

The comparative evaluation of safety and efficacy of unilateral paravertebral block with conventional spinal anaesthesia for inguinal hernia repair

Address for correspondence:
Dr. Manpreet Kaur,
E 19 Ayurvigyan Nagar,
New Delhi - 110 049, India.
E-mail: manpreetkaurrajpal@
yahoo.com

Sunil Kumar Sinha, Yudhyavir Brahmchari, Manpreet Kaur, Aruna Jain
Department of Anaesthesia and Intensive Care, Lady Hardinge Medical College, New Delhi, India

ABSTRACT

Background and Aims: Unilateral paravertebral block (PVB) as a sole anaesthetic technique is underutilised even in experienced hands. Hence, this study was undertaken regarding the efficacy and safety of PVB and compared with subarachnoid block (SAB) for inguinal hernia repair procedures. **Methods:** Sixty-three consenting adult male patients scheduled for unilateral inguinal hernia repair were randomly assigned to receive either PVB or SAB (Group P: PVBs at T10–L2 levels, 5 mL of 0.5% bupivacaine at each segment; Group S: SAB at L3–L4 level with 12.5 mg 0.5% of hyperbaric bupivacaine). Primary objective was to compare duration of post-operative analgesia and time to reach discharge criteria (modified Aldrete scores and modified post-anaesthetic discharge scoring [PADS] scores). Secondary objectives were to compare the block characteristics (time required for performing the block, time to surgical anaesthesia, time to ambulation, time to the first analgesic, total rescue analgesic consumption) and adverse effects. Independent Student's *t*-test was used for continuous data and Pearson Chi-square test for categorical data. $P < 0.05$ was considered as statistically significant. **Results:** The duration of post-operative analgesia (min) was 384.57 ± 38.67 in Group P and 194.27 ± 20.30 in Group S ($P < 0.05$). Modified PADS scores were significantly higher at 4 h and 6 h ($P < 0.0001$) in Group P. Time to reach the discharge criteria was early in Group P than Group S. **Conclusion:** PVB provides excellent post-operative analgesic conditions with lesser adverse effects and shorter time to reach the discharge criteria compared to SAB.

Key words: Anaesthetic technique, early ambulation, inguinal hernia repair, paravertebral block, spinal

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INTRODUCTION

Inguinal herniorrhaphy (IH) is a common day care procedure that can be performed under general anaesthesia (GA),^[1] peripheral nerve blockade, regional anaesthetic techniques-subarachnoid block (SAB)^[1-3] or paravertebral block (PVB).^[4,5] PVB is advantageous in providing long-lasting unilateral anaesthesia, haemodynamic stability, early ambulation and prolonged pain relief. However, its use as a sole anaesthetic technique is underutilised in view of technical difficulty in inexperienced hands.^[5-8]

PVB produces ipsilateral segmental analgesia through injection of local anaesthetic onto the spinal nerve roots alongside the vertebral column. It is advocated

predominantly for unilateral procedures such as thoracotomy, breast surgery, chest wall trauma, hernia or renal surgery.^[9,10] However, there are very few studies comparing its potential as an effective anaesthetic technique with SAB.^[6,11] Hence, this study was undertaken to compare safety and efficacy between unilateral PVBs and SAB in patients undergoing IH.

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METHODS

The study was a prospective randomised, comparative and single blind study. After ethical clearance and obtaining written and informed consent, 66 male patients, aged 18–65 years, American Society of Anesthesiologists (ASA) physical status Grade I or II, posted for unilateral inguinal hernia-fully reducible direct or indirect hernia (Nyhus classification^[12]) were randomly allocated into two groups using computer-generated randomisation sequence [Figure 1].

Group P patients received PVB from T₁₀ to L₂ with 5 ml of bupivacaine (0.5%) with 1:400,000 epinephrine injected at each segment, and Group S patients received SAB with 12.5 mg of hyperbaric bupivacaine.

