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Original Research Article

# Effects of Nalbuphine versus Dexmedetomidine as Adjuvant to Bupivacaine in Paravertebral Block for Postoperative Pain Management Following Modified Radical Mastectomy

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**Abstract**

**Background and Aim:** After modified radical mastectomy (MRM), paravertebral block (PVB) is a frequently utilized procedure for postoperative analgesia. Although many adjuvants to bupivacaine in PVB have been used for postoperative analgesia, none have been shown to be optimum. After MRM, we compared the duration of analgesia in PVB utilizing adjuvants like nalbuphine and dexmedetomidine with bupivacaine.

**Methods:** Two groups of sixty female patients who were scheduled for MRM with axillary dissection were divided into two groups. Group D received 20 ml of bupivacaine 0.25% with dexmedetomidine 1 µg/kg, while Group N received PVB with 20 ml of bupivacaine 0.25% with nalbuphine 10 mg. All patients underwent surgery under general anaesthesia following PVB confirmation. Our study's major goal was the time for the first rescue analgesic request. Visual analogue score (VAS) for pain during rest and movement, as well as total analgesic consumption, were our study's secondary goals. In the 24 hours following surgery, symptoms such as nausea and vomiting, hemodynamic, and sedation were also evaluated.

**Results:** Compared to group N (4.46 ± 3.24 hours), the initial rescue analgesic demand was delayed in group D (7.12 ± 2.28 hours). In contrast to group N (3.8 ±0.25 gm), group D's mean total paracetamol consumption as rescue analgesia during the first 24 hours following surgery was significantly lower (2.9 ±0.68 gm). ($p<0.001$)

**Conclusion:** When used with bupivacaine in PVB for modified radical mastectomy, dexmedetomidine offers longer-lasting analgesia than nalbuphine.

**Keywords:** Analgesia, Paravertebral Block, Bupivacaine, Dexmedetomidine, Nalbuphine.

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## Introduction

Although general anaesthesia is routinely used for this procedure (MRM), it does not alleviate postoperative pain control. Breast cancer is the most common cancer in women that often necessitates surgical intervention. Additionally, this is linked to a very high incidence of postoperative nausea and vomiting. [1]

Inadequate management of postoperative pain and PONV can result in poor recovery, longer hospital stays, and an increased risk of developing chronic post-surgical pain (CPSP).

Various modalities, such as intercostal block, thoracic epidural anaesthesia, local anaesthetic infiltration, paravertebral block, pectoral nerve blockage, and opioids have been used for pain. PVB lowers the incidence of PONV in addition to postoperative pain and narcotic intake. Bupivacaine is combined with a number of adjuvants, including fentanyl, clonidine, magnesium, epinephrine, tramadol, dexamethasone, opioids, and dexmedetomidine to improve both the quality and duration of analgesia in PVB. [2] Nalbuphine, which is derived from 14-hydroxymorphine, is regarded as a powerful analgesic with a combination of k agonist and µ competitor profiles.

Dexmedetomidine has demonstrated its effectiveness in paravertebral block by reducing postoperative pain with less opioid consumption, but it has produced a significant reduction in heart rate and mean arterial pressure intraoperatively. [3]

According to reports, nalbuphine's pain-relieving effectiveness is the same as morphine's, but it differs in that it has a top-limit effect on respiratory depression.[4] We compared the effectiveness of additives like dexmedetomidine and opioids like nalbuphine with bupivacaine in paravertebral block

for postoperative pain in patients undergoing breast surgery.

## Methods

After receiving approval from the Institutional Ethical Committee, this prospective trial was carried out at a tertiary care facility. Every patient provided written informed consent. This study included sixty ASA I/II patients, ages 18–70, who were scheduled for elective breast cancer surgery. Patients with coagulopathy, allergies to the study medication, and infections at the paravertebral block site, pregnancy, and serious cardiopulmonary disorders were not allowed to participate in the study. All patients were evaluated and investigations were reviewed during the pre-anaesthetic checkup after a history was taken. The visual analogue scale (VAS 0–10) was explained to each patient. Using a computer-generated random number assignment in sealed opaque envelopes, all patients were divided into two groups of thirty patients each. The study medication was prepared using randomization by an anaesthesiologist who was not involved in the research. Allocation was concealed from both the patients and the researcher who collected the data.

