

Prospective Study

Using Percutaneous Endoscopic Outside-In Technique to Treat Selected Patients with Refractory Discogenic Low Back Pain

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Background: Controversy is not uncommon in the diagnosis of discogenic low back pain (DLBP) and in the identification of the location of the pain source for the symptomatic disc in patients with DLBP. Various techniques, from minimally invasive procedures to fusion surgery, are used to treat chronic DLBP, but the clinical outcomes are variable. Percutaneous endoscopic discectomy by transforaminal or interlaminar approach is considered to be an effective method to treat DLBP, but the evidence is limited; the lack of clear evidence may be associated with patient selection and surgical technique.

Objectives: The purpose of this study is to evaluate the clinical results of percutaneous endoscopic treatment for annular tear in selected patients with DLBP by using the outside-in technique.

Study Design: A prospective study and retrospective observations were performed on 24 consecutive patients with a minimum 2 years of follow-up. This study was approved by the Institutional Review Board (IRB) of Buddhist Dalin Tzu-Chi General Hospital Foundation (IRB number: 10504004) and written informed consent was obtained from all patients.

Setting: This research took place within an interventional pain management and spine practice.

Methods: Twenty-four consecutive patients with single-level DLBP diagnosed by positive high-intensity zone on magnetic resonance imaging, positive provocative discography, and block test underwent a percutaneous endoscopic procedure from January 2014 to December 2015. The transforaminal approach or interlaminar approach was selected according to the location of the annular tear. The torn lesions were visualized directly and treated by puncture and debridement of the inflammatory tissues from the outer annulus fibrosus to the inner nucleus using the outside-in technique. The Visual Analog Scale (VAS) score and Oswestry Disability Index (ODI) score were evaluated before and after surgery. The clinical global outcomes were assessed on the basis of modified MacNab criteria.

Results: These patients included 13 men and 11 women with a mean age of 43.8 years (range, 32-55 yrs). There were 15 lesion levels at L4/L5 and 9 lesion levels at L5/S1. Among them, 15 levels were accessed by transforaminal approach and 9 levels by interlaminar approach. No serious complications were observed during the follow-up periods. All except 2 patients experienced significant symptomatic and functional improvements at the 2-year follow-up with a success rate of 91.7%.

Limitations: Significant limitations include nonrandom format and small sample size. Future research may focus on controlled prospective studies with larger sample sizes and long-term follow-up to examine the validity of this protocol.

Conclusions: The percutaneous endoscopic procedure provides a safe and effective treatment for selected patients with DLBP. The outside-in technique allows the surgeons to visualize and treat the torn or inflammatory lesions directly, and the success rate is high at 2 years follow-up.

Key words: Transforaminal, interlaminar, outside-in technique, endoscopic discectomy, discogenic low back pain

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Discogenic low back pain (DLBP) is a complex medical problem and accounts for 26% to 42% of patients with chronic low back pain attributed to the annular tear of an intervertebral disc (1). The pathologic examination of discs from patients with DLBP shows the formation of vascularized granulation tissue on the outer part of the annulus fibrosus, with extensive innervation in fissures extending into the nucleus pulposus. Magnetic resonance imaging (MRI) may identify a degenerative disc and an annular tear, but it cannot clearly differentiate between a pathologically painful disc and a physiologically aging disc. A high-intensity zone (HIZ) on the T2-weighted MRI is identified in the posterior annulus fibrosus (2). Aprill and Bogduk reported high sensitivity (71%) and specificity (89%) rates for the correlation between HIZs and concordant pain during discography (3). However, there was a controversy regarding the diagnostic value of HIZs because of the high prevalence (25%) of HIZ lesions that occurred in asymptomatic individuals (4). Signal intensity may account for such variabilities. The true HIZ, defined as at least 50% brighter than adjacent cerebrospinal fluid (CSF), was considered to be a reliable marker for DLBP; this suggests that the high-intensity signal, rather than any white spot noted on the MRI, represents an annular tear (5).

Provocative discography, despite the invasiveness and high false positive rates (33-35%), is still the gold standard for diagnosis of DLBP (6). The test is positive when it presents contrast leakage and reproduces patients' concordant pain during the procedure. A study showed that positive provocative discography screening significantly improved surgical outcomes (7). Combined MRI and discography may provide more information for the process of patient selection for surgery. The evidence does not support the stand-alone use of discography for selecting patients for fusion, due to poor results (8). A higher surgical success rate (75%) was noted in symptomatic patients with positive MRI and positive discography versus a lower success rate (50%) in symptomatic patients with negative MRI and negative discography (9).

Fluoroscopically-directed epidural injections with or without steroids under local anesthetics provide short-term improvements in back and lower extremity pain for patients with DLBP (10). A review showed that transforaminal epidural injection with steroid for DLBP results in 68% pain relief at 2 months, 56% at 6 months, and 59% at 12 months (11). Therefore, epidural injection has been used as a block test for diagnosis and as

a predictive test for surgical prognosis for patients with DLBP (12).

