Original Article

Segmental thoracic spinal anesthesia versus general anesthesia for breast cancer surgery: A prospective randomized-controlled open-label trial

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Abstract

Background and Aims: Breast surgery is associated with moderate-to-severe postoperative pain, nausea, and vomiting. For this, neuraxial anesthesia might be a better alternative to general anesthesia (GA), providing superior analgesia, with higher patient satisfaction and lesser incidence of nausea vomiting. This randomized-controlled open-label trial was done to compare segmental spinal and GA for breast cancer surgery.

Material and Methods: The present study enrolled 56 female patients scheduled to undergo breast cancer surgery. They were randomly divided into two groups, group G (received standard GA) and group TS (received segmental thoracic spinal anesthesia with 0.5% isobaric levobupi vacaine at T5–T6 inter spaces). The primary objective of this study was patient satisfaction with the anesthetic technique, while secondary objectives were hemodynamic changes, perioperative complications, time of first rescue analgesic, total opioid consumption in first 24 h, and surgeon satisfaction score. Data were expressed as mean (SD) or number (%) as indicated and were compared using Chi-square, Fisher's exact, or Student's *t*test as appropriate.

Results: Patient in group TS had significantly higher satisfaction score median 5 (IQR 1) compared to patients in group G median 4 (IQR 3.5) ($P = 0.0001$). Nausea and vomiting were significantly higher in group G compared to group TS ($P = 0.01$). Mean time to rescue analgesia was 33.21 ± 7.48 min in group G as compared to 338.57 ± 40.70 in group TS and opioid consumption was also significantly lower in group TS (70.00 ± 27.38) as compared to group G (366.07 ± 59.40). There was no significant difference in hemodynamic parameters (except significantly lower heart rate at 15 min in group TS ($P = 0.001$) and surgeon satisfaction score between groups. Quality of postoperative analgesia was better in group TS.

Conclusion: Segmental thoracic spinal anesthesia technique provides better satisfaction with superior postoperative analgesia and fewer complications in patients undergoing breast cancer surgery compared to GA.

Keywords: Anesthetic technique, general anesthesia, isobaric levobupivacaine, segmental thoracic spinal anesthesia

Introduction

General anesthesia (GA) is considered to be the standard technique for breast cancer surgery. However, the associated higher stress response, higher incidence of nausea vomiting and increasing length of hospitalization demand for an alternative technique.[1] Regional anesthesia techniques can attenuate surgical stress response and provide better analgesia with reduction in postoperative opioid consumption. Additionally, direct protective action of local anesthetics on cancer cell migration has prompted anesthesiologists worldwide to adopt various regional anesthesia techniques.[2]

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Conventionally used regional anesthesia techniques for breast cancer surgery like thoracic epidural,[3] and thoracic paravertebral block,[4] are very effective but delayed onset of block, patchy sensory block and the large volume of local anesthetic used with the potential of local anesthetic toxicity are still concerning. Blocking of required dermatomes essential for the proposed surgery could be provided by thoracic segmental spinal anesthesia with an exceedingly low dose of local anesthetic. Patients have motor control over the legs, which decrease anxiety and exhibit a high level of satisfaction.

Few studies have assessed the efficacy of segmental thoracic spinal anesthesia in laparoscopic cholecystectomy and breast cancer surgery with axillary lymph node clearance concluding that the technique could be a potential alternative to GA.[5,6] Encouraged by the results of these studies, we had decided to study the feasibility of using segmental thoracic spinal anesthesia in the Indian subpopulation as the sole regional anesthetic technique for breast cancer surgery. We hypothesized that segmental thoracic spinal anesthesia could be a potential alternative to GA in patients undergoing breast cancer surgery. Patient satisfaction was our primary objective while hemodynamic changes, time to first rescue analgesic, total opioid consumption in first 24 h, peri-operative complications and surgeon satisfaction score were secondary objectives.