A lactated Ringer's solution (10 ml/kg) was started and an 18-gauge IV cannula was inserted upon arrival in the operating room. Temperature, O2 saturation, noninvasive blood pressure, and electrocardiography were all monitored. Patients were premedicated with intravenous midazolam (0.03 mg/kg) and tramadol (1 mg/kg) while seated for block. Two ml of 2% lidocaine infiltration were administered after the needle entrance point was defined 2.5 cm lateral to the spinus process from the intercostal space between the T5 and T6 ribs. A 23 G 100 mm peripheral blockade needle (Stimupleks® Ultra, B. Braun, and Melsungen, Germany) was used to provide paravertebral block.

The internal intercostal membrane at the top and the pleura at the bottom were used to calculate the thoracic paravertebral area. Using ultrasonography, a nerve block needle was inserted perpendicularly into the skin until the transverse process was reached. After the paravertebral space was confirmed, 21 millilitres of the prepared drug were injected to provide paravertebral blockage.[5] Patients in group D received 20 ml of bupivacaine 0.5% + 1 μg/kg dexmedetomidine (diluted to 1 ml), while patients in group N received 20 ml of bupivacaine 0.5% with 10 mg (1 mL) nalbuphine. All patients who had a successful block were included in this study once the block's effectiveness was assessed after ten minutes. The patients were put in the supine position right after the block and general anaesthesia was administered as per institutional protocol. Mean arterial pressure (MAP), heart rate (HR), and preoperative spo2 were measured and tracked during surgery. Following the procedure, patients were extubated, sent to the postanaesthetic care unit. Following surgery, VAS [6] at rest (VAS.R) and during movement or ipsilateral arm abduction (VAS.M) were measured at 0, 0.5, 1, 2, 4, 6, 12, and 24 hours. When the VAS was > 4, intravenous paracetamol 15 mg/kg was administered as rescue analgesia. The first analgesic request time and the total amount of analgesics used during the first 24 hours were noted. Hypotension, bradycardia, respiratory depression, pruritus, and postoperative nausea and vomiting were among the complications that were evaluated. All patients experiencing nausea, vomiting, or retching were administered ondansetron (4 mg). Statistical analysis: The initial pilot trial, which included 10 patients and had "time needed for first rescue analgesic" as its main outcome, served as the basis for calculating the sample size. The N group's time to first analgesic request was 3.84 ± 1.38 hours, while the D group's was 5.32 ± 1.42 hours. The sample size was determined to be roughly 28 in each group with α error of 0.05 and power of the study (1− α) at 80% in order to detect a minimum of 120 min difference in the time needed for rescue analgesia between the two groups. To account for potential dropouts, we included thirty patients in each group. The study did not include the patients who participated in the pilot study. Student's unpaired t-test and Chi-square test were used to properly classify and assess the patients' data and the time of onset, and the length of the block. Statistical significance was defined as a $P < 0.05$ and statistical high significance as a $P < 0.001$.

## Result

65 patients were included in our study and 5 patients were excluded for not following inclusion criteria. Demographic data such as age, sex, weight and duration of surgery between two groups were comparable. The request for first rescue analgesic was significantly earlier in Group N than Group D. The mean total consumption of intravenous paracetamol as rescue analgesia in the postanesthesia care unit in the first 24 hours postoperatively was significantly decreased in group D compared to group N.(table 1)

VAS.R measured showed significant reduction in both groups up to 4 hrs but VAS started to increase significantly after 4 hrs in N group compared to D group. There was no significant changes in VAS.M in both study group postoperatively.(fig 3,4)There was a significant decrease in HR and MAP throughout the intraoperative period, in group D compared to group N which was statistically significant.(fig 1,2) HR and MAP in postoperative period in both group were comparable.

**Table 1: Post-operative pain profile**

| Variable | Group D (n=30) mean±sd | Group N (n=30) mean±sd | P value |
|---|---|---|---|
| Time to first analgesic request(hour) | 7.12 ± 2.28 | 4.46 ± 3.24 | <0.001 |
| Paracetamol consumption(gm) | 2.9 ±0.68 | 3.8 ±0.25 | <0.001 |

**Table 2: Complications**

| Variable | Group D (n=30) | Group N (n=30) | P- value |
|---|---|---|---|
| PONV(n) | 5 | 8 | 0.263 |
| Bradycardia(n) | 4 | 3 | 0.228 |
| Hypotension(n) | 4 | 3 | 0.381 |

