

CLINICAL EFFICACY OF TARGETED INJECTION OF DRUGS IN COMBINATION WITH OZONE IN THE TREATMENT OF LUMBAR DISC PROTRUSION

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ABSTRACT

Objective: To investigate the clinical efficacy of targeted injection of drugs surrounding the protruded lumbar disc in combination with the ozone in the treatment of lumbar disc protrusion.

Methods: Between January 2019 and January 2021, a total of 120 patients with lumbar disc protrusion were recruited in this study and divided into the control group and observation group, with 60 patients in each group. Patients in the control group received the ozone treatment, while those in the observation group additionally took the targeted injection of betamethasone surrounding the protruded lumbar disc. Following one month of treatment, we compared the short-term efficacy, joint range of motion in bending forward or backward of the lumbar disc, limb function, life quality, and functional disturbance before and after treatment.

Results: In the observation group, the short-term effectiveness rate was higher than that in the control group ($P < 0.05$), while after treatment, the joint range of motion in bending forward or backward of lumbar disc in the observation group was improved when comparing to the control group ($P < 0.05$). After treatment, BI and Fugl-Meyer scale were all higher in the observation than those in the control group ($P < 0.05$), with a lower Oswestry score ($P < 0.05$).

Conclusion: Targeted injection of betamethasone surrounding the protruded lumbar disc in combination with the ozone performs well in short-term efficacy, conducive to the improvement of the lumbar disc function and limb function and alleviation in function disturbance. Thus, this strategy is worthy of being promoted in clinical practice

Keywords: Targeted injection of betamethasone surrounding the protruded lumbar disc, ozone, lumbar disc protrusion, clinical efficacy.

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Introduction

Lumbar disc protrusion refers to the degenerative changes in the nucleus pulposus, fibrous rings, and cartilage plate of the lumbar disc under the external stimuli to damage the fibrous rings, thereby resulting in the protrusion of the nucleus pulposus from the rupture into the canalis spinalis, and thus giving rise to the suppression and stimuli to the adjacent spinal nerves, mostly affecting the L4-5 and L5-S1 segment, taking up nearly 95%, with clinical manifestations like waist pains or limb numbness, severely affecting the health and life of patients⁽¹⁾. Surgical treatment is the most common treatment method for the treatment of lumbar disc

protrusion and is able to improve the symptoms and mitigate the pains but it is limited due to the severe trauma, high risk, and poor compliance and tolerance of patients⁽²⁾. As shown in the previous studies⁽³⁾, targeted injection of betamethasone surrounding the protruded lumbar disc in combination with the ozone has been reported to improve the lumbar disc function and the limb function, but the efficacy remains to be validated. Thus, in this study, we enrolled a total of 120 patients with a lumbar disc protrusion in this hospital between January 2019 and January 2021 as the subjects to explore the clinical efficacy of targeted injection of betamethasone surrounding the protruded lumbar disc in combination with the ozone.

Materials and methods

General data

Between January 2019 and January 2021, a total of 120 patients with lumbar disc protrusion were recruited in this study and divided into the control group and the observation group, with 60 patients in each group. No significant differences were shown in the comparison of the general data, including the sex ratio and age, of the patients between the two groups ($P > 0.05$), suggesting that the data were comparable ($P > 0.05$; Table 1). This study was approved by the Ethical Committee of Yulin orthopaedic hospital of Chinese and Western Medicine.

Item		Observation group	Control group
Sex(males/females)		34/26	31/29
Age/average age(year)		31~65/51.29±5.77	30~67/52.31±5.82
Disease course/average disease course(-year)		1~18/10.21±2.69	1~19/10.25±2.72
Protrusion type	protrusion	30	28
	prolapse	20	21
	dissociation	10	11
Protrusion site	L3-4	25	24
	L4-5	29	28
	L5-S1	6	8

Table 1: Comparison of general data between the two groups.

