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ORIGINAL ARTICLE

#### **Randomized Controlled Trial**

# Coaxial radiography guided puncture technique for percutaneous transforaminal endoscopic lumbar discectomy: A randomized control trial

Li-Ping Chen, Bin-Song Wen, Heng Xu, Zheng Lu, Lai-Jun Yan, Han Deng, Hong-Bo Fu, Hong-Jie Yuan, Pei-Pei Hu

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## Abstract

#### BACKGROUND

The coaxial radiography-guided puncture technique (CR-PT) is a novel technique for endoscopic lumbar discectomy. As the X-ray beam and the puncturing needle are maintained in a parallel and coaxial direction, the X-ray beam can be used to guide the trajectory angle, facilitating the choice of the puncture site and providing real-time guidance. This puncture technique offers numerous advantages over the conventional anterior-posterior and lateral radiography-guided puncture technique (AP-PT), especially in cases of herniated lumbar discs with a hypertrophied transverse process or articular process, high iliac crest, and narrowed intervertebral foramen.

#### AIM

To confirm whether CR-PT is a superior approach to percutaneous transforaminal endoscopic lumbar discectomy compared to AP-PT.

#### **METHODS**

In this parallel, controlled, randomized clinical trial, herniated lumbar disc patients appointed to receive percutaneous endoscopic lumbar discectomy treatment were recruited from the Pain Management Department of the Affiliated Hospital of Xuzhou Medical University and Nantong Hospital of Traditional



Chinese Medicine. Sixty-five participants were enrolled and divided into either a CR-PT group or an AP-PT group. The CR-PT group underwent CR-PT, and the AP-PT group underwent AP-PT. The number of fluoroscopies during puncturing, puncture duration (min), surgery duration (min), VAS score during puncturing, and puncture success rate were recorded.

#### RESULTS

Sixty-five participants were included, with 31 participants in the CR-PT group and 34 in the AP-PT group. One participant in the AP-PT group dropped out due to unsuccessful puncturing. The number of fluoroscopies [median (P25, P75)] was 12 (11, 14) in the CR-PT group vs 16 (12, 23) in the AP-PT group, while the puncture duration (mean  $\pm$  SD) was 20.42  $\pm$  5.78 vs 25.06  $\pm$  5.46, respectively. The VAS score was 3 (2, 4) in the CR-PT group vs 3 (3, 4) in the AP-PT group. Further subgroup analysis was performed, considering only the participants with L5/S1 segment herniation: 9 patients underwent CR-PT, and 9 underwent AP-PT. The number of fluoroscopies was  $11.56 \pm 0.88 vs 25.22 \pm 5.33$ ; the puncture duration was  $13.89 \pm 1.45 vs 28.89 \pm 3.76$ ; the surgery duration was 105 (99.5, 120) vs 149 (125, 157.5); and the VAS score was  $2.11 \pm 0.93$  vs  $3.89 \pm 0.6$ , respectively. All the above outcomes demonstrated statistical significance (P < 0.05), favoring the CR-PT treatment.

#### CONCLUSION

CR-PT is a novel and effective technique. As opposed to conventional AP-PT, this technique significantly improves puncture accuracy, shortens puncture time and operation time, and reduces pain intensity during puncturing.

Key Words: Herniated lumbar disc; Coaxial; Puncture; Anterior-posterior; L5/S1

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Core Tip: Puncturing is the first step for percutaneous endoscopic lumbar discectomy. Compared with the anterior-posterior and lateral radiography-guided puncture technique (AP-PT), the coaxial radiographyguided puncture technique (CR-PT) has the advantage of guiding the trajectory angle, facilitating the choice of the puncture site, and also providing real-time guidance for puncturing. This study aimed to compare the two techniques. In this randomized controlled trial, the CR-PT technique demonstrated significantly better puncture accuracy, and shorter puncturing and operation duration. We argue that the CR-PT technique is an advisable option in percutaneous endoscopic lumbar discectomy, especially for unusual cases.

