ORIGINAL RESEARCH PAPER
Volume - 10 | Issue - 03 | March - 2021 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

SINGLE NEEDLE THORACIC PARAVERTEBRAL BLOCK AS AN ALTERNATIVE TO GENERAL ANESTHESIA FOR MODIFIED RADICAL MASTECTOMY OPERATION : A RANDOMISED CONTROL STUDY

Anaesthesiology

Archana Roy	Assistant Professor , Dept. of Anaesthesiology, NRS Medical College, Kolkata.
Pratibha Bhunia*	Assistant Professor , Dept. of Anaesthesiology, NRS Medical College, Kolkata. *Corresponding Author
Sampriti Sadhukhan	Post Graduate Trainee, Dept. of Anaesthesiology, NRS Medical College, Kolkata.
Dipankar Mukherjee	Professor, Dept. of Anaesthesiology, NRS Medical College, Kolkata.
Shrawan Soni	Post Graduate Trainee, Dept. of Anaesthesiology, NRS Medical College, Kolkata.

ABSTRACT

Background and Aims: Conventionally, surgery for breast carcinoma is done under general anaesthesia (GA). Recently thoracic paravertebral block (TPVB) is gaining popularity because it produces unilateral block and minimal haemodynamic changes. It also facilitates post-op analgesia, early ambulation, and reduces hospital stay. Aim was to observe effectiveness of single needle TPVB with bupivacaine as the sole anaesthetic technique for Modified radical mastectomy (MRM).

Methods: 60 consenting female patients of ASA I & II, aged 18-60 years scheduled for modified radical mastectomy were randomly assigned into two groups: Gr. P (n=30), Gr. G(n=30). For Gr. P: TPVB was given at T4 vertebral level with 18G Tuohy needle and an epidural catheter inserted 2-3cm inside the paravertebral space. Bupivacaine 0.5% isobaric 15-20ml (not exceeding 2 mg/kg b.w.) injected through the epidural catheter. Dexmedetomidine infusion given for sedation. Gr. G: GA was given with Midazolam, Fentanyl, Propofol and Atracurium. Measured parameters were baseline and intraoperative haemodynamics , induction time, recovery time, fentanyl requirement, average blood loss, post-op pain score by VAS at 0,1/2,1,2,4,8,12,24hrs, duration of analgesia, patient and surgeon satisfaction scores(PSS,SSS),and incidence of post-op nausea vomiting(PONV).

RESULTS: Group P patients had prolonged induction (12.25±3.66) and recovery was faster (1.61±0.69) in comparison to group G. Intraoperatively Group P patients required less Fentanyl & also had less blood loss. Post op VAS score, incidence of PONV were more in group G.

Conclusion: TPVB may be used as an alternate anaesthetic technique for MRM as it provides adequate analgesia both in intra and post op period with minimal adverse effects.

KEYWORDS

Thoracic Paravertebral Block, Modified Radical Mastectomy, General Anaesthesia.

INTRODUCTION

Incidence of breast carcinoma in developing countries like India is gradually increasing day by day and recently has become 25.8 per 1,00,000 women in India. So, radical surgery for breast cancer has become one of the most common operation performed in hospitals. Conventionally, this radical surgery for breast carcinoma is performed under general anaesthesia (GA) but this is associated with various side effects such as post-operative pain, nausea, vomiting and increased narcotic demands.

Moreover 40% of post-operative breast surgery patients experience significant acute post-operative pain whereas incidence of chronic post-operative pain in breast surgery is as high as 50%. In addition, most of the patients undergo chemotherapy prior to surgery which make them unsuitable for GA to some extent. Hence, there is a search for anaesthetic technique for breast surgery alternative to GA which will cut down the side effects and complications associated with GA as well as providing adequate post-operative analgesia with minimum narcotic requirements. So, this technique can be applied to the patient incapable of tolerating GA.

Regional anaesthesia like thoracic paravertebral block (TPVB) has been used previously for unilateral surgery like thoracotomy, herniorrhaphy and cholecystectomy[1,2]. This technique is gaining a lot of popularity as it produces unilateral effects and it causes minimal hemodynamic changes, lesser need of opioid in post-operative period, decreased incidence of post-operative nausea vomiting, lowered incidence of post-operative pulmonary complications and also allows early ambulation, decreased duration of hospital stay.

TPVB is being used for unilateral breast surgery without any significant side effects by eliminating the cortical responses to thoracic dermatomal stimulation[3,4,5].

