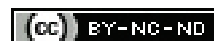


# Comparative Study of the Efficacy and Safety of Ultrasound-guided and Landmark-based Paravertebral Block Technique in Patients undergoing Elective Unilateral Breast Surgery

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## ABSTRACT

**Introduction:** Identifying the Paravertebral Space (PVS) by its anatomical landmarks is associated with high failure rates and complications. With the advent of Ultrasonography (USG), failure rate has decreased leading to an increased interest in performing USG-guided Thoracic Paravertebral Block (TPVB).

**Aim:** To assess the efficacy and safety of ultrasound guided TPVB and its comparison with the landmark-based technique, in patients undergoing elective unilateral breast surgery.

**Materials and Methods:** This cross-sectional study was carried out at Command Hospital, Pune from July 2014 to December 2015, on females between 18-70 years, accepted in American Society of Anaesthesiology (ASA) I-III for unilateral breast surgeries. Patients were divided into two groups with 40 subjects in each group. Group A subjects were treated with anatomical landmark technique and group B subjects with Ultrasound-guided (USG-guided) technique. The p-value <0.05 was considered to be statistically significant.

**Results:** Demographic parameters (age, height, weight and Body Mass Index (BMI) and the scheduled surgery were comparable

in between the groups. In group A, success rate of the block was 82.5%, compared to 95% in group B (p-value >0.05 using Fisher's-Exact test). Mean (SD) time taken for performing the block in group A was 371.10 (10.37) seconds while it was 613.73 (37.15) seconds in group B (p-value <0.05 by two independent sample t-tests). No statistically significant difference was seen in haemodynamic parameters, except for the Heart Rate (HR) at 70, 80, 90 minutes after administering the block and at the end of surgery. Correlation analysis for quantitative variables with PVS depth (dependent variable), measured sonologically, showed very good linear correlation of PVS depth with weight (Pearson's correlation coefficient,  $r=0.819$ , p-value <0.001). BMI ( $r=0.884$ ; p-value <0.001).

**Conclusion:** The success rate is higher with ultrasound-guided TPVB compared to the landmark technique, though statistically insignificant. But it is recommended to use ultrasound-guided TPVB for advantages such as lesser requirement of opioid supplementation, real time visualisation of the spread of drugs in PVS with lesser complication rates.

**Keywords:** Anatomic landmark, Heart rate, Paravertebral, Thoracic, Ultrasonography

## INTRODUCTION

Ultrasound-guided TPVB is a topic of renewed interest amongst the practitioners, however concerns regarding its safety and efficacy still exist. Many practitioners, however, remain hesitant to perform TPVB owing to the associated risk of pneumothorax (0.5%-2%), in addition to the risk of dural puncture with landmark approaches [1]. The anatomical landmark techniques rely on indirect methods of identification of the PVS with failure rates of 10.7-15% and complication rates of 5% [2,3]. Luyet C et al., in a cadaver model demonstrated direct visualisation of the superior costotransverse ligament via high-resolution USG, which is an important structure to be traversed while performing the paravertebral block [4]. The growth of USG and the ability to visualise the pleura and other anatomical structures in and around the PVS with the needle and real time spread of local anaesthetic in PVS has fuelled a tremendous increased interest in performing USG-guided TPVB [5].

Considering the hypothesis that, USG-guided TPVB leads to an increase in efficacy with an accurate estimation of PVS depth from skin, the present study was undertaken to assess the efficacy and safety of USG-guided TPVB and its comparison with the landmark-based technique in patients undergoing elective unilateral breast surgery.

The primary objective of the study was to compare the success rate with the time required to perform the block and the secondary

objective was to compare the average depth of the PVS from the skin along with complications, if any, in between the two techniques.

## MATERIALS AND METHODS

This cross-sectional study was carried out in a tertiary care teaching hospital at AFMC and Command Hospital, Pune, from July 2014 to December 2015 after taking appropriate Institutional Ethical consent (IEC S.No.IEC/2011/Oct 2011).

**Inclusion criteria:** Females between 18-70 years of age, planned for unilateral breast surgeries, accepted in physical status class ASA I-III were included in the study.