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#### INTRODUCTION

Percutaneous endoscopic lumbar discectomy (PELD) is a promising treatment for herniated lumbar disc (HLD). Its advantages over conventional surgery include less intraoperative bleeding, minimal paraspinal muscle injury, high clinical efficacy, and rapid functional recovery. Therefore, PELD has become a popular surgical method[1-8]. Furthermore, in PELD surgery, only a tiny part of the bone tissue is removed, which does not compromise spinal stability [9,10].

Despite its numerous advantages, PELD is technically challenging and has a steep learning curve[11, 12]. Accurate puncturing and working channel intubation are required to create favorable conditions for endoscopic surgery [13,14]. However, the puncture technique is relatively difficult, especially in percutaneous transforaminal endoscopic lumbar discectomy (PTELD), which requires specific puncture angles to certain parts of the intervertebral foramen. In addition, for a L5/S1 segment HLD case with a hypertrophied L5 transverse process and articular process, high iliac crest, and narrowed intervertebral foramen, the puncturing is more difficult[15,16].

Conventionally, intermittent anteroposterior and lateral radiography is used for accurate puncturing. However, this process relies on the surgeon's experience to determine and adjust the trajectory angle and depth of the needle. Occasionally, an inappropriate puncture angle leads to failure of the

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endoscopic surgery [17,18]. Repeated puncturing results in a prolonged operation and increased exposure to radiation [19,20]. Moreover, repeated puncturing increases the patient's pain perception.

This paper describes a novel coaxial radiography-guided puncture technique (CR-PT) that we developed in our clinical practice. This technique focuses on maintaining the X-ray beam and the puncturing needle in a parallel and coaxial direction [21,22]. With the coaxial technique, the X-ray beam can be used to facilitate puncture site selection and guide the trajectory angle while providing real-time guidance. We hypothesized that this new technique reduces the difficulty of the puncture process, reduces the number of Xray fluoroscopies, shortens the puncture duration, and increases the puncture accuracy. Therefore, the new puncture technique was compared with the conventional anteriorposterior and lateral radiography-guided puncture technique (AP-PT) in order to confirm its superiority.

#### MATERIALS AND METHODS

#### Study design

This is a parallel, controlled, single-blinded, randomized clinical trial. The participants were recruited from the Pain Management Department of the Affiliated Hospital of Xuzhou Medical University and Nantong Hospital of Traditional Chinese Medicine and were assigned to two parallel groups: CR-PT group and AP-PT group. The CR-PT group underwent CR-PT, and the AP-PT group underwent AP-PT. This study complied with The Declaration of Helsinki, and the trial was approved by the Institutional Ethics Committee of Clinical Research of Nantong Hospital of Traditional Chinese Medicine. The clinical trial was registered on the Chinese Clinical Trial Registry website (Registration number ChiCTR2200058894) and written informed consent was obtained from all the participants. No external funding was available for the trial.

Inclusion criterion: HLD patients appointed to receive PELD treatment.

Exclusion criteria: Patients with verbal communication disorders; patients with mental disorders; patients who underwent percutaneous inter-laminar endoscopic lumbar discectomy.

#### Randomization and masking

One researcher was in charge of the enrollment and allocation. The participants were allocated according to their year of birth. Participants with an odd-numbered birth year were assigned to the CR-PT group, while participants with an even-numbered birth year were assigned to the AP-PT Group. The participants were blinded to which group they were assigned.

Another researcher was assigned to evaluate the outcomes. The operations were performed by two surgeons in the two respective hospitals. They were not blinded to the allocation. Data processing and statistical analysis were performed by another researcher who was blinded to the allocation. The allocation method was revealed after the completion of the statistical analysis.

