Percutaneous transforaminal endoscopic discectomy compared with microendoscopic discectomy for lumbar disc herniation: 1-year results of an ongoing randomized controlled trial

*Zihao Chen, MD, Liangming Zhang, MD, Jianwen Dong, MD, Peigen Xie, MD, Bin Liu, MD, Qiyong Wang, MD, Ruiqiang Chen, MD, Feng Feng, MD, Bu Yang, MD, Tao Shu, MD, Shangfu Li, MD, Yang Yang, MD, Lei He, MD, Mao Pang, MD, and Limin Rong, MD

Department of Spine Surgery, The Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China

OBJECTIVE A prospective randomized controlled study was conducted to clarify whether percutaneous transforaminal endoscopic discectomy (PTED) results in better clinical outcomes and less surgical trauma than microendoscopic discectomy (MED).

METHODS In this single-center, open-label, randomized controlled trial, patients were included if they had persistent signs and symptoms of radiculopathy with corresponding imaging-confirmed lumbar disc herniation. Patients were randomly allocated to the PTED or the MED group by computer-generated randomization codes. The primary outcome was the Oswestry Disability Index (ODI) score 1 year after surgery. Secondary outcomes included scores of the Medical Outcomes Study 36-Item Short-Form Health Survey bodily pain and physical function scales, EuroQol Group's EQ-5D, and the visual analog scales for back pain and leg pain. Data including duration of operation, in-bed time, length of hospital stay, surgical cost and total hospital cost, complications, and reoperations were recorded.

RESULTS A total of 153 participants were randomly assigned to 2 treatment groups (PTED vs MED), and 89.5% (137 patients) completed 1 year of follow-up. Primary and secondary outcomes did not differ significantly between the treatment groups at each prespecified follow-up point ($p > 0.05$). For PTED, there was less postoperative improvement in ODI score in the median herniation subgroup at 1 week ($p = 0.027$), 3 months ($p = 0.013$), 6 months ($p = 0.027$), and 1 year ($p = 0.028$) compared with the paramedian subgroup. For MED, there was significantly less improvement in ODI score at 3 months ($p = 0.008$), 6 months ($p = 0.028$), and 1 year ($p = 0.028$) in the far-lateral herniation subgroup compared with the paramedian subgroup. The total complication rate over the course of 1 year was 13.75% in the PTED group and 16.44% in the MED group ($p = 0.642$). Five patients (6.25%) in the PTED group and 3 patients (4.11%) in the MED group suffered from residue/recurrence of herniation, for which reoperation was required.

CONCLUSIONS Over the 1-year follow-up period, PTED did not show superior clinical outcomes and did not seem to be a safer procedure for patients with lumbar disc herniation compared with MED. PTED had inferior results for median disc herniation, whereas MED did not seem to be the best treatment option for far-lateral disc herniation.

Clinical trial registration no.: NCT01997086 (clinicaltrials.gov).

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KEY WORDS percutaneous transforaminal endoscopic discectomy; microendoscopic discectomy; lumbar disc herniation; minimally invasive spine surgery; randomized controlled trial; lumbar

ABBREVIATIONS LDH = lumbar disc herniation; LSD = least-significant difference; MD = microdiscectomy; MED = microendoscopic discectomy; MISS = minimally invasive spine surgery; ODI = Oswestry Disability Index; PTED = percutaneous transforaminal endoscopic discectomy; SF36-BP = 36-Item Short-Form Health Survey bodily pain; SF36-PF = SF36 physical function; TESSYS = Transforaminal Endoscopic Spine System; VAS-back = visual analog scale for back pain; VAS-leg = VAS for leg pain.

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* Drs. Z. Chen and L. Zhang contributed equally to this work and share first authorship.

LUMBAR disc herniation (LDH) is the most common cause of sciatica, and most cases of acute attacks of sciatica can be managed conservatively.¹¹ However, surgical treatment is considered to be more effective in providing rapid pain relief in patients for whom surgery is indicated.^{11,22} This is supported by the results of the Spine Patient Outcomes Research Trial (SPORT), which suggested that patients who underwent surgery had greater reduction in pain, improvement in function, and higher treatment satisfaction than those who were managed nonoperatively.^{27,40,41} Currently, microdiscectomy (MD), in which a microscope is used for better visualization, is considered to be the gold standard surgical procedure for the treatment of LDH.^{22,30}

Over the past few years, minimally invasive spine surgery (MISS) has been improving rapidly due to the development of endoscopes and other related instruments, more experienced surgeons, and patients' demands.³⁴ Percutaneous transforaminal endoscopic discectomy (PTED) and microendoscopic discectomy (MED) are 2 of the most popular MISS techniques that have been used in recent years.

