www.jmscr.igmpublication.org
Impact Factor (SJIF): 6.379
Index Copernicus Value: 71.58
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v6i3.75

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Thoracic Paravertebral Block, a Suitable and Safe Adjunct for General Anaesthesia, for Post-Operative Pain Relief in Modified Radical Mastectomies

Authors
Gayatri Sasikumar[1], Rachel C Koshy[2], Deepthi J Prabhu[3]
[1]Junior resident, Division of Anesthesiology, Regional Cancer Centre, Trivandrum, Kerala, India
[2]Professor & HOD, Division of Anesthesiology, Regional Cancer Centre, Trivandrum, Kerala, India
[3]Assistant Professor Division of Anesthesiology, Regional Cancer Centre, Trivandrum, Kerala, India
Corresponding Author
Dr Deepthi. J Prabhu
Assistant Professor, Division of Anaesthesiology, Regional Cancer Centre, Trivandrum
Email: *drdeepthiprabhu@gmail.com*, Mob: 9895006045

Introduction

Paravertebral block (PVB) has been safely used as a sole anaesthetic or as a supplement to GA in patients undergoing breast surgery.[1] It's analgesic effect is attributed to its distinctive property of eliminating cortical responses to thoracic dermatomal stimulation.[2,3] which clinically translates to prolonged sensory neural block resulting in decreased analgesic requirements.[4] Further merits of PVB include a reduced incidence of post operative nausea and vomiting, early ambulatory discharge & preventive benefit in chronic pain following mastectomy[1]. Acute post operative pain has been postulated to be an important contributory factor in perioperative immune suppression which has been hypothesized to have a role in tumour progression and recurrence[5]. PVB due to its superior analgesic efficacy may thus have a beneficial role in contributing to a recurrence free survival in patients with carcinoma breast.

In this study, we aim to show the prolonged post-operative analgesic effect provided by PVB, when used as a supplement to general anaesthesia and the resultant reduction in postoperative opioid and analgesic requirements. Our rationale in using paravertebral block, is its relative ease of performance with lesser incidence of complications & hemodynamic variations.

Methodology

This prospective randomized controlled trial was conducted in the Department of Anaesthesiology, at Regional Cancer Centre, Thiruvananthapuram; India after Institute review board and Ethics committee approval. The study was conducted over a period of nine months. Female patients belonging to ASA class I - III, aged 18 years and older, scheduled to undergo elective modified radical mastectomy, for breast cancer, were included. Those excluded from the study were patients with BMI > 30 kg/m^2 ,pregnant or

lactating and those with a history of severe bleeding disorders, contraindication to non-steroidal anti-inflammatory drugs (NSAID's), infection at the thoracic paravertebral injection site, significant spinal deformities and allergy to amide local anaesthetics . Preoperatively, all the patients included in the study were familiarized with the use of VAS (Visual analog scale) and informed written consent taken. Patients were randomly allocated into two groups (P and G) using a computer generated random number. Patients in group P received multisite thoracic (T2 –T5) PVB on the side to be operated, followed by induction of general anaesthesia. Patients in group G received general anaesthesia alone.

Oral Pantoprazole 40mg and Alprazolam 0.25 mg premedication, was given to all enrolled patients at 6 am on the morning of surgery. In the operating room, base line hemodynamic parameters were recorded and the side to be operated was verified. Both the study groups were given 1mg midazolam and 50micrograms fentanyl intravenously. Using the landmark technique, paravertebral block was performed by the investigators in group P ,in the sitting position using a 23G Quinke spinal needle and3-4 ml of 0.5% bupivacaine (total dose not exceeding 2mg/kg) was administered at each level. General anaesthesia was then administered similarly in both groups by a consultant anaesthetist not involved in the study, with 2-3mg/kg propofol IV followed by 0.1mg/kg vecuronium. Airway was secured with an appropriately sized supraglottic airway device. Anaesthesia was maintained with nitrous oxide, oxygen and isoflurane. Analgesia was supplemented with additional doses of fentanyl up to a total dose of 2 mcg/kg. Propofol infusion (standard recommended dose 50-100microgram/kg/min) was started to further maintain MAP between 60-70mm of Hg. Antiemetic prophylaxis was given with intravenous ondansetron 4mg, before the end of surgery. The patient was reversed with neostigmine and glycopyrrolate and shifted out to the recovery room. The time to perform paravertebral block (time from attaching monitors until supine position), time to perform general anaesthesia (time from attaching monitors until SGAD placement), the resulting anesthesia preparation time from the above (time from attaching monitors to SGAD placement) and total intra operative dose of fentanyl was recorded by the anaesthesia resident assisting in the case. Post operatively, VAS scores with shoulder flexion and abduction were recorded at 30 and 60 minutes in the recovery room and thereafter in the post surgical ward at 2, 6, 12 and 18 hours by a trained nurse blinded to the study. Rescue analgesia was provided with intravenous tramadol 50 mg (given Q6H PRN) for patients with VAS ≥3. Subsequent complaints of pain between two consecutive doses of tramadol were addressed with intravenous diclofenac sodium 75 mg (given Q8H PRN). Inj.ondansetron 4mg IV and Inj. Ranitidine 50mg IV were continued postoperatively every 8 hours. Inj Metoclopramide 10 mg IV was given if patient continued to complain of PONV. The VAS scores, total analgesic requirements, timing of drug administration and procedure related complications if any were collected. Patient satisfaction at the end of 24 hrs was recorded based on a 3 point scoring system (1= not satisfied; 2= partially satisfied; 3= very satisfied).

