original article

Fluoroscopically guided interlaminar needle for lumbar disc herniation: a series of 43 patients

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BACKGROUND: Lumbar disc herniation (LDH) is the most common cause of back and leg pain. We developed a specially designed needle and a minimally invasive interventional procedure to treat LDH.

OBJECTIVES: Assess outcomes of procedure and describe our methodology and clinical application.

DESIGN: Case series.

SETTING: A chronic pain management center.

PATIENTS AND METHODS: Patients with LDH underwent fluoroscopically guided interventional interlaminar needling using a specially designed curved round needle. The outcome measures were evaluated three times: before the intervention and at 6 and 12 months after the intervention.

MAIN OUTCOME MEASURES: Visual analog scale (VAS) pain score, Oswestry Disability Index (ODI).

SAMPLE SIZE: 43 patients.

RESULTS: Six months after the intervention, the VAS pain score decreased by 5.1 (2.2) points and the ODI decreased by 30.7% (16.6%) compared to baseline. Twelve months after the intervention, the VAS pain score decreased by 6.2 (1.7) points and the ODI decreased by 36.9% (15.2%) compared to baseline.

CONCLUSIONS: This study suggests that fluoroscopically guided interventional interlaminar needling has clinical significance in managing pain resulting from LDH.

LIMITATIONS: This was an exploratory case series study. Additional studies and randomized clinical trials are needed to evaluate the efficacy of the technique compared to other treatments.

CONFLICT OF INTEREST: None.

About 70% to 85% of all people experience back or radicular pain at some time during life.[1] The economic and public health burdens of back disorders are enormous.[2] Lumbar disc herniation (LDH) is the most common cause of back and leg pain in adults.[3] Nonsurgical methods such as medication, physical therapy, manual therapy, and epidural steroid injection are recommended as first-line treatments for LDH. However, for patients experiencing severe pain while receiving nonsurgical treatment or having progressive neurological deficits, spinal surgery is recommended.

Dry needling has been used to manage musculoskeletal disorders.[4] Chu reported significant reductions in radiculopathic pain after electromyographic needling.[5] James et al used dry needling to treat patellar tendinosis.[6] A randomized controlled trial showed that it effectively treated plantar heel pain.[7] The procedure is believed to trigger autonomic vasodilation and lower the pain level.[8] Hypodermic, electromyographic, or acupuncture needles are used in these dry needling treatments. However, these needles have drawbacks as treatment tools: hypodermic needles have a sharp bevel and a cutting edge, so they may cause unintended damage to the surrounding tissue at the treatment site; while electromyographic and acupuncture needles are short, thin, and bend easily, so it is difficult to provide effective treatment to deep or firm structures, including the intervertebral discs.

We developed a specially designed needle to use in a minimally invasive interventional procedure for the treatment of musculoskeletal disorders, including adhesive capsulitis of the shoulder,[9,10] lumbar spinal stenosis,[11] and instability.[12] We describe our method and the clinical application of the procedure to treat LDH.

PATIENTS AND METHODS

We enrolled patients who visited the Ahnkang Hospital for Pain Free: 327, Eonju-ro, Gangnam-gu, Seoul, Korea between November 2013 and October 2014. All were diagnosed with LDH and visual analog scale pain scores were ≥4; pain thus ranged from moderate to very severe. We excluded patients with tumors, infections, or progressive neurological deficits, or who were pregnant. This study was not supported by any individual or organization and there are no financial conflicts of interest to disclose. The Institutional Review Board of CHA University approved the study protocol (approval no. 201605-HR-011–01).

Physiotherapy (n=25), nerve block (n=24), medication (n=16), and acupuncture (n=16) were the four most frequent previous treatments. Three patients had undergone lumbar surgeries before the intervention. We took comprehensive medical histories, physically examined the lumbar spine, and obtained MRI scans. We comprehensively explained the benefits and potential risks (e.g., infection, bleeding, and post-dural puncture headache) of our intervention; all patients gave written informed consent prior to treatment.

Needle

Figure 1 shows the specially designed round needle (Hansung Precision, Siheung, Korea). The needle is streamlined with a solid but flexible body, a blunt and round curved tip, about 1.2 mm in diameter and 140 mm long, and made of stainless steel. We placed a triangular handle on the side opposite the curved tip to facilitate manipulation. A circular yellow marker was attached to the handle to identify the side of the curved tip. The needle is patented in Korea (patent no. 10–2004–41689).