Material and Methods

The present prospective, open-label, randomized-controlled study was conducted in the department of anesthesiology and critical care at a tertiary care center after obtaining approval from institutional ethical committee (Certificate Ref No: F.1/Acad/MC/JU/18/14034) and informed written consent from patients. Fifty-six female patients aged between 20 and 65 years, belonging to American Society of Anesthesiologist (ASA) physical status I and II and scheduled for modified radical mastectomy (between March 2019 and January 2020), were enrolled. Exclusion criteria included were patient refusal, conditions contraindicating spinal anesthesia, inflammatory breast cancer, previous surgery for breast cancer except diagnostic lumpectomy, and body mass index above 35kg/m^2.

Preoperative evaluation and preparation were standardized. All patients were explained about both procedures (thoracic segmental spinal anesthesia and GA), pain scale (numeric rating scale (NRS)), and verbal rating scale (VRS) for patient satisfaction.

Randomization was done using computer-generated random number table and allocation concealment was done using sequentially numbered opaque sealed envelope that was opened on the day of surgery prior to induction. Patients were allocated into one of the two predefined groups (group TS and group G).

On arrival at the operating room, ASA standard monitoring including continuous electrocardiogram, noninvasive blood pressure, and pulse oximetry were attached and baseline vitals [heart rate (HR), mean arterial pressure (MAP), and peripheral oxygen saturation (SpO_2)] were recorded. Intravenous (IV) access was secured and Ringer's acetate solution was commenced at 10 mL/kg/h. Thereafter, according to the group, assigned patients underwent segmental thoracic spinal anesthesia or GA.

Patients enrolled in group TS received IV fentanyl 1μg/kg and IV Midazolam 0.02 mg/kg prior to placement of thoracic spinal block. Patient was placed in lateral decubitus position and under all aseptic precaution the skin of the puncture site (T5–T6) was infiltrated with 3 mL of 1% lignocaine. The puncture was performed via a median approach with a 27-G Quincke spinal needle (B Braun, Melsungen, AG). Once ligamentum flavum was pierced, the needle's stylet was removed and the hub was observed for the free flow of CSF. A maximum of two attempts was allowed to localize the spinal space. After confirming the free flow of clear CSF, a mixture of 1mL 0.5% isobaric levobupivacaine and 20μg of fentanyl (total volume 1.4mL) was injected. Patients were then placed in the supine position and the onset of sensory block [response to pinprick from the lower border of the clavicle (T2) to the inferior costal margin (T8)] was assessed at every 2 min. The block was considered as failed if the sensory block was not achieved in the required dermatome even after 10 min. Patients with failed block were administered standard GA and were excluded.

Patients enrolled in group G received GA. Premedication (IV fentanyl 2 μg/kg and IV midazolam 0.02 mg/kg) was administered and patients were pre-oxygenated with 6–8 L/min flow and 1.0 FiO_2 of oxygen for 3 min. Induction of anesthesia was done with IV propofol 2.0–2.5mg/kg and intubation was facilitated by IV atracurium besylate 0.5mg/kg. After intubation, anesthesia was maintained with 1.0–1.2% isoflurane with 40% oxygen in air. At the end of surgery, neuromuscular blockade was reversed with 50μg/kg neostigmine and 10μg/kg of glycopyrrolate and trachea was extubated when patient responded to verbal commands.

Vitals including MAP, HR, SpO_2, and respiratory rate (RR) were recorded at every 5 min after induction till the end of surgery. Episodes of hypotension (fall in MAP by 30% from baseline) and bradycardia (HR less than 60 beats/min)

were treated with IV crystalloid bolus or IV mephentermine 6mg and for significant bradycardia (HR <40 beats/min) IV atropine 0.01mg/kg, respectively, and recorded. Other perioperative complications such as the occurrence of paresthesia, nausea, vomiting, pruritus, and urinary retention were also recorded. Postoperative pain was assessed, by an assessor blinded to the group allocation, using NRS (0–10: 0 = no pain and 10 = worst imaginable pain) after receiving patients in post-anesthesia care unit (PACU) (0 h) and then at every 2 h interval till 12 h and then at 24 h. Patients were prescribed IV paracetamol 1 g every 6 hourly and pain between two doses of paracetamol was treated with IV fentanyl 1 μg/kg (rescue analgesic). Time to first rescue analgesia and total opioid consumption over 24 h was recorded. Patient and surgeon satisfaction scores were assessed using a 5-point VRS (1—very dissatisfied, 2—dissatisfied, 3—neutral, 4—satisfied, and 5—very satisfied).

