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Original Article

Comparative Study of Ropivacaine and Levobupivacaine given Paravertebrally in Breast Cancer Surgeries

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Abstract

Background: "Pain" an unpleasant sensory and emotional experience associated with any surgery. In modern medicine, pain control is the standard of care and right of a patient. Providing post-operative analgesia to the patient gives subjective comfort which helps in restoring the altered physiology and immunological response.

Aim: To assess the efficacy of injection ropivacaine with fentanyl and injection levobupivacaine with fentanyl given paravertebrally for providing intraoperative and post-operative analgesia in elective surgeries for breast cancer patients.

Study Design: Prospective randomized double blind study.

Materials and Methods: Our study included 90 patients aged between 18 and 60 years of ASA Grade I and II scheduled for elective breast cancer surgeries. Group A received general anesthesia (GA) along with injection ropivacaine 0.25% (0.3 ml/kg) with injection fentanyl 25 mcg in thoracic paravertebral space. Group B received GA along with injection levobupivacaine 0.25% (0.3 ml/kg) with injection fentanyl 25 mcg in thoracic paravertebral space. Group C received GA alone. For assessing the intraoperative hemodynamic stability and post-operative analgesia, various parameters were recorded.

Results: The result of our study demonstrated that thoracic paravertebral block (PVB) led to superior intraoperative hemodynamic stability and post-operative analgesia of higher degree when compared with GA alone in a patient undergoing breast cancer surgeries. Thoracic PVB with both A and B Groups produced comparable analgesia.

Conclusion: It was concluded that injection ropivacaine and injection levobupivacaine with fentanyl as an additive given paravertebrally during breast cancer surgeries under GA provides equal and effective hemodynamic stability and satisfactory post-operative analgesia of the same duration and substantially less incidence of any post-operative complication such as nausea and vomiting with reduced post-operative stay.

Key words: General anesthesia, Intraoperative hemodynamic stability, Post-operative analgesia, Thoracic paravertebral block

INTRODUCTION

Pain is a distressing feeling or an unpleasant sensory, and emotional experience often associated with intense or damaging stimuli like surgery.[1] Breast cancer is perhaps the most common cancer in women often requiring surgical intervention.[2] Breast cancer patients usually experiences post-operative pain in about 40% cases reflecting the inadequacy of conventional pain management.[3] Post-operative pain is considered a form of acute pain which is a combined constellation of severe unpleasant sensory, emotional and mental experience precipitated by surgical trauma leading to a cascade of autonomic, endocrine, metabolic physiologic and behavioral responses ultimately contributing to organ dysfunction, morbidity, increased hospital stay, and mortality.[4,5]

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General anesthesia (GA) is currently the standard technique used for surgical treatment of breast cancer and has failed to achieve adequate post-operative pain control.[6] With the advent of regional anesthesia using paravertebral block (PVB) in the last two decades as a part of "multimodal" approach to post-operative analgesia in breast surgeries has overall reduced the severity of chronic pain after mastectomy and reduction in post-operative nausea and vomiting and has also improved the potential for early discharge.[7]

Paravertebral analgesia (PVA)-based anesthetic approach reduced pain scores and opioid requirements along with reduced doses of inhalational anesthetics.[8,9]

A PVB for breast surgeries has gained popularity and considered a technique of choice for anesthesia and post-operative analgesia during breast surgeries. PVB reduces intraoperative drug requirement, and by reducing the post-operative pain and nausea and vomiting, it improves the post-operative recovery. The increasing popularity of PVA as an effective method of intra- and post-operative pain relief for breast surgery warrants more research on combinations of local anesthetics and adjunctive analgesics.[10] The addition of adjunctive analgesics, such as Fentanyl and clonidine to local anesthetics has been shown to enhance the quality and duration of sensory neural blockade, and decrease the dose of local anesthetic and supplemental analgesia. Consequently, smaller doses of local anesthetic may be used and non-toxic plasma levels achieved.[11]

There is little systematic research on the efficacy and tolerability of the addition of adjunctive analgesic agents in PVA.

