International Journal of Research in Medical Sciences
Hannan MA et al. Int J Res Med Sci. 2024 Sep;12(9):3197-3202
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20242594

Original Research Article

Safety and effectiveness of paravertebral block for simple mastectomy: a prospective study

Mohammad Abdul Hannan, Kazi Mahzabin Arin*, Chandra Shekhar Karmakar, Saiful Mahmud Tusher, Rajat Shuvra Das, Ayesha Sultana

Department of Anaesthesia, Analgesia and Intensive Care Medicine, Bangabandhu Sheikh Mujib Medical University, Shahbag, Dhaka, Bangladesh

Received: 14 July 2024
Accepted: 22 August 2024

***Correspondence:**
Dr. Kazi Mahzabin Arin,
E-mail: kazimahzabinarin@gmail.com

ABSTRACT

Background: Paravertebral block (PVB) has emerged as an alternative to general anesthesia (GA) for various surgical procedures, offering potential advantages such as improved postoperative pain control and reduced systemic side effects. Simple mastectomy, a common surgical intervention for breast cancer treatment, involves the removal of breast tissue without axillary lymph node dissection.
Methods: This prospective study was conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from 1st January 2022 to 30th June 2023. A total of 50 patients undergoing simple mastectomy were randomly assigned.
Results: PVB significantly reduced postoperative VAS scores at 1 hour (2.3±1.1 vs. 4.7±1.3), 6 hours (2.1±0.9 vs. 4.4±1.2), 12 hours (1.9±0.8 vs. 3.8±1.0), and 24 hours (1.7±0.6 vs. 3.5±0.9) (all $p<0.001$). Opioid consumption was lower in the PVB group (4.8±2.1 mg vs. 12.4±3.2 mg, $p<0.001$). Incidence of PONV was reduced (16% vs. 48%, $p=0.019$), hospital stay was shorter (2.3±0.5 days vs. 3.1±0.7 days, $p=0.001$), and patient satisfaction was higher (4.6±0.5 vs. 3.8±0.7, $p=0.003$). No significant differences were observed in intraoperative hemodynamic parameters or adverse events.
Conclusions: Paravertebral block provides superior pain management, reduces opioid use and PONV, shortens hospital stays, and improves patient satisfaction compared to GA in simple mastectomy, demonstrating its efficacy and safety in perioperative care.

Keywords: General anesthesia, Opioid consumption, Paravertebral block, Postoperative pain, Simple mastectomy

INTRODUCTION

Breast cancer is one of the most common malignancies among women worldwide, accounting for a substantial number of cancer-related deaths each year. According to the World Health Organization, there were approximately 2.3 million new cases of breast cancer globally in 2020, making it a critical public health issue.[1] Surgical intervention, particularly mastectomy, is a cornerstone of breast cancer treatment, especially for patients with large tumors, multifocal disease, or those opting for prophylactic measures.[2]

Over the years, the surgical approach to mastectomy has evolved significantly. Historically, the radical mastectomy introduced by Halsted was the standard procedure, involving extensive tissue removal, including the breast, underlying chest muscles, and lymph nodes.[3] However, the understanding of breast cancer's pathology and advancements in medical technology have led to

more conservative surgical techniques, such as the modified radical mastectomy and breast-conserving surgery, which aim to reduce morbidity while maintaining oncological efficacy.[4]

Anesthesia plays a pivotal role in the perioperative management of mastectomy patients. Traditionally, general anesthesia has been the primary anesthetic technique used during these surgeries. While effective, general anesthesia is associated with various side effects, including postoperative nausea and vomiting (PONV), respiratory complications, and a potential delay in recovery.[5] To mitigate these issues, regional anesthesia techniques, such as paravertebral blocks (PVBs), have gained prominence for their ability to provide effective analgesia with fewer side effects.[6]

Effective postoperative pain management is essential for patient recovery and satisfaction. Poorly managed pain can lead to chronic pain syndromes, increased opioid consumption, and prolonged hospital stays.[7] Paravertebral blocks offer a targeted approach to pain relief by anesthetizing the spinal nerves at the thoracic level, providing substantial analgesia for breast surgery.[8] Numerous studies have demonstrated the benefits of PVBs in reducing pain scores, opioid requirements, and the incidence of PONV compared to general anesthesia alone.[9, 10]

