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Original article

Direct versus Ultrasound Guided PECS Block Effect on Controlling Postmastectomy Pain: A Randomized Single-Blind Trial

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Abstract:

Background: Persistent post-mastectomy pain has serious physical and psychological effects on the lives of patients. The PECS block combines motor and sensory nerve blocks and is distinct from sympathetic block. This study aimed to compare intraoperative with preemptive ultrasound guided (US guided) PECS block effect on controlling acute postmastectomy pain. **Methods:** Sixty cases arranged for elective simple mastectomy were involved in this randomized, single-blind, controlled trial. Cases were randomized equally into three groups. Group C (the control group): received no block, Group D (direct PECS group): received direct pecs block by surgeon after closure of pectoralis muscle under direct vision and before skin closure and Group U (US guided PECS group): received US guided PECS block done after induction and before skin incision. **Results:** Morphine consumption in 1st 24h postoperative was significantly lower in U group compared to C and D groups (P value <0.001) without significant difference between group Cand group D (P=0.169).Post operative pain scores measurements were significantly lower in group U than group C and group D at 2h, 4h and 8h (P value <0.05) without significant difference between group C and D. Onset of first request to analgesia delayed significantly in group U than C and D groups and in group D on comparison with group C (P value <0.001). **Conclusions:** Preemptive US guided combined PECS block provided superior analgesic effect than direct intraoperative PECS block as evidenced by significantly smaller post operative opiate consumption, lower pain score and delayed time for first request for analgesia.

Keywords: Direct PECS; Ultrasound Guided PECS; Mastectomy; Analgesia.

Introduction

Breast cancer is the most prevalent cancer among women and the principal cause of mortality on a global scale. The age-specific incidence rates in Egypt climb gradually after the age of 30, reaching a significant peak between the ages of 60 and 64 [1]. Surgery is typically the initial managment option for breast cancer [2]. Significant acute postoperative discomfort following breast surgery may develop into chronic pain [3]. The prolonged pain has serious physical and psychological effects on the lives of patients [4]. Significant amounts of opioids are used to control pain during perioperative analgesia for breast cancer surgery. However, Changes in the tumor's microenvironment may be influenced by opioids to affect oncological outcomes. Additionally, Use of opioids is connected with unpleasant adverse events such as nausea, vomiting, constipation, dread of dependency, and tolerance. Concurrent drugs are important to counter these undesirable adverse effects [5]. To give adequate and tolerable analgesia, supplemental analgesics are required which make cases susceptible to drug interaction and adverse events. These variables worsen the psychological condition and quality of life of patients [1].

Regional anesthetic minimises the requirement for opioids during surgery, which may enhance patient outcomes [6]. Epidural and paravertebral thoracic blocks have become the gold standard for post-breast surgery analgesia, although not all anesthesiologists are comfortable executing these techniques [7, 8]. As a replacement for these procedures, a new sequence of pectoral nerve blocks (PECS I and PECS II) is being investigated [1]. The PECS1 block, a technique of regional anesthesia, involves the hydro-dissection of the fascial plane situated between the pectoral muscles, coupled with the administration of local anesthesia. The block is performed on a supine patient with the arm either parallel to the chest or abducted 90 °. The recommended volume of a prolonged-acting local anesthetics is 0.2 ml/kg [9]. The PECS 2 block is an expansion of this approach and comprises extra infusion beneath the pectoralis minor and anterior serratus, laterally to the PECS1 injection site [10].

The combined PECS1 and PECS 2 under US guidance provided better post-operative analgesia than placebo after breast cancer surgery [1]. However, US guided modified pectoral nerve block is costly regarding trained personnel and specialized apparatus [5].

Direct PECS II block under vision following tumour excision, without US as well, afforded postoperative analgesic and opioid sparing benefits.in cases undergoing modified radical mastectomy [5].

However, data is limited regarding the comparisons of analgesic effect of combined preemptive PECS1 and PECS 2 under US guidance with the same combination under direct vision for acute post mastectomy pain. Therefore, this trial aimed to compare intraoperative with preemptive US guided PECS block effect on controlling postmastectomy pain.

Methods:

This randomized prospective single blinded study included 60 cases of aged 20-50 years old, American Society of Anesthesiologists (ASA) physical status classification I or II who underwent elective simple mastectomy. The trial was done from April- 2023 to July -2023. The study was carried out at Benha university Hospitals.

Each patient supplied informed written consent. The research was conducted after the approval of the Ethical Committee Benha university Hospitals (approval code: RC.5.1.2023), registration of clinicaltrials.gov (ID: NCT05825430) and the date of first registration was (15/04/2023).

