Study protocol

Ultrasound-assisted vs. real-time ultrasound-guided paracentral approach combined lumbar and epidural anesthesia in elderly patients: a randomized controlled study

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1. Research background

Traditional body surface marker guided intraspinal anesthesia can meet most of the clinical anesthesia needs, but for the presence of obesity, spinal deformity, senile ligament calcification, previous lumbar surgery history, etc., intraspinal puncture often has technical difficulties. Ultrasound-guided intraspinal puncture can provide anatomical information related to the puncture site, including intervertebral segment, posterior median line of the spine, vertebral canal depth, and distribution characteristics of each ligament, providing a solution for difficult puncture and improving the accuracy and safety of intraspinal puncture 1,2.

During the implementation of lumbar anesthesia, multiple punctures through ligaments and dura can easily lead to postoperative headache, low back pain, and may increase the incidence of paresthesia and spinal cord hematoma. Ultrasonic-guided spinal anesthesia can reduce the number of passages required to enter the subarachnoid space compared with the traditional signpost guided midline approach. Ultrasound examination before hip and knee replacement provides guidance for intraspinal puncture, which can significantly reduce the number of entry into the subarachnoid space and the number of attempts3. In addition, a pre-ultrasound scan of the spine before puncture can estimate the distance from the skin to the epidural space and determine the appropriate puncture point, which is important in obese women (BMI: 33~86 kg/m^2) epidural labor analgesia is especially effective when the epidural needle is placed at the intended puncture point, 76.1% of women did not change the point of re-puncture, 67.4% of women did not redirection4. However, despite the ability of ultrasound to provide anatomical information about the spine, 23 (10.7%) of 218 women in a study had misidentification of 2 or more intervertebral Spaces, which increases the risk of intraseptic puncture complications. Subgroup analysis showed that the degree of access to the maternal spinous process had an impact on the recognition of the lumbar space in spinal ultrasound. Women with easy access to the spinous process have a higher success rate of ultrasound-assisted first puncture 5. Based on the posterior longitudinal ligament ultrasonic image scoring system, Weed JT et al. 's study showed that the puncture frequency and puncture time were significantly reduced in the group with a high rating of clear images, suggesting that the calcification level of the posterior longitudinal ligament may be one of the important factors affecting the success rate of ultrasound-guided intra spinal puncture through the posterior median approach.

It can be seen from the above description that ultrasound assisted positioning before intraspinal anesthesia has more technical advantages than body surface marking, but at the same time, the puncture process of the above two methods is still a "blind exploration" operation with or without anatomical preview, and the puncture path is easily blocked by vertebrae and its accessory structures, and the puncture Angle is not visible. Real-time ultrasound guidance can solve the problem of path selection in difficult puncture. Therefore, Lee, P. J., et al. developed a technique for real-time ultrasound guidance of intraspinal anesthesia via the Taylor approach (auxiliary approach in the L5-S1 space) by conducting a preliminary cadential study on 5 unembalmed cadasses. Subsequently, 10 patients undergoing joint replacement underwent successful hip arthroplasty using real-time ultrasound-guided intraspinal anesthesia in prone position. Subsequently, Chong, S. E. et al. compared real-time ultrasound guided (UG) and body surface marking touch (PG), and the results showed that the success rate of the first puncture in the UG group (≤6 skin piercings with or without redirection) was significantly higher than that in the PG group (87% vs. 43%, P<0.001). UG also had a higher success rate of single needle passage (47% vs. 20%, p = 0.028)8. The mean (SD) time to success of dural puncture was shorter in UG group [0.69(1.01) and 1.60 (1.19)min, P=0.002]. This is comparable to the results of the Conroy9 study, which showed a time of 1.2 minutes (0.2-15 minutes). It can be seen that both real-time ultrasound-guided intraspinal anesthesia and preoperative ultrasound-assisted intraspinal anesthesia have certain technical advantages compared with body surface labeling.

The ultrasound imaging along the longitudinal median path of the spine has less bone and ligament occlusion, and the intravertebral canal image is often clearer, which is better than the transverse or longitudinal scan of the posterior median line. Therefore, the real-time ultrasound guidance technology should adopt the paramedical approach. Chen L et al. conducted a comparison of the effects of ultrasound assisted positioning (USAS) and real-time ultrasound guidance (USRTG) in intra spinal anesthesia. In a study of 114 elderly hip fracture patients (≥70 years), they found that the USAS group had a higher success rate on the first attempt (successful dural puncture without redirection) (80.7% vs 52.6%) and a higher success rate on the first pass (63.2% vs 31.6%). Fewer attempts (skin piercings) (1 [1-1]vs 1 [1-3]) and median pass rates were significantly lower in the USAS group than in the USRTG group. However, the USRTG group had a shorter positioning time (175 s [129-234 s]vs 315 s [250-390 s]).