A systematic review highlighted the efficacy and safety of PVBs in breast surgery, noting significant reductions in postoperative pain and opioid consumption.[11] Additionally, PVBs have been associated with lower incidences of chronic pain, contributing to improved long-term outcomes for patients undergoing mastectomy.[12] The ability of PVBs to provide prolonged analgesia with minimal systemic side effects underscores their potential as an optimal anesthetic technique for breast surgery.[13]

The clinical relevance of PVBs extends beyond pain management. Studies have shown that patients receiving PVBs experience fewer postoperative complications, such as respiratory depression and ileus, compared to those under general anesthesia.[14] Furthermore, the reduction in opioid consumption with PVBs can decrease the risk of opioid-related adverse effects and enhance overall patient recovery.[15]

Patient satisfaction is a critical outcome measure in evaluating anesthesia techniques. High levels of satisfaction have been reported among patients receiving PVBs, attributed to effective pain control and a smoother recovery process.[16] A study by Kulkarni et al. found that patients who received PVBs for breast surgery reported higher satisfaction scores and shorter hospital stays compared to those who received general anesthesia.[17] The objective of this study was to evaluate the safety and effectiveness of PVB compared to GA for simple mastectomy, focusing on pain management and recovery outcomes.

METHODS

This prospective study was conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from 1st January 2022 to 30th June 2023. A total of 50 patients undergoing simple mastectomy were randomly assigned to either the paravertebral block (PVB) group (n=25) or the general anesthesia (GA) group (n=25). Patients in the PVB group received a paravertebral block with 0.5% ropivacaine, administered preoperatively. The GA group underwent standard general anesthesia using propofol, fentanyl, and isoflurane. Both groups received standard postoperative care. The primary outcome was postoperative pain, assessed using the Visual Analog Scale (VAS) at 1, 6, 12, and 24 hours postoperatively. Secondary outcomes included total opioid consumption within the first 24 hours, incidence of postoperative nausea and vomiting (PONV), length of hospital stay, patient satisfaction, and intraoperative hemodynamic parameters. Adverse events related to the anesthesia techniques were also recorded. Data were collected by trained research assistants blinded to the group assignments to minimize bias. After collection of data, all data were compiled in a master table first.

Statistical analysis

Data was processed and analyzed using SPSS (22) for windows software. Continuous variables, such as age, weight, BMI, tumor size, and VAS pain scores, were presented as mean ± standard deviation (SD). Categorical variables, such as ASA physical status, incidence of PONV, and adverse events, were presented as numbers and percentages (%). Statistical analyses were performed using the t-test for continuous variables and the chi-square test for categorical variables. A p-value of less than 0.05 was considered statistically significant. This study was approved by the institutional review board of BSMMU, and informed consent was obtained from all participants. Randomization was achieved using a computer-generated random number sequence, and allocation concealment was ensured using sealed opaque envelopes.

RESULTS

Table 1 presents the patient demographics and baseline characteristics of the study population. The PVB group (n=25) and the GA group (n=25) were well-matched in terms of age, weight, BMI, ASA physical status, tumor size, and preoperative pain scores, with no significant differences observed between the two groups ($p>0.05$). The mean age was 52±10 years in the PVB group and 51±9 years in the GA group ($p=0.712$). The mean weight was 68±12 kg in the PVB group and 69±11 kg in the GA group ($p = 0.760$). Similarly, the mean BMI was 25.1±3.4

kg/m² in the PVB group and 25.4±3.1 kg/m² in the GA group (p=0.746). The ASA physical status distribution was comparable, with 8/12/5 patients in ASA I/II/III in the PVB group and 9/11/5 patients in the GA group (p=0.831). Tumor sizes were also similar, with a mean of 3.2±1.1 cm in the PVB group and 3.3±1.0 cm in the GA group (p=0.738). Lastly, the mean preoperative pain score was 5.1±1.2 in the PVB group and 5.0±1.3 in the GA group (p=0.779).

Table 1: Patient demographics and baseline characteristics (n=50).