The sample size calculation was based on previous study which showed a 2.7 ± 0.8 (mean ± SD) patients' satisfaction score in patient receiving GA. We assume that patient receiving segmental thoracic spinal would be having higher satisfaction score compared to those who received GA. To calculate a difference of 0.6 between the two mean at an α of 0.05 and power of the study $(1-\beta)$ at 80%, the sample size required would be 28 in each group. We included 30 patients in each group to compensate for possible dropouts.

Data collected were compiled and analyzed statistically using Statistical Package for Social Sciences version 20 (IBM SPSS Statistics for Windows, Version 20.0, Armonk, NY: IBM Corp., NY, USA). Descriptive statistics were presented in terms of numbers and percentages for categorical variables and in terms of the mean, standard deviation, and/or median for the continuous variables. Categorical data were compared using Chi-square test, whereas continuous variables were compared using Student's $t-$ test or the Mann–Whitney $U-$ test when criteria for normal distribution were met or not met, respectively. $P < 0.05$ was considered statistically significant.

Results

A total of 60 patients were screened for enrollment; out of them 3 did not meet inclusion criteria and 1 declined to participate; remaining 56 patients were randomly divided into 2 groups [Figure 1]. The demographic profile [age and body mass index (BMI)], ASA physical status, and duration of surgery were comparable between groups [Table 1].

The patient satisfaction score for the anesthesia technique was significantly better in group TS median 5 (IQR 1) as compared to group G median 4 (IQR 3.5) ($P = 0.001$) [Table 2]. Intraoperatively eight patients (28.5%) in group TS encountered bradycardia, at 15 min, which was statistically significant ($P = 0.004$) [Figure 2]. MAP showed no significant difference between the groups [Figure 3]. The time to first rescue analgesic request was significantly higher in group TS (338.57 ± 40.70 min) compared to group G (33.21 ± 7.48 min) ($P < 0.001$) [Table 2].The NRS scores were significantly better in group TS at all time point of observation [Table 3] leading to significantly lesser opioid consumption over 24 h in group TS (70.00 ± 27.38 μg) as compared to group G (366.07 ± 59.40 μg) [Table 2]. Three patients in group TS (10.71%) experienced paresthesia during spinal puncture, which resolved after stylet removal and needle withdrawal, without sequelae. Nausea and vomiting were significantly higher in group G as compared to group TS ($P = 0.051$ and $P = 0.01$). One patient

Table 1: Comparison of demographic profile, ASA physical status, and duration of surgery between study groups

Variable	Group TS	Group G	*P*
Age (years)	51.96±9.93	52.35±0.15	0.895
BMI (kg/m^2)	24.63±1.50	24.84±1.8	0.637
ASAI/II	23/5 (82.14/17.86)	21/7 (75/25)	0.514
Duration of surgery (min)	75.53±24.43	66.96±12.34	0.103

Table 2: Comparison of patient satisfaction score, surgeon satisfaction score, time to first analgesic request, number of patients requiring rescue analgesia, and total opioid consumption between study groups

Parameters	Group TS	Group G	*P*
Patients satisfaction score median (IQR)	5 (1)	4 (3.5)	0.001
Surgeons satisfaction score median (IQR)	5 (1)	4 (1)	0.036
Total opioid consumption (μg)	70.00±27.38	366.07±59.40	<0.0001
No. of patients requiring rescue analgesia	5 (17.85%)	28 (100%)	<0.0001
Time of first analgesia (min)	338.57±40.70	33.21±7.48	<0.001

