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*Original Article*

# Clinical effect of needle knife injection under C-arm X-ray-imaging guidance for the treatment of lumbar disc herniation

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**Abstract:** Objective: To compare the clinical outcomes of needle knife injection (into the intervertebral foramen) and release under C-arm X-ray-imaging guidance with those of simple injection into the intervertebral foramen for the management of lumbar intervertebral disc herniation (LDH). Methods: Sixty patients with single-segment LDH, either L4/5 or L5/S1, were recruited and randomly divided into two groups. Thirty patients underwent needle knife injection into the intervertebral foramen under C-arm X-ray-imaging guidance, plus release therapy, and 30 patients underwent transforaminal nerve block only under C-arm X-ray-imaging guidance. Patients were assessed using the Evaluation Criteria for Lumbago of the Japanese Orthopedic Association (JOA) and visual analogue scale (VAS) pain scores, before treatment and at 1 week, 1 month, and 6 months after treatment. Results: There were no significant differences in the JOA scores between the two groups before treatment ($P = 0.553$). One week, 1 month, and 6 months post-treatment (all $P < 0.001$), the JOA score in the needle knife injection group was higher than that in the simple injection group. The VAS scores in the two groups before treatment were not statistically significantly different ($P = 0.812$). However, 1 week, 1 month, and 6 months post-treatment (all $P < 0.001$), the needle knife injection group had lowerer VAS scores than the simple injection group. Conclusion: Needle knife injection into the intervertebral foramen under the guidance of C-arm X-ray imaging is superior to release and simple intervertebral foramen injection for the treatment of LDH.

**Keywords:** C-arm X-ray, intervertebral foramen, lumbar disc herniation, needle knife injection

## Introduction

Lumbar disc herniation (LDH) is a common disease among patients receiving treatment at medical clinics [1, 2]. An epidemiological survey conducted by MacDonald et al. [3] revealed that the annual incidence of lower back pain is about 2-5%, and that 80% of people experience lower back pain more than once in their lifetime. Lumbar disc herniation is the most common cause of lower back pain and sciatica [4]. Lower back pain can severely affect individuals' quality of life, and can reduce their ability to work, even to the point of disability [5], and places a burden on medical resources. Although there are currently many types of treatments available, they can be roughly divided into non-surgical and surgical therapies [6, 7]. Most patients can be treated using non-surgical treatments, which involve a protracted treatment course, and a high rate of relapse [8].

The needle knife is a product of the combination of acupuncture and moxibustion theory with Western medicine closed-surgery theory. Needle knife therapy is an interventional treatment that thus combines surgical and non-surgical treatment [9]. Since the development of the small needle knife by Zhu Hanzhang 30 years ago, the needle knife has increasingly been used in the treatment of LDH, with remarkable clinical efficacy [10]. However, clinical outcomes remain unclear following needle knife injection into the intervertebral foramen, release under the guidance of C-arm X-ray imaging, and simple injection into the intervertebral foramen for the management of LDH.

This study compared the outcomes of using needle knife injection through the intervertebral foramen plus release and those of nerve block using simple intervertebral foramen injection, both under the guidance of C-arm X-ray