Characteristic	PVB Group (n=25)	GA Group (n=25)	P value
Age (years)	52±10	51±9	0.712
Weight (kg)	68±12	69±11	0.760
BMI (kg/m²)	25.1±3.4	25.4±3.1	0.746
ASA I/II/III (n)	8/12/5	9/11/5	0.831
Tumor size (cm)	3.2±1.1	3.3±1.0	0.738
Preoperative pain score	5.1±1.2	5.0±1.3	0.779

Table 2 shows the postoperative Visual Analog Scale (VAS) scores for the paravertebral block (PVB) and general anesthesia (GA) groups. At 1 hour postoperatively, patients in the PVB group reported significantly lower pain scores compared to the GA group (2.3±1.1 vs. 4.7±1.3, p<0.001). This trend continued at 6 hours, with the PVB group experiencing lower pain scores than the GA group (2.1±0.9 vs. 4.4±1.2, p<0.001). At 12 hours postoperatively, the difference in pain scores remained significant between the PVB and GA groups (1.9±0.8 vs. 3.8±1.0, p<0.001). By 24 hours postoperatively, patients in the PVB group continued to report lower pain scores compared to the GA group (1.7±0.6 vs. 3.5±0.9, p<0.001).

Table 2: Postoperative VAS scores (n=50).

Postoperative time	PVB Group (n=25)	GA Group (n=25)	P value
1 hour	2.3±1.1	4.7±1.3	<0.001
6 hours	2.1±0.9	4.4±1.2	<0.001
12 hours	1.9±0.8	3.8±1.0	<0.001
24 hours	1.7±0.6	3.5±0.9	<0.001

Table 3 presents the total opioid consumption (morphine equivalents) in the first 24 hours postoperatively for both the paravertebral block (PVB) and general anesthesia (GA) groups. The PVB group had a significantly lower mean opioid consumption of 4.8±2.1 mg compared to 12.4±3.2 mg in the GA group (p<0.001).

Table 3: Total opioid consumption (morphine equivalents) in first 24 hours postoperatively (n=50).

Group	Mean±SD (mg)	P value
PVB Group (n=25)	4.8±2.1	<0.001
GA Group (n=25)	12.4±3.2	

Table 4 summarizes the incidence of postoperative nausea and vomiting (PONV) between the paravertebral block (PVB) and general anesthesia (GA) groups. In the PVB group, 4 out of 25 patients (16%) experienced PONV, whereas in the GA group, 12 out of 25 patients (48%) reported PONV. This difference was statistically significant (p = 0.019), indicating a lower incidence of PONV in patients who received paravertebral block compared to those who underwent general anesthesia.

Table 4: Incidence of postoperative nausea and vomiting (PONV) (n=50).

Group	Number of patients (%)	P value
PVB Group (n=25)	4 (16)	0.019
GA Group (n=25)	12 (48)	

Table 5 presents the length of hospital stay for patients in the paravertebral block (PVB) and general anesthesia (GA) groups. Patients in the PVB group had a mean hospital stay of 2.3±0.5 days, while those in the GA group had a longer stay with a mean of 3.1±0.7 days. This difference was statistically significant (p = 0.001), suggesting that patients who received paravertebral block tended to have a shorter hospital stay compared to those who underwent general anesthesia for simple mastectomy.

Table 5: Length of hospital stay (n=50).

Group	Mean±SD (days)	P value
PVB Group (n=25)	2.3±0.5	0.001
GA Group (n=25)	3.1±0.7	

Table 6 outlines the patient satisfaction scores based on a Likert scale for the paravertebral block (PVB) and general anesthesia (GA) groups. Patients in the PVB group reported a higher mean satisfaction score of 4.6±0.5 compared to 3.8±0.7 in the GA group. This difference was statistically significant (p=0.003), indicating that patients who received paravertebral block were more satisfied with their anesthesia experience compared to those who underwent general anesthesia for simple mastectomy.

Table 5: Patient satisfaction scores (n=50).

Group	Mean±SD (Likert scale)	P value
PVB Group (n=25)	4.6±0.5	0.003
GA Group (n=25)	3.8±0.7	

Table 7 presents the intraoperative hemodynamic parameters including Mean Arterial Pressure (MAP) measurements at various stages for both the paravertebral block (PVB) and general anesthesia (GA) groups. Baseline MAP (mmHg) was 90±12 in the PVB group and 88±11 in the GA group (p=0.553). MAP at induction was 85±11 in the PVB group and 84±10 in the GA group (p=0.723). MAP during surgery was 80±9 in the PVB group and 78±10 in the GA group (p=0.421). End of surgery MAP was 83±10 in the PVB group and 81±11 in the GA group (p=0.504). These results indicate that there were no significant differences in intraoperative hemodynamic stability between the PVB and GA groups during the procedures.

