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Original Article

Comparison of Paravertebral Plane Block for Post-Operative Analgesia in Modified Radical Mastectomy with Intravenous Nalbuphine

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ABSTRACT

Objective: To compare the post-operative analgesic efficacy and adverse effect profile of ultrasound-guided paravertebral plane block with intravenous Nalbuphine in patients with breast cancer planned for modified radical mastectomy.

Study Design: Quasi-experimental study.

Place and Duration of Study: Anesthesia Department Combined Military Hospital, Rawalpindi Pakistan, from Jun to Dec 2022.

Methodology: A total of 106 patients diagnosed with breast cancer Stage I and II requiring modified radical mastectomy were included. Comparison of the post-operative analgesic efficacy and adverse effect profile of ultrasound-guided paravertebral plane block and intravenous Nalbuphine were noted.

Results: One hundred six patients were included in the study, and divided into the Nalbuphine Group (n=53) and the Paravertebral Block (PVB) Group (n=53). The per-operative Nalbuphine requirement was significantly reduced in the PVB-Group, 2.28±0.37 mg versus 5.30±0.24 mg in the Nalbuphine-Group (p<0.001). Similarly, the time to the first dose of rescue analgesia was significantly prolonged in the PVB Group at 238.32±5.22 minutes versus 37.71±1.72 minutes in the Nalbuphine Group. The mean satisfaction score between both Groups was 4.33±0.64 in the Nalbuphine was 5.69±0.66 and in the PVB Group (p<0.001).

Conclusion: We conclude that paravertebral block is superior to intravenous opioids in decreasing the per-operative and post-operative dose of intravenous opioids with a more favourable profile and a decreased incidence of adverse events.

Keywords: Analgesia, Modified radical mastectomy, Nalbuphine, Paravertebral block.

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INTRODUCTION

Breast cancer remains one of the most commonly diagnosed malignancies in women worldwide, accounting for as much as 36% of all oncological tumours diagnosed in females.[1] There is a great disparity in the global prevalence of breast cancer, with an increasing burden seen in the developing world.[2] Modified radical mastectomy remains the surgical treatment of choice in patients with breast cancer in the first and second stages of the disease.[3,4] A few years ago, intravenous opioids were the mainstay for pain relief in these patients.[5] However, they were associated with a guarded adverse effect profile, especially in breast cancer patients undergoing chemo and radiotherapy.[6,7]

The paravertebral plane block (PVB), pioneered in 1905 and refined in 1919, has emerged as one of the most effective analgesic modalities for surgeries in the thoracic and lumbar regions.[8] The use of this regional block modality has gained widespread acceptance for post-operative pain relief in patients, especially breast cancer surgeries and those experiencing chronic pain post-chemotherapy or breast phantom syndrome.[9] While most of these patients present in the age Groups between 35-55 years of age, the debilitating effects of chemotherapy and the tumour itself make them prone to hemodynamic disturbances and respiratory depression seen with opioids.[10] It, therefore, has become pertinent to develop better analgesic modalities in line with patient compliance and safety.

This study compares whether the ultrasound-guided paravertebral block provided superior efficacy and analgesia, resulting in better patient satisfaction and decreased hospital stay compared to intravenous Nalbuphine.

METHODOLOGY

The quasi-experimental study was conducted at the Department of Anesthesiology, Combined Military Hospital, Rwalpinid Pakistan, from June to December 2022 after approval from the Ethical Review Board

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(vide letter no.295). Sample size was calculated using the WHO calculator, keeping the population proportion at 6.66%.[11]

Inclusion Criteria: Female patients of ASA-I and II aged 25-55 years presenting at the Female Surgical Department for modified radical mastectomy for Stage I and II breast cancer, were included.

Exclusion Criteria: Patients with metastatic disease, major cardiac or respiratory disease, low ejection fraction, post-chemotherapy, allergy to bupivacaine or Nalbuphine, infection at site of block, coagulation disorders or spine deformity, were excluded.

The study method included all patients as per the inclusion criteria furnished. The patients were divided into the Paravertebral-Group (n=5) & the Nalbuphine-Group (n=53). Once the patients were divided into the two Groups, an informed written consent was taken, and the paravertebral Group was explained in detail about the procedure and possible complications. Standard monitoring, including non-invasive blood pressure, heart rate, capnography and ECG, was attached to participants in both Groups.

