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ORIGINAL ARTICLE

A comparison between transforaminal lumbar epidural injection performed under picture archiving and communication systems-based magnetic resonance imaging planning and injection under immediate X-ray guidance

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The effect of transforaminal lumbar epidural injection (TFLEI) in the treatment of lumbar disc herniation has been recognized[1,2] and included in treatment guidelines.[3] However, most of the treatment schemes reported in the literature have involved puncture under the real-time guidance of X-ray, computed tomography (CT), or color ultrasound.[4-6] Although the puncture operation

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ABSTRACT

Objectives: The study aimed to compare the treatment cost, operation time, clinical effect, and complications between punctures done under magnetic resonance imaging (MRI) planning based on picture archiving and communication systems (PACS) and punctures done under immediate X-ray fluoroscopy guidance in the treatment of lumbar disc herniation by transforaminal lumbar epidural injection.

Patients and methods: In this prospective study conducted between October 2016 and June 2021, 128 patients were randomly divided into Groups A and B by the random number table method. In Group A (n=66; 36 males, 30 females; mean age: 64.5±2.4 years, range, 50 to 72 years), puncture was performed by planning with PACS-based MRI; in Group B (n=62; 34 males, 28 females; mean age: 65.3±2.6 years; range, 48 to 73 years), puncture was performed under immediate X-ray guidance. The cost of treatment, duration of procedure, clinical outcome, and complications were compared between the two groups.

Results: The difference in treatment cost in Groups A and B was statistically significant ($p<0.001$), with 755.67±29.45 yuan and 1.158.08±43.92 yuan, respectively. The mean treatment time was statistically significant ($p<0.001$) between the groups, with 21.16±1.91 min in Group A and 37.26±2 min in Group B. However, there was no significant difference between Group A and Group B in terms of improvement in pain scores and Oswestry disability index (both $p>0.05$). There was also no significant difference between Group A and Group B in terms of complication rates (both $p>0.05$).

Conclusion: Compared to immediate X-ray guided puncture, the puncture method using PACS for MRI planning shortened the transforaminal lumbar epidural injection procedure time and reduced the treatment costs without exposing the physician or patient to additional radiation, while there was no significant difference in the short-term clinical outcome or complication rate.

Keywords: Lumbar disc herniation, magnetic resonance imaging, operation time, picture archiving and communication systems, transforaminal lumbar epidural injection, treatment cost, X-ray fluoroscopy.

under the guidance of C-arm X-ray fluoroscopy is relatively simple, it results in radiation exposure to both patients and operators.[7] Moreover, patients need to be sent to the operating room for the procedure, which also increases the time and economic cost of the clinical work. Therefore, our research team intended to find a method that has a shorter operation time and lower treatment costs and is consistent with the clinical effect of traditional methods, with no additional radiation exposure. Picture archiving and communication systems (PACS)-based magnetic resonance imaging (MRI) can clearly visualize the lumbar disc herniation segments and nerve compression, and at the same time, it can accurately measure the depth and angle of the injection site. Therefore, we used PACS-based MRI to develop a TFLEI plan without the immediate guidance of X-ray or ultrasound and compared it with the traditional method of X-ray-guided TFLEI.

PATIENTS AND METHODS

In this prospective study, a total of 128 patients with lumbar disc herniation and radicular pain treated in the West China Fourth Hospital between October 2016 and June 2021 were selected and randomly divided into two groups with a random number table: Group A (test group) and Group B (control group). Group A included 66 patients (36 males, 30 females; mean age: 64.5±2.4 years, range, 50 to 72 years) who underwent TFLEI by planning with PACS-based MRI. Group B included 62 patients (34 males, 28 females; mean age: 65.3±2.5 years; range, 48 to 73 years) who underwent TFLEI under C-arm X-ray fluoroscopy guidance. The follow-up times of both groups were one day and one week after treatment. During the study period, we treated a total of 525 patients with lumbar disc herniation; 220 patients were treated with noninvasive maneuvers with good results, and a total of 128 patients received epidural injections.