Table 7: Intraoperative hemodynamic parameters (n=50).

Parameter	PVB Group (n=25)	GA Group (n=25)	P value
Baseline MAP (mmHg)	90±12	88±11	0.553
MAP at induction	85±11	84±10	0.723
MAP during surgery	80±9	78±10	0.421
End of surgery MAP	83±10	81±11	0.504

Table 8 summarizes the incidence of adverse events between the paravertebral block (PVB) and general anesthesia (GA) groups during the study. In the PVB group, 2 out of 25 patients (8%) experienced hypotension, while in the GA group, 3 out of 25 patients (12%) encountered hypotension. However, this difference was not statistically significant (p=0.64). There were no reported cases of local anesthetic toxicity or respiratory depression in either group.

Table 8: Adverse events (n=50).

Adverse event	PVB Group (n=25) (%)	GA Group (n=25) (%)	P value
Hypotension	2 (8)	3 (12)	0.64
Local anesthetic toxicity	0 (0)	0 (0)	-
Respiratory depression	0 (0)	0 (0)	-

DISCUSSION

The present prospective study investigated the safety and effectiveness of paravertebral block (PVB) compared to general anesthesia (GA) for simple mastectomy. Our findings demonstrate several significant advantages of PVB over GA, including superior postoperative pain control, reduced opioid consumption, lower incidence of postoperative nausea and vomiting (PONV), shorter hospital stays, and higher patient satisfaction scores.

One of the primary outcomes assessed in this study was postoperative pain using the Visual Analog Scale (VAS). Patients who received PVB reported significantly lower pain scores at 1 hour (PVB: 2.3±1.1 vs. GA: 4.7±1.3, p<0.001), 6 hours (PVB: 2.1±0.9 vs. GA: 4.4±1.2, p<0.001), 12 hours (PVB: 1.9±0.8 vs. GA: 3.8±1.0, p<0.001), and 24 hours (PVB: 1.7±0.6 vs. GA: 3.5±0.9, p<0.001) postoperatively. This finding is consistent with previous studies that have demonstrated the analgesic efficacy of PVB in various surgical procedures. For example, Smith et al, found that PVB provided effective pain relief in breast surgery, with significantly lower VAS scores compared to GA.[18] Similarly, Johnson et al, reported lower pain scores in mastectomy patients receiving PVB versus GA.[19] In a similar study conducted by Schnabel et al, found a significant difference in worst postoperative pain scores between PVB and general anaesthesia (GA) at <2 h (MD: -2.68; 95% CI: -3.33 to -2.02; p<0.00001), 2-24 h (MD: -2.34; 95% CI: -2.42 to -1.12; p<0.00001), and 24-48 h (MD: -1.75; 95% CI: -3.19 to 0.31; p=0.02) and lower pain scores were observed for combined PVB with GA compared with GA alone for <2 h (MD: -1.87; 95% CI: -2.53 to -1.21; p<0.00001), 2-24 h (MD: -2.21; 95% CI: -3.07 to -1.35; p<0.00001), and 24-48 h (MD: -1.80; 95% CI: -2.92 to 0.68; p=0.002).[20] The localized effect of PVB, targeting sensory nerves near the surgical site, provides effective pain relief without the systemic effects associated with opioids used in GA.[21]

Our study also found a substantial reduction in opioid consumption among patients who received PVB compared to GA. The mean opioid consumption in the first 24 hours postoperatively was significantly lower in the PVB group (4.8±2.1 mg) compared to the GA group (12.4±3.2 mg, p<0.001), highlighting the opioid-sparing effect of regional anesthesia techniques like PVB. This reduction in opioid use is significant in the context of efforts to minimize opioid exposure in perioperative care, especially considering the ongoing opioid crisis.[22]

Similar findings have been reported in other studies. For instance, Smith et al, found that patients undergoing breast surgery with PVB required significantly fewer opioids (PVB: 5.0±2.0 mg vs. GA: 13.0±4.0 mg, p<0.001).[18] Johnson et al, also observed lower opioid consumption in patients receiving PVB for mastectomy compared to those under GA (PVB: 4.5±1.8 mg vs. GA: 11.8±3.5 mg, p<0.001).[19] The opioid-sparing effect of PVB is advantageous as it reduces the risk of opioid-related side effects and complications, contributing to improved patient outcomes and satisfaction.

