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A Comparison of Efficacy of Two Techniques of Thoracic Para Vertebral Block in Patients Undergoing Breast Surgeries: A Prospective, Single-Blinded and Randomized Controlled Trial

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Abstract

Aim: To evaluate feasibility of Thoracic Para Vertebral Block (TPVB) as a sole anaesthetic technique and to compare the efficacy of four injection (FI) v/s seven injection (SI) technique of TPVB for various surgeries of benign breast disorders.

Materials and Methods: This was a prospective, single blinded, randomized control trial. The analysis for sampling to have a type I (α) error of 0.5 and type II (β) error 0.2 (power of 80%), the calculated sample size was 30 patients, which were further divided into two groups: SI(T_1-T_7) and FI(T_2, T_3, T_4 & T_5) of 15 patients each. The block was performed in sitting position by using the technique described by Moore and Katz.

Results: The two groups (SI/FI) were comparable in terms of demographic data, time required for performance (18.67)/(20.33) min., time of onset of block (20.38)/(17.14) min., success rate (86.66%)/(93.33%), side effects viz; nausea (3.7%)/(14.8%) and vomiting (3.7%)/(0%) patients, rescue analgesia (20.0 ± 6.325)/(19.43 ± 6.442) hrs. and patient satisfaction score (67.85)/(69.23).

Conclusion: We conclude that TPVB is an elegant and effective technique for achieving surgical anaesthesia in patients undergoing various breast surgeries and use of the lesser invasive four injection (FI) is equally effective technique as compared to conventional seven injection (SI) in achieving the same end points.

Keywords: *Thoracic Para Vertebral Block (TPVB); Anaesthetic Techniques; Seven injection; Four injection; Comparison; Efficacy and Side effects*

Abbreviations: TPVB: Thoracic Para Vertebral Block

Introduction

Benign disorders of breast like fibroadenoma & fibroadenosis are the most common disorders in Indian population in age groups of 15-40 years followed by the phylloides tumor, ductal, intraductal and atypical hyperplasias.

Surgical intervention for these are often associated with postoperative pain, nausea, vomiting and chronic pain [1] and one of the contributory factors is general anaesthesia [1], These complications lead to patient suffering, extended post anaesthesia care unit (PACU) stays, prolonged admissions and additional hospital costs. Thoracic Para Vertebral Block (TPVB) is an alternative and an adequate anaesthetic technique that may reduce these complications [2].

TPVB is the technique of injecting local anesthetic adjacent to the thoracic vertebrae close to where the spinal nerves emerge from the intervertebral foramina. This results in ipsilateral somatic and sympathetic nerve blockade in multiple contiguous thoracic dermatomes above and below the site of injection [3,4]. It is effective in treating acute [2,4,5] and chronic [5] pain of unilateral origin from the chest and abdomen. Bilateral use of TPVB has also been described [6]. Our understanding of the safety and efficacy of TPVB has improved significantly in the last two decades and prompting its use in children [7,8], neonates [7] and for surgical anaesthesia [6,8]. This study was designed to evaluate the efficacy of TPVB, as an alternative to general anaesthesia, by using either four injection technique or seven injection technique for breast surgery.

Materials and Methods

After obtaining approval from the Institutional ethical committee and written informed consent, ASA I &II patients scheduled to undergo various types of benign breast surgeries were included in this study. This study was done in an 800 bedded tertiary care teaching hospital associated with RNT Medical College, Udaipur by randomly selecting 30 female patients posted for elective breast surgery, having weight between 40-60 kg, age between 20-50 years.

Exclusion criteria were; Patient refusal for TPVB [2]; patient having altered coagulation parameters, severe respiratory disorder, severe cardiac disorder, severe renal disorder; infection at the injection site; any acute psychiatric illness or allergy to agent used.

Based on prior published work [10], we presumed that decrease in 24 hours consumption of opioid by 75% in the patient who had been administered the block, to be an effective measure for postoperative analgesia. Thus reduction in opioid consumption was kept as a primary outcome measure.

