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CLINICAL ARTICLE

Outcome predictors of percutaneous endoscopic lumbar discectomy and thermal annuloplasty for discogenic low back pain

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Abstract
Purpose Endoscopic discectomy with annuloplasty is considered as a novel minimally invasive technique for treating chronic discogenic low back pain (DLBP). The purpose of this study was to evaluate the outcome predictors and to describe technical aspects for endoscopic solutions against DLBP.
Materials and methods We performed a prospective study of 87 patients who underwent percutaneous endoscopic lumbar discectomy and thermal annuloplasty (PELDTA) for DLBP. The inclusion criteria were disc degenerations with annular tear confirmed by imaging studies and discography. Clinical outcomes were assessed using the visual analog scale (VAS), the Oswestry disability index (ODI), and the modified MacNab criteria. The univariate and multivariate analyses were performed to evaluate the outcome predictors.
Results The 2-year follow-up rate was 90.8% (79 of 87 patients). The VAS and ODI scores at postoperative 6 months and 2 years were significantly improved ($p<0.001$). Based on the modified MacNab criteria, the global outcomes were excellent in 39 out of 79 patients (49.4%), good in 17 patients (21.5%), fair in 10 patients (12.7%), and poor in 13 patients (16.5%). Therefore, the percentage of symptomatic improvement was 83.5% and the success rate (excellent or good) was 70.9%. In the univariate and multivariate analyses, the presence of concurrent disc herniation with DLBP was the most significant predictor (OR=3.207, 95% CI 1.02–10.06, $p=0.046$).
Conclusions PELDTA may be effective for patients with chronic DLBP in selected cases. Central disc herniation causing DLBP was the most important predictor for clinical success.

Keywords Endoscopic · Lumbar · Discogenic pain · Disc herniation · Annuloplasty

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Introduction

Chronic low back pain is a major medical issue which may disrupt normal daily activities including work and recreation [5]. The prevalence of internal disc disruption among patients with chronic low back pain is estimated to be about 40% [22].

The treatment of chronic, non-radicular, and discogenic low back pain (DLBP) remains controversial. In particular, for patients who have not responded to conservative treatment, surgical treatment options may be considered. Conventional surgical procedures for DLBP are spinal fusion or disc replacement surgery [1, 3, 8, 16, 26]. Recently, a variety of minimally invasive percutaneous intradiscal therapies have been introduced.

There are two categories in the percutaneous treatment modalities for DLBP. One is intradiscal thermal annuloplasty using a radiofrequency electrode such as intradiscal electrothermal therapy (IDET). The other is endoscopic discectomy accompanied by annuloplasty using a laser and/or radiofrequency electrode. Recently, Tsou et al. [24] reported on the surgical technique and clinical outcome of selective endoscopic discectomy and thermal annuloplasty,

and Lee and Kang [13] described the theoretical basis of endoscopic laser annuloplasty. The main benefit of the latter category is that the procedure can provide a decompression effect as well as a thermal annuloplasty effect at the same time.

However, the reported success rates of these procedures varied from 70% to 90% [4, 13, 19, 24]. This variation may be due to the differences in patient selection, technical aspects, and outcome measurement. Although the fundamental principles of these procedures are similar, the criteria for patient selection have been variable. We believe that the clinical outcome is definitely dependent on proper patient selection according to strict inclusion criteria. To our knowledge, there have been few reports on the outcome predictors of this intradiscal procedure. The purpose of this study was to evaluate the clinical outcome of endoscopic discectomy with annuloplasty and to determine the factors predicting a favorable outcome.

Materials and methods

Patient population and outcome evaluation

A total of 87 consecutive patients who had undergone PELDTA for chronic DLBP at our institute from January 2003 to December 2005 were evaluated. The inclusion criteria were as follows: (1) intractable chronic low back pain without improvement after conservative treatment for 6 months; (2) disc degeneration without disc space collapse (grades 2–4) on magnetic resonance imaging [18], with no segmental instability on the dynamic flexion–extension radiography; (3) a demonstrated annular tear and discogenic pain confirmed by provocative discography; and (4) no history of previous back surgery. The patients who had an extruded disc causing radiculopathy, lateral recess stenosis, motor weakness, or other pathologic conditions such as fractures, tumors, or infection were excluded from this study.