Percutaneous endoscopic lumbar discectomy (PELD) through foramen and thermal annuloplasty has been used to treat DLBP, but satisfaction varied widely among different studies; this variation was attributed to both patient selection and surgical technique (13-15). With improvements in the endoscopic instrument and technique, a bony procedure such as foraminoplasty is performed to enlarge working space and the disc can be examined thoroughly. The percutaneous endoscopic interlaminar approach provides another method to access the L5-S1 disc, especially in patients with a high iliac crest (16). Based on the levels of disc and location of the lesion, a transforaminal or interlaminar approach is selected to visualize and manage the lesion comprehensively.

METHODS

The hypothesis of this study is that the pain sources of DLBP are the fissures or vascularized granulation tissues located on the annulus fibrosus and can be relieved by complete excision or debridement of those lesions. Concerning the "outside-in" technique, the endoscope does not enter into the disc initially after foramenoplasty, but stays on the surface of the annulus in order to find the pathological area. This method manages the torn lesion precisely without disturbing the remaining healthy parts. On the contrary, the "inside-out" technique creates a cavity in the disc for viewing and manipulating endoscopic tools intradisally for debridement (17). This study was approved by the Research Ethics Committee of Dalin Tzu Chi General Hospital, Taiwan (IRB ID number: 10504004). All of the medical records were anonymous, and no patient information was extracted except for that required for research purposes.

From January 2014 to December 2015, there were 52 patients who received an MRI due to severe back pain without neurologic symptoms. True HIZs were detected in 42 patients. Among them, 36 patients underwent discography in which contrast medium leakage was detected in 32 patients and concordant pain was induced in 34 patients. Most patients (35 of 36) who received discography experienced some degree of back pain relief after epidural injection of local anesthesia, but the period of relief varied from 3 days to 12 months. Among the 35, 24 patients including 11 women and 13 men met the criteria and underwent percutaneous endoscopic lumbar disc surgery with L4/5

being involved in 15 cases and L5/S1 in 9 cases (Table 1). Their ages ranged from 32 to 55 years (mean, 43.8 years). The inclusion criteria involved: (1) chronic low back pain that failed at least 6 months of conservative treatment (including medication, exercise, and physical therapy), (2) a HIZ on a single-level disc, (3) positive discography of contrast medium leakage and concordant pain, and (4) positive transforaminal epidural injection test (at least short-term palliation of back pain after local epidural infiltration of anesthesia and steroid). The exclusion criteria were: (1) clinical manifestation of neurological deficits; (2) more than one level of involvement; (3) significant disc herniation, segmental instability, or spinal stenosis that resulted in lower extremity pain greater than low back pain; (4) spinal infection, tumor, or fracture; (5) history of lumbar spinal surgery; and (6) coexisting psychological disorders.

Procedure and Surgical Technique

A 2-staged protocol was arranged for those patients with HIZ lesions.

Provocative Discography and Transforaminal Epidural Injection Test

The purpose of the first stage was to make an accurate diagnosis. The procedure involved provocative discography and block test by transforaminal epidural injection. Discography was performed on the level with the HIZ. Under fluoroscopy, a 22-gauge needle was inserted and directed into the central nucleus of each intervertebral disc. One to 3 mL iohexol (Omnipaque; GE Healthcare, Piscataway, NJ) was injected slowly into the nucleus. Concordant pain was defined as provoked low-back pain of similar character, location, and intensity. Annular tear was proved when extravasation of radiopaque contrast from the disc was noted during fluoroscopy. The positive provocative discography was recognized as a real DLBP when both concordant pain and contrast extravasation presented. After discography, the needle was withdrawn a short distance and its tip was placed just outside the annulus fibrosus. A 4-mL mixture of 2 mL xylocaine (0.25%) and 80 mg triamcinolone acetonide was injected. The block test was positive when palliation of back pain occurred.

The second stage of surgery using the outside-in technique was performed for the patients who still suffered from back pain after a previous study showed positive findings on the provocative discogram and block test. This procedure involved 2 steps: (1) percutaneous endoscopic discectomy by either transforaminal

Table 1. Demographic data and outcomes for 24 patients with HIZ lesion

Item	n (%) or Mean ± SD	Range
Gender		
Men	13 (54.2%)	
Level		
L4/5	15 (62.5%)	
L5/S1	9 (37.5%)	
Age (yrs)	43.83 ± 7.58	32-60
VAS		
Pre-op	6.83 ± 0.87	5-8
Post_2 week	3.42 ± 0.81	2-5
Post_1 month	3.37 ± 0.50	3-4
Post_3 month	2.88 ± 0.80	2-5
Post_6 month	2.04 ± 0.81	1-4
Post_12 month	1.62 ± 0.77	1-4
Post_24 month	1.33 ± 0.48	1-2
ODI		
Pre-op	61.58 ± 5.37	51-72
Post_1 month	29.17 ± 5.33	23-48
Post_3 month	22.54 ± 7.33	13-45
Post_6 month	14.91 ± 2.58	11-21
Post_12 month	12.26 ± 1.76	10-16
Post_24 month	11.83 ± 1.50	10-15

VAS: Visual Analog Score, ODI: Oswestry Disability Index; HIZ: High-intensity zone

or interlaminar approach, depending on the level of disc and location of the HIZ; and (2) endoscopic thermal annuloplasty with bipolar coagulator.

