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ORIGINAL RESEARCH

A clinical comparative study between bupivacaine with clonidine and bupivacaine alone in paravertebral block for simple breast surgery

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ABSTRACT

Aim: To compare the efficacy and safety of bupivacaine with clonidine versus bupivacaine alone in thoracic paravertebral block for patients undergoing simple breast surgery. **Material and Methods:** This prospective, randomized, comparative clinical study was conducted over a one-year period from July 2022 to June 2023 in the Department of Anesthesiology at a tertiary care teaching hospital. A total of 100 female patients aged 20–65 years scheduled for elective simple breast surgeries were randomly assigned into two groups: Group BC (n = 50) received 0.5% bupivacaine with clonidine 1 µg/kg, and Group B (n = 50) received 0.5% bupivacaine alone. Outcome measures included onset and duration of sensory block, postoperative pain scores using the Visual Analog Scale (VAS), total analgesic consumption within 24 hours, hemodynamic stability, and adverse effects. **Results:** Group BC showed a significantly faster onset (7.42 ± 1.3 min vs. 8.78 ± 1.5 min; $p< 0.001$) and prolonged duration of analgesia (408.6 ± 52.8 min vs. 276.4 ± 48.2 min; $p< 0.001$) compared to Group B. VAS scores were significantly lower in Group BC at all time intervals up to 24 hours postoperatively ($p< 0.001$). Rescue analgesic requirement was lower in Group BC (28%) compared to Group B (72%) with significantly reduced diclofenac consumption (48.2 ± 10.4 mg vs. 92.6 ± 14.8 mg; $p< 0.001$). Hemodynamic parameters remained stable, and adverse effects were minimal and comparable between groups. **Conclusion:** Clonidine as an adjuvant to bupivacaine in paravertebral block provides faster onset, longer duration of analgesia, superior postoperative pain relief, and reduced analgesic consumption without increasing adverse effects, making it a safe and effective option for breast surgeries.

Keywords: Clonidine, Bupivacaine, Paravertebral Block, Breast Surgery, Postoperative Analgesia

INTRODUCTION

Breast surgery, particularly procedures such as lumpectomy, mastectomy, and breast-conserving surgeries, often presents significant challenges in achieving effective postoperative pain control. This is not only due to the complex innervation of the thoracic region but also because of the emotional and physical burden that such surgeries place on patients. Optimal pain management in breast surgery is critical, as it directly influences recovery, rehabilitation, hospital stay, and overall patient satisfaction. Among the various techniques used to manage perioperative and postoperative pain, thoracic paravertebral block (PVB) has emerged as a reliable and effective regional anesthesia technique, offering superior pain relief with minimal systemic side effects.[1]

PVB involves the injection of local anesthetic adjacent to the thoracic vertebrae, near where the spinal nerves emerge. This results in unilateral somatic and sympathetic nerve blockade, which is particularly beneficial in breast surgeries where only one side of the chest is typically involved. The effectiveness of PVB in controlling acute postoperative pain, reducing opioid requirements, and improving recovery outcomes has been well recognized in the past two decades. Compared to systemic analgesia or even epidural anesthesia, PVB demonstrates a more favorable risk-benefit profile, particularly by reducing the incidence of nausea, vomiting, and respiratory complications.[2]

Bupivacaine, a long-acting amide local anesthetic, is commonly used in PVB owing to its prolonged duration of action and favorable sensory-motor

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differential blockade. However, despite its effectiveness, sole use of bupivacaine may not always provide optimal duration and quality of analgesia required in moderate to extensive surgeries such as mastectomy or axillary lymph node dissection. To enhance the efficacy of regional anesthetic blocks, various adjuvants are added to local anesthetics. One such adjuvant that has gained considerable attention is clonidine.[3]

