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Original Research Article

Clinical Efficacy of Percutaneous Endoscopic Lumbar Annuloplasty and Nucleoplasty for Treatment of Patients with Discogenic Low Back Pain

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Abstract

Objectives. This study assessed the effectiveness of percutaneous endoscopic lumbar annuloplasty and nucleoplasty (PELAN) for the treatment of patients with discogenic low back pain.

Study Design. Retrospective design

Setting. Spine hospital

Subjects. Forty-seven patients diagnosed as having discogenic low back pain, who were refractory to conservative treatments.

Methods. Outcomes were assessed using a numeric rating scale for back pain, the Oswestry disability index, and modified MacNab's criteria, at 2–3 weeks and at least 12 months after treatment.

Results. At long-term follow-up, 33 patients (70%) had successful outcomes for relief of pain, and the same proportion had successful reduction of disability. Although all patients took oral analgesics for pain control before PELAN, 25 (53%) required no analgesics at long-term follow-up. If success is defined as simultaneously achieving greater than 50% reduction in pain, greater than 40% reduction of disability, good or excellent MacNab criteria, and no need for analgesics, 23 patients (49%; with 95% confidence interval of 35–63%) achieved successful outcomes.

Conclusions. In patients with discogenic low back pain refractory to conservative treatment, PELAN provided favorable clinical outcomes with success rates that rival those of surgery for this condition.

Key Words. Discogenic Pain; Low Back Pain; Endoscopy; Nucleoplasty; Annuloplasty

Introduction

It is estimated that discogenic low back pain (LBP) resulting from internal disc disruption accounts for approximately 40% of the cases of chronic low back pain [1–6]. Internal disc disruption is characterized by degradation of the matrix in the nucleus pulposus, and the development of radial and circumferential fissures in the annulus fibrosus [5,6]. Pain is believed to arise as a result of a combination of increased mechanical stress in the posterior annulus, and chemical irritation of nociceptors by inflammatory mediators in the tears of the annulus fibrosus [5]. The pain is mediated by nociceptors that are normally present in the outer third of the annulus, and by nociceptors that grow into the fissures [7–10]. Although discogenic LBP is sometimes associated with sitting intolerance, an extension catch, difficulty lifting, or an inability to maintain the same posture [11,12], no clinical features are diagnostic of the

condition [13]; and its features are difficult to distinguish from those of pain stemming from the lumbar zygapophysial joints or the sacroiliac joint [4,13]. Certain features seen on magnetic resonance imaging (MRI), such as Modic lesions or a high-intensity zone, correlate with the affected disc being the source of pain, but these features occur in only a minority of patients with low back pain [5].

Some authorities advocate provocation discography as the definitive diagnostic test for discogenic LBP [5]. In response to concerns about the false-positive rate of discography, studies have shown that the false-positive rate is less than 10% [5,14]. However, there are few data on the false-negative rate of discography; that is, how often a disc might be symptomatic despite discography failing to reproduce pain [15].

No studies have tested any form of conservative therapy for discogenic LBP. Conservative therapies are typically applied without a diagnosis of discogenic pain having been made. Surgical treatments include spinal fusion and disc arthroplasty [16,17]. However, spinal surgery is very invasive, and can incur complications that lead to persistent pain and functional impairment, even though the procedures are correctly performed [18].

As an alternative to surgery, a variety of minimally invasive, percutaneous, intradiscal procedures have been explored, such as intradiscal eletrothermal therapy [19], transdiscal biacuplasty [20], and nucleoplasty [21]. However, by design or in practice, these procedures target the nucleus pulposus or the inner annulus, and either avoid or fail to capture the outer annulus where nociception is primarily generated. Moreover, these procedures rely on fluoroscopic guidance to place instruments at the inferred location of the target tissues, which are not directly visualized [11].

Percutaneous endoscopic lumbar annuloplasty and nucleoplasty (PELAN) is a minimally invasive treatment designed specifically to decompress the posterior nucleus or granulation tissue in the torn annulus [11], PELAN is distinctive in that it allows physicians to remove tissues, using laser energy or forceps, under direct visualization by endoscopy and under fluoroscopy. This property allows for effective removal of targeted tissues while preserving as much of the remainder of the disc as possible. The present study was undertaken to determine the clinical outcomes of PELAN.