Percutaneous Endoscopic Discectomy and Annuloplasty using the Outside-In Technique

Transforaminal Approach

The surgery was performed under local anesthesia in the prone position. The skin entry point and the angle of trajectory were decided by preoperative planning according to the location of the HIZ. After local anesthesia, an 18-gauge spinal trocar punctured the disc and 2 mL of methylene blue was injected to dye the nucleus pulposus and the displaced fragment blue. A guide wire was inserted through the puncture needle. A dilator was then inserted and docked on the facet joint. Next, an 8-mm working channel was inserted and stayed outside the disc. An endoscope (SPINEDOS GmbH, Germany) was then inserted. Foraminoplasty

was applied in some cases to enlarge the working space by removal of some bony tissue using reamer, Kerrison punch, or high-speed burr. The torn annulus could be found by visualization and palpation; it was usually bulging and surrounded by reddish inflammatory tissues or vessels. The lesion surface was soft, thin, and loose, and could be distinguished from an intact annulus by palpation with a probe. The stained blue material representing nucleus pulposus (NP) debris was visible around the torn annulus when the tear was complete or when the outer surface became thinned. When the tear of the annulus was not complete, the stained blue NP was clearly visualized after debridement and removal of the torn annulus. Some debris and embedded disc material were removed with a disc grasp through the hole of the tear. We tried to make the torn lesion as small as possible for prevention of possible subsequent herniation. The thermal annuloplasty was performed after the torn annulus was debrided and the granulation tissues and displaced NP were removed. A bipolar probe was applied to the outer surface of the annulus adjacent to the torn lesion for hemostasis and ablation of inflammatory soft tissues. The annular defect could be altered physically and became smaller in size by thermal effect. Patients were observed for 6 to 12 hours postoperatively before discharge.

Interlaminar Approach

The surgical procedure was performed under general anesthesia. The entry point was targeted on the superolateral corner of the interlaminar window. After a small skin and fascia incision, a dilator was introduced and docked to the lateral edge of the interlaminar window. A working sheath was introduced through the dilator and the final position was checked by the fluoroscope. The surgery was performed after introducing an endoscope (SPINEDOS GmbH, Germany) to incise the ligamentum flavum 3-5 mm and enter the epidural space. A little bony structure, including lamina or facet joints, was resected to create enough working space. With a nerve hook to probe the nerve root shoulder, the neural structures were then retracted medially and protected by rotating the beveled opening inwards to expose the disc clearly (16). The inflammation tissues were debrided, the embedded disc fragments were removed, and thermal annuloplasty was performed. Wound closure was performed after endoscope removal.

Outcome Assessment and Statistical Analysis

Outcomes were evaluated using the VAS (0-100)

scores for back pain and ODI (0-100) scores for functional disability. The modified MacNab criteria were used for clinical global outcome assessment. Patients were asked to complete these questionnaires at preoperation, and 2 weeks, 1 month, 3 months, 6 months, 12 months, and 24 months postoperatively. Preoperative and postoperative scores on the VAS, ODI, and modified MacNab criteria were compared using the Wilcoxon signed-rank test. Results were considered to be statistically significant if the *P* value was less than .05. Statistical analysis was performed using SPSS Version 13.0 (SPSS Inc., Chicago, IL) (Fig.1.).

RESULTS

General Information

Twenty-four patients, including 11 (45.8%) women and 13 (54.2%) men, were enrolled in the present study to manage 15 lesion levels (62.5%) at L4/L5 and 9 lesion levels (37.5%) at L5/S1. Patient age averaged 43.8 years (range, 32-55 years) at surgery. The mean duration of pain was 3.2 years (range, 1.5-20 years). Patients with comorbidities included 4 (16.7%) who smoked and 3 (12.5%) with diabetes. The average skin-to-skin duration was 65.2 minutes (range, 55-80 minutes), and blood loss was minimal. On average, the hospital stay was 1.2 days. No patients encountered major complications such as wound infection or nerve root injury (Table 1).

Patient Follow-up

Of the total 24 patients undergoing percutaneous endoscopic surgery, 2 patients still suffered from back pain one year after operation. One patient underwent fusion surgery under the impression of segmental instability, and the other patient underwent repeated percutaneous endoscopic surgery on the same level. Both of them had improved back pain after additional surgery. VAS scores, ODI scores, and modified MacNab criteria were available for all patients preoperatively and at least 24 months follow-up. VAS and ODI scores significantly improved from preoperative baseline to follow-up assessments at 2 weeks, 1 month, 3 months, 6 months, 12 months, and \geq 24 months postsurgery (*P* < 0.05). Patient demographics and outcome results are summarized in Table 2.

Modified MacNab criteria were used to assess overall outcomes. The success rate (excellent and good) was 87.5% (21 of 24) at one month and 91.7% (22 of 24) at the 3-month, 6-month, and more than one-year