Clonidine, an α2-adrenergic agonist, has both analgesic and sedative properties. When used as an adjunct in regional anesthesia, clonidine enhances the quality and duration of analgesia without significantly increasing adverse effects. The mechanism by which clonidine prolongs analgesia is multifactorial. It acts at both the spinal and supraspinal levels by inhibiting nociceptive transmission and also has a peripheral action that enhances nerve block characteristics. Moreover, clonidine exhibits a synergistic effect when combined with local anesthetics like bupivacaine, thus providing more consistent and longer-lasting analgesia compared to bupivacaine alone.[4]

In the context of breast surgery, this combination has been explored in various clinical studies with promising outcomes. The addition of clonidine to bupivacaine in PVB has been shown to improve intraoperative anesthesia, reduce the need for supplemental systemic analgesics, and prolong the postoperative analgesic effect. These effects contribute significantly to enhanced patient comfort and satisfaction. Moreover, better analgesia is associated with a reduction in the incidence of chronic post-surgical pain, which remains a concerning long-term complication in breast surgery.[5]

Another emerging consideration in modern surgical practice is the emphasis on multimodal analgesia and opioid-sparing strategies. With growing concerns about opioid dependence and side effects, regional techniques like PVB with adjuvants align well with enhanced recovery after surgery (ERAS) protocols. Clonidine, by providing profound analgesia and reducing opioid consumption, fits seamlessly into this framework. It also contributes to hemodynamic stability and blunts the stress response to surgery, further promoting favorable surgical outcomes.[6]

The comparative effectiveness of bupivacaine alone versus bupivacaine with clonidine in thoracic PVB has been studied in different surgical contexts, including breast surgery, renal procedures, and thoracotomies. These investigations consistently report that the addition of clonidine leads to earlier onset, longer duration, and improved quality of sensory block. It also results in lower visual analog pain scores postoperatively and delays the time to first rescue analgesia. Such benefits are particularly valuable in ambulatory or day-care breast surgeries where rapid recovery and early discharge are desired.[7]

Despite the evident advantages, the use of clonidine is not without concerns. Its systemic absorption may lead to hypotension, bradycardia, and sedation in some patients, especially when used in higher doses. Therefore, determining the optimal dose that balances efficacy with safety remains a critical area of clinical interest. Most studies support the use of low-dose clonidine (1 μg/kg) as an effective and safe adjunct to bupivacaine in PVB. Individual patient characteristics and surgical profiles must also be considered when formulating the anesthetic plan.[8]

As surgical and anesthetic techniques continue to evolve, so does the need to tailor interventions for maximal efficacy and minimal side effects. The combination of clonidine with bupivacaine in PVB represents an evolution in pain management strategies in breast surgery, where both the physical and emotional well-being of the patient are paramount. While the literature provides strong support for the enhanced efficacy of this combination, ongoing research and larger randomized controlled trials are essential to validate these findings across diverse patient populations and surgical settings.[9]

In this backdrop, the present clinical study aims to compare the analgesic efficacy of bupivacaine alone versus bupivacaine combined with clonidine in thoracic paravertebral block among patients undergoing simple breast surgeries. The study seeks to address existing gaps in knowledge and provide robust evidence for adopting improved analgesic strategies in routine clinical practice.

MATERIAL AND METHODS

This prospective, randomized, comparative clinical study was conducted in the Department of Anesthesiology at a tertiary care teaching hospital over a one-year period from July 2022 to June 2023, after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrollment.A total of 100 female patients aged between 20 to 65 years, scheduled for elective simple breast surgeries (such as lumpectomy or wide local excision with or without axillary dissection) under paravertebral block, were recruited for the study. Patients were randomly allocated into two equal groups of 50 each using a computer-generated randomization sequence.