The inclusion criteria were as follows: all patients presenting with low back pain combined with unilateral lower-limb shooting pain and radicular symptoms, such as numbness, decreased or absent tendon reflex, and decreased muscle strength (according to the Medical Research Council); a positive straight leg elevation test (Lasègue's test) and strengthening test on the affected side; a CT or MRI examination of the lumbar spine confirming lumbar disc herniation. *The exclusion criteria were as follows:* lumbar spine stenosis, cauda equina syndrome, lower extremity pain and sensory abnormalities caused by other diseases (peripheral vascular disease, multiple neuropathies, or diabetic peripheral neuropathy), intraspinal space occupation, lumbar infectious disease, tumors, severe medical conditions, coagulopathies, patients with significant structural vertebral abnormalities on imaging (CT or MRI), transverse process hypertrophy, migrating vertebrae, and unclear bony markers on the body surface. The patients' enrollment process is shown in Figure 1.

Puncture based on MRI planning in PACS

The Signa 1.5 T superconducting MRI device (GE HealthCare Technologies Inc., Chicago, IL, USA) was utilized for imaging in Group A. In the browsing interface of PACS, on the axial MRI section of the predetermined injection level, the distance between the puncture target and the spinous process, the puncture depth, and the horizontal angle were measured, and the measurement data was recorded for standby. All patients underwent the puncture operation in the ward. The patients were placed on the bed in the prone position, with a height of 10 cm under the abdomen, and the posterolateral approach through the intervertebral foramen was adopted.

After the exclusion of the transitional vertebra, the level of the spinous process was located by the sign of a bony process on the body surface. The line of the posterior superior iliac spine was the L4/5 level of the spinous process gap, as demonstrated by Step 1 in Figure 2, which moved down approximately 10 mm to reach the L5 spinous process (Step 2). Afterward, the sacral clivus was palpated downward, and the L5/S1 gap was also verified by determining the sacral clivus. The L4/5 spinous process space was palpated horizontally along with the L4 spinous process, and finally, the L3 spinous process was palpated upward.

Since the probability of disc herniation in L1/2 and L2/3 is very low, these segments were not included in this study. On the surface of the body, at approximately 2 to 5 cm away from the spinous process of the treatment layer to be punctured, a mark was placed on the skin surface according to the obtained image measurement data: the distance between the spinous process, the puncture depth, and the horizontal angle, as demonstrated by Step 3 in Figure 2, which displays the operation process diagram.

Puncture under the guidance of C-arm X-ray fluoroscopy

The puncture point was at the junction of 1/3 of the line between the same interspace and the

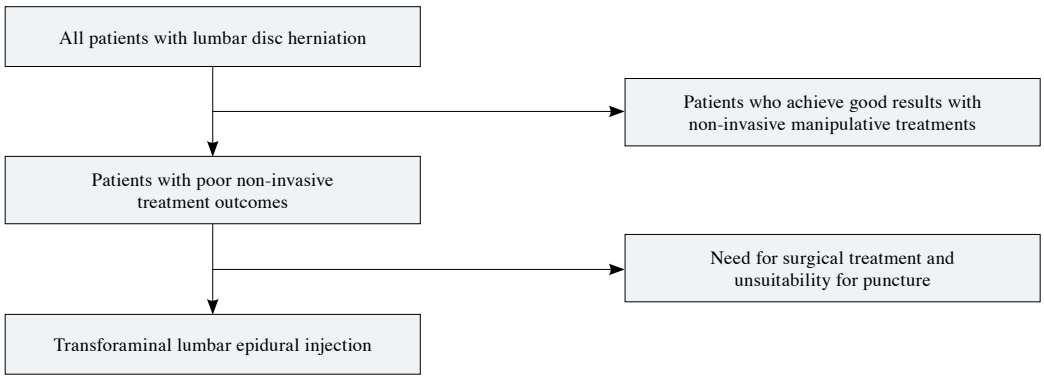

FIGURE 1. Patient enrollment process.