The present study aims to evaluate the efficacy of TPVB with 0.5% bupivacaine as a sole anaesthetic approach for modified radical mastectomy (MRM) as an alternative to GA. Intraoperative analgesic requirement i.e. total fentanyl requirement is the primary goal of the study.

METHODOLOGY

After obtaining approval from the institutional Ethics committee, 60 consenting female patients, American society of anaesthesiology (ASA) physical status I and II, aged 18–60 years, scheduled for MRM, were enrolled in this randomised single blinded prospective clinical study.

Patients who refused to participate, <18 years, ASA III or more, body mass index (BMI) >35, lactating mothers, bleeding disorders, allergy to study drugs, patients with contraindication to placement of TPVB, kyphoscoliosis, presence of acute herpes zoster, chronic pain syndrome, chronic analgesic use and psychiatric disease were excluded from this study.

We did a pilot study first. Considering a 20 mcg decrease in intraoperative fentanyl requirement to be clinically relevant, with a power of 80% (β=0.2) at 0.05 level of significance (α=0.05), we required 27 patients in each group. We took 30 patients in each group (total of 60), considering the possibility of dropouts. Patient were randomly allocated by using the sealed envelope technique, into group P (n=30) and group G (n=30) to receive either TPVB or GA, respectively.

Patients were thoroughly explained in pre anaesthetic visit about the procedures to be undertaken and the risks and benefits involved. They were made well conversant about the use of visual analogue scale (VAS) for expressing pain. They were premedicated with tab diazepam (10 mg) on the night before surgery.

On day of surgery, an intravenous infusion of Ringer's lactate solution was started. All necessary equipment for GA and resuscitation were kept ready. Baseline vital parameters like heart rate (HR), non-invasive blood pressure (NIBP), respiratory rate and peripheral arterial oxygen saturation (SpO_2) were noted. Patients was monitored throughout the

intra operative procedure & vitals were recorded at 15min interval intraoperatively and at 1hour intervals in the post-operative period upto 24 hours.

Patient in group P was given single needle continuous TPVB at the level of T4 on the side to be operated. With the patient in sitting position with neck flexed, T4 vertebral spine was located. A point 2.5 cm lateral to the spine was marked. Following local infiltration with 2% lignocaine 2 ml, an 18 G Tuohy needle was introduced with bevel facing upwards. The needle was advanced perpendicular to the skin till transverse process of T4 vertebra was

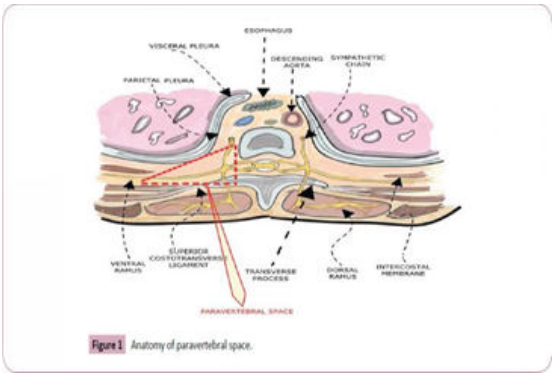

Figure 1. Anatomy of Paravertebral Space

touched at a depth of 4-5 cm. Then the needle was walked off the upper border of the transverse process and advanced slowly 1- 1.5 cm until a loss of resistance to saline was obtained. An epidural catheter was inserted 2-3 cm in the paravertebral space and patient was made supine.

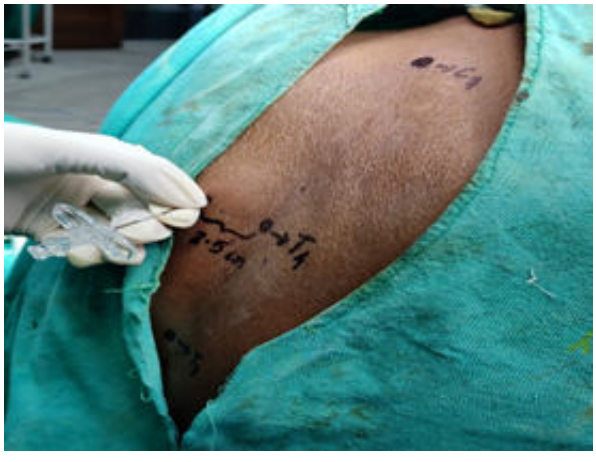

Figure 2: Technique of Performing TPVB with Tuohy needle.