#### Outcomes

The primary outcomes included the number of fluoroscopies during puncturing and the puncture duration (min). The puncture duration was defined as the time taken from setting the operation position to the needle tip reaching the correct target. The secondary outcome was the surgery duration (min), which was defined as the time taken from setting the operation position to suturing. The VAS score during puncturing and the puncture success rate were also evaluated as secondary outcomes. Successful puncturing was defined as the needle tip reaching the correct target; otherwise, the puncture was deemed unsuccessful. The outcomes were recorded during and after the surgeries by a separate researcher.

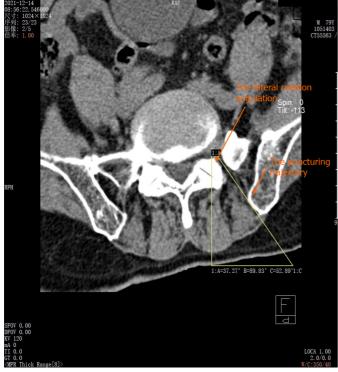
#### Sample size

The sample size was set based on the number of fluoroscopies. According to the previous literature, the effect size was set to be 4 and the standard deviation was set to be 4.6, with  $\alpha$  = 0.05 and beta = 0.1. The sample size was 32 for each group. As no follow-up work was needed in the study, no dropout rate was considered. The sample size was calculated to be 64.

#### Interventions

**CR-PT procedure:** MRI or CT was performed before surgery, and the proper lateral and cranial tilt angle of the trajectory was measured (Figure 1). The participant was placed in the prone position, and a cushion was placed under the abdomen to reduce lumbar lordosis. Then, the C-arm was tilted to the predetermined lateral and cranial oblique angulation, and the superior part of the lateral border of the superior articular process (SAP), also known as the shoulder of the SAP, was identified as the target. In some circumstances, some modifications were made to the target selection. In L5/S1 segment cases, if the intervertebral foramina and the SAP were obstructed by the iliac crest, the C-arm was tilted cranially





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Figure 1 Proper trajectory angle measured in computed tomography scan. For this far lateral type herniated lumbar disc case, a much smaller lateral tilt angulation of the trajectory was measured in the computed tomography scan beforehand.

and slightly medially until the intervertebral foramina and the SAP could be visualized. The radiopaque marker was then placed on the skin superimposing the target, which was marked, disinfected, and draped. Subsequently, the marked skin and subcutaneous tissues were anesthetized. A needle (17G, 15 cm) was inserted a short distance until it was seated in the subcutaneous tissues overlying the target, and the angle of the needle was adjusted until it was parallel to the X-ray axis. In this instance, the needle hub projected directly over the tip and was aligned with the target, as displayed in Figure 2. The needle was advanced while maintaining a parallel direction to the X-ray axis until contact with the shoulder of the SAP was made. Then, anteroposterior and lateral radiography was performed to confirm the needle placement.

In some cases, the SAP could not be visualized clearly despite setting the C-arm to the predetermined angulation, and mild angulation adjustments were made to allow for proper visualization. This situation occurred when the lateral oblique angle of the C-arm was very large. In such cases, a guiding needle was utilized in addition to the puncturing needle (Figure 3).

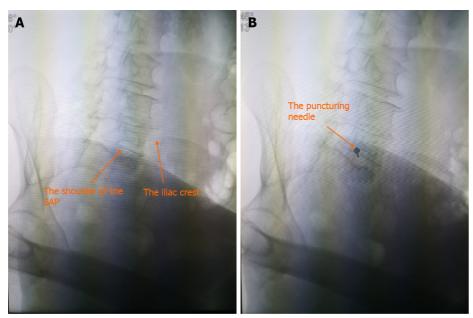
First, the radiopaque marker was placed and the skin was prepared for puncture as described above. The guiding needle (20G, 15 cm) was inserted sagittally under X-ray guidance until contact was made with the SAP, and the needle was repositioned and advanced slightly along the lateral border of the SAP. The needle was further advanced slightly to ensure that the needle tip was situated near the ventral margin of the SAP, and the anteroposterior and lateral view was taken to confirm the position (Figure 4). Then, the tip of the guiding needle was set as the puncturing target, and the coaxial technique was performed as described above (Figure 5).