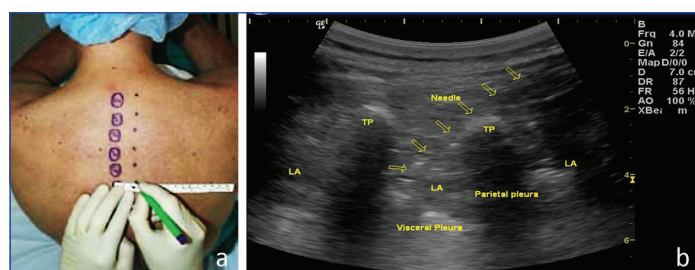
**Exclusion criteria:** Spinal disorders such as kyphoscoliosis, local infection, coagulopathies, septicaemia, allergic to local anaesthetics and refusal to participate in the study were excluded.

**Sample size calculation:** Sample size was decided as 40 in each group considering an alpha error of 5%, power of the study 80% and assuming success rates of anatomical landmark-based technique and ultrasound guided TPVB to be 80% and 99%, respectively, based on a pilot study in the same Institute [6]. However, all 123 patients who reported for undergoing elective breast surgery during the study period were assessed for eligibility to be included in the study. After satisfying the inclusion criteria, 80 out of these 123 patients were included in the study for final analysis. These patients were allocated into two groups by consecutive sampling: Group A (receiving TPVB by anatomical landmark technique) and Group B (receiving ultrasound-guided TPVB).

After obtaining the written informed consent, all patients were kept fasting as per standard guidelines. Intravenous (i.v.) catheter placement was done following application of Eutectic Mixture of Local Anaesthetics (EMLA) cream. Standard monitoring like Electrocardiogram (ECG), Oxygen saturation ( $\text{SpO}_2$ ), Heart Rate (HR), and Non Invasive Blood Pressure (NIBP) was instituted. Catheter was inserted in thoracic PVS in sitting position using either of the two techniques.

**Group A:** For the anatomical landmark-based technique, under strict asepsis, 3 mL of 2% lignocaine was infiltrated, 2.5 cm lateral to upper border of T4 spinous process and a skin wheal was raised. 16 Gauge Tuohy's needle was then inserted at this point advancing anteriorly in the parasagittal plane (perpendicular to the back). After the Tuohy's needle got fixed in the subcutaneous tissue, its stylet was removed and a Loss Of Resistance (LOR) syringe was attached to it. The needle was further advanced until it contacted the transverse process. Thereafter, the needle shaft was grasped with the fingers 1 cm from the skin surface so that the fingers served as a "backstop" to prevent the needle from passing beyond 1 cm into the PVS and possibly contacting the parietal pleura. Then the needle tip was withdrawn to the subcutaneous tissue and angled to "walk off" the cephalad edge of the transverse process, advancing it further, till a "pop" or LOR was appreciated indicating that the needle tip had pierced the superior costotransverse ligament. The LOR syringe was then detached from the Tuohy's needle and 25 cm extension tubing with syringe containing the initial test dose (3 mL of 2% lignocaine with 1:2,00,000 epinephrine) was attached to the Tuohy's needle for delivering the same after negative aspiration for blood. Thereafter, epidural catheter (18-gauge in size) was threaded into the PVS and left 3-4 cm in-situ. This catheter was then secured on the skin with sterile adhesive dressing [Table/Fig-1a].

**Group B:** For USG-guided TPVB, a parasagittal in-plane approach was used. The local area was first properly prepared and disinfected following which a point 2.5 cm lateral to the upper border of the T4 spinous process was marked. A linear array transducer (Sonosite 5-8 MHz) was placed parallel to the T4 spinous process in vertical orientation and the transverse process, superior costotransverse ligament and parietal pleura were identified. Slight tilting of the probe allowed for better visualisation of the superior costotransverse ligament and pleura. Skin and the planned trajectory pathway of the Tuohy's needle, was infiltrated with 2% lignocaine (3-5 mL). A 16-gauge Tuohy's needle connected to 25 cm extension tubing was inserted under ultrasound guidance, using a parasagittal in-plane approach in the cephalad direction. The PVS was entered midway between the two transverse processes avoiding any bony contact. The tip of the needle was advanced under direct vision to puncture the superior costotransverse ligament which was associated with a tactile "pop". After negative aspiration for blood, test dose was injected slowly into the PVS which resulted in anterior displacement of the pleura. An epidural catheter (18-gauge) was threaded into the PVS and left 3-4 cm in-situ as done in the other technique [Table/Fig-1b].