Questionnaires with outcome measurements evaluating pain intensity and functional disability were completed preoperatively, at 6 months, and at the 2-year follow-up visit or during telephone interviews by the independent observer. At each follow-up, the pain intensity of the low back pain was measured using a visual analog scale (VAS, 0–10 points), and the functional status was assessed using the Oswestry disability index (ODI). The global outcome was also assessed as excellent, good, fair, or poor based on the modified MacNab criteria at the final follow-up. A favorable outcome was defined as excellent or good. One blinded radiologist analyzed the radiological findings and the relationships between the preoperative variables and a favorable outcome. Two-tailed P values <0.05 were considered as significant. Parameters noted to be significant determinants of a favorable outcome on univariate analysis were then evaluated using a multivariate logistic regression model with SPSS software (version 14.0K, SPSS, Chicago, IL, USA).

Surgical technique

The surgical procedure used was similar to that of previous reports [13, 24], with the same theoretical basis. The operative procedures can be summarized in three steps: (1) preoperative provocative discography; (2) selective endoscopic discectomy using endoscopic forceps and laser; and (3) endoscopic thermal annuloplasty using a bipolar radiofrequency (RF) probe. All patients underwent preoperative provocative discography to verify the discogenic pain. Provocative discography was performed with manual injection of ioxitalamate meglumine (Televrix 30 Meglymine; Guerbet, France) containing 300 mg/mL iodine concentrate, without manometry [13]. Cases with leakage of dye through the annular tear and positive pain provocation were selected. If there was no concordant pain or no leakage of dye on the fluoroscopy, the procedure was not performed.

The procedure was conducted in the prone position and under local anesthesia. The skin entry point was typically approximately 9–12 cm from the midline and was dictated by the size of the patient, the dimensions of the facet joints, and the desired location for the tip of the needle in the triangular working zone. To determine the appropriate entry point, preoperative imaging studies and intraoperative fluoroscopy should be performed. An 18-gauge spinal needle was inserted after infiltration of local anesthetics. The needle tip was positioned at the medial pedicular line in the AP projection and on the posterior vertebral line in the lateral projection. After insertion of the needle, an intraoperative discography was performed with a mixture of 6 mL of contrast media (telebrix) and 1 mL of indigo carmine. The pathologic nucleus and annular fissure can then be stained for easy discrimination through both the fluoroscope and endoscope. A guide wire was then inserted through the needle into the annulus and a small stab incision was made at the needle entry site. After the needle was withdrawn, a tapered cannulated obturator was slid over the guidewire and introduced gently into the foramen. A bevel-ended working cannula was then introduced over the obturator. After the obturator was withdrawn, a 5.8× 5.1-mm ellipsoidal endoscope, with an eccentrically placed 2.7-mm working channel and two irrigation channels, was inserted. The initial endoscopic view consisted of the undersurface of the annulus and annular tear with a pinched and inflamed herniated nucleus. At first, the border of annular tear could not be clearly defined because the herniated disc or fibrotic scar tissues were tightly attached to the annular fissure. In case of disc herniation, the surgeon could see the congested and inflamed nucleus