This study assessed the efficacy of PVB used in conjunction with general anesthesia for better intraoperative hemodynamic stability and post-operative analgesia as compared to general anesthesia alone. We compared injection levobupivacaine and injection ropivacaine with adjuvant fentanyl using peripheral nerve stimulator in a single level thoracic PVB instead of multiple levels. Single level thoracic PVB would prevent overdose toxicity of local anesthetic agent and is safer than multiple levels.

Anatomy

The paravertebral space is a wedge shaped area with parietal pleura as anterolateral boundary; base is formed by the posterlateral aspect of vertebral body, the intervertebral disc and the foramen is the base, the superior costotransverse ligament (SCTL), which is located between the lower border of the transverse process above and the upper border of transverse process below, the internal intercostal membrane as the posterior boundary and is continuous with the intercostal space laterally. Within this space, the spinal root emerges from the intervertebral foramen and divides into dorsal and ventral rami. The sympathetic chain lies in the same fascial plane, just anterior to the intercostal nerve and communicates with it via the rami communicantes. This is the reason why PVB produces unilateral sensory, motor, and sympathetic blockade. Each space communicates superiorly and inferiorly across the heads and neck of the ribs with the spaces above and below. Interposed between the parietal pleura and the SCTL is the endothoracic fascia. The fascia divides the space into two compartments, anterior "extrapleural paravertebral compartment" and the posterior "subendothoracic paravertebral compartment." The nerves are located behind this fascia.[12]

MATERIALS AND METHODS

In this clinical prospective study 90 patients, ASA physical Status I and II, 18-60 years scheduled for unilateral breast surgery were enrolled randomly in three groups after obtaining institutional ethics committee approval. Patients with pre-existing respiratory diseases such as obstructive pulmonary disease, coexisting cardiovascular diseases, infection at the site of thoracic PVB, pregnant and breast feeding females, psychiatric disorders, severe obesity (body mass index >35 kg/m^2), H/o allergy, and bleeding diathesis were excluded from the study.

Patients undergoing breast surgeries with PVB followed by GA and GA alone were randomly divided into three groups, each group containing 30 patients.

Group A

Patients in Group A received GA along with ropivacaine 0.3 ml/kg of 0.25% with fentanyl 25 mcg in thoracic PVB.

Group B

Patients in Group B received GA along with levobupivacaine 0.3 ml/kg of 0.25% with fentanyl 25 mcg in thoracic PVB.

Group C

Patients in Group C received GA alone.

During the pre-operative day patients were thoroughly explained about the procedures to be undertaken and were made well conversant with the visual analog scale (VAS) for post-operative pain assessment and their consent was taken. Patients were premedicated with alprazolam 0.25 mg on the night before the surgery. In the operation theatre, I/V access was established, and standard monitors were attached. Baseline vital parameters such as pulse rate, noninvasive blood pressure, respiratory rate, peripheral arterial oxygen saturation,

and electrocardiogram were recorded. Now, in the sitting position anatomical landmarks were marked. The spinous process of T4 vertebra was identified and local infiltration of 2% lignocaine given at 2-2.5 cm lateral to mid-point of T4 spinous process. Peripheral nerve stimulator with 5 cm needle was inserted perpendicular to the skin, and at around 4-4.5 cm distance the transverse process of the thoracic vertebra was contacted. The needle was withdrawn and redirected caudally below the transverse process not more than 1-1.5 cm deeper than the initial insertion, and motor stimulation of intercostal muscles was noted. Best motor stimulation was achieved with minimum current strength. Although peripheral nerve was initially setted at 2.5 mA and was repositioned till the best stimulation was achieved with minimum current strength, i.e., 0.5-0.8 mA. After careful aspiration, the drug was injected in the paravertebral space, and after few minutes the sensation was tested by pin prick method at the surgical site. After conforming sensory anesthesia following PVB the patient was induced with injection propofol at the rate of 2 ml/kg with injection succinylcholine at the rate of 1.5 ml/kg to facilitate tracheal intubation and the patient was maintained with isoflurane and nitrous oxide plus oxygen (60:40). Neuromuscular blockade was achieved using vecuronium 0.04 mg/kg. The patients underwent intraoperative hemodynamic monitoring at an interval of 30 min and then postoperatively every 3 h for 24 h.