The same anaesthesiologist performed the procedure of giving either block. Residents not participating in the study recorded intra- and post-operative data. Exclusion criteria included patients with untreated and uncontrolled systemic illness, infections at block site, morbid obesity, history of substance abuse, chronic analgesic use, history of allergy to local

anaesthetics, mental dysfunction, metabolic disease and active gastrointestinal reflux.

Eight hours fasting was ensured and patients were premedicated with oral ranitidine 150 mg on the night prior to surgery. Patients were preloaded with 10 ml/kg lactated Ringer's solution and given supplemental oxygen (4 L/min) with Venturi mask in the operation room (OR). Standard monitoring included heart rate (HR), non-invasive blood pressure, respiratory rate and oxygen saturation (SpO₂). All the patients were pre-medicated with intravenous (IV) midazolam 2 mg and fentanyl 50 µg in the OR before block placement. In case of any discomfort during the surgery, intermittent boluses of fentanyl 25–50 µg IV were administered.

In Group P, PVB was performed using the technique described by Moore and Katz.^[13-15] In the sitting position, at five levels from T₁₀ to L₂, 5 ml of bupivacaine (0.5%) with 1:400,000 epinephrine was injected at each segment (total 62.5 µg adrenaline). Then, the patient was turned supine, and the onset of unilateral pinprick discrimination assessed every 5 min and up to 30 min. The block was considered as 'successful' if the onset of pinprick discrimination

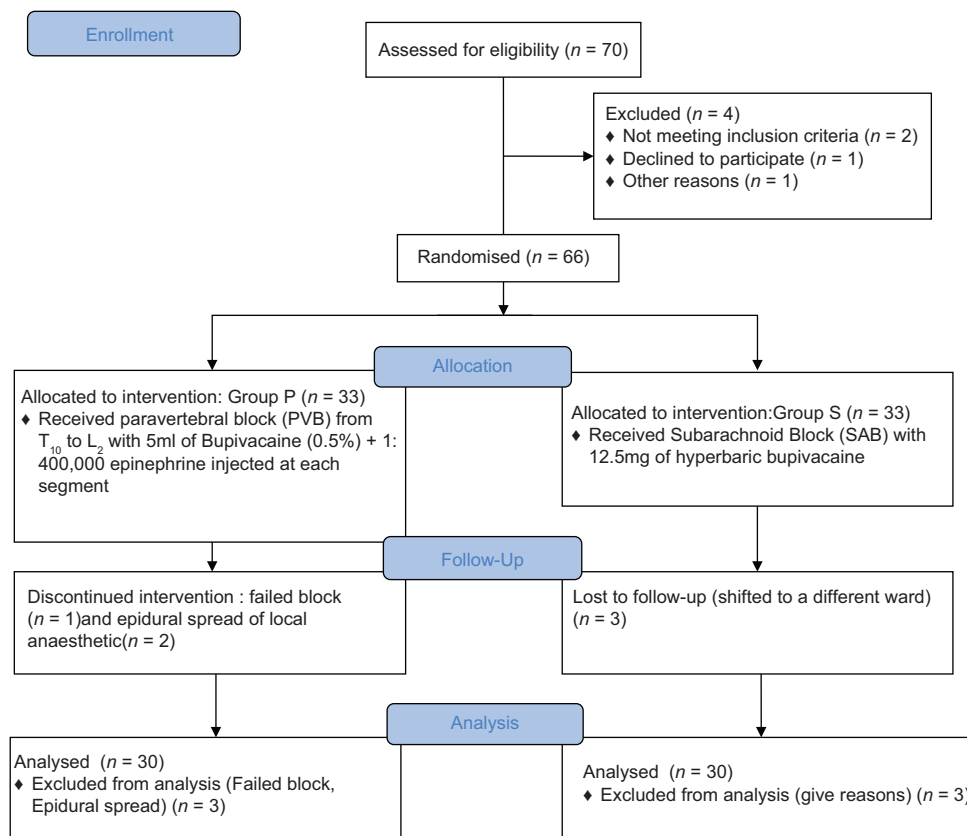


Figure 1: Consort diagram

started within 15 min (endpoint) or if the sensory block (T₁₀-L₂) was achieved within maximum period of 30 min. Otherwise, it was considered 'block failure' and the patient was given GA and excluded from the study. Motor block was evaluated at the end of surgery using a modified Bromage scale^[16] of 0-3 (0 = full flexion of knees and feet; 1 = just able to flex knees, full flexion of feet; 2 = unable to flex knees, but some flexion of feet possible; 3 = unable to move legs or feet).