MED uses a microendoscope for visualization, and in this procedure the paraspinal muscles are handled by muscle splitting through dilators.^{30,33} Because of this, there is minimal injury to muscle and soft tissue, which is an advantage of MED compared with MD. A systematic review of 4 randomized controlled trials compared MED and MD and concluded that, if performed skillfully, the former is as effective as the latter. Another benefit of MED is the excellent visualization provided by the microendoscope.³³

On the other hand, discectomy can also be performed under full-endoscope visualization through the posterolateral transforaminal approach. This technique, PTED, is thought to be more minimally invasive because the posterior column structures are preserved.^{31,34,47} A systematic review and meta-analysis have suggested that the clinical outcomes are comparable between PTED and MD.^{10,21} In addition, patients who undergo PTED are likely to have smaller surgical scars, shorter hospital stays, and an earlier return to daily activities.¹⁰

To our knowledge, there is no class I evidence suggesting that PTED is superior to MED in regard to pain relief and functional improvement in LDH cases. Therefore, a randomized controlled trial comparing these 2 common MISS techniques is warranted. We aimed to clarify whether PTED yields better clinical outcomes and causes less surgical trauma than MED.

Methods

Study Design and Inclusion/Exclusion Criteria

We conducted a single-center, open-label, randomized controlled trial to compare the efficacy and safety of PTED and MED in patients with LDH for whom surgery was warranted. This study was registered with the ClinicalTrials.gov database (<http://clinicaltrials.gov>), and its registration no. is NCT01997086. Between November 2013 and September 2015, patients with a diagnosis of LDH, who were admitted to the spine surgery department

in The Third Affiliated Hospital of Sun Yat-sen University, were assessed for their eligibility to participate in the trial.

Potential participants were patients who had radicular pain and signs of radiculopathy. These signs included evidence of nerve root compression as shown by a positive nerve root tension sign (straight leg-raising test or femoral tension sign) or a corresponding sign of neurological deficit (asymmetrical depressed tendon reflex, impaired sensation in a dermatomal distribution, or weakness in a myotomal distribution). In addition, patients must have had an imaging study (MRI or CT) showing LDH at the level and side corresponding to the patient's radicular signs or symptoms.

Patients were excluded from the trial if they were < 18 years or > 65 years of age; if their conservative treatment was insufficient (6 weeks); if they had cauda equina syndrome or a progressive neurological deficit requiring urgent surgical intervention; if they had LDH in combination with other spinal disorders requiring advanced surgeries (e.g., lumbar stenosis, spondylolisthesis, deformity, fracture, infection, tumor, and so on); if there were ≥ 2 responsible levels; if they had high-grade migrated disc herniation; if they had previous spinal surgery; if they were pregnant; or if they had other comorbid conditions contraindicating surgery.

Patients who met inclusion criteria were selected and asked to consider participating in this clinical trial. Then, patients who agreed to participate in the trial were randomly assigned to the PTED group or the MED group using computer-generated randomization codes with a block size of 5. To ensure the concealment of intervention assignment, an opaque, sealed envelope that contained randomization codes was opened 1 day prior to the surgery by a blinded clinical research assistant. The surgical procedure could not be masked for patients and surgeons; however, it was blinded to data collectors and data analysts.

The clinical research ethics committee at The Third Affiliated Hospital of Sun Yat-sen University approved the clinical trial, and all participants provided written informed consent.

Surgical Interventions

All of the surgeons in this trial were highly experienced. They were qualified in MISS, with > 3 years of experience and 200 MISS procedures performed. They had also received formal training in PTED and MED and strictly adhered to the standard operating procedure.

In the PTED group, patients were operated on with the Transforaminal Endoscopic Spine System (TESSYS) while under local anesthesia. Patients were placed lateral, lying on the unaffected side with their legs flexed. The entrance point was located superior to the iliac crest, approximately 10–14 cm from the midline. Next, after local infiltration of lidocaine, an 18-gauge needle was introduced from the entrance point to the lateral foramen under the guidance of C-arm fluoroscopy. A 22-gauge needle was then inserted through the 18-gauge needle into the herniated disc, followed by the injection of contrast medium (9 ml of iohexol with 1 ml of methylene blue) into the disc.