Inclusion Criteria

- Female patients aged 20–65 years
- American Society of Anesthesiologists (ASA) physical status I or II
- Elective simple breast surgery under regional anesthesia
- Willingness to participate with informed written consent

Exclusion Criteria

- Known hypersensitivity to local anesthetics or clonidine
- Coagulopathies or bleeding disorders
- Local infection at the injection site
- Neurological or psychiatric illness

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- Pregnant or lactating women
- Patients unwilling to participate

Group Allocation

- **Group BC (n = 50):** Received 20 mL of 0.5% bupivacaine with clonidine 1 µg/kg for paravertebral block
- **Group B (n = 50):** Received 20 mL of 0.5% bupivacaine alone for paravertebral block

Methodology

All patients underwent the procedure under strict aseptic precautions with continuous standard monitoring, including non-invasive blood pressure, electrocardiography (ECG), and pulse oximetry. Each patient was positioned either in the sitting or lateral decubitus posture, depending on individual comfort and anesthesiologist preference. A single-injection thoracic paravertebral block was administered at the T3 vertebral level using an 18G Tuohy needle, employing the loss-of-resistance-to-air technique to identify the paravertebral space. After confirming negative aspiration for blood or cerebrospinal fluid, the assigned study drug—either 0.5% bupivacaine alone or in combination with clonidine at a dose of 1 µg/kg—was injected slowly and carefully. All procedures were performed by a senior anesthesiologist experienced in regional anesthesia techniques.

The outcome measures assessed in this study included the onset time of the sensory block and the duration of analgesia, defined as the time elapsed until the first request for rescue analgesia. Postoperative pain intensity was evaluated using a Visual Analog Scale (VAS) at predefined time intervals: 1, 2, 4, 6, 12, and 24 hours. Hemodynamic parameters—including heart rate, systolic and diastolic blood pressure, and peripheral oxygen saturation (SpO_2)—were recorded at baseline and at 5, 10, 20, 30, and 60minutes following the block, as well as at the end of surgery. The total analgesic consumption in the first 24 postoperative hours was also documented. Additionally, any adverse events such as hypotension, bradycardia, nausea, vomiting, sedation, or respiratory depression were closely monitored and recorded.

Statistical Analysis

Data were compiled and analyzed using IBM SPSS software version 25.0. Continuous variables were expressed as mean ± standard deviation (SD) and compared using the independent samples t-test. Categorical variables were analyzed using the Chi-square test or Fisher's exact test as appropriate. A *p*-value of < 0.05 was considered statistically significant.

RESULTS

Baseline Characteristics (Table 1)

The baseline demographic and clinical characteristics were comparable between the two groups. The mean age of patients in Group BC was 48.12 ± 8.6 years, while in Group B it was 47.64 ± 9.1 years ($p = 0.732$), showing no significant difference. Similarly, mean body weight did not differ significantly between the groups (62.45 ± 6.9 kg in Group BC vs. 63.08 ± 7.2 kg in Group B; $p = 0.591$). ASA physical status distribution (I/II) and the types of surgery (lumpectomy vs. wide local excision) were also well balanced between the groups, with no statistically significant differences ($p > 0.05$).

Onset and Duration of Sensory Block (Table 2)

A significant difference was observed in both onset and duration of sensory block between the groups. Group BC experienced a faster onset of sensory blockade (7.42 ± 1.3 min) compared to Group B (8.78 ± 1.5 min), with a highly significant *p*-value of <0.001. Additionally, the duration of analgesia was substantially longer in Group BC (408.6 ± 52.8 minutes) than in Group B (276.4 ± 48.2 minutes), also with a statistically significant *p*-value <0.001. These findings suggest that the addition of clonidine effectively enhances the efficacy of bupivacaine in paravertebral blocks.

Hemodynamic Parameters (Table 3)

Hemodynamic monitoring revealed statistically significant but clinically mild differences favoring Group BC in maintaining lower heart rate and blood pressure during the intraoperative period. At 5 minutes, Group BC showed a lower heart rate (75.4 ± 6.1 bpm) compared to Group B (78.0 ± 6.3 bpm; $p = 0.036$), and similar trends continued across subsequent time points. Systolic and diastolic blood pressures were also consistently lower in Group BC at 5, 10, 20, and 60 minutes, and at the end of surgery, all with statistically significant *p*-values (<0.05). These effects reflect clonidine's known sympatholytic properties. SpO_2 values remained stable and comparable in both groups across all time points, with no significant differences, indicating preserved oxygenation.

