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Original Article

Efficacy of coblation nucleoplasty under CT-guidance in lumber paracentral disc herniation: parasagittal interlaminar vs posterolateral extrapedicular approach

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Abstract: Objective: To compare the efficacy of coblation nucleoplasty under computed tomography (CT) guidancein treating radicular pain related to lumbar disc herniation using the parasagittal interlaminar versus the posterolateral extrapedicular approach. Methods: This randomized, prospective, observational study included fifty-six patients with radicular pain who received coblation annuloplasty under CT guidance. Patients were randomized into two groups according to the approach used: the parasagittal interlaminar group (PIL group) or the posterolateral extrapedicular group (PEL group). The primary clinical outcome was pain assessed using the Visual Analog Scale (VAS). Secondary clinical outcomes were functional status according to modified MacNab criteria, and numbers of patients with significant pain relief (≥50%) and significant reduction (≥50%) in anesthetic intake. All outcome assessments were recorded for 12 months postoperatively. Results: The VAS had significantly decreased to 2.0±1.1 in the PIL group and 2.0±1.4 in the PEL group at postoperative 12 months. There was no significant difference between the two groups in VAS, modified MacNab criteria, or numbers of patients with significant pain relief (≥50%) or significant reduction (≥50%) in anesthetic intake. Five patients in the PIL group experienced cerebrospinal fluid leakage, but there was no significant difference in complication rate between groups. Conclusion: Under CTguidance, coblation nucleoplasty using either the parasagittal interlaminar or the posterolateral extrapedicular approach decreased pain intensity and improved modified MacNabcriteria in patients with radicular pain related to lumbar disc herniation. Both approaches were effective, safe, minimally invasive, and caused minimal discomfort.

Keywords: Coblation, nucleoplasty, lumbardisc herniation, interlaminar, parasagittal, posterolateral

Introduction

A compressed nerve root originating from a herniated disc is a common cause of radicular pain, which is a significant social and public health problem affecting quality of life [1, 2]. If radicular pain is unresponsive to conservative therapy, decompression of the affected nerve root using coblation nucleoplasty is recommended as a part of a stepwise treatment plan [3, 4]. However, different herniated locations can compress different nerve roots in the same disc level [5]; paracentral disc herniation compresses the traversing root (**Figure 1A**) and far lateral disc herniation compressesthe exiting root (**Figure 1B**). Hence, an appropriate approach is essential for coblation nucleoplasty to provide optimal decompressive effect at different sites of disc herniation.

Previous studies on coblation nucleoplasty have notprovided an explicit description of the location of disc herniation. Contrarily, for both far lateral and paracentral disc herniation, the posterolateral extrapedicular approach is commonly used for coblation nucleoplasty [6-30]. Although for paracentral disc herniation the targeted herniated site can also be reached using the parasagittal interlaminar approach, there has been no research published on coblation nucleoplasty using the parasagittal interlaminar approach in treating lumbar paracentral disc herniation. This may be because this approach carries the potential for iatrogenic injury of intraspinal structures including nerve roots, dural sac, spinal cord, and blood vessels.

Computed tomography (CT) guidance can provide axial images of excellent anatomic detail

