockade was reversed with neostigmine and glycopyrrolate. Heart rate and haemodynamic parameters were recorded before induction and at predefined intervals until completion of surgery.

Postoperatively, all patients received intravenous paracetamol (10–15 mg/kg every 8 hours) as part of multimodal analgesia. Intravenous tramadol (1–2 mg/kg) was administered as rescue analgesia when the Visual Analogue Scale (VAS) score exceeded 4. Postoperative nausea and vomiting were treated with ondansetron, while patient satisfaction and block-related complications were documented by blinded observers.

Outcome Measures and Statistical Analysis: The primary outcome was postoperative pain intensity assessed using the VAS at rest and during ipsilateral arm abduction at 1, 6, 12, 18, and 24 hours. Secondary outcomes included onset and duration of sensory blockade, time to first rescue analgesia, 24-hour tramadol consumption, haemodynamic variables, postoperative nausea and vomiting, patient satisfaction, and block-related complications. Statistical analysis was performed using SPSS version 23.0.

Continuous variables were expressed as mean ± SD and compared using the unpaired Student's t-test, while categorical variables were presented as frequencies and percentages. A P value <0.05 was considered statistically significant.

Results

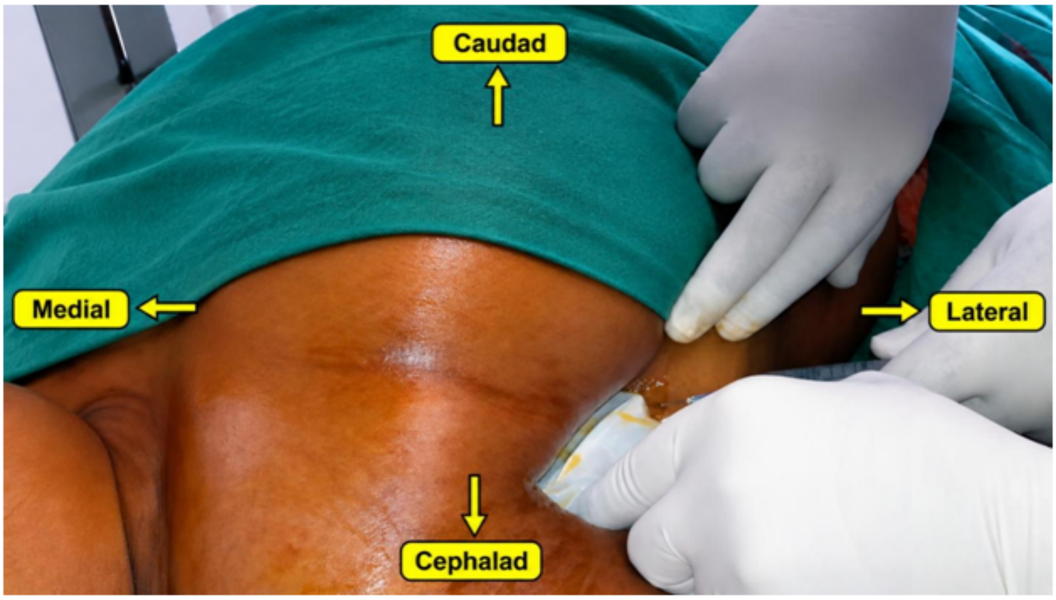

Figure 2: probe position in SAP block

