Clinical Research

Volume Navigation with Fusion of Real-Time Ultrasound and CT Images to Guide Posterolateral Transforaminal Puncture in Percutaneous Endoscopic Lumbar Discectomy

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Background: The use of percutaneous endoscopic lumbar discectomy (PELD) is increasing in the treatment of lumbar disc herniations (LDH). Nerve and vessel injury may happen during the establishment of the transforaminal working channel. Also, there is usually exposure to intraop radiation when the C-arm is used to help establish the location of the transforaminal working channel.

Objective: To evaluate the accuracy and safety of the volume navigation technique for guiding transforaminal puncture in cadaver and clinical patient treatment.

Study Design: Cadaver experiment and comparative clinical research.

Setting: Changhai Hospital, the Second Military Medical University.

Method: Volume navigation guided transforaminal puncture was performed in 15 cadavers. The registration error, time of overall puncture, ultrasound (US) observed distance between needle tip and target (DNT), and puncture error were recorded. Clinical research was performed in 63 patients who had undergone PELD. Comparative research was done between 2 groups: Those who had transforaminal puncture carried out under C-arm guidance (n = 30), and those patients whose transforaminal puncture was carried out under volume navigation guidance (n = 33). Puncture times and frequency of fluoroscopy were recorded. Both groups were evaluated with Oswestry Disability Index (ODI), and visual analog scale (VAS) before surgery at 1, 3, and 6 months, and 1 year post-surgery.

Results: In the cadaver experiment, mean registration error was 2.66 ± 1.10 mm; DNT 20.08 ± 1.32 mm; puncture error 2.91 ± 1.29 mm; overall time of puncture 22.10 ± 5.20 min. In the clinical patient research, puncture times and frequency of fluoroscopy were significantly lower in the volume navigation group compared with the C-arm group ($P < 0.001$). There were no significant differences between the 2 groups in ODI and VAS scores ($P > 0.05$) at different time points.

Limitations: The correlation between the registration errors and the puncture errors requires further analysis. Also, due to the relatively small number of cases studied, additional cases need to be collected to obtain reliable results.

Conclusion: The volume navigation technique can be used for PELD because it helps to guide percutaneous posterolateral transforaminal puncture accurately with reduced puncture times and intraop radiation.

Key words: Lumbar disc herniation (LDH), ultrasound volume navigation (US VNav), percutaneous endoscopic lumbar discectomy (PELD), foramen, puncture

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Percutaneous endoscopic lumbar discectomy (PELD) is increasingly used to treat lumbar disc herniations (LDH) because of the following advantages: less destruction of the bony structures and the peripheral soft tissue, no need to retract the nerve root and dura, and rapid postoperative recovery (1,2).

This procedure is often performed via a posterolateral approach. First, the target level is localized, then the transforaminal working channel is established, and finally the nucleus pulposus is removed. Most surgeons consider the transforaminal puncture as the most critical and complicated step in this surgery, which is usually carried out under C-arm guidance. The surgeon needs to be familiar with the related lumbar spine anatomy, and well experienced with open surgery; otherwise, the frequency of exposure to radiation during the puncture increases significantly for both the patient and the surgeon (3-5). In addition, an inaccurate puncture may cause vessel, nerve, and abdominal organ injuries. Therefore, this full-endoscopic technique has a very steep learning curve (6,7).

The navigation techniques used in computer-aided surgery (CAS) is helpful in improving the accuracy and safety of the puncture, and in reducing operating time. The conventional navigation techniques normally use intraop computed tomography (CT) or the O-arm (8), which involves exposure to intraop radiation for the patient and surgeons. The preoperative CT or magnetic resonance imaging (MRI) can reduce intraoperative radiation doses effectively. However, the registration also depends on intraoperative fluoroscopy-based CAS (9). Real-time anteroposterior and lateral fluoroscopy images are still needed to identify the anatomy and tools. Repeatedly repositioning the C-arm is often time consuming and exposure to radiation therefore cannot be ignored.

Ultrasound (US) has many advantages, including noninvasive, convenient, radiation free and real time navigation. However, compared with navigation devices for spine surgery, such as C-arm fluoroscopy or a computer assisted navigation system, it is difficult to use routine US to get a clear display of the musculoskeletal system due to complete reflection of US from the cortical bone. Therefore, US has been rarely used in spine surgery.

Recently, however, a new US volume navigation (V Nav) technique has been developed, which can overcome many of the earlier drawbacks of US. The new technique allows the real-time US images to be visualized with the previously collected 3-dimensional CT or MRIs. And the use of an electromagnetic tracking system allows the surgeon to promptly locate the target, using real-time US images (10-13). This technique is particularly suitable for targets that cannot be easily detected by routine US due to factors such as bone, gas, and body shape.

In the present study, we evaluated the accuracy of using US V Nav technique to guide transforaminal puncture by using fusion of real-time US and CT images. Three-dimensional CT was used to display the bone tissue, and the real-time and nonradiation US was used to demonstrate and accurately locate the foramen.

Methods

Cadaver Experiment

Eligibility Criteria

Fifteen formalin-fixed cadavers (9 men and 6 women) were selected. The mean age at death was 75.5 years (range: 67-83 years). None of the cadavers had undergone prior spine surgery. There were no spinal deformities or injuries and the foramens were intact. All the cadavers were voluntarily donated to medical research.

