Posterolateral Transforaminal Selective Endoscopic Diskectomy With Thermal Annuloplasty for Discogenic Low Back Pain

A Prospective Observational Study

Jiwei Cheng, MD,∗† Wenjie Zheng, MD,† Hongwei Wang, PhD,† Changqing Li, MD,† Jian Wang, MD,† Zhengfeng Zhang, PhD,† and Yue Zhou, MD†

Study Design. A prospective observational study on 113 patients with 3 years of follow-up.

Objective. To evaluate the clinical results of therapy for discogenic low back pain (DLBP) with posterolateral transforaminal selective endoscopic diskectomy and thermal annuloplasty (PEDTA).

Summary of Background Data. Currently, various minimally invasive techniques are widely used to treat chronic DLBP with variable clinical outcomes. PEDTA is considered to be a novel, minimally invasive technique for treating chronic DLBP, but the evidence supporting this technique is very limited, and there are no studies demonstrating at least 3 years of follow-up.

Methods. One hundred thirteen consecutive patients with DLBP with positive concordant pain in discography underwent PEDTA from March 2008 to March 2010. These patients included 64 males and 49 females with a mean age of 43.7 years (range, 16–75 yr). The visual analogue scale score, Japanese Orthopedic Association score, and Oswestry Disability Index were evaluated before therapy and each year after surgery. The clinical global outcomes were assessed on the basis of modified MacNab criteria at 3 years after surgery.

Results. Ninety-six patients underwent a single-level procedure, and 17 patients underwent multilevel procedures. One hundred one (89.4%) cases were followed up for 3 years. There were no serious complications observed during follow-up. The success rate (excellent and good) was 73.8%. The visual analogue scale score, Japanese Orthopedic Association score and Oswestry Disability Index had significantly improved at each year after surgery (P < 0.01, compared with presurgery). The success rate in patients who underwent a single-level procedure was remarkably higher than that in patients who underwent multilevel procedures (78.2% vs. 50.0%, P = 0.041).

Conclusion. PEDTA presents a safe and effective treatment for carefully selected groups of patients with DLBP. Better clinical results occurred in patients with single-level discogenic pain.

Key words: posterolateral transforaminal, endoscopic diskectomy, discogenic low back pain, thermal annuloplasty

Level of Evidence: 4

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surgical therapy method has not yet been established. Some open surgical treatments, such as open discectomy and spinal fusion and total disk replacement, have shown significant positive effect in DLBP. However, many patients do not opt for these treatments because of the surgical trauma and potential complications. A recent systematic review suggested that total disk replacement should be considered with caution considering the possibility of harm and complications some years later. Currently, various minimally invasive techniques are widely used in this field, such as intradiscal electrothermal annuloplasty (IDET) and percutaneous disk decompression. Unfortunately, the clinical efficacies of these techniques are controversial. Some clinical trials reported marked therapeutic effects with high proportions of excellent and good scores, whereas others showed limited improvement. Specifically, recent randomized trials did not support the effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of DLBP.

Recently, Tsou et al reported on the surgical technique of posterolateral transfemoral selective endoscopic discectomy and thermal annuloplasty (PEDTA) to treat chronic DLBP. The procedure can provide disk decompression and thermal annuloplasty at the same time. In very few studies on the treatment of DLBP using this technique, Tsou et al reported a success rate (excellent or good) of 43.3% in 2004, whereas Ahn and Lee reported a success rate of 70.9%, 6 years later. The authors think that this difference may be related not only to outcome measurement but also to patient selection. Moreover, there are no studies using this technique for DLBP with 3 or more years of follow-up. The authors designed this prospective observational study with 3 years of follow-up to evaluate the clinical results of therapy for DLBP with PEDTA to determine the factors that affect the outcomes.

MATERIALS AND METHODS

This study was approved by the Ethics Committee of the Third Military Medical University. All of the medical records were anonymous, and no patient information was extracted except for research purposes.