#### **AP-PT** procedure

The C-arm was set at the correct alignment to achieve a standard lumbar anteroposterior radiography. This process ensured that the X-ray beam was parallel to the disc and that the endplate was displayed as a straight line. Subsequently, the center longitudinal line of the lumbar spine and an oblique line passing through the shoulder of the SAP were marked. For the L5/S1 Lumbar disc, the oblique line should reach above the peak point of the iliac crest. Then, a longitudinal line parallel and 10-14 cm lateral to the center line was drawn. The intersection of the lateral longitudinal line and the oblique line was defined as the puncture point (Figure 6). After disinfection, draping, and anesthesia, a needle was inserted. During the procedure, anteroposterior and lateral views were taken every 1 cm of needle advancement, confirming that the needle was oriented to the shoulder of the SAP (Figure 7). Slight modifications in direction were performed as necessary. When the needle tip touched the SAP, anteroposterior and lateral radiographs were taken to confirm the needle position.

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Chen LP et al. Coaxial radiography guided puncture technique



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Figure 2 X-ray films of the coaxial radiography-guided puncture technique. A: For the coaxial radiography-guided puncture technique, the target should be identified first, which is usually the shoulder of the superior articular process; B: The needle was maintained coaxial to the X-ray beam and parallel to the X-ray axis. In this instance, the needle hub projected directly over the tip and aligned with the target, and the needle appeared as a dot instead of a line. SAP: Superior articular process.



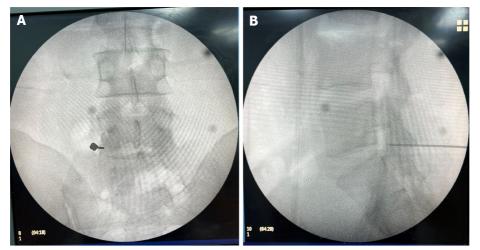
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Figure 3 Picture of the coaxial radiography-guided puncture technique with an additional guiding needle. If the superior articular process could not be visualized clearly, a guiding needle was used in addition to the puncturing needle. This usually occurred when the lateral oblique angle of the C-arm was very large.

#### Statistics

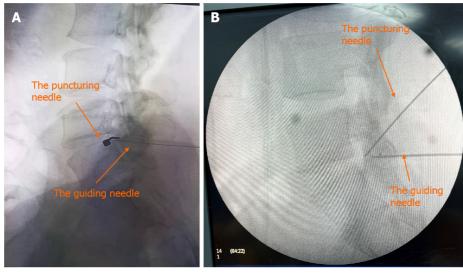
Quantitative variables with a normal distribution are presented as the mean  $\pm$  SD, while non-normally distributed variables are reported as the median (P25, P75). An independent *t*-test was performed to analyze normally distributed data with homogeneity of variance. A separate variance estimated *t*-test was performed to analyze normally distributed data without homogeneity of variance. The remaining quantitative data were statistically analyzed by the Wilcoxon rank sum test. For qualitative variables, Fisher's exact test and Pearson chi-square test were applied. In this study, *P* < 0.05 was considered statistically significant. SPSS version 26 was utilized for statistical analyses. Moreover, a subgroup analysis of the patients with L5/S1 HLD was performed using the same statistical methodology.

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Figure 4 X-ray films of a successful puncturing of a guiding needle. The anteroposterior and lateral views confirmed the needle tip placement near the ventral margin of the superior articular process.



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Figure 5 X-ray films of a successful puncturing with an additional guiding needle. A: The C-arm was set at the coaxial position and puncture was performed under coaxial radiography guidance. In this position, the puncturing needle was shown as a dot rather than a line; B: The lateral view shows that the puncturing needle has reached the tip of the guiding needle, indicating a successful puncture.