Procedure

The patients were placed on a table in the prone position. A pillow was placed under the abdomen to minimize lumbar lordosis and widen the interlaminar space. A C-arm fluoroscope was used to identify the

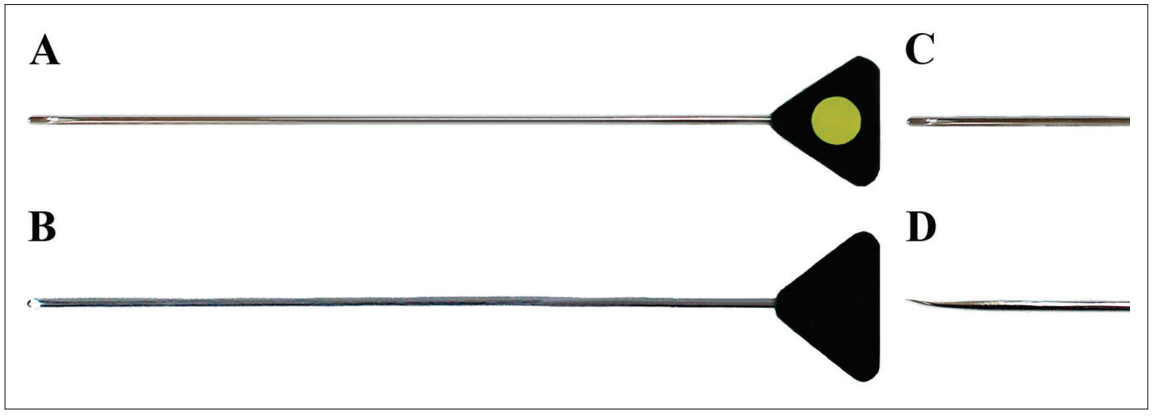

Figure 1. A: Front of the curved round needle; B: The back of the curved round needle; C: Close-up view of tip of the round needle; D: Close-up side-view of tip of the round needle.

interlaminar space in anteroposterior view and an image intensifier was adjusted cranially or caudally to obliterate any double end plates. The target treatment points were marked and sterilized, and patients were sedated with intravenous propofol. Before the intervention, the operator evaluated magnetic resonance images of the patient and determined individual needle entry point(s) and the pathway of the curved round needle (**Figure 2A**). The needle was placed at the contralateral caudal side of the interlaminar space against the target lesion, which was predetermined before the intervention. It was advanced medially and cranially angled 45° to 70° from the horizontal plane and 10° to 30° from the transverse plane toward the point where the superior end plate and medial side of the pedicle interfaced with the concave surface facing the contralateral side (**Figures 2B and 2C**). After the needle passed the lateral aspect of the interlaminar space and contacted the superficial border of the facet joint, the C-arm was turned to the lateral view and it was turned with the concave surface facing the ipsilateral side (**Figures 2D and 2E**). The needle was advanced further toward the point where the superior end plate and posterior side of the vertebral body interfaced (**Figure 2F**). During the passage of the needle through the facet joint, the operator held the needle close against the internal wall of the facet joint, so that it passed between the ligamentum flavum and the internal wall of the facet joint. The needle was moved back and forth a few millimeters several times until a marked reduction in resistance was felt at the tip of the needle. We performed interventions at 1-month intervals until pain and disability improved by ≥50% compared to baseline. The maximum number of interventions was five and the maximum treatment time 6 months.

Outcome measurement and data analyses

We used two outcome measures in this study to evaluate the results; the visual analog scale (VAS) pain score and the Oswestry Disability Index (ODI). The outcome measures were evaluated three times in this study: before the intervention and at 6 and 12 months after the intervention.

We used Wilcoxon's signed-rank test to evaluate the statistical significance of differences in outcomes.