Data Collection Process

After the cadaver was placed in the prone position on the CT table, the intersection of the line connecting the highest points of the bilateral iliac crests and the posterior midline was established as the center, and 4 points were randomly selected in a circle within a radius of 5 cm. One metal nail was inserted into each point as an external marker. A Toshiba Aquilion™ ONE 320 Slice CT scanner (Toshiba Medical Systems, Japan) was used to complete three-dimensional reconstruction of the lumbar spine in the prone position. The range of scan was from the superior margin of the L1 vertebral body to the inferior margin of the S1 vertebral body. The CT scan parameters were as follows: slice thickness = 0.5 mm; interlayer distance = 0; detector collimation = 64 × 0.5 mm; speed of rotation = 0.5 sec/lap; tube voltage = 120 kV; current = 500 mA; and matrix = 512 × 512.A LOGIQ™ E9 US system (GE Healthcare, USA) with a 5-MHz 9L-D linear array probe was applied. (Note: Because formalin-soaked bodies normally have a hard surface, the convex probe cannot closely adhere to the skin surface, which may affect the outcome of US imaging.) An electromagnetic tracker was connected with

the cadaver in the prone position, and the distance between it and the US probe was maintained at less than 80 cm. Before registration, an electromagnetic tracking system composed of a transmitter and a small receiver, mounted on the US probe, provided the position and orientation of the US probe in relation to the transmitter. The distance between the tracking transmitter and the receiver must not exceed 80 cm. The position of the tracker remained unchanged throughout the entire experiment. The 3-dimensional CT data were imported into the US device, 3 of the 4 points on the body surface were randomly selected, and the CT and US images of these 3 points were precisely identified and locked, one by one. Registration of the inner marker was carried out after registration of the outer marker was completed. The apex of the L5 spinous process was identified on the sagittal plane of the CT image and locked as an inner marker. Then, the corresponding point was identified on the real-time US image and locked. The registration error was measured. Volume Navigation technology, which is based on an electromagnetic tracking system (accuracy = 0.1 mm), automatically provides a quality feedback of the registration (registration error) by applying a sophisticated algorithm. If the registration error was greater than 5 mm, it was corrected by selecting the apex of the L4 spinous process as another inner marker. The image registration error was reduced to less than 5 mm using double registration that included the outer and inner markers to complete image fusion.

After image fusion, transforaminal puncture was carried out, while maintaining the positional relationship between the electromagnetic tracker and the cadaver (Fig. 1). The lowest margin of the affected foramen on the CT sagittal image was selected as the target, and this point was displayed by the real-time US simultaneously and locked (Fig. 2A). The probe was then rotated and adjusted to obtain the target image on the axial plane and to guide in-plane needle technique to the target (Figs. 2B and 2C). The cadavers were kept on the CT table when puncture was finished. Three-dimensional CT reconstruction of the lumbar spine was then repeated and the location of the needle tip was observed by CT scan (14,15), to verify the accuracy of the puncture under US guidance.

Fig. 1. *After image fusion, the positional relationship between the electromagnetic tracker and the cadaver was unchanged. The target was selected on the sagittal CT image and displayed simultaneously in real-time US. After the target was locked, the probe was rotated to the axial plane (vertical to the posterior midline) and adjusted to make the target become the smallest box (exact location) and obtain the target image on the axial plane. According to the target position and the puncture line, transforaminal puncture was carried out at the affected level under real-time US guidance.*

Thirty puncture passes were performed on 30 lumbar foramens (bilateral L4/5 foramens) in 15 cadavers. The registration error, overall time of puncture (including the time required for image registration and needle insertion), US observed distance between the needle tip and target (DNT), puncture error (CT-measured distance between the needle tip and target at the end of navigation) were recorded. Figures 3A and 3B show the method used to measure the DNT, and the technique used to measure puncture error is shown in Figs. 4A and 4B.

Patient Surgery

Protocol and Registration

Sixty-three patients with LDH at L4/5, who underwent PELD between June 2012 and October 2013, were included. All these procedures were approved by the ethics committee of our hospital, and written informed consent was obtained from each subject. The study group included 37 men and 26 women. The mean age was 33.2 years (range: 17-64 years). Patients were excluded if they had