FIG. 1. Flow diagram showing patient enrollment, treatment assignment, and follow-up.

In the next step, the 22-gauge needle was removed and a guidewire was inserted via the 18-gauge needle. Then, an 8-mm incision was made in the region of the guidewire. Next, dilators were inserted consecutively and reamers were used to dilate the bony foramen appropriately. The working cannula, through which the endoscope with a working channel and irrigation systems was inserted, was advanced along the dilator. Then the blue-stained degenerated disc material was identified and removed by the endoscopic forceps until sufficient decompression of the nerve root was achieved. The working cannula and the en-

doscope were removed following proper homeostasis and lastly, the skin was sutured.

All patients in the MED group were operated on while under combined spinal-epidural anesthesia. They were laid prone and, using a cushion, the abdomen was left free. The operating level was confirmed using fluoroscopy. A 2-cm incision was made approximately 1.5–2.0 cm from the midline. A K-wire was then introduced toward the junction of the inferior part of the lamina and the medial part of the facet joint, which was confirmed by fluoroscopy. Next, a series of dilators was introduced consecutively through the

TABLE 1. Baseline clinical characteristics and demographic data of 153 patients

Variable	PTED	MED	p Value
No. of patients	80	73	
Age, yrs	40.2 ± 11.4	40.7 ± 11.1	0.589
Male sex	52 (65.0)	37 (50.7)	0.073
BMI, kg/m ²	23.4 ± 2.9	23.6 ± 3.6	0.704
Heavy labor	17 (21.3)	11 (15.1)	0.323
Sedentariness*	16 (20.0)	11 (15.1)	0.424
Smoking history	21 (26.3)	18 (24.7)	0.821
Positive nerve root tension test	60 (75.0)	51 (69.9)	0.477
Decreased sensation	26 (32.5)	28 (38.4)	0.449
Myotomal weakness	25 (31.3)	16 (21.9)	0.193
Depressed reflex	23 (28.7)	26 (35.6)	0.363
Type of disc herniation			0.149
Median	15 (18.8)	19 (26.0)	
Paramedian	56 (70.0)	48 (65.8)	
Far lateral	9 (11.3)	6 (8.2)	
Surgical segment			0.504
L3–4 or higher	4 (5.0)	0	
L4–5	35 (43.8)	35 (47.9)	
L5–S1	41 (51.2)	38 (52.1)	
ODI score	44.2 ± 21.8	43.8 ± 20.4	0.908
SF36-PF score	52.6 ± 25.5	52.1 ± 26.5	0.917
SF36-BP score	45.5 ± 19.0	49.0 ± 20.8	0.280
EQ-5D score	0.53 ± 0.25	0.52 ± 0.25	0.819
VAS-back score	3.9 ± 2.6	3.7 ± 2.6	0.683
VAS-leg score	5.5 ± 1.9	5.5 ± 2.2	0.862

BMI = body mass index.

Values expressed as the mean ± SD or number (%) of patients.

* Sedentariness defined as sitting > 8 hours per day.

K-wire. After an 18-mm tubular retractor was placed over the final dilator, the articulated arm was attached to the bed and the retractor was held in its position. The microendoscope was then attached to the tubular retractor.

Next, a disc forceps was used to remove soft tissues. Then, appropriate laminotomy (as well as resection of part of the facet joint for far-lateral herniation) and partial excision of the ligamentum flavum were performed. After access to the spinal canal was obtained, the dural sac and traversing nerve root were identified and retracted medially to expose the herniated disc. In the following step, the extruded and loose disc material was removed with the disc forceps until the nerve root was decompressed adequately. After meticulous hemostasis, the tubular retractor was removed and a drainage tube was placed outside the lamina. Finally, the muscular fascia, subcutaneous tissue, and skin were sutured.

Outcome Assessment

Participants were assessed preoperatively and 1 week, 1 month, 3 months, 6 months, and 1 year postoperatively. A research assistant collected baseline and follow-up data by administering questionnaires via telephone, email, mail, or in person.