Group S patients were administered SAB in the sitting position using midline approach with a 25 gauge needle at L₃-L₄ or L₂-L₃ intervertebral space with 12.5 mg of hyperbaric bupivacaine. Sensory block was assessed by pinprick from T4 downwards and surgery allowed to commence when the sensory block was higher than T₁₀. Patients with inadequate block were converted to GA and excluded from the study.

Continuous monitoring of electrocardiogram, HR, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and SpO₂ was done at baseline (before premedication), immediately before the block, after the block (positioned supine) and then every 3 min for 1st 15 min and thereafter, at 10 min till the end of surgery and post-operatively at 2, 4, 6, 12 and 24 h. Any episode of hypotension (MAP lower than 20% of baseline value) was treated with IV fluids and if needed, 6 mg bolus of IV mephentermine. Bradycardia (HR <60 beats/min) was closely observed and managed with IV atropine (0.6 mg) if HR was <50 beats/min. Various parameters noted included time required for performing the block (TRPB) (from premedication to the end of block procedure), time to surgical anaesthesia (TSA) (from end of block to readiness of surgery), duration of surgery (DS) (from the skin incision to the closure of the skin), post-anaesthesia care unit (PACU) transfer time [PTT] (from the end of surgery to transfer to ward).

Recovery room residents were blinded to the type of anaesthetic technique used. In PACU, the patient was evaluated using Modified Aldrete Scoring system^[17] wherein if score was ≥9, patient bypassed the PACU directly to ward. In the ward, the patient was assessed by modified post-anaesthetic discharge scoring (PADS) system^[18] for home readiness and discharge. Time from the end of surgery to home readiness was noted and was taken as time to reach the discharge criteria. Patients who achieved a modified PADS score ≥9 were considered fit for discharge (or home readiness).

Post-operatively, all the data were collected at 2, 4, 6, 12 and 24 h after surgery. Time to first post-operative analgesic requirement (duration of post-operative analgesia), total analgesic consumption in the first 24-h period, visual analogue score (VAS), and incidence of side effects (nausea, vomiting, pruritus, headache, urinary retention, etc.) were noted. VAS score >4 was treated with tramadol in bolus of 50 mg IV and post-operative nausea and vomiting (PONV) was treated with 4 mg of ondansetron IV.

Considering 30% increase in duration of post-operative analgesia in P group to be clinically relevant and taking confidence interval ($\alpha = 0.05$) and the power of test (1- β) as 80%, we required a sample size of 50 (25 in each group). We enrolled 35 patients in each group considering the possibility of dropouts in each group.

All statistical tests were performed using commercially available statistical software (SPSS for windows version 16.0 Chicago, IL, USA) and graphs were produced using Microsoft Excel for MAC 2011 (version 14.1.2, Microsoft Corporation. Bloomsbury publishing Plc.) Microsoft Corporation. Discrete categorical data were presented as *n* (%) and median; continuous data were measured as mean \pm standard deviation. Difference in demographic, surgical, anaesthetic and post-operative data was tested by independent Student's *t*-test (continuous data) and categorical data using Pearson Chi-square test. *P* < 0.05 was considered as statistically significant.

