

## Treatment of large lumbar disc herniation with percutaneous ozone injection *via* the posterior-lateral route and inner margin of the facet joint

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facet joint is effective and safe for treatment of large lumbar disc herniation.

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### Abstract

**AIM:** To evaluate the effects of percutaneous ozone injection *via* the posterior-lateral route and inner margin of the facet joint in the treatment of large lumbar disc herniation.

**METHODS:** Fifty-eight patients with large lumbar disc herniation were treated with percutaneous injection of ozone *via* the posterior-lateral route and inner margin of the facet joint under digital subtraction angiography. Second injections were performed 5 d after the initial injection. All patients were followed up for 6-18 mo. A modified Macnab method was used for assessing clinical outcomes after oxygen-ozone therapy.

**RESULTS:** Successful puncture was obtained in all patients. The overall efficacy was 91.4%; the outcome was the excellent in 37 cases (63.8%), good in 16 cases (27.6%) and fair/poor in 5 cases (8.6%) according to the Macnab criteria. No severe complications were found throughout this study.

**CONCLUSION:** Percutaneous intradiscal ozone injection *via* the posterior-lateral route and inner margin of the

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### INTRODUCTION

In 2000, the Interventional Department of Nanfang Hospital, Southern Medical University, China was the first in our country to perform ozone therapy for lumbar disc herniation, and obtained good efficacy<sup>[1,2]</sup>. Because there is little pain, few complications and broad indications as well as being a minimally invasive method, ozone therapy has been widely used clinically before now<sup>[3,4]</sup>. At present, intradiscal and paravertebral injections through the posterior-lateral route are conventionally used in the treatment of lumbar disc herniation. For patients with minimal or inclusive disc herniation, the efficacy of ozone treatment is very significant, but for patients with large lumbar disc herniation, the efficacy is poor<sup>[5]</sup>. Since 2005, we have injected ozone *via* a route through both the posterior-lateral

pathway and inner margin of the facet joint in the treatment of 58 patients with large lumbar disc herniation, and we obtained good efficacy.

## MATERIALS AND METHODS

### *Clinical materials*

From January 2005 to December 2007, 58 patients with large lumbar disc herniation were enrolled in this study. A large lumbar disc hernia was where the greatest distance between the edges of the herniated material and the edges of the base of disc were more than 5 cm. Inclusion criteria were as follows: (1) diagnosis of a herniated disc by clinical symptoms, and physical signs matched with computed tomography (CT) and/or magnetic resonance imaging; (2) sciatic pain of 5 or more on a visual analogue scale; and (3) pain radiating to an area appropriate to a herniated disc. There were 43 and 15 females, aged from 22 to 78 years (mean, 40 years). Fifty-eight patients had 69 disc herniations. The positions of the herniated disc levels were L4-L5 ( $n = 31$ ), L5-S1 ( $n = 16$ ) and L4-L5 combined with L5-S1 ( $n = 11$ ). The disease duration ranged from 1 mo to 12 years. The disc herniation portions ranged from 5 to 8 mm, with a mean of  $5.87 \pm 1.72$  mm.

Four patients had disc protrusion and the protruding nucleus pulposus tilted to the lower extremity; the herniated discs of 3 patients were significantly calcified, with combined bony spinal canal stenosis at the same level as the herniated discs. Patients with the following were excluded: bony spinal canal stenosis, ligamentum flavum hypertrophy, and facet joint syndrome. The main clinical manifestations were radiating pain and numbness of the unilateral or bilateral hip and lower extremity, sometimes accompanied by low back pain and sacral pain. Only one case showed interruption of urinary and fecal excretion. As for physical signs, the straight leg raising test and/or strength test were positive in 51 cases, but both were negative in 7 cases. Thirteen cases showed muscular atrophy of the unilateral limb. Ten cases showed a reduction in the flexor muscle strength of the hallux combined with hyporeflexia of the knee and/or Achilles tendon. No beneficial effect had been achieved in any patient during at least 8 wk' conservative treatment.