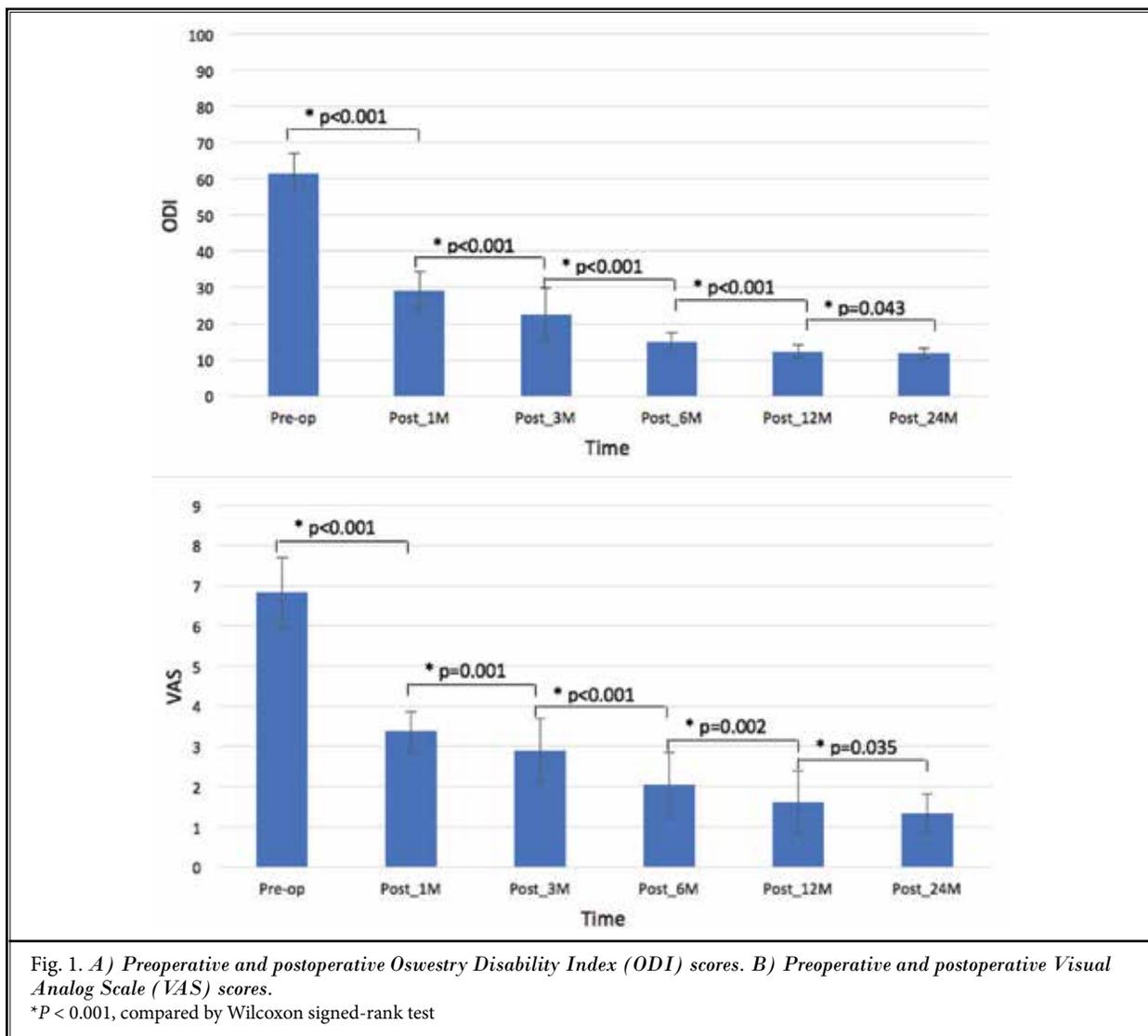


Table 2. Surgical outcomes assessment using modified MacNab criteria

Grade	Post-OP	1 mo	3 mo	1 yr	2 yrs
	n (%)				
Excellent	20 (83.3%)	10 (41.7%)	15 (62.5%)	16 (69.6%)	17 (73.9%)
Good	4 (16.7%)	13 (54.2%)	8 (33.3%)	7 (30.4%)	6 (26.1%)
Fair	0 (0%)	1 (4.2%)	1 (4.2%)	0 (0%)	0 (0%)
Poor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

follow-up assessments (Table 2). The 2 patients who underwent additional operations were rated poor.

Demonstration Case 1

A 51-year-old male laborer suffered from low

back pain for more than 5 years. The T2-weighted MRI showed degeneration of the L4/5 disc and a HIZ in the sagittal and axial images (Fig. 2-1). Provocative discography showed contrast leakage (Fig. 2-2) and concordant low back pain, which was relieved by the



Fig. 2. A) Sagittal and axial images on T2-weighted MRI showed a high-intensity zone (HIZ) in the L4/5 disc. B) Discography showed leakage of contrast media. The patient reported concordant back pain, which was completely relieved by transforaminal epidural injection.

L4/5 transforaminal epidural steroid injection. He experienced another episode of severe low back pain 3 months later, and underwent percutaneous endoscopic surgery using the outside-in technique. The transforaminal approach was selected and an entry point was made about 12 cm from the midline. The endoscopic views are shown in Fig. 3; histology disclosed the penetration of vessels to the inner annulus and nucleus, as

shown in Fig. 4. The DLBP resolved within one month of surgery. He returned to work 3 months after surgery without recurrence at the 24-month follow-up. An MRI performed 2 years after the procedure did not reveal a HIZ lesion (Fig. 5).