RESULTS

In Group P, one patient had failed block and two patients had epidural spread of local anaesthetic (bilateral sensory block) and were excluded from the study. Data from sixty patients were analysed, thirty in each group [Figure 1]. The baseline demographic variables and baseline haemodynamic parameters (HR, SBP, DBP, MAP, SpO₂) were statistically comparable in between the two groups [Table 1]. The time TRPB (*P* < 0.0001) and TSA (*P* < 0.0001) was longer in-Group P and differences were statistically significant [Table 2]. Intra-operative vitals [Figure 2] were comparable in both groups except for the MAP (*P* < 0.001), which was significantly reduced in the Group S (*P* < 0.0001). No patients in the Group P needed either mephentermine or atropine for any haemodynamic changes. However, three patients in the S group needed mephentermine 6 mg IV for the

treatment of hypotension. Bradycardia occurred in four patients in the Group S as compared to the Group P. A significantly high number of patients in-Group P had low Bromage scores [Table 2]. Total fentanyl usage was found to be higher in the Group P ($P < 0.0001$) [Table 2]. There was significant difference in the VAS scores between the two groups at 4 h ($P < 0.0001$) and 6 h ($P < 0.002$) but not at 2, 12 and 24 h. The VAS scores were lowest at 2 h for both groups and highest at 6 h for Group P and at 4 h for Group S [Figure 3] respectively. Duration of post-operative analgesia was significantly higher in Group P ($P < 0.001$) (384.57 ± 38.26 min vs. 194.26 ± 20.30 min), and the total dose of analgesic required [Table 2] was significantly reduced in Group P ($P < 0.001$).

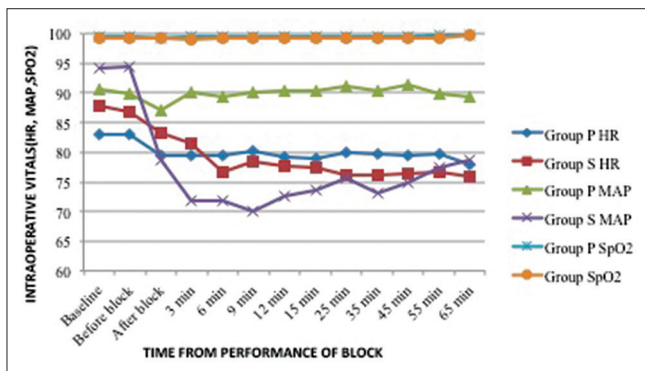


Figure 2: Comparison of vitals (HR: Heart rate, MAP: Mean arterial pressure, SpO₂: Oxygen saturation between groups)

Modified PADS scores [Figure 4] was not significant at 2 h ($P > 0.10$) but it was significantly higher at 4 h ($P < 0.0001$) and 6 h ($P < 0.0001$) in Group P. Time to reach the discharge criteria (home readiness) was early in Group P than Group S, and this difference was highly significant ($P < 0.0001$) [Table 2]. All the 30 (100%) patients of Group P bypassed the recovery room whereas 30% ($n = 9$) in Group S bypassed the same [Table 3]. In the Group S, more patients had been satisfied and had no discomfort associated with the block than in P group. Five patients in Group S experienced episodes of nausea and were treated with IV ondansetron (4 mg), but none of the patients of Group P experienced it.

DISCUSSION

In our study, the use of PVB for inguinal herniorrhaphy was found to be a useful alternative to SAB with the advantage of prolonged post-operative analgesia, shorter time to reach the discharge criteria, better haemodynamic stability and minimal adverse effects.

Inguinal hernia repair, being a day care procedure warrants adequate post-operative analgesia, rapid recovery, early home readiness and prevention of PONV or other adverse effects. The choice of anaesthetic technique for inguinal hernia repair depends on skill of the anaesthesiologist, the feasibility of the

Table 1: Distribution of subjects according to baseline demographic profile, baseline hemodynamic parameters

	Group P	Group S	P	Significance
Age (years)	39.57±12.27	39.17±11.39	0.899	NS
Weight (kg)	65.40±7.34	63.27±6.45	0.237	NS
ASA grade (I/II)	28/12	30/10	0.617	NS
Pre-operative heart rate (/min)	82.93±14.00	87.77±15.32	0.208	NS
Pre-operative MAP (mm Hg)	90.70±9.53	94.06±5.60	0.101	NS
Pre-operative oxygen saturation (%)	99.43±0.56	98.87±0.86	0.111	NS
Duration of surgery (min)	58.93±7.8	60.83±6.57	0.315	NS

