Randomized Trial

The Analgesic Efficacy of Pecto-Intercostal Fascial Block Combined with Pectoral Nerve Block in Modified Radical Mastectomy: A Prospective Randomized Trial

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Background: Pectoral nerve (Pecs) block is one of the most promising regional analgesic techniques for breast surgery. However, Pecs II block may not provide analgesia of the medial aspect of the breast or the entire nipple-areolar complex.

Objectives: The aim of the present study was to investigate the efficacy of combining the pectointercostal fascial block (PIFB) and Pecs II block for perioperative analgesia following modified radical mastectomy (MRM).

Study Design: A prospective randomized study.

Setting: An academic medical center.

Methods: Sixty women undergoing unilateral MRM were randomly divided into 2 groups. The Pecs II group received Pecs II block using 20 mL bupivacaine 0.25% between the serratus anterior and the external intercostal muscles, and 10 mL bupivacaine 0.25% between the pectoralis major and minor muscles, together with sham PIFB using 15 mL normal saline solution in the interfascial plane between the pectoralis major muscle and the external intercostal muscle. PIFB-Pecs II group received the same Pecs II block combined with PIFB using 15 mL bupivacaine 0.25%.

Results: The median (interquartile range [IQR]) time to the first morphine dose was significantly longer in the PIFB-Pecs II group (327.5 [266.3–360.0] minutes) than the Pecs II group (196 [163.8–248.8] minutes) (P < 0.001, 95% confidence interval [CI] 79.98, 150.00). The median (IQR) cumulative morphine consumption was higher in the Pecs II group (14.0 [11.0–18.0] mg) than the PIFB-Pecs II group (8.0 [7.0–9.0] mg) (P < 0.001; CI, 4.0–8.0). Intraoperative consumption of fentanyl was significantly lower in PIFB-Pecs II group with a median (IQR) of 0 (0–15 μ g) than the Pecs II group median 57.5 (0–75 μ g) (P = 0.022, CI; 0–60). The Visual Analog Scale scores for the first 12 postoperative hours were lower in the PIFB-Pecs II group than the Pecs II group at rest and on moving the ipsilateral arm (P < 0.001). The dermatomal block on the lateral chest wall was comparable between the 2 studied groups. PIFB-Pecs II provided extensive sensory block on the anterior chest wall, whereas Pecs II block failed to achieve any sensory block.

Limitations: This study was limited by its small sample size.

Conclusions: The combination of Pecs II and PIFB provide better perioperative analgesia for MRM than Pecs II alone.

Key Words: Pectoral nerves, postoperative pain, modified radical mastectomy

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reast cancer is the most prevalent female cancer and most cases require surgery (1,2). Undertreatment of acute postmastectomy pain frequently predisposes to the development of persistent chronic pain (3).

Although patient-controlled analgesia (PCA) is a frequently used pain-relieving modality, its analgesic efficacy is limited by its undesirable side effects (4). Numerous regional analgesic techniques have been investigated, including local wound infiltration (5), intercostal nerve block (6), epidural (7), and paravertebral blocks (8).

Pectoral nerve (Pecs) block is an interfascial plane block with reported analgesic efficacy following mastectomy. Pecs I involves injection of local anesthetics in the tissue plane situated between the pectoralis major and minor muscles. Pecs II is an extension of Pecs I, with placement of additional local anesthetic between pectoralis minor and serratus anterior muscles (SAM) (9,10). These techniques block the medial and lateral pectoral nerves, lateral branches of the thoracic intercostal nerves, long thoracic and thoracodorsal nerves (10,11).

To improve interfascial spread, Pérez et al (12) proposed a modification of the Pecs II block, wherein the deep injection is performed deep to the SAM rather than superficial to the SAM.

Although it has been used successfully for analgesia after breast surgery (13,14), Pecs block does not block the anterior branches of the intercostal nerves or the entire nipple-areolar complex (11). Pecto-intercostal fascial block (PIFB) targets the anterior cutaneous branch of the intercostal nerve (15) and can be beneficial for postoperative analgesia following surgical procedures of the thorax and breast (16,17).

The aim of this trial was to compare the analgesic efficacy of the combined PIFB and Pecs II block to that of the Pecs II block alone in patients undergoing unilateral modified radical mastectomy (MRM).