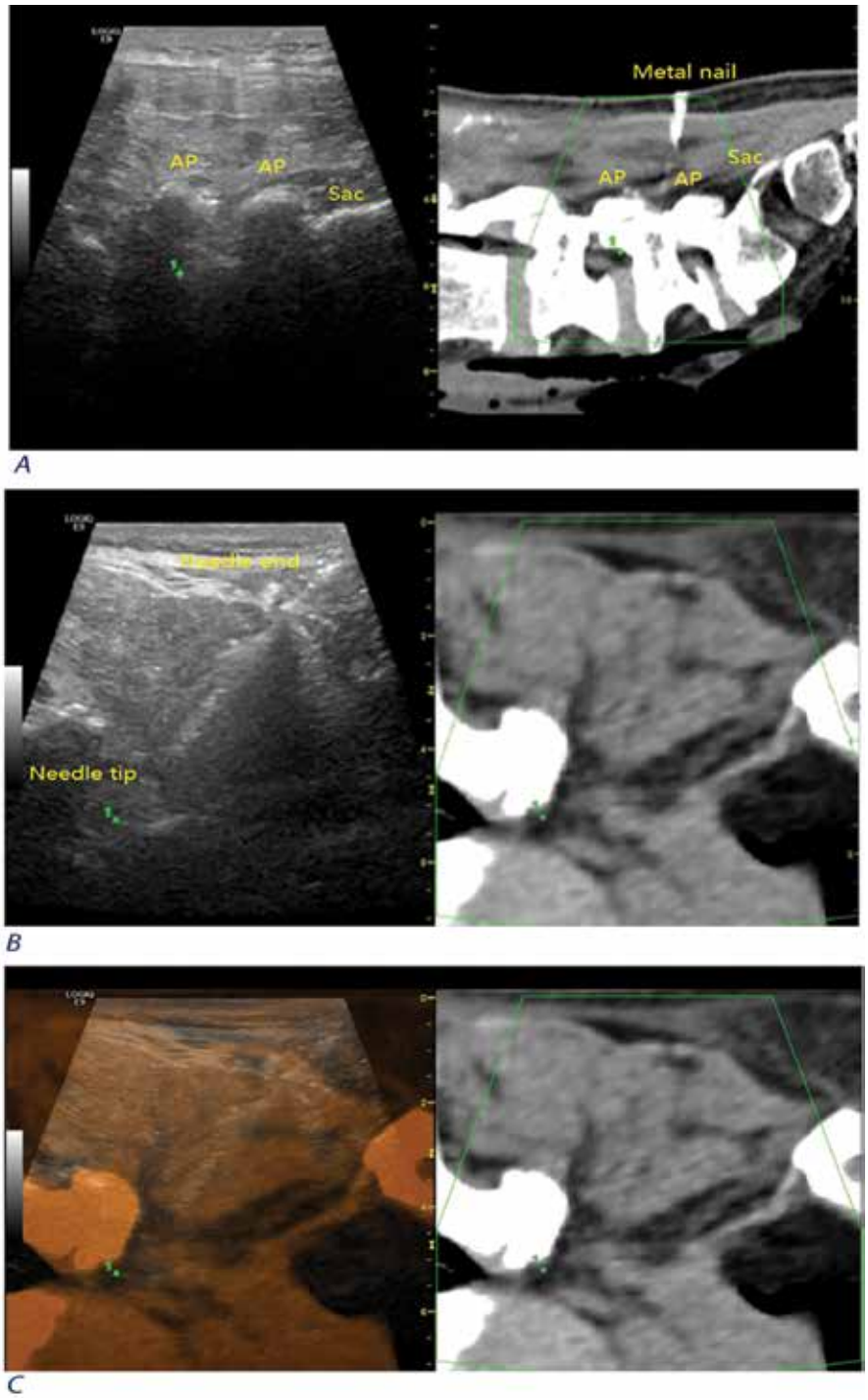

Fig. 2. *A. After image fusion, the lowest margin of the affected foramen (L4/5) was taken as the target on the CT sagittal image, and real-time display of this target was carried out by US simultaneously (the green cross marked as "1"). The probe was rotated to the axial plane and adjusted to make the target become the smallest box or a cross (exact location), and then the puncture needle was passed through the axial plane into the target area (AP = articular process; Sac = sacrum). B.The image shown on the divi-screen display.C. The image obtained after fusion of CT and US images.*

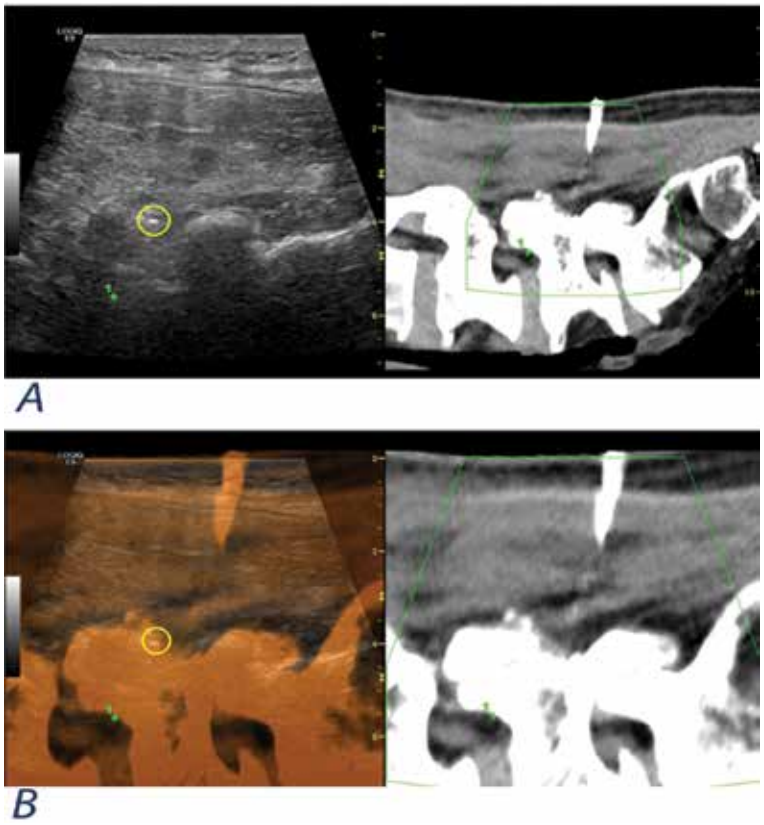

Fig. 3. *A. US scanning was carried out on the sagittal plane of the midline. US could not display the whole needle and deep structures beneath the cortical bone. The white hyperechoic signal within the yellow circle (left) is the last position of the needle tip observed by US. B. The direction and distance of the puncture needle to be advanced was determined according to the distance between the target verified by the V Nav (the green cross marked as "1") and the last position of the needle tip observed by US (DNT).*