Methods

This retrospective study was approved by the Institutional Review Board of our hospital. All patients who had undergone PELAN for discogenic LBP, between August 2012 and May 2014, at the Department of Physical Medicine and Rehabilitation, were included.

During this period, a prima facie diagnosis of discogenic LBP was made in 316 patients who satisfied the following criteria: 1) chronic low back pain with two or more typical clinical manifestations: sitting intolerance, extension catch, lifting difficulty, or an inability to maintain the same posture; 2) no radicular pain or signs of radiculopathy on physical examination of the lower extremity; 3) a high-intensity zone (HIZ) or low-signal intensity without disc space collapse on MRI, with no significant segmental instability on dynamic flexion-extension radiography; 4) no prominent disc herniation, spinal stenosis, previous lumbar surgery, or other pathologic findings such as fracture, tumor, or infection.

Of these patients, 105, who were refractory to conservative treatments, such as medication, physical therapy, exercise program, and transforaminal epidural steroid injection at least for 3 months, were selected for further screening. Transforaminal injections were used not to treat radicular pain, but in an effort to relieve discogenic pain or retrodiscal epidural inflammation by blocking the sinuvertebral nerves, which run through the target zone for transforaminal injections.

Of the 105 patients, 48 were excluded when they reported positive responses either to medial branch blocks or sacroiliac joint blocks. Medial branch blocks, using 0.5 ml of 0.5% bupivacaine, were performed bilaterally at segmental levels corresponding to the targeted disc. For example, if MRI revealed disc degeneration or HIZ in an L4-5 intervertebral disc, blocks were performed of the L3 and L4 medial branches, where they crossed the L4 and L5 transverse processes. Sacroiliac joint blocks were performed bilaterally using 2.5 ml of 0.5% bupivacaine. Positive responses were regarded as a 50% or more reduction of the numeric rating scale (NRS) [22].

PELAN was recommended for the remaining 57 patients, but 10 declined. Subsequently, 47 patients constituted the sample for the present study. Provocation discography was performed in all 47 patients either in order to determine the symptomatic disc when more than one disc was a possible target, or to confirm that a single, selected disc was, indeed, painful. A positive response was defined as reproduction of concordant pain at an intensity greater than 7/10 on an NRS, at a pressure less than 15 pounds per square inch above opening pressure, and at a volume less than 3.0 ml [5,12].

PELAN was performed with the patient in a prone position. The skin entry site was typically established at approximately 10–12 cm from the midline. After anesthetizing the entry site, an 18-gauge spinal needle was inserted and advanced until its tip reached a point on the medial pedicular line in the anteroposterior (AP) view and at the posterior vertebral line in the lateral view. Upon insertion of the needle into the disc, a discogram was obtained using a mixture of contrast medium and indigocarmine (Figure 1 A,B). The contrast medium served to fill the annular fissure so that it could be seen in AP and lateral fluoroscopic views. The indigocarmine served to dye the nuclear tissue within the fissure so that it could be recognized under endoscopy.