METHODS

Patients

After obtaining approval from the hospital ethics committee (31675/07/17), registration in the Pan African Clinical Trials Registry (PACTR201709002647413), and informed written consent from the patients, adult female patients aged 30–70 years, American Society of Anesthesiologists (ASA) I to II, undergoing unilateral MRM were enrolled in this prospective randomized study between November 2017 and August 2018 (Table 1).

The study protocol, the use of PCA device, and the Visual Analog Scale (VAS) (0–100 mm) for pain measurement were explained to the patients during the preanesthetic consultation.

Exclusion Criteria

Patients with local infection at the injection site, coagulation abnormality, body mass index (BMI) greater than 35 kg/m², mental disorders, allergy to the study drug, pregnancy, drug or alcohol abuse were excluded from the trial. Patients were randomly allocated into 2 groups using a computer-generated random 1:1 allocation sequence concealed in sealed opaque envelopes.

Group I (Pecs II group)

Patients received ipsilateral ultrasound-guided Pecs II block and sham PIFB.

Group II (PIFB-Pecs II group)

Patients received ipsilateral ultrasound-guided Pecs II block and PIFB (Fig. 1).

All patients were premedicated with intravenous (IV) midazolam (0.05 mg/kg). After standard monitoring, Pecs II block, PIFB, and sham blocks were performed preoperatively by the same investigator.

Ultrasound-Guided Pecs II Block

With the patient in a supine position, her arm in a neutral position, and under complete aseptic technique,

Table 1. Demographic data in both groups.

	Pecs II Group	PIFB-Pecs II Group	<i>P</i> Value (95% CI)
Age (years)	56.37 ± 7.65	54.53 ± 8.52	0.384 (-2.35; 6.02)
BMI (kg/m2)	26.17 ± 3.47	27.53 ± 3.98	0.162 (-3.30; 0.57)
ASA physical status (I/II)	11/19	14/16	0.432
Duration of surgery (min)	108.3 ± 13.6	112.3 ± 12.2	0.234(-2.67; 10.67)

Data presented as mean \pm standard deviation or patient number.

a 6 to 13 MHz ultrasound linear transducer probe was positioned below the distal one-third of the clavicle to visualize the pectoralis major and minor muscles, SAM, pectoral branch of the thoracoacromial artery, the second and third ribs, and the external intercostal muscles between the ribs (12).

After local anesthetic infiltration of the skin, a 20-gauge, 100-mm needle (Visioplex, Vygon, France) was inserted in-plane in a medial to lateral direction until its tip was placed between the SAM and the external intercostal muscles. The first injection was done below the SAM using 20 mL bupivacaine 0.25% at the level of the second rib to block the intercostobrachial nerves and the lateral branches of the third to the sixth intercostal nerves. The needle was then withdrawn until its tip was placed between the pectoralis major and minor muscles, during which the pectoral branch of the thoracoacromial artery was identified, and an additional 10 mL bupivacaine 0.25% was injected (Fig. 2).

Ultrasound-Guided PIFB

Under complete aseptic technique with the patient in the decubitus position, a 6 to 13 MHz ultrasound linear transducer probe was placed 2 or 3 cm parallel to the long axis of the sternal bone to identify the second to fourth costal cartilages and targeting the fourth costal cartilage. A 20-gauge, 100-mm needle (Visioplex) was inserted in-plane with the ultrasound probe, in a caudal-to-cranial direction. The needle was advanced until the tip was positioned in the interfascial plane between the pectoralis major muscle and the external intercostal muscle. After confirmation of the correct position of the tip of the needle, as shown by separation of the fascial layers on injecting 2 mL normal saline solution, 15 mL of bupivacaine 0.25% was injected (15).

Sham PIFB was performed in group II patients using 15 mL normal saline solution.