#### RESULTS

In total, 86 participants were evaluated from April 2022 to May 2023, and 65 participants were enrolled in the trial. Among the enrolled participants, 16 were from the Nantong Hospital of Traditional Hospital, and 49 were from the Affiliated Hospital of Xuzhou Medical University. One participant in the AP-PT group dropped out due to AP-PT failure and eventually underwent CR-PT. Therefore, statistical analysis was performed for 64 participants, with 31 participants in the CR-PT group and 33 in the AP-PT group.

The demographic characteristics of the patients showed no statistically significant difference between the two groups, as displayed in Table 1.

The number of fluoroscopies [median (P25, P75)] was 12 (11, 14) in the CR-PT group vs 16 (12, 23) in the AP-PT group, while the puncture duration (mean  $\pm$  SD) was  $20.42 \pm 5.78 vs 25.06 \pm 5.46$ , respectively. All the variables demonstrated statistically significant differences (P < 0.05), as displayed in Table 2.

Furthermore, a subgroup analysis of the clinical outcomes was performed on the participants who underwent L5/S1 segment surgery. In total, 15 participants were included in the subgroup analysis, with 7 patients from the CR-PT subgroup and 8 from the AP-PT subgroup. The number of fluoroscopies was  $11.56 \pm 0.88 vs 25.22 \pm 5.33$ , and the puncture duration was  $13.89 \pm 1.45 vs 28.89 \pm 3.76$ , respectively. All the variables demonstrated statistically significant differences (P < 0.05), as displayed in Table 3.



Table 1 Demographic data of patients included in the two groups			
	CR-PT group (31)	AP-PT group (34)	<i>P</i> value
Sex (male:female)	19:12	18:16	0.5
Height (cm)	$168.29 \pm 7.99$	$167.53 \pm 8.18$	0.71
Weight (kg)	66 (62, 75)	69 (60, 80)	0.17
BMI (kg/cm <sup>2</sup> )	25.3 (22.63, 28.04)	27.25 (23.19, 33.35)	0.15
Age	55 (41, 65)	58 (38, 66)	0.5
Surgical segment			
L1/L2	0	2	0.57
L2/L3	1	0	
L3/L4	1	3	
L4/L5	20	19	
L5/S1	9	10	
Laterality (left:right)	18:13	12:22	0.07
Pain duration (mo)	6 (1, 24)	6 (2, 24)	0.64

Normally distributed data are presented as the mean ± SD; non-normally distributed data are presented as the median (P25, P75). AP-PT: Radiographyguided puncture technique; CR-PT: Coaxial radiography-guided puncture technique.

Table 2 Clinical outcomes of the two groups			
	CR-PT group (31)	AP-PT group (33)	P value
Number of fluoroscopies	12 (11, 14)	16 (12, 23)	0.002
Puncture duration	$20.42 \pm 5.78$	$25.06 \pm 5.46$	0.002
Surgery duration	115 (107, 124)	123 (92, 148.5)	0.173
VAS score during puncturing	3 (2, 4)	3 (3, 4)	0.021
Puncture success rate (34 participants included for AP-PT group)	100%	97.06%	1

AP-PT: Radiography-guided puncture technique; CR-PT: Coaxial radiography-guided puncture technique.

Table 3 Clinical outcomes of the two groups in the L5/S1 segment			
	CR-PT subgroup (9)	AP-PT subgroup (9)	<i>P</i> value
Number of fluoroscopies	$11.56 \pm 0.88$	25.22 ± 5.33	0
Puncture duration	$13.89 \pm 1.45$	$28.89 \pm 3.76$	0
Surgery duration	105 (99.5, 120)	149 (125, 157.5)	0
VAS score during puncturing	$2.11 \pm 0.93$	$3.89 \pm 0.6$	0

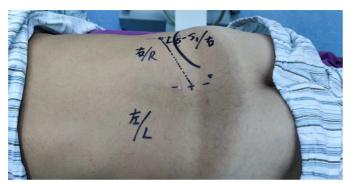
AP-PT: Radiography-guided puncture technique; CR-PT: Coaxial radiography-guided puncture technique.