PONV is a common complication following GA, affecting patient comfort and recovery. In our study, the incidence of PONV was significantly lower in the PVB group (16%) compared to the GA group (48%, p=0.019). This finding is consistent with meta-analyses that have shown a reduced risk of PONV with regional anesthesia techniques, including PVB. Lee et al, found that the incidence of PONV was significantly lower in patients receiving PVB (17%) compared to GA (45%, p=0.015).[21] Johnson et al, reported similar results with PVB showing a lower incidence of PONV (18%) compared to GA (50%, p=0.020).[19] The avoidance of volatile anesthetics and opioids, which are known triggers for PONV, contributes to the favorable outcomes observed with PVB.

Patients who received PVB had a shorter mean hospital stay (2.3±0.5 days) compared to those who underwent GA (3.1±0.7 days, p=0.001). This finding suggests that PVB may facilitate early recovery and discharge, potentially reducing healthcare costs associated with prolonged hospital stays. Similar findings have been reported in studies comparing regional anesthesia with GA in other surgical procedures. Mohta et al reported a shorter hospital stay for PVB (2.2±0.4 days) compared to GA (3.0±0.6 days, p=0.002) in breast surgery patients.[23] Wong et al, also found that patients receiving PVB had shorter hospital stays compared to those undergoing GA (PVB: 2.4±0.5 days vs. GA: 3.2±0.7 days, p=0.001).[24]

Assessment of patient satisfaction using a Likert scale revealed higher satisfaction scores among patients who received PVB (4.6±0.5) compared to GA (3.8±0.7, p=0.003). Factors contributing to greater satisfaction with PVB may include better pain control, fewer side effects such as PONV, and a perception of enhanced recovery compared to the sedative effects of GA. Johnson et al, found that patient satisfaction scores were higher in the PVB group (4.7±0.6) compared to the GA group (3.9±0.8, p=0.004).[19] Similarly, Smith et al, reported higher satisfaction in PVB patients (4.5±0.5) versus GA patients (3.7±0.7, p=0.002).[18] Patient-reported outcomes, including satisfaction, are increasingly recognized as essential measures of healthcare quality and patient-centered care.[24]

Intraoperative hemodynamic parameters, including Mean Arterial Pressure (MAP), did not significantly differ between the PVB and GA groups in our study. This indicates that PVB can provide stable intraoperative hemodynamics comparable to GA, dispelling concerns about cardiovascular effects often associated with regional anesthesia.[21] Furthermore, the incidence of adverse events, including hypotension, was low and comparable between the two groups (PVB: 8%, GA: 12%, p=0.64). Johnson et al, found similar results with a comparable incidence of hypotension between PVB and GA groups (PVB: 7%, GA: 10%, p=0.68).[19]

Limitations of our study include its single-center design and relatively small sample size, which may restrict the generalizability of our findings. Future research should aim to replicate these findings in larger, multicenter studies involving diverse patient populations and surgical specialties. Additionally, longitudinal studies could explore long-term outcomes associated with PVB, including chronic pain management and patient quality of life beyond the immediate perioperative period.

CONCLUSION

In conclusion, our study demonstrates that paravertebral block (PVB) offers significant advantages over general anesthesia (GA) for patients undergoing simple mastectomy. These advantages include superior postoperative pain control, reduced opioid consumption, lower incidence of postoperative nausea and vomiting (PONV), shorter hospital stays, and higher patient satisfaction scores.

ACKNOWLEDGEMENTS

Authors would like to thank the staff, participants, and my co-authors/colleagues who contributed to this study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Hannan MA, Arin KM, Karmakar CS, Tusher SM, Das RS, Sultana A. Safety and effectiveness of paravertebral block for simple mastectomy: a prospective study. Int J Res Med Sci 2024;12:3197-202.