Fifteen minutes after performing the block, the sensory level was tested using pin prick. Afterward,

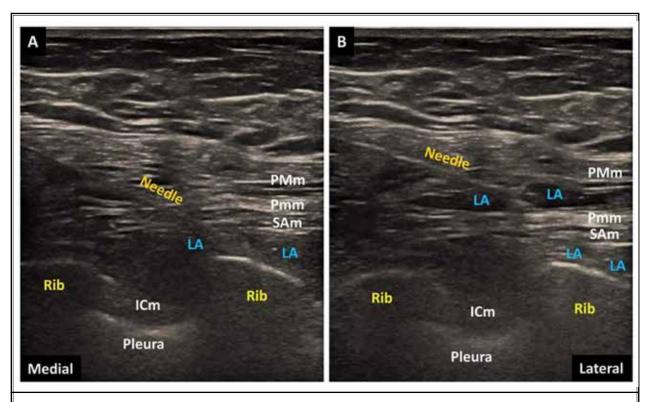


Fig. 1. Ultrasound-guided demonstration of the Pecs II block. (A) PMm (pectoralis major muscle), Pmm (pectoralis minor muscle), SAm (serratus anterior muscle), ICm (intercostal muscle). The needle inserted from medial to lateral with local anesthetic (LA) deposited between serratus anterior and external intercostal muscles. (B) Needle subtracted with LA deposited between pectoralis major and minor muscles.

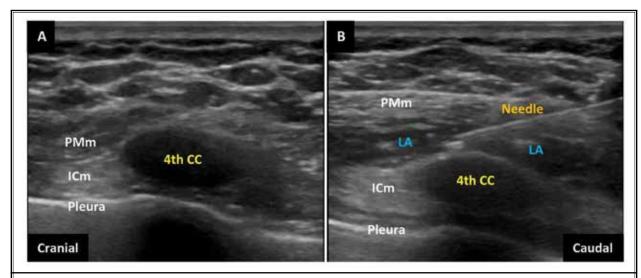


Fig. 2. Ultrasound-guided demonstration of the PIFB. (A) Ultrasonographic anatomy: PMm (pectoralis major muscle), ICm (intercostal muscle), 4th cc (4th costal cartilage). (B) Targeting the 4th costal cartilage, needle inserted in a caudal-to-cranial direction with local anesthetic (LA) deposited in the interfascial plane between the pectoralis major and the external intercostal muscles.

standardized general anesthesia technique was induced in all patients using fentanyl 1 µg/kg, propofol 1 to 2mg/kg, and cisatracurium 0.15 mg/kg. After tracheal intubation, anesthesia was maintained with 1.2% to 1.5% isoflurane and 50% oxygen/air combination. Inadequate analgesia indicated by increased blood mean arterial pressure (MAP) and/or heart rate (HR) more than 20% above the baseline was managed by fentanyl 1 µg/kg. The total consumption of intraoperative fentanyl was calculated. Anesthesia management and data collection were performed by an anesthesiologist blinded to group allocation.

At the end of the surgical procedure, all patients received IV infusion of 1 g paracetamol, initiated 10 minutes before the end of surgery, and maintained at a dose of 1 g per 6 hours. Patients were transferred to the postanesthesia care unit (PACU) where the MAP, HR, O2 saturation, and respiratory rates were monitored.

At patient wake-up, an attending anesthesiologist blinded to group allocation performed IV morphine titration (18) for all patients to achieve a VAS score 30 or less. In case of patients complaining of pain at rest, VAS score 40 or more, or patient requested rescue analgesia, IV morphine was administered in 3 mg increments every 5 minutes with no upper limit for the total administered dose (18).

Morphine titration was stopped if the patient appeared sedated (Ramsay sedation score >2) (19), or if se-

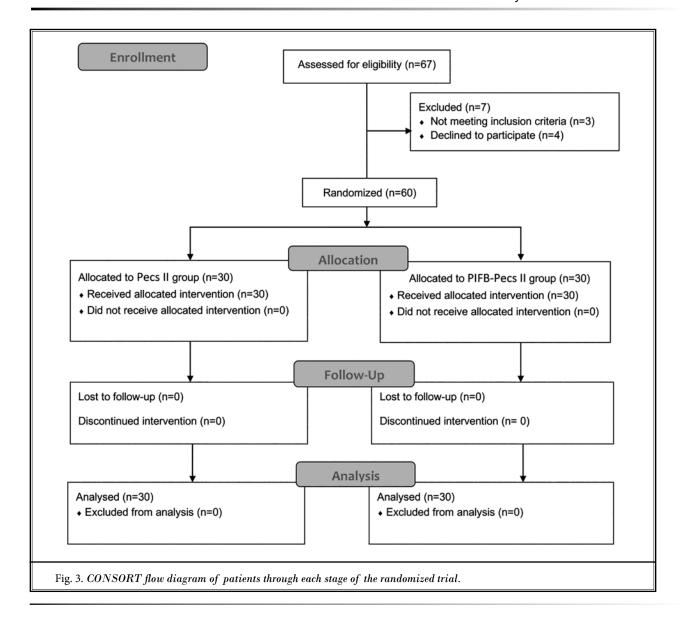
vere morphine-related adverse effects were observed, that is respiratory depression (defined as SpO2 <95% and/or respiratory rate <12 breaths/min under 3 L/min oxygen flow), vomiting, allergy reaction/cutaneous rash, or severe pruritus (18). Time to the first morphine dose was recorded. After morphine titration, patients were instructed to use the morphine PCA device that was preprogrammed to administer a bolus dose of 1 mg with a 7-minute lockout interval.