Inclusion criteria: 1) Patients conforming to the diagnostic criteria of lumbar disc protrusion, with manifestations of waist pain or leg pain in the nerve region; 2) patients with the indications of targeted injection of drugs surrounding the protruded lumbar disc and ozone treatment; 3) patients in good compliance.

Exclusion criteria: 1) Patients complicated with the osseous spinal canal stenosis, ligamentum flavum hypertrophy, or bone tuberculosis; 2) patients complicated with the discitis, bone marrow tumors, or tolerating the surgery poorly; 3) patients with malignancies or diseases in the immune system.

Methods

Patients in the control group received the ozone treatment. In brief, patients in the supine position were anesthetized locally by use of 2% lidocaine, and under the guidance of a C-arm X-ray, a needle was used to penetrate the target zone. After the needle was ascertained to be located inside the lumbar disc, sensory and motor nerves were sequentially stimulated to determine the anomaly. Radiofrequency ablation was then performed for those without any anomaly, and afterwards, 4 to

10 mL ozone in the concentration of 50 $\mu\text{g/mL}$ was injected into the lumbar disc. Patients were delivered back to the wards and required to stay in bed for 1 to 2 days.

Those in the observation group additionally took the targeted injection of betamethasone surrounding the protruded lumbar disc. In brief, after the ozone treatment similar to that in the control group, they were required to take the prone position in a computed tomography machine to perform the location of the lumbar disc. In light of the local anatomic structure and the protrusion target in the lumbar disc, the distance and angle of the needle site to the target site were measured. Following the infiltrative anesthesia at the penetrating site, penetration was performed using 21G (15 cm) PTC (Hekko-medical, Japan) as per the angle. A contrast agent was given when a patient complained about the pains in the waist or soreness and swelling in affected limbs to make sure that the agent was delivered successfully to the target site under the guidance of CT. Then, a mixture of 2 mL compound betamethasone (diprospan, Beijing Four Rings Biopharmaceutical.Co., Ltd.; SFDA Approval No.: H20051410), mecobalamin tablet (mecobalamin, China Associate Pharmaceutical Co., Ltd; SFDA Approval No.: H20050320) and 8 mL salviae miltiorrhizae in normal saline. Following treatment, patients were required to keep in a prone position for at least 2 h to guarantee the sufficient diffusion of drugs, and not to participate in the labor. One month after the treatment, the efficacy was evaluated.

Evaluation of efficacy

Short-term efficacy

Macnab function evaluation criteria were adopted to assess the short-term efficacy (5). The total effectiveness rate = (Number of excellence and improvement)/total $\times 100\%$.

Joint range of motion in the vertebra

X-ray examination was performed to determine the joint range of motion in the lumbar disc bending forward or backward.

Limb function, life quality, and functional disturbance

Fugl-Meyer scale (higher score representing the better limb function, Barthel scale (higher score representing the better life quality), and Oswestry index (lower score representing the better recovery

from the functional disturbance) were used to evaluate the improvement in limb function, life quality, and functional disturbance.

Statistical analysis

SPSS 18.0 software was used to process the data. Count data were presented in form of percentages (%) and compared by the chi-square test. Measurement data were presented in form of mean ± standard deviation and compared by the t-test. P < 0.05 suggested the statistical significance of the difference.

Results

Comparison of the short-term efficacy between two groups

The short-term effectiveness rate in the observation group was 93.33%, higher than 86.67% in the control group (P < 0.05; Table2).

Group	N	Excel- lence	Improve- ment	Failure	Total effectiveness rate
Observation group	60	49(81.67)	7(11.66)	4(6.67)	56(93.33)
Control group	60	42(70.00)	10(16.67)	8(13.33)	42(86.67)
χ^2					6.982
P					0.037

Table 2: Comparison of the short-term efficacy between two groups [n (%)].

Comparison of the joint range of motion in the lumbar disc of patients between two groups

Before treatment, the comparison of the joint ranges of motion in the lumbar disc bending forward and backward revealed no significant difference (P > 0.05), while after treatment, these indexes were improved in the observation group (P < 0.05; Figure 1).