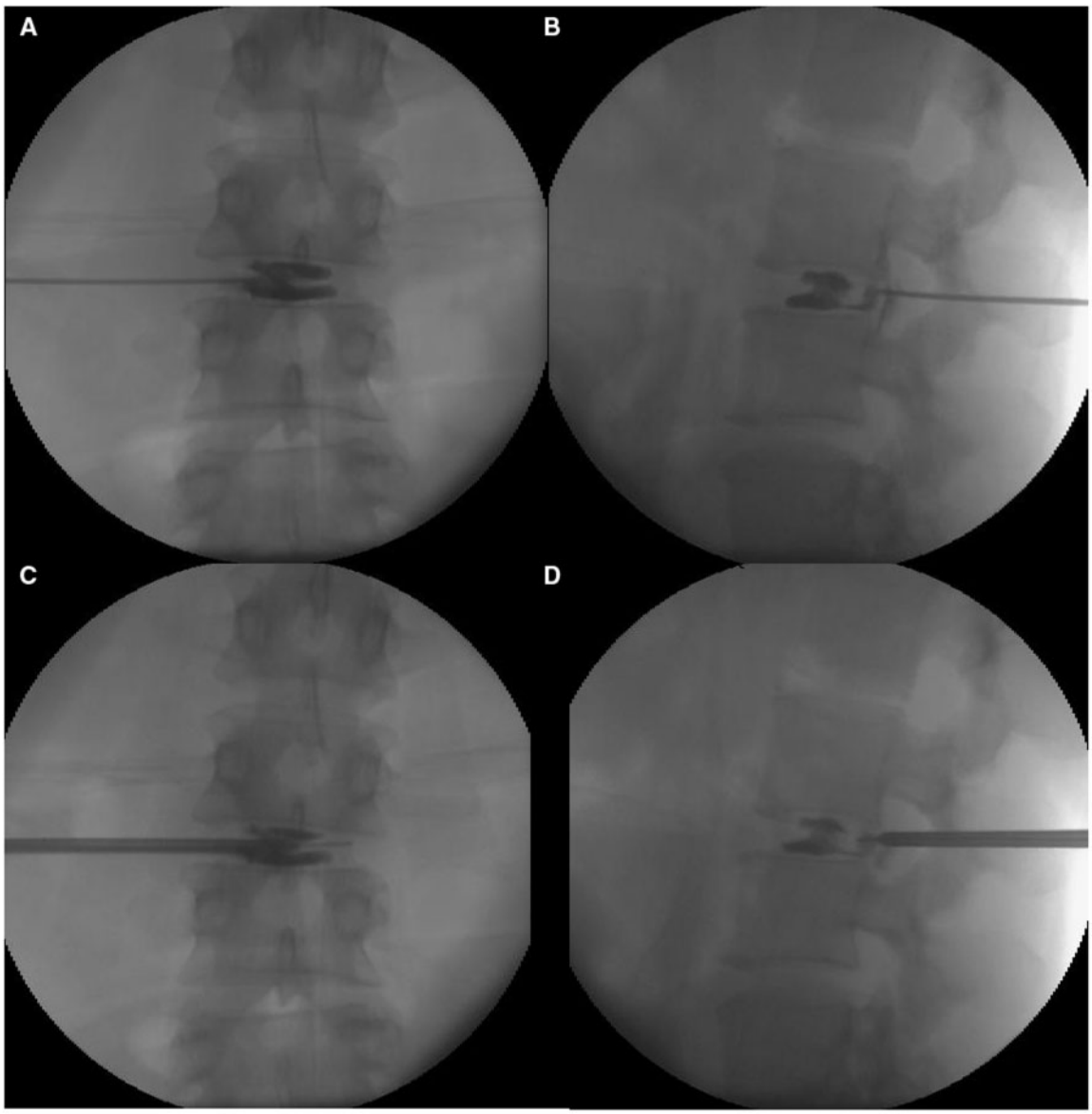

Figure 1 Fluoroscopy views of stages in the performance of percutaneous endoscopic lumbar annuloplasty and nucleoplasty. An 18-gauge spinal needle was inserted into the posterior portion of the annulus fibrosus, and placement confirmed by discography. (A) Anteroposterior view. (B) Lateral view. A working cannula was inserted along the path that was made by a guide wire. (C) Anteroposterior view. (D) Lateral view.

A guide wire was then inserted through the needle into the annulus, and a small stab incision was made at the needle entry site to accommodate the introduction of a working cannula. After the needle was withdrawn, the working cannula was slid over the guide wire, and inserted gently into the posterior part of annulus. Under fluoroscopy, the cannula was placed in the annulus as close as possible to the deep surface of the posterior longitudinal ligament. The flexible endoscopic catheter equipped with laser tip was then introduced through the cannula (Figure 1 C,D). The endoscope was adjusted to view the undersurface of the posterior longitudinal ligament, the annular fissure, and the nuclear material within it. The Holmium yttrium–aluminum–garnet (Ho:YAG) laser was then used to perform thermal removal and ablation of the nuclear material, any granulation tissues, and the damaged elements of the annulus fibrosus, under direct visualization using the endoscope. The laser power level was set at 0.5 J to 1.2 J. Sometimes, when large nucleus fragment or fibrotic tissues were observed, they were released and removed by forceps through same working channel.