Demonstration Case 2

A 31-year-old male truck driver suffered from

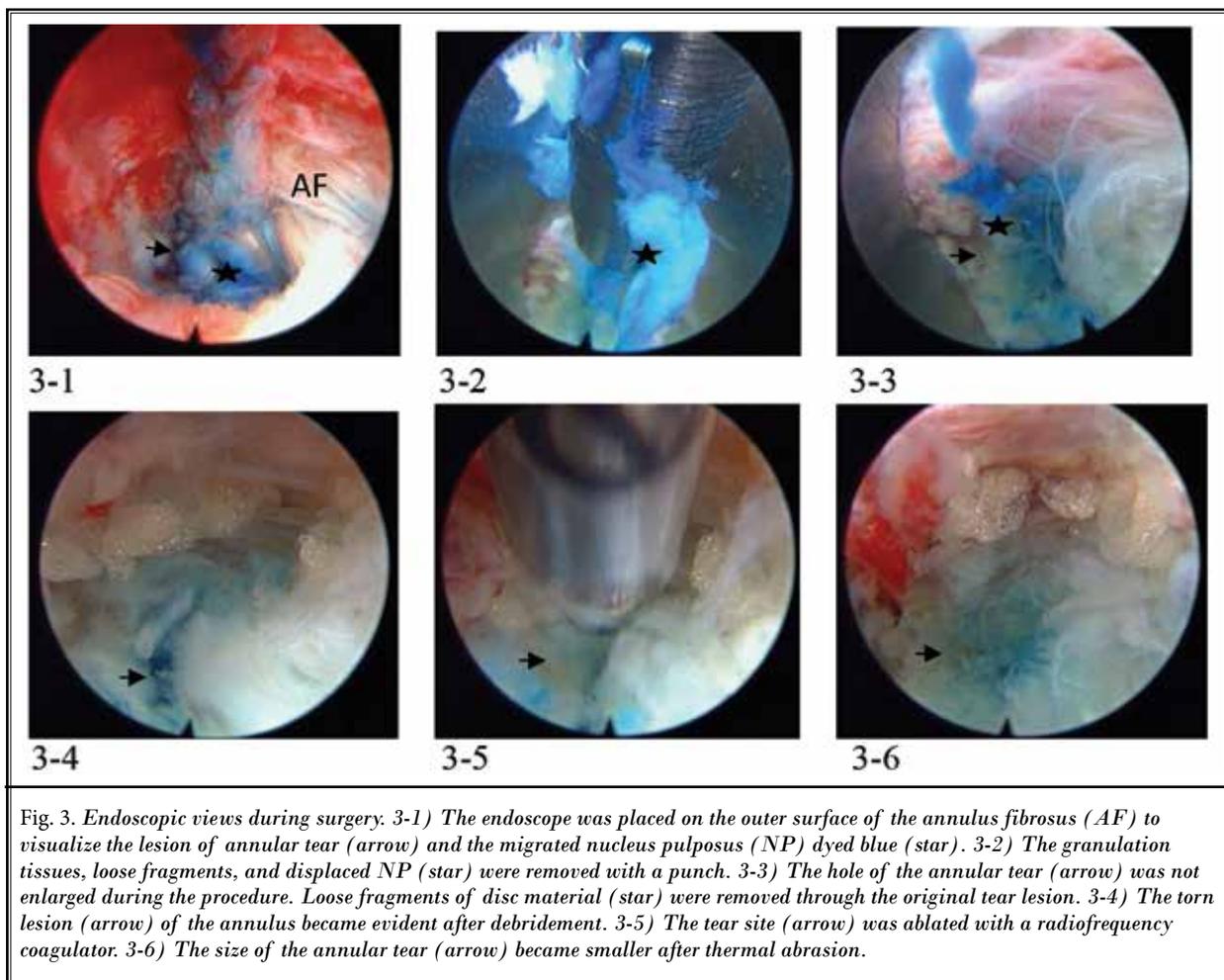


Fig. 3. Endoscopic views during surgery. 3-1) The endoscope was placed on the outer surface of the annulus fibrosus (AF) to visualize the lesion of annular tear (arrow) and the migrated nucleus pulposus (NP) dyed blue (star). 3-2) The granulation tissues, loose fragments, and displaced NP (star) were removed with a punch. 3-3) The hole of the annular tear (arrow) was not enlarged during the procedure. Loose fragments of disc material (star) were removed through the original tear lesion. 3-4) The torn lesion (arrow) of the annulus became evident after debridement. 3-5) The tear site (arrow) was ablated with a radiofrequency coagulator. 3-6) The size of the annular tear (arrow) became smaller after thermal abrasion.

chronic low back pain for more than 10 years. A T2-weighted MRI showed a HIZ in the L5/S1 disc (Fig. 6). The provocative discography and block test were positive. The interlaminar approach was selected because of the high iliac crest; a transforaminal approach might not have reached the lesion in L5/S1 (Fig. 7). Endoscopic views are illustrated in Fig. 8, and histology disclosed the infiltration of vessels in the annulus fibrosus, as shown in Fig. 9. His back pain subsided within one month after surgery. He started to drive a truck 2 months later, and did well at the 18-month follow-up assessment.