**[Table/Fig-1]:** Techniques of needle placement for thoracic paravertebral block. a) Anatomical landmarks for thoracic PVB with patient in sitting position; b) Sagittal in plane needle insertion. (Note the small distance between the transverse processes (TP) determines the steep angle of insertion. Local anaesthetic (LA) can be seen in the paravertebral space at the levels adjacent to the insertion point when a curved probe is used).

## Study Procedure

Following the initial test dose, 10-15 ml bolus (0.2 ml/kg) of 0.5% bupivacaine was injected over a period of 30 seconds after negative aspiration and continuous infusion of 0.25% bupivacaine at the rate of 6-10 mL/hour (0.15 mL/kg/hour) through the catheter intraoperatively. Postoperatively, all the patients received 0.1 mL/kg/hour of 0.125% bupivacaine, which was continued for a period of 48 hours.

Time taken for performing the TPVB using either technique was noted along with the perioperative haemodynamic variables like HR, NIBP, Mean Arterial Pressure (MAP),  $\text{SpO}_2$  at 1, 3, 5, 10 minutes after instituting the block and every 10 minutes, thereafter, till completion of surgery.

Time taken for performing the block in group A was recorded from when the Tuohy's needle was taken in hand for performing the block till the point of securing the paravertebral catheter. In group B, it was taken from the time of placing the ultrasound probe on the back of the patient over the target area till the point of securing the paravertebral catheter. Both the groups were observed for the complications like pneumothorax, vascular puncture, hypotension and arrhythmia.

Onset of TPVB (approximately after 10-15 minutes of administering the block) was noted by checking for the loss of pin prick sensation on the chest wall in the mid-clavicular line on the ipsilateral side.

All patients received general anaesthesia as per the following protocol. Patients were premedicated with Injection (Inj.) Glycopyrrolate 0.1 mg i.v. (given prior to performing the block using either technique), Inj. Midazolam 2 mg iv. and Inj. Fentanyl 1 mcg/kg, i.v. (given after administering the block using either technique). Induction was done with propofol 2-3 mg/kg i.v. and intubation with appropriately sized endotracheal tube (ETT) using Inj. Vecuronium 0.1 mg/kg i.v. Maintenance of anaesthesia was achieved with  $\text{O}_2 + \text{N}_2\text{O}$  (1:2) + isoflurane (0.6-1%), with intermittent doses of vecuronium as required. Extubation was done following reversal of neuromuscular blockade using Inj. Neostigmine 50 µg/kg i.v. and Inj. Glycopyrrolate 10 µg/kg i.v.

The success of the block was corroborated by change in HR less than 20% on surgical incision or by change in MAP less than 20% with respect to pre-incision value for a period of less than five minutes along with no opioid supplementation in a period of 24 hours following surgery.

Inj. Morphine (0.1 mg/kg i.v. intraoperatively) and (0.05 mg/kg postoperatively) was decided as rescue analgesia. Intraoperative increase in HR >30%, (ruling out other causes) and patient's demand for pain relief in the post-operative period were considered for opioid supplementation.

Postoperative observation was continued till 24 hours after the surgery by the anaesthesiologist not involved in performing the procedures. All the continuous catheters of TPVB were removed on the second postoperative day.

## STATISTICAL ANALYSIS

Data was tabulated on Microsoft Excel worksheet and statistical analysis was done using Statistical Package of the Social Sciences (SPSS) version 17.0 (SPSS Inc., Chicago, IL, USA). All categorical data were expressed in the form of numbers and percentage while continuous data were expressed in the form of mean and Standard Deviation (SD) and studied using appropriate statistical tests ( $p$ -value <0.05 was considered to be statistically significant). Demographic parameters (age, height, weight and BMI) between the two groups were analysed by two independent sample t-test. The type of scheduled elective unilateral breast surgeries, either Breast Conservation Surgery (BCS) or Modified Radical Mastectomy (MRM) was compared using Chi-square test. Success rates of the block were compared using Fisher's-Exact test. Mean (SD) time

taken for performing the block was compared by two independent sample t-tests. For age and height, Pearson correlation coefficient (r) was used to assess the linear correlation of age and height with PVS depth.