last interspace with disc herniation. The target of the puncture was 2 to 5 cm away from the spinous process. After routine disinfection and local infiltration of anesthesia, a 20-gauge PTC puncture needle (Kangdelai Medical Devices Co., Ltd., Shanghai, China) was slowly inserted into the epidural space through the puncture point, with the inclined direction to the skin and a vertical angle of 5-25°. The posterior edge of the vertebral body was encountered when the needle went through the articular process for approximately 6 to 10 cm. The needle was returned 2 to 3 mm, and 1 mL of meglumine diatrizoate was injected through the needle. The diffusion of contrast agent in the epidural cavity along the nerve root was observed by X-ray fluoroscopy and recorded. The treatment solution was injected after the location was determined.

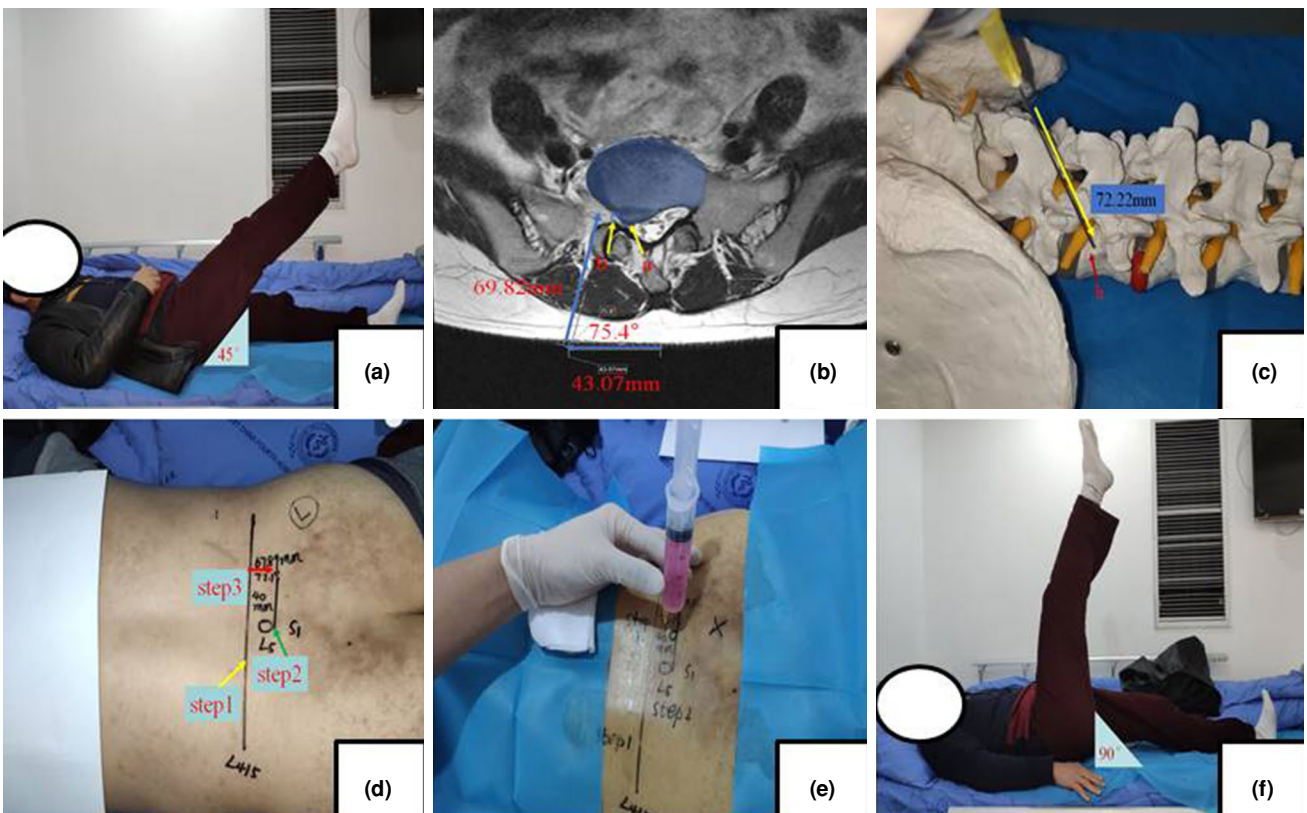

FIGURE 2. Flow chart of diagnosis of lumbar disc herniation and puncture operation under MRI planning based on PACS.