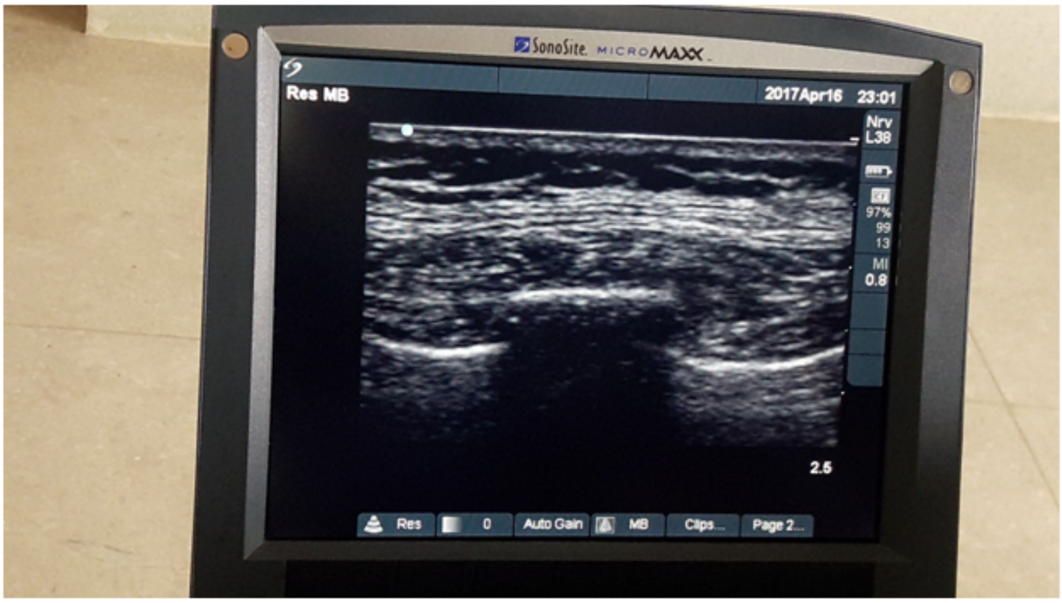

Figure 3: sonoanatomy in SAP block

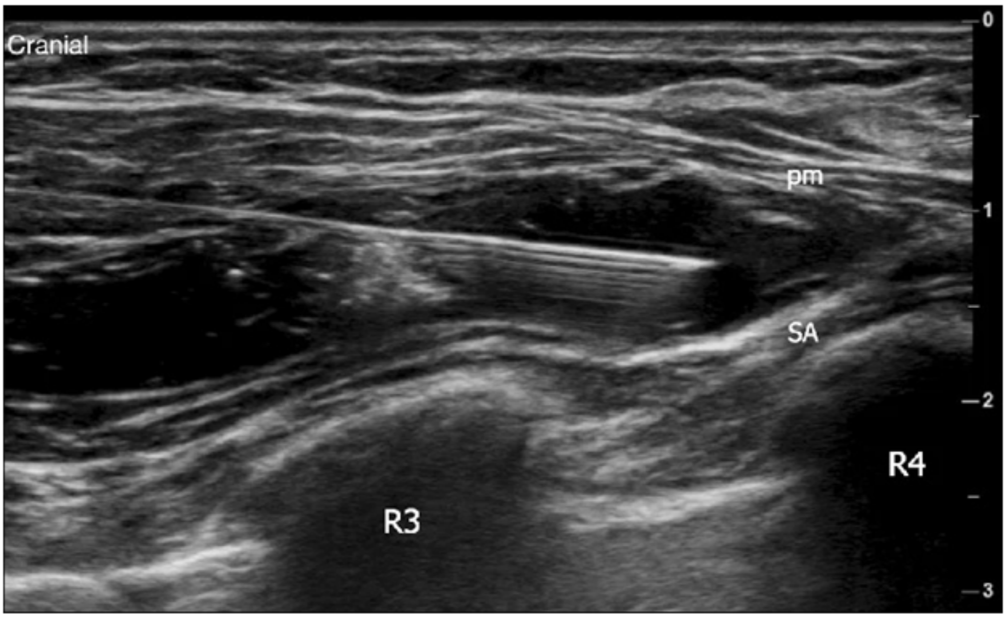

Figure 4: Needle position in SAP block

Figure 5: drug deposition in SAP Block

Fifty female patients undergoing unilateral modified radical mastectomy were randomized equally into Group P (PECS II block, n=25) and Group S (SAP block, n=25). All patients completed the study and were included in the final analysis.

Baseline demographic characteristics were comparable between the groups (Table 1). Mean age (44.0±6.1 vs. 43.36±9.65 years; P=0.78), BMI (27.52±3.13 vs. 28.30±3.35 kg/m²; P=0.39), and ASA physical status (ASA I/II: 22/3 vs. 21/4) did not differ significantly. The duration of surgery was similar in both groups (1.8±0.2 vs. 1.9±0.4 hours; P=0.27). However, SAP block produced a significantly faster onset of sensory blockade than PECS II block (11.8±1.9 vs. 15.9±1.6 minutes; P<0.0001). Rescue analgesia during the first 24 postoperative hours was required in 5/25 (20%) patients in Group P and 3/25 (12%) in Group S. Consequently, 20/25 (80%) and 22/25 (88%) patients, respectively, required no rescue analgesia. Among patients requiring rescue analgesia, the time to first rescue analgesic was significantly longer in Group S (17±0.7 vs. 13±0.7 hours; P<0.0001), with significantly lower postoperative tramadol consumption (100±0 vs. 180±54.2 mg; P=0.04) (Table 2).