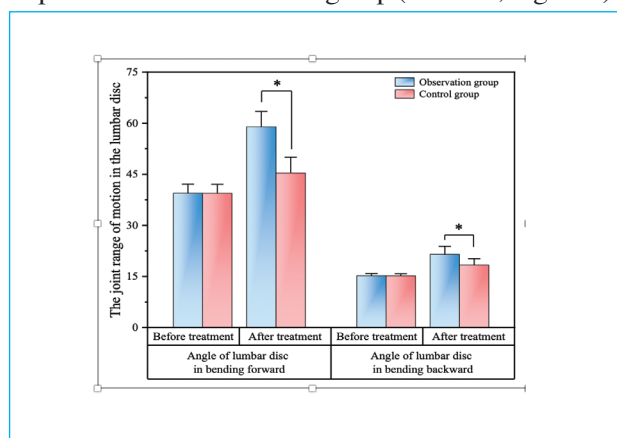


Figure 1: Comparison of the short-term efficacy between two groups [n (%)].

Note: *p<0.05 vs. the Control group

Comparison of the limb function, life quality, and functional disturbance of patients between two groups

Before treatment, the differences in evaluating the limb function, life quality, and functional disturbance between the two groups showed no statistical significance (P > 0.05), but after treatment, the patients in the observation group had better improvement than their counterparts in the control group (P < 0.05; Figure 2).

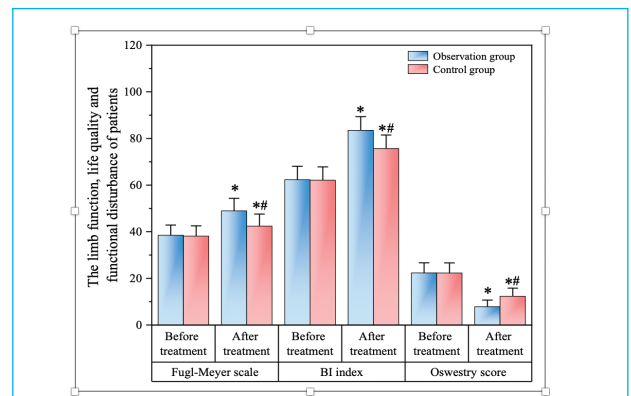


Figure 2: The limb function, life quality and functional disturbance of patients.

Note: *p<0.05 vs. the before treatment: Note: **p<0.05 vs. the Control group

Discussion

Lumbar disc protrusion mainly manifests the back pain or sciatica, complicated with the numbness in unilateral or bilateral lower limbs, and has been regarded as the major cause of the pains in the waist or legs^(6, 7). Degenerative changes in the lumbar disc, the major cause of lumbar disc protrusion, is mostly caused by the long-term incorrect waist posture, sudden weight-bearing, extremely cold environment, and increase in abdominal pressure due to the pregnancy or coughing⁽⁸⁾. Generally, lumbar disc protrusion has no evident symptoms in the early stage, and as the disease progresses, patients gradually complain about the pains or numbness in the waist or lower limbs, while in some severe cases, patients may be tortured by the Cauda equina or pressured marrow, resulting in the dysfunction in excretion, or even the paralysis in lower limbs, which has deteriorated the life quality of patients⁽⁹⁾.

At present, three hypotheses have been developed for elucidating the pathogenesis of lumbar disc protrusion: Hypothesis of local pressure by the protrusion, autoimmune hypothesis, and inflammatory mediator hypothesis⁽¹⁰⁾. Thus, we infer that the efficacy of treatment for lumbar disc

protrusion depends on the pathogenesis. In recent years, targeted injection of drugs surrounding the protruded lumbar disc in combination with the ozone treatment has been widely applied in the lumbar disc protrusion patients, with promising efficacy.

As for the mechