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# Comparison between ultrasound-guided paravertebral nerve block and subarachnoid block for elderly male patients under unilateral-opened inguinal hernia repair operation: A randomised controlled trial

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ABSTRACT

*Background:* Paravertebral block (PVB) as a sole anesthetic technique is difficult even in experienced hands. Hence, this study was undertaken to study the safety and efficacy of PVB and to compare with subarachnoid block (SAB) for inguinal hernia repair surgery (IHRS) in elderly male patients.

*Materials and methods:* Sixty-five male patients aged 65 to 89 scheduled for IHRS were allocated randomly by computer-generated randomisation sequence into two groups. They underwent PVB (Group PVB: 33 patients were injected with 10 ml ropivacaine 0.5% at each level from T12 to L1) or SAB (Group SAB: 32 patients were injected with 15 mg ropivacaine 0.5% at L3–L4 level).

Primary outcomes were hemodynamic changes and duration of postoperative analgesia. Secondary outcomes were dosage of remedial analgesics, time to perform the block, side effects and satisfaction of patients.

*Results:* The hemodynamics in the Group PVB were more stable than those in the Group SAB during surgery ($P < 0.05$). The duration of post-operative analgesia was significantly longer in the Group PVB ($P < 0.001$). The total dose of fentanyl was smaller in the Group PVB in the first 24 h ($P < 0.001$). The time to perform the block was significantly longer in the Group PVB ($P < 0.001$). There was a significant difference in the visual analogue scales (VAS) scores between the two groups at 4 h, 6 h, 8 h and 10 h ($P < 0.05$) but not at 2 h, 12 h and 24 h ($P > 0.05$). The VAS scores were lowest at 2 h for both the 2 groups, highest at 12 h for Group PVB and at 8 h for Group SAB respectively. The Group PVB had fewer adverse effects ($P < 0.05$) and higher satisfaction of patients ($P < 0.05$).

*Conclusion:* Ultrasound-guided PVB can ensure the anesthetic effects of unilateral-opened IHRS in elderly male patients. It has a small impact on hemodynamics, a longer postoperative analgesia time and less complications.

## 1. Introduction

IHRS is usually performed under intraspinal anesthesia or general anesthesia [1,2]. The elderly male patients often have cardiopulmonary dysfunction, and the use of anticoagulants makes tracheal intubation general anesthesia and intraspinal anesthesia limited [3]. PVB was used to block the spinal nerve root by injecting local anesthetics, so as to achieve the effect of unilateral anesthesia. Unilateral PVB was promoted comprehensively for unilateral surgeries [4], such as breast surgery, thoracic trauma, hernia and renal surgery. However, few studies had been conducted to evaluate the anesthetic effect of PVB and spinal anesthesia in elderly male patients for hernia repair. Therefore, this study compared the safety and effectiveness between PVB and SAB for unilateral-opened IHRS in elderly male patients.

## 2. Material and methods

### 2.1. Statement

This study has been reported in line with Consolidated Standards of Reporting Trials (CONSORT 2010) Guidelines.

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### 2.2. Participants

This study was a prospective, randomised, comparative and single blind controlled trial and the patients all signed an informed consent form. 65 male patients prepared for unilateral IHRS between April 2018 and February 2019 were randomly allocated into two groups using computer-generated randomisation sequence.

Inclusion criteria included: male patients, aged 65–89 years, American Society of Anesthesiologists (ASA) I-II, stable blood pressure control, normal heart and lung function, coordinated with treatment.

Exclusion criteria included: patients with untreated and uncontrolled systemic illness, infections at block site, morbid obesity, history of substance abuse, using chronic analgesics, history of allergy to local analgesics, mental dysfunction, metabolic disease, active gastrointestinal reflux, using anticoagulants.

### 2.3. Study design

The same anesthesiologist performed the procedure of block. The residents who did not participate in the study recorded data during and post operation. Group PVB patients received PVB from T12 to L1 with 10 ml of ropivacaine (0.5%) injected at each segment and Group SAB patients received SAB with 15 mg ropivacaine 0.5% at L3–L4 level.

All patients were fasted for 8 h and were fasted in liquid for 4 h. Patients were given oxygen (3 L/min) with nasal catheter in operation room (OR). Standard monitoring included heart rate (HR), mean arterial pressure (MAP), respiratory rate (R) and oxygen saturation ($SpO_2$). All patients were arranged intravenous injection (IV) with midazolam 1 mg and fentanyl 50 μg in OR before the block. Another 50 μg fentanyl was injected if anyone felt discomfortable during the operation.