Exclusion criteria were diabetes mellitus, Intradialytic hypotension, chronic kidney disease and Bronchial Asthma.

Randomization and blindness

Computer-generated randomization numbers wase applied to randomly assign 60 cases equally into three groups. Group C (control group): did not receive any block, Group D (direct PECS group): received direct PECS block by surgeon after closure of pectoralis muscle under direct vision and before skin closure and Group U (US guided PECS group): received US guided PECS block done after induction and before skin incision. Sealed envelopes were used to ensure random allocation by a nurse who did not take part in the study. Allocation ration was 1:1:1 in ap parallel manner. Due to different guidance techniques, only cases were blinded to the study blocks. Drugs were prepared by an additional pharmacist who did not join in the remaining phases of trial. All containers were identical in appearance.

Preoperative

During the preoperative appointment, cases were educated how to utilize the visual analogue scale (VAS) (0, no discomfort and no pain; 10 extreme discomfort and maximal pain). Before the induction of anesthesia, all cases underwent routine monitoring and were connected to a monitor consisted of pulse oximetry, non-invasive blood pressure, 5-lead ECG, a temperature probe and capnography. Insertion of an intravenous line and a urine catheter was done.

Intraoperative

The cases were subsequently transferred to the operating room to undergo surgery.

All cases got the same method of general anaesthesia: In the form of IV induction with 2 mg/kg propofol, fentanyl 2 mic/ kg and 0.5 mg/kg of atracurium improved intubation. Isoflurane 1.5 MAC and progressive doses of atracurium 0.15 mg/kg every 20 minutes were used to maintain anesthesia. At the end of operation, the neuromuscular blocker was neutralized using IV neostigmine 50 micrograms per Kg and atropine 20 micrograms per Kg.

Both two groups D & U received the combination of PECS I and PECS 2 following administration of general anesthesia and before skim incision in group U and before skin closure in group D.

Both two groups, D & U, were given the same local anesthetic volume and concentration. PECS I block was performed with 10 ml bupivacaine 0.25% which was introduced between two pectoral muscles and PECS II block was achieved with 20 ml bupivacaine 0.25% which was allocated between the pectoralis minor and serratus muscles.

Cases were given IV paracetamol 1 gm/8 hours. If VAS >4 was observed, rescue analgesia (morphine 0.1 mg/Kg IV) was administered. Postoperative hemodynamics and VAS score were record at PACU, 1h, 2h, 4h,8h, 12h and 24h. time to first rescue for analgesic and total morphine consumption were recorded.

The primary outcome was the total intake of morphine during the first 24h postoperatively. The secondary outcome was VAS, at different time intervals during the first 24h postoperatively.

Sample size calculation.

The sample size calculation was done by G*Power 3.1.9.2 (Universitat Kiel, Germany). We conducted a pilot study (five cases per group) and we observed that the mean difference (± SD) of total morphine intake (1ry outcome) was 3.18 mg between direct and US guided PECS groups with a common SD of 3.74 The sample size was determined by the following factors:: 0.835 effect size, 95% confidence limit, 80% power of the study, group ratio 1:1 and one additional case was provided to each group to combat dropout. Therefore, 20 cases were recruited for each group.

Statistical analysis

Statistical analysis was done by SPSS v28 (IBM©, Chicago, IL, USA). Using the Shapiro-Wilks test and histograms, the normality of the data distribution was

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determined. Parametric quantitative data were given as mean and standard deviation (SD) and analysed using the ANOVA (F) test with post hoc comparisons (Tukey). Quantitative non-parametric data were expressed as median and interquartile range (IQR) and compared across groups using the Kruskal-Wallis test and the Mann Whitney test. The Chi-square test was utilised to examine qualitative variables expressed as frequency and percentage (%). A two-tailed P value of 0.05 or less was judged statistically significant.

Results

In this study, eligibility was dedicated to 98 participants, 29 participants did not match the eligibility requirements, and 9 cases declined to contribute in the study. The left 60 cases were randomly assigned to three groups of equal size (60 cases per group). All allocated cases were monitored and statistically assessed. (Figure 1)

Age, weight, Hight, BMI, ASA physical status and duration of surgery were matched among the three groups. (**Error! Reference source not found.**)

Post operative mean blood pressure measurements and heart rate were insignificantly different among the three groups at PACU, 1h, 12 and 24h. Post operative mean blood pressure measurements were significantly lower in group U than group D and group C and were comparable between C and D groups after 2h,4h and 8h. Figure 2