The primary outcome of this study was the cumulative morphine consumption (morphine titration and the 24-hour morphine PCA consumptions). The secondary outcome was the postoperative VAS score. Postoperative pain assessment was done at rest and on moving the ipsilateral arm (abducting the arm to 90°) and was performed at admission to PACU, 1, 2, 4, 6, 12, 18, and 24 hours postoperatively.

Any adverse events, that is hypotension (as a decrease of the blood pressure >20% of the baseline), bradycardia (defined as decrease of HR below 50 beats/min), nausea and vomiting, sedation, dizziness, and pruritus were recorded. Patient satisfaction using a 4-point scale (4 = very satisfied, 3 = satisfied, 2 = dissatisfied, 1 = very dissatisfied) was also documented.

Statistical Analysis

The cumulative postoperative opioid consumption in the first 24 postoperative hours was used for calculation of the sample size. Based on the results of a previ-



ous trial (20), 28 patients were needed in each group to detect a significant difference of 10 mg in the 24 hours postoperative morphine consumption between both groups at a study power of 95% and α error of 0.05.

The statistical analysis was performed utilizing the statistical software SPSS 16 (SPSS Inc., Chicago, IL). Kolmogorov–Smirnov test and visual inspection of histograms were performed to verify the assumption of normality. The quantitative parameters that normality distributed were expressed as mean ± standard deviation and analyzed utilizing independent sample t-test. The parameters that did not follow the normal distribution were expressed as median with IQR and analyzed using the Mann–Whitney test. Categorical data were

presented as patients' number or frequencies (%) and were analyzed utilizing the $\chi 2$ test or the Fisher exact test as appropriate. P < 0.05 was considered significant.

RESULTS

The details of patient recruitment are shown in Fig. 3 in which 67 patients were examined for recruitment in the present trial, 4 patients refused to participate, 3 patients were excluded (2 patients had coagulation disorders and 1 patient had a mental disorder), and the remaining 60 patients were randomly recruited into 1 of 2 groups (30 patients each).

Table 1 represents the details of the patient demographic characteristics.

www.painphysicianjournal.com 489

The median (interquartile range [IQR]) time to the first morphine dose was significantly longer in the PIFB-Pecs II group (327.5 [266.3–360.0] min) than the Pecs II group (196 [163.8–248.8] minutes) (P < 0.001; 95% confidence interval [CI], 79.98, 150.00). The median (IQR) of morphine titration consumption in the Pecs II group (6.0 [3.0–9.0] mg) was higher than the PIFB-Pecs II group (3.0 [3.0–3.75] mg) (P = 0.002; 95% CI, 0.0–3.0). The PCA morphine consumption in the first 24 postoperative hours was higher in the Pecs II group (8.0 [6.0–10.0] mg) than the PIFB-Pecs II group (5.0 [4.0–5.0] mg) (P < 0.001; CI, 3.0–5.0). The median cumulative morphine consumption was higher in the Pecs II group than the PIFB-Pecs II group (14.0 [11.0–18.0) mg vs. 8.0 [7.0–9.0] mg, respectively) (P < 0.001; CI, 4.0–8.0) (Table 2).

Intraoperative consumption of fentanyl was significantly lower in the PIFB-Pecs II group with a median (IQR) of 0 (0–15 μ g) than the Pecs II group median 57.5 (0–75 μ g) (P = 0.022; CI, 0–60) (Table 2).