Patients in Group PVB were placed in lateral position with the affected side upward. The low frequency probe (3–5 MHz) of Sonosite series S ultrasonic diagnostic instrument (US sonosite company) was wrapped with sterile cover and placed vertically against the spine after the skin was sterilized. The inside of the probe was placed on the superior border of the T12 spinous process. The ultrasonic image showed a high echo from the lateral being the parietal pleura. The inner side of the image were superior rib transverse process ligament, transverse process, joint process and spinous process. The target injection position was in the middle of the parietal pleura, the superior rib transverse process ligament and the transverse process [5]. The in-plane technique was used to puncture the tip of the to the target position. Once no blood or gas was pumped back, 10 ml of ropivacaine 0.5% was injected and then the parietal pleura declined. The probe was shifted to the caudal side by one segment to locate and bypass L1 transverse process. 10 ml ropivacaine 0.5% was injected at 1.5 cm below the transverse process after no blood or gas was withdrawn.

Blunt needles were used for stabbing every 5mins to evaluate the blocking effect. The evaluation lasted for 20mins after the patient was in supine position. The block was considered successful if paresthesia (T8-L2) occurred within 20mins. Otherwise, the block was considered as failure, and the patient was given general anesthesia and excluded from the study.

Patients in Group SAB were placed in a lateral position and received the gauge No. 25 puncture needle through the median approach at L3-L4 space. 0.5% 15 mg ropivacaine was injected after the needle reached the subarachnoid space. Sensory regression was measured by blunt needles. The block was considered successful if the anesthesia level was between T6 and T10. General anesthesia was used and the study was excluded if the block was incomplete.

### 2.4. Safety assessment

Electrocardiogram, HR, MAP, R and $SpO_2$ were recorded every 3 min after patients entered the OR until the end of the operation. Accelerated intravenous fluids or injection of intravenous ephedrine 6 mg should be arranged when hypotension occurs (MAP wass 20% below baseline). Atropine 0.5 mg was immediately injected intravenously when HR $<$ 50 beats/min. The time for puncture, operation time and the number of patients satisfied with the puncture were recorded.

### 2.5. Data records

VAS scores were recorded at 2 h, 4 h, 6 h, 8 h, 10 h, 12 h and 24 h after surgery. The first time analgesic after operation was required, total analgesics consumption in the first 24 h period and incidence of side effects (post-operative nausea and vomiting (PONV), urinary retention, headache, etc.) were all noted. Fentanyl 50 μg was used when patients' VAS score was higher than 4 and tropisetron 2 mg was used if PONV occurred.

### 2.6. Statistical analysis

On the basis of previous studies assuming a significant difference of 40% in the incidence of VAS scores higer than 4 in the first 24 h after operation with a type I error of 0.05 and a power of 0.8 [6], a sample size of 30 patients per group was required. We decided to include 65 patients to take into account possible loss of follow-up at 3 day evaluation. Raw data were entered into a Microsoft Excel Spreadsheet and analyzed using Statistical Package for the Social Sciences (SPSS Inc., version 22.0, Chicago, IL, USA). Continuous data were presented as mean with standard deviation while discrete categorical data were expressed as median (range) and number of patients and/or percentage of cases. Categorical variables were analyzed using Pearson's Chi-square test and normally distributed continuous variables were analyzed using the independent sample *t*-test. $P < 0.05$ was considered statistically significant difference and $P < 0.001$ as highly significant difference.

## 3. Results

One patient was given general anesthesia because of the failed blocking in Group SAB. Another patient was given epidural anesthesia because of epidural spread of local anesthetic (bilateral sensory block) in Group PVB.

Table 1. Data from 65 patients were analyzed: 33 patients in Group PVB and 32 patients in Group SAB. The two groups of patients were comparable in terms of demographic data, i.e.: age, weight, ASA, basic hemodynamic parameters (HR, MAP, SpO2), duration of surgery and hospitalization days ($P > 0.05$).

Table 2. Duration of post-operative analgesia was significantly longer in Group PVB($P < 0.001$). Time to perform the block was significantly longer in Group PVB ($P < 0.001$) and total dose of rescue analgesics in first 24 h was significantly smaller in Group PVB ($P < 0.001$).