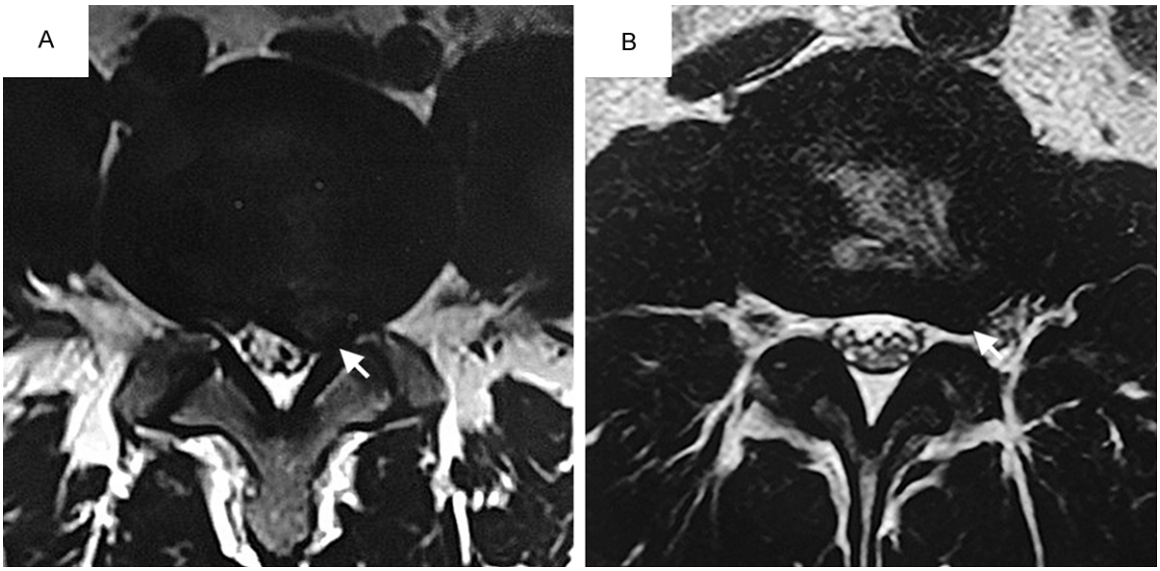

Figure 1. Paracentral disc herniation was indicated by white arrow (A); and far lateral disc herniation was indicated by white arrow (B).

for accurate needle placement, which can prevent accidental injury to intraspinal tissues [8]. In 2013, a study investigating lumbar radicular pain treated using the lateral parasagittal interlaminar approach for epidural injection confirmed the safety of this approach [31]. Therefore, the purpose of this study was to compare the therapeutic efficacy of the lateral parasagittal interlaminar approach with the posterolateral extrapedicular approach in CT-guided coblation nucleoplasty for treatment of lumbar paracentral disc herniation.

Methods

This clinical, randomized, prospective study was approved by the Ethics Examining Committee of Human Research at our institution. Fifty-six patients who complained of low back pain with radicular pain related to lumbar contained paracentral disc herniationprovided written informed consent and were scheduled to receive coblation nucleoplasty between October 2013 and December 2014.

Inclusion criteria

The inclusion criteria were as follows: (1) both sexes; (2) ≥18 years old; (3) low back pain with unilateral radicular pain and no neurological deficits such as sensory or motor deficits or loss of reflexes; (4) pain intensity of ≥4 rated using the Visual Analog Scale (VAS); (5) pain duration of ≥3 months; (6) short-term or no response to conservative management, including medication, physical therapy, and epidural injection therapies; (7) magnetic resonance imaging (MRI) findings showing a focal paracentral protrusion lying medial to the medial pedicle border (MPB), herniated disc ≤6 mm, and disc height of ≥50%; and (8) selected nerve root block confirming a compressed traversing nerve root at the suspected disc protrusion level.

Exclusion criteria

The exclusion criteria were as follows: (1) infection; (2) spinal tumor or fracture; (3) disc herniation with sequestration or spinal instability; (3) coagulopathy; (4) history of surgery on the spine at the same lumbar level; (5) drug abuse; (6) allergy to local anesthetics; (7) psychological or psychiatric disorders; (8) unwillingness to participate in the study.

All patients were randomly divided into either the parasagittal interlaminar group (PIL group) or the posterolateral extrapedicular group (PEL group) using a computer-generated table of random numbers that were kept in opaque sealed envelopes and opened by a nurse not involved in the study. The patients were blinded to their group assignment (**Figure 2**).

Therapeutic procedures

After entering the sterile operating room, all patients received standard monitoring of heart