Following negative aspiration for blood or cerebrospinal fluid (CSF) a test dose of 3 ml of 2% lignocaine with adrenaline was given. Five minutes later, 15-20ml of 0.5% bupivacaine (not exceeding 2 mg /kg body weight) was injected through the catheter in the paravertebral space.

Sensory level of anaesthesia was assessed by the onset of loss of unilateral pinprick sensation tested at 5 min and every 5 minutes thereafter until 30 min after the end of drug injection. TPVB block was considered unsuccessful if the onset of loss of pinprick sensation was not obtained within 15 min or sensory block not achieved within a maximum of 30 min time after the block. In case of block failure, the patient was given GA and not included in the study.

Intraoperative sedation was given with Inj. dexmedetomidine and nasal oxygen supplementation at 3 litres/min throughout the operation. The control underwent conventional GA with endotracheal intubation. They were premedicated with midazolam 0.05 mg/kg, fentanyl as analgesic 2mcg/kg, induced with propofol intravenously 2mg/kg followed by atracurium 0.5mg/kg for tracheal intubation. Anaesthesia was maintained with nitrous oxide, oxygen and atracurium 0.1mg /kg. Fentanyl 1 mcg/kg was repeated after one hour. At the end of the surgery all patients were reversed from residual muscle relaxation by neostigmine 50 mcg/kg and glycopyrrolate 10 mcg/kg.

Intraoperative HR and MAP were maintained within 20% of the baseline value in both the groups. Any increase in HR and MAP more than 20% was managed with intravenous fentanyl 0.5mcg/kg. Following parameters were recorded in both the groups.

Induction time: In Gr. G it was measured as the time interval between pre oxygenation to successful intubation and in Gr. P as the time interval between completion of local anaesthetic injection to loss of unilateral pinprick sensation of at least 3 segments.

Duration of surgery: In both groups it was defined as the time interval between surgical incision to application of adhesive dressing after wound closure.

Recovery time: In Gr. G, it was measured as the time interval between administration of reversal (neostigmine and glycopyrrolate) and eye opening. In Gr. P, it was measured as the time interval between completion of surgery and opening eyes on verbal command.

Total OT time: It was measured from entry of the patient to operation theatre to transfer to the recovery room.

Blood loss: Amount was estimated in all patients.
Surgeon Satisfaction Score: During surgery surgeon assessed quality of surgical anaesthesia using a numeric rating scale (NRS) of 0- 100.

Total fentanyl requirement was assessed in both groups.
Post operatively, patients of both groups were monitored in the recovery room for the first 24 hours by a resident, not involved in the study. All patients were assessed for pain score (VAS) and nausea and vomiting (PONV) at 0 hr, ½, 1 ,2,4,8,12 and 24 hrs. Any incidence of PONV was treated with intravenous Ondansetron 4 mg.

Duration of analgesia i.e. time between last suture application to first request of analgesia was recorded when VAS more than 3. VAS more than 3 was treated with injection Tramadol 50 mg in Gr G patients and dose of 10 ml 0.125% bupivacaine through paravertebral catheter in Gr P patients as top up. Thereafter top ups were repeated at 6 hourly intervals. If analgesia was still inadequate Diclofenac sodium 75 mg intramuscular was administered as back up analgesic in Gr G and tramadol 50 mg intravenous in Gr P patients.

Patient satisfaction scores: At the time of discharge all patients were asked about their satisfaction regarding respective anaesthetic procedure following a NRS (0- 100).

RESULTS

Duration of study period was 12-month. Two patients in group P had block failure. They were converted to GA and excluded from the study. Therefore, data from 58 patients were analysed; group P (n=28) and group G (n=30).

CONSORT CHART FOR PATIENT ENROLMENT :

Discrete categorical data were represented as n (%) and median. Continuous data were presented as mean ± SD. Differences in demographic, surgical, anaesthetic and post-operative data were tested by independent Student's t-test (continuous data) or by Pearson Chi-square test (categorical data). P value differences <0.05 was considered significant. All analyses were conducted using SPSS for Windows (version 20.0; SPSS Inc., Chicago, IL, USA). Demographic characteristics i.e., age, BMI, ASA physical status and pre-operative vital parameters were similar when the two groups were compared [Table 1].