Assuming a sensitivity of 80% and alpha error of 5%, the largest sample size obtained was 36 in each group, in order to get statistically significant results. Statistical analyses were performed with SPSS for Windows (SPSS; version 17.0; SPSS, Chicago, IL, USA). Normally distributed data were analyzed using unpaired Student's t-tests and Fisher exact test, whereas for analysis of categorical and skewed data, Chi square and Mann-Whitney U-tests were used as appropriate. The results are presented as mean ± sd, median (inter quartile range), or number of patients. $P < 0.05$ was considered statistically significant.

Result

Seventy-two patients completed the study protocol. The two groups were similar with respect to demographic characteristics (Table 1) – age (P=0.33); weight (P=0.84); height (P=0.11) and ASA physical status (P=0.43).The mean time for anaesthesia preparation was 5±1 min in G group and 20±5 min in P group. The mean duration of anaesthesia was 95.7±13.2 min in G group and 96.1±15 in P group (P=0.9) (Table 2). The intraoperative requirement of fentanyl was 25% lesser in group P and this difference was found to be statistically significant (p<0.001). PVB did not alter primary awakening from general anaesthesia, as indicated by similar recovery times in both the groups. Lower VAS scores at 30min (P<0.001) and 60 min (P<0.001), longer times to first analgesic dose (P<0.001) and smaller tramadol consumption (P<0.001) in the recovery unit (Table 3) was noted in group P. The analgesic effect continued even after the patients were shifted to the postoperative ward as indicated by the significant differences in the VAS scores at 2h, 6h, 12h and 18h (P<0.001)(Table 4; Fig.1). Though amount of tramadol administered for postoperative analgesia was significant between the 2 groups at 6 to 18h (P<0.001), it did not attain statistical significance in the 1 to 6h period (P=0.48). The intensity of pain at its first onset after surgery, was significantly higher in group G (P<0.001). There was also a major difference in the maximum and minimum VAS scores recorded between the 2 groups (P<0.001). In group G, 19 more patients required rescue analgesic (diclofenac IV) postoperatively (P<0.001). The overall patient satisfaction was significantly better in the PVB group at the time of discharge (P<0.001) (Table 5; Fig.2).

Table 1 Patient Characteristics

Variable	G group (n=36)	P group (n=36)	P value
Age (yr)	55.8 ± 8.9	53.6 ± 9.6	0.33
Weight (kg)	53.1 ± 2.6	52.9 ± 3.2	0.84
Height (cms)	149.9 ± 3.2	151.1 ± 3.4	0.11
Body Mass Index (kg/m^2)	23.6 ± 1.1	23.1 ± 1.4	0.13
ASA status I/ II/ III (n)	8 / 28 / 0	12 / 24 / 0	0.43

Data are presented as mean ± sd. Groups are presented as the number of patients. There were no statistically significant differences between groups.

Table 2. Intraoperative Data

Variable	G group (n=36)	P group (n=36)	P value
Total fentanyl dose (mcg)	100(100/110)	75(50/100)	<0.001
No of patients requiring intraoperative propofol infusion (n)	20 (55.6%)	0	<0.001
Duration of Anaesthesia (min)	95.7± 13.2	96.1 ± 15	0.90

Data are presented as mean ± sd or median (interquartile range) as appropriate. Groups are presented as the number of patients.