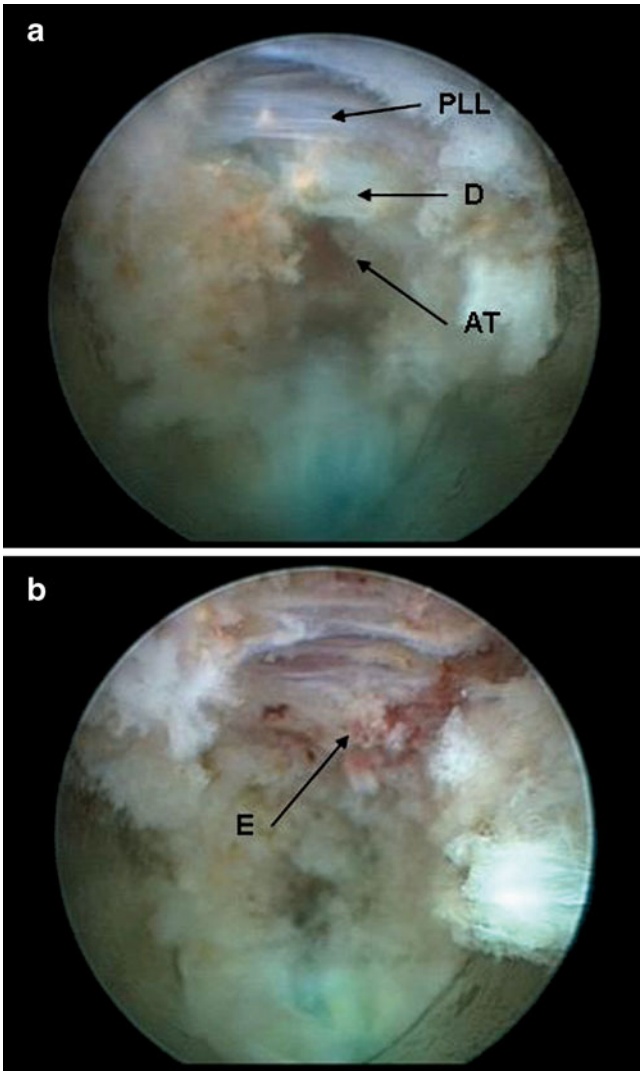

Fig. 1 Intraoperative endoscopic view demonstrating the annular tear with a herniated disc (**a**) and inflamed epidural space with new vessel formation (**b**). *PLL* posterior longitudinal ligament, *D* disc fragment in annular tear, *AT* annular tear, *E* inflamed epidural space after disc removal

being anchored by the annular fissure. The herniated disc and fibrotic scar tissues were then released and removed using endoscopic forceps and a side-firing, Holmium yttrium–aluminum–garnet (Ho:YAG) laser (Fig. 1). The therapeutic effects of this procedure can be summarized in two ways. Firstly, as the annular anchorage is released and the herniated fragment is removed, the annular fissure can be defined clearly and the epidural space can be visualized through the annular fissure (decompression step). In the meantime, the inflamed annulus and fibrotic tissues containing free nerve endings and new vessels can be treated with a bipolar RF probe and laser (thermal modulation step). These procedures should be performed though the whole length of the posterior annulus while the central nucleus should remain intact. At the end of the procedure, the surgeon can identify the full undersurface of the annulus, treated annular fissure, and decompressed dural sac. In a final step, the anatomic layers (e.g., epidural fat, dural sac, traversing root, posterior longitudinal ligament, annular fissure, and remaining normal nucleus) were confirmed. The patient was asked if the pain had decreased or disappeared and if any complications had occurred. All patients are permitted to go home within 24 h if there are no postoperative problems.

Results

Among the 87 patients, eight patients were lost to follow-up. Therefore, the 2-year follow-up rate was 90.8% (79 of 87 patients). There were 42 men and 37 women with a mean age of 36.9 years (range, 21–58 years). Sixty-seven patients had a single-level and 12 patients had two-level procedures; therefore, 91 disc levels were treated with PELDTA. Table 1 summarizes the demographic characteristics.