Rescue analgesia with injection diclofenac 75 mg was given postoperatively when VAS score reached >3 in each group.

Statistical Analysis

Descriptive statistics were used to describe the baseline characteristics. Numerical data were expressed as a mean and standard deviation. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the relation between qualitative variables. For quantitative data, comparison between the groups was done using independent sample *t*-test. For descriptive purposes, *P* value differences <0.05 were noted in the tables. All analysis was conducted using SPSS version.

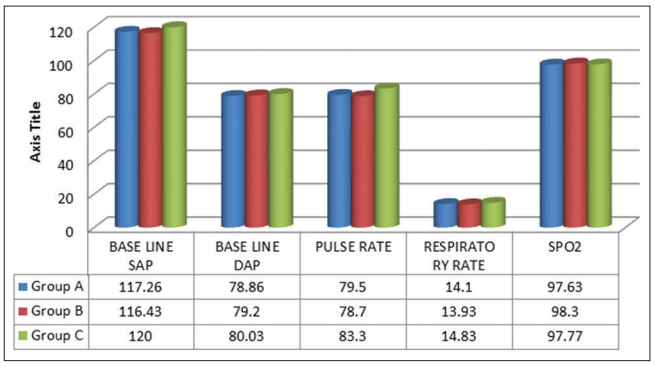
OBSERVATION AND RESULTS

Pre-operative vital parameters were similar when the groups were compared. There were no statistically significant differences between the three groups in terms of pre-operative parameter (Table1 and Graph 1).

In terms of hemodynamic stability, Group A and B were comparable ($P > 0.005$) which is not significant whereas *P* value for Group A and C as well as Group B and C was <0.005 which is significant. This shows that Group A and B were hemodynamically stable than Group C (Table 2 and Graph 2).

When time of rescue analgesia was compared in three groups, it showed that mean duration of analgesia in Group A and Group B was 42.53 ± 13.27 h and 46.4 ± 13.27 h, respectively, which is statistically insignificant whereas in Group C it was 4 h (Table 3 and Graph 3).

When doses of I/V diclofenac were compared it showed that maximum cumulative dose of it was required in Group C, i.e., 635 mg as compared to Group A and Group B which were 185 mg and 160 mg, respectively.

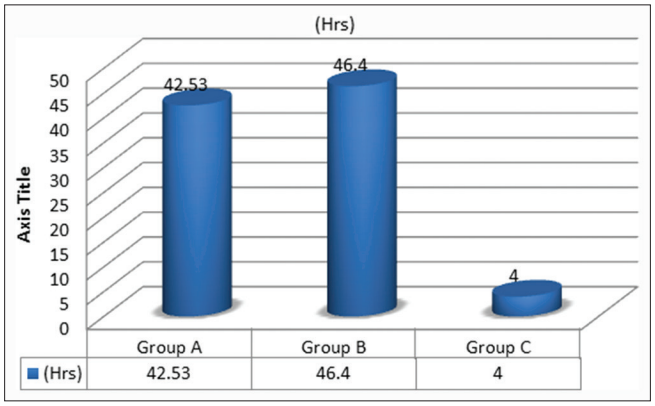


	BASE LINE SAP	BASE LINE DAP	PULSE RATE	RESPIRATORY RATE	SPO2
Group A	117.26	78.86	79.5	14.1	97.63
Group B	116.43	79.2	78.7	13.93	98.3
Group C	120	80.03	83.3	14.83	97.77

Graph 1: Comparison of pre-operative base line hemodynamic parameters

	sbp30min	dbp30min	HEART RATE AT 30 MIN	sbp60min	dbp60min	HEART RATE AT 60min	sbp90min	dbp90min	HEART RATE AT 90min
Group A	119.83	74.66	70.63	111.23	73.3	69.13	108.3	73.23	68.87
Group B	117	74.83	73.26	111.5	65.1	69.1	111.36	74.1	68.86
Group C	128.73	83.53	86.9	132.1	85.87	87.4	131.3	86.87	89.53