TABLE 2. Primary and secondary outcomes of treatment with PTED versus MED

Variable	PTED	MED	p Value
ODI score			
Baseline	44.2 ± 21.8	43.8 ± 20.4	0.908
1 wk	29.7 ± 18.9*	31.0 ± 18.8*	0.673
1 mo	18.9 ± 17.9*	19.6 ± 14.8*	0.807
3 mos	11.3 ± 13.6*	9.2 ± 9.1*	0.302
6 mos	6.0 ± 8.4*	5.1 ± 6.7*	0.487
1 yr	3.9 ± 7.6*	3.2 ± 5.7*	0.533
SF36-PF score			
Baseline	52.6 ± 25.5	52.1 ± 26.5	0.917
1 wk	63.5 ± 24.6*	62.0 ± 26.6*	0.726
1 mo	78.7 ± 21.9*	81.5 ± 8.2*	0.414
3 mos	89.5 ± 15.4*	92.7 ± 8.2*	0.138
6 mos	96.3 ± 4.6*	96.2 ± 5.1*	0.927
1 yr	97.2 ± 6.4*	97.9 ± 3.6*	0.488
SF36-BP score			
Baseline	45.5 ± 19.0	49.0 ± 20.8	0.280
1 wk	67.5 ± 21.1*	66.1 ± 19.7*	0.666
1 mo	78.5 ± 18.2*	80.5 ± 15.9*	0.486
3 mos	86.6 ± 16.8*	87.6 ± 14.1*	0.720
6 mos	90.4 ± 17.0*	91.6 ± 9.6*	0.595
1 yr	91.0 ± 21.6*	95.6 ± 6.7*	0.156
EQ-5D score			
Baseline	0.53 ± 0.25	0.52 ± 0.25	0.819
1 wk	0.74 ± 0.22*	0.69 ± 0.23*	0.166
1 mo	0.82 ± 0.23*	0.83 ± 0.17*	0.767
3 mos	0.91 ± 0.16*	0.91 ± 0.12*	0.851
6 mos	0.94 ± 0.12*	0.95 ± 0.08*	0.631
1 yr	0.96 ± 0.11*	0.97 ± 0.07*	0.562
VAS-back score			
Baseline	3.9 ± 2.6	3.7 ± 2.6	0.683
1 wk	1.4 ± 1.8*	1.6 ± 1.8*	0.488
1 mo	1.1 ± 1.5*	1.1 ± 1.6*	0.859
3 mos	0.9 ± 1.5*	0.8 ± 1.3*	0.617
6 mos	0.6 ± 1.2*	0.5 ± 0.8*	0.589
1 yr	0.5 ± 1.3*	0.4 ± 0.8*	0.483
VAS-leg score			
Baseline	5.5 ± 1.9	5.5 ± 2.2	0.862
At 1 wk	1.8 ± 2.3*	2.1 ± 2.2*	0.555
1 mo	1.5 ± 1.9*	1.3 ± 1.7*	0.497
3 mos	1.1 ± 1.5*	1.0 ± 1.7*	0.962
6 mos	0.6 ± 1.3*	0.6 ± 1.2*	0.919
1 yr	0.6 ± 1.4*	0.4 ± 1.0*	0.525

Values expressed as the mean ± SD.

* Significantly different than baseline data.

The primary outcome was the Oswestry Disability Index (ODI) score (ranging from 0 to 100, with higher scores indicating more disability related to pain) 1 year after surgery. The ODI is one of the condition-specific outcome measures that has been used widely to evaluate the degree

of disability in patients with spinal disorders.^{6,7} Secondary outcomes included scores of the Medical Outcomes Study 36-Item Short-Form Health Survey bodily pain (SF36-BP) and physical function (SF36-PF) scales (scores ranging from 0 to 100, with higher scores indicating better outcomes),^{6,39} EQ-5D (ranging from -0.149 to 1, with a higher score indicating better quality of life),^{4,37} and visual analog scales (scores ranging from 0 to 10, with higher scores indicating more severe pain) for back pain (VAS-back) and leg pain (VAS-leg).^{6,17} Data for factors including duration of operation, in-bed time, length of hospital stay, surgical cost and total hospital cost, complications, and reoperations were recorded.