Patients in the Paravertebral Group were taken to the procedure room before the start of surgery. The paravertebral block was given in a sitting position with the arms of the patient extended. Local infiltration with 2.0 mL of 2% Lignocaine using a 24-G hypodermic needle at the site of puncture was done. The ultrasound probe was placed in the craniocaudal direction at the level of T4 interspinous space, about 5cm from the midline, and the transverse process and parietal pleura were identified by moving the probe medially. The superior costotransverse ligament was identified as echogenic homogeneous bands extending between the transverse processes. US-guided paravertebral space was identified, and a needle was passed through the superior costotransverse ligament. The confirmation of the correct placement of the needle was done by deflection of the pleura downwards on injecting 3mL of saline. 20ml of local anesthetic solution (10ml 0.25% bupivacaine combined with 10ml 2% lignocaine) was injected. The patients were observed for 30 minutes, and any adverse effects like bradycardia, hypotension, vessel injury, or pleural rupture were observed. Bradycardia was defined as a heart rate of <60 beats per minute and hypotension as MAP <50 mm Hg12 and was treated with 5 mg Ephedrine and 600 mcg of Glycopyrrolate where needed.[12] A blinded observer assessed the sensory level of the block every 5 min with pin-prick sensation from T1-T9 dermatomes. If, up to 30 min, there was no decrease in pin-prick sensation in any segment, then it was considered as a block failure (at least two segments should have decreased sensation to be considered as block success). Patients in the Nalbuphine Group received 0.1 mg/kg of the drug at induction of anaesthesia.

Table-III: Side Effects Observed in Study Groups (n=106)

Variables	Nalbuphine Group n(%)(n=53)	PVB Group n(%)(n=53)
Hypotension	10(18.9%)	02(3.8%)
Nausea	04(7.5%)	03(5.7%)
Shivering	05(9.4%)	01(1.9%)
Respiratory Depression	07(13.2%)	00(0%)

Anesthesia was induced in both Groups with IV Propofol 2 mg/kg, IV Atracurium 0.5 mg/kg with maintenance done with 50% oxygen with Isoflurane at 1.0 MAC. Patients in the Nalbuphine received IV Nalbuphine at 0.1 mg/kg at the start of surgery. If heart rate and BP exceeded 20% of the baseline values post-induction, 0.05 mg/kg bolus of Nalbuphine was given, and total per-operative analgesia boluses needed were recorded. Patients were extubated after Neostigmine 0.05 mg/kg, and Glycopyrrolate 0.01 mg/kg was given to reverse the neuromuscular block.

Post-operatively, patients were kept in the high dependency unit (HDU) and observed for post-operative pain every hour for the next 24 hours. 0.5 mg/kg of Nalbuphine was once pain on the visual analogue scale (VAS) reached 5, and the total dose in 24 hours was calculated. Patient satisfaction was evaluated and recorded 24 hours after surgery on a 7-point Likert scale. (1-Extremely dissatisfied, 2-Very dissatisfied, 3-Dissatisfied, 4-Neither satisfied nor dissatisfied, 5-Satisfied, 6-Very satisfied, 7-Extremely satisfied) in both Groups.

Statistical Package for Social Sciences (SPSS) version 26.0 was used for the data analysis. Quantitative variables were expressed as Mean±SD and qualitative variables were expressed as frequency and percentages. Chi-square test and Independent sample t-test were applied to explore the inferential statistics. The *p*-value of 0.05 or less was taken as significant.

RESULTS

A total of 106 patients were included in the study and divided into the Nalbuphine Group (n=53) and the paravertebral block (PVB) Group (n=53). Total duration of surgery was comparable between both

Groups at 128.94±6.02 minutes versus 129.0±6.54 minutes (p=0.954). The per-operative Nalbuphine requirement was significantly reduced in the PVB Group (2.28±0.37 mg) versus 5.30±0.24 mg in the Nalbuphine Group (p<0.001). Similarly, the time to the first dose of rescue analgesia was significantly prolonged in the PVB Group at 238.32±5.22 minutes versus 37.71±1.72 minutes in the Nalbuphine Group (p<0.001). This resulted in a reduction in the total analgesia given intravenously in the 24 hours post-surgery, with 8.88±0.75 mg in the Nalbuphine Group versus 4.47±0.66 mg in the PVB Group (p<0.001) (Table-I).