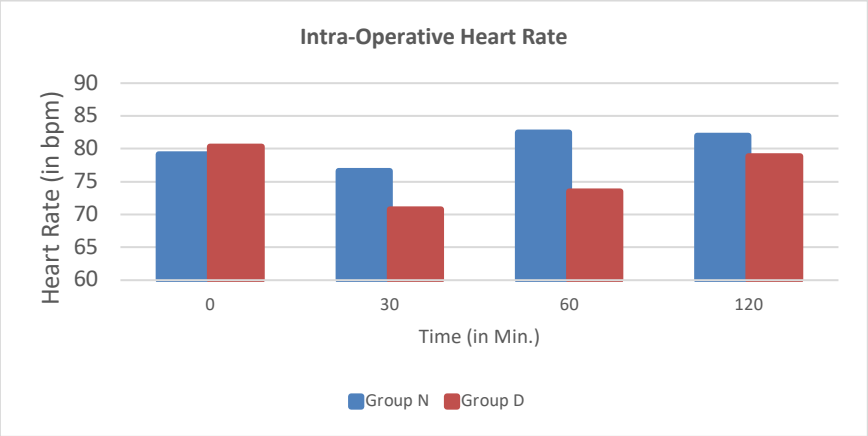


**Figure 1: Intraoperative changes in heart rate in studied group**

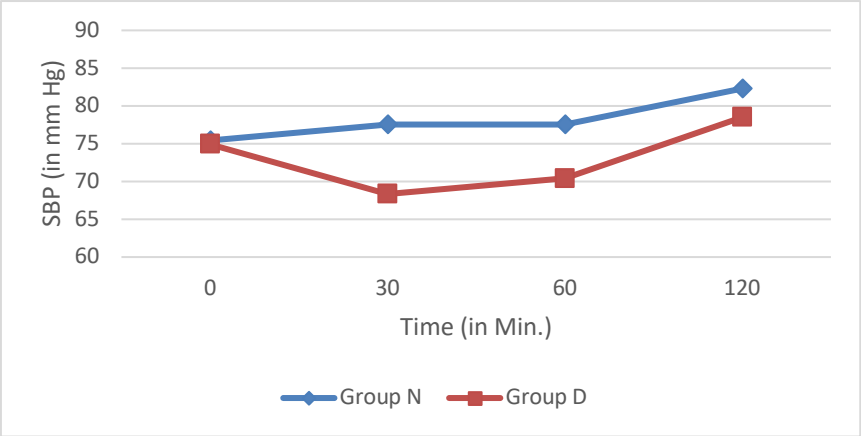


**Figure 2: Intraoperative changes in MABP in studied group**

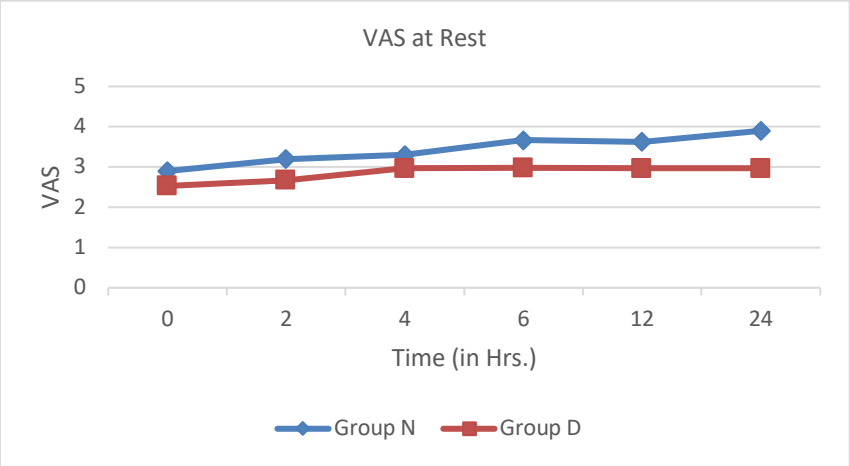


**Figure 3: VAS at rest**

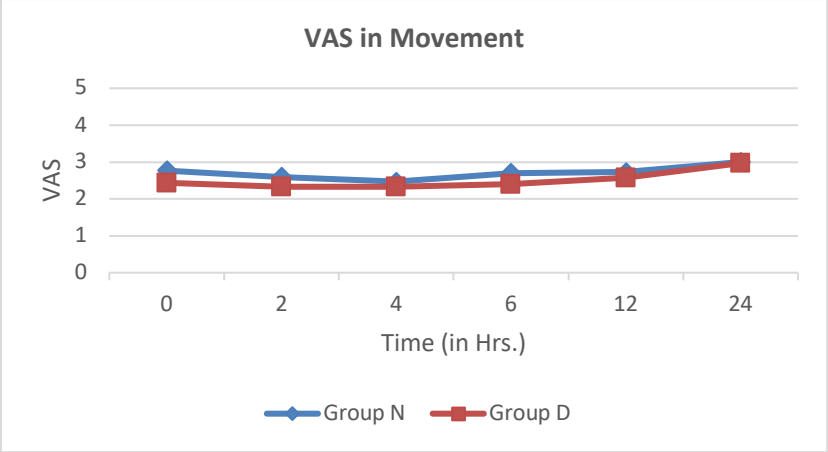


**Figure 4: VAS in movement**

Regarding adverse effects noted in the first 24 hours postoperatively5 patients in group D and 8 patients in group N had postoperative nausea and vomiting. There was no significant difference in the incidence of other postoperative complications like, bradycardia and hypotension between the two groups. (Table 2)

## Discussion

Our study's findings demonstrated that, in contrast to nalbuphine, dexmedetomidine as an adjuvant to bupivacaine in paravertebral block caused sustained analgesia and postponed the first need for rescue analgesia in patients posted for MRM. Additionally, it resulted in a notable decrease in the overall amount of rescue analgesia used during the first 24 hours following surgery. In comparison to a placebo, Kairaluoma et al. [7] shown that a single dosage of PVB application reduces severe pain six hours after breast surgery at a statistically significant level. Local anaesthetic enters the dorsal ramus, sympathetic chain, and spinal nerves during paravertebral block. Because local anaesthetics are found in tiny bundles without a fascial coating, they can enter the spinal nerves. The selectivity (α2: α1) ratio of dexmedetomidine, a selective α2-adrenal receptor agonist, is 1600:1. It has a number of pharmacological characteristics, including anaesthetic sparing action and sedation without respiratory depression. We have compared dexmedetomidine and nalbuphine as an adjuvant in PVB because of its additional qualities, which include analgesia, anxiolysis and hemodynamic stability. In their study, Bicer et al. [8] concluded that adding dexmedetomidine to bupivacaine reduces postoperative pain scores and morphine consumption in thoracotomy patients receiving ultrasonography guided paravertebral blockade. Also, Hassan et al [9] found that