All patients were assessed at 2 or 3 weeks, for short-term follow-up, after PELAN, and at least after 12 months for long-term follow-up. A nurse, who was not

involved in the treatment of the patients, conducted the assessments, using an NRS for back pain, the Oswestry disability index (%) (ODI%) for functional impairment, and the modified MacNab's criteria for patients' subjective satisfaction with treatment [23]. At long-term follow-up, the requirement for analgesics for pain control was assessed. If the patients needed to take analgesics on 3 days or less per week, the requirement was defined as "intermittent." If the patients took analgesics more often, the requirement was defined it as "frequent." Mean values and standard deviations of group scores for the NRS and ODI(%) were calculated, and changes at short-term and long-term follow-up from values at inception were tested for statistical significance using a two-sample *t*-test. A *P* value of less than 0.05 was considered significant. All statistical analyses were performed using the SPSS Version 12.0 statistical package.

A successful outcome for relief of pain was defined as a 50% or greater reduction of the NRS; for functional impairment, success was defined as a 40% or more reduction of the ODI(%) [24]. For various clinical outcomes, alone and combination, success rates were calculated as the number of patients who achieved a successful outcome divided by the total number of patients treated.

Results

Table 1 shows the clinical and demographic data of all subjects. Their mean age was 35, with a range of 19–72 years. The mean duration of back pain was 17 months with a range of 6–80 months. Long-term follow-up ranged from 12–35 months with a mean of 17 months. Of the 47 patients, 22 had two or more disc lesions. All of them reported a positive response to provocation discography in one or two discs, which became the ones treated by PELAN. The other 25 patients had single disc lesions, of whom 20 patients (80%) reported positive responses to provocation discography of the index disc. Five patients had negative responses, but were nevertheless treated.

Table 2 summarizes the clinical outcomes of all subjects at short-term and long-term follow-up. At short-term follow-up, the mean scores (± standard deviation) for pain were reduced from 7.3 ± 1.0 to 2.8 ± 1.9; and scores for disability improved from 40.0 ± 10.3 to 18.0 ± 11.4. Four patients, however, had poor results and underwent surgery. These patients were censored from long-term follow-up, but were nevertheless included as failures in the calculation of success rates.

In the remaining 43 patients as a group, outcomes remained stable over time. Pain scores at short-term follow-up (2.6 ± 1.8) were not significantly different from those at long-term follow-up (2.2 ± 1.7) ($P = 0.25$). Likewise, disability scores were not different between short-term (17.0 ± 11.1) and long-term (14.2 ± 9.6) follow-up ($P = 0.22$).

In terms of categorical outcomes at long-term follow-up, 33 patients (70%; with 95% confidence intervals [CI] of 48–76%) achieved a successful outcome with respect to relief of pain. The same number and proportion had a successful outcome for disability. Eight patients obtained complete relief of pain, and three reported zero disability. Two patients had complete relief of pain coupled with complete restoration of function; five were completely relieved of pain coupled with improvement of function by more than 40%; and another 23 patients achieved at least 50% relief of pain coupled with at least 40% improvement of function.

With respect to the modified McNab criteria, at long-term follow-up the results were excellent in nine patients (19%), good in 16 patients (34%), fair in 13 patient (28%), and poor in seven patients (15%).

Before PELAN, all patients took oral analgesics for pain control. At long-term follow-up, of the 33 patients for whom PELAN provided 50% or greater relief of pain, 24 required no analgesics; eight required analgesics intermittently, and one frequently. Of the 10 patients in whom PELAN was not successful, one took no analgesics; six required analgesics intermittently, and three frequently.

If successful clinical outcomes are defined as simultaneously fulfilling all four criteria: 50% or greater reduction in pain, 40% or greater reduction in disability, good or excellent McNab criteria, and no need for analgesics, 23 patients (49%; 95% CI: 35–63%) achieved successful outcomes.

Serious complications were not observed. Eight patients suffered from increased back pain after PELAN, which diminished few days later. Two patients had leg weakness and five patients had tingling sensation of lower limb, but these resolved a few days later without any treatment.