Table-I Comparison of Operative Parameters between Study Groups (n=106)

Variables	Nalbuphine-Group (n=53)	PVB-Group (n=53)	*p*-value
Per-Operative Analgesia Required (mg)	5.30±0.24	2.28±0.37	<0.001
Duration Of Surgery (Minutes)	128.94±6.0	129.0±6.56	0.954
Mean Time To First Dose Rescue Analgesia (Minutes)	37.71±1.72	38.32±5.22	<0.001
Mean Volume Of Analgesia Given In HDU (mg/24 hr)	8.88±0.75	4.47±0.66	<0.001
MEAN HDU STAY (HOURS)	49.81±3.99	27.77±2.35	<0.001
Mean Patient Satisfaction Score For Pain Relief (24 hrs) (Likert Scale)	4.33±0.64	5.69±0.66	<0.001

When the patients gave their objective assessment on the Likert scale for overall pain relief satisfaction after the surgery, the patients were comprehensively more satisfied in the PVB Group. When assessed on the standard scale (1-7, 1 being very dissatisfied to 7 being extremely satisfied) (Table-II). The adverse effect profile is shown in the Table-III.

Table-II: Satisfaction Score in Study Groups for Pain Relief after 24 Hours (n=106)

Likert Scale Score	Nalbuphine Group n (%) (n=53)	PVB Group n(%) (n=53)
01 (Extremely Dissatisfied)	00(0%)	00(0%)
02 (Very Dissatisfied)	00(0%)	00(0%)
03 (Dissatisfied)	05(9.4%)	00(0%)
04 (Neither Satisfied Nor Dissatisfied)	25(47.2%)	00(0%)
05 (Satisfied)	23(43.4%)	22(41.5%)
06 (Very Satisfied)	00 (0%)	25 (47.2%)
07 (Extremely Dissatisfied)	00 (0%)	06 (11.3%)
Total	53 (100%)	53 (100%)

DISCUSSION

The study was carried out at a tertiary care hospital receiving a major burden of clientele under its load for breast cancer surgery. The main aim was to offer these patients the best possible anaesthesia modality for pain relief, which is a major concern for these patients since the majority of them have undergone chemotherapy, and their chronic pain already causes considerable distress.

Incidentally, none of the patients in both Groups had received prior chemotherapy and were scheduled for surgery following diagnosis of Stage I and II breast cancer. The block was effective in all patients and provided superior analgesia during the per-operative period in the paravertebral block Group. It was associated with a favourable hemodynamic profile with heart rate and MAP in the lower ranges than the Nalbuphine Group. This was also in line with a study by Zemedkun *et al*. commenting on the superior hemodynamic profile.[13]

Rescue analgesia provided a far superior time and effective block, resulting in little or no pain on the VAS when subjectively used in the patient's post-surgery. The same was seen in a study by FS Saad *et al*.[14] It also resulted in considerable patient comfort with no need for IV analgesics and the need to rescue analgesia exceeding 6 hours compared with multiple doses of Nalbuphine required in the other Group after the first hour of surgery. The block's longevity was also discussed in studies by Chu *et al*.[15] and Zhong *et al*.[16]

The total dose of analgesia required in the IV form was considerably reduced and, by far, was the most important characteristic that resulted in very favourable patient satisfaction in the PVB Group versus the Nalbuphine Group. The Likert scale was used as a subjective assessment of pain relief in the 24 hours post-surgery. Furthermore, patients were inclined towards the effectiveness of the block in reducing acute pain. Patient satisfaction was exceedingly favourable in the PVB Group, with half of the patients in the Group more than satisfied with the pain relief provided. The same satisfaction trend was seen in similar studies by Yeap *et al*.[17] and Chen *et al*.[18]

RECOMMENDATIONS

The study recommends the use of paravertebral block as a superior substitute to per- and post-op analgesia to intravenous opioids.

CONCLUSION

We conclude that paravertebral block is superior to intravenous opioids in decreasing the per-op and post-op

dose of intravenous opioids with a more favourable profile and a decreased incidence of adverse events.

Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

ASK: & AH: Data acquisition, data analysis, critical review, approval of the final version to be published.

NTB: & SQAS: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

AN: & MAR Concept, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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