No complications were reported in the trial.

#### DISCUSSION

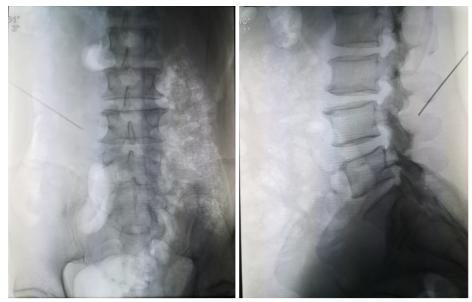
This clinical trial was carried out to compare the two puncturing techniques. The aim of the study was to confirm whether CR-PT is a superior approach to percutaneous transforaminal endoscopic lumbar discectomy compared to AP-PT. The number of fluoroscopies during puncturing, puncture duration,





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Figure 6 Picture of puncturing direction in the radiography-guided puncture technique marked in the skin. A lateral longitudinal line parallel to the center longitudinal line was drawn, about 10-14 cm from the center line, and the intersection of the lateral longitudinal line and the obligue line passing through the tip of the superior articular process was chosen as the puncture point.



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Figure 7 X-ray films of the radiography-guided puncture technique. The needle should be oriented to the shoulder of the superior articular process under both the anteroposterior and lateral views.

surgery duration, VAS score during puncturing, and puncture success rate were recorded.

One participant with L5/S1 segment HLD dropped out due to an unsuccessful AP-PT procedure. All the clinical outcomes demonstrated superiority with statistical significance favoring the CR-PT group except the surgery duration. Additionally, a subgroup analysis was performed, focusing on L5/S1 segment participants. All the clinical outcomes demonstrated statistically significant superiority in the CR-PT subgroup compared to the AP-PT subgroup. The superiority was more obvious in the subgroup analysis.

The superiority of CR-PT over AP-PT may be attributed to the following points. In the coaxial puncturing technique, the puncturing needle and X-ray beam share a common axis, which is easier to observe on radiography and allows for less needle repositioning. Additionally, as opposed to AP-PT, this novel puncturing technique does not require shifting the C-arm machine between the lateral position and the anteroposterior position repeatedly. The working cannula tilt angulation is crucial for PTELD, as it should be accurate and individualized. For example, a central-type disc herniation requires a larger lateral oblique angulation, whereas a small lateral oblique angulation is warranted in a foraminal type or far lateral type HLD case. Similarly, caudal hernia prolapses require a larger cranial tilt angulation, otherwise minor cranial tilt angulation is necessary. In the coaxial technique, the individualized puncturing angle and the individualized puncturing spot can be predetermined and guaranteed by setting the C-arm angulation beforehand. Hence, the angulation of the working cannula intubation can be optimized, which facilitates subsequent endoscopic surgery. However, for AP-PT, selecting the optimal puncture point and puncturing angulation depends on the surgeon's expertise,



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which is much less accurate.

Our research demonstrated a more obvious superiority of CR-PT in HLD of the L5/S1 segment, which may be due to the following reasons. First, L5/S1 segments typically require a smaller lateral rotation angle, allowing easy visualization of the SAP. Therefore no guiding needle is required, which shortens puncturing time. Second, in the coaxial technique, the iliac crest is relatively easily avoided due to the more accurate angulation. Therefore, we believe that CR-PT is far more advantageous in L5/S1 cases.