## RESULTS

After satisfying the inclusion criteria, 80 out of 123 patients were included and allocated into two groups in the study for final analysis. No statistically significant difference in any of the demographic parameters (age, height, weight and BMI) between the two groups was observed (two independent sample t-test p-value >0.05). All the 80 patients were scheduled for elective unilateral breast surgeries, either BCS or MRM. When compared, (p-value >0.05, Chi-square test) there was no association between the technique of block used and the type of surgery [Table/Fig-2].

Distribution of demographic parameters			
Particulars Mean (SD)	Group A (Landmark) Mean (SD)	Group B (USG) Mean (SD)	p-value (t test)
Age (in years)	46.55 (7.35)	49.23 (7.65)	0.115
Height (in cm)	159.38 (2.60)	160.20 (3.24)	0.213
Weight (in kg)	53.95 (4.92)	55.65 (5.26)	0.140
BMI (in kg/m <sup>2</sup> )	21.22 (1.58)	21.67 (1.84)	0.242
Details of the surgical procedures			
Type of surgery	Group		p-value (Chi-square test)
	Anatomical (n)	USG (n)	
BCS	20	17	0.654
MRM	20	23	
Total	40	40	80

**[Table/Fig-2]:** Comparison of demographic parameters (age, height, weight and BMI) and the association between the technique of block used and the type of surgery.

In Group A (anatomical landmark technique group), success rate of the block was seen in 33 (82.5%) patients as compared to 38 (95%) in group B (USG group). This difference was not statistically significant (p-value >0.05, Fisher's-Exact test). A total of 88.75% (71 out of 80) patients had successful block [Table/Fig-3].

Success (Efficacy)	Group		Total	p-value (Fisher's-Exact test)
	Anatomical n (%)	USG n (%)		
Yes	33 (82.5%)	38 (95%)	71 (88.75%)	0.154
No	7 (17.5%)	2 (5%)	9 (11.25%)	
Total	40	40	80	

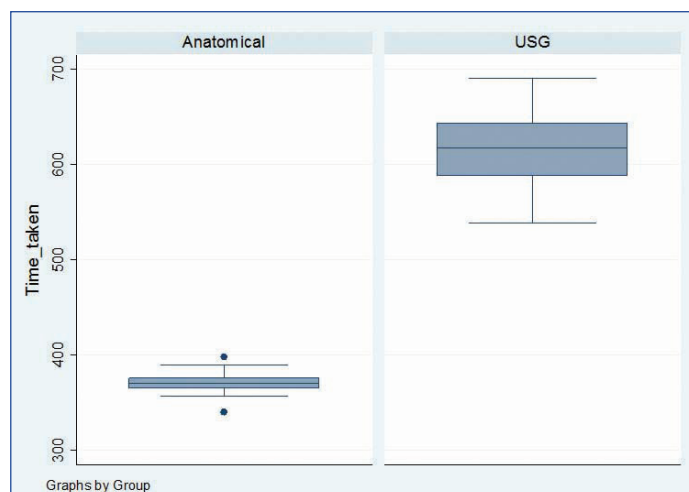
**[Table/Fig-3]:** Success rate of paravertebral blocks in both groups.

There were two failures in the ultrasound group (one developed hypotension and one required opioid supplementation), whereas there were seven failures in the anatomical landmark technique group (two developed hypotension and five required opioid supplementation).

Mean (SD) time taken for performing the block in the anatomical group was 371.10 (10.37) seconds while it was 613.73 (37.15) seconds in the USG group. (p-value <0.05, two independent sample t-tests). (p-value <0.05; Mann-Whitney U test) [Table/Fig-4].

Two patients had vascular puncture and two patients developed hypotension. In Group A whereas there was no vascular puncture and only one patient developed hypotension in Group B. (p-value >0.05; Fisher's-Exact test [Table/Fig-5]).