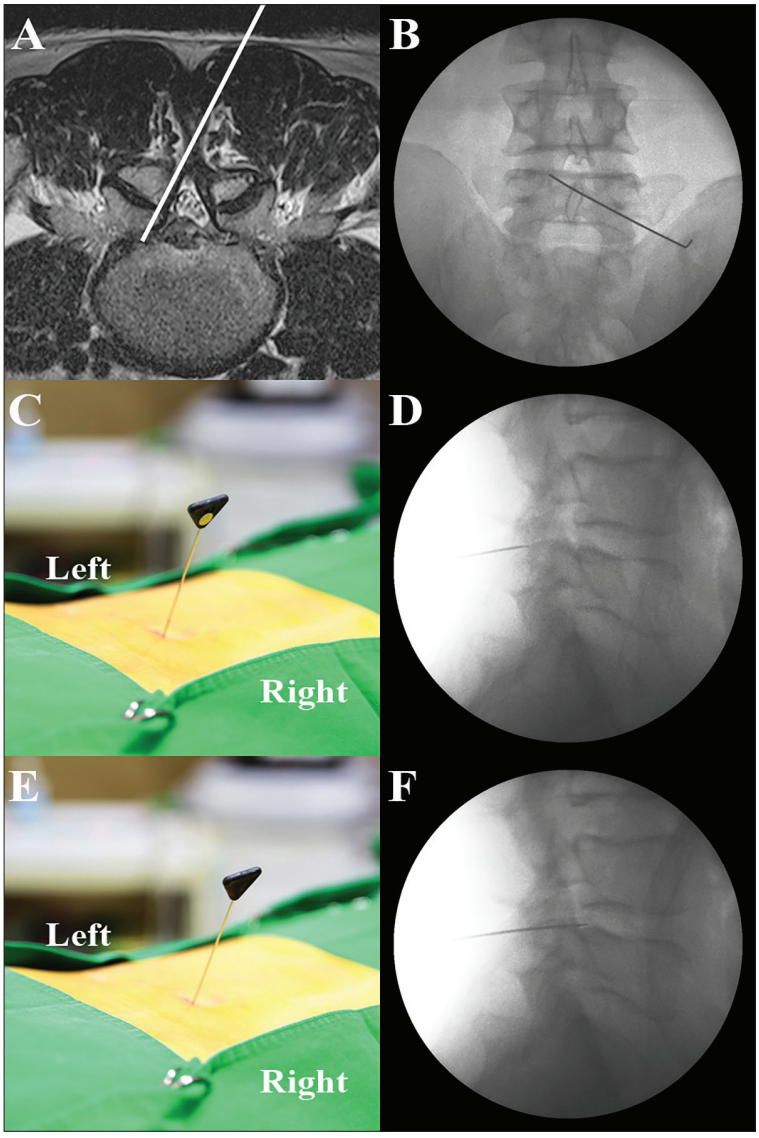

Figure 2. A: MRI image of patient. The white line indicates pathway of the curved round needle for the treatment of left L4-L5 lumbar disc herniation; B: AP C-arm fluoroscopic image of a patient undergoing intervention; C: The curved round needle advancing toward the point where the superior end plate and medial side of the pedicle interfaced with the concave surface facing the contralateral side; D: Lateral C-arm fluoroscopic image when the needle passed the lateral aspect of the interlaminar space and contacted the superficial border of the facet joint; E: The curved round needle was turned with the concave surface facing the ipsilateral side after contacting the superficial border of the facet joint; F: Lateral C-arm fluoroscopic image showing further advancement of the needle toward the point where the superior end plate and posterior side of the vertebral interfaced

RESULTS

We enrolled 43 consecutive patients (27 males and 16 females). The average age of the patients was 46.0 (14.9) years (43.7 [13.4] for men, 50.1 [16.9] for women). The average duration of pain prior to treatment was 29.8 (50.9) months (22.6 [36.5] for men, 41.9 [68.4] for women). L4–5 right (69.8%), L4–5 left (67.4%), L5–S1 right (30.2%), and L3–4 left (25.6%) were the most common treatment levels in the patients. Four patients (9.3%) underwent treatment only once, 13 (30.2%) underwent treatment twice, 23 (53.5) were treated three times, and 3 (7.0%) were treated four times (**Table 1**).

The mean (standard deviation) for the VAS pain score before the intervention was 7.4 (1.5) points and the average percentage disability of ODI before the intervention was 41.8% (15.7%). Six months after the intervention, the average VAS score decreased by 5.1 (2.2) points ($P<.0001$) and the average percentage disability of ODI decreased by 30.7% (16.6%) ($P<.0001$) compared to baseline. Twelve months after the intervention, the mean VAS score decreased by 6.2 (1.7) points ($P<.0001$) and the average percentage disability of ODI decreased by 36.9% (15.2%) ($P<.0001$) compared to the baseline (**Table 2**) No significant complications or fatal adverse events occurred following treatment. Furthermore, none of the patients required medical treatment after 12 months of intervention.

DISCUSSION

We conducted fluoroscopically guided interventional interlaminar needling using a specially designed curved round needle in 43 patients with LDH. Outcome measures improved significantly in all patients with this intervention. These results suggest that fluoroscopically guided interventional interlaminar needling has clinical significance in managing pain resulting from LDH.