LDH: Lumbar disc herniation; MRI: Magnetic resonance imaging; PACS: Picture archiving and communication systems. Step 1: Determine the L4/5 level; Step 2: Determine the position of the L5 spinous process; Step 3: Determination of the position of the puncture point.

Puncture process and precautions

The type and dose of drugs injected for the TFLEI procedure in Group A and Group B were identical, all of which were dexamethasone 5 mg, 2% lidocaine 100 mg, and 1 mg of vitamin B12 diluted to 20 mL with normal saline. Dexamethasone and vitamin B12 were not included if the procedure was conducted for diagnostic purposes. For diagnostic purposes, 2 mL of the prepared drug was used, whereas 10 mL was administered for the treatment procedure. Strictly abiding by aseptic techniques, an iodophor was employed for skin preparation. A local anesthesia puncture channel was used, and a 20-gauge PTC puncture needle was guided to the side of the dorsal nerve root in the intervertebral foramen. If there was radiating pain along the nerve in the process of puncture, the patient was asked if the pain site was consistent with the normal symptom site. If consistent, the needle was withdrawn approximately 2 to 3 mm, and the drug was injected.

During injection, the syringe was gently and intermittently withdrawn to confirm whether a local blood vessel was punctured, in which case, the needle was withdrawn approximately 2 to 3 mm. The final position of the needle tip was adjacent to the nerve root and the segmental artery of the vertebral body to ensure that the injection drug was located around the nerve root and in the epidural space without entering the blood vessel. The needle was pulled out after the injection, and the puncture site was covered with the dressing. If the targeted nerve root was responsible for the patient's clinical symptoms, the pain would be relieved after several minutes, and many patients would have a sensation of heat in the unilateral/bilateral lower limbs after injection.

According to the clinical experience of this study, if the patient had this heat sensation, the treatment effect was usually satisfactory. After the operation, patients were recommended to lie in supine position for 2 h; they were observed for the occurrence of adverse reactions and were reevaluated for the relief of lower limb symptoms.

Outcome measures

Operation times, treatment costs, the efficacy of the procedure, and complications were recorded and compared between the groups. For operation times, the starting time for Group A was when the MRI was performed on the PACS for measurement, and the end time was when the wound was dressed. The starting time for Group B was when the patient entered the operating room, and the end time was when the patient left the operating room.

The treatment cost of Group A was calculated with the following formula: outpatient imaging examination fee + drug fee + nerve block operation fee + bed fee. In Group B, the additional cost of puncture guidance under C-arm X-ray fluoroscopy was included.

The Visual Analog Scale (VAS), straight leg raise test, and the Oswestry disability index (ODI) were used to evaluate the efficacy. The evaluation time was before treatment, on the first day after treatment, and one week after treatment.

In the assessment of complications, the incidence of nerve irritation, blood vessel injury, decrease in muscle strength, increase of lumbago, hypotension, and digestive and respiratory discomfort in Groups A and B were analyzed.

Statistical analysis

The sample size analysis was conducted using the G*Power software version 3.1.9.4 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The minimum sample size for each group was calculated as 31 cases.

Data were analyzed using IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). The Shapiro-Wilk method was used to test the normal distribution of quantitative data; the measurement data conforming to a normal distribution were expressed by. A nonpaired t-test was used for comparisons between groups, and the percentage was used for continuous variables. The chi-square test was used for comparison of rate and frequency. A p-value <0.05 was considered statistically significant.