On admission to PACU, the median (IQR) VAS score was significantly higher in the Pecs II group (30.0 [20.0-50.0] and 55.0 [37.5-72.5]) than the PIFB-Pecs II group (15 [10.0-30.0] and 30.0 [20.0-40.0]) at rest and on moving the ipsilateral arm, respectively (P < 0.001) (Fig. 4).

VAS score remained significantly higher in the Pecs II group compared with the PIFB-Pecs II group at 1, 2, 4, 6, and 12 hours with a P value (95% CI) of 0.003 (0.0–20.0), 0.002 (0.0–20.0), 0.002 (0.0–10.0), 0.004 (0.0–10.0), and 0.005 (0.0–10.0) at rest, and <0.001 (10.0–30.0), <0.001 (10.0–30.0), 0.001 (10.0–20.0), 0.003 (0.0–20.0), and 0.007 (0.0–20.0) on moving the ipsilateral arm, respectively (Fig. 4).

At 18 and 24 hours, the VAS scores were compa-

rable in both groups (P = 0.246 and 0.112 at rest, and 0.464 and 0.2 on moving the ipsilateral arm, respectively) (Fig. 4).

Regarding the dermatomal block obtained by each block, on the lateral chest wall, all patients in both groups showed block at T3-5 dermatomes. Twenty-two patients showed dermatomal block at T2 in the Pecs II group compared with 21 patients in the PIFB-Pecs II group. At T6 dermatome, 16 patients showed sensory block in the Pecs II group compared with 18 patients in the PIFB-Pecs II group.

On the anterior chest wall, no cases in the Pecs II group showed sensory block at any dermatome from T2-6. In the PIFB-Pecs II group, dermatomal block was observed in all patients at T3-5 dermatomes, 24 patients at T2, and 20 patients at T6.

Nine patients developed postoperative nausea and vomiting in the Pecs II group compared with 5 patients in the PIFB-Pecs II group (P = 0.360). Three patients developed pruritis in the Pecs II group compared with 1 patient in the PIFB-Pecs II group (P = 0.612).

Regarding patient satisfaction, 27 patients were very satisfied and 3 patients were satisfied in the PIFB-Pecs II group, compared with 22 and 8 patients in the Pecs II group, respectively (P = 0.181).

DISCUSSION

The results of our study showed that the combination of PIFB and Pecs II block provided lower postoperative pain scores and less morphine consumption within the first 24 postoperative hours than Pecs II block alone.

From the anatomic point of view, the nerve supply to the breast is very complex. Innervations may be divided into 3 groups originating from the superficial

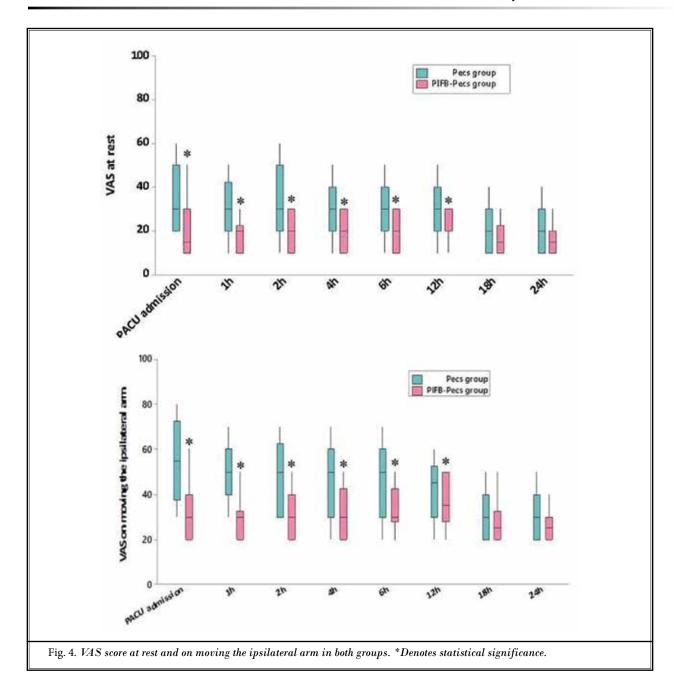
Table 2. Intra- and	l postoperative opio	id consumption	in both groups.
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	Pecs II Group	PIFB-Pecs II Group	Relative Risk/Median Difference	P Value	(95% CI)
Number of patients who required intraoperative fentanyl (%)	17 (56.7%)	7 (23.3%)	2.43	0.018	1.182-4.991
Intraoperative fentanyl consumption (µg)	57.5 (0-75)	0.0 (0-15)	0	0.022	0-60
Time to first morphine dose (min)	196 (163.8–248.8)	327.5 (266.3–360.0)	115	< 0.001	79.98, 150.00
Morphine titration consumption (mg)	6.0 (3.0-9.0)	3.0 (3.0-3.75)	3.0	0.002	(0.0; 3.0)
PCA morphine consumption in the first 24 hours (mg)	8.0 (6.0–10.0)	5.0 (4.0-5.0)	4.0	< 0.001	(3.0; 5.0)
Cumulative morphine consumption (mg)	14.0 (11.0-18.0)	8.0 (7.0-9.0)	6.0	< 0.001	(4.0; 8.0)