* $P < 0.05$: Statistically significant; Results are presented as mean±SD. Group P – Unilateral paravertebral group; Group S – Conventional spinal group; MAP – Mean arterial pressure; ASA – American Society of Anesthesiologists; NS – Not significant; SD – Standard deviation

Table 2: Distribution of subjects according to block characteristics and use of fluids and drugs

Parameters	Group P (n=30)	Group S (n=30)	P	Significance
Time to perform block (min)	18.83±1.98	6.07±1.17*	0.000	S
Time to surgical anaesthesia (min)	17.23±1.52	5.33±1.12*	0.0000	S
Bromage scores [†] (3/2/1/0)	0/2/6/22	30/0/0/0		
Intravenous fluids (ml)	1186.67±121.01	1666.67±232.42*	0.0000	S
Mephenteramine boluses [†] (6 mg)	0	3		
Total fentanyl (mcg)	85.83±22.44	50±00*	0.0001	S
Duration of post-operative analgesia (min)	384.57±38.26	194.26±20.30*	0.001	S
Time to reach the discharge criteria (min)	166.50±27.38	360.20±18.77*	0.001	S
Total rescue analgesics (tramadol in mg)	121.67±25.20	206.67±25.37*	0.0001	S

[†]Parametric data expressed as mean±SD and evaluated by student's t-test categorical data expressed as frequency (%) and evaluated by Pearson's Chi-square test; * $P < 0.05$: Statistically significant. S – Significant; SD – Standard deviation

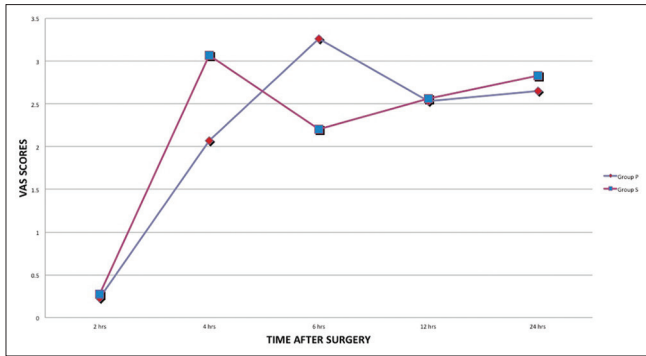


Figure 3: Trends in post-operative visual analogue scale (median value). (Group P: Patients received paravertebral block from T₁₀ to L₂ with 5 ml of bupivacaine (0.5%) +1:400,000 epinephrine injected at each segment. Group S: Patients received subarachnoid block with 12.5 mg of hyperbaric bupivacaine. VAS: Visual analogue scale, PVB: Paravertebral block, SAB: Subarachnoid block

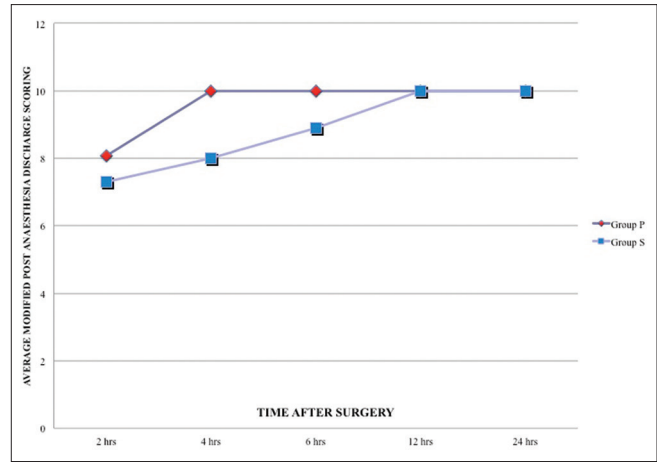


Figure 4: Mean modified post-anaesthesia discharge scoring score at 2, 4, 6, 12, and 24 h. Group P: Patients received paravertebral block from T₁₀ to L₂ with 5 ml of bupivacaine (0.5%) +1:400,000 epinephrine injected at each segment. Group S: Patients received subarachnoid block with 12.5 mg of hyperbaric bupivacaine. PVB: Paravertebral block, SAB: Subarachnoid block