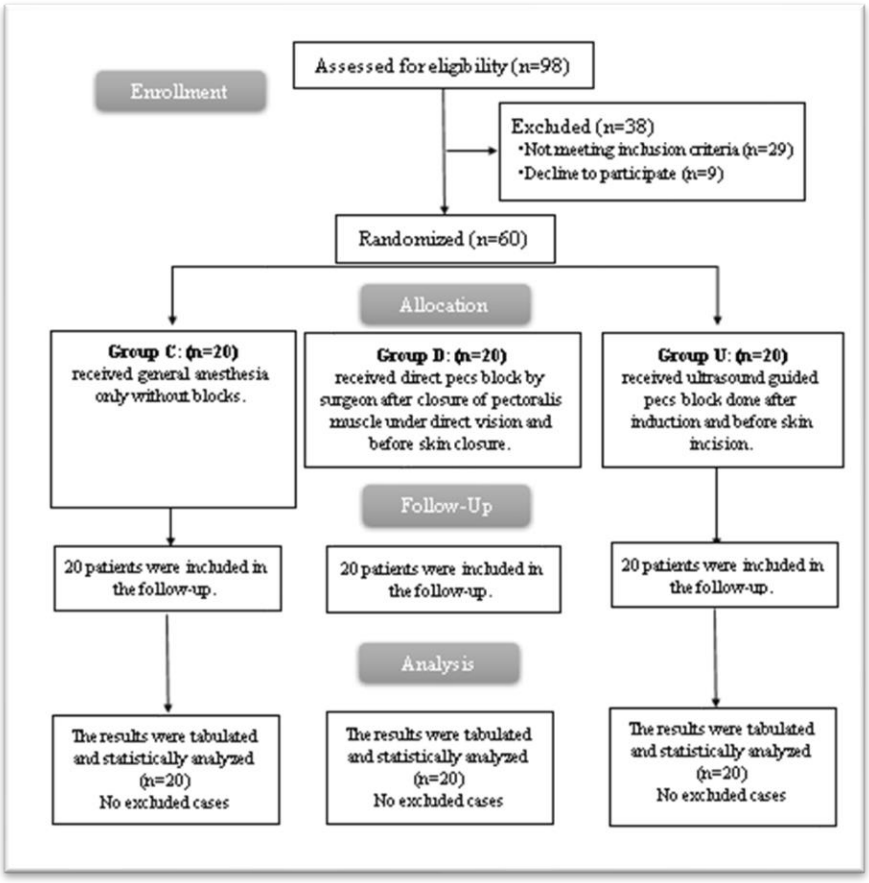

Figure 1: CONSORT flowchart of the enrolled cases.

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

		Group C (n=20)	Group D (n=20)	Group U (n=20)	P value
Age (years)		37.9 ± 12.72	40 ± 12.16	44.7 ± 12.81	0.229
Weight (Kg)		65.9 ± 7.02	66.8 ± 7.66	64.8 ± 8.22	0.723
Hight(m)		1.7 ± 0.08	1.7 ± 0.08	1.7 ± 0.1	0.942
BMI(Kg/m^2)		24.4 ± 3.83	24.5 ± 3.76	23.7 ± 3.86	0.791
ASA physical status	I II	15 (60%) 5 (20%)	12 (48%) 8 (32%)	17 (68%) 3 (12%)	0.198
Duration of surgery (min)		85 ± 9.18	84 ± 8.68	84.5 ± 9.99	0.944

Data are presented as mean ± SD or frequency (%), BMI: Body mass index, ASA: American society of anesthesiologists.