Graph 2: Intraoperative hemodynamic parameters



	Group A	Group B	Group C
(Hrs)	42.53	46.4	4

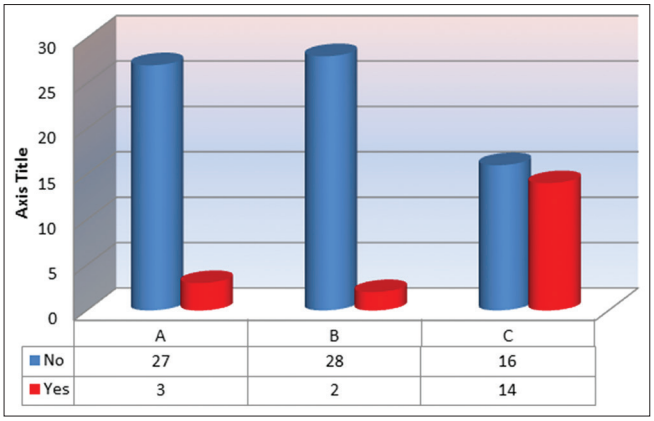
Graph 3: Comparison between time of rescue analgesia

The incidence of post-operative nausea and vomiting (PONV) in Group A and B was 10% and 6.9%, respectively, whereas Group C it was 48.3% (Table 4 and Graph 4).

Both the Group A and B provided acceptable analgesia as shown by the pain scores by Mann–Whitney test. Data for assessment of pain in Group A and B were statistically not significant at VAS 4, 8, 12, 24, 36, 48, and 72 h (Table 5). There were no complications attributable to post-operative pain.

DISCUSSION

Several surveys have demonstrated that post-operative pain management is still inadequate. Approximately, 40% of women after breast surgery complain about acute pain with pain scores above 5 reflecting inadequacy of conventional pain management.[3] Insufficiently, controlled post-operative pain may delay the recovery further leading to persistent chronic pain with prolonged hospital stay and also extended medical costs. With the advent of regional anesthesia using PVB in the last two decades as a part of "multimodal" approach for better post-operative recovery and pain control in breast surgeries has overall reduced the severity of chronic pain after mastectomy and reduction in post-operative nausea and vomiting.[7]



Graph 4: Incidence of post-operative nausea and vomiting

Several studies investigated the feasibility of PVB to improve post-operative pain relief after breast surgery. By analyzing these studies, it was observed that PVB in addition to GA or alone provides better post-operative analgesia, indicating that a perioperative PVB is a feasible and effective method for an improved post-operative pain treatment after breast surgery.[13] Two recent meta-analyses reported that a PVB provided same pain relief compared with thoracic epidural analgesia after thoracotomy.[9,14]

Another important issue for a successful PVB may be the appropriate drug choice, dose and administration technique. By analyzing the included data of the present meta-analysis, there was variability in drug concentration, combination with different additives, and type of local anesthetics administered into the paravertebral space. Bupivacaine and ropivacaine 0.5% were most commonly administered for MPVB or SPVB, while levobupivacaine or ropivacaine 0.25% was administered as a bolus and continuous infusion via a paravertebral catheter. Hura *et al.* recently randomized 70 patients scheduled for mastectomy

Table 1: Comparison of pre-operative base line hemodynamic parameter

Pre-operative parameter	Mean±SD		
	Group A	Group B	Group C
Basal SBP (mm Hg)	117.26±4.13	116.43±6.55	120±9.84
Basal DBP (mmHg)	78.86±2.44	79.2±3.38	80.03±3.5
Pulse rate (/min)	79.5±3.15	78.7±4.06	83.3±6.49
Respiratory rate (/min)	14.1±1.423	13.93±0.365	14.83±1.31
SPO_2 (%)	97.63±1.245	98.3±0.466	97.77±1.524

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SPO_2: Peripheral arterial oxygen saturation, SD: Standard deviation