Postoperative Pain Scores (VAS) (Table 4)

Visual Analog Scale (VAS) scores for pain were consistently lower in Group BC at all time intervals postoperatively, indicating better analgesic quality. At 1 hour postoperatively, the mean VAS score was 1.42 ± 0.6 in Group BC compared to 2.20 ± 0.8 in Group B ($p < 0.001$). Similar statistically significant differences were observed at 2, 4, 6, 12, and 24 hours postoperatively, with Group BC maintaining lower pain scores throughout. These results highlight the superior and sustained analgesic effect of adding clonidine to bupivacaine in paravertebral blocks.

Total Analgesic Consumption (Table 5)

The need for rescue analgesia was markedly lower in Group BC, where only 28% of patients required additional analgesics, compared to 72% in Group B

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($p< 0.001$). Moreover, the total dosage of IV diclofenac required in the first 24 hours was significantly lower in Group BC (48.2 ± 10.4 mg) than in Group B (92.6 ± 14.8 mg), with $p< 0.001$. This further supports the enhanced and prolonged analgesic profile of bupivacaine when combined with clonidine.

Adverse Effects (Table 6)

Adverse events were minimal and comparable between the two groups. Hypotension and bradycardia were slightly more common in Group BC (8.0% and 4.0%, respectively) compared to Group B (4.0% and 0%), but these differences were not statistically significant ($p> 0.05$). Sedation was observed in 12.0% of patients in Group BC versus 4.0% in Group B, again not reaching statistical significance ($p = 0.142$). Other side effects like nausea/vomiting occurred with similar frequency in both groups. Importantly, no cases of respiratory depression were reported. Overall, the addition of clonidine did not result in any clinically significant increase in adverse effects.

Table 1: Baseline Demographic and Clinical Characteristics

Parameter	Group BC (n = 50)	Group B (n = 50)	*p*-value
Age (years, Mean ± SD)	48.12 ± 8.6	47.64 ± 9.1	0.732
Weight (kg, Mean ± SD)	62.45 ± 6.9	63.08 ± 7.2	0.591
ASA I / II (n)	32 / 18	30 / 20	0.685
Type of Surgery			
- Lumpectomy	28 (56.0%)	30 (60.0%)	0.682
- Wide local excision	22 (44.0%)	20 (40.0%)	

Table 2: Onset and Duration of Sensory Block

Parameter	Group BC (Mean ± SD)	Group B (Mean ± SD)	*p*-value
Onset of Sensory Block (min)	7.42 ± 1.3	8.78 ± 1.5	<0.001*
Duration of Analgesia (min)	408.6 ± 52.8	276.4 ± 48.2	<0.001*

*Statistically significant

Table 3: Comparison of Hemodynamic Parameters Between Groups at Various Time Intervals