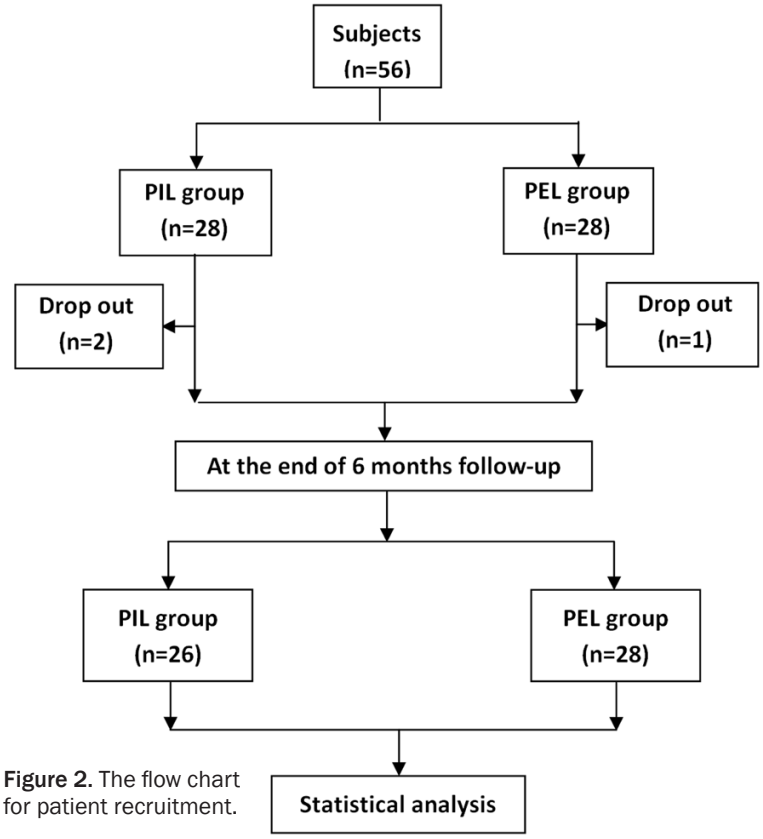

Figure 2. The flow chart for patient recruitment.

and respiratory rate, and fingertip digital oximetry. An intravenous injection of etimicin (1.0 g) and fentanyl (50 μg) was administered prophylactically 30 min prior to surgery to provide analgesia, but no other sedatives were administered; this kept the patient conscious and able to respond to nerve root stimulation during surgical procedures.

All patients were placed in the lateral position on the CT table, and radiopaque marks were made on the skin at the posterior median of the spinal column. Axial CT slices were taken through the area of interest at 1 mm increments to enable precise selection of the necessary pathway. The approach needle entry point was identified and marked on the skin before preparation. After sterilization of the surgical area, 5 ml of 10 mg/ml lidocaine without adjuvants was injected subcutaneously for local analgesia. In the PIL group, a T12-gauge, 15-cm introducer needle was advanced via the left or right parasagittal interlaminar approach to the target disc (**Figure 3A**). In the PEL group, a T12-gauge, 15-cm introducer needle was advanced via the left or right posterolateral extrapedicular approach to the target disc (**Figure 3B**). Under intermittent CT guidance, the introducer needle was inserted slowly until the tip reached the posterior annulus-nucleus junction; the advancement was stopped immediately if the patient reported twitch movement or paresthesia in the corresponding lower limb. The coblation wand (UNITEC, China America United Technology (Beijing) Co. Ltd, China) was inserted into the introducer needle until its tip was extended approximately 10 mm beyond the tip of the needle. Test coagulation was performed with the radiofrequency controller set at 2' for 0.5-1 second to ensure no limb movement or paresthesia occurred. Nucleoplasty was accomplished by creating six channels at the 12, 2, 4, 6, 8 and 10 o'clock positions circumferentially through advancement in ablation mode at 2' intensity and retraction in coagulation mode at 2' intensity. The coblation wand was then withdrawn, and 2 ml of 0.5% lidocaine was injected along the introducer needle tract.

All patients were instructed to remainin bed in the supine position for at least 48 h postoperatively. After discharge from the hospital, patients were instructed to avoid bending of the neck and strenuous activities for 1 month postoperatively.

Therapeutic efficacy assessment

The primary outcome was the pain VAS score, ranging from 0 (no pain) to 10 (worst pain); this was recorded at 1 week, and 1, 3, 6, and 12 months postoperatively.