### *Puncture through the posterior-lateral route*

Ten milligrams diazepam was intramuscularly injected 30 min before the procedure. The patients lay in the lateral position on a digital subtraction angiography (DSA) operating table, with the affected side upwards. The operation was performed under sterile conditions. In general, the puncture site was 6-10 cm (mean, 8 cm) away from the vertebral line and 5 mL of 2% lidocaine (Xian Changcheng Pharmaceutical Factory, Xi'an, China) was used for local anesthesia of the puncture site, with attention paid to avoidance of damage to the nerve roots. The 21G needle (conical needlepoint and containing 3 side-holes) was used to puncture the center of the disc under DSA, with an angle of 30-40°, with insertion along the 'security triangle' through the posterior-lateral pathway. Once the position of the needle tip was confirmed in the

center of the disc by both posterior-anterior and lateral fluoroscopy images, 5-10 mL of 30-40 µg/mL ozone was injected. The ozone generator used in our study was made by Humazon ProMedic, Germany. While the needle tip was withdrawn to near the intervertebral foramen, paravertebral injection of 10 mL ozone and 3-4 mL of an anti-inflammatory and analgesic solution (a mixture of diprospan (Schering-Plough, Shanghai, China), vitamin B12 (Hezhong Biochemistry Co. Ltd, Wuhan, China) and lidocaine) was performed. When the puncture site was at the level of L5-S1, a pillow was placed under the healthy hip and the lumbosacral angle was increased to shift the puncture point upwards, then the needle set at an angle of 150-160° to increase the success rate of puncture and injection of ozone along the margin of the disc.

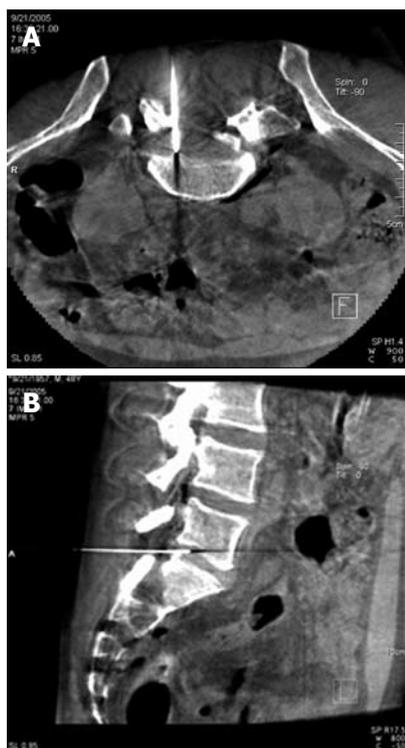
### *Puncture through the inner margin of the facet joint*

The patients lay in a prone position, and the angle of the plate of the DSA was adjusted so that its plane was perpendicular to the disc punctured, in order to show that the intervertebral space was clear, with the spinal process in the center. The puncture site was 2 cm away from the diseased spinal process in the intervertebral space and 5 mL of 2% lidocaine was injected for local infiltration anesthesia. Then a 20G needle was advanced stepwise into the hernia through the skin, subcutaneous tissue, and the space between the medial border of the articular process and the lateral border of the dural sac after the erector spinae. On meeting an obstacle, the angle of the needle was adjusted under lateral fluoroscopy to avoid the posterior margin of the vertebrae for entering the hernia, the ideal position of the needle tip being inside the herniated portion of the disc. When no blood or cerebrospinal fluid were drawn through the needle, ozone gas (5-6 mL of 30-40 µg/mL) was then injected slowly.

After ozone injection, patients were required to lie on the bed for 48 h. Later, limited activity was allowed but the duration of sitting or standing was not more than 15 min. The patients were administrated with mannitol and neurotrophin for 3 d. Five days later, the treatment above was repeated. All patients were followed up by returning to the hospital to have physical examination or answering the questions by telephone. The efficacy was assessed by modified Macnab criteria<sup>16,71</sup>: excellent referred to return to work, but with occasional low back pain or leg pain, no need for painkillers and no physical signs of nerve root injury, and good physical fitness; good/fair referred to general ability to work, with intermittent slight low back pain or radiating pain, no need for painkillers and no physical signs of nerve root injury, and good physical fitness; poor referred to inability to work, with constant pain, requirement for painkillers, and limited physical activity, with physical signs of nerve root injury. The effective rate of the ozone therapy was assessed. The  $\chi^2$  test was used to evaluate the significant difference in efficacy among the 3 sub-groups (L4-L5 group, L5-S1 group and L4-L5 combined with L5-S1 group).