Fig. 1 and Fig. 2. HR and MAP of Group PVB were more stable than

**Table 1**
Comparison of demographic data and basic hemodynamic parameters between the two groups.

| Parameters | GroupPVB | GroupSAB | P |
|---|---|---|---|
| Age(years) | 75.47 ± 10.36 | 76.29 ± 11.15 | 0.760 |
| Weight(kg) | 56.73 ± 5.28 | 58.42 ± 4.63 | 0.176 |
| ASA I/II | 7/26 | 8/24 | 0.775 |
| Pre-operative HR (beats/min) | 80.64 ± 13.81 | 82.02 ± 12.95 | 0.679 |
| Pre-operative MAP (mmHg) | 92.10 ± 8.53 | 91.67 ± 8.14 | 0.836 |
| Pre-operative $SpO_2$ (%) | 99.25 ± 0.55 | 99.31 ± 0.51 | 0.650 |
| Duration of surgery (min) | 63.73 ± 4.69 | 61.50 ± 5.86 | 0.095 |
| Hospitalization days | 3.82 ± 1.74 | 4.26 ± 1.21 | 0.242 |

Data shown as mean ± standard deviation, or number of patients, as indicated.

**Table 2**
Comparison of analgesic data between the two groups.

| Parameters | Group PVB | Group SAB | P |
|---|---|---|---|
| Duration of post-operative analgesia(min) | 538.80 ± 39.46 | 295.32 ± 26.37 | 0.000 |
| Time to perform the block(min) | 13.62 ± 1.05 | 5.81 ± 0.79 | 0.000 |
| Total fentanyl(μg) | 81.53 ± 22.67 | 209.18 ± 17.24 | 0.000 |

Data shown as mean ± standard deviation, as indicated.

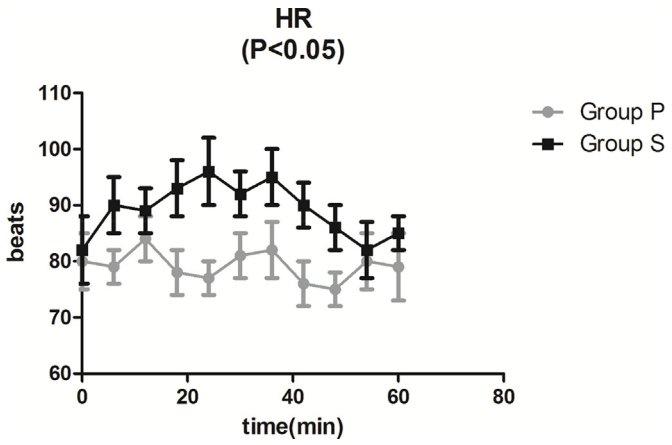


**Fig. 1.** Comparison of HR between the two groups.

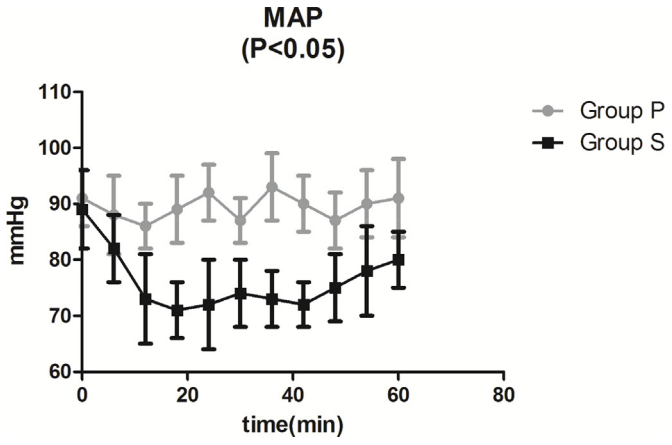


**Fig. 2.** Comparison of MAP between the two groups.

those of Group SAB during the operation (P < 0.05). There was no patients needing ephedrine or atropine for any haemodynamic changes in Group PVB. However, there were four patients needing ephedrine 6 mg for the hypotension and five patients occurring bradycardia (HR < 60 beats/min) in Group SAB.

Fig. 3. There was significant a difference in the VAS scores between the two groups at 4 h, 6 h, 8 h and 10 h (P < 0.05), but not at 2 h, 12 h and 24 h (p > 0.05). The VAS scores were lowest at 2 h for both groups, highest at 12 h for Group PVB and at 8 h for Group SAB.