The following variables were recorded as the secondary outcomes. The patients' functional status was evaluated as "excellent", "good", "fair", or "poor" according to the modified MacNab criteria and recorded at 1, 3, 6, and 12 months postoperatively. The numbers of patients with significant relief (≥50%) of pain

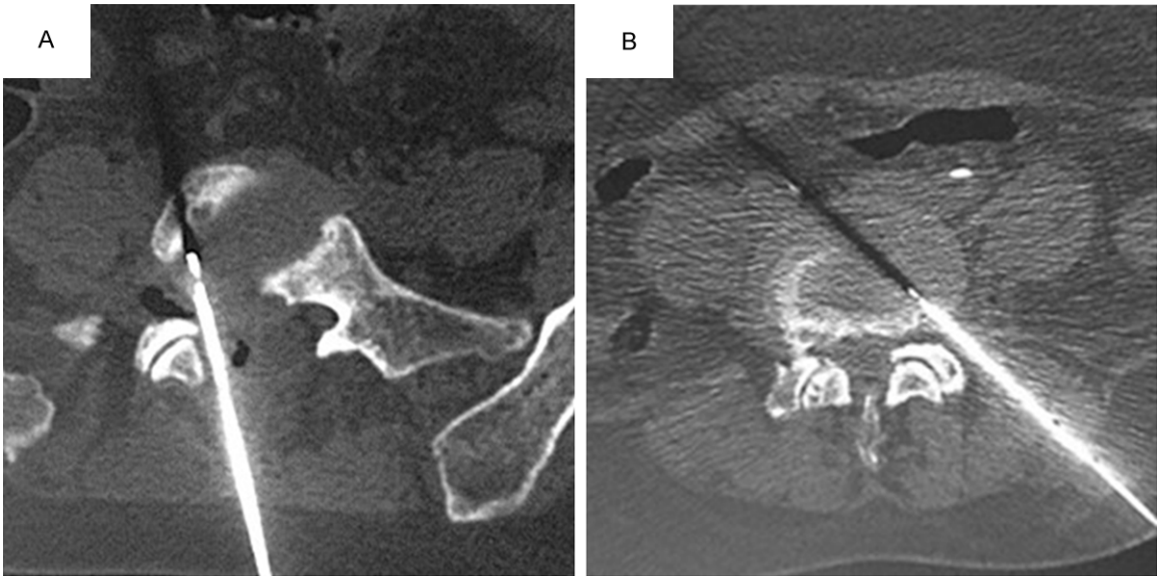

Figure 3. The tip of coblation wand was advanced beyond the posterior annulus-nucleus junction at L5/S1 in parasaggital interlaminar approach (A); and the tip of coblation wand was advanced beyond the posterior annulus-nucleus junction at L4/5 in posterolateral extrapedicular approach (B).

Table 1. Demographic characteristics, pain VAS of preoperative 1 day, pain duration and treated disc level

	PIL Group	PEL Group
Gender n(%)		
Male	11 (42.3)	14 (51.9)
Female	15 (57.7)	13 (48.1)
Age (years)	45±11.0	48±12.0
Weight (kg)	67.9±12.1	64.9±10.1
Height (cm)	171.6±9.5	167.6±11.5
Pain VAS	6.2±0.9	6.2±0.9
Pain duration (years)	4.1±2.1	3.6±2.6
treated disc level n (%)		
L4/5	10 (38.5)	12 (44.4)
L5/S1	16 (61.5)	15 (55.6)

and significant reduction (≥50%) in anesthetic intake were recorded at 1 week and 1, 3, 6, and 12 months postoperatively. Complications such asnerve root injury, dural sac injury, infection, and paresthesia were also recorded.

Statistical analysis

We needed a sample size of 25 per group to obtain a power of 90% to show a difference of six points on the VAS between the two groups at the 5% significance level (two-tailed). Taking into account a potential dropout rate of 10% (three patients), we increased the sample size to 28 per group. Complete data were acquired in 57 patients (two cases dropped out in the PIL group and one case in the PEL group). All data were processed using SPSS version 19.0. The statistical methods used were general statistical descriptions (such as the mean and standard deviation), Mauchly's test, and multi-way repeated measures analysis of variance followed by Fisher's least significant difference test for post hoc multiple comparisons. Statistical significance was accepted at the level of $P<0.05$.

Results

The demographic characteristics, pain VAS on preoperative day 1, pain duration, and treated disc level are shown in **Table 1**. No significant difference was observed between the two groups preoperatively.