## RESULTS

All 58 patients with 69 hernias had successful puncture



**Figure 1** The placement of the needle tip measured accurately by Dyna-CT reconstruction under rotary digital subtraction angiography (DSA). A: The needle advanced into the disc through the inner margin of the facet joint and the needle tip was placed in the hernia under Dyna-CT cross-sectional reconstruction; B: The needle tip advanced into the disc through the posterior-lateral route under Dyna-CT sagittal reconstruction.

*via* the 2 paths, a success rate of 100%. The placement of the needle tip could be measured accurately by Dyna-CT reconstruction under rotary DSA (Figure 1A and B). After injection, all patients were followed up for 6 to 18 mo (mean, 10.5 ± 4.3 mo). According to the modified Macnab criteria, the therapeutic outcomes (Table 1) were: excellent efficacy in 37 cases (63.8%), good/fair in 16 (27.6%) and poor in 5 (8.6%), and the total effective rate (excellent and good/fair) was 91.4%. The total effective rate was 96.8% for L4-L5, 87.5% for L5-S1, and 81.8% for L4-L5 combined with L5-S1. According to statistical analysis, there was no significant difference among the 3 groups of patients with disc herniation at different levels ( $\chi^2 = 4.407$ ,  $P = 0.354$ ). In this study, there were no complications such as disc infection, nerve or vascular injury, and so on.

## DISCUSSION

The treatment of lumbar disc herniation with ozone has been widely applied in our country, and at present, the main mechanism of action may be considered as follows<sup>[8,9]</sup>: (1) Immediate oxidation: ozone is a strong oxidizer, by which proteoglycan in the nucleus pulposus could be oxidized immediately, the osmotic pressure reduced and water lost. Then, the nucleus pulposus would denaturize, necrotize and atrophy, and the volume decrease. At the time of osmotic pressure reduction, the local blood circulation would also be changed. Increasing the oxygen supply could improve the symptoms; (2)

**Table 1** Clinical outcome of 58 patients with lumbar disc herniation after ozone treatment according to modified Macnab's criteria *n* (%)

Herniated disc (case)	Macnab evaluation		
	Excellent	Good	Poor
L4-L5 ( <i>n</i> = 31)	23 (74.2)	7 (22.6)	1 (3.2)
L5-S1 ( <i>n</i> = 16)	9 (56.3)	5 (31.3)	2 (12.5)
L4-L5 and L5-S1 ( <i>n</i> = 11)	5 (45.5)	4 (36.4)	2 (18.2)
Total	37 (63.8)	16 (27.6)	5 (8.6)

$$\chi^2 = 4.407, P = 0.354.$$

Anti-inflammatory effect: as the nerve root and the vein and lymphoid tissue were compressed by the herniated nucleus pulposus and annulus fibrosus, the venous and lymphatic backflow was obstructed, accompanied by nerve edema and exudation. Then antigenic substances, such as glycoprotein and  $\beta$ -lipoprotein, could be released to induce an immune response, resulting in aseptic inflammation, adhesion, *etc.* All these factors could lead to the pain of disc herniation. Ozone could have an anti-inflammatory effect by releasing antagonistic immune factors; and (3) Analgesic effect: the reason that the disc herniation caused pain was that some inflammatory mediators and enzyme-products (substance P, phospholipase A2, *etc.*) stimulated the nerve endings on the disc surface and near ligament, the facet articular process and lumbar muscle. The strong oxidative activity of ozone could inactivate the above inflammatory mediators for pain relief.

For small- or medium-sized disc herniations and contained disc herniations, which showed that the annulus fibrosus and posterior longitudinal ligament had not been completely ruptured, ozone injected into the center of disc through the conventional posterior-lateral route had good efficacy. In 2003, Andreula reported a multicenter study of a large group of patients (300 cases), with excellent and good outcomes of 78.3%<sup>[10]</sup>. However, for large disc herniation, ozone could not directly remove the hernia compressing the nerve root so that the symptoms could not be eliminated quickly and the efficacy of reduced compression was limited<sup>[11]</sup>. In another aspect, because the annulus fibrosus was partially or completely ruptured, the ozone injected could diffuse through the tear into the tissues surrounding the spinal or vertebral disc, such that the nucleus pulposus and hernia could not be fully oxidized<sup>[12]</sup>. Ozone injected through the inner margin of the facet joint by directly placing the needle into the herniated disc could directly oxidize the hernia, thus the efficacy was increased. At the same time, ozone diffusing between the dura mater and hernia could relieve nerve root pain.