Table 2: Comparison of intraoperative hemodynamic parameters

Parameters	Mean±SD		
	Group A	Group B	Group C
SBP at 30 min	119.83±8.437	117±7.54	128.73±8.851
DBP at 30 min	74.66±4.67	74.83±4.91	83.53±5.981
Heart rate at 30 min	70.63±6.594	73.26±5.91	86.9±7.567
SBP at 60 min	111.23±8.629	111.5±8.71	132.1±7.989
DBP at 60 min	73.3±5.51	65.1±10.97	85.87±5.329
Heart rate at 60 min	69.13±3.989	69.1±3.98	87.4±7.379
SBP at 90 min	108.3±8.54	111.36±7.03	131.3±5.22
DBP at 90 min	73.23±4.326	74.1±4.64	86.87±3.946
Heart rate at 90 min	68.87±5.794	68.86±5.79	89.53±4.967

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SD: Standard deviation

Table 3: Comparison between time of rescue analgesia

Time of rescue analgesia	*N*	Mean±SD (h)	Comparison between the groups
Group A	30	42.53±13.59	Group A versus Group C *P*<0.005 (significant)
Group B	30	46.4±13.27	Group B versus Group C *P*<0.005 (significant)
Group C	30	4±0	Group A versus B *P*=0.270 (not significant)

Table 4: Incidence of PONV

PONV	Groups		
	Number of patients (%)		
	A	B	C
No	27 (90.0)	28 (93.1)	16 (51.7)
Yes	3 (10.0)	2 (6.9)	14 (48.3)
Total	30 (100.0)	30 (100.0)	30 (100.0)

PONV: Post-operative nausea and vomiting

Table 5: Comparison of VAS score by Mann–Whitney test (mean rank)

Time interval (h)	Group A (mean rank)	Group B (mean rank)	Mann–Whitney *U*-test *Z* value	*P* value
4	30.50	30.50	0.000	*P*>0.05 (not significant)
8	30.50	30.50	0.000	*P*>0.05 (not significant)
12	29.72	31.28	−0.362	*P*=0.717 (not significant)
24	31.63	29.37	−0.531	*P*=0596 (not significant)
36	32.38	28.62	−0.892	*P*=0.373 (not significant)
48	30.93	30.07	−0.226	*P*=0.821 (not significant)
72	29.97	31.03	−0.269	*P*=0.788 (not significant)

VAS: Visual analog scale

to receive a single injection of ropivacaine 0.5% or bupivacaine 0.5% at the T4 level. Repeated assessment of the sensory blockade was performed at frequent intervals. Both drugs provided good analgesia, but ropivacaine was characterized by a more rapid onset, a large initial spread and a longer duration of the blockade.[15]

Many of the previous studies on PVB in breast surgery suffer from methodological errors: The study design is retrospective, samples are small, and randomization and blinding are either absent or inappropriate. Kairaluoma *et al.* used a single level injection at T3 using bupivacaine (0.3 ml/kg) or saline (2 ml). Patients who received bupivacaine needed less I/V opioid medication in the postanesthesia care unit and had less pain at rest after 24 h.[16] In an observer–blinded study Pusch *et al.* randomized 86 patients to receive either a single injection of bupivacaine 0.3 ml/kg at T4 or general anesthesia. Pain during movement was lower in the PVB group 1, 6, and 24 h after surgery.[17] Similar results were obtained in a randomized study by Klein *et al.* using a multilevel injection PVB at T1-T7.[18]

Naja *et al.* randomized 60 patients to receive either a PVB at T1-T5 using nerve stimulator guided technique or general anesthesia. Pain scores both at rest and during movement and consumption of analgesics were significantly lower in the PVB group during the first three post-operative days.[19]

There are several approaches to achieve the block. Both single and multilevel paravertebral injections have been reported to provide good analgesia.

Encouraged by the utility of nerve stimulator guidance in other peripheral nerve blocks, Wheeler *et al.* utilized nerve stimulation technique in performing PVB for breast surgery. They recommended twitching of the intercostal muscle at 0.4 mA intensity current as the stimulation end point for the block.[20] A similar technique was also reported by Lang *et al.* in 2002.[21]

Among the analgesic techniques aimed at patients undergoing breast surgeries, thoracic PVB combined with general anesthesia stands out for the good results and favorable risk–benefit ratio.

In this context, thoracic paravertebral injection of local anesthetics results in ipsilateral somatic nerve block including the posterior ramus in multiple contiguous thoracic dermatomes and is advocated as the technique of choice for analgesia in a patient undergoing breast surgeries.