Table 3. Data on Postoperative Pain, and Opioid Consumption in the Recovery Unit

Variable	G group (n=36)	P group (n=36)	P value
Postoperative pain (10-cm VAS)			
30 min	2(0/5)	0(0/0)	<0.001
60 min	2(1/3)	0(0/1.5)	<0.001
Tramadol IV consumption (mg)	50(50/50)	0(0/0)	<0.001
Time to first analgesic (min)	30(30/60)	210(60/690)	<0.001
VAS at first analgesic	4.5(4/5)	3.0(3/3.75)	<0.001

Data are presented as median (interquartile range).

Table 4 Data on Pain and Tramadol Consumption on the Ward up to 18 Hours

Variable	G group (n=36)	P group (n=36)	P value
Postoperative pain (10-cm VAS)			
2 h	2(1/2)	0(0/2)	<0.001
6 h	2(2/3)	0(0/1)	<0.001
12 h	2(2/3)	1(0/1)	<0.001
18 h	3(2/3)	1(0/1)	<0.001
Maximal pain (10-cm VAS) in the 18-h period	4(4/5)	3(1/3)	<0.001
Minimal pain (10-cm VAS) in the 18-h period	1(0/1)	0(0/0)	<0.001
Tramadol consumption (mg) after discharge from recovery unit			
Tramadol dose IV upto 6 h (mg)	50(0/50)	0(0/50)	0.48
Tramadol dose IV 6 -18 h (mg)	50(50/50)	0(0/50)	<0.001
Number of patients requiring rescue analgesic (diclofenac IV)	27	8	<0.001
Median dose of diclofenac (mg)	75(18.8/75)	0(0/0)	<0.001

Data are presented as median (interquartile range). Groups are presented as the number of patients.

Table 5. Patient satisfaction at time of discharge

Patient satisfaction	G group (n=36)	P group (n=36)	P value
Unsatisfied	5 (13.9)	0(0)	0.001
Partially satisfied	15(41.7)	6(16.7)	<0.001
Very satisfied	16(44.4)	30(83.3)	<0.001

Groups are presented as the number of patients (%).

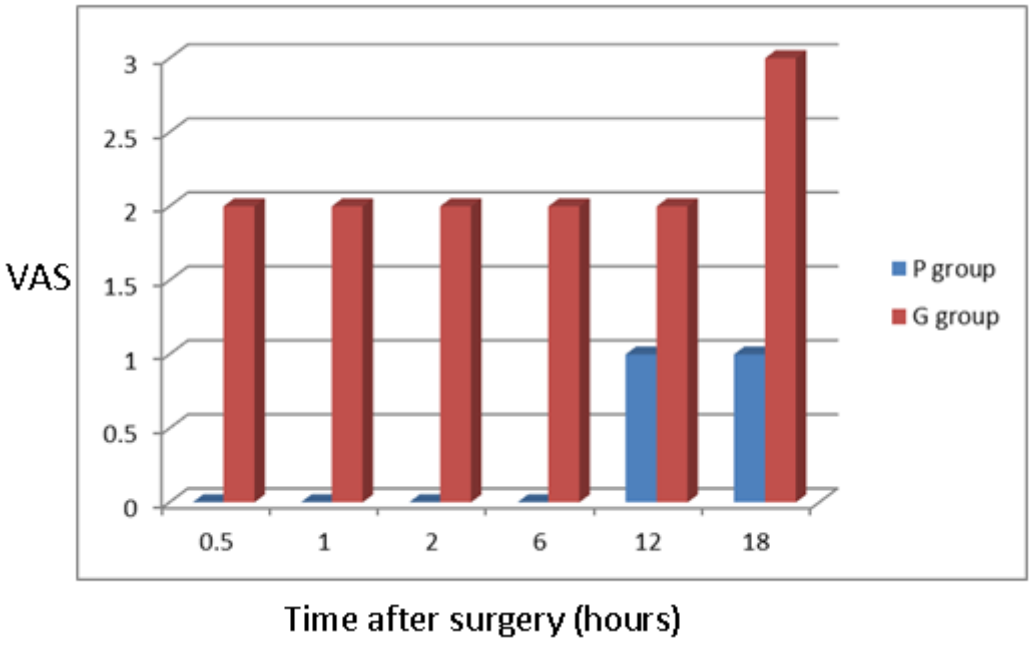

Fig. 1. Visual Analogue score at different times after surgery in both the groups