Patient Selection

We evaluated 139 consecutive patients in our study from March 2008 to March 2010. The inclusion criteria were as follows: (1) chronic low back pain for more than 6 months with failed conservative treatment (including medication, exercise, and physical therapy); and (2) more than 1 “black disk” without disk space collapse (grades 2–7, modified Pfirrmann criteria) on T2-weighted magnetic resonance imaging (Figure 1A).

The exclusion criteria included the following: (1) typical clinical manifestation of neurological impairment; (2) disk herniation, segmental instability, or spinal stenosis; (3) psychological diseases (all suspected patients had been screened through the psychiatrist); (4) spinal infection, tumor or malformation; and (5) history of lumbar spinal surgery.

Surgical Technique

The surgical procedure was similar to previous reports and involved 3 steps: (1) provocative discography, (2) selective endoscopic discectomy, and (3) endoscopic thermal annuloplasty.

The surgical procedures are performed under local anesthesia in the prone position. The skin entry point is normally 10 to 12 cm from the midline, depending on the size of the patient. After local anesthesia, an 18-gauge spinal trocar punctures the disk. The tip of the needle should reach the annulus fibrosus at the pedicle level on the AP view and “enter” the disk at 20° to the coronal plane. The ideal trajectory is a key point for sufficient intradiscal decompression and thermal annuloplasty for the entire posterior annulus fibrosus. After the trocar is inserted, patients undergo preoperative provocative discography to verify the discogenic pain. A 0.4- to 2-mL mixture of ioxanol (Omnipaque; GE Healthcare, Piscataway, NJ) and methylene blue (1%; Jiangsu Jumpcan Pharmaceutical Ltd., Jiangsu, China) is injected slowly into the nucleus at a ratio of 8:1 (Figure 1B). Patients with positive concordant pain and leakage of contrast media are real patients with DLBP. By strict definition, the patients with DLBP always had at least 1 negative contrast disk nearby positive disk (Figure 1B) and they are surgical candidates. The trocar is withdrawn and replaced by a guide wire. Sequential dilators are then inserted and docked on the facet joint. Next, a 7-mm working channel is inserted into the center of the disk. A rod endoscope (Joimax GmbH, Karlsruhe, Germany) with an eccentric working channel and 2 irrigation channels are inserted to complete the nucleus pulposus removal and thermal annuloplasty (Figure 1C). After intradiscal decompression by pulposus removal (2–4 g), the surgeon adjusts the depth of the outer sheath to observe and address the annular tear and intradiscal inflammatory granuloma with the bipolar radiofrequency probe. Under the ideal trajectory of the puncture, curving the bipolar probe allows the surgeon to perform a thermal annuloplasty over the entire posterior annulus fibrosus to guarantee that all areas suspected of generating pain are treated. Patients are observed for 6 to 12 hours postoperatively before discharge.

Outcome Measures

The authors evaluated patients using a visual analogue scale (0–10) score, Japanese Orthopedic Association (−6 to 29) score, and Oswestry Disability Index (0–100) before and after therapy. The authors used the modified MacNab criteria (Table 1) for clinical global outcome assessment.

Statistical Analysis

Statistical analysis was performed using the SPSS 19.0 software (SPSS Inc, Chicago, IL). The \( \chi^2 \) test was used to analyze the frequency data. For nonparametric pain score values, 95% confidence intervals and independent and paired samples \( t \) tests were used to compare pre- and post-treatment data. Results were considered to be statistically significant if the \( P \) value was less than 0.05.
RESULTS

General Information
Among the 139 patients, 26 patients were excluded because of negative discography; 113 patients with positive concordant pain on discography underwent surgical treatment. The study population included 64 males and 49 females with a mean age of 43.7 years (range, 16–75 yr). The mean duration of pain was 3.5 years (range, 0.5–20 yr). Ninety-six patients underwent single-level procedures, and 17 patients underwent multilevel procedures (Table 2).

Patient Follow-up
Of the total 113 patients undergoing PEDTA, 2 patients experienced a persistent pain within 1 year after the operation, necessitating additional open surgical treatments. Ten patients were lost to follow-up because they could not be contacted by telephone or mail. Thus, the pain score data were reported on 105 (92.9%) patients at 1 year, 103 (91.2%) at 2 years, and 101 (89.4%) at 3 years.