Table 1: Demographic And Pre-op Vitals

PARAMETERS	GROUP P(n=28) mean ± SD	GROUP G(n=30) mean ± SD	P value
AGE (years)	49.29±6.38	50.67±4.93	0.18
BMI (Kg/m^2)	22.91±2.02	23.39±1.92	0.16
ASA (I/II)	15/13	16/14	0.6
Pre op Heart rate (bpm)	74.32±32	75.53±4.68	0.3
Pre op MAP (mm of Hg)	96.21±4.83	95.63±5.37	0.33
Pre op SpO2	99.18±0.77	99.17±0.8	0.5

Intraoperative HR and mean arterial pressure (MAP) at different time interval were significantly less in group P than group G (Table 2).

Table 2: Intra Operative Vitals

PARAMETERS	GROUP P(n=28) mean ± SD	GROUP G(n=30) mean ± SD	P value
HR 15	68.75±4.90	98.17±5.75	<0.00001
MAP 15	92.57±6.77	113.47±4.21	<0.00001
SpO2 15	99.32±0.61	99.4±0.62	0.31
HR 30	64.5±4.35	88.53±8.74	<0.00001
MAP 30	89.14±6.57	108±6.17	<0.00001
SpO2 30	99.57±0.57	99.63±0.5	0.33
HR 45	64.57±8.27	85.1±6.46	<0.00001
MAP 45	88.93±10.72	101.07±3	<0.00001
SpO2 45	99.54±0.74	99.4±0.7	0.23
HR 60	69±16.04	82.87±10.27	<0.0001
MAP 60	91.04±14.52	102±6.9	<0.0001
SpO2 60	99.54±0.74	99.37±0.72	0.19

It is evident from Table 3 that, induction time was significantly prolonged in group P (12.25±3.70 min) compared with group G (6.53±0.94 min). On the other hand, recovery was faster in Gr P (1.61±0.69) than Gr G (7.23±1.83) which was statistically significant. Durations of surgery were 80.89±10.10 and 82±12.43min in group P and group G, respectively, the values being comparable (P>0.05). Total time spent in the OT was also similar in the two groups; 105.71±7.70 min in group P and 102.83±10.50 min in group G (P>0.05). The requirement of Fentanyl during the surgery was significantly lower in group P (9.28 ±23.52mcg) as compared with group G (37.33±36.21mcg), P<0.001. Blood loss was also significantly less in Group P (210.71±51.56 ml) than group G (615±110.76 ml). Though surgeon's and patient's satisfaction scores (SSS, PSS) were comparable in both the groups.

Table 3: Additional Intraoperative Parameters

PARAMETERS	GROUP P(n=28) mean ± SD	GROUP G(n=30) mean ± SD	P value
INDUCTION TIME (min)	12.25±3.66	6.53±0.94	<0.0001
RECOVERY TIME (min)	1.61±0.69	7.23±1.83	<0.00001
DUR OF SURGERY (min)	80.90±10.10	82±12.43	0.35
TOTAL OT TIME (min)	105.71±7.66	102.83±10.48	0.12
Blood loss	210.71±51.56	615±110.76	<0.00001
SSS	96.96±4.78	97.83±4.09	0.23
PSS	95.36±4.7	95.67±5.21	0.41
Total Fentanyl requirement(ug)	9.28 ±23.52	37.33±36.21	<0.001

Time for first request of analgesia was considered as the duration of postoperative analgesia. As shown in Table 4, The mean duration of post-operative analgesia was 531.43±100.29 min in group P and 130±77.33 min in group G, the difference was statistically significant (P<0.001). The VAS scores in the immediate post-operative period and after ½,1, 2 ,4,12 h in the post-operative period were significantly higher in group G (P<0.05) whereas at 8th post-operative hour VAS score was more in Group P. The VAS scores at 24 h were comparable in the two groups, but at the expense of higher analgesic consumption in group G. The incidence of PONV requiring treatment was 7.14% in group P and 53.8% in group G. So, episodes of PONV requiring treatment was also significantly less in Group P. (P value <0.0001)

