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Randomized Controlled Trial

Coaxial Radiography Guided Puncture Technique for Percutaneous Transforaminal Endoscopic Lumbar Discectomy: A Randomized Control Trial

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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 conventional anterior-posterior and lateral radiography-guided puncture techniques (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

This paper aimed 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 (HLD) patients appointed to receive PELD 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 two groups. The CR-PT Group underwent CR-PT, and the AP-PT Group underwent AP-PT. The number of fluoroscopies during puncturing, the puncture duration (minutes), the surgery duration (minutes), the VAS score during puncturing, and the puncture success rate were recorded.

RESULTS

Sixty-five participants were included, with 31 participants in the CR-PT Group and 34 participants 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 ± 5.78 vs. 25.06 ± 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 ± 0.88 vs. 25.22 ± 5.33 ; the puncture duration was 13.89 ± 1.45 vs. 28.89 ± 3.76 ; the surgery duration was 105 (99.5, 120) vs. 149 (125, 157.5); and the VAS score was 2.11 ± 0.93 vs. 3.89 ± 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.

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 para-spinal 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 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. The current trial hypothesized that this new technique reduces the difficulty of the puncture process, reduces the number of X-ray fluoroscopies, shortens the puncture duration, and increases the puncture accuracy. Therefore, the new puncture technique was compared

with the conventional anterior-posterior 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 into two parallel groups. 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 (minutes). 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 (minutes), 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 previous literature, the effect size was set to be 4 and the standard deviation was set to be 4.6, $\alpha = 0.05$, $\beta = 0.1$. 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

The MRI or CT was observed 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 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, 15cm) 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, 15cm) 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.

Statistics

For quantitative variables with a normal distribution, the mean \pm SD was used, while the median (P25, P75) ¹ was used for non-normally distributed variables. 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, ³ $P < 0.05$ was considered statistically significant. SPSS version 26 was utilized for statistical analysis. Moreover, a subgroup analysis of the patients with L5/S1 HLD was performed with the same statistical methodology.

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 participants were from the Nantong Hospital of Traditional Hospital, and 49 participants 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 participants in the AP-PT Group.

The demographic characteristics of the patients showed ¹ 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; 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.

No complications were reported in the trial.

DISCUSSION

This clinical trial was carried out to compare the two puncturing techniques. The aim of the manuscript 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, the puncture duration, the surgery duration, the VAS score during puncturing, and the 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, 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. Firstly, 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. Secondly, 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. Yuedong Zeng reported a novel targeted puncture technique using a lumbar disc herniation target collimator, indicating superiority over the conventional free-hand injection method [14]. Guoxin Fan 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 [23]. Moreover, C-arm navigation and 3D printing technologies have been applied in multiple studies. Hao Qin reported that using the C-arm navigation system could dramatically reduce the number of fluoroscopies and puncture attempts compared with the conventional method. H Yener Erken reported the use of a collimation device to facilitate puncturing in PELD [24]. 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. Secondly, 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, inaccurate needle angulation, and so on. 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 the CR-PT group and AP-PT group. The number of fluoroscopies during puncturing, the puncture duration (minutes), the surgery duration (minutes), the VAS score during puncturing, and the 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.

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

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