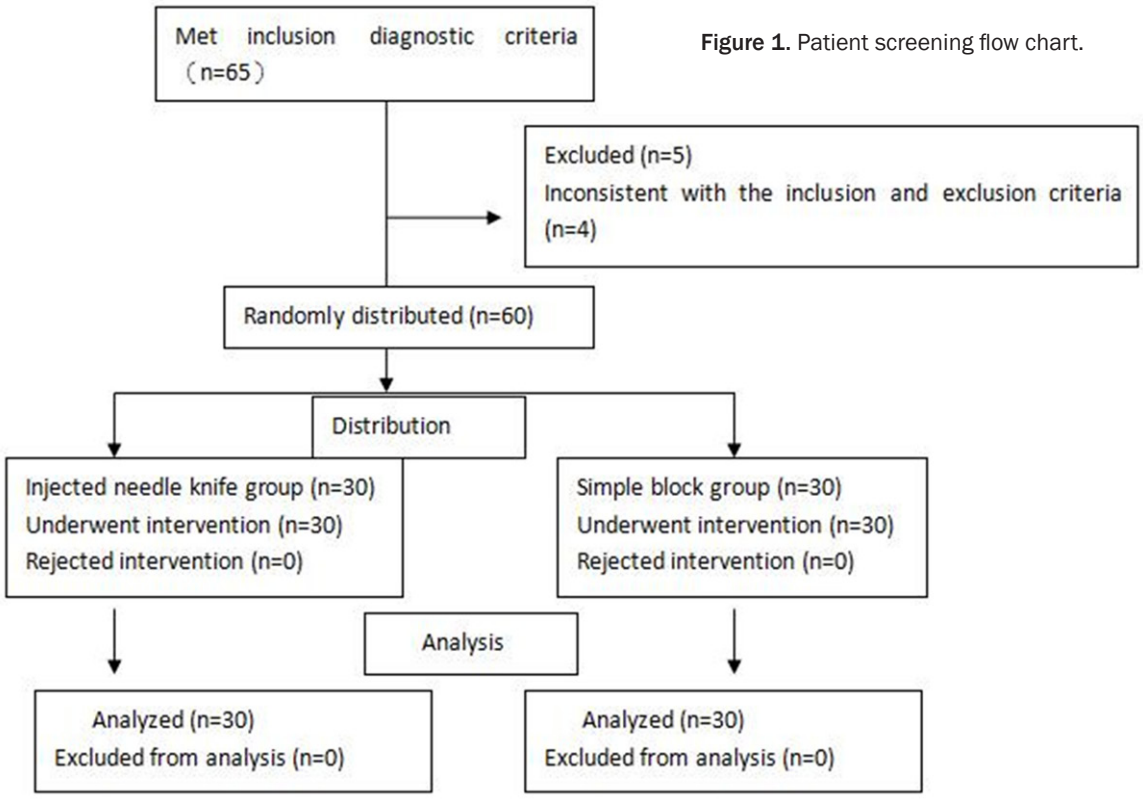


**Figure 1.** Patient screening flow chart.

imaging, for treatment of LDH, over a 6-months follow-up period.

## Materials and methods

### *Patients*

During the period from January 2016 to March 2017, 60 patients who met the inclusion criteria for LDH were enrolled in this study. All patients had L4/5 or L5/S1 single-segment LDH. The relevant Ethics Committee approved the study and informed consent was signed by all enrolled patients. Patients were randomly divided into two groups based on computer-randomization. Patients in one group underwent needle knife injection, into the intervertebral foramen, plus release under the guidance of C-arm X-ray (needle knife injection group [n = 30]), while patients in the other group underwent simple intervertebral foramen injection under C-arm X-ray-imaging guidance (simple block group [n = 30]). The patient flow chart is shown in **Figure 1**. Thirteen patients in the needle knife injection group and 14 patients in the simple block group had L4/5 single-segment LDH, while 17 patients in the needle knife injection group and 16 patients in the simple block group had L5/S1 single-segment LDH. Of the 30 patients in the needle knife group, 21 were outpatient and 9 were inpatient; 12 were men and 18 were women; and their age ranged from 30 to 51 years, with an average of 41.68 ± 5.26 years. These patients had a history of pain ranging from 7 to 32 months, with an average duration of 14.31 ± 8.23 months. In the simple block group, there were 21 outpatient and 9 inpatient; 13 were men and 17 were women, and they were aged 31-59 years (average: 43.60 ± 5.68 years). Their history of pain ranged from 7 to 57 months, with an average duration of 12.06 ± 10.12 months. There was no statistically significant difference between the two groups with respect to sex, age, duration of pain, and location of lumbar disc herniation. The general information of the two groups of patients is shown in **Table 1**.