DISCUSSION

DLBP is a very challenging condition to treat because the diagnosis is really controversial to begin with. A diagnostic protocol should be helpful in determining the disc level which is related to discogenic back pain. A

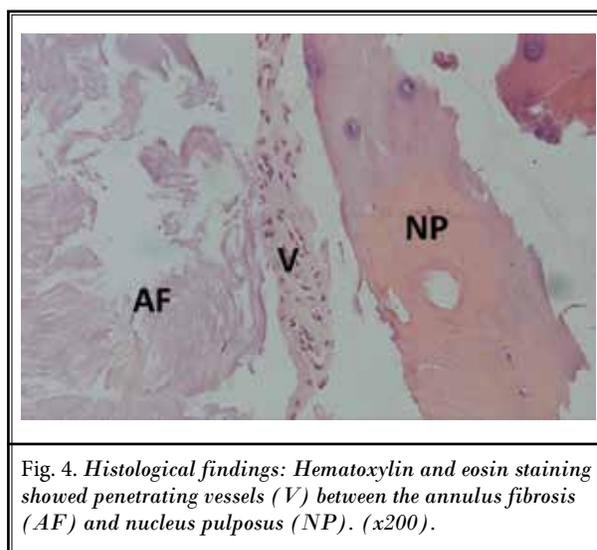


Fig. 4. Histological findings: Hematoxylin and eosin staining showed penetrating vessels (V) between the annulus fibrosus (AF) and nucleus pulposus (NP). (x200).

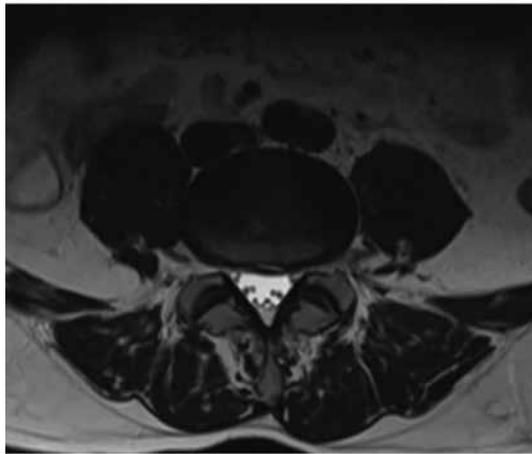


Fig. 5. Magnetic resonance imaging performed 2 years after the procedure. A high-intensity zone was not found on sagittal and axial images at L4/5 disc level.

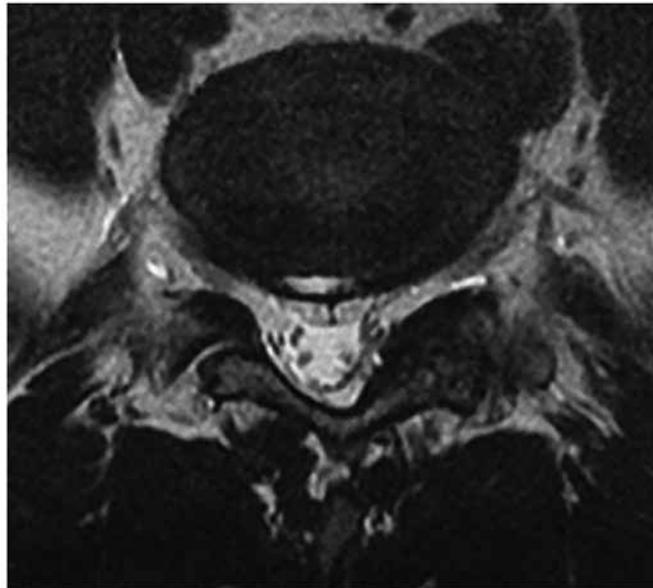


Fig. 6. A high-intensity zone was obvious on the posterior area of the L5/S1 disc.

high-intensity signal rather than a low- or medium-intensity signal is the reliable marker in MRI for diagnosis of DLBP. The true HIZs should be recognized as at least 50% brighter than CSF. Provocative discography is still the gold standard to make the diagnosis, because not every patient presenting with a HIZ on MRI experiences concordant pain. The HIZ noted on MRI can be used as

a marker for screening, while provocative discography remains the best test that provides both anatomical and diagnostic information about a suspected abnormal disc. Discography is concerned due to the invasive nature and associated complications such as discitis or worsening of disc degeneration (18). In this study, after the MRI screening, discography was performed on the