Pain VAS

In the PIL group, the pain VAS significantly decreased from 6.2±0.9 preoperatively to 1.7±1.0 at 1 week postoperatively, and 1.7±1.0, 1.8±1.0, 1.9±1.1, and 2.0±1.1 at 1, 3, 6, and 12 months postoperatively, respectively. In the PEL group, the pain VAS significantly decreased from 6.2±0.9 preoperatively to 2.0±1.4 at 1

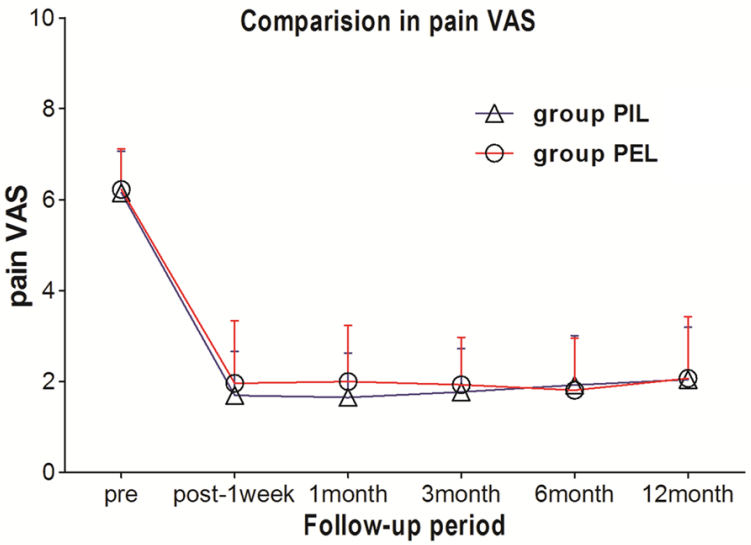

Figure 4. The pain VAS was presented at preoperative 1 day, postoperative 1 week and 1, 3, 6, 12 month in two groups.

Table 2. The efficacy of treatments during 6 months follow-up

		PIL Group (n, %)	PEL Group (n, %)	*P* value
Post-operative 1 month	Excellent	12 (46.2)	10 (37.0)	0.361
	Good	8 (30.8)	8 (29.6)	
	Fair	5 (19.2)	6 (22.2)	
	Poor	1 (3.8)	3 (11.1)	
Post-operative 3 month	Excellent	10 (38.5)	10 (37.0)	0.540
	Good	11 (42.3)	8 (29.6)	
	Fair	4 (15.4)	8 (29.6)	
	Poor	1 (3.8)	1 (4.0)	
Post-operative 6 month	Excellent	9 (35.0)	10 (37.0)	0.932
	Good	11 (42.3)	10 (37.0)	
	Fair	3 (11.5)	5 (18.5)	
	Poor	3 (11.5)	2 (7.4)	
Post-operative 12 month	Excellent	9 (35.0)	10 (37.0)	0.978
	Good	10 (38.5)	9 (33.3)	
	Fair	4 (15.4)	5 (18.5)	
	Poor	3 (11.5)	3 (11.1)	

week postoperatively, and 2.0±1.2, 1.9±1.0, 1.8±1.1, and 2.1±1.4 at 1, 3, 6, and 12 months postoperatively, respectively. No statistical difference was observed between the two groups at anytime-point (**Figure 4**).

Modified MacNabscore

In both groups, there was no significant change in the proportion of patients rated as "excellent", "good", "fair" and "poor" during the 12 months of follow-up. In the PIL group, the number of "excellent" ratings at postoperative 1, 3, 6 and 12 months, respectively, was 12 (46.2%), 10 (38.5%), 9 (35.0%), and 9 (35.0%); "good" was 8 (30.8%), 11 (42.3%), 11 (42.3%), and 10 (38.5%); "fair" was 5 (19.2.1%), 4 (15.4%), 3 (11.5%), 4 (15.4%); and "poor" was 1 (3.8%), 1 (3.8%), 3 (11.5%) and 3 (11.5%). In the PEL group, the number of assessments rated as "excellent" at postoperative 1, 3, 6 and 12 months, respectively, was 10 (37.0%), 10 (37.0%), 10 (37.0%), 10 (37.0%); "good" was 8 (29.6%), 8 (29.6%), 10 (37.0%), and 9 (33.3%); "fair" was 6 (22.2%), 8 (29.6%), 5 (18.5%), 5 (18.5%); and "poor" was 3 (11.1%), 1 (4.0%), 2 (7.4%) and 3 (11.1%) (**Table 2**).