### *Inclusion criteria*

Patients' diagnoses were based on the Criteria for the Diagnosis and Efficacy of TCM Disease formulated by the Chinese Medicine Administration of the People's Republic of China in 1994. The criteria were as follows. 1) History of lumbar trauma, chronic strain, or cold and dampness with most patients having had a history of chronic lower back pain before disc

**Table 1.** Comparison of general data between two groups of patients

| | Needle knife injection group | Simple block group | Test value | *P* value |
|---|---|---|---|---|
| Gender (number) | | | | |
| Male | 12 | 13 | $X^2 = 0.069$ | 0.793 |
| Female | 18 | 17 | | |
| Ag (x ± s, year) | 41.68 ± 5.26 | 43.60 ± 5.68 | T = 1.36 | 0.180 |
| Duration (x ± s, month) | 14.31 ± 8.23 | 12.06 ± 10.12 | T = 0.72 | 0.476 |
| Level distribution (number) | | | | |
| L4/5 | 13 | 14 | $X^2 = 0.067$ | 0.795 |
| L5/S1 | 17 | 16 | | |

herniation. 2) Back pain radiates to the buttocks and lower extremity and pain increases with an increase in abdominal pressure (such as during coughing, sneezing). 3) Disappearance of scoliosis and lumbar physiological curvature, tenderness around the paravertebral site of lesions, radiating to the lower extremities, and limitation of waist activity.

Patients were included if they met the above diagnostic criteria, with L4/5 or L5/S1 single-segment disc herniation, were aged 25-60 years, and had a disease duration of ≤ 5 years. Patients also agreed to forego other conservative treatments for more than half of their washout period before enrollment. For inclusion, patients also had to be able to understand the purpose, methods, possible treatment benefits, and possible adverse reactions of this clinical trial, agree to participate in the study and provide written informed consent, and fully cooperate with the doctor.

*Exclusion criteria*

Patients with severe disc protrusion and stenosis of the spinal canal, posterior edge of the lumbar spine centrum, facet joint hyperosteogeny, posterior longitudinal ligament, significant hypertrophic ligamentum flavum, and significant stenosis of the lateral crypt were excluded. Patients with mental illness, patients who did not provide written informed consent, or who could not cooperate with the doctor were excluded. Patients with significantly reduced myodynamia, with foot drop or cauda equina nerve injury syndrome, skin ulceration or infection at the puncture site, cardiovascular, liver, kidney, and other serious primary diseases, severe diabetes, spinal tuberculosis, tumors, etc., or who had a history of undergoing lumbar surgery or the presence of a lumbar deformity were also excluded.

*Needle knife injection procedure*

For needle knife treatment, the patient was placed in a prone position by placing a soft pillow under the abdomen so that the physiological lumbar curvature and sacral cornu were flattened. This increased the gap in the transverse process, which facilitated the insertion of the needle knife into the intervertebral foramen. The superficial positions of the lumbar 4 and lumbar 5 spinous processes were located using Kirschner wire under the guidance of C-arm X-ray imaging (**Figures 2** and **3**).

*Lumbar 4/5 intervertebral foramen injection and needle knife release*: A horizontal line was drawn parallel to the horizontal axis of the lumbar 4 spinous process. Then a longitudinal line, approximately 8-cm long, was drawn on the ipsilateral side of the spine. A sterile towel was spread and a Hanzhang No. 3 needle knife was inserted under local anesthesia. The needle knife entered the body at an angle of 45° to the patient's lumbosacral plane along the horizontal axis. After the knife penetrated the sclerotin, the blade of the needle knife was observed through the C-arm to be immediately outside the lumbar 4/5 facet joint. The needle blade was then retracted by 1-2 cm. The blade of the needle knife was slid over the facet joint, until a loss of resistance was experienced, which indicated that the needle knife had entered the lumbar 4/5 intervertebral foramen. A 10-ml syringe containing anti-inflammatory and analgesic solution was connected to the end of the inserted needle knife, and 5-6 ml of the solution was slowly injected after pumping back the blood or cerebrospinal fluid. Under C-arm monitoring, the needle knife was placed on the bone surface of the facet joint. When the needle blade was released, the needle knife was then fully retracted.