In each case, LDH was classified by median, paramedian, and far-lateral (foraminal or extraforaminal) types, depending on the location of herniation in different cases.⁴⁴

Statistical Analysis

We calculated that a sample size of 250 participants (125 patients in each group) would be required for the trial to have 90% power to detect a 10-point difference on the ODI (the minimum clinically important difference for the ODI was 10 points)^{6,12,29} between treatment groups, at a 2-sided significance level of 0.05, with the assumption of a 20% dropout rate. As of September 2015, 153 participants were included in this trial and 1-year follow-up was expected to be complete in September 2016. Our calculations showed that with this sample size, the study would still have a power > 80% to detect the minimum clinically important difference (a 10-point difference on the ODI) at a significance level of 0.05. Hence, we conducted the statistical analysis of data in these 153 participants to evaluate the preliminary results of the trial.

Differences between groups were compared using the Student t-test, whereas differences between baseline and each follow-up point within each group were assessed using a paired t-test. Similarly, the differences in complication and reoperation rates were analyzed using the chi-square test. Analysis of variance was used to conduct the stratified analysis. Differences between 2 of the 3 stratifications were further assessed using the least-significant difference (LSD) test. *p* values were 2-sided, and *p* < 0.05 indicated a statistical difference. SPSS (version 17.0) software was used for all analyses.

Results

Between November 1, 2013, and September 30, 2015, we screened 268 patients for their eligibility to participate. During this period, a total of 153 patients were determined eligible for the trial, and they were randomly assigned to 1 of the 2 treatment groups. Figure 1 shows the eligibility, randomization, and follow-up of patients in the trial. Of the total number of participants, 80 were randomly assigned to the PTED group and the remaining 73 to the MED group. There were no crossovers from either randomized treatment group. The dropout rates were equivalent between treatment groups at each follow-up point, and we did not find any evidence of differential dropout according to assigned treatment. A total of 137 patients (89.5%) completed 1-year follow-up. There were no significant differences

FIG. 2. Scores on the primary outcome measure of ODI. The graph shows that there was no significant difference in ODI score between the groups at each follow-up point. The ODI scores decreased significantly following surgery in both groups and continued to decline throughout the follow-up period. Figure is available in color online only.

between the groups in any of the baseline characteristics, including primary and secondary outcomes (Table 1). The mean age of participants was 43.4 years, and male participants accounted for 58.2% of the total. The most common type of disc herniation was paramedian, which accounted for 68% of cases. L4–5 and L5–S1 were the most commonly encountered surgical segments (> 95%).

In terms of primary outcome, the treatment groups did not differ significantly at each postoperative follow-up point (more detailed results are shown in Table 2). The mean ($\pm$ SD) ODI score in the PTED group was 3.9 ± 7.6 at the 1-year follow-up point compared with 3.2 ± 5.7 in the MED group (*p* = 0.533). The ODI scores decreased significantly following surgery in both groups and continued to decline throughout the follow-up period (*p* < 0.05; Fig. 2).

Similarly, no significant difference was observed in any of the secondary outcomes at each follow-up point, including the SF36-PF, SF36-BP, EQ-5D, VAS-back, and VAS-leg scores (Table 2, Fig. 3). The results showed that the differences between baseline and each follow-up point in all primary and secondary outcomes were statistically significant.

Stratified analysis of primary outcome was conducted according to the type of disc herniation and surgical segment. Because the preoperative ODI scores were inconsistent in each stratification, the change in values from baseline in ODI score was used for comparison. We found that in the PTED group, the improvement in ODI score was significantly less in the median herniation type than in the paramedian type at 1 week (*p* = 0.027), 3 months (*p* = 0.013), 6 months (*p* = 0.027), and 1 year (*p* = 0.028) postoperatively (Table 3).

On the other hand, in the MED group, the far-lateral type had significantly less improvement in ODI score compared with the paramedian type at 3 months (*p* = 0.008), 6 months (*p* = 0.028), and 1 year (*p* = 0.028) postoperatively. Regarding central disc herniation, there was less improvement in ODI score, without significant difference, in the PTED group compared with the MED group at each follow-up point. For far-lateral disc herniation, the improve-

FIG. 3. Scores on secondary outcome measures of SF36-PF (A), SF36-BP (B), VAS-back (C), VAS-leg (D), and EQ-5D (E). The graphs show that there was no significant difference between treatment groups in any of the secondary outcomes at each follow-up point. The differences in all secondary outcomes between baseline and each follow-up point were statistically significant in both treatment groups. Figure is available in color online only.

ment in ODI score was much less (without significant difference) in the MED group. Our stratified analysis showed that in both the PTED and MED groups, the changes in ODI score were not significantly different for each surgical segment at any of the follow-up points ($p > 0.05$).