Data presented as median (IQR) or patient number (%).

CI for differences in medians or risk ratios.

^{*}P < 0.05 denotes statistical significance.



cervical plexus, the brachial plexus, and the anterior

branches of the thoracic nerves.

The supraclavicular nerves arise from the superficial cervical plexus (C1–C4) and innervate the upper pole of the mammary region. The brachial plexus gives rise to the lateral (C5–C7) and medial (C8–T1) pectoral nerves, the long thoracic nerve (C5–C7), and the thoracodorsal nerve (C6–C8). The second to sixth intercostal nerves also innervate the breast and divide into the

lateral and anterior cutaneous branches. The intercostobrachial nerve (the lateral cutaneous branch of the second intercostal nerve) innervates the interior of the upper arm (11).

In our study, we used the modification of the Pecs II block proposed by Pérez et al (12) in which the injection is performed deep to instead of superficial to the SAM. In this technique, the intercostal nerves can be blocked just after emerging from the external inter-

www.painphysicianjournal.com 491

costal muscle. Because this injection is confined into a poorly distensible space, traversed by the intercostobrachial and the perforating lateral intercostal cutaneous, this method can attain better spread into the serratus intercostal fascial plane with enhanced local anesthetic dispersion by the respiratory movements. Sparing of the long thoracic nerve is also a potential advantage of this technique given the risk of surgical injury to this nerve during axillary dissection causing winged scapula syndrome and the fact that injecting local anesthetic above the SAM may also produce temporary palsy of the long thoracic nerve (12).

Another proposed advantage of this technique is the relative simplicity to deposit the local anesthetic in the fascial plane between the SAM and external intercostal muscle and the lower rate of complications (12).

Single injection and continuous Pecs block had been documented to decrease the postoperative pain in many previous studies (13,14,20-25).

However, Pecs blocks do not block the anterior branches of the intercostal nerves or the entire nipple-areolar complex (11). Thus a Pecs II block alone would be expected to leave sensory innervation of the medial breast intact (26).

PIFB involves local anesthetic injection in the interfascial plane between the pectoralis major and the external intercostal muscles at the emergence site of the anterior cutaneous branch from the lateral side of the sternum (15). Hong et al (17) investigated the addition of PIFB to modified Pecs II block successfully in a 34-year-old parturient woman with recurrent breast cancer.

In our study, although the dermatomal block on the lateral chest wall was comparable between the 2 studied groups, Pecs II block failed to achieve any sensory block on the anterior chest wall in all patients, however, PIFB provided extensive sensory block in all patients at T3-5 dermatomes, 24 patients at T2, and 20 patients at T6.

Transversus thoracic muscle plane block performed between the transversus thoracic and the internal intercostal muscles between the fourth and fifth ribs had also been proposed as an adjunct to Pecs block to improve its analgesic efficacy (27). However, PIFB is a more superficial block, relatively safer as it is far from the pleura and the internal thoracic artery located in the vicinity of the transversus thoracic muscle plane block (28).

Our study is limited by the relatively small sample size and the higher total local anesthetic amount in the PIFB-Pecs II group compared with the Pecs II group. Another limitation is that we excluded patients with a BMI greater than 35 kg/m² to avoid difficulties in block performance, and hence increased success rate of the regional blocks to allow proper assessment of dermatomal sensory loss.

CONCLUSIONS

The combination of PIFB and Pecs II blocks provided more effective analgesia and less analgesic consumption than the Pecs II block alone in patients undergoing MRM.

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