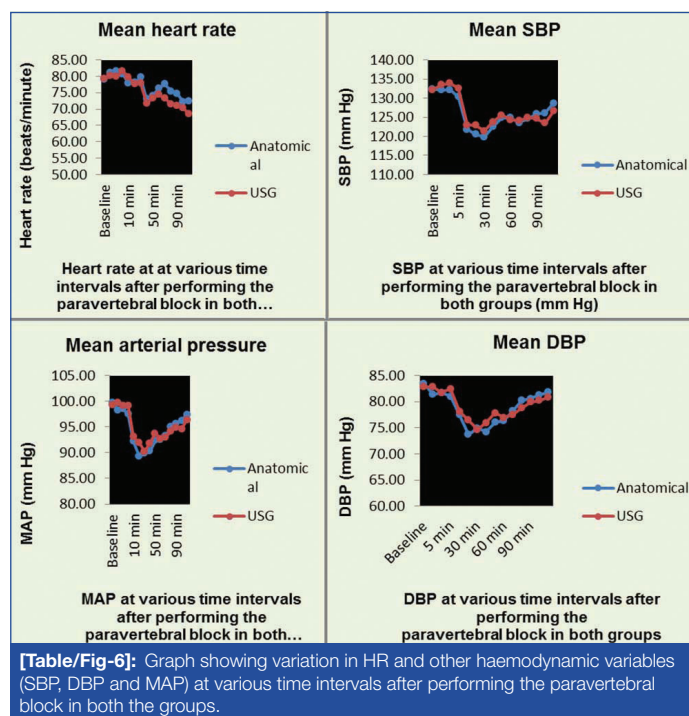
No statistically significant difference was seen in heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) and MAP, using the two-sample t-test at baseline, and at any point of time after performing the block except a statistically significant difference for the HR at 70, 80, 90 minutes after administering the block and at the end of surgery [Table/Fig-6].



**[Table/Fig-4]:** Box and whisker plot showing median time required for performing block in both groups. p-value <0.05, using Mann-Whitney U test

Complications	Group		p-value
	Anatomical	USG	
Vascular punctures	2	0	0.359
Hypotension	2	1	
No complication	36	39	

**[Table/Fig-5]:** Incidence of complications in both the groups. p-value >0.05; statistically non significant using Fisher's-Exact test



**[Table/Fig-6]:** Graph showing variation in HR and other haemodynamic variables (SBP, DBP and MAP) at various time intervals after performing the paravertebral block in both the groups.

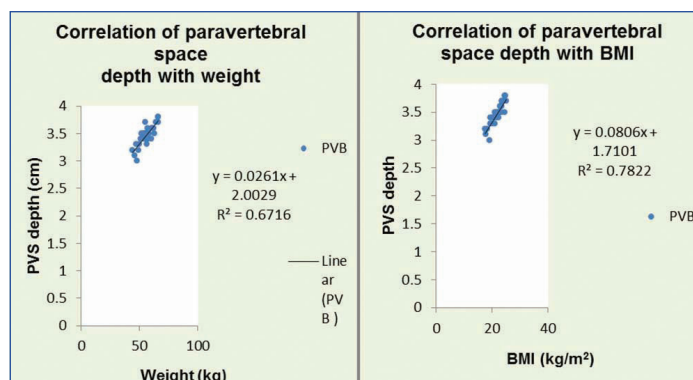
Correlation analysis was performed between the quantitative variables: age, height, weight, BMI with PVS depth (dependent variable) measured sonologically in patients receiving USG-guided block [Table/Fig-7].

There was no statistically significant difference in the mean needle insertion length (cm) to PVS using the two techniques (p-value >0.05) [Table/Fig-8].

## DISCUSSION

There are a lot of interests in TPVB by different approaches. Some studies have shown that the single-shot thoracic PVB can be a component of a multimodal analgesic regimen for abdominal surgery for up to 24 hours in the postoperative period [7]. USG guidance is the new awareness in approaching for paravertebral





**[Table/Fig-7]:** Correlation of paravertebral space depth measured by Ultrasonography (USG) with Weight in Kg and with BMI (Kg/m<sup>2</sup>).

Group	Number of patients	Needle insertion length (cm)		p-value (independent sample t-test)
		Mean	SD	
Anatomical	40	4.18	0.17	0.140
USG	40	4.31	0.16	

**[Table/Fig-8]:** Comparison of needle insertion length to paravertebral space by both the techniques (Landmark Vs USG).

block. In the present study, a parasagittal in-line approach was taken. This approach for performing TPVB under USG guidance has been observed to be highly efficacious with minimal complications and adequate needle visualisation can be achieved [8]. Chelly JE et al., have also supported the use of parasagittal approach, as in this technique the needle is advanced under direct visualisation and the spread of local anaesthetic in PVS can be monitored limiting the rate of complications [6]. Moreover in this approach, the neural foramen which is the anatomical point of entry into the epidural space is approached perpendicularly, making the procedure safer in approach [8]. On the other hand, the transverse or 'latero-medial' approach makes the needle aligned directly with the neural foramen with a potential risk for epidural blockade [2,4].