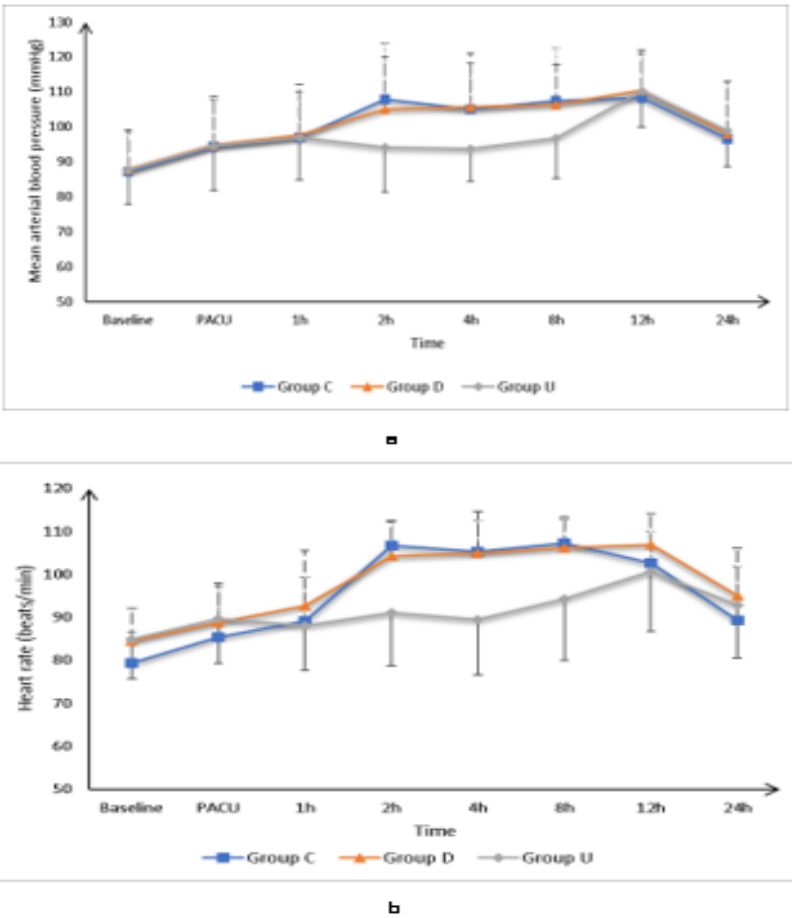

Figure 2: (a): Post operative mean blood pressure MBP (mmHg) and

(b): Post heart rate (beat/min) of the studied groups.

Post operative pain scores measurements were significantly lower in group U than group C and group D at 2h, 4h and 8h (P value <0.05) without significant difference between group C and D. Post operative pain scores measurements were comparable among the three groups at

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PACU, 1h, 12 and 24h. **Error! Reference source not found.**

The mean ± SD of time to first rescue analgesia was 0.8 ± 0.25 in group C, 1.6 ± 0.75 in group D and 4.6 ± 0.94 in group U. Time to first demand for analgesic significantly delayed in group U than group C and group D and in group D than group C (P value <0.001).

The mean ± SD morphine consumption in 1st 24h postoperative was 33.96 ± 10.52 mg in group C, 29.2 ± 6.56mg in group D and 12.39 ± 5.02 mg in group U. Morphine consumption in 1st 24h postoperative was lower significantly in U compared to C and D groups (P value <0.001) without statistically significant difference between C and D groups (P=0.169).

Incidence of PONV was 9 (45%),6 (30%) and 3 (15%) in group C, D and U without significant difference among the groups (p=0.117).

Table 2: Time to first rescue analgesia, Total morphine consumption in 1st 24h postoperative (mg) and incidence of PONV among the studied groups.

	Group C (n=20)	Group D (n=20)	Group U (n=20)	P value
Time to first analgesic request (h)	0.8 ± 0.25	1.6 ± 0.75	4.6 ± 0.94	P1=0.002 P2<0.001 P3<0.001
Total morphine consumption in 1st 24h postoperative (mg)	33.96 ± 10.52	29.2 ± 6.56	12.39 ± 5.02	P1=0.169 P2<0.001 P3<0.001
Incidence of PONV	9 (45%)	6 (30%)	3 (15%)	0.117

Data are presented as mean ± SD or frequency (%), PONV: Postoperative nausea and vomiting. P1: p value between group C and group D, P2: p value between group C and group U, P3: p value between group D and group U.

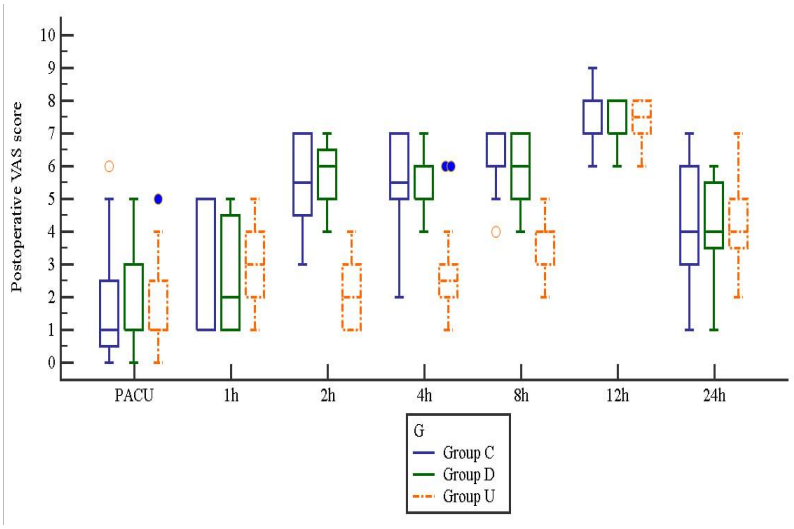

Figure 3: Postoperative pain score of the studied groups.