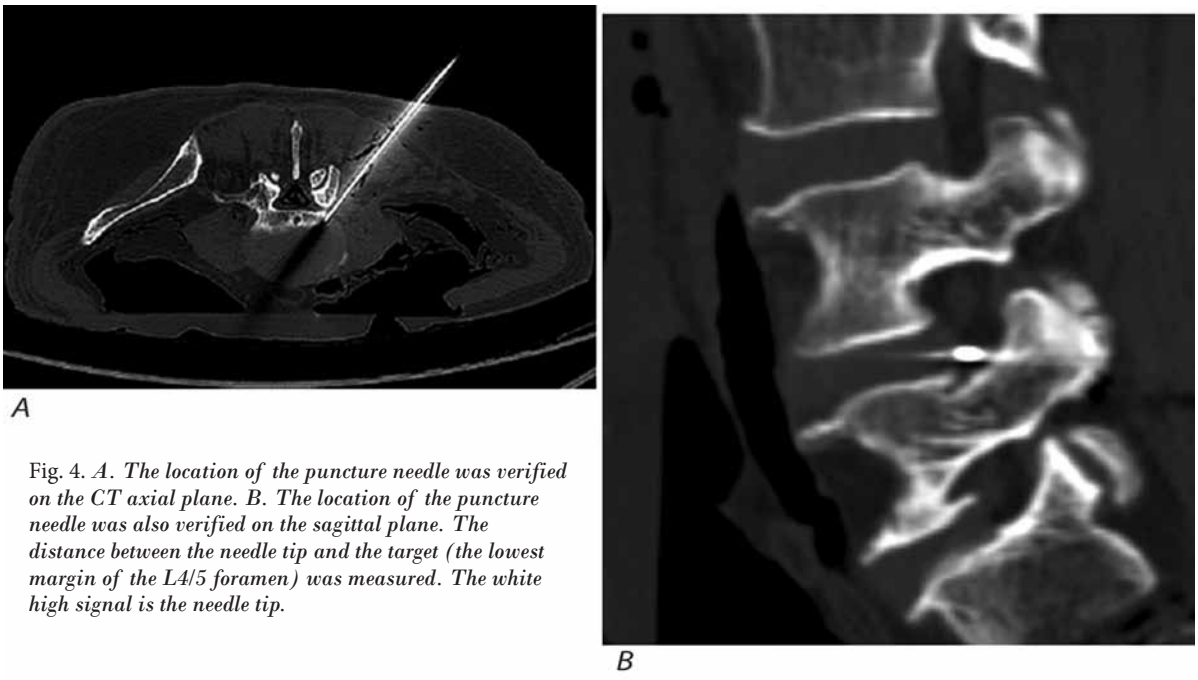

Fig. 4. *A. The location of the puncture needle was verified on the CT axial plane. B. The location of the puncture needle was also verified on the sagittal plane. The distance between the needle tip and the target (the lowest margin of the L4/5 foramen) was measured. The white high signal is the needle tip.*

any of the following: a history of spinal trauma or spine surgery; a history of a spinal tumor; spinal deformities; significant spinal degeneration; or the presence of a pacemaker (which would disturb the electromagnetic tracking system).

Data Collection Process

Before surgery, patients were randomly divided into 2 groups, according to the applied navigation methods (C-arm guidance or V Nav) for the transforaminal puncture. We divided patients into 2 groups according to their identification (ID) number. Patients with odd ID numbers were distributed to the C-arm guidance group, and those with even numbers were distributed to the V Nav group. Thirty patients were included in the C-arm guidance group, and 33 patients were included in the V Nav group. Three-dimensional CT and MRI were taken of each patient before the PELD operation, to determine whether the anatomic structure had any variations, and whether it was suitable for PELD treatment.

In the C-arm guidance group, surgery was performed according to the standard procedure. A GE Brivo™ OEC 850 C-arm (GE Healthcare, USA) was used for fluoroscopy during surgery. The scanning parameters were: tube voltage = 80 kV; tube current = 2.3 mA; and time of exposure to radiation = 0.1 sec (to ensure the same amount of radiation dose each time). The puncture time and frequency of exposure to radiation were recorded.

In the V Nav group, 4 outer marking points were identified in the lower back using the same method as in the cadaver experiment. Metal markers, which appear in the CT images, were temporarily pasted on the patients. After three-dimensional CT reconstruction of the lumbar spine (the instrument type and the scanning parameters were the same as those used in the cadaver experiment), the markers remained intact and the marking points could be clearly identified. A LOGIQ E9 US system with a C1-5-D convex probe was used (the convex probe can closely adhere to the skin because the body surface is soft, in contrast to the hard surface of a cadaver). The probe frequency was 4 MHz. With the patient prone on a Jackson Spine Table, the three-dimensional CT data were imported into the US device. The image registration of the inner and outer marking points and the image fusion were carried out in the same manner as in the cadaver experiment.