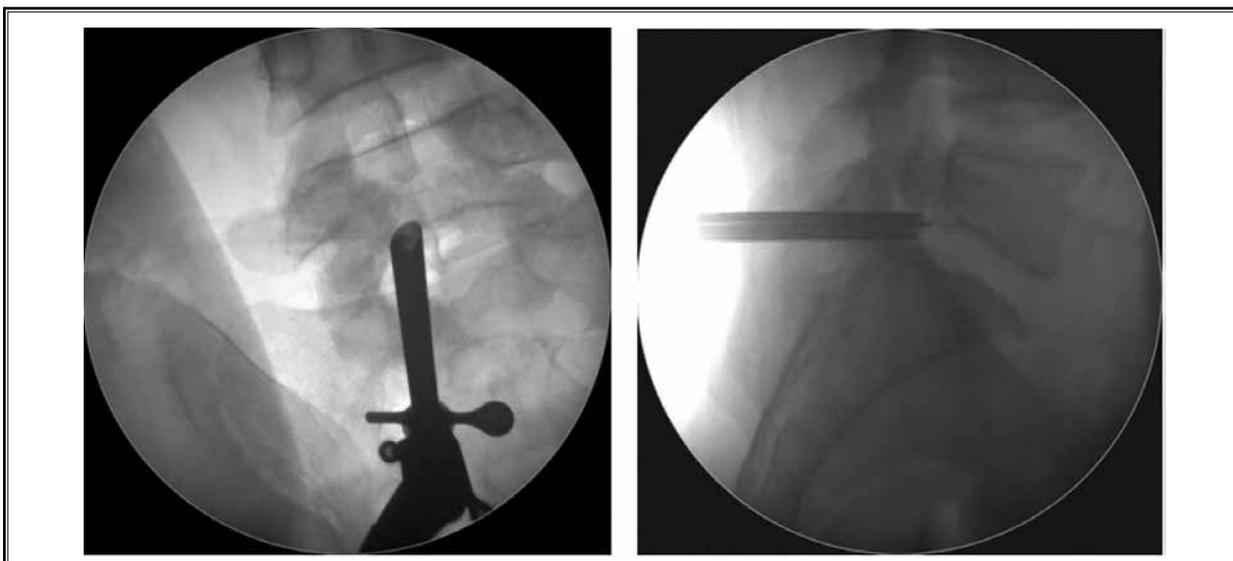


Fig. 7. An interlaminar approach was selected for the L5/S1 lesion.

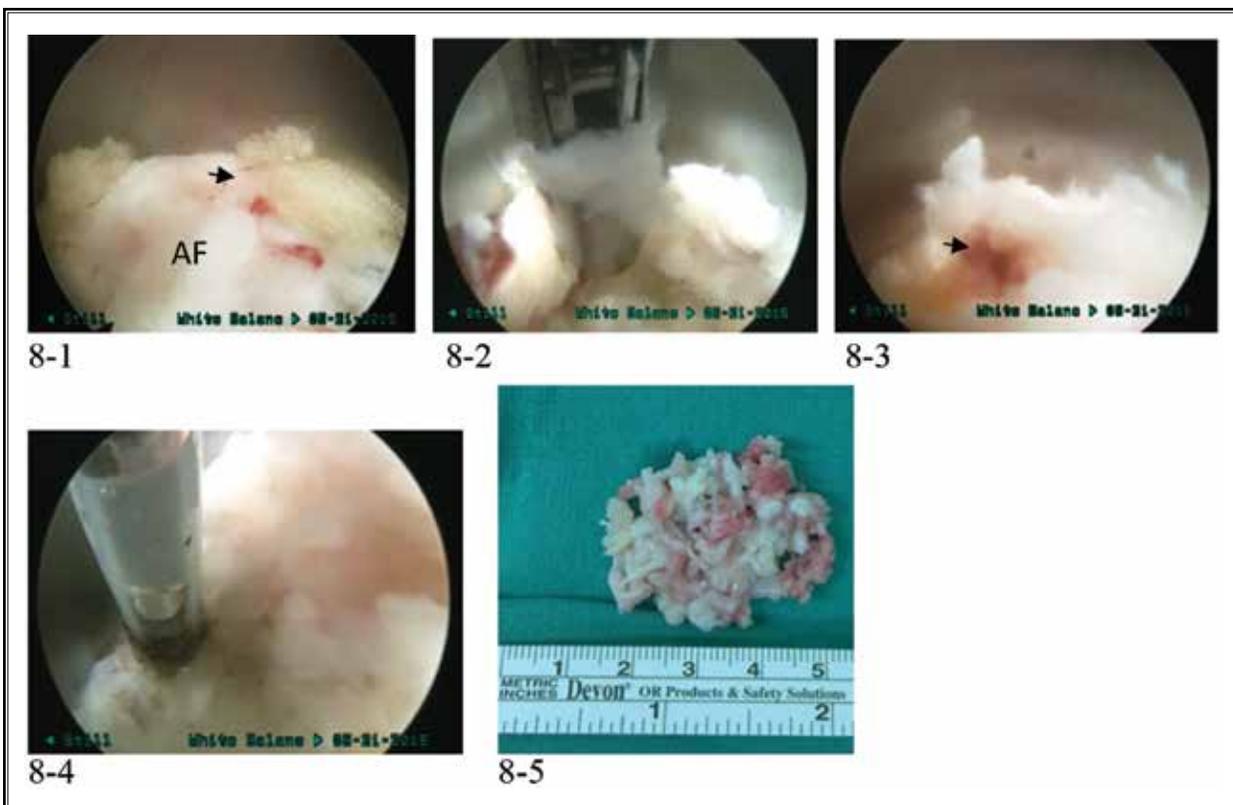


Fig. 8. Endoscopic views and the removed disc material during surgery. 8-1) The torn lesion on the annulus fibrosus (AF) was bulging, loose, and covered with vessels and red granulation tissues (arrow). 8-2) Those inflammatory tissues were removed with a punch. 8-3) The vessels and red granulation tissues (arrow) also could be found on the inner layer of the AF and in the nucleus pulposus (NP) suggesting penetration of new vessels into the AF and NP. 8-4) The lesion was ablated with a radiofrequency coagulator. 8-5) The removed disc material appeared slightly red in color.