RESULTS

Group A included eight cases of L3/4, 28 cases of L4/5, and 30 cases of L5/S1 herniation, with a course of three days to 10 years and a mean course of 95.25±12.53 days. Group B included six cases of L3/4, 27 cases of L4/5, and 29 cases of L5/S1 herniation. The course of the disease varied from five days to 9.8 years, with a mean course of 97.56±13.24 days.

The average cost of treatment was lower in Group A than in Group B, with a statistically significant difference ($p<0.001$); the average cost in Groups A and B was respectively 755.67±29.45 yuan and 1,158.08±43.92 yuan. The mean procedure duration was 21.16±1.91 min in Group A and 37.26±2.34 min in Group B; the duration was shorter in Group A

TABLE I
Comparison of the operation time and treatment cost between the two groups

	Operation time (min)	Treatment cost (Yuan)
	Mean±SD	Mean±SD
Group A (n=66)	21.16±1.91*	755.67±29.45#
Group B (n=62)	37.26±2.34	1158.08±43.92
t value	42.82	61.21
p value	<0.001	<0.001

SD: Standard deviation; * p<0.05 Group A *vs.* Group B operation time; # p<0.05 Group A *vs.* Group B treatment cost.

than in Group B, and the difference was statistically significant (p<0.001, Table I).

Following treatment, the scores of lumbago, leg pain, and the straight leg raise test improved significantly in Groups A and B (Table II). When comparing the treatment efficacy, there was no significant difference in the pain, straight leg raise test (Table II), and ODI scores between Groups A and B (p>0.05, Table III).

Regarding data on relevant potential complications, there were no major complications in Groups A and B. Among the 128 injection treatment procedures, there were 25 patients with affected limbs that had a sense of electric shock, which was considered nerve root irritation. Twenty-two patients had blood in the syringe, which was considered to have occurred due to blood vessel puncture. Twenty patients had a temporary decrease in key muscle strength due to the anesthetic effect, consistent with the innervated area of the injection site; however, the general duration was only 2 to 4 h. Nineteen patients had a slight increase in lumbar pain after injection but not more than 12 h in general. Four patients had

TABLE II
Comparison of the VAS pain score and straight leg raise test degree between the two groups before and after therapy

	Group A (n=66)	Group B (n=62)	Group A (n=66)	Group B (n=62)	Group A (n=66)	Group B (n=62)
	Lumbago		Leg pain		SLRTD (°)	
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Pre-therapy	4.23±1.24*	4.16±1.21*	6.15±1.43**	6.25±1.35**	35.62±5.73***	36.25±5.64***
Post-therapy Day 1	2.35±0.85#	2.33±0.78#	2.78±1.27†	2.81±1.34†	72.35±8.12‡	73.45±8.55‡
Post-therapy Week 1	1.98±0.76¶	1.94±0.81¶	2.26±1.05§	2.32±1.61§	76.89±9.12◊	77.93±9.36◊
p value	<0.001		<0.001		<0.001	

SD: Standard deviation; * p>0.05; ** p>0.05; *** p>0.05; *** p>0.05 Group A *vs.* Group B before therapy; # p>0.05; † p>0.05; ‡ p>0.05 Group A *vs.* Group B after therapy One day; ¶ p>0.05; § p>0.05; § p>0.05; ◊ p>0.05 Group A *vs.* Group B one week after therapy.

TABLE III
Comparison of ODI scores between the two groups before and after treatment

	Pre-therapy	Post-therapy Day 1	Post-therapy Week 1
	Mean±SD	Mean±SD	Mean±SD
Group A (n=66)	32.36±5.18*	17.47±2.25#	15.47±1.88†
Group B (n=62)	32.28±5.25	17.56±2.46	15.59±1.74
t value	0.913	0.210	0.861
p value	0.363	0.8357	0.391

SD: Standard deviation; * p>0.05 Group A *vs.* Group B before therapy, # p>0.05 Group A *vs.* Group B one day after therapy, † p>0.05 Group A *vs.* Group B one week before therapy.