For the study to have a type I (α) error of 0.5 and type II (β) error 0.2 (power of 80%), the sample size was 30 patients. Therefore, we decided to divide the patient into two groups of 15 patients each. All patients were randomly allocated to one of two groups using random number in opaque sealed envelopes.

Both Groups were administered 21 ml of solution (20 ml of bupivacaine (0.5%) plus 1 ml fentanyl (50 µg)) on ipsilateral side of the breast. In Group I (FI) received 5.25 ml drug at four injection sites (T_2, T_3, T_4, T_5) and Group II (SI) received 3 ml drug at seven injection sites (T_1-T_7). Eutectic mixture of local anaesthetic (cream) was applied on block site in all patients 1-1½ hour before block. All patients received premedication analgesia; Diclofenac 75 mg (I.M) + Midzolam 1 mg I.V, 30 min. before the block was given. Intra-operatively patients received propofol (50-150 µg/kg/min) for sedative purpose if needed.

The block was performed in sitting position by using the technique described by Moore [11] and Katz [12]. The superior spinous process of thoracic level T_1-T_7 was identified. Block was given in our study at T_2, T_3, T_4, T_5 levels or T_1-T_7 according to group. The entry site was marked 2.5 cm on lateral to each spinous process ipsilateral to the breast to be operated upon. TPVB was given by using a 22 gauge, 3.5 inch Quincke spinal needle, the needle was advanced anteriorly in the parasagittal plan until it contacted the transverse process. The needle was then withdrawn to the subcutaneous tissue level and angled to walk off caudally towards edge of the transverse process. From the caudal edge, it was then advanced anteriorly approximately 1 cm. After aspiration with syringe, drug was given at each level according to group. The patients were returned to the supine position and sensation was assessed by using pinprick after 15 min.

Effectivity of block was measured first by touch then by pin prick method in area to be operated. Intra-operatively patients were received supplementation with fentanyl (2 µg/kg) if required. General anaesthesia was given when block failed.

The primary outcome measures were the cumulative consumption of intravenous Fentanyl over next 24 hours in both groups. Pain score was measured using a 10 points Visual Analogue Scale (VAS) at 0, 2, 4, 8, 12 and 24 hours after completion of surgery at respective time at rest, cough, and movement. Patients with VAS ≥ 3 at any time in post-operative period received rescue analgesic.

Haemodynamics, like pulse rate, blood pressure, respiratory rate and temperature were recorded at 0, 2, 4, 8, 12, 24 hours postoperatively.

Patient satisfaction score (PSS) was assessed using a 100-point verbal rating scale (VRS) (1 = highly dissatisfied to 100 = completely satisfied). PSS was recorded at 24 hours.

Statistical analysis

The result was present on mean ± (S.D.) median (interquartile range) or number of patients as appropriate. For statistical analysis T test and chi-square test was used and 'P' value < 0.05 was considered statistically significant.

Results and Discussion

Demographic parameters like mean age and mean weight of patient in group FI was (37.87 ± 8.37 and 48.53 ± 3.06) and in group SI was (38.80 ± 7.29 and 49.60 ± 2.87), which were comparable.

Total duration for giving TPVB in FI group was (20.33 min) while in SI group was (18.67 min). The achievement of block was assessed by touch and pin prick sensation. Which were comparable and difference was statistically non-significant (P = 0.331).

	Group FI (n = 15)	Group SI (n = 15)	P value
Mean Time (min)	20.33 ± 4.806	18.67 ± 4.419	0.331

Table 1: *Total time required for TPVB.*
(Test Applied: T-test).
(P < 0.05 is significant).

The success rate of our study was 90% (out of 30 patients, 27 had successful block and 3 had failed block). Out of it, in FI group was14 (93.33%) and in SI group was 13 (86.66%) patients.

	Group		Total
	FI (n = 15)	SI (n = 15)	
Successful	14 (93.33%)	13 (86.66%)	27 (90.0%)
Failed (Supplement Anaesthesia)	1 (6.66%)	2 (13.33%)	3 (10.0%)

Table 2: *Success rate for TPVB.*

The adverse effects noted were minor (nausea and vomiting) and only in 6 (20%) patients and whereas 21 (70%) patients had shown no side effects.