The decision of administering general anaesthesia to all the patients in addition to Continuous Catheter Paravertebral Block (CPVB) was based on a meta-analysis of fifteen randomised controlled trials including 877 patients for breast surgery, in which it was mentioned that CPVB in combination with general anaesthesia may provide the most effective perioperative analgesia for breast surgery [9]. In the present study, there was no statistically significant difference between the groups when analysed for the success rate. These results are comparable to the study done by O Riain SC et al., in which 66% patients were observed to have either partial or complete sensory loss measured at (mean±SD) 20±4.8 minutes after performing ultrasound guided TPVB, which increased to 100% in the recovery room [5]. Various studies have quoted a failure rate of TPVB using anatomical technique to be approximately 10.7-15% [3,4]. Fewer studies have addressed the success rate of CPVB, with Renes et al reporting a success rate of 100% for catheter insertion [10]. In this study, less number of patients developed hypotension and required opioid supplementation in the ultrasound group than the anatomical landmark technique group.

Mean time (in seconds) required for performance of the block was significantly prolonged in USG-guided TPVB. This finding is comparable to the study by O Riain SC et al., who reported a mean (±SD) block time of 523 (211) seconds for USG-guided TPVB. This increased time in performing the block should be weighed against the efficacy of USG-guided TPVB [5].

Though haemodynamic variables (HR, SBP, DBP and MAP) did not show any statistically significant difference in between the groups, but change in HR at 70, 80, 90 minutes after administering the block and at the end of surgery were different and statistically

significant. This may be attributed to more precise TPVB achieved under ultrasound guidance leading to a relatively more stable HR.

There was no inadvertent vascular puncture, pleural puncture, pneumothorax and only one patient developed hypotension when the block was performed under USG guidance. However, this observation was not statistically significant when compared with the other group. Studies have shown that the landmark technique failure rate appears to be higher than the USG-guided with quoted rates between 1.98 and 5.6 [11,12].

However, it is difficult to determine the present complication rates while performing paravertebral blocks on basis of the past scientific publications as higher success rate is anticipated due to use of ultrasound and nerve stimulation. Furthermore, as elucidated by Vogt A, there is strong evidence to suggest that use of ultrasound for TPVB increases its efficacy and safety with accurate placement of needle in the PVS, thereby reducing the incidence of pleural puncture and pneumothorax. These findings have been reinforced and brought out in the present study [13]. In this study, there was no statistically significant difference between the mean (SD) needle insertion length to PVS by anatomical landmark technique or under USG guidance. Estimation of this PVS depth is important, more so if the block is performed at T4 level as PVS is shallower and its depth is dependent on various variables such as age, height, weight and BMI [6].

The present study showed very good linear correlation of PVS depth with weight and BMI, whereas the linear correlation obtained with age and height was poor. Chelly JE et al., in their review of 559 surgical patients undergoing 1,318 TPVB mentioned that in the high thoracic region (i.e., between T4-T8 level), PVS depth is dependent on gender, weight, thoracic level and age of the patients [6].

Naja MZ et al., in their study comprising of 527 patients undergoing TPVB, stated that the PVS depth was significantly influenced by BMI at upper and lower thoracic levels, but not in the mid-thoracic region. These findings are comparable to the results obtained in this present study except for the correlation of PVS depth with age. This may be attributable to the limited sample size achieved in the said duration of this study [14]. The present study results support the hypothesis that USG-guided TPVB leads to an increased efficacy within accurate estimation of PVS depth.

### Limitation(s)

This could not be blinded, given the need to use the ultrasound machine, with the possibility of operator bias. Also, there is a learning curve to be surmounted before the anaesthesiologist becomes proficient in performing the USG-guided TPVB. Considering the small sample size in the present study, results cannot be extrapolated to find out the incidence of complications.

### CONCLUSION(S)

The success rate is higher with USG-guided TPVB compared to the anatomical landmark technique though statistically insignificant. Although the time taken to perform the block is prolonged with the use of ultrasound, but this is acceptable considering the advantages provided by the ultrasound as lesser requirement of preoperative opioid supplementation, real time visualisation of the spread of drug in PVS, with lesser complication rates.

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