VAS scores at rest remained comparable up to 18 hours after surgery and were significantly lower in Group S at 24 hours (P<0.0001) (Table 3). During arm abduction, pain scores were similar during the early postoperative period but were significantly lower in Group S at 12, 18, and 24 hours (P=0.02, 0.04, and <0.0001, respectively) (Table 4), indicating superior dynamic analgesia with SAP block. Perioperative pulse rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure remained clinically stable in both groups (Tables 5–12). Although isolated statistically significant differences were observed at a few intraoperative and postoperative time points, no consistent haemodynamic advantage of either technique was demonstrated, and none of the patients required intervention for haemodynamic instability.

No adverse events were observed in either group. Postoperative nausea and vomiting, local anaesthetic systemic toxicity, urinary retention, pneumothorax, pruritus, and respiratory depression were absent in all patients (0/25 in each group) (Table 13).

Discussion

This randomized comparative study assessed the effectiveness of ultrasound-guided PECS II block and serratus anterior plane (SAP) block in providing pain relief for patients who underwent unilateral modified radical mastectomy. Both methods were found to offer effective postoperative pain control with stable blood pressure and heart rate during the perioperative period, as well as a good safety record.However, the SAP block showed quicker onset of pain relief, longer-lasting pain control, less need for postoperative opioid medication, and lower pain levels in the later stages after surgery.

The baseline characteristics of the patients, their physical health status, and the length of the surgery were similar between the two groups, which shows the randomization was successful and helps to reduce the effect of other factors that could influence the outcome.

One key finding of this study was the quicker onset of pain relief with the SAP block. This could be because the local anesthetic is placed in the serratus fascial area, allowing it to reach the nerves that control the skin on the sides of the ribs without needing to spread further. This was also observed in a similar study involving patients with multiple rib fractures, which supports these results. Pain levels at rest were low in both groups during the first 24 hours after surgery, indicating that both techniques provided adequate pain relief. However, the SAP block led to even lower pain scores at 24 hours. When patients moved their arms, the SAP group had significantly lower pain scores after 12 hours, suggesting better pain control during arm movement. This could be due to the local anesthetic staying in the serratus fascial plane longer and blocking the long thoracic and thoracodorsal nerves, which are involved in shoulder movement pain.Similar benefits have been reported in other studies examining fascial plane blocks. Patients receiving the SAP block also needed rescue pain medication later and used less tramadol in the first 24 hours after surgery.

These findings indicate that SAP block helps reduce the need for opioid medication. Although some studies have shown that PECS block provides longer-lasting pain relief than paravertebral block, the use of a more comprehensive pain management plan and a larger amount of local anesthetic in this study may explain the longer duration of pain relief. Compared to studies using paravertebral blocks, our findings suggest that SAP block is a safe and effective option that avoids the challenges and risks of more complex techniques.

Heart rate and blood pressure stayed within normal ranges in both groups during the perioperative period. Although some changes were seen at certain time points, they did not cause any instability or require extra treatment and are unlikely to be important clinically. The lower heart rate and blood pressure in the SAP group are likely due to better pain control rather than any direct effect of the block on the circulatory system.

No patients experienced any serious side effects, including systemic toxicity from local anesthetic, pneumothorax, nausea, vomiting, breathing problems, urinary retention, or other complications related to the block, confirming that both techniques are safe when performed by skilled practitioners.

The main strengths of this study are its randomized approach, uniform anesthesia plan, and consistent use of local anesthetic concentration and volume in both groups.

However, the study has certain limitations, such as a small number of participants, being conducted at a single center, relying on self-reported pain using the VAS scale, not using patient-controlled analgesia to objectively measure opioid use, and lacking long-term follow-up to check for ongoing pain. In conclusion, both PECS II and SAP blocks are effective and safe options for managing postoperative pain after modified radical mastectomy.

However, the SAP block offers faster pain relief, longer lasting pain control, reduced opioid use, and better pain management during the later stages of recovery, making it a preferred regional anesthetic technique for breast surgery.

Conclusion

Both ultrasound-guided PECS II and serratus anterior plane (SAP) blocks provided effective and safe postoperative analgesia following unilateral modified radical mastectomy. Compared with PECS II block, SAP block demonstrated a faster onset of sensory blockade, prolonged duration of analgesia, lower postoperative pain scores during the late postoperative period, delayed requirement for rescue analgesia, and reduced tramadol consumption, while maintaining comparable perioperative haemodynamic stability without block-related complications. These findings suggest that SAP block is an effective regional analgesic technique for breast surgery. However, larger multicentre randomized controlled studies are warranted to validate these findings and establish long-term clinical outcomes.

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