However, the operation time was longer (488 seconds [260-972 seconds]vs 200 seconds [127-328 seconds]) and the total time was longer (694 seconds [421-1133 seconds]vs 540 seconds [432-641 seconds]). The USAS group had higher satisfaction scores. Overall, anesthesiologists rated the USRTG group as "more difficult." Chen L and his colleagues believe that in elderly patients with hip fractures, USRTG technique is not superior to USAS technique for lumbar anesthesia, because USRTG technique has a lower success rate, longer operation time, lower satisfaction score, and greater difficulty in operation. Therefore, USAS technology may be more suitable for elderly patients.

Both continuous epidural anesthesia (CSA) and lumbar anesthesia (SA) can be used in elderly patients undergoing hip fracture surgery. Based on a study of 74 elderly hip fractures. In the SA group, 68 percent of patients experienced at least one episode of hypotension (a decrease in systolic blood pressure greater than 20 percent of baseline values), compared to 31 percent of patients in the CSA group. In the SA group, 51 percent of patients experienced at least one episode of severe hypotension (a drop in systolic blood pressure greater than 30 percent of baseline value), compared to only 8 percent of patients in the CSA group. Patients in the SA group required more ephedrine doses. Therefore, the authors suggest that CSA may reduce the onset of hypotension and severe hypotension12. Through A review by Perlas A et al., we found data from eight studies showing that ultrasound can identify a given lumbar space more accurately than palpation alone. Thirteen studies reported a good correlation between depth measured by ultrasound and needle insertion depth in the epidural or intravaginal space, with the average difference between the two measurements within 3 mm in most studies. Spinal canal ultrasound increased the success rate of puncture and reduced the difficulty of puncture 1.

According to the clinical experience of our center in using ultrasound to guide intraspinal operation, we believe that skilled use of ultrasound is also an important factor affecting the success rate of the first intraspinal puncture and shortening the puncture time, and the conclusion may be different from Chen L et al. Therefore, we designed this study to explore the difference in clinical effects between the application of ultrasound-assisted positioning by experienced operators and real-time ultrasound-guided paramedical approach combined lumbar and epidural anesthesia in elderly patients, providing validation for the clinical use and promotion of real-time intraspinal ultrasound technology.

2. Research purpose

The purpose of this study was to investigate the difference of clinical effect between ultrasound-assisted positioning and real-time ultrasound-guided paracentral combined epidural anesthesia in elderly patients.

3. Study design

This was a prospective randomized controlled study.

3.1 Patient selection and alloctaion.

3.1.1 sample size calculating

This study is intended to include all patients who will undergo combined spinal and epidural anesthesia from October 2023 to October 2024. Adopt PASS V21.0.3 software (2021; NCSS LLC) calculated the study sample size. According to a preliminary study by Chen L et al., the success rate of the first puncture using the USAS technique and the USRTG technique was 80.7% vs 52.6%, respectively. It was calculated that 43 patients were required in each group at a bilateral significance level of 0.05 (α = 0.05) and 80% efficacy (β = 0.2). Taking into account 10% of possible patients dropping out, the sample size was increased to 48 patients per group for a total of 96 patients.

3.1.2 Inclusion criteria

1) Elderly patients (≥ 60 years old);

2) ASA Grade I to III.

3.1.3 Exclusion criteria

1) Severe obesity (BMI>35kg/m2);
2) Spinal deformity or surgical history;
3) Allergic to local anesthetics;
4) There are coagulation disorders;
5) Communication barriers

4. Research process

1. Preoperative records

Patients were visited according to clinical routine on the day before surgery, and their age, gender, height, weight, ASA grade, and operation name were recorded. Patients were identified according to inclusion and exclusion criteria, informed consent was signed, and basic patient information was recorded.

2. Anesthesia protocol and intraoperative records

Based on a computer-generated table of random numbers, they were randomly assigned to receive combined lumbar and epidural anesthesia in either the US-AS group (n=48) or the US-RTG group (n=48). Patient assignments are hidden by sequentially numbered and sealed opaque envelopes that can only be opened by the attending anesthesiologist when the patient enters the operating room. Patients know nothing about grouping. Neither the intraoperative parameter collector nor the anesthesiologist performing the procedure can blind the groups.