The technique was developed based on our clinical experience in interventional treatment of lumbar spinal pain using a specially designed round needle. We have reported interventional transforaminal needling procedures using the needle for the treatment of lumbar spinal pain.[11,12] We applied the transforaminal needling approach for the treatment of lumbar spinal pain, including LDH. Although most of the patients with lumbar spinal pain reported improved clinical outcomes after receiving a transforaminal needling approach, some patients did not experience improvement. Therefore, a new interventional procedure different from the transforaminal approach was necessary, and we conceived an interlaminar approach.

The muscle tightness that usually accompanies LDH is attributable to neuronal hypersensitivity caused by the herniated disc. Kang et al reported that herniated intervertebral discs produced inflammatory cytokines and that these induced hypertrophy of the ligamentum flavum.[13] Therefore, we suggest that lower back muscle tightness and hypertrophy of the ligamentum flavum may explain the resistance encountered by the tip of the needle as it was moved.

Table 1. Clinical data on the 43 patients.

Clinical data	N (%)
Sex	
Male	27 (62.8)
Female	16 (37.2)
Age (years)	
≤29	3 (7.0)
30–39	13 (30.2)
40– 49	10 (23.3)
50–59	9 (20.9)
60–69	5 (11.6)
70–79	3 (7.0)
Pain duration (months)	
≤12	25 (58.1)
13–24	7 (16.3)
> 24	11 (25.6)
Treatment level	
L3–4 Right	4 (9.3)
L3–4 Left	11 (25.6)
L4–5 Right	30 (69.8)
L4–5 Left	29 (67.4)
L5–S1 Right	13 (30.2)
L5–S1 Left	6 (14.0)
Number of treatments	
1	4 (9.3)
2	13 (30.2)
3	23 (53.5)
4	3 (7.0)

Table 2. Treatment responses.

Outcome Measure	Baseline	Six months after intervention		Twelve months after intervention	
Visual analog scale pain score (points)	7.4 (1.5)	2.2 (2.1)	$P< .0001$	1.2 (1.1)	$P<.0001$
Oswestry Disability Index (% disability)	41.8 (15.7)	11.1 (13.1)	$P< .0001$	5.3 (7.0)	$P<.0001$

Data are mean (standard deviation). Statistical comparisons are to baseline.

The back and forth movement of the needle may transfer mechanical stimulation to structures of the lumbar spine along its entire course, thus including the back muscles, the ligamentum flavum, nerve root, dorsal root ganglion, and dura mater, which are irritated by the herniated disc. We feel that mechanical stimulation from the movement of the needle provokes neuronal impulses to the structures that are irritated by the herniated disc, and these impulses may be transmitted to the central nervous system (i.e., spinal cord and brain), which becomes sensitized in response to disc degeneration and changes in neuronal modulation.[14] We infer that the reduction in resistance felt at the tip of the needle after needling resulted not only from muscle relaxation because of a neuronal reflex induced by mechanical stimulation from movement of the needle, but also because of partial breakdown of the tight muscles and the hypertrophied ligamentum flavum. Needling produces minute wounds, generating a current of injury continuously for several days or weeks, which promotes the natural healing process. Therefore, we hypothesize that our intervention reduces neuronal hypersensitivity and promotes the natural healing process, resulting in the alleviation of pain resulting from LDH.

The lateral recess is a principal compression site in the lumbar spine,[15] where the lateral margin of the nerve root sleeve contacts the medial cortical bone of the pedicle. In our experience with epiduroscopy of the lumbar spine, abnormal findings, including epidural inflammation, fibrosis, and obliteration of fatty tissue, are usually found at the lateral recess.[12] The pathway presented here safely leads the needle to the lateral recess. The pathway was determined based on a thorough review of anatomy and a long period of clinical experience in interventional needling. Prior to selecting the pathway of the needle presented in this study, we used other pathways and experienced several cases of dural puncture. However, no significant or fatal complications, including dural puncture, occurred in any of the patients in this study while undergoing the intervention or during follow-up after selecting the needle pathway presented here. Key safety measures are following the exact pathway of the needle, adherence of the needle between the ligamentum flavum and the internal wall of the facet joint, gentle manipulation, and clinical experience in interventional needling. Improvement after the intervention might have been due to natural resolution of LDH and a co-treatment effect rather than a needling effect. But given the severe pain and disability of all patients at baseline, we suggest that the improvements are not readily explained by natural resolution of LDH. Most patients received our intervention only, and did not receive co-treatments. We taught all patients exercises that might relieve back pain, but prescribed only minimal medications. Therefore, we believe that the improvements are attributable to our intervention.

Several limitations should be taken into consideration when interpreting the results of this study. The design of this study, a case series and thus exploratory, poses a limitation; additional studies or randomized clinical trials are needed to evaluate the efficacy of our technique compared to other treatment methods for LDH.

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