After image fusion, the positional relationship between the electromagnetic tracker and the patient was maintained, and skin preparation and draping were carried out routinely (care was taken not to erase the marking points during skin preparation). The lowest margin of the affected foramen on the CT sagittal image was selected as the target, and this point was displayed by real-time US (Figs. 5A and 5B), which was applied to guide the puncture needle advancing within the controlled plane (Figs. 6A-6C). When the needle was close to the target, the probe was rotated to the sagittal plane to observe the last position of the needle tip, and the puncture needle was further advanced to the target based on the DNT value (Figs. 7A and 7B). Since this is an early exploration of this new technique, we are observing the process with special care. In this manner, C-arm fluoroscopy can be used to assist localization before puncture and identification of the needle direction during puncture. If the patient feels radiating pain in the lower extremity during puncture, C-arm fluoroscopy should be applied. If there is a certain deviation in the direction of puncture, secondary image registration and fusion should be carried out according to the marking points, to make the puncture needle reach the target successfully. After successful puncture, the position of the needle should be further verified using C-arm fluoroscopy. The registration error, DNT, overall time of puncture (including the registration time and the time for placing the needle), and frequency of exposure to radiation were recorded.

In both groups, a working channel was established after successful puncture and L4/5 discectomy was performed. All patients filled out Owestry Disability Index (ODI) and Visual Analog Scale (VAS) forms before surgery and again at 1, 3, and 6 months and 1 year after surgery. All the US V Nav was performed by the same US specialist, and the transforaminal puncture was also carried out by the same attending spine surgeon.

Statistical Analysis

Data analysis was performed using SPSS version 20.0 (SPSS Inc., Chicago, IL, USA). Continuous data were compared between the C-arm and V Nav groups using the independent t-test or the Mann-Whitney U test. The difference was considered statistically significant when the *P*-value was < 0.05.

Results

Cadaver Experiment

Thirty L4/5 transforaminal punctures were carried out in 15 cadavers. The registration error was 2.66 ±

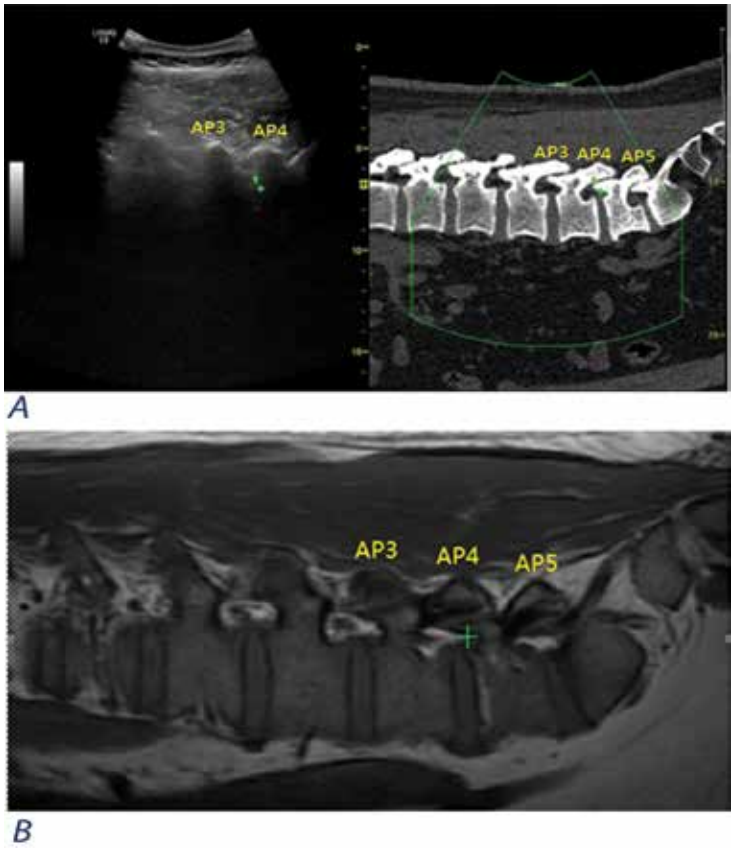

Fig. 5. *A. The target could be displayed on the CT sagittal plane and real-time US image simultaneously. At this moment, the US probe was located at the paramedial sagittal articular process view of the lumbar spine and corresponding CT image and MRI scan for scanning) (AP3 = articular process of L3, AP4 = articular process of L4, AP5 = articular process of L5). B. The bright wavy white hyperechoic line is the facet joint, and the deep layer of wave peak is the lower margin of the foramen. The positional relationship between anatomical structures in the US image can be clearly seen by comparing them with CT and MRIs.*

1.10 mm (0.9-4.7 mm); the DNT was 20.08 ± 1.32 mm (17.8-22.9 mm); and the puncture error was 2.91 ± 1.29 mm (1.1-6.1 mm). In 2 cases, the puncture error was 5.3 mm and 6.1 mm; in a clinical setting, such a large puncture error could damage the nerve root or make the establishment of a working channel difficult. The mean time for image registration was 19.13 ± 4.94 min (range: 14-29 min); the mean time for needle placement was 2.97 ± 0.56 min (range: 2-4 min); and the overall time of puncture was 22.10 ± 5.20 min (range: 16-33 min).

Clinical (Patient) Surgery

In the C-arm guidance group, the mean puncture time was 27.93 ± 1.74 min (range: 25-32 min) and the mean frequency of exposure to radiation was 14.27 ± 1.20 times shot of the C-arm (range: 13-17 timesshot of the C-arm). In the V Nav group, 30 patients underwent successful puncture after the primary registration; 3 patients felt lower-extremity pain that radiated during puncture, and successful puncture was achieved after the second registration. The overall puncture time was 20.39 ± 3.02 min (range: 16-28 min); the mean time for image registration was 15.52 ± 2.29 min (range: 13-22 min); the mean time for needle placement was 4.88 ± 1.02 min (range: 3-7 min); the mean frequency of exposure to radiation was 4.88 ± 0.78 times shot of the C-arm (range: 4-7 times shot of the C-arm); and the mean registration error was 3.25 ± 0.86 mm (range: 1.9-4.8 mm). The overall time of puncture and frequency of exposure to radiation are shown in Table 1. Both the overall puncture time and the exposure to radiation in the volume navigation group were less than those in the C-arm guidance group ($P < 0.001$).