TABLE IV
Comparison of minor complications between the two groups

	Minor complications											
	Nerve root irritation		Vascular puncture		Decreased muscle strength		Increased lumbago		Hypotension		Digestive/respiratory discomfort	
	n	%	n	%	n	%	n	%	n	%	n	%
Group A (n=66)	13	19.69	12	18.18	11	16.67	10	15.15	2	3.03	1	1.52
Group B (n=62)	12	19.35	10	16.13	9	14.52	9	14.52	2	3.23	1	1.61
χ^2	0.002		0.094		0.112		0.010		0.004		0.002	
p value	0.961		0.758		0.738		0.920		0.949		0.965	

hypotension immediately after injection, and after supportive management with rehydration or oral glucose solution, the pressure returned to normal within a few minutes. Two patients had adverse reactions related to digestion or respiration, such as vomiting, nausea, and dyspnea, all of which were transient and relieved by themselves after observation for no more than 10 min (Table IV).

DISCUSSION

Lumbar disc herniation with radicular pain syndrome is common in orthopedic outpatient consultation; however, given their advanced age and large number of medical comorbidities, some patients are not eligible for surgery. The application of TFLEI can prevent numerous patients from undergoing surgical treatment with satisfactory clinical result; the effectiveness of this method has been confirmed by a large number of studies.[1,8-12] The mechanism of epidural injection in the treatment of lumbar disc herniation has anti-inflammatory action,[13] reducing nerve root edema,[14] and it induces analgesia.[15] Selective lumbar spinal nerve root block has a better diagnostic value in locating the involved segment of multilevel lumbar disc herniation.[16,17]

Although many studies have reported that there are several adverse reactions to the treatment of lumbar disc herniation by epidural injection of glucocorticoids, common complications include nausea, headache, dizziness, facial flushing, and vasovagal attack.[18] Some rare major complications reported include paralysis, cerebrospinal fluid leakage, spinal cord infarction, cerebral ischemia, spinal cord myoclonus, and epidural hematoma inhibition of the hypothalamic-pituitary-adrenocortical axis,[2,18-21] and most of the adverse reactions can be attributed either to direct damage of blood vessels or the injection of drugs into the blood vessels. It is suggested that the exact location of the puncture needle, the use of nongranular glucocorticoids, such as betamethasone, real-time fluoroscopy, digital subtraction angiography, and the operator's familiarity with the contrast pattern of fluoroscopy should be used as much as possible to reduce the occurrence of these risks.[22]

In this study, the syringe could draw back the blood of 12 patients in Group A and 10 patients in Group B during the operation. The needle could be properly withdrawn up to 2 to 3 mm. After the drawn-out needle showed the absence of blood, the drug solution could be injected continuously. No complications related to the injection of drug into the blood vessels occurred.

Although puncture under the real-time guidance of CT, C-arm X-ray fluoroscopy, and color ultrasound was a conventional method used in the past, we found some limitations in clinical practice using these guidance methods. For example, our research team belongs to a medical college-affiliated hospital, where more than 100 patients per day require CT examination in our radiology department. In addition to this, the same CT machines and the same rooms are also used for patients who need to carry out CT-guided punctures, as well as ordinary examinations. Moreover, a complete CT-guided TFLEI procedure takes approximately 30 to 40 min, within which conventional CT scans of five to eight ordinary patients can be completed. Therefore, the operation under CT guidance will certainly delay other patients who need to be examined. Additionally, it takes more time to disinfect a room with an air disinfector as the lumbar puncture needs a relatively sterile environment. In this study, Group A patients were treated by planning with MRI. The mean time to complete a patient's treatment was 21.16±1.91 min, which was significantly lower than that of Group B patients (37.26±2.34 min) under the guidance of X-ray fluoroscopy in the operating room. The total cost of

treatment in Group A was lower than that in Group B since there was no need to use contrast medium and real-time guidance.