The mean ($\pm$ SD) duration of surgery in the PTED group (97.2 ± 45.8 minutes) was similar to that in the MED group (91.7 ± 42.5 minutes). However, postoperative in-bed time (32.7 ± 27.3 hours) and length of hospital stay (8.1 ± 4.2 days) in the PTED group were significantly shorter than those in the MED group (70.6 ± 38.9 hours and 11.2 ± 3.8 days, respectively). Furthermore, surgical and total hospital costs were significantly higher in the PTED group

(¥14,984.5 $\pm$ ¥2393.2 and ¥21,592.1 $\pm$ ¥5294.4, respectively) compared with the MED group (¥5093.4 $\pm$ ¥2851.3 and ¥13,090.8 $\pm$ ¥4006.4, respectively).

The total complication rate over the course of 1 year was 13.75% in the PTED group and 16.44% in the MED group ($p = 0.642$; Table 4). Both treatment groups had a dural tear in 1 patient each (1.25% in the PTED group and 1.36% in the MED group). Whereas neural injury occurred in 3 patients (3.75%) in the PTED group, there was no such injury in the MED group. Moreover, there were new occurrences of transient dysesthesia in 2 patients (2.50%) in the PTED group and 7 patients (9.59%) in the MED group without significant difference. One patient (1.36%) in the MED

TABLE 3. Changes in ODI score from baseline according to type of disc herniation

Outcome	Change in ODI Score From Baseline			p Value
	Median Type	Paramedian Type	Far-Lateral Type	
PTED group				
1 wk	-1.5 ± 26.1*	17.3 ± 27.6	18.7 ± 24.2	0.075
1 mo	14.5 ± 23.5	27.1 ± 26.8	27.7 ± 22.5	0.273
3 mos	17.6 ± 28.6*	36.7 ± 23.6	32.1 ± 22.5	0.045
6 mos	25.1 ± 20.7*	40.8 ± 22.9	39.0 ± 21.9	0.084
1 yr	26.6 ± 20.5*	42.0 ± 22.8	42.6 ± 22.6	0.080
MED group				
1 wk	10.5 ± 20.6	15.9 ± 29.6	2.4 ± 25.9	0.505
1 mo	17.8 ± 25.6	29.2 ± 24.8	18.9 ± 20.5	0.217
3 mos	29.0 ± 19.1	40.2 ± 22.5	12.8 ± 14.0*	0.014
6 mos	32.5 ± 20.4	43.6 ± 22.1	18.5 ± 11.5*	0.033
1 yr	34.5 ± 20.5	43.4 ± 22.0	20.5 ± 12.0*	0.034

Values expressed as the mean ± SD.

* Significantly different than paramedian type according to the LSD test.

group had poor wound healing postoperatively. Residue/recurrence of herniation (Figs. 4–7 show 4 cases), which required reoperation, occurred in 5 patients (6.25%) in the PTED group and 3 patients (4.11%) in the MED group. The reoperation rate was comparable between the treatment groups (PTED 6.25% and MED 4.11%; $p = 0.818$).

Discussion

We believe that this is the first randomized controlled trial that aimed to clarify the differences between the surgical procedures PTED and MED. The 1-year follow-up results of this ongoing trial, which included 153 participants, demonstrated that both procedures were equally safe to use and their effectiveness was also comparable to LDH. However, the results did not show that PTED has superior benefits compared with MED with regard to functional disability, back pain, leg pain, and quality of life at all follow-up points, including up to 1 year after the procedure. The results of this trial support the conclusion of a previous comparative retrospective study by Sinkemani et al.,³² which concluded that PTED and MED can achieve equivalent and satisfactory outcomes.

Our results demonstrated that patients with LDH who underwent PTED obtained satisfactory outcomes. It is commonly believed that, in certain aspects, PTED has equal or even better clinical results than open discectomy in selected patients.^{9,10,28,46} The early PTED technique, such as the Yeung Endoscopic Spine System (YESS) described by various authors,^{43,46,47} was indicated for foraminal or extraforaminal disc herniation, as well as for intracanal herniation. Nevertheless, large central and extraligamentous herniations were contraindicated for this procedure. The TESSYS technique advocated by Hoogland and others^{15,31} made it possible to operate inside the spinal canal by enlarging the intervertebral foramen through foraminoplasty.