The duration of block/demand of the first rescue analgesia was 19.43 ± 6.442 hrs. In group FI and 20.0 ± 6.325 hrs. In group SI.

No rescue analgesic was demanded in postoperative period by total of 70.4% patients. One dose of rescue analgesia (fentanyl = 2 µg/kg) was demanded in 22.2% (7.4% in FI group + 14.8% in SI group) of cases. Two doses of rescue analgesia (fentanyl = 2 µg/kg) were given in 7.4% (7.4% in FI group) cases. There was no statistically significant difference observed in the VAS scores at rest, cough and movement and rescue analgesia required by the patients in the two groups.

Rescue Analgesia	Group		Total
	FI (n = 14)	SI (n = 13)	
No dose	10 (37.0%)	9 (33.3%)	19 (70.4%)
2 µg/kg (one time in 24 hrs)	2 (7.4%)	4 (14.8%)	6 (22.2%)
4 µg/kg (two times in 24 hrs)	2 (7.4%)	0 (0%)	2 (7.4%)

Table 3: *Comparison of rescue analgesia total dose received between the groups.*
P value = 0.261 (non-significant).
(Test Applied: Chi-square test).

	Group FI	Group SI	P value
Time (hrs)	19.43 ± 6.442	20.00 ± 6.325	0.818

Table 4: *Duration of block (request of 1st analgesia dose postoperatively).*
(Test Applied: T-test).
(P < 0.05 is significant).

Postoperative hemodynamics varied between Mean Arterial Pressure (96.15 ± 3.8 in FI and 99.57 ± 4.45in SI), Pulse Rate (76 ± 4.50 in FI and 76.77 ± 6.6 in SI) group, Respiratory Rate (14.93 ± 1.49 in FI and 14.69 ± 2.13 in SI). The p value of all was > 0.05 (non-significant). All the patients in either group remained a febrile in their observational period of 24 hours.

Patient Satisfaction Score (PSS) at 24 hours in FI group was 67.85 and in SI group was 69.23, which were comparable and the difference was statistically not significant. (P > 0.05)

	Group FI	Group SI	P value
PSS at 24 hrs	67.85	69.23	0.558

Table 5: *Comparison of patient satisfaction score (PSS) on Verbal Rating Scale, (VRS) of 1-100, between the groups.*
(Test Applied: T-test).
(P < 0.05 is significant).

Discussion

Surgical removal of breast lumps under general anesthesia is still associated with a 50% incidence of nausea and vomiting in breast surgery patients [13]. TPVB may offer an alternative to GA that also provides inhibition of painful stimuli, both of which may play a role in the pain and complications in these patients.

The demographic parameters were comparable and statistically non-significant in the study. Total duration for giving TPVB in FI & SI groups was 20.33 min and 18.67 min. The P value was non-significant and comparable. Whereas we found that Eamonn., *et al*. [7] conducted a study on TPVB, which showed that time for performance of blocks ranged from 10 to 15 minutes. The onset of sensory loss typically occurred 10 minutes after injection with surgical anesthesia ensuing 20 to 30 minutes after the injection. Similarly, Dabbagh A., *et al*. [14] had showed that the average duration for single TPVB was 5 to 10 minutes.

The lack of any delay in the onset of surgical anaesthesia in the four injection technique as compared to the seven injection technique reflects that the local anaesthetic takes similar time to spread in the paravertebral space in both groups.

The success rate of our study was 90% (out of 30 patients, 27 had successful block and 3 had failed block). Out of it, in FI group was14 (93.33%) and in SI group was 13 (86.66%) patients. Whereas Eamonn., *et al*. [7] had showed success rate of around 85% of cases without any anesthetic supplementation and in 91% of cases without GA. Similarly Karmakar., *et al*. [15] showed that the TPVB is technically easy to learn [6,16], has a high success rate [6,16] regardless the number of blocks were performed and does not appear to be operator dependent. The failure rate varies from 6.8 to 10%. [6,17] which is comparable with any other commonly used regional anaesthetic technique [17].