This study showed that the treatment of large lumbar disc herniation with percutaneous ozone injection *via* the posterior-lateral and inner margin of facet joint was very effective. Also, the efficacy was not significantly different among the 3 levels of herniation including L4-L5, L5-S1, and both L4-L5 and L5-S1. It was proven that the dual approach treatment had a reliable outcome. If the herniation was on the L5-S1 level, it might be difficult to puncture because of an excessively high iliac crest and hypertrophic

transverse process. Thus, the needle path of the inner margin of the facet joint could be used to prevent puncture failure as a result of poor needle placement. In this way, the needle was advanced into the hernia through the gap between the lateral nerve root and the inner margin of the facet joint. However, for central herniation, the needle could be advanced through the gap between the lateral position of the nerve root and the dural sac. Because the needle was very thin and the ozone was minimally invasive for nerve root treatment, the inner margin of the facet joint approach has been a common path for minimally invasive treatment of disc herniation. Zhao<sup>[12]</sup> had performed this treatment with ozone and collagenase, with an effective rate of 94.4%. Because puncture through the inner margin of the facet joint had a straight path, a short distance, was an easy operation, and could allow 'target' injection, the efficacy was always good, especially for those patients with large disc herniation or prolapse. Ozone injection into or around the hernias not only improved the local ablation, but also eliminated local aseptic inflammation. The author had reported an excellent and good rate of 91.4%, which was higher than that of the route of the posterior-lateral approach only as reported by Yu *et al.*<sup>[13]</sup>, and that of the inner margin of the facet joint only as reported by Zhao<sup>[12]</sup>. Thus, the treatment of large lumbar disc herniation with percutaneous ozone injection *via* the posterior-lateral and inner margin of facet joint was a safe and effective method, which is worthy further promotion.

To ensure efficacy, the concentration of ozone should be adequate and the rupture of the annulus fibrosus by extremely high intradiscal pressure should be avoided. At present, there is pulse injection, low-pressure repeated injection and rapid injection with a large dose of ozone. The authors believed that, for large disc herniation, low-pressure repeat injections of ozone were preferable. By pushing and pulling the syringe repeatedly, the ozone could completely contact and oxidize the nucleus pulposus. Then the residual ozone was abandoned, and new ozone was injected repeatedly to avoid rupture of the annulus fibrosus. At the same time, the injection pressure should also be monitored by a pressure monitoring device to avoid the rupture of the annulus fibrosus.

## COMMENTS

### Background

Oxygen-ozone therapy is a minimally invasive treatment for lumbar disc herniation that exploits the biochemical properties of a gas mixture of oxygen and ozone. Oxygen-ozone therapy is a useful treatment for lumbar disc herniation that has failed to respond to conservative management.

### Research frontiers

Although intradiscal and paravertebral ozone injections through the posterior-lateral route are effective in the treatment of lumbar disc herniation, the efficacy is poor for patients with large lumbar disc herniation. We report injection of ozone *via* both the posterior-lateral route and the inner margin of the facet joint to successfully treat large lumbar disc herniation.

### Innovations and breakthroughs

This study showed that the treatment of large lumbar disc herniation with percutaneous ozone injection *via* the posterior-lateral route and inner margin of the facet joint was very effective. Ozone injected *via* the inner margin of the facet joint, by direct placement of the needle into the herniated disc, could directly oxidize the hernia. Because of its high penetration, the efficacy was

increased. The efficacy was similar for the 3 levels of herniation including L4-L5, L5-S1, and both L4-L5 and L5-S1. It was proved that the dual approach to treatment had a reliable effect.

### Applications

Large lumbar disc herniation had a poor response to ozone injection *via* the posterior-lateral route. Ozone injected through the inner margin of the facet joint could improve the efficacy. In our study, the overall efficacy was 91.4%, excellent in 37 cases (63.8%) and good in 16 cases (27.6%). The indication for ozone therapy has expanded to include large lumbar disc herniation.

### Terminology

A zygapophysial joint (zygapophyseal, or facet joint) is a synovial joint between the superior articular process of one vertebra and the inferior articular process of the vertebra directly above it. There are 2 facet joints in each spinal motion segment. Large lumbar disc herniation is where the greatest distance between the edges of the herniated material and the edges of the base of disc are more than 5 cm. Dyna-CT is an innovative system for 3-dimensional reconstruction of anatomical structures.

### Peer review

The manuscript is generally acceptable. However, some points must be reconsidered.

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