Because of the improvements in techniques, PTED was thought to be suitable for almost all types of herniation,

TABLE 4. Complication and reoperation rates in PTED compared with MED

Variable	PTED	MED	p Value
No. of patients	80	73	
Complication			
Dural tear	1 (1.25)	1 (1.36)	0.948
Neural injury	3 (3.75)	0	0.247
Transient dysesthesia	2 (2.50)	7 (9.59)	0.129
Poor wound healing	0	1 (1.36)	0.477
Residue/recurrence	5 (6.25)	3 (4.11)	0.818
Total no. of complications	11 (13.75)	12 (16.44)	0.642
Reoperation	5 (6.25)	3 (4.11)	0.818

Values expressed as number (%) of patients.

including migrated disc herniations.^{10,15,16,19,20,31,42,43,45} Yet, according to the results of our trial, PTED had inferior clinical outcomes for the treatment of the median type of herniation. Although we were confident that it was possible to easily locate the working cannula exactly at the area of central herniation, the PTED was comparatively less useful in this type of herniation. One reason was that because of restriction by the narrow neural foramen and small working cannula, it was not easy to completely remove large central disc herniations.^{1,46}

FIG. 4. Case 40. MR images obtained in a 22-year-old man with radiculopathy on the right side. Preoperative MR images show an L4–5 disc herniation (**A and B**). Despite undergoing PTED, the patient did not have relief of radicular pain and numbness. Postoperative MR images show incomplete decompression and residual herniation (**C and D**). MED was chosen as the revision procedure, and there was gradual relief of symptoms after the second surgery.

FIG. 5. Case 95. MR images obtained in a 50-year-old woman with radiculopathy on the right side. Preoperative MR images show an L4–5 disc herniation (**A and B**). Radicular pain was relieved after PTED surgery. However, 3 months postoperatively, the patient had recurrence of pain after a sudden lumbar sprain. Subsequently obtained MR images show a large recurrent L4–5 disc herniation (**C and D**), which required a second PTED surgery. Ultimately, the radicular pain was relieved.

FIG. 6. Case 86. MR images obtained in a 42-year-old woman with radiculopathy on the right side. Preoperative MR images show an L5–S1 disc herniation (**A and B**). This patient underwent MED and experienced relief of radicular pain after surgery. However, 2 months later, there was recurrence of pain due to stooping and lifting of heavy objects. MR images show a recurrent migrated disc herniation at L5–S1 (**C and D**), which required PTED surgery. Thereafter, the patient had relief of symptoms.

Another reason was that the potential for postoperative improvement was smaller because the preoperative ODI scores were much lower in the median subgroup (35.1 ± 18.5) than in the other subgroups (paramedian 46.1 ± 22.2 and far lateral 47.4 ± 22.1). On the other hand, MED could easily handle central disc herniation by allowing medial retraction of the dural sac to clearly expose the herniation. On the basis of the statistical results and our clinical experience, we believe that MED may be more suitable for treatment of central disc herniation.

Our results suggest that patients who underwent MED also had satisfactory outcomes. As an effective MISS, MED (using a broad surgical scope similar to that in open discectomy) is widely preferred for the treatment of LDH.^{3,13,30,38} Treatment of far-lateral disc herniation is technically demanding, and MED was thought to be an effective technique that offered good clinical results for this special type of herniation without sacrificing stability.^{8,25,48}

However, our results showed significantly inferior clinical outcomes for far-lateral disc herniation in the MED group, in which the familiar midline interlaminar approach was used. To obtain proper exposure of the herniation, a significant amount of bony resection (including the facet joint) was typically required. Because we were concerned about postoperative segment instability, a wide and clear surgical field could not be achieved due to insufficient bony resection, and this may have led to inferior outcomes.^{2,8,48}

Moreover, direct compression and irritation of the dor-

sal root ganglion from far-lateral herniation results in poor neural recovery, which may be another factor leading to an inferior outcome.^{2,8,49} In contrast, PTED can remove foraminal and extraforaminal herniated disc material directly without compromising the posterior column structures. Hence, it is thought to be a more optimal choice for the treatment of far-lateral disc herniation.^{24,49}