Clinical Results
No severe postoperative complications occurred, including infection and nerve root injury.

The authors used the modified MacNab criteria to assess the overall outcomes at 3 years after operation. The 2 patients who underwent additional operations were rated poor. Thus, the overall outcomes were reported on 103 (91.2%) patients at 3 years. The success rate (excellent and good) was 73.8% (76/103). The improvement rate (excellent, good, and fair) was 87.4% (90/103). The success rate in patients undergoing a single-level procedure was remarkably higher than that in patients who underwent multilevel procedures (78.2% vs. 50.0%, \( P = 0.041 \)). Details are shown in Table 3.

According to the visual analogue scale score, Japanese Orthopedic Association score, and Oswestry Disability Index criteria, postoperative pain and functional disability had significantly improved at 1 year, 2 years, and 3 years after surgery.

### Table 1. Modified MacNab Criteria

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<th>Outcome</th>
<th>Description</th>
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<td>Excellent</td>
<td>No pain and no restriction of activity</td>
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<tr>
<td>Good</td>
<td>Occasional pain, relief of presenting symptoms, able to return to modified work</td>
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<tr>
<td>Fair</td>
<td>Handicapped by intermittent pain of sufficient severity to curtail work or leisure activity but improved functional capacity</td>
</tr>
<tr>
<td>Poor</td>
<td>Unimproved symptoms, insufficient improvement to allow increased activity, or requirement of reoperation at the same level</td>
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in all patients compared with pretreatment ($P < 0.01$). The 3 scores had slightly improved each year (2 yr vs. 1 yr, 3 yr vs. 2 yr) but these comparisons showed no significant difference ($P > 0.05$). Details are shown in Table 4.

Before surgery, the visual analogue scale score, Japanese Orthopedic Association score, and Oswestry Disability Index were not significantly different between patients undergoing single-level procedures and those requiring multilevel procedures. Postoperatively, the 3 scores in patients who underwent single-level procedures were always significantly better than those in patients undergoing multilevel procedures at each follow-up ($P < 0.01$). Details are shown in Table 4, Figure 2A–C.

**DISCUSSION**

In the literature, discogenic pain is described as low back pain with or without leg pain caused by disk degeneration and/or annular rupture.14,16,24–26 The authors used stricter criteria in this study. All patients experienced from chronic low back pain or occasional leg pain without neurological impairment.25,26 The authors performed provocative discography in all cases to confirm discogenic pain.

Provocative discography is very important for diagnosing of DLBP. There are several pain generators for low back pain, such as facet joint, muscle, and fascia. For chronic low back pain, more than one pain generators might be involved simultaneously. Provocative discography is useful for finding the source of pain. Patients with positive provocative discography always experienced pain from degenerative disk instead of facet joint, muscle or fascia. A high-intensity zone was also reported to be correlated with the presence of discogenic pain, but such a zone occurred in asymptomatic control patients as well.27,28 Despite the controversy,29,30 provocative discography is still the “gold standard” for diagnosing DLBP.31–33

Currently, various minimally invasive techniques are used to treat chronic DLBP. Percutaneous endoscopic discectomy accompanied by annuloplasty was first reported to treat chronic DLBP in 2004.18 The procedure can significantly reduce the intradiscal pressure, remove the inflammatory nucleus pulposus, provide thermal annuloplasty effects, and reduce the inflammatory factors involved in pain through...
irritation. The procedure is theoretically superior to IDET and other percutaneous intradiscal procedures. IDET is a blind procedure because it is performed solely based on fluoroscopic guidance. In addition, when performing IDET, it is difficult to remove the interposed tissue within the annular tears or achieve sufficient decompression. In the past 10 years, the success rates of IDET have been reported to range from 53% to 90% in nonrandomized trials, but a recent systematic review reported that the evidence for IDET in randomized controlled trials was fair. Using PEDTA, Ahn and Lee reported symptomatic improvement of 83.5% and a success rate of 70.9% at 2 years after treatment. Our results were similar. At 3 years after treatment, we found the success and improvement rates to be 73.8% and 87.4%, respectively.