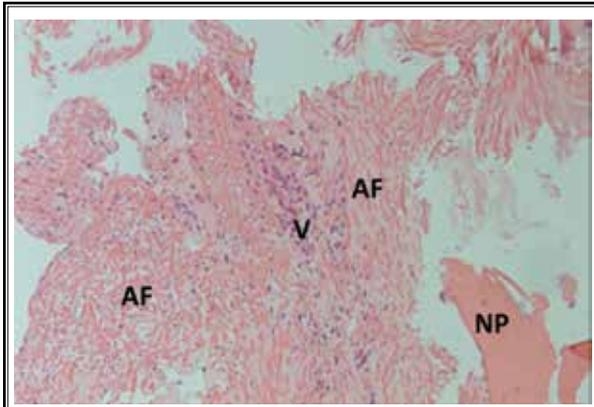


Fig. 9. Hematoxylin and eosin staining of removed disc material involving the annulus fibrosus (AF) and nucleus pulposus (NP). Infiltration of vessels (V) in the AF was noted ($\times 100$).

target level only and procedure-related complications were reduced. Concordant pain induced by provocative discography, and relieved by injection of local analgesic and steroid, provided a clear clue to localize the pain source and predicted the prognosis of treatment. Therefore, a combination of positive MRI findings, positive discography, and block test may increase the accuracy of diagnosis for DLBP.

The treatment for DLBP traditionally has been limited to either conservative management or lumbar fusion surgery. Lumbar fusion is the surgical procedure of choice in patients who failed aggressive nonsurgical programs, but the results have varied considerably in different studies (19-21). The surgical invasiveness and complications after fusion should be considered. Persistent symptoms may be associated with patient selection and approach-related muscle denervation, disruption of the facet joints, or pseudoarthrosis. Over the past decade, many percutaneous techniques such as intradiscal electrothermal therapy, annuloplasty, nucleoplasty, and percutaneous disc decompression have been advocated to treat DLBP (22,23). These procedures aimed at altering the internal mechanics or innervation of the disc, but limited or poor evidence existed for their benefits. Randomized trials did not support the effectiveness of the percutaneous intradiscal thermal procedure for the treatment of DLBP (24).

Percutaneous endoscopic treatment for chronic DLBP has been reported since 1991, but the success rates ranged from 41.6% to 91% in different studies (13,14,25). Patient selection and surgical technique are

likely to be the reasons for this variation. There are 2 techniques, so called inside-out and outside-in, for placement of cannula into the disc in the transforaminal approach. The transforaminal inside-out technique was widely used in previous studies. In the inside-out technique, the cannula was inserted into the disc directly, and the annular tear was visualized after the nucleus was removed and annulus was cut. The endoscope might penetrate the disc through the intact annulus rather than the torn lesion, and the annular tear would be enlarged. Also, there might be more nucleus removed to create a working cavity in the disc for viewing and manipulating the endoscopic tools intradiscally. The healthy part of the annulus and nucleus might be damaged; it is not easy to manage the lesion located on the central part using the inside-out technique without removing a lot of disc material. On the contrary, by using an outside-in technique, the central lesion can be accessed directly via a shallow trajectory and targeted below the facet, with the landing of instruments on the outside of the annulus. If necessary, the bony foramen can be enlarged for better visualization of the annulus. The percutaneous interlaminar approach provides posterior access to the disc, especially for the L5-S1 level and in patients with a high iliac crest. The term "outside-in" is not usually used in the interlaminar approach, but its usage in this article attempts to emphasize that the cannula or endoscope does not enter the disc before the torn lesion is discovered, and the intradiscal procedure is performed through the torn lesion. The outside-in technique used in either the transforaminal or interlaminar approach allows the surgeons to visualize the torn annulus first and focus treatment mainly on the lesion. Compared to the inside-out technique, the outside-in technique causes much less injury to the healthy annulus and nucleus.

In this study, we detected the inflammatory granulation tissues or annular defect showing the true HIZ on MRI in every patient. After adequate debridement of inflammatory tissues, all 24 patients experienced relief in back pain to some degree. Only 2 patients received additional surgery within one year, one of whom underwent fusion surgery under the impression of segment instability, and the other who repeated endoscopic surgery due to recurrence of DLBP. According to the preoperative and postoperative scores on the VAS, ODI, and modified MacNab outcome assessment for back pain and functional activity, 22 of 24 patients achieved significant improvements at the 24-month follow-up assessment.

CONCLUSION

The combination of clinical symptoms, true HIZ, positive discography, and block test provided strict criteria to make an accurate diagnosis of DLBP. Patients who met the above selection criteria received percutaneous endoscopic management and experienced symptomatic and functional improvements at the short-term and 2-year follow-up assessments. The outside-in technique allows the surgeon to visualize and treat the lesion directly. The significant limitation of this study is its non-random format and small sample size. Future research may focus on controlled prospective studies with larger sample sizes and long-term follow-up to examine the validity of this protocol.

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Declarations

Ethics approval and consent to participate: This study (IRB number: 10504004) was approved by the Institutional Review Board (IRB) of Buddhist Dalin Tzu-Chi General Hospital Foundation and written informed consent was obtained from all patients.

Authors' contributions: KL and SY created the ideas and study design. BO and MH provided the study materials. CT and CC provided the cases and surgical experience. KL drafted the manuscript and performed the statistics. KL and SC analyzed and interpreted the data and are responsible for revisions. All authors read and approved the final manuscript.

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