Other innovative puncturing techniques have been reported for PELD. Zeng *et al*[14] reported a novel targeted puncture technique using a lumbar disc herniation target collimator, indicating superiority over the conventional free-hand injection method. Fan et al [23] applied a so-called HELLO system, which consisted of a self-made surface locator and a puncture-assisted device to guide the percutaneous puncturing process. The report also indicated improved puncturing accuracy and reduced fluoroscopic duration, as well as preoperative location duration. Moreover, C-arm navigation and 3D printing technologies have been applied in multiple studies. Qin et al[13] reported that using the C-arm navigation system could dramatically reduce the number of fluoroscopies and puncture attempts compared with the conventional method. Erken et al<sup>[24]</sup> reported the use of a collimation device to facilitate puncturing in PELD. However, all these methods require additional equipment and could increase the cost of the procedure. In contrast, our method requires no additional device and provides a more convenient and practical approach.

Nevertheless, the limitations of this study should be acknowledged. The sample size was small. Thus, further clinical research with a larger sample size is required. Second, the puncturing technique relies on personal expertise and surgeons have their personal preferences, and our result can only provide an alternative reference.

#### CONCLUSION

CR-PT in PTELD is a novel and effective technique. It enables individualized cranial and lateral tilt angulation during puncturing, accurate identification of the puncturing location, fewer needle direction adjustments, and no need for repeated C-arm angulation shifting. This technique significantly improves puncture accuracy, shortens puncture time and operation time, and reduces pain during puncturing. Therefore, CR-PT could be an advisable option in PTELD.

## ARTICLE HIGHLIGHTS

#### Research background

As a conventional puncture technique in endoscopic discectomy, anterior-posterior and lateral radiography-guided puncture technique (AP-PT) has limitations, such as repeated intermittent radiographs and inaccurate needle angulation. Although some innovative puncturing techniques have been reported, most of them require additional equipment. This paper describes an innovative coaxial radiography-guided puncture technique (CR-PT) and verifies its feasibility and superiority compared to the traditional AP-PT technique.

#### Research motivation

The coaxial radiography-guided puncture technique (CR-PT) is commonly applied in conventional procedures; however, we applied this technique in endoscopic lumbar discectomies. For some difficult cases, a guiding needle was used and the tip of the guiding needle was set as the target, which subsequently enabled the coaxial puncture technique to be performed.

#### Research objectives

The aim of the research was to verify the superiority of CR-PT over AP-PT in endoscopic lumbar discectomies.

#### Research methods

This is an RCT trial. The participants were assigned to either a CR-PT group or an AP-PT group. The number of fluoroscopies during puncturing, puncture duration (min), surgery duration (min), VAS score during puncturing, and puncture success rate were recorded and compared.

#### Research results

The trial verified the superiority of CR-PT over AP-PT in terms of puncture duration, puncture accuracy, and VAS score during puncturing.



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#### Research conclusions

The CR-PT technique is a novel and effective technique. This technique significantly improves puncture accuracy and shortens puncture duration. Therefore, CR-PT could be an advisable option in endoscopic discectomy.

#### Research perspectives

This study lays a foundation for further research on the CR-PT technique in trans-interlaminar endoscopic lumbar discectomies and endoscopic cervical discectomies.

#### FOOTNOTES

Author contributions: Yuan HJ, Chen LP, and Xu H designed the research study; Yuan HJ and Chen LP performed the procedure; Hu PP, Fu HB, and Xu H recorded the outcomes; Wen BS, Deng H, and Lu Z did the statistical work, Wen BS, Yan LJ, and Yuan HJ wrote the manuscript; all authors have read and approved the final manuscript.

Institutional review board statement: This study complied with The Declaration of Helsinki, and the trial was approved by the Institutional Ethics Committee of Clinical Research of Nantong Hospital of Traditional Chinese Medicine (Approval No. 20221230-5).

Clinical trial registration statement: The clinical trial was registered on the Chinese Clinical Trial Registry website (Registration number ChiCTR2200058894).

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement: All authors declare no potential conflicting interests related to this paper.

Data sharing statement: No additional data are available.

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