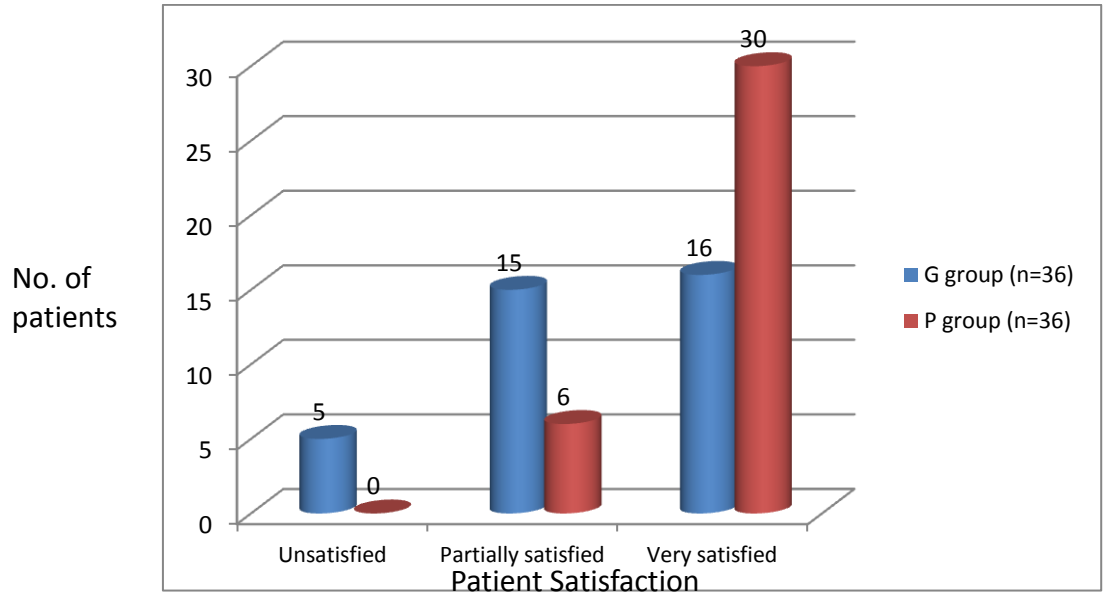

Fig.2. Patient satisfaction at the time of discharge

Discussion

The postoperative analgesia attributable to PVB when used alone or in combination with GA has been studied at various time intervals. In two studies done by Dabbagh and Elyasi[41(6)] and El Nasr et al[38(7)], the VAS scores reported were significantly lower (<3) in the first 6hrs following breast surgeries done solely under PVB. This led to more patients from the PVB group bypassing the PACU & being discharged earlier. However the VAS scores at 24, 48 &72 hrs were not significantly different in both the groups. Similarly, Klein et al.[1] followed VAS scores up to 72 hrs following surgery and after discharge from PACU in patients with PVB. They concluded that patients in this group had lower VAS scores at 30 minutes, 1hr, 24hrs, and 72 hours (P=0.05 for all); however, VAS pain scores 24, 48, and 72 hours after discharge were similar in the two groups.

Therefore, it seems that after surgery, PVB provides early improved pain relief compared with GA; though, no consistently sustained effect has been observed beyond the immediate postoperative period. In contrast, we found a significant decrease in the number of patients in the PVB group, who reported ≥3 on the VAS in the first 18 hours following surgery (P<0.001).

The requirement of analgesics in the recovery unit (in the first 60 minutes following surgery) was significantly less in the patients receiving PVB (P<0.001). A similar effect was noticed 6 to 18hrs (P<0.001) postoperatively. Though the requirement of analgesics in the interim period viz. 1 to 6h was also less in the P group, this difference did not attain statistical relevance (P=0.48). This could probably be explained by the increased usage of analgesics in the recovery unit in the (G) group which resulted in better pain scores. The gradual wearing down of the analgesic effect after 6h led to higher VAS scores in the G group whereas the P group continued to have low pain scores as a result of the PVB. There was also a significant difference in the time to first onset of pain between the 2 groups (P<0.001). This is similar to the observation made by Kairaluoma et al.[25 (8)] in their study on 60 patients who obtained benefits of PVB in the first postoperative day. However in contrast to their study, where no significant difference was noted in the total intra operative use of fentanyl, propofol, sevoflurane or rocuronium; we observed a significant decrease in the intraoperative use of fentanyl in the P group (P<0.001).