Table 3. There was more satisfaction of the analgesic (P = 0.049) in Group PVB. Although more patients in Group SAB were satisfied with the puncture process, there was no significant statistical difference between the two groups (P = 0.452). There were three patients having PONV (P = 0.240), two patients having headache (P = 0.493) and all patients needing catheterization (P < 0.001) in Group SAB, but none in Group PVB.

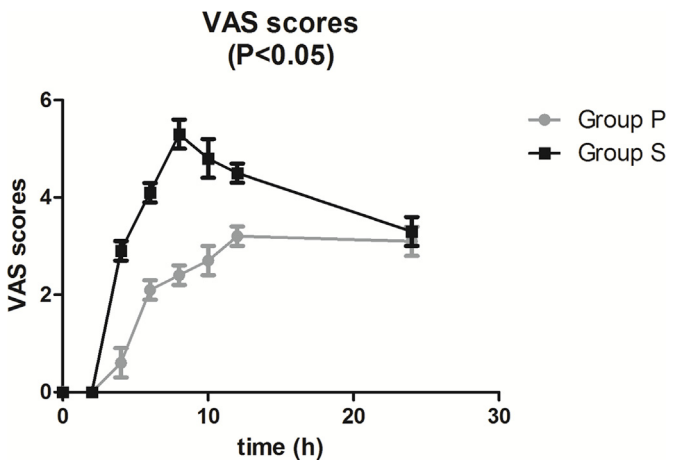


**Fig. 3.** The trend of VAS scores during post-operation.

**Table 3**
Comparison of side-effects and satisfaction of the two groups.

| Parameters | Group PVB | Group SAB | P |
|---|---|---|---|
| PONV | 0 | 3(9.38%) | 0.240 |
| Urinary retention | 0 | 32(100%) | 0.000 |
| Headache | 0 | 2(6.25%) | 0.493 |
| Satisfaction of the puncture | 21(63.64%) | 28(87.50%) | 0.452 |
| Satisfaction of the analgesic | 31(93.94%) | 13(40.63%) | 0.049 |

Data shown as number of patients, as indicated.

## 4. Discussion

IHRS is a common operation in department of general surgery, general anesthesia and subarachnoid anesthesia are the traditional anesthetic techniques of IHRS [2,3], but these methods can aggravate the economic burden of patients, prolong their hospital stays and against the enhanced recovery after surgery (ERAS)' philosophy. IHRS is mainly applied for elderly patients, often combined with cardiopulmonary dysfunction. Anesthesiologists should promote the enhanced recovery of patients from the perspective of anesthesia [5]. Some surgeons have tried to operate with local anesthesia in recent years, but the effect was poor and the patients' satisfaction was low [7].

The selection of anesthesia methods should take into account the following factors: the anesthesiologist's skills, technical feasibility, surgical complexity and possible time, intraoperative and postoperative pain control, recovery time, postoperative prognosis and economic benefits. IHRS requires adequate postoperative analgesia, quick recovery, early discharge, less side-effects and higher satisfaction. The application rate of general anesthesia in IHRS is 60%–70%, subarachnoid block is 10%–20% and local infiltration anesthesia is 5%–10% according to the epidemiological investigation [1,7,8]. Although SAB is most comprehensively used in IHRS, it is not an ideal anesthetic method for ERAS. Therefore, it is very important to adopt a safer, more effective and convenient anesthetic method. PVB can provide anesthesia on the affected side or surgical area while maintaining the lower limb movement function of the uninjured side, which has little influence on vital signs, prolonging postoperative analgesia time and reduceing the incidence of side-effects [9,10]. It is a new choice of anesthesia for IHRS.

The sensory level and puncture point of the block should be determined first in the process of PVB. The ideal level of sensory block in the IHRS should be between T11 and L2. However, the level of T10 - L2 block is ideal due to the need of surgical traction and abdominal muscle relaxation. Previous studies used different puncture points, anesthesia drugs' doses and types, resulting in statistically significant differences [11,12]. Injection of 10 ml of ropivacaine 0.5% at each segment can

spread to at least two segments according to previous reports combined with our experience in PVB [13]. Therefore injection of 10 ml of ropivacaine 0.5% at T12 and L1 can spread to T10 and L3. It can not only meet the needs of IHRS, but also reduce the number of puncture, the time of blocking, alleviate the discomfort of patients and improve the satisfaction of patients in theory.