The mean follow-up period for patients in the C-arm guidance group was 18.83 ± 4.29 months (range: 12-28 months) and that of the V Nav group was 18.36 ± 4.62months (range: 12-28 months). Preoperative and postoperative VAS scores and ODI scores are shown in Table 2. There were no significant differences between the 2 groups in the ODI and VAS scores at the same time points. No complications, such as nerve injury or wound infection, were reported in either one of these groups.

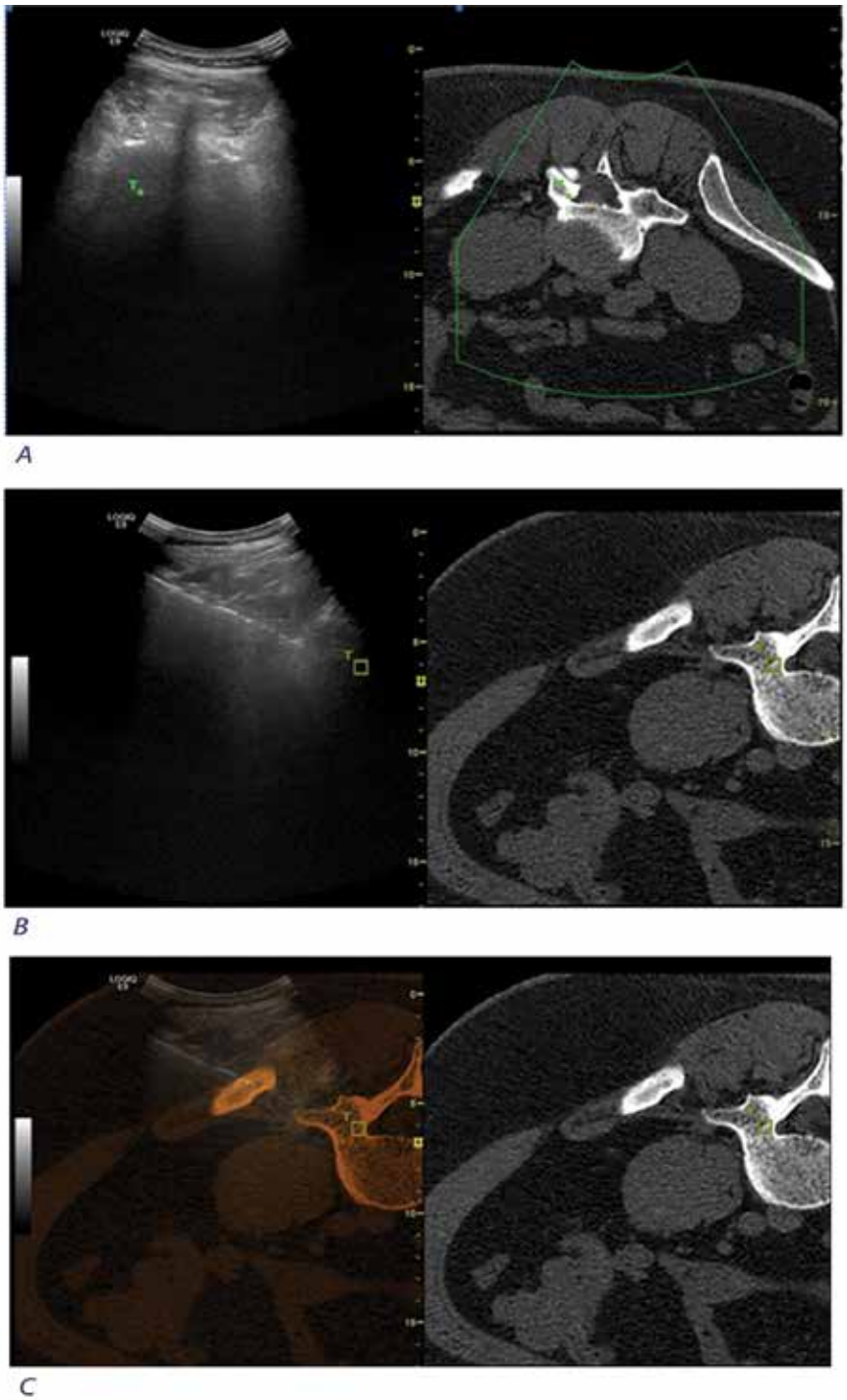

Fig. 6. A. During a cross-sectional scan, the area between the lateral margin of the facet joint and the root of the transverse process was taken as the target, which was shown on the CT axial plane and then on the real-time US image using V Nav technique. B. The probe was adjusted to make the target area become the smallest box or a cross (exact location; the puncture needle was then advanced on the axial plane to the target using an in-plane technique). C. The image obtained after fusion of the CT and US images.

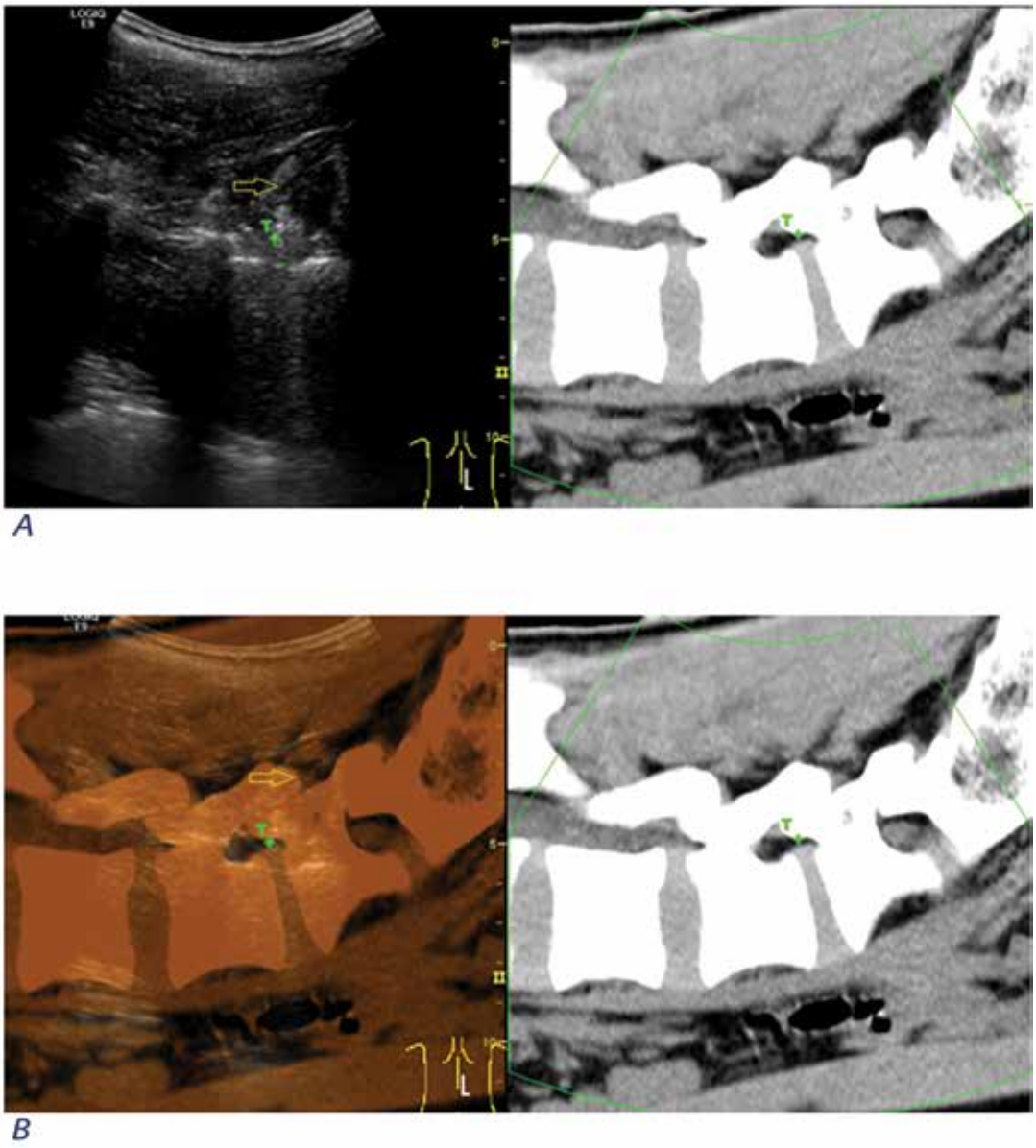

Fig. 7. *A. The US scan was carried out on the sagittal plane of the midline. US could not display the whole needle and deep structures beneath the cortical bone. B. The yellow arrow (left) indicates the last position of the needle tip observed by ultrasound. The direction and distance of the puncture needle to be advanced were determined according to the distance between the target verified by V NAV (the green cross marked as "1") and the last position of the needle tip observed on US (DNT).*

Table 1. *Comparison of puncture time and mean frequency of exposure to radiation (frequency of shots of C-arm) in the 2 groups.*

	C-arm group	V Nav group	P-value
Puncture time (min)	27.93 ± 1.74	20.39 ± 3.02	< 0.001
Mean frequency of exposure to radiation (times)	14.27 ± 1.20	4.88 ± 0.78	< 0.001

Table 2. *Clinical effects of the patients before and after surgery.*

	Oswestry Disability Scale (%)			Visual Analog Scale (leg)		
	C-arm	V Nav	*P*-value	C-arm	V Nav	*P*-value
Preoperatively	67.6 ± 12.5	66.4 ± 12.3	0.696	6.6 ± 1.2	6.7 ± 1.0	0.600
Postoperatively						
1 month	22.1 ± 10.9	21.1 ± 10.3	0.706	2.2 ± 0.9	2.1 ± 0.9	0.545
3 months	15.2 ± 10.8	13.8 ± 9.5	0.749	1.5 ± 1.0	1.5 ± 0.8	0.882
6 months	9.4 ± 9.2	9.4 ± 7.7	0.819	1.0 ± 0.9	0.9 ± 0.8	0.603
1 year	6.3 ± 7.3	6.4 ± 7.3	0.763	0.7 ± 0.8	0.8 ± 0.8	0.580

No recurrent disc herniation was observed during any of the follow-up visits in either group.