*Lumbar 5/sacrum 1 intervertebral foramen injection and needle knife release:* The patient was placed in the same position as described

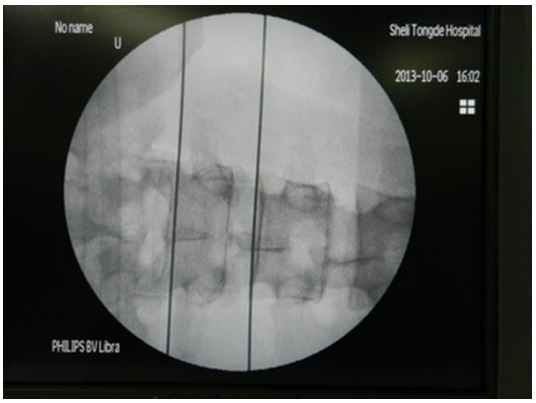


**Figure 2.** Electrotransparent image of positioning of the body surface metal objects.

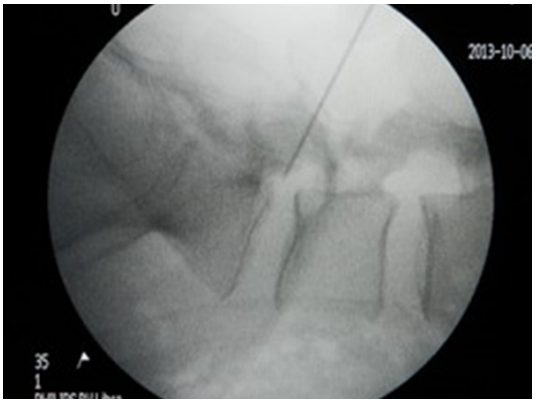


**Figure 3.** Needle knife release of the L5S1 intervertebral foramen.

above. A horizontal line was drawn parallel to the horizontal axis of the lumbar 5 spinous process. A line was also drawn between the affected side and the horizontal axis, at an upward angle of 15°. An 8-cm longitudinal line was drawn above this line, from the lumbar 5 spinous process. The needle knife was inserted along the straight line perpendicular to the lumbar 5 spinous process into the intervertebral foramen, at the same angle and using the same technique of intervertebral foramen soft tissue adhesion release, as described above.

After retracting the needle knife, sterile gauze was pressed on the puncture wound in a clockwise direction for 1 minute. This compression was performed to achieve hemostasis, after which the wound was covered with a plaster. The patient was then placed in a supine position and rested in bed for more than half an hour. This treatment was administered once a week for 3 weeks. The anti-inflammatory and analgesic solution contained 2% lidocaine (2.5 ml), triamcinolone acetonide (15 mg), mecobalamin (500 μg), and physiological saline (5 ml).

*Simple injection procedure*

*Lumbar 4/5 intervertebral foramen injection:* The patient was placed in a prone position by placing a soft pillow under the abdomen such that the physiological lumbar curvature and sacral cornu were flattened, as described for the above procedures. The superficial position of the lumbar 4 and lumbar 5 spinous process was located under guidance of the C-arm X-ray imaging, as described above.

After drawing horizontal and longitudinal lines as described above, followed by sterile draping, a No. 9 syringe needle was inserted under local anesthesia at an angle of 45° to the patient's lumbosacral plane, along the horizontal line. After the knife penetrated the sclerotin, the blade of the needle knife was observed through the C-arm to be immediately outside the lumbar 4/5 facet joint. The needle blade was then retracted by 1-2 cm and slightly offset to the outside. The blade of the needle knife was slid over the facet joint, until a loss of resistance indicated that the needle knife had entered the lumbar 4/5 intervertebral foramen. A 10-ml syringe containing anti-inflammatory and analgesic solution was connected to the end of the injected needle knife, and 5-6 ml of the solution was slowly injected as described above.

*Lumbar 5/sacrum 1 intervertebral foramen injection:* The procedure for lumbar 5/sacrum 1 intervertebral foramen injection was essentially the same for the needle knife group.

After retracting the needle, patients were treated as for the needle knife group.

*Efficacy evaluations*

The needle knife injection group, the simple injection control group, and the simple needle knife release control group were evaluated to observe the efficacy of the treatment, based on the Japanese Orthopedic Association (JOA) criteria, which are a specific instrument developed by the JOA in 1986 to measure outcomes for patients with lower back problems. The JOA score rating system for lower back pain has a total possible score of 29 points and has been

**Table 2.** JOA scores before and after the treatment in both groups

| | Before the treatment | 1 week after the treatment | 1 month after the treatment | 6 months after the treatment |
|---|---|---|---|---|
| Needle knife injection group | 12.60 ± 1.92 | 25.50 ± 1.76 | 24.33 ± 2.04 | 22.43 ± 2.22 |
| Simple block group | 12.30 ± 1.91 | 22.77 ± 2.31 | 19.10 ± 1.94 | 15.77 ± 2.24 |
| T value | 0.61 | 5.15 | 10.19 | 11.57 |
| *P* value | 0.553 | 0.0008 | 0.0004 | 0.0002 |

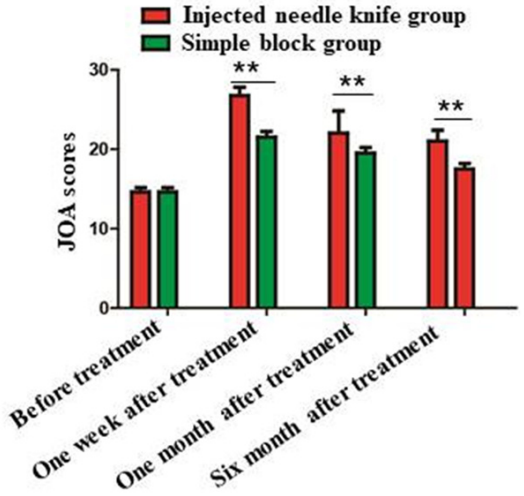


**Figure 4.** JOA scores for lower back pain before and after treatment in both groups. **: P < 0.05.

widely utilized to evaluate the functional results of various interventions for patients with lower back pain. JOA score evaluation was performed before treatment and again at 1 week, 3 months, and 6 months after treatment. Complications occurring after the treatment were recorded in both groups of patients.

*Statistical analysis*

SPSS 21.0 statistical software was used for statistical analyses. Age, medical duration of pain/LDH, and JOA scores were compared between groups at various time points, using *t*-tests. The number of male and female patients and the number of segments involved were evaluated using the chi-square test. Values of $P < 0.05$ were considered statistically significant.

## Results

*Efficacy of treatments*

The efficacy of the two types of treatment for lower back pain was evaluated according to the JOA criteria. There was no statistically significant difference between the two groups before treatment (P = 0.553). One week after treatment, the mean JOA scores in each of the two groups were statistically significantly higher than those before treatment (P = 0.0008). The score in the needle knife injection group was higher than that in the simple injection group (P = 0.004). At 1 month and 6 months after the treatment, the JOA scores in the needle knife injection group were also higher than those in the simple injection group (P = 0.0002). The JOA scores before and after treatments in the two groups are shown in **Table 2** and **Figure 4**.

*VAS pain scores*

The VAS pain score was used to assess the pain level before and at 1 week, 1 month, and 6 months after treatment. There was no statistically significant difference in VAS scores between the two groups before treatment (P = 0.812). One week after treatment, the scores in both groups were lower than those before treatment, and the difference was statistically significant (P = 0.004). The score at 1 week after treatment in the needle knife injection group was lower than that in the simple injection group (P = 0.0005). At 1 month and 6 months after treatment, the scores in the needle knife injection group were also lower than those in the simple block group (P = 0.0002). The VAS scores before and after treatment in the two treatment groups are shown in **Table 3** and **Figure 5**.

There were five patients in the needle knife injection groups and three in the simple block groups whose clinical symptoms worsened on the treatment day. There was no statistically significant difference between the two groups with respect to symptom worsening (P = 0.706). For all patients with worsening symptoms, these symptoms disappeared within 3 days, and the original clinical symptoms gradually decre-

**Table 3.** VAS scores before and after the treatment in both groups

| | Before the treatment | 1 week after the treatment | 1 month after the treatment | 6 months after the treatment |
|---|---|---|---|---|
| Needle knife injection group | 6.54 ± 1.08 | 0.84 ± 0.48 | 0.96 ± 0.85 | 1.45 ± 1.01 |
| Simple block group | 6.47 ± 1.03 | 1.42 ± 0.93 | 2.08 ± 1.14 | 2.68 ± 1.35 |
| T value | 0.26 | 3.04 | 4.31 | 4 |
| *P* value | 0.812 | 0.004 | 0.0005 | < 0.0003 |

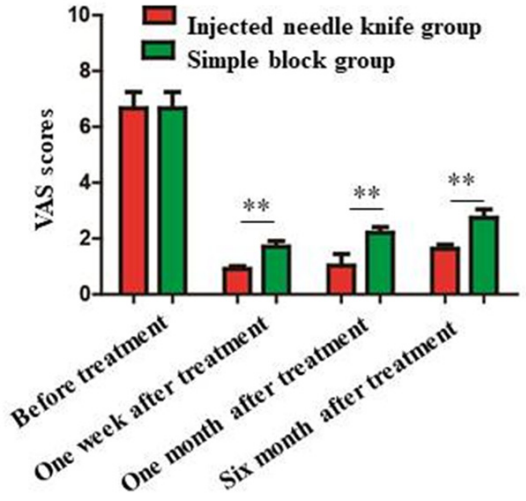


**Figure 5.** VAS pain scores before and after treatment in both groups. **: P < 0.05.

ased. Two local hematomas occurred in the needle knife injection group, and no local hematoma occurred in the simple block group. There was no statistically significant difference between the two groups in this respect (P = 0.492). All local hematomas completely disappeared within 1 month. None of the patients developed local infection after treatment in both groups. The complications of treatments in both group are shown in **Table 4**.

## Discussion

Nerve block therapy is one of the most common non-surgical treatments for the management of LDH worldwide [11-13]. The initial use of epidural drugs can significantly reduce or eliminate the symptoms [14]. However, careless operations can cause some complications, such as epidural hematoma [15], arachnoiditis [16] due to injections of steroid into the subarachnoid space, and even permanent paralysis [17]. The incidence of puncture of the dura mater is generally 0.2-0.6%, and the incidence of total spinal anesthesia is 0.2%. The interior edge of the facet joint or laminectomy are rarely used as puncture pathways. However, both of these methods require penetration of the ligamentum flavum to reach the lateral dura mater space, posing a potential risk for infection, adhesions, hematoma, and rupture of the dura mater [18]. To avoid these complications, some reports have described use of the transforaminal approach to achieve nerve block [19]. The drug is applied to the external opening of the nerve in the intervertebral foramen. There is no need for the puncture needle to pierce the ligamentum flavum, and most of the injected drugs are delivered around the lesions, which greatly enhances the symptom improvement and cure rate. This is a new nerve block method, that provides non-surgical treatment for LDH. When using intervertebral foramen puncture for nerve block treatment, C-arm X-ray imaging guidance should be used [20]. Despite the financial burden this places on the patient, it is necessary to ensure precision during puncture, and improves safety and reduces complication rates. Moreover, the image data acquired during the puncture procedure is easy to archive and analyze later.