Many local anesthetics and other adjuvant drugs are being investigated for use in this technique, to improve the quality of analgesia and reduce adverse effects. The most commonly administered local anesthetic used was 0.25-0.5% bupivacaine,[16,17,22-24] 2% lidocaine in one study,[25] while another tested a mixture of 2% lidocaine, 0.5% bupivacaine with epinephrine, fentanyl, and clonidine.[11] The addition of fentanyl (0.05%) was associated with nausea and vomiting, while clonidine resulted in hemodynamic changes (arterial hypotension).[11]

There was a significant difference in the levels of "worst pain during the post-operative period" between TPVB with GA compared with GA alone at <2 h. Data on the need for rescue analgesia were assessed in four studies.[11,23-25] Fewer patients required opioid during 0-24 h after surgery with TPVB and GA compared with GA alone. TPVB with GA group also required a lesser amount of morphine during the interval of 0-24 h.

In the current medical literature, there are no clinical trials comparing single level nerve stimulator guided thoracic PVB using injection ropivacaine 0.25% with fentanyl 25 mcg and injection levobupivacaine 0.25% with fentanyl 25 mcg in patients scheduled for various breast surgeries.

The results of our study also demonstrated that thoracic PVB resulted in superior post-operative pain relief when compared with GA alone. PVB using injection ropivacaine 0.25% with fentanyl 25 mcg and injection levobupivacaine 0.25% with fentanyl 25 mcg produced comparable analgesia which persisted for many hours in most of the patients. Group A and B showed the mean duration of analgesia of 42.53 h and 46.4 h, respectively, ($P > 0.005$) which is comparable. Hence, local anesthetic ropivacaine and

levobupivacaine are equally effective and provided the same duration of analgesia in PVB using nerve stimulator guided single level technique which is in accordance with the previous studies by Kairaluoma *et al.*, Klein *et al.,* and Naja *et al.*, as they also observed improved acute post-operative pain management.[16,18,19]

We were able to confirm these facts based on mean time of rescue analgesia in Group A and B which was statistically insignificant among the groups. Rescue analgesia was required in Group C at 4 h which means that patients in Group C needed earlier rescue analgesia. TPVB using ropivacaine 0.25% with fentanyl 25 mcg and levobupivacaine 0.25% with fentanyl 25 mcg produced superior and comparable post-operative pain relief compared to GA. In Group A, 70% of cases needed rescue analgesia in 48 h and in Group B, 63% of cases needed rescue analgesia in 48 h. In our study, 2 cases in Group A and 3 cases in Group B needed rescue analgesia at 72 h, so the duration of analgesia is up to 72 h in few cases.

We have used nerve stimulator guided single level technique which provides more patient comfort and lowers the need for sedation during the procedure, thereby improves the patient satisfaction than multilevel injection technique. Nerve stimulation has increased the safety and reliability of the block and hence, may contribute to its ever increasing applications in operative as well as nonoperative pain interventions.

However, on the other hand, inadvertent injection of a larger volume of local anesthetic is more risky than the multiple injections of small volume, but we have not noticed such complication in our study.

The incidence of PONV in Group A and B patients was relatively infrequent than Group C considering that the general risk of PONV in women undergoing breast surgery under general anesthesia is high, which was in accordance with Kairaluoma *et al.*,[22] Klein *et al.*,[18] and Naja *et al.*,[19] as they also found less nausea due to intense analgesia and low requirement of rescue analgesia in post-operative period as compared to control group.

PVB is technically easy to learn with a high success rate. Inadvertent vascular puncture, hypotension, epidural or intrathecal spread, pleural puncture, and pneumothorax are the recorded complications. However, no such complication occurred in our study.

CONCLUSION

It was concluded that combination of injection ropivacaine and injection levobupivacaine with fentanyl as an additive given paravertebrally during breast cancer surgeries under GA provides equal and effective hemodynamic stability and satisfactory post-operative analgesia of the same duration and substantially less incidence of any post-operative complication such as nausea and vomiting with reduced post-operative stay.

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