Discussion

PELAN is a treatment specifically designed to treat discogenic LBP. Therefore, in order to test its effectiveness, it is critical that the sample treated does, indeed, have the index condition. In the present study, patients were screened for discogenic LBP on the basis of clinical features and MRI, but these were not relied upon to establish the diagnosis. Additional measures were taken. In the first instance, other sources of pain, which mimic discogenic LBP, were investigated and excluded using medial branch blocks and sacroiliac joint blocks. Thereafter, all patients underwent discography to confirm discogenic LBP.

Discography was positive in 42 of 47 patients (87%). Even allowing for a 10% false-positive rate, this figure provides an 80% confidence that the sample selected did have discogenic pain. The five patients who were negative to discography were nevertheless included for

Table 1 Demographic and clinical data of subjects

Patients number	Gender	Age	Lesion level	PELAN level	Duration of symptom	Follow-up period (months)	Discography	Decreased signal intensity	High-intensity zone	Modic change
1	F	44	L3/4 L4/5 L5/6	L3/4 L4/5	9	12	Positive	Present	Present	Absent
2	M	35	L5/6	L5/6	80	12	Positive	Present	Present	Absent
3	M	23	L5/6	L5/6	6	30	Negative	Present	Absent	Absent
4	M	22	L4/5	L4/5	24	26	Positive	Present	Absent	Absent
5	M	24	L3/4 L4/5	L3/4, L4/5	30	12	Positive	Present	Absent	Present
6	F	31	L3/4 L4/5	L3/4	6	12	Positive	Present	Present	Present
7	F	32	L3/4 L4-5	L3/4	6	35	Positive	Present	Absent	Absent
8	M	38	L2/3 L3/4 L4/5	L3/4 L4/5	6	22	Positive	Present	Present	Absent
9	F	35	L3/4 L4/5	L4/5	6	15	Positive	Present	Present	Absent
10	M	40	L4/5	L4/5	8	12	Negative	Present	Absent	Absent
11	F	19	L4/5	L4/5	36	12	Positive	Present	Absent	Absent
12	F	38	L3/4 L4/5 L5/6	L4/5	10	12	Positive	Present	Present	Absent
13	F	36	L3/4 L4/5 L5/6	L4/5	8	12	Positive	Present	Present	Absent
14	F	40	L4/5	L4/5	40	13	Positive	Present	Absent	Absent
15	M	26	L4/5	L4/5	12	22	Positive	Present	Absent	Absent
16	M	28	L4/5 L5/6	L4/5	8	12	Positive	Present	Absent	Absent
17	F	40	L4/5 L5/6	L4/5	38	27	Positive	Present	Absent	Absent
18	F	37	L4/5	L4/5	10		Positive	Present	Absent	Absent
19	F	24	L4/5	L4/5	24	22	Positive	Present	Present	Absent
20	F	21	L4/5	L4/5	20	12	Negative	Present	Absent	Absent
21	F	38	L4/5	L4/5	40	12	Positive	Present	Absent	Absent
22	F	41	L3/4 L4/5 L5/6	L4/5	45	12	Positive	Present	Present	Absent
23	F	42	L4/5	L4/5	50	12	Positive	Present	Absent	Present
24	M	60	L3/4 L4/5	L4/5	24	20	Positive	Present	Absent	Present
25	M	42	L3/4 L4/5 L5/6	L4/5	6	15	Positive	Present	Absent	Present
26	M	40	L3/4 L4/5	L4/5	8	12	Positive	Present	Absent	Present
27	F	54	L4/5	L4/5	6	13	Positive	Present	Present	Absent
28	M	26	L4/5	L4/5	6	13	Positive	Present	Absent	Absent
29	M	72	L3/4 L4/5 L5/6	L4/5	24	12	Positive	Present	Absent	Absent
30	M	32	L4/5	L4/5	12	12	Negative	Present	Absent	Absent
31	M	27	L4/5	L4/5	18	30	Positive	Present	Present	Absent
32	F	32	L4/5	L4/5	10	33	Positive	Present	Absent	Absent
33	F	27	L4/5	L4/5	6	23	Positive	Present	Absent	Absent
34	M	29	L4/5	L4/5	12	18	Positive	Present	Absent	Absent
35	F	33	L4/5	L4/5	6	16	Negative	Present	Absent	Absent
36	F	34	L5/6	L5/6	20	12	Positive	Present	Absent	Absent
37	M	37	L5/6	L5/6	6	18	Positive	Present	Absent	Present
38	M	31	L5/6	L5/6	7	19	Positive	Present	Absent	Absent
39	M	25	L4/5 L5/6	L5/6	7	20	Positive	Present	Absent	Absent
40	M	43	L5/6	L5/6	40	12	Positive	Present	Present	Absent
41	F	27	L4/5 L5/6	L4/5 L5/6	6	18	Positive	Present	Absent	Absent
42	F	26	L5/6	L5/6	6	18	Positive	Present	Absent	Absent
43	M	28	L4/5 L5/6	L5/6	6	12	Positive	Present	Absent	Absent
44	F	39	L5/6	L5/6	30	14	Positive	Present	Present	Absent
45	F	46	L3/4 L4/5 L5/6	L5/6	6		Positive	Present	Present	Present
46	M	20	L3/4 L4/5 L5/6	L5/6	6	13	Positive	Present	Absent	Absent
47	F	46	L3/4 L4/5 L5/6	L4/5 L5/6	8	12	Positive	Present	Absent	Absent

M=male, F: female; PELAN=percutaneous endoscopic lumbar annuloplasty and nucleoplasty.

treatment on the grounds that the false-negative rate of discography is not known, and it was not impossible for these patients to have had discogenic pain. Theoretically, it is conceivable that in some patients with discogenic pain, particularly those with little chemical sensitization, disc provocation with an injection could fail to generate sufficient intradiscal pressure to evoke mechanical nociception.

It transpired that including these five patients did not compromise the outcomes of treatment. At long-term follow-up, four had successful outcomes for relief of

Table 2 Clinical outcomes at short- and long-term follow-up after PELAN

Patients number	NRS at pretreatment	NRS at short term	NRS at long term	ODI(%) at pretreatment	ODI(%) at short term	ODI(%) at long term	MacNab at short term	MacNab at long term	Analgesics at long term*	Surgery†	Final success‡
1	8	2	2	42	18	18	Good	Good	No		success
2	7	1	0	40	6	15	Good	Good	No		success
3	6	3	2	36	6	10	Fair	Fair	No		success
4	8	5	2	40	30	12	Fair	Fair	Intermittent		failure
5	7	4	5	38	26	30	Poor	Poor	Frequent		failure
6	8	5	5	54	34	32	Fair	Good	Intermittent		failure
7	7	4	0	30	10	0	Fair	Good	No		success
8	7	3	2	35	6	4	Good	Good	No		success
9	8	5	1	44	12	22	Fair	Fair	No		failure
10	9	2	2	32	8	6	Good	Good	No		success
11	7	3	3	38	26	25	Fair	Fair	Intermittent		failure
12	9	1	2	30	10	12	Good	Good	Intermittent		failure
13	8	6	5	48	36	26	Poor	Good	No		failure
14	8	0	0	58	10	12	Excellent	Excellent	No		success
15	8	1	0	45	0	0	Excellent	Excellent	No		success
16	7	1	1	34	2	6	Excellent	Excellent	No		success
17	8	0	0	60	4	8	Excellent	Excellent	No		success
18	8	6		22	24		Fair			Done	failure
19	8	5	2	36	28	14	Good	Fair	Intermittent		failure
20	6	5	5	46	37	29	Fair	Fair	Intermittent		failure
21	7	0	1	51	8	8	Excellent	Excellent	No		success
22	7	4	2	38	26	18	Fair	Good	No		success
23	9	3	5	52	38	36	Fair	Poor	Frequent		failure
24	8	5	1	60	40	22	Fair	Fair	No		success
25	7	4	4	28	20	20	Fair	Poor	Intermittent		failure
26	8	5		30	26		Poor	Poor		Done	failure
27	8	3		58	22		Good	Poor		Done	failure
28	7	3	0	43	16	0	Good	Excellent	No		success
29	7	4	5	36	22	24	Fair	Fair	Intermittent		failure
30	7	0	0	30	6	2	Excellent	Excellent	No		success
31	5	1	1	20	4	6	Fair	Fair	Intermittent		failure
32	6	0	1	38	6	6	Fair	Good	Intermittent		failure
33	7	0	1	35	0	10	Good	Excellent	No		success
34	7	1	2	38	16	10	Good	Good	No		success
35	8	3	4	34	14	30	Good	Fair	Intermittent		failure
36	7	3	1	58	22	8	Fair	Fair	No		success
37	8	3	5	28	12	14	Good	Fair	Intermittent		failure
38	6	1	1	26	18	4	Good	Fair	Frequent		failure
39	6	2	0	32	12	6	Good	Excellent	No		success
40	8	6	5	30	30	32	Poor	Poor	Frequent		failure
41	7	4	4	35	22	13	Poor	Poor	Intermittent		failure
42	7	1	2	33	14	12	Good	Good	No		success
43	8	1	2	50	22	14	Good	Good	No		success
44	9	2	3	55	10	10	Good	Good	No		success
45	7	5		46	44		Poor			Done	failure
46	7	2	3	47	22	16	Good	Good	No		success
47	7	4	2	38	24	10	Fair	Good	Intermittent		failure