PVB offers an added benefit of reducing the incidence of PONV.[3,9,10,11]. the incidence of nausea and vomiting after breast cancer surgery with general anaesthesia in the first 24 hrs `is59%.[44 (12)] In a systematic meta-analysis, six

studies reported on PONV.[1,7,13,14,15,16] Of these, three RCTs that compared PVB and GA for anaesthesia during breast surgery, showed that the pooled relative risk for PONV was 0.25 (95% CI: 0.13– 0.50), significantly in favour of PVB.[7,13,15] Of the next three studies, one study reported that nausea occurred significantly less frequently after PVB compared with GA.[16] The 2nd study reported significantly less PONV after PVB , 24 hours after surgery.[1] The 3rd study reported a similar incidence of PONV in both the PVB & GA groups.[14] In our study we did not assess PONV in both the groups as all the patients were on prophylactic ondansetron all through postoperative period. This was essential since most of the patients had received neo-adjuvant chemotherapy prior to the surgical procedure. However, we did find an increased usage of metoclopramide in the GA group in comparison to the PVB group, though it did not attain statistical significance.

In a systematic review of eight randomized controlled trials (RCTs) (level II evidence) by Thavaneswaran et al.,[17] seven RCTs[1,7,13-16,18] reported on the failure rates of PVB which were between 0-13%. Wassefet al.[18] reported that 100% of field blocks were effective. Therefore, although any form of regional block will have more failures than GA, the PVB failure rate was not >13%. In our study we did not encounter any failed block.

The time taken for preparation of anesthesia in P group was more in comparison to the control group. Similarly, in the study by Klein et al.,[1] the mean time for anaesthesia preparation was 4 ± 1 min in the GA group and 24 ± 7 min for the PVB group (P=0.0001). Despite the additional time required, the technique offers patients postoperative benefits that may justify the increased effort by the anaesthesiologist.

Studies reporting on patient satisfaction with anesthetic procedures compared PVB vs field block[18] and general anesthesia.[15]. Patient satisfaction scores for PVB was found to be higher than those with field block (P= 0.05) and those following GA (P =0.008).[18] In our study we found that 83% of patients (n =30) were very satisfied with the degree of pain relief that PVB provided in comparison to 44% in group G (n=16).

Reviews of randomized studies on PVB[17] have not provided conclusive evidence on perioperative mortality rates. We fortunately did not encounter any mortality during the study.

Lönnqvist et al.[19] prospectively evaluated complications after PVB (thoracic and lumbar) in 367 patients (319 adults, 48 children) and observed the complications in the following frequency: vascular puncture 3.8%, hypotension 4.6%, pleural puncture 1.1%, and pneumothorax 0.5%. We had no complications related to the PVB procedure.

There are several approaches to the paravertebral block. Both single[8,13,20] and multilevel[1,9,15,21,22] injections have been reported to provide good analgesia. We used a multilevel injection PVB which has been shown to produce a more reliable sensory block than a single injection technique.[23] Drugs used for PVB include bupivacaine, ropivacaine, and levobupivacaine with or without epinephrine. In our study, bupivacaine 0.5% was used, as it is more readily available and less expensive.

Our study has many limitations. The extent of sensory block achieved with the PVB was not assessed. Lack of a placebo group may have unblinded the nurses recording the VAS scores. Different nurses recorded pain scores at various points since a dedicated pain nurse was absent. So inter observer variability in the data could have occurred. Also, the tolerance to pain and its interpretation is subjective and hence may vary among population. The recording of VAS after surgery at fixed intervals of time may also have led to observer bias, since documentation of VAS during the night when patient prefers to sleep might have been lower when the same was recorded during the day.

Conclusion

The usefulness of a pre incisional, multilevel, thoracic paravertebral block (PVB) for postoperative analgesia in women undergoing surgery for breast cancer, was substantiated in this randomized study. A reduction in the perioperative requirement of analgesics, absence of restriction of shoulder mobility and increased patient satisfaction were the significant advantages offered by the PVB over GA alone. The analgesic effect was measurable for upto 18 hours after surgery. The additional time and effort required for the performance of the block is amply rewarded by the postoperative pain relief and well being of the patients. The incidence of complications in the hands of trained anaesthetists is also minimal and hence the use of this procedure as a routine adjunct to general anaesthesia in breast cancer surgery could be recommended.