Significant painrelief (≥50%)

The PIL group and the PEL group had similar numbers of patients who experienced significant pain relief (≥50%) during the 12 months of follow-up (P>0.05). At postoperative 1 week, and 1, 3, 6, and 12 months, respectively, 20 (76.9%), 20 (76.9%), 21 (80.8%), 20 (76.9%), and 19 (73.1%) patients in the PIL group expressed significant pain relief, compared with 20 (74.1%), 18 (66.7%), 18 (66.7%), 20 (74.1%), and 19 (70.4%) patients in the PEL group (**Table 3**).

Significant reduction (≥50%) in anesthetic intake

In both groups, there was no significant change in the number of patients with significant reduction (≥50%) in anesthetic intake during the 12 months of follow-up (P>0.05). At postoperative 1 week, and 1, 3, 6, and 12 months postoperatively, 25 (96.2%), 25 (96.2%), 25 (96.2%), 23 (88.5%), and 23 (88.5%) patients, respectively,

Table 3. The proportion of significant relief (≥50%) in pain during 6 months follow-up

	PIL Group (n, %)	PEL Group (n, %)	*P* value
Post-operative 1 week	20 (76.9)	20 (74.1)	1.0
Post-operative 1 month	20 (76.9)	18 (66.7)	0.5444
Post-operative 3 month	21 (80.8)	18 (66.7)	0.3520
Post-operative 6 month	20 (76.9)	20 (74.1)	1.0
Post-operative 12 month	19 (73.1)	19 (70.4)	1.0

Table 4. The proportion of significant reduction (≥50%) in anesthetics intake during 6 months follow-up

	PIL Group (n, %)	PEL Group (n, %)	*P* value
Post-operative 1 week	25 (96.2)	23 (85.2)	0.3507
Post-operative 1 month	25 (96.2)	24 (88.9)	0.6104
Post-operative 3 month	25 (96.2)	26 (96.3)	1.0
Post-operative 6 month	23 (88.5)	25 (92.6)	0.6687
Post-operative 12 month	23 (88.5)	24 (88.9)	1.0

experienced a significant reduction in anesthetic intake in the PIL group, compared with 23 (85.2%), 24 (88.9%), 26 (96.3%), 25 (92.6%), and 24 (88.9%) patients, respectively, in the PEL group (**Table 4**).

Complications

In the PIL group, five patients experienced cerebrospinal fluid leakage during the puncture process, one patient experienced moderate headache, one patient experienced ecchymoma, and four patients reported soreness. In the PEL group, two patients experienced ecchymoma, and six patients reported soreness. There was no statistically significant difference in complication rate between the two groups.

Discussion

We reported the clinical outcomes of CT-guided coblation nucleoplasty via the parasagittal interlaminar or the posterolateral extrapedicular approach in treating radicular pain related to paracentral disc herniation. Both approaches were associated with significant reduction in pain and improvement in modified MacNab score during 12 months of follow-up. However, the reduction in pain VAS score after coblation nucleoplasty via the parasagittal interlaminar approach was similar to that obtained via the posterolateral extrapedicular approach, and there were similar modified MacNab scores and pain relief observed using either approach. Although cerebrospinal fluid leakage caused by unintentional dura mater laceration during the puncture process occurred in five patients in the PIL group, the complication rate was similar in both groups.

Minimally invasive coblation nucleoplasty was approved by the US Food and Drug Administration in 1999, and was first performed in 2000. Encouraging clinical outcomes have been published on the use of coblation nucleoplasty to treat contained lumbar disc herniation and associated symptoms via depression of the nerve root, reduction of intradiscal pressure, and interruption of nociceptors in the nucleus or annulus [30]. Previous studies have used the posterolateral extrapedicular approach as the first choice in coblation nucleoplasty; this may be due to the relative safety of conducting the puncture within Kambin's triangle, in which the hypotenuse is the exiting nerve root, the base (width) is the superior border of the caudal vertebra, and the height is the dura/traversing nerve root [32].