PELAN = percutaneous endoscopic lumbar annuloplasty and nucleoplasty.
*The patients required analgesics at the time of long-term follow-up after PELAN.
Intermittent: less than 3 days per week.
Frequent: more than 3 days per weeks.
†Surgical treatment was performed due to persistent pain after PELAN.
‡Final success meant the conditions that met all of these criteria: 50% or more reduction of NRS, 40% or more reduction of ODI(%), Good or Excellent response of MacNab criteria, no need for analgesics.

pain, and three had successful improvement of function (Table 2).

PELAN was not universally successful in the present study. A substantial proportion of patients did not benefit. The reasons for this are not evident and would need to be explored. Possibilities include insufficient removal or destruction of offending tissues, regeneration of inflammatory exudates, or persistence of other sources of pain within the affected disc that were not targeted for treatment.

Despite these failures, the success rate of PELAN was appreciable. Few patients had complete relief of pain, but 70% had at least 50% reduction in pain coupled with 40% improvement in disability; and 49% had 50% reduction in pain, 40% improvement in disability, and no further need for analgesics. These outcomes need to be viewed in the context of a cause of back pain for which there is no proven, effective treatment.

According to one cohort study of surgical treatment, at 1 year after surgery, about 50% of patients with discogenic LBP attained clinically successful results, defined as 30% reduction in pain and 30% improvement in Roland-Morris score [25]. This proportion was reduced to 33% if the criteria of clinical success were 30% reduction in pain, 30% improvement in Roland score, no opioid medication, and return to work [39]. Using the liberal criteria of visual analog scale less than 4, ODI less than 30, and no use of opioids, 43% of patients achieved successful outcomes [25].

The results obtained with PELAN rival these outcomes from surgery. Equal or greater success rates were achieved, but with more demanding criteria, such as 50% relief of pain rather than 30% relief. Meanwhile, as a minimally invasive procedure, PELAN avoids the risks of complications associated with surgery and general anesthesia. Therefore, PELAN might potentially be a viable alternative to surgery. However, certain steps need to be taken before PELAN is ready for wholesale use.

It is generally regarded that prospective data are more convincing than retrospective data, but in the present study, the potential flaws of retrospective studies were avoided. All patients who underwent the treatment were captured for assessment; outcome measures were uniformly applied; and no data were missing. Therefore, the present study is unlikely to misrepresent the expectable success rate of the treatment. In that regard, however, it needs to be shown that comparable results can be obtained by other operators in other populations.

Otherwise, it is customary for certain academic requirements to be satisfied. Optimal would be a randomized study with a sham control, which would corroborate success rates while also testing for non-specific effects of intervention, and for natural history. Such a trial might be difficult to mount, ethically and logistically, but has been achieved for other minimally invasive, intradiscal procedures [26–28]. Otherwise, a head-to-head comparison of PELAN with either conservative therapy or surgery would formally test for any advantages of PELAN over the only mainstream alternatives for discogenic LBP.

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