Previously, PTED was considered difficult to perform at the L5–S1 level due to anatomical limitations such as a high iliac crest or narrow foramen. However, because of advances in this technique, a lesion at the L5–S1 level is no longer a relative contraindication for PTED. Our results showed that the clinical outcomes of PTED performed at the L5–S1 level were comparable with those at the L4–5 level, a finding that may be contrary to the expectations of some surgeons. The TESSYS technique provides transforaminal access to the L5–S1 level, even in cases involving a high iliac crest.^{5,15,23}

The total complication, reoperation, and residue/recurrence rates in our study were comparable to those in previous studies.^{1,14,16,18,31,35,36,38,46} As a more minimally invasive spine surgery, PTED did not show results superior to MED with regard to complications. It is noteworthy that in the MED group, the rate of new postoperative transient dysesthesia was approximately 10%. This complication resulted from medial retraction of the dural sac and the traversing nerve root during surgery. Therefore, the surgical proce-

FIG. 7. Case 143. MR images obtained in a 53-year-old woman with radiculopathy on the right side. Preoperative MR images show an L5–S1 disc herniation (**A and B**). Radicular pain and numbness were relieved after MED. Two weeks later, the patient had to undergo reoperation with MED because of recurrence of the pain and numbness. MR images show a recurrent herniation at L5–S1 (**C and D**).

cedure should be performed gently to avoid such complications.

Other technical tips have been suggested to avoid complications, for instance, making the initial landing as close to the target herniation as possible.¹ In addition, the end point of the procedure should be free mobilization of neural tissues. Risk factors that lead to reoperation after discectomy include old age, high-grade lumbar degeneration, Modic changes, and adjacent segment degeneration.^{14,44} For such patients, the treatment modality should be carefully considered.

Recovery following the procedure differed between the treatment groups. Patients in the PTED group recovered comparatively faster than those in the MED group (the postoperative in-bed time and length of hospital stay were shorter in the PTED group). This allowed patients to have early ambulation, rehabilitation, and a quicker return to daily life activities.²⁶ Nevertheless, PTED was associated with significantly higher surgical and hospital costs because of the expensive endoscopic instruments.

Our study had certain limitations. One was the relatively short duration of follow-up; hence, the long-term results of these 2 procedures are unclear. However, this should not be an issue because this is an ongoing clinical trial, which will include more participants and will yield long-term follow-up. Another limitation was that the treatment could not be masked for patients. As a result, knowledge of their treatment assignment may have had an effect on patients' responses to the outcome assessments. However, we

tried to reduce potential bias by blinding the treatment assignment to data collectors and data analyzers. Last, both of the treatment groups had relatively small sample sizes for the subgroup of far-lateral herniation, which may have weakened the conclusion made for this type of herniation.

Conclusions

Over the 1-year follow-up period, our ongoing randomized controlled trial clarified that PTED did not have superior clinical outcomes and did not seem to be a safer procedure for patients with LDH compared with MED. Our study also showed that PTED had inferior results for median disc herniation, whereas MED did not seem to be the best treatment option for far-lateral disc herniation. Furthermore, the PTED group had the advantages of shorter postoperative in-bed time and length of hospital stay; however, the surgical and hospital costs were on the higher side. This trial is ongoing to obtain results with a larger sample size and to achieve long-term follow-up.

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Rong, Z Chen, Zhang, Dong, Xie, Liu,

Wang, R Chen. Acquisition of data: Z Chen, Zhang, Dong, Xie, Liu, Wang, R Chen, Feng, B Yang, Shu, Li. Analysis and interpretation of data: Z Chen, Zhang, Dong, Xie, Liu, Wang, R Chen, Feng, B Yang, Shu, Yang, He. Drafting the article: Rong, Z Chen, Zhang, Dong, Xie, Liu. Critically revising the article: Rong, Z Chen, Zhang, Dong, Xie, Liu. Reviewed submitted version of manuscript: Rong, Z Chen, Zhang. Approved the final version of the manuscript on behalf of all authors: Rong. Statistical analysis: Z Chen, Zhang, Wang, R Chen, Feng, Pang. Administrative/technical/material support: Rong. Study supervision: Rong.

Correspondence

Limin Rong: The Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China. drronglimin@21cn.com.