addition of dexmedetomidine to paravertebral bupivacaine in patients undergoing thoracic surgeries provides more effective analgesia with improvement in post-operative pulmonary functions. Dutta et al [10] evaluated the role of dexmedetomidine when added to ropivacaine in the paravertebral block, found significant improvement of the duration of postoperative analgesia and decreased rescue analgesia consumption. In TAP block Chen et al, [11] has concluded that dexemedtomidine provided prolonged analgesia compared to fentanyl which was similar to our findings. Ahmed et al. [12] in their study concluded that both fentanyl and dexemedetomidine showed comparable efficacy in PVB in renal surgeries. We found similar finding in our studies. But few studies have also shown morphine as superior to dexemedetomidine in PVB. Megha et al, [13] concluded that morphine is superior adjuvant to bupivacaine in PVB for modified radical mastectomy than dexmedetomidine. Also Ahmed et al, [14] found that as an adjunct to bupivacaine in PVB for MRM, morphine is superior to dexmedetomidine. In both above studies they have used higher dose (3mg) of morphine which could led to its superiority. Intraoperative mean arterial pressure and heart rate were significantly lower in the dexmedetomidine group than in the fentanyl group. This result was consistent with that of Mohamed et al. [15], who conducted thoracic PVB using either bupivacaine alone or bupivacaine with dexmedetomidine and discovered a significant decrease in intraoperative pulse rate and mean arterial pressure in the dexmedetomidine groups. Similar to our study, Omar et al. [16] found that while rescue analgesic consumption was lower and the time to first analgesic request was longer in the dexmedetomidine group.

## Conclusion

In patients scheduled for modified radical mastectomy with axillary dissection, the addition of an adjuvant such as dexmedetomidine to bupivacaine in PVB enhances the duration of analgesia and decreases the use of rescue analgesics with no significant adverse effects when compared to nalbuphine.

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