Table 4: Post Operative Analgesia And Ponv

PARAMETERS	GROUP P(n=28) mean ± SD	GROUP G(n=30) mean ± SD	P value
DUR OF ANALGESIA	531.43±100.28	130±77.32	<0.00001
VAS 0	0.17±0.47	1.03±0.81	<0.00001
VAS ½	0.25±0.52	1.63±0.49	<0.00001
VAS1	0.36±0.56	2.73±0.94	<0.00001
VAS 2	0.96±0.69	2.26±0.78	<0.00001
VAS 4	1.68±0.47	2.63±0.99	<0.00001
VAS 8	3.25±0.89	2.37±0.89	<0.00001
VAS 12	2.32±0.86	3.1±0.99	<0.001
VAS 24	3.93±0.57	3.83±0.7	0.5
PONV	2/26	16/30	<0.0001

We did not observe any incidence of epidural spread, accidental intravascular injection, haemodynamic instability or persistent pain after the TPVB procedure. No patient showed bilateral spread of sensory block. Significant bleeding was not observed in any patient. No inadvertent pleural puncture was observed

DISCUSSION:

TPVB results in ipsilateral analgesia by providing somatic and sympathetic nerve block including posterior ramus in multiple contagious thoracic dermatomes. The extension of somatic and sympathetic blockade (a mean of 5 dermatomes and 7 dermatomes respectively) and its extent of spread, longitudinal and lateral have been evaluated by Cheema et al[25]. The variability of its spread can be explained by the presence by endothoracic fascia as reported by Karmakar et al[26].

In MRM operation for successful analgesia C4 – T6 dermatomes are required to be blocked. As we have introduced epidural catheter for drug delivery, the drug is distributed over few successive spinal segments and avoids the need for multiple injections.

It is evident from our study that TPVB along with sedation can provide adequate analgesia and anaesthesia for MRM. Duration of analgesia after a single dose of injection is very long (postoperative analgesia in Gr. P is 531.43 ± 100.28 min). On the other hand, after general anaesthesia with opioid, analgesia does not last for long (postoperative analgesia in Gr. G. 130 ± 77.32 min). As a result, total perioperative opioid consumption is much less in TPVB (total opioid consumption in Gr. P is 9.28 ± 23.52 µg and in Gr. G is 37.33 ± 36.21 µg.

Coveney E et al shared similar experience in their study over 156 patients[9].

Many investigators reported successful use of this technique for MRM in high risk patients such as patients with ischemic heart disease, obstructive cardiomyopathy, myasthenia gravis even in pregnancy avoiding GA.[11,12,13,14.]

The general risk of PONV in women undergoing MRM under GA is appreciably high. Because of better post-operative pain control and lesser opioid consumption in group P the overall incidence of PONV was found statistically less in this group.

So, in the view of adequate surgical anaesthesia with less opioid consumption, excellent postoperative analgesia with less adverse events (PONV) and faster recovery, TPVB may be a reasonable alternative to GA for MRM. It can be used in high risks patients in future.

Limitation

Probability of inconsistent block leaves a few grey areas in its implication as the ideal alternative to GA. Use of nerve stimulator or Ultrasonography (USG) can improve block quality. USG is a better method for guiding the needle and the catheter through paravertebral space, there by minimize the risk of complication. Due to

nonavailability of USG in our institution we couldn't adhere to this technique.

CONCLUSION:

Single needle TPVB can be an effective alternate for GA for MRM. It provides adequate surgical anaesthesia as well as stable intraoperative hemodynamic and good postoperative analgesia.