The mean VAS for low back pain preoperatively, postoperatively, 6 months and 2 years were 7.44±1.74, 2.89±1.53, and 2.07±1.38, respectively(Fig. 2). The mean ODI scores at each follow-up were 50.71±13.42, 24.47±12.41, and 20.80±12.96, respectively (Fig. 2). Based on the modified MacNab criteria, the global outcomes were excellent in 39 out of 79 patients (49.4%), good in 17 patients (21.5%), fair in 10 patients (12.7%), and poor in 13 patients (16.5%). Therefore, the percentage of symptomatic improvement was 83.5%, whereas the rate of favorable outcome (excellent or good) was 70.9% (Fig. 3). Nine out

Table 1 Demographics of 79 patients with discogenic low back pain

Data	No. of patients	Percentage
Sex		
Male	42	53.2
Female	37	46.8
Age (years)		
<30	14	17.7
30–39	42	53.2
40–49	16	20.2
≥50	7	8.9
Spinal level operated		
L2-3	1	1.3
L3-4	0	0
L4-5	56	70.9
L5-S1	10	12.6
L2-3 and L4-5	1	1.3
L3-4 and L4-5	2	2.5
L4-5 and L5-S1	9	11.4

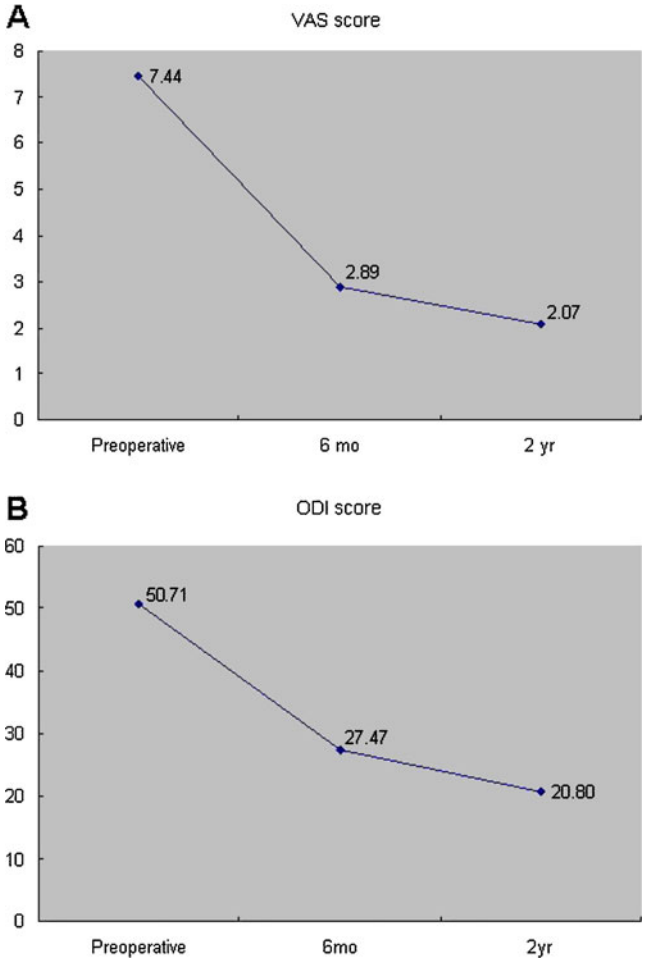

Fig. 2 Mean VAS and ODI preoperatively, at 6 months, and at 2 years postoperative

of the 13 patients with a poor outcome had subsequent open surgery: Six patients had a lumbar fusion, two patients had a total disc replacement, and one patient had a lumbar microdiscectomy. The remaining four patients in the poor category had no further lumbar surgery and continued conservative therapy including injections, physical therapy, and therapeutic exercise. There were no postoperative infections, vascular complications, or neurological deficits. Five patients complained of postoperative dysesthesia or flare, which improved within 6 months.