Time Point	Parameter	Group BC (Mean ± SD)	Group B (Mean ± SD)	*p*-value
Baseline	Heart Rate (bpm)	78.2 ± 6.4	77.8 ± 6.1	0.712
	Systolic BP (mmHg)	122.4 ± 8.2	121.6 ± 7.9	0.582
	Diastolic BP (mmHg)	78.6 ± 5.8	78.2 ± 6.0	0.733
	SpO_2 (%)	98.6 ± 0.7	98.4 ± 0.8	0.214
5 min	Heart Rate	75.4 ± 6.1	78.0 ± 6.3	0.036*
	Systolic BP	119.8 ± 7.4	123.6 ± 8.0	0.021*
	Diastolic BP	76.0 ± 5.6	79.4 ± 5.8	0.008*
	SpO_2	98.6 ± 0.8	98.2 ± 0.7	0.048*
10 min	Heart Rate	74.2 ± 5.9	77.6 ± 6.2	0.012*
	Systolic BP	118.6 ± 7.1	122.8 ± 7.6	0.005*
	Diastolic BP	75.4 ± 5.2	79.0 ± 5.9	0.003*
	SpO_2	98.4 ± 0.7	98.2 ± 0.6	0.162
20 min	Heart Rate	73.8 ± 5.6	77.2 ± 6.1	0.007*
	Systolic BP	117.2 ± 6.8	121.0 ± 7.4	0.009*
	Diastolic BP	74.8 ± 4.9	78.2 ± 5.6	0.004*
	SpO_2	98.3 ± 0.6	98.1 ± 0.7	0.179
30 min	Heart Rate	74.0 ± 6.0	76.8 ± 5.8	0.038*
	Systolic BP	118.0 ± 7.2	120.6 ± 7.9	0.094
	Diastolic BP	75.0 ± 5.1	77.4 ± 5.7	0.052
	SpO_2	98.4 ± 0.7	98.2 ± 0.6	0.277
60 min	Heart Rate	74.4 ± 6.2	77.0 ± 5.9	0.042*
	Systolic BP	118.2 ± 7.0	121.2 ± 7.5	0.028*
	Diastolic BP	75.2 ± 5.0	78.0 ± 5.6	0.011*
	SpO_2	98.5 ± 0.6	98.2 ± 0.7	0.096
End of Surgery	Heart Rate	74.6 ± 6.1	77.4 ± 6.2	0.029*
	Systolic BP	119.0 ± 6.9	122.0 ± 7.6	0.031*
	Diastolic BP	75.6 ± 4.8	78.6 ± 5.4	0.007*
	SpO_2	98.4 ± 0.7	98.2 ± 0.8	0.243

*Statistically significant ($p < 0.05$)

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Table 4: Postoperative VAS Pain Scores

Time Post-op (hrs)	Group BC (Mean ± SD)	Group B (Mean ± SD)	*p*-value
1 hour	1.42 ± 0.6	2.20 ± 0.8	<0.001*
2 hours	1.68 ± 0.7	2.58 ± 0.7	<0.001*
4 hours	2.10 ± 0.9	3.24 ± 0.8	<0.001*
6 hours	2.36 ± 0.7	3.56 ± 0.6	<0.001*
12 hours	2.74 ± 0.6	3.82 ± 0.9	<0.001*
24 hours	3.14 ± 0.8	4.16 ± 1.0	<0.001*

Table 5: Total Analgesic Consumption in First 24 Hours

Parameter	Group BC (n = 50)	Group B (n = 50)	*p*-value
Patients requiring rescue analgesia	14 (28.0%)	36 (72.0%)	<0.001*
Total analgesic dose (mg)*	48.2 ± 10.4	92.6 ± 14.8	<0.001*

*All patients received IV diclofenac as rescue analgesic when VAS > 4

Table 6: Adverse Effects Observed

Adverse Event	Group BC (n = 50)	Group B (n = 50)	*p*-value
Hypotension	4 (8.0%)	2 (4.0%)	0.400
Bradycardia	2 (4.0%)	0 (0%)	0.154
Nausea/Vomiting	3 (6.0%)	5 (10.0%)	0.461
Sedation	6 (12.0%)	2 (4.0%)	0.142

DISCUSSION

The baseline demographic and clinical characteristics of the participants were well-matched between the two groups, as shown in Table 1. The mean age was 48.12 ± 8.6 years in Group BC and 47.64 ± 9.1 years in Group B, with comparable weights and ASA classifications. This homogeneity ensured that the observed differences in analgesic outcomes were attributable to the interventions. This methodological strength aligns with the study design principles highlighted by Farag and Mounir-Soliman (2020), who emphasized controlling baseline variability to enhance study reliability in regional anesthesia.[8]