References

1. Klein SM, Bergh A, Steel SM, Georgiade GS, Greengrass RA. Thoracic paravertebral block for breast surgery. AnesthAnalg 2000;90:1402–5.
2. Stevenson GW, Hall SC, Rudnick S, Seleny FL, Stevenson HC. The effect of anesthetic agents on the human immune response. Anesthesiology 1990;72:542–52.
3. Oakley N, Dennison A, Shorthouse A. A prospective audit of simple mastectomy under local anesthesia. Eur J SurgOncol 1996;2:131– 6.
4. Coveney E, Weltz CR, Greengrass R, et al.Use of paravertebral block anesthesia in the surgical management of breast cancer: experience in 156 cases. Annals of surgery.1998; 227(4): 496-501)
5. Divatia JV, Ambulkar. Anaesthesia and cancer recurrence:What is the evidence? Journal of Anaesthesiology, Clinical pharmacology.2014;30(2):147-150.
6. Dabbagh A, Elyasi H. The role of paravertebral block in decreasing post-operative pain in elective breast surgeries. Med SciMonit 2007;13:CR464–7.
7. El Nasr G, El Moutaz H, Youssef M. Paravertebral block versus general anaesthesia in breast surgery. JESMP 2002;20:125–30.
8. Kairaluoma PM, Bachmann MS, Korpinen AK, Rosenberg PH, Pere PJ. Single-injection paravertebral block before general anesthesia enhances analgesia after breast cancer surgery with and without associated lymph node biopsy. AnesthAnalg 2004;99:1837–43
9. Coveney E, Weltz CR, Greengrass R, Iglehart JD, Leight GS, Steele SM, et al. Use of paravertebral block anesthesia in the surgical management of breast cancer: experience in 156 cases. Ann Surg 1998;227:496-501.
10. Buckenmaier CC 3 rd , Klein SM, Nielsen KC, Steele SM. Continuous Paravertebral Catheter and Outpatient Infusion for breast surgery. AnaesthAnalg 2003;97:715-7.
11. Matthews PJ, Govenden V. Comparison of continuous paravertebral and extradural infusions of bupivacaine for pain relief after thoracotomy. Br J Anaesth 1989;62:204-5.
12. Miguel R, Rothschiller J, Majchrzak J. Breast surgery is a high risk procedure for development of nausea and vomiting. Anesthesiology 1993;79:A1095.
13. Pusch F, Freitag H, Weinstabl C, Obwegeser R, Huber E, Wildling E. Single injection Paravertebral block compared to general anaesthesia in breast surgery. ActaAnaesthesiolScand 1999;43:770-4.
14. Terheggen MK, Wille F, BorelRinkes IH, Ionescu TI, Knape JT. Paravertebral blockade for minor breast surgery. AnesthAnalg 2002;94:355-9.
15. Naja MZ, Ziade MF, Lonnqvist PA. Nerve-stimulator guided paravertebral blockade vs. general anaesthesia for breast

surgery: a prospective randomized trial. Eur J Anaesthesiol 2003;20:897–903

16. Hadzic A, Kerimoglu B, Loreio D, Karaca P, Claudio R, Yufa M, Wedderburn R, Santos A, Thys D. Paravertebral blocks provide superior same-day recovery over general anaesthesia for patients undergoing inguinal hernia repair. Anesth Analg 2006;102:1076–81
17. Thavaneswaran P, Rudkin GE, Cooter RD, Moyes DG, Perera CL, Maddern GJ. Brief reports: paravertebral block for anesthesia: a systematic review. AnesthAnalg. 2010 Jun 1;110(6):1740-4.
18. Wassef M, Randazzo T, Ward W. The paravertebral nerve root block for inguinal herniorrhaphy—a comparison with the field block approach. RegAnesth Pain Med 1998;23:451–6.
19. Lönnqvist PA, MacKenzie J, Soni AK, Conacher ID. Paravertebral blockade. Failure rate and complications. Anaesthesia 1995;50:813-5.
20. Hura G, Knapik P, Misiolek H, Krakus A, Karpe J. Sensory blockade after thoracic paravertebral injection of ropivacaine or bupivacaine. Eur J Anaesthesiol 2006;23:658–64.
21. Weltz CR, Greengrass RA, Lyerly HK. Ambulatory surgical management of breast carcinoma using paravertebral block. Ann Surg 1995;222:19–26.
22. Najarian MM, Johnson JM, Landercasper J, Havlik P, Lambert PJ, McCarthy D. Paravertebral block: an alternative to general anesthesia in breast cancer surgery. Am Surg 2003;69:213–8
23. Naja ZM, El-Rajab M, Al-Tannir MA, Ziade FM, Tayara K, Younes F, Lonnqvist PA. Thoracic paravertebral block: influence of the number of injections. Reg Anesth Pain Med 2006;31:196–201.