We performed the univariate analysis for each demographic and geometric parameter that influenced the clinical success. The patient's age was found to have a predictive value for a favorable outcome (Table 2). Patients younger than 40 years tended to have better outcomes than older patients (78.6% vs. 52.2%, $p<0.05$). The presence of concurrent disc herniation was also significantly related to the outcome (Table 3). Patients with concurrent disc herniation (disc herniation group) showed a better outcome than those with only disc degeneration (disc degeneration group). Thirty-two (86.5%) out of the 37 disc levels of the herniation group showed favorable outcomes, while a favorable outcome was seen in 34 (63.0%) out of the 54 disc levels of the non-herniation group ($p<0.05$). Moreover, the length of disc herniation also showed a statistical significance in that the larger herniation had the better clinical outcome. Other parameters, including sex, BMI, smoking, alcohol intake, sitting intolerance, level of surgery, modic change, high-intensity zone (HIZ), degree of disc degeneration [18], and segmental range of motion had no significant influence on the outcome.

The multivariate logistic regression model was then used to determine if the individual parameters were independently associated with the outcomes. The results of this analysis can be used for preoperative evaluation of patients with DLBP to infer the predictive probability of favorable outcomes. With forward stepwise multivariate logistic regression, DLBP with disc herniation (OR=3.207, 95% CI 1.02–10.06, $p=0.046$) was the most important predictive factor for clinical success. In contrast, the younger age that was significant in the univariate analysis was not associated with the outcome in the multivariate analysis (Table 4). The predictive probability was calculated by the following equation: $P = \exp Z/(1+\exp Z); Z = 0.442 + 2.181X_1; X_1 =$ presence of disc herniation $(0,$ herniation group; $1,$ non$-$ herniation group). Table 5 shows the calculated predictive probabilities of favorable outcomes between the herniation group and the non-herniation group.

Discussion

Percutaneous intradiscal thermal procedures for DLBP have been discussed since the late 1990s [7, 9, 10, 20]. IDET, nucleoplasty, and radiofrequency rhizotomy are representa-

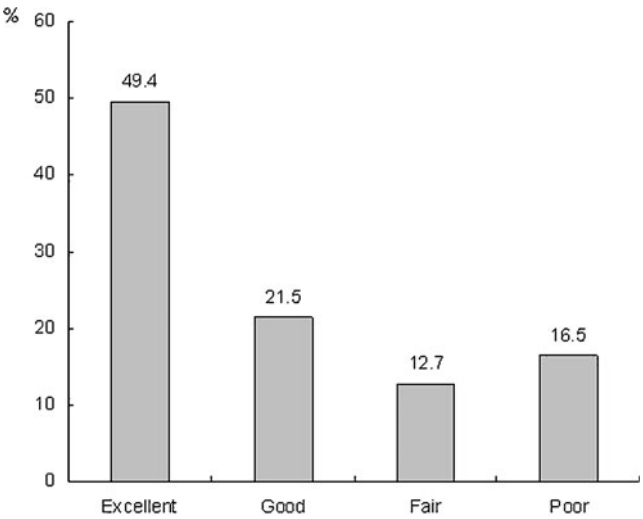

Fig. 3 Bar diagram showing the global outcome based on the modified MacNab criteria

Table 2 Univariate analysis for demographic parameters (N=79 patients)

Parameters	Favorable group	Unfavorable group	p value
Age<40 years	44	12	0.019[c]
Age≥40 years	12	11	
Male	26	16	0.061
Female	30	7	
Smoker	19	12	0.131
Nonsmoker	37	11	
Drinking	23	11	0.626
Non-drinking	32	12	
Sitting intolerance (+)	14	4	0.464
Sitting intolerance (−)	42	19	
Height[a]	166.3±8.9	167.6±9.1	0.564
Weight[a]	64.1±9.4	65.3±8.0	0.598
Body mass index (BMI)[b]	23.2±3.3	23.2±1.5	0.486

Chi-square test

[a] Independent two-sample t test

[b] Mann–Whitney U test (mean ± SD)

[c] Statistically significant value

tive of minimally invasive intradiscal procedures. They have been considered as attractive items by spinal practitioners because they possibly treat the inflammatory reaction related to the annular tear or disc degeneration using a percutaneous technique. However, there are hereditary limitations which may reduce the effectiveness of the procedures: being a blind technique and incapable of removing an extruded nucleus pinched in the annular fissure.