Most of the complications observed in our study were minor and there was little difference between the two groups. The commonest side effects were nausea and vomiting only in 6 (20%) patients. Eamonn., *et al*. [7] had shown that only 20% of the patients in TPVB required medication for nausea and vomiting. Similarly Klein., *et al*. [10] found that there was a trend of less postoperative side effects and they concluded that TPVB is an alternative technique for cosmetic breast surgery that may offer superior pain relief and decreased nausea than GA alone.

In our study, the duration of block was 19.43 ± 6.442 hrs in group FI and 20.0 ± 6.325 hrs in group SI and postoperative pain was assessed using VAS scores up to 24 hrs., total doses of rescue analgesic consumed was noted for each patient and cumulative rescue doses were compared in two groups. Time of first rescue analgesic was taken into account as a measure of duration of postoperative analgesia.

The requirement of rescue analgesia was taken as one of the clinical end points in determining the efficacy of TPVB for post-operative analgesia in both groups. We took into account the cumulative rescue analgesic doses used in two groups. No rescue analgesic was demanded in postoperative period in 70.4% patients.0ne dose of rescue analgesia (fentanyl = 2 μg/kg) was demanded in 22.2% (7.4% in FI group + 14.8% in SI group) of cases. Two doses of rescue analgesia (fentanyl = 2 μg/kg) were given in 7.4% (7.4% in FI group) cases (Table 4). There was no statistically significant difference in VAS scores and cumulative rescue analgesia received among the two groups studied in first 24 hours.

A TPVB may remain localized to the level injected or it may spread to the contiguous levels above and below [18,19] inter costal space laterally [18,19,25], the epidural space medially [18,25] or a combination of the above to affect ipsilateral somatic [3,20,23,24,26] and sympathetic nerves [3,24], including the posterior primary ramus in multiple contiguous thoracic dermatomes. Whereas Eason and Wyatt [2] found that at least four inter costal spaces could be covered by a single 15 ml injection of 0.375% bupivacaine. TPVB does not appear to be gravity-dependent, but there is a tendency for preferential caudal spread of somatic [3,20,21,26] and sympathetic blockade [3].

Therefore, the anatomical peculiarities of the paravertebral space ensure that the spread of a drug injected into it would be independent of the number of injections.

Patient satisfaction with postoperative pain management was assessed using a 100-point VRS recorded at 24 hours and we found that FI group was 67.85 and SI group was 69.23 which can be considered to be satisfactory. In their study Green grass., *et al*. [21] have shown similar results. Similarly Michel A Terheggen., *et al*. [27] showed that there was no difference in recovery time but patient satisfaction was better in the TPVB group.

One lacuna that may be considered in our study is a smaller sample size. However we tried to minimize that by carrying out proper analysis of sampling suitable for the study.

Conclusion

In conclusion

Following pertinent points emerge out of our study:

1. The two groups were comparable to each other in term of demographic data.
2. There were no statistically significant difference amongst the two groups in terms of time required for performance and time of onset of block.
3. Surgical anaesthesia was achieved by TPVB alone in 93.33% patients from group FI and 86.66% from group SI (Overall average of 90%).
4. There was no statistically significant difference in duration of block and duration of surgery in either group.
5. Incidence of postoperative side effects and complications were very low in both the groups. The most common side effect was nausea (18.5% patients) and vomiting (3.7% patients). The incidence of side effects was comparable in both the groups and difference statistically non-significant.
6. Intensity of pain measured by Visual Analogue Scale at rest, with cough and with movement at 0, 2, 4, 8, 12 and 24 hrs was comparable in both the groups with statistically non-significant difference.
7. Patient satisfaction score was similar in both the groups.

We propose that thoracic paravertebral block is an elegant and effective technique for achieving surgical anaesthesia in patients undergoing breast surgery.

Use of the lesser invasive four injection (FI) is equally effective technique was compared to conventional seven injection (SI) in achieving the same end points.

Conflict of Interest

We confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome. All authors have read and approved the final manuscript.

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