The puncture method using PACS for MRI planning shortened the TFLEI procedure's time and reduced the treatment costs without exposing the physician or patient to additional radiation compared to X-ray-guided puncture, and there was no significant difference in the short-term clinical outcome or complication rate.[23]

Ultrasound,[24] spectral tissue sensors,[25] and other technologies have been applied in recent years during epidural injection to improve the accuracy of puncture, reduce the incidence of complications, and prevent radiation exposure caused by fluoroscopy. It is emphasized that under the guidance of color ultrasound, the puncture needs to be performed by professional ultrasound interventional physicians. In addition to this, many medical institutions are not equipped with spectral tissue sensors for their use.

Although operating a puncture under the guidance of X-ray fluoroscopy is simple, it causes certain radiation exposure to patients and physicians. Computed tomography may be associated with significantly higher radiation doses compared to conventional fluoroscopy. A study showed that the effective radiation dose to the patient during CT-guided epidural puncture was 1.34±0.05 mSv.[26] Additionally, it has also been shown that ultrasound-guided epidural injections neither improve the success rate nor shorten the duration of the block; rather, they have a higher success rate of first puncture and a lower complication rate.[27] Dietrich et al.[7] found that the mean effective dose of patients with TFLEI under the guidance of fluoroscopy is 0.24±0.22 mSv. The interventional physician's radiation measurements under the guidance of X-ray fluoroscopy are as follows: body, $(0.42\pm0.99)\times10^3$ mSv; wrist, $(1.44\pm2.69)\times10^3$ mSv. Therefore, from October 2016, we initiated the use of PACS module coupled with the hospital information system to plan the puncture path on MRI and locate it according to the bone location mark taken as reference on the spine surface. During these years, more than 60 patients with lumbar disc herniation and radiation neuralgia were treated. As can be seen from the results, all patients were able to successfully complete the surgery and achieved good clinical results compared to the preoperative period ($p<0.001$). The study group (Group A) achieved the same treatment effect as the control group (Group B) in terms of VAS pain score, straight leg raise test degree, and ODI score ($p>0.05$). Although major complications of transforaminal epidural injection have been reported in previous literature, no major complications were found in the current study, which, in our opinion, can be related to our relatively strict inclusion and exclusion criteria.

Following the results of the current study and our experience, we can suggest that this nonreal-time guidance operation technology should be carried out after mastering the operation technology of C-arm X-ray fluoroscopy guidance and after the physician has acquired a certain amount of experience. Additionally, it is not suitable for patients who are too obese (body mass index >30) since the surface anatomy of bone through skin palpation cannot be properly assessed.

The current study is not without limitations. First, this study excluded patients with L5 transverse process hypertrophy, who could have been potential study participants. Second, there is no comparative study on the types and doses of corticosteroids injected in this study, but there have been related studies.[28,29] Additionally, the location of the puncture needle in the Kambin triangle or the subpedicular approach is not clear in this study method.[30] Finally, this study only compares the short-term efficacy of the treatment under the two guidance methods. Therefore, we strongly believe that more studies with long-term clinical assessment, as well as consideration of other approaches, will contribute to consolidating the findings of the current research.

In conclusion, TFLEI based on the MRI planning of PACS demonstrated no significant difference in the clinical efficacy and complication rate in the studied patients compared to puncture under C-arm X-ray fluoroscopy guidance. However, the operation duration could be significantly shortened, which would decrease the risk of additional X-ray radiation for patients and interventional physicians. Moreover, the patients need not be injected with contrast agents; hence, there would be no risk of contrast agent allergy, and the total cost for the patient would be reduced. Generally, PACS-based MRI planning for TFLEI is a safe, accurate, and reliable operation technology compared to the operation technique guided by C-arm X-ray fluoroscopy.

Ethics Committee Approval: This study was reviewed by the Ethics Committee of West China School of Public Health/ West China Fourth Hospital of Sichuan University (no: HXSY-EC-2022033). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Responsible for statistical analysis and the revision of articles: Z.Y.; Responsible for research design and article writing: C.K.; Lecture of the manuscript and literature review: L.W., G.R.K.; Orthopedic care of the patient, collect and sort out relevant original data: C.D., G.T., H.W., X.P.

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