Intradiscal therapies combined with an endoscopic discectomy technique can solve these problems. As described before, this procedure provides a therapeutic effect for DLBP in two ways. Endoscopic selective discectomy can relieve the compressed dural sac and reduce the intradiscal pressure. In the meantime, thermal modulation using a laser and bipolar RF probe can ablate the pain producing neovascularization and free nerve endings around the inflamed annular fissure. This is the main advantage of PELDTA compared with the other intradiscal procedures such as IDET or similar procedures. Our technique is theoretically similar to the technique of Tsou et al. [24]. or Lee and Kang [13]. However, there are delicate differences among the procedures from the technical aspect. The unique benefit of our technique is the combination of those surgical tools. The selective discectomy can be performed using endoscopic forceps and a side-firing laser while preserving the central nucleus (Fig. 4a). In the meantime, the thermal annuloplasty can be achieved using a bipolar RF probe and a side-firing laser (Fig. 4b).

Our data showed that improvements in low back pain and functional status after the PELDTA are clinically significant and durable through 2 years of follow-up, with a symptom improvement rate of 83.5% and an overall success rate of 70.9% using strict criteria. These results are comparable to those of several recently published studies of IDET procedure [6, 14, 17]. The overall symptom improvement or success rates after IDET in previous studies are 50% to 75%.

Among all parameters, the presence of a central disc herniation showed the most powerful predictive value. The age factor was significant only in the univariate analysis.

Table 3 Univariate analysis for geometric parameters (N=91 levels)

Parameters	Favorable group	Unfavorable group	p value
L2-3	2	0	1.000
L3-4	2	0	
L4-5	48	20	
L5-S1	14	5	
Disc herniation	32	5	0.014[b]
Disc degeneration	34	20	
Disc degeneration grade <4	46	15	0.380
Disc degeneration grade ≥4	20	10	
Modic change (+)	12	3	0.752
Modic change (−)	54	22	
HIZ (+)	35	16	0.347
HIZ (−)	31	9	
Herniation length[a] (%)	16.0±17.7	5.6±10.2	0.010[b]
Sagittal range of motion[a] (deg)	10.6±5.5	11.5±4.4	0.619

Chi-square test (level and Modic change, Fisher's exact test)

HIZ high-intensity zone

[a] Mann–Whitney U test (mean ± SD)

[b] Statistically significant value

Table 4 Multivariate analysis (binary logistic regression analysis)

Parameters	*B*	SE	Wald	EXP(*B*) = OR	*p* value	95% CI for EXP(*B*)
Age	0.971	0.541	3.225	2.641	0.073	0.915–7.622
Disc herniation	1.165	0.583	3.988	3.207	0.046[a]	1.022–10.061
Constant	0.442	0.302	2.139	1.556	0.144	

B unstandardized regression coefficient, *SE* standard error, *Wald* Wald static, *OR* odds ratio, *CI* confidence interval

[a] Statistically significant value

Younger patients <40 years old tended to have a better outcome than older ones. There has been a consensus of opinion in many previous studies that younger age can be one of the predictors of favorable outcome in spinal procedures [2, 11, 21, 25]. This finding corresponds closely to those of previous studies on other spinal procedures. In the multivariate analysis, however, the age factor did not show any statistical significance.

In the meantime, patients from the disc herniation group showed better outcomes than those of the disc degeneration group in both univariate and multivariate analyses. Moreover, the degree of disc herniation was correlated to the outcome: the more herniation, the better the outcome. The definite reason for this phenomenon is not clear. PELDTA can provide a decompression effect as well as a thermal modulation effect at the same time. Thus, we postulate that the mechanical dural sac decompression through selective discectomy may provide a synergic effect with the thermal ablation of pain-generating structures in the annulus. The causes of DLBP may be variable. Axial back pain is caused by disc end plate inflammatory changes or dural and posterior longitudinal ligament irritation, whereas mechanical compression or chemical irritation around the root sheath contributes to radicular leg pain [7, 12, 15, 23]. Therefore, mechanical decompression of the dural sac is important to reduce back pain. In other words, selective discectomy can be as effective for axial back pain through dural sac decompression as for radicular leg pain through nerve root decompression.