Table 3: Comparison of NRS score at different time point between study groups

Time (h)	Group TS [median (IQR)]	Group G [median (IQR)]	*P*
0	1 (1, 2)	6 (4, 8)	<0.0001
2	1 (1, 2)	5 (4, 7)	<0.0001
4	2 (1, 3)	5 (4, 7)	<0.0001
6	2 (1, 3)	5 (4, 6)	<0.0001
8	3 (2, 4)	4 (3, 6)	<0.0001
10	2 (1, 3)	6 (4, 8)	<0.0001
12	3 (2, 5)	4 (3, 6)	<0.0001
24	1 (1, 2)	2 (1, 3)	0.0004

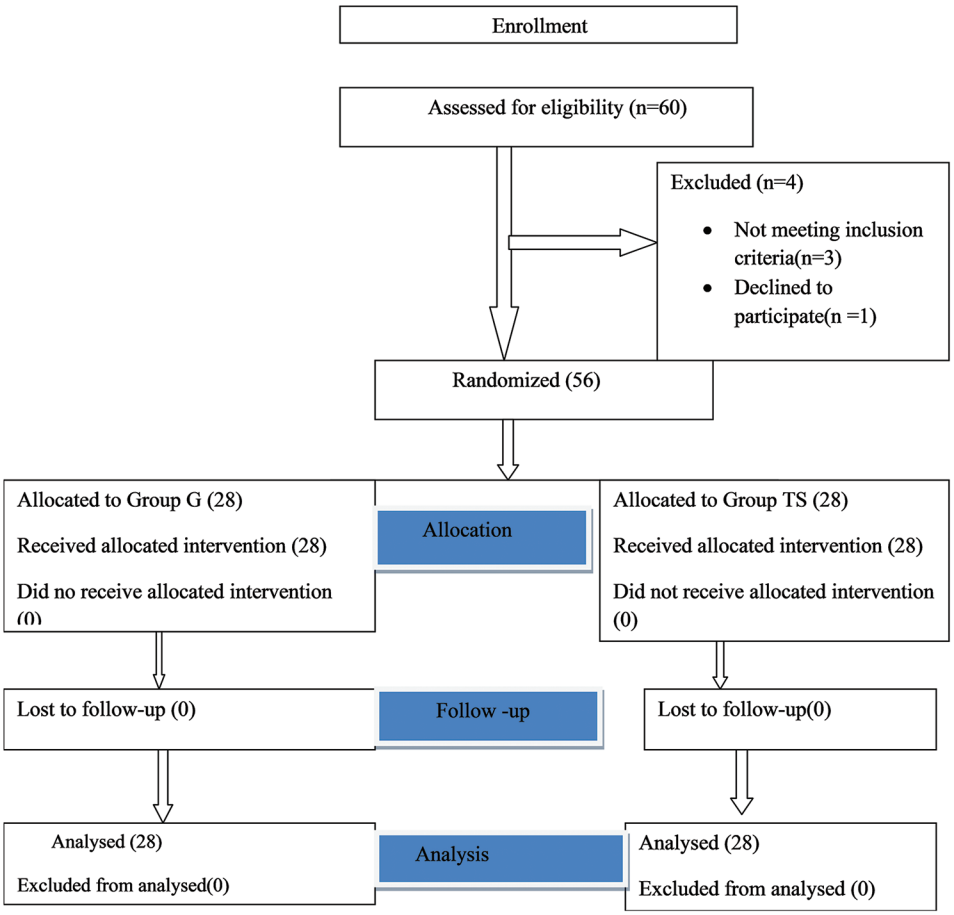

Figure 1: Consort flow diagram

developed nausea in group TS, which was not associated with hypotension. None of the patient in any group developed pruritus and urinary retention.

Discussion

The present study demonstrated that as an anesthesia technique, the segmental thoracic spinal provides better patient and surgeon satisfaction with significantly better post-operative pain, longer time to first rescue analgesia, lesser postoperative opioid consumption, and lesser nausea vomiting compared to GA. Although more significant number of patients developed bradycardia (as per the definition) after thoracic spinal anesthesia, it did not require intervention.