Discussion

The PECS block combines the motor and sensory nerve blocks; a significant benefit of the PECS block is that, unlike the TPVB and epidural blocks, it is not accompanied by sympathetic block [7].

Our results revealed that Morphine consumption in 1st 24h postoperative was significantly lower in U group than C and

D groups without significant difference between C and D groups. Post surgical pain scores measurements were significantly lower in group U than group C and group D at 2h, 4h and 8h (P value <0.05) without significant difference between group C and D. The mean ± SD of time to first rescue analgesia was 0.8 ± 0.25h in group C, 1.6 ± 0.75h in group D and 4.6 ± 0.94h in group U. Time to first demand analgesia delayed significantly in group U than C and D groups and in group D than group C.

The incidence of PONV was 9 (45%),6 (30%) and 3 (15%) in group C, D and U which was comparable among the groups.

Preoperative US guided pecs block is better effective than direct PECS block in controlling the postmastectomy pain with less postoperative opioids consumption, as this is because of achievement of preemptive analgesia in US guided PECS block group than in direct group. Preemptive analgesia inhibits the development of central sensitization resulting from incisional and inflammatory damage during surgery and the immediate postoperative period. Local anaesthetics inhibit pain impulses flowing to the central nervous system and decrease the need for postoperative analgesia [(11)].

Also, in direct PECS block the plane not easy identified accurately in some cases due to there was sometimes bleeding, aggressive muscle manipulation, and or oedema leading to dividing the local anesthetics between the correct plane and intramuscular injection which can give less pain control postoperatively in direct pecs block group. As complete pecs block requires the full anatomy to be intact which is ensured before skin incision under US guidance.

Our findings agreed with Bell et al.[(12)] who observed a statistically significant lower VAS scores, consumption of morphine following surgery in cases who got PECS II block with US prior to breast cancer surgery than in the comparison group (cases who had general anaesthetic alone).

Supporting our findings, Lovett-Carter et al. [(13)] reported in their meta-analysis of randomized controlled trials that the PECS block is efficient at decreasing postoperative narcotic usage and discomfort in mastectomy cases. They recommended PECS block as an efficient method for enhancing analgesic outcomes in breast cancer cases performing mastectomy.

Also agreed with [(14)] who approved that US combined PECS blocks are an efficient analgesic technique for breast surgery cases throughout the perioperative phase.

Moreover, Karaca et al. [(15)] concluded that the combination of PECS I and II blocks present greater pain control postoperatively and reduces hospital stays in cases experiencing breast augmentation.

A new systematic review and meta-analysis by Zhang et al. [(16)] documented that in mammoplasty using submuscular implants, PECS block can alleviate immediate postoperative pain successfully, the use of opiates, and the frequency of PONV, demonstrating its extensive clinical application potential.

Another systematic review and meta-analysis by Zhao et al. [(17)] highlighted that in modified radical mastectomy, the PECS II block is an efficient anaesthetic protocol which can successfully minimise intraoperative and postoperative opiate use, postsurgical PONV, and the requirement for postoperatively analgesic request and help decrease early postoperative pain (0-6 hours).

However, in contrast to our results, Thomas et al. [(5)] reported longer time for first request of analgesia (353.93 ± 135.03 min) in cases who received intraoperative PEC block which was significantly delayed than control group. Different local anesthetic used as they used ropivacaine while we used bupivacaine may explain this difference.

Limitations: The trial was in a single center with a relatively short follow-up period and single blinded. Thus, further large-scale multicenter collaboration

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studies and longer monitoring duration are necessary to validate our findings.

Conclusions:

Preemptive US guided combined PECS block provided superior analgesic effect than direct intraoperative PECS block as evidenced by significantly smaller post operative morphine consumption, lower pain score and delayed time for first analgesic request.

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Stamen and Declarations

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Competing interests

The authors have no relevant financial or non-financial interests to disclose.

Author contributions

All authors participated in preparing this clinical trial and approved of the work as it is being submitted. All authors read and approved the final manuscript.

Availability of data and materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate.

This study was performed in line with the principles of the Declaration of Helsinki. Each patient provided written informed consent. The research was performed after the approval of the Ethical Committee Benha university Hospitals (approval code: RC.5.1.2023), registration of clinicaltrials.gov (ID: NCT05825430) and the date of first registration was (15/04/2023).

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