The presence of HIZ did not affect the outcome. HIZ has been considered the sign of an annular tear and a possible source of back pain. We postulate that there are both painful and non-painful HIZ. Lee and Kang [13] classified the morphology and function of HIZ. However, it is difficult to differentiate painful HIZ from non-painful HIZ even with a discography. We believe that further extensive studies on painful HIZ should be performed in the near future. If we can discriminate painful HIZ from non-painful, HIZ might be another important predictor. Although the Modic change can be an important source of back pain, its presence was not related to the outcome. There was no correlation between clinical outcome and disc degeneration grade. In our study, cases with grade 5 disc degeneration were not included in our study, and most treated discs corresponded to grade 3 or grade 4. Therefore, it is difficult to conclude that the degree of disc degeneration does not affect the clinical outcome of intradiscal therapies.

When treating patients with a chronic DLBP, one of the most important factors is patient selection. We do not believe that all DLBP or IDD can be treated with these kinds of intradiscal procedures. Based on the results of this study, PELDTA can be more effective for DLBP from a central disc herniation or definite annular tear than those from advanced disc degeneration, Modic change, or segmental instability.

Table 5 Predictive probability of clinical success*

Concurrent disc herniation	Predictive probability (%)
+	84.9
-	84.9

*Evaluated by the modified MacNab criteria

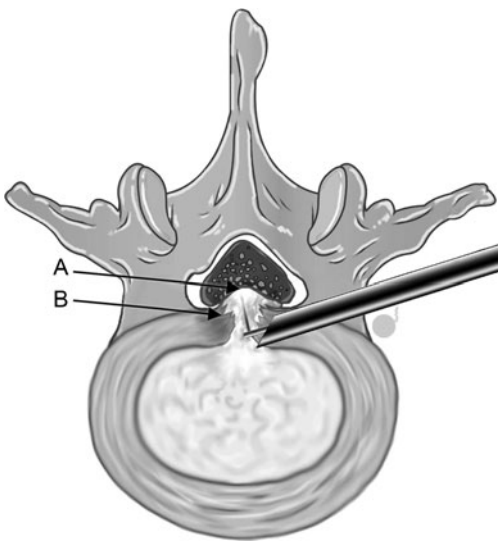

Fig. 4 Schematic illustration depicting the therapeutic mechanism against discogenic back pain. The decompression effect can be obtained by endoscopic selective discectomy using endoscopic forceps and a side-firing laser (**a**). At the same time, a thermal modulation effect can be obtained by annuloplasty using a bipolar radiofrequency probe and a laser (**b**)

In addition to a proper patient selection, technical consideration is another important aspect. The main technical points can be summarized in three ways. Firstly, herniated nucleus fragments should be totally removed to decompress the dural sac as remaining fragments may cause recurrent symptoms or incomplete symptom improvement. Secondly, the annular fissure should be thoroughly treated with thermal modulation. Incomplete coverage of annuloplasty may bring about a failure. In particular, the contralateral border of the pathologic annular fissure may be passed unnoticed. Therefore, the surgeon must try to cover the full length of posterior annulus from the ipsilateral pedicle to the contralateral pedicle zone. Finally, the innocent central nucleus should be preserved to maintain the spinal stability and disc height.

Conclusion

Percutaneous endoscopic lumbar discectomy and thermal annuloplasty may be effective for carefully selected patients suffering from chronic DLBP. It offers its therapeutic effect by both decompression and thermal modulation. Based on the statistical analysis, the presence of concurrent disc herniation was the most important predictive factor for clinical success.

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