In most of the published literatures, this technique has been studied for patient satisfaction and results were expressed in percentage,[6,8] Although the other studies have scored the patient satisfaction on a 5-point scale.[9,10] We also used 5-point scale score for patient satisfaction considering it to be less subjective. Our findings are particularly relevant to the anesthesiologists working in a resource-limited setting and also to the patients who has relative contraindications for GA.

Chronic pain and post-operative nausea and vomiting (PONV) are the most troublesome complications associated with breast surgery, which leads to delayed recovery and hence prolonged hospitalization.[11] Neuraxial anesthesia attenuates the neuro-endocrine, metabolic, and immune response to surgery. It also reduces postoperative opioid requirement, due to prolonged sensory block.[12] Hence, neuraxial anesthesia is a better alternative to GA.

There are two main issues related to spinal at midthoracic level: risk of neuronal injury and chances of high spinal from cephalad spread of local anesthetic. In recent studies, it was found that the space between the duramater and spinal cord in thoracic region measured with MRI was 5.19 mm at T2, 7.75 mm at T5, and 5.88 mm at T10 and also that the spinal cord and the cauda equina are touching the duramater posteriorly in the lumbar region and anteriorly in the thoracic region.[13] The angle of insertion of the spinal needle at T5 and T6 (almost 50°) further elongates the distance from the tip to the posterior surface of the cord.