Parameters	Group P (n=30)	Group S (n=30)	P value
Nausea*	0	5	0.052
Urinary catheterization	0	1 (3%)	0.99
Recovery room bypass*	30 (100%)	9 (30%)	0.002
Headache	0	3 (10%)	0.23
Backache	0	4 (13%)	0.44

*P<0.05: Statistically significant; data expressed as frequency (%) using Pearson Chi-square analysis

technique, the complexity and expected duration of the procedure, intra- and post-operative pain control, recovery time, post-operative morbidity and cost-effectiveness. According to the epidemiological data, GA is used in 60–70%, central neuraxial blocks in 10–20% and local infiltration anaesthesia in 5–10% of cases.^[19,20] PVB have been used with success, both as an anaesthetic and analgesic technique, for inguinal herniorrhaphy.

In our hospital, SAB is a preferred technique of anaesthesia for IH that however is not an ideal anaesthetic technique for a fast track ambulatory surgery. SAB has some adverse effects such as prolonged motor blockade, intra-operative hypotension, post-dural puncture headaches, urinary retention, delayed mobility and discharge from the hospital. Hence, quest for an ideal technique for anaesthetising IH patients is still on. Unlike SAB, PVB preserves lower extremity motor function and provides unilateral, segmental anaesthesia of the operative site, prolonged post-operative analgesia and lowers incidence of PONV.^[21] For this reason, we decided to compare the effectiveness of PVB and SAB in terms of post-operative pain relief and early ambulation.

The population sample studied was homogenous with regards to the preanaesthetic characteristics such as age, weight, ASA grade, DS and baseline haemodynamic parameters. We used 1 in 4 lakh adrenaline to limit the absorption of bupivacaine that had reached its highest safe limit of local anaesthetic.

The mean HR and SpO₂ was statistically comparable in both groups throughout surgery [Figure 2] which is similar to the study results found by Bhattacharya *et al.*^[6] In Group P, there were no significant changes in the MAP compared to the baseline [Figure 2] due to less significant sympathetic blockade and unilateral nature of the block. The results of our study were consistent with those of other studies.^[8,22] However, in group S, there was a significant decrease in MAP compared to the baseline that remained throughout the surgery attributable to the sympathetic blockade. This resulted in higher fluid requirement and mephentermine boluses in Group S compared to Group P (1666.67 ± 232.42 ml vs. 1186.67 ± 121.01 ml and 10% vs. 0%) [Table 2]. On intergroup comparison, MAP was statistically significantly decreased in Group S compared to Group P after the block and throughout the surgery. In Group P, the time to perform the block was 18.83 ± 1.98 min that was significantly higher than Group S of 6.07 ± 1.17 min because in PVB multiple injections were required and anatomical landmarks were difficult to identify as compared to SAB. This time was longer in studies when a single level (L1) PVB was used.^[6] The time to onset of

surgical anaesthesia was significantly higher in Group P as compared to Group S which was similar to study results of Bhattacharya *et al.*^[6] and Akcaboy *et al.*^[7] in view of injections given at multiple levels.