It is well known that the sympathetic nerve is located at the center of the full length of the thoracic segment of the spinal cord and the lateral angle of the gray matter of the 1–3 segments of the lumbar spinal cord. SAB blocks the sympathetic nerve in the lower extremities, resulting in decreased MAP and HR, and the higher the block level the greater the influence [12]. PVB also blocks parts of the sympathetic nerve, but the block range is unilateral and small, and has no obvious influence on MAP and HR [10]. This characteristic works well for elderly patients with poor cardiovascular function and most patients receiving IHRS have such diseases. The results of this study showed that the MAP and HR of Group PVB at different time points after operation showed no statistical significance compared with that before anesthesia, while the MAP and HR of Group SAB were significantly lower than that before anesthesia.

This study showed that the analgesic effect of Group PVB at 4 h, 6 h, 8 h and 10 h after surgery was significantly better than that of Group SAB. The VAS scores of the two groups were lower at 2 h after surgery, but significant pain appeared at 12 h and 24 h.There was no significant difference in VAS scores between the two groups at these three time points. The total dose of fentanyl used after surgery in Group PVB was significantly smaller than that of Group SAB due to the reason that the analgesic duration of PVB is significantly longer than that of SAB. This important feature of PVB is due to the absence of vessels in the paravertebral space and the slow absorption of anesthetics [14,15]. This study result indicated that PVB could prolong postoperative analgesia compared with SAB.

PONV, urinary retention and headache could occur after SAB [16], and the incidences in this study were 9.38%, 100% and 6.25%, respectively. Group PVB patients had stable vital signs and low incidence of PONV. The high incidence of PONV after SAB was related to postural hypotension caused by sympathetic blockade. Perioperative usage of opioids also contributed to this complication, which could not be completely avoided. This limited patients' early activities. Urinary retention was the most common complication after SAB due to sacropelvic nerve was blocked [16]. So catheters were indwelled in Group SAB. There was no urinary retention occurred in patients in Group PVB due to PVB did not block sacropelvic nerve. There was no headache occurred in Group PVB because PVB did not break through the arachnoid. This study indicated that the incidence of PVB's complications was significantly lower than that of SAB.

Disadvantages of PVB include the need for adequate training, longer time to perform operations, the possibility of blocking failure and the risk of developing pneumothorax [17]. PVB puncture above the T12 can lead to pneumothorax because the pleura extends to the T12 level [18]. The pneumothorax was not observed in our study because puncture was performed at the T12 and L1 level. One patient in Group PVB was excluded from the study because the anesthetic had strayed into the epidural space.

The shortcomings of this study were that long-term follow-up of patients could not be conducted and the efficacy of PVB in chronic pain after IHRS could not be observed due to the time limit of the study [19]. In addition, ultrasound-guided nerve block is a new technique with deep location of paravertebral nerves, which is difficult for beginners. Only ropivacaine or bupivacaine is used in lumbar anesthesia, we have no experience in adding opioids. Opioids can be tried in the future work. The starvation ties of 8 h for solids and 4 h for liquids before surgery are a tradition in most Chinese hospitals. In response to ERAS 'request, we are working to change this tradition.

## Data statement

The authors do not have permission to share data.

## Provenance and peer review

Not commissioned, externally peer reviewed.

## Research data for this article

Due to the patients' opinions in the study, raw data would remain confidential and would not be shared.

## Ethical approval

The study had been approved by the Human Research Ethics Committee of Shanghai Pudong Hospital (NO. LX2018-002).

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## Author contribution

Pengcheng Xie, Yiming Wu and NannanZhang were involved in study concept and design, drafting of the manuscript and study supervision.

Nannan Zhang performed Doppler ultrasound screening.

Pengcheng Xie, Zhanfang Li and Jingli Yang drafted the article and interpret the data.

Yiming Wu collected and analyzed the data.

Pengcheng Xie design the study and critically revise the manuscript.

All authors finally approved the submitted version.

## Conflict of interest statement

We have no conflicts of interest to declare.

## Research registration number

This study was registered in Chinese Clinical Trial Registry (NO.ChiCTR1800017575).).

## Guarantor

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijsu.2019.06.004.

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