REFERENCES

1. Eason M J, Wyatt R (1979) *Paravertebral thoracic block- a reappraisal*. Anaesthesia 34: 638-642.
2. Weltz C R, Greengrass RA, Lyerly HK: *Ambulatory surgical management of breast carcinoma using paravertebral block*. Ann Surg 1995; 222: 19–26.
3. Davies RG, Myles PS, Graham JM (2006) *A comparison of the analgesic efficacy and side-effects of paravertebral vs epidural blockade for thoracotomy--a systematic review and meta-analysis of randomized trials*. Br J Anaesth 2006: 418-426.
4. Richardson J, Sabanathan S, Jones J, Shah RD, Cheema S, et al. (1999) *A prospective, randomized comparison of preoperative and continuous balanced epidural or paravertebral bupivacaine on post-thoracotomy pain, pulmonary function and stress responses.* Br J Anaesth 7:626-634.
5. Votg A (2013) *Paravertebral block –A new standard for perioperative analgesia*. Trends in Anaesthesia and Critical Care 3:331-335.
6. Naja MZ, Lonnqvist PA (2001) *Somatic paravertebral nerve blockade: incidence of failed block and complications.* Anaesthesia. 56: 1184-1188.
7. YoshidaT, FujiwaraT, FarutaniK, OhashiN, BabaH (2014) *Effects of ropivacaine concentration on the spread of sensory block produced by continuous thoracic paravertebral block: a prospective, randomised, controlled, double-blind study*. Anaesthesia. 69: 231-239.
8. Matthews PJ, Pr V: *Comparison of continuous paravertebral and extradural infusions of bupivacaine for pain relief after thoracotomy*. Br J Anaesth 1989; 62: 204–5
9. Coveney E, Weltz CR, Greengrass R, Iglehart JD, Leight GS, Steele SM, Lyerly HK: *Use of paravertebral block anesthesia in the surgical management of breast cancer: Experience in 156 cases*. Ann Surg 1998; 227: 496–501
10. D'Ercole FJ, Scott D, Bell E, Klein SM, Greengrass RA: *Paravertebral blockade for modified radical mastectomy in a pregnant patient*. Anesth Analg 1999; 88: 1351–3
11. NikamS,Marghade P,Paliwal N,Lawhale (2014)S.*Thoracic paravertebral block for breast surgery in a patient with ischemic heart disease.* Anaesth, Pain and Intensive Care 18:280.
12. Buckenmaier 3rd CC, Steele SM, Nielsen KC (2002) *Paravertebral somatic nerve blocks for breast surgery in a patient with hypertrophic obstructive cardiomyopathy*. Can J Anaesth49:571-574.
13. Oğuz S, Küçük C, Eskiçirak E (2007) *Thoracic paravertebral block or breast surgery in a patient with myasthenia gravis.* J Anesth21:449-450.
14. Park S, Kim Y, Han K(2010) *Thoracic paravertebral block for breast surgery in a pregnant woman*. Korean J Anesthesiol59:73-76.
15. Karmakar MK (2001) *Thoracic paravertebral block*. Anaesthesiology 95:771-780.
16. Fibla JJ, Molins L, Mier JM, Sierra A, Vidal G. *Comparative analysis of analgesic quality in the postoperative of thoracotomy: Paravertebral block with bupivacaine 0.5% vs ropivacaine 0.2%* Eur J Cardiothorac Surg. 2008;33:430–4.[PubMed]
17. Brown DL, Carpenter RL, Thompson GE. *Comparison of 0.5% ropivacaine and 0.5% bupivacaine for epidural anesthesia in patients undergoing lower-extremity surgery*. Anesthesiology. 1990;72:633–6. [PubMed]
18. Pusch F, Freitag H, Weinstabl C(1999) *Single-injection paravertebral block compared to general anaesthesia in breast surgery*. ActaAnaesthesiolScand43: 770-804.
19. (Richardson J, Sabanathan S (1995) *Thoracic paravertebral analgesia*. Acta AnaesthesiolScanda39: 1005-1015.
20. Koh D,KhaiL (2013) *The Use of Single-injection Thoracic Paravertebral Block in Breast Cancer Surgeries in our Asian Population: The Singapore General Hospital Experience*. Proceedings of Singapore Healthcare22:1
21. Schnabel A, Reichl SU, Kranke P, Pogatzki-Zahn, Zahn PK (2010) *Efficacy and safety of paravertebral blocks in breast surgery: A meta-analysis of randomized controlled trials* BJA 105: 842-852.
22. Beyaz SG, Ergönenç T, Altıntoprak F, FuatErdem A (2012) *Thoracal paravertebral block for breast surgery*. Dicle Med J 39: 594-603.
23. Kulkarni KRR. *Single Needle Thoracic Paravertebral Block with Ropivacaine and Dexmeditomidine for Radical Mastectomy: Experience in 25 Cases*. Int J Anesth Pain Med. 2016, 2:1. doi: 10.21767/2471-982X.100013
24. Das S, Bhattacharya P, Mandal MC, Mukhopadhyay S, Basu SR, Mandol BK. *Multiple-injection thoracic paravertebral block as an alternative to general anaesthesia for elective breast surgeries: A randomised controlled trial*. Indian J Anaesth 2012; 56:27-33.
25. Cheema SP, Ilsley D, Richardson J, Sabanathan S. *A thermographic study of paravertebral analgesia*. Anaesthesia. 1995 Feb;50(2):118-21.
26. Karmakar MK, Chung DC. *Variability of a thoracic paravertebral block. Are we ignoring the endothoracic fascia*. Reg Anesth Pain Med. 2000 May-Jun;25(3):325-7.