Since post-operative pain is one of the common reasons that can delay early ambulation and discharge, addition of local anaesthetics or non-steroidal anti-inflammatory drugs (NSAIDS) can improve post-operative analgesia, thus facilitating an earlier discharge.^[23] In our study, very few patients had significant pain in either P or S group, as shown by the low VAS scores at 2 h in the post-operative period. However, duration of analgesia was much more prolonged in Group P compared to Group S (300–438 min vs. 138–228 min) allowing earlier ambulation. This finding of post-operative analgesia (median, 6 h 24 min) in our study corroborate with the some studies (median, 5 h 45 min)^[6] but are in contrast with others.^[5,7] Prolonged sensory block enabling prolonged analgesia is the most significant characteristics of the PVB technique. This results from relative avascularity of the paravertebral space and hence, slow uptake of local anaesthetics.^[13] Mean total post-operative analgesic requirement of tramadol was significantly lower ($P < 0.001$) in Group P as compared to Group S (121.67 ± 25.20 mg vs. 206.67 ± 25.37 mg), the longer duration of analgesia lessening analgesic requirement.

In our study, all the 30 (100%) patients in Group P and nine (30%) patients in S group were able to bypass the recovery room. The time to reach the discharge criteria was significantly earlier in the Group P (166.50 ± 27.38 min) as compared to Group S (360.20 ± 18.77 min), so early home readiness could be caused by a reduced amount of pain experienced by this group. Bilateral SAB with high dose of bupivacaine may explain the delayed ambulation, increased need for recovery room and increased time required to reach the discharge criteria attributable to the residual motor and sympathetic blockade. In contrast ambulation is much earlier after PVB for inguinal hernia repair, probably due to minimum motor blockade of lower extremities, as shown by lower Bromage scores in Group P.

Comparing the side effects in both groups, Group S was associated with higher incidence of nausea, urinary catheterisation, headache and backache (33%, 3%, 10% and 13%) while none in group P had such complications. SAB is associated with higher PONV because of the associated sympathetic blockade

causing postural hypotension. This fact further precludes early ambulation and early transfer to the ward from the recovery room in patients receiving SAB. PVB provides better peri-operative haemodynamic control resulting in lesser incidence of PONV.^[21] Headache and backache occurred in three (10%) and four (13.3%) patients of Group S, respectively and in none of the patients of Group P. Both these symptoms were of a minor degree and manageable with rest or NSAIDS.

Some perceived disadvantages of PVB include the need for adequate training, the longer time required to perform the block, the possibility of block failure and the risk of pneumothorax.^[5,8,13] Although the block performance time was longer than SAB is consistent with some studies,^[7] but this did not affect the home readiness time. In our study, one patient (3%) had to be given GA due to block failure which is consistent with failure rates in any teaching institute, as shown by Lönnqvist *et al.*^[24] Multiple segments PVB were not comfortable for the patient and increased the risk of pneumothorax. Deep needle penetration during PVB above T12 level can result in pneumothorax^[8,13] because the lung pleura extends up to T12 level. Although the blocks were performed at the T10–L2 levels, no pneumothorax was observed in our study. Bilateral anaesthetic spread reflects unintentional injection into the epidural space.^[8,13] Two patients in the Group P had epidural spread and was excluded from the study that is comparable to the incidence reported in other studies. In two patients, femoral nerve block was a finding as the block was given at L5, but that did not cause the overall prolonging of the discharge.

One of the limitations of our study was small sample size but it had significantly important results, and we suggest future studies to be undertaken with a larger population size. Another limitation of our study was that it was a single-blind study but double-blinding was not possible because of the varied difference between the two techniques so used.

Another limitation of the study was that we used landmark technique and not ultrasound-guided block. With the advent of ultrasonography into clinical practice, assessment of the distance to the thoracic paravertebral space and pleura or real-time monitoring of the position of the needle and the injection during the block is gaining popularity.^[25] There are at least nine different ultrasound-guided approaches to PVB

described in literature and it must be realised that though it has increased safety of block performance, it has longer learning curve.

CONCLUSION

Unilateral PVB is more efficacious than conventional SAB for inguinal hernia repair in terms of prolonged post-operative analgesia, better haemodynamic control, shorter time required for reaching the discharge criteria and lesser incidence of side effects. Hence, PVB could be a better and safe alternative to SAB for early home readiness.

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Conflicts of interest

There are no conflicts of interest.

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