Discussion

Summary of Evidence

The endoscopic technique has recently become a hot topic in minimally invasive spine surgery. PELD has been reported to be better than traditional surgery regarding blood loss, operative time, postoperative recovery time, cost of surgery, and impact on the biomechanical structure of the lumbar spine, while its treatment outcome is similar to that of traditional surgery (16-18). Because of these advantages, the PELD technique has been applied more and more widely in clinical practice (19-21). Since the key point of this technique is to reach the target working zone – Kambin's triangle via the working channel established by the posterolateral transforaminal puncture (22), it is very important to establish the working channel as accurately and as quickly as possible while avoiding damage to the nerve root and vessels.

Compared with conventional navigation devices, such as the C-arm and computer assisted navigation system, US examination is a convenient, noninvasive, radiation-free, and real-time imaging technique. In addition, it can provide real-time monitoring during surgery. However, it is difficult for routine US examination to display the inner structures of deep bone and joint tissue due to complete reflection of US from cortical bone, which may induce significant loss of acoustic energy. Therefore, the US technique is rarely used in spine surgery; it has only been used in US-guided nerve blocks (23-29).

As a newly developed technique, US V Nav using an image fusion technique can recognize and identify lesions confirmed by other imaging modalities (such as CT and MRI), and can greatly expand the range of detection of lesions. For example, it has been widely and successfully used in the diagnosis and treatment of celiac disease and breast diseases (30-35). Based on the works of Galiano (36) (who carried out facet joint block and nerve root block in the lumbar spine and cervical spine using the image fusion technique), and Gofeld (37) (who proved the feasibility of US-guided transforaminal injection), and our experience in the cadaver experiment, in which the mean registration error was 2.66 mm, we considered that the US V Nav technique could be used in the navigation of transforaminal PELD.

In this study, we proved in the cadaver experiment that the US V Nav technique could overcome the shortcomings of conventional US, which cannot display the deep, complicated bony structures of the spine, and could accurately guide transforaminal puncture. After accumulating experiences in transforaminal puncture under the guidance of US V Nav, we applied this technique in clinical patient practice. In the current research, the time for image registration decreased, while the accuracy of registration increased gradually, as the number of patients treated with V Nav and puncture increased.

The results showed that image registration and fusion were the most important and time-consuming parts during the entire procedure, and obtained only after a high consistency matching was obtained between the CT and US images to improve the accuracy of puncture. In this experiment, we defined 5 mm as the maximum allowable registration error, and we conducted further registration only if the registration error was less. This is based on the fact that the height of the foramen is about 21 mm (38) and a 5 mm error is allowable for transforaminal puncture. However, the puncture error exceeded 5 mm in 2 cadavers, while the registration error was less than 5 mm in the entire clinical study. This error might cause nerve root injury and make the

placement of a working channel difficult. Therefore, the correlation between the registration error and the puncture error should be further analyzed. Also, due to the currently relatively small number of cases, more cases need be studied to reach a solid conclusion.

The registration error of V Nav for transforaminal puncture is higher than that for abdominal soft tissue puncture (30,33,34). A possible explanation for this is that we used a registration method combining the outer and inner markers (apex of the spinous process). We did not conduct registration completely using the relatively fixed inner anatomical makers because the foramen is surrounded by numerous bony structures, leading to poor sound transmission and difficult imaging. Moreover, the inner markers are not selected due to the complicated and irregular anatomical structures around the foramen.

During the experiment, we noticed that several factors may affect the registration process. First, the skill of the US specialist is very important. Manipulation should be gentle and consistent. If the force is excessive or inconsistent, the deformed fat tissue or the probe movement over the body surface may result in an error. This is especially likely to occur in obese patients. Second, during the registration of the inner marker, anatomical structures that can be easily recognized on CT and US images should be selected, and they should be thin. We selected the apex of the spinous process on the sagittal plane based on this principle. Because the apex of the spinous process has a certain thickness, the thickness on the axial plane easily results in errors during cross-sectional selection. Third, the operating table surface and the patient's abdomen should be in as close contact as possible to avoid position-caused errors. Fourth, metal instruments and metal-containing devices may affect the magnetic field of the tracker. Gradual solution of these problems may improve image registration errors and thereby improve the accuracy of the puncture.

The V Nav group doesn't need a C-arm to register and to navigate the puncture. It can finish the entire puncture process without using a C-arm. However, because these were early explorations of this new technique, we observed it with particular care, and used the C-arm to confirm the position of the needle. As a result, there was some exposure to radiation in the V Nav group. We compared the intra-op radiation exposure between the 2 groups. The frequency of exposure to radiation in Table 1 shows how many C-arm shots occurred during the operation. The average radiation in every shot of the C-arm was approximately equal. Therefore the low frequency of exposure to radiation in the V Nav group showed a statistically significant decrease. We believe that as the technology matures, radiation exposure during the surgery will be avoided entirely.

In future studies, once doctors have been trained in this technique, the significant advantages of this technique in the accuracy of puncture, and decrease in radiation exposure will become obvious.

Limitation

The correlation between the registration error and the puncture error needs to be further analyzed. Also, due to the relatively small number of cases, an additional number of cases will need to be studied to arrive at a solid conclusion.

Conclusion

In summary, the volume navigation technique can be applied in PELD because it helps to accurately guide percutaneous posterolateral transforaminal puncture, while reducing puncture time and exposure to intraop radiation.

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