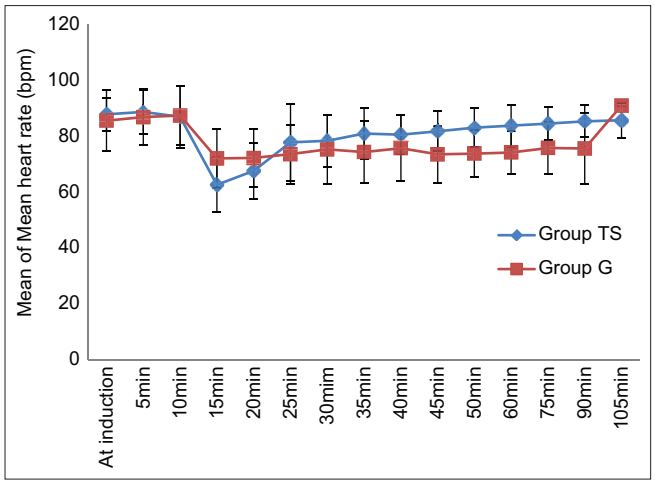

Figure 2: Mean heart rate in both groups

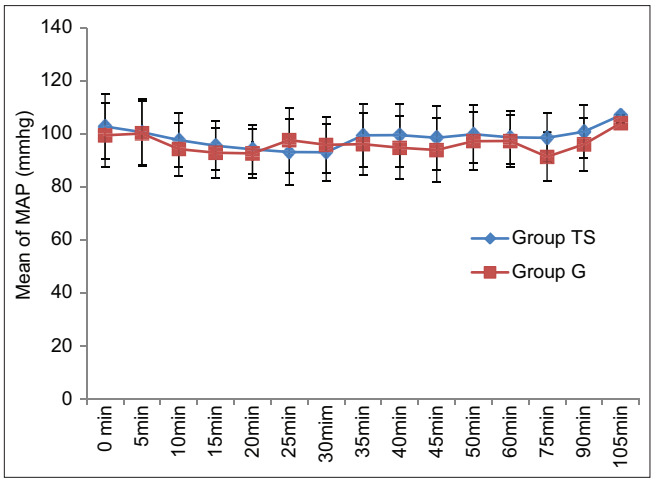

Figure 3: Mean arterial pressure in both groups

As compared to lumbar and cervical level, CSF amount at the thoracic level is diminished and nerve roots are thinner, both these factors predict efficient blockade of these segments with lower doses of local anesthetic (5mg isobaric levobupivacaine).[14,15] Similar doses were used by authors who studied minor breast surgery (lumpectomy or simple mastectomy) under segmental thoracic spinal anesthesia at T5 level with 1 mL plain bupivacaine (5 mg/mL) and 0.3 mL fentanyl (50 μg/mL).[7] We performed the block at the T5–T6 level as subarachnoid space is widest at this region and the thoracic segment of the cord lies anteriorly; this was shown in studies conducted by Imbelloni *et al.*[16] and Lee *et al.*[13] The incidence of paresthesia was 10.71% in our study. In a study performed by Imbelloni *et al.*,[17] the incidence of paresthesia was 4.67% with cut needle and 8.67% with pencil-point needle when spinal puncture was performed at T10–T11 level; similar incidents were reported in lumbar spinal anesthesia by other investigators.[18,19]

Intraoperatively quality of anesthesia was adequate in all patients in group TS and there was no conversion to GA. No respiratory complications like affective dyspnea, hypopnea, or hypoxia (SpO_2 <94%) were noted in group TS. This can be explained by the fact that the main inspiratory muscle is the diaphragm, which is innervated by the phrenic nerve (C3–C6), which is unaffected and expiration occurs passively. Similar results were obtained in a case report, where a patient with COPD with severe emphysema on oxygen therapy underwent cholecystectomy under the thoracic CSE technique, with a minute dose of local anesthetic, without any respiratory complications.[5]

Hemodynamic changes studied were MAP and HR. MAP changes were minor and insignificant; in spite of the neuraxial blockade, this is because the motor power of the lower limbs was preserved, a low dose of local anesthetic was used, and the patient remained conscious throughout the procedure, avoiding central depression of circulation. Bradycardia occurred in eight patients (28.57%) in group TS. In contrast, Imbelloni,[20] used a similar low dose of hyperbaric bupivacaine (7.5 mg) in combination with fentanyl (T10–T11) and achieved less bradycardia (2.85%), whereas Elakany *et al.*[6] proved that hypotension and bradycardia developed in 15% of cases, who received segmental thoracic spinal anesthesia.

PONV is one of the most troublesome complications associated with breast surgery, can prolong recovery, and is among the most common causes of hospitalization following ambulatory surgery.[21] When compared with GA, regional anesthesia has a lower incidence of PONV, as demonstrated in several studies.[22] In our study, the incidence of PONV was 25% in GA as compared to 3.75% in the segmental thoracic spinal group, which was significantly lower. Our findings are inconsistent with those of Bansal *et al.*,[23] who reported 45% of PONV in GA group within 30 min of surgery and 75% of patients required antiemetic in the first 24 h.

Adequate pain control is very important in breast cancer surgery. In our study, the pain assessed throughout any time in post-operative period was significantly lesser in group TS as compared to group G, and this was attributed to the residual sensory block of local anesthetic and fentanyl in subarachnoid space; similar results were obtained by Yousef *et al.*[8] who studied the effect of thoracic spinal anesthesia in laparoscopic cholecystectomy.

The length of stay in the recovery room and the hospital was shorter in group TS as compared to group G and this was following the findings of Ellakamy *et al.*,[9] who studied recovery time between two groups of patients (thoracic spinal vs. GA) for laparoscopic cholecystectomy.

Patients in group TS were highly satisfied with the anesthetic technique, due to motor control of lower limbs, early mobilization, good analgesia, and low incidence of PONV. Similar results were obtained by Ellakany *et al.*[10] who studied thoracic spinal anesthesia is safe for patients undergoing abdominal cancer surgery.

Our study has a few limitations. First, being an open-label (non-blinded) study, the biases inherent to the design could not be excluded. Second, the patients were not followed for long-term benefits or complications of the technique. Third, onset and duration of motor block were not assessed. We need to conduct RCTs with more number of patients to reciprocate our findings.

Conclusion

Single-dose segmental thoracic spinal anesthesia with low-dose local anesthetic and opioid can be a substitute to GA for breast cancer surgery, as it resulted in faster recovery, higher patient satisfaction, better post-operative pain control, and lower incidence of PONV with consequent early hospital discharge.

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Conflicts of interest
There are no conflicts of interest.

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