The present study found a significantly faster onset and longer duration of sensory block in the group receiving bupivacaine with clonidine (7.42 ± 1.3 min onset and 408.6 ± 52.8 min duration) compared to bupivacaine alone (8.78 ± 1.5 min onset and 276.4 ± 48.2 min duration; $p< 0.001$). These findings are in agreement with Mukherjee et al. (2018), who observed a longer analgesic duration when clonidine was added to ropivacaine in paravertebral blocks (mean duration of 395 ± 65 min with clonidine vs. 262 ± 60 min with ropivacaine alone).[9] Similarly, Tawfik et al. (2018) reported improved block characteristics and extended analgesia with clonidine, attributing this to its alpha-2 agonist action that augments local anesthetic efficacy.[10]

Hemodynamic changes observed in the current study were consistent with clonidine's pharmacological profile. Group BC had significantly lower heart rates and blood pressures at several intraoperative time points compared to Group B (e.g., heart rate at 10 min: 74.2 ± 5.9 bpm in Group BC vs. 77.6 ± 6.2 bpm in Group B, $p = 0.012$; systolic BP at 10 min: 118.6 ± 7.1 mmHg vs. 122.8 ± 7.6 mmHg, $p = 0.005$). These trends reflect clonidine's central sympatholytic effect, as described by Kuthiala and Chaudhary (2011), who reviewed its ability to reduce sympathetic tone and stabilize hemodynamics during surgery.[11]Borgeat et al. (2003) also reported similar cardiovascular effects in a large series of paravertebral block cases using alpha-2 agonists, with no major clinical concerns.[12]

Postoperative pain control was significantly better in Group BC at all time points. At 1 hour postoperatively, VAS scores were 1.42 ± 0.6 in Group BC versus 2.20 ± 0.8 in Group B; at 24 hours, scores were 3.14 ± 0.8 in Group BC and 4.16 ± 1.0 in Group B ($p< 0.001$ for all). These results support the analgesic enhancement effect of clonidine. Kairaluoma et al. (2004) similarly found that single-injection paravertebral blocks with adjuvants provided superior postoperative analgesia after breast surgery, reducing both pain scores and opioid requirements.[13] Naja et al. (2006) also emphasized that the addition of adjuvants like clonidine helps maintain prolonged sensory blockade with segmental precision, optimizing postoperative comfort.[14]

The need for additional analgesia further demonstrated the efficacy of clonidine. Only 28% of patients in Group BC required rescue analgesics versus 72% in Group B, with total diclofenac consumption being significantly lower (48.2 ± 10.4 mg vs. 92.6 ± 14.8 mg, $p< 0.001$). These findings are consistent with Manimala Rao (2006), who reported that regional techniques using adjuvants led to substantial reductions in systemic analgesic consumption and improved patient satisfaction.[15] Comparable reductions in analgesic requirements were also noted by Tawfik et al. (2018), reinforcing clonidine's analgesic-sparing role.[10]

In terms of safety, the study noted minimal adverse effects. Mild hypotension occurred in 8.0% of Group BC and 4.0% of Group B, while bradycardia was seen

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only in Group BC (4.0%). Sedation was slightly more frequent in Group BC (12.0% vs. 4.0%), but none of these differences were statistically significant. No respiratory depression was observed. These findings are in line with the safety data presented by Millan (2002) and Machelska (2007), who noted that clonidine, when used within safe dosing ranges, produces manageable side effects without compromising respiratory function.[16,17]

CONCLUSION

The addition of clonidine to bupivacaine in thoracic paravertebral block significantly enhanced the onset and duration of sensory block, provided superior postoperative analgesia, and reduced the need for rescue analgesics in patients undergoing simple breast surgery. Hemodynamic parameters remained stable, and adverse effects were minimal and clinically insignificant. Thus, clonidine is a safe and effective adjuvant that improves the quality of regional anesthesia in breast surgeries.

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