In the present study, there was a significant decrease in pain VAS score from 8 preoperatively to 1 at the 12-month follow-up in the PEL group. Furthermore, 23 PEL group patients reported significant relief in radicular pain at 12 months postoperatively. The present clinical outcomes are consistent with recent studies. In 2015, CT-guided nucleoplasty resulted in a significant decrease in Numeric Rating Scale pain score and Oswestry Disability Index (ODI) values for patients with radicular pain [8]. In 2013, coblation nucleoplasty was proved to be effective for relieving the associated symptoms secondary to lumbar disc herniation [9, 12]. In 2012, a prospective study investigating the efficacy of nucleoplasty in terms of pain assessed via the VAS score and quality of life assessed via the ODI index reported that 65% of patients showed good results at the 12-month follow-up [14]; similar satisfactory clinical outcomes were published in another four studies in 2011 [16-19]. Therefore, the clinical effectiveness of coblation nucleoplasty via the posterolateral extrapedicular approach in treating lumbar disc degeneration-related pain has been confirmed.

Although the posterolateral extrapedicular approach has been used for over a decade in coblation nucleoplasty, puncture difficulty may potentially be encountered in some special cases, such as those with a high iliac crest, facet hyperplasia or narrowing of the intervertebral space [33]. According to the anatomic structures of the lumbar spine, the introducer needle also can be inserted into discsvia the parasagittal interlaminar approach. However, this approach is only potentially suitable for paracentral disc herniation, not far lateral disc herniation. To date, the therapeutic efficacy of coblation nucleoplasty via the parasagittal interlaminar approach to treat paracentral disc herniation-related pain remains uncertain.

In the present study, we first performed coblation nucleoplasty to treat paracentral disc herniation-related pain via the parasagittal interlaminar approach under CT guidance. We defined paracentral disc herniationasa focal paracentral protrusion lying medial to the MPB on MRI [5]. The PEL group and the PIL group showed similar decreases in pain VAS score at the 12-month follow-up. At postoperative 12 months, up to 25 patients expressed significant relief in radicular pain, and no unintended nerve root or spinal cord injury was reported. These encouraging clinical outcomes may have benefited from the following: (1) CT guidance provided distinct images to avoid damaging nerve roots, dural sac, and the spinal cord during the puncture process [8, 34]; (2) a steep drop-off in temperature from the tip of the Perc-D wand prevented inadvertent heat injury of the nerve root or spinal cord during the nucleoplasty process [35].

Five patients in the PIL group experienced cerebrospinal fluid leakage during the puncture process, which possibly originated from unintentional dura mater laceration. After 2 days of strict bedrest and intravenous infusion, only one patient complained of moderate headache; this headache was completely relieved by postoperative day 5. One and two patients experienced ecchymoma in the PIL group and the PEL group respectively, and four and six patients reported soreness at the needle insertion site in the PIL group and the PEL group respectively. These symptoms had completely resolved at postoperative 2 weeks, which is similar to the known clinical outcomes of side effects associated with coblation nucleoplasty [36].

One of the limitations of this study is that the comparison was made only between patients who received nucleoplasty via the parasagittal interlaminar approach or the posterolateral extrapedicular approach, without a placebo group. However, it is unethical to enroll patients with serious pain in a placebo group. In addition, this comparison of the two approaches is justifiable as no previous randomized study has evaluated the clinical outcome of nucleoplasty via the parasagittal interlaminar approach. Another limitation is that all patients were followed up for only 12 months postoperatively, so it is hard to say whether nucleoplasty via the parasagittal interlaminar approach can provide long-term pain relief; further research is needed to confirm this. Despite these limitations, the present study demonstrated the feasibility of nucleoplasty via the parasagittal interlaminar approach in treating paracentral disc herniation-related pain.

Conclusion

Coblation nucleoplasty via the parasagittal interlaminar approach or the posterolateral extrapedicular approach provided dramatic improvement in pain intensity and modified MacNabcriteria in patients with radicular pain related to lumbar disc herniation. These improvements were similar using both approaches. No serious iatrogenic injury of intraspinal structures was reported using the parasagittal interlaminar approach. Under CT guidance, coblation nucleoplasty via either the parasagittal interlaminar approach or the posterolateral extrapedicular approach is an effective, safe, minimally invasive procedure that causes minimal discomfort.

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Disclosure of conflict of interest

None.

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