All ultrasound-guided CSEA blocks were performed by an attending anesthesiologist (>100 cases per year) who was skilled in ultrasound-assisted and real-time ultrasound-guided intra spinal block, and another attending physician who was familiar with the procedure was responsible for parameter recording. When the patient enters the room, connect the monitor. Nasal catheter oxygen (oxygen flow 3 L/min) to establish peripheral venous access. 1. Assess the difficulty of palpating the spinous process (1 degree: easy - slight or moderate pressure on the tissue; Grade 2: moderately significant tissue compression; 3 degrees: Difficult/unable to palpate). 2. If the patient could not cooperate due to hip pain, iliofascial space block (20mL, 0.4% ropivacaine) was performed in the supine position, and 15min later, the patient lay on his side (affected side up).

In the US-AS group, the intraspinal structure was evaluated using a portable ultrasonic system (Sonosite, low frequency convex array probe 2-5 MHz) (ultrasonic prescan to determine the best intervertebral space, best puncture Angle and best puncture depth). The measurement methods (in-plane measurement of paracentral transverse section (LTP), out-of-plane measurement of paracentral sagittal section (LSC) and in-plane measurement

of paracentral sagittal section (IPP)) were recorded, and the optimal puncture section considered by the operator (the widest acoustic window at the back of the complex) was selected to record the best gap, puncture Angle and depth. In the sterile state, traditional blind operation was performed; The positioning time, the depth and width of the retrodural complex, the first successful attempt (first skin piercing without redirection), the number of skin piercings, the number of redirects, and the operation time (probe touching the skin until the end of the operation) were recorded. After successful epidural puncture, 25G lumbar anesthesia needle was inserted (if CSF outflow was not smooth, the epidural needle could be rotated in place and then re-inserted into the epidural puncture). Subarachnoid block (2.5mL/12.5mg of 0.5% ropivacaine without high glucose) was performed immediately after CSF outflow was smooth, followed by epidural catheter. If there is no CSF after withdrawal, skin puncture should be performed again. The maximum number of skin puncture should be 6 times, and the cumulative redirection of each skin puncture should not exceed 6 times. If six skin piercings are unsuccessful, traditional palpation, replacement of puncture Spaces, or general anesthesia are considered and recorded.

In the US-RTG group, the optimal puncture section considered by the operator was selected and recorded directly in the plane of the paracentral transverse section, out of the plane of the paracentral sagittal section or in the plane of the paracentral sagittal section for real-time ultrasound guided lumbar epidural anesthesia. The positioning time, the depth and width of the retrodural complex, the first successful attempt (first skin piercing without redirection), the number of skin piercings, the number of redirects, and the operation time (probe touching the skin until the end of the operation) were recorded. After successful epidural puncture, 25G lumbar anesthesia needle was inserted (if CSF outflow was not smooth, the epidural needle could be rotated in place and then re-inserted into the epidural puncture). Subarachnoid block (2.5mL/12.5mg of 0.5% ropivacaine without high glucose) was performed immediately after CSF outflow was smooth, followed by epidural catheter. If there is no CSF after withdrawal, skin puncture should be performed again.

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Whether the patient was in the left or right decubitus position, the operator used the puncture needle manually and the ultrasound probe non-manually. Adverse reactions and complications were recorded in both groups, including radicular pain, bloody cerebrospinal fluid puncture, headache after dural puncture, paresthesia, back pain, whether traditional palpation was used, the puncture space was changed, or general anesthesia was used. Patient satisfaction score: Patients were asked to use a 5-point numerical rating scale to evaluate their satisfaction (1, very dissatisfied; 5, very satisfied). The VNRS, verbal numerical rating scale (0-10) and whether to add analgesic drugs were recorded in the two groups.

3. Outcomes

Primary outcomes: first attempt success rate (first skin piercing, no redirection);

Secondary outcomes: operation time (seconds), positioning time, depth and width of posterior dural complex, skin puncture number, redirection number; Patient satisfaction score: Patients were asked to use a 5-point numerical rating scale to evaluate their satisfaction (1, very dissatisfied; 5, very satisfied). Operation difficulty score: After the operation, the anesthesiologist will score the difficulty of this operation (1, very dissatisfied; 5, very satisfied). Change of anesthesia method (traditional blind method, USAS or USRTG, change of puncture space, general anesthesia).

Adverse reactions and complications: include radicular pain, bleeding, puncture, headache after dural puncture, paraesthesia, and back pain.

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