Needle knife therapy combines traditional acupuncture needles with modern scalpels. It has the following advantages: it is simple to perform, has proven clinical efficacy, is associated with less pain, has a lower cost, high safety, and greater acceptance by patients [21]. It can often achieve rapid results, even immediately after treatment. The small needle knife is a needle as well as a knife. Since its invention, needle knife therapy has become an important and effective method for treating LDH [22]. By releasing soft tissue adhesions, scars, and contractures, the needle knife can restore the dynamic state of the soft tissues, improve the local microcirculation, eliminate muscle tension and spasms, reduce metabolism to promote the removal of algesic substances, reduce tetany, and relieve pain. By releasing the lumbar zygapophyseal joint capsule at the intervertebral foramen, bone fiber tube, it can

**Table 4.** Complications after the treatment in three groups

| | Aggregation | Infection | Hematoma |
|---|---|---|---|
| Needle knife injection group | 5 | 0 | 2 |
| Simple block group | 3 | 0 | 0 |
| Chi-square value | 0.577 | - | 2.069 |
| *P* value | 0.706 | - | 0.492 |

reduce the abnormal increase in pressure, reduce joint capsule swelling, enlarge the intervertebral foramen indirectly, and reduce adjacent spinal nerve branch and root compression and irritation [23]. However, blind release of the intervertebral foramen is associated with greater risk of inaccuracy. In order to improve the safety and effectiveness of needle-knife therapy, it is necessary to consider clinical manifestations in combination with pathological anatomy and imaging examination of LDH to locate the precise target point. Then, an accurate procedure can be performed under image guidance, reducing the risk of unnecessary damage to normal structures.

The needle knife not only has a blade, but also has an aperture for the injection of drug solutions. This design can be used to perform nerve block through the intervertebral foramen under C-arm X-ray-imaging guidance [24]. It is not necessary to retract the needle knife after the puncture, as its angle and direction in the body can be changed directly. The blade edge of the inserted needle knife remains close to the lateral edge of the facet joint and releases the root of the transverse process, followed by a release of the transverse process (semispinalis muscle, multifidus muscle, and rotator muscle), until the needle knife reaches the space between the papillae and anapophysis. There it releases the papillae and anapophysis ligament around the bone fiber tube, relieves the compression of the posterior branch of the spinal nerve, and continues from the interior to the superior border of the root of the transverse process. It cuts the deep fascia outside the intervertebral foramen, reaching the lower middle part of intervertebral foramen through the superior border of the root of the transverse process, and releases the intervertebral foramen ligament and the surrounding fascia. This simplifies the operation steps and reduces the amount of radiation from the C-arm.

Although implementation of needle knife nerve root release and nerve root block under CT guidance has been reported in the treatment of LDH [25], there has been no report on the use a small needle knife to release the intervertebral foramen for the treatment of LDH under dynamic monitoring with C-arm X-ray imaging. Compared with needle knife treatment under CT guidance, needle-knife treatment under C-arm X-ray guidance is easier to perform, and it is more practical for the treatment of LDH. Because CT equipment is generally available only at imaging centers, they have a limited role in clinical practice when using the needle knife. In addition, it is not possible to perform a needle knife operation and CT scanning at the same time; this can affect the clinical performance of needle knife release and may lead to clinical error and damage to important anatomical structures. In addition, the amount of radiation from the C-arm is considerably less than that associated with CT scanning, and a small needle knife release operation can be performed in real time with X-ray imaging. Therefore, compared with CT scanning, X-ray imaging is significantly easier, less time-consuming, safer, and more acceptable to the patient.

Our results demonstrate that performance of nerve block by needle knife injection through the intervertebral foramen, along with soft tissue release, under the guidance of C-arm X-ray imaging has a significantly better short-term and long-term efficacy, and is safer and more practical for the treatment of LDH. This treatment conforms to the trend in the development of minimally invasive procedures in modern medicine.

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## Disclosure of conflict of interest

None.

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