Compared with IDET, PEDTA results in slightly more damage to surrounding tissue. First, the 7-mm working channel is more aggressive and increases the risk of herniation. Fortunately, no patients experienced ipsilateral herniation at the same level after PEDTA in this study, which is similar to previous studies. The authors think that this channel provided sufficient decompression in the PEDTA procedure. Second, the risk of complications associated with PEDTA, such as infection or nerve root injury, may theoretically be higher than that after IDET. However, PEDTA is performed under local anesthesia, and patients can provide feedback if they think any nerve root irritation. The use of local anesthesia and a C arm system greatly decreases the risk of nerve root injury. In previous studies, postoperative dysesthesia or flare were occasionally detected, but these effects always improved within 6 months. In this study, no severe complications occurred in the 3 years after surgery.

Only a few clinical trials attribute chronic discogenic pain to single-disk degeneration. It is interesting that reports showing very limited improvement included many more patients with multilevel degeneration than those with single-level degeneration. In the research by Ahn and Lee, 84.8% (67/79) of patients underwent single-level procedures, and the success rate was 70.9%. In the research by Tsou et al, only 41.6% (47/113) of patients underwent single-level procedures, with a success rate of 43.3%. In this study, 85.0% (96/113) of patients underwent single-level procedures, and the success rate was similar to that of the research by Ahn and Lee.

Few clinical reports focus on the difference in postoperative results among patients with single-level degeneration versus multilevel degeneration. Peng et al reported a study using methylene blue in the treatment of DLBP, which obtained better relief in single-level degeneration cases compared with double-level degeneration. In the study by Tsou et al, study on PEDTA for chronic lumbar discogenic pain, the success rate was only slightly better in single-level surgery than in 2-level surgery. In this study, the demographics of patients with single-level procedures were compared with those of patients with multilevel procedures (Table 5). No statistically significant differences in age or sex distribution were found between the 2 groups of patients (P > 0.05). There were also no statistically significant differences in preoperative pain scores between the 2 groups (P > 0.05). However, at 3 years after treatment, better clinical results were found in patients with single-level discogenic pain (Figure 2). More research on pathophysiology and clinical results are needed to explain this outcome. On the basis of this result, the authors suggest that PEDTA may be more suitable for patients with pain at a single level.

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<th>TABLE 5. Baseline Characteristics of the Patients Before Operation</th>
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<td>Characteristics</td>
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</tr>
<tr>
<td>Male</td>
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<tr>
<td>Female</td>
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<tr>
<td>Age (yr)</td>
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<tr>
<td>Duration of pain (yr)</td>
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<tr>
<td>VAS</td>
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<td>JOA</td>
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*P < 0.05; compared with single level.

JOA indicates Japanese Orthopedic Association; ODI, Oswestry Disability Index; VAS, visual analogue scale.

Figure 2. Comparison of the VAS score (A), JOA score (B), and ODI (C) at different time points between single-level and multilevel procedures. JOA indicates Japanese Orthopedic Association; ODI, Oswestry Disability Index; VAS, visual analogue scale; Preop, preoperation.
CONCLUSION

A significant shortcoming of this study is its nonrandom format. The authors carefully told each patient about other treatment methods, such as conservative treatments and spinal fusion, so the patients’ choices did not permit randomization for comparison. Thus, the information for comparison in this study should be considered with caution. However, as a prospective observational study on PEDTA during 3 years, the outcomes for DLBP could provide some insight. On the basis of this study, PEDTA presents a safe and effective treatment for carefully selected patients with DLBP, and better clinical results occurred in patients with pain at a single level. However, large-sample prospective studies with long-term follow-up are needed.

Key Points

- We prospectively observed the effectiveness of PEDTA for 113 consecutive patients with DLBP.
- PEDTA presents a safe and effective treatment for carefully selected patients with DLBP. Pain scores had significantly improved after surgery.
- The success rate in patients who underwent a single-level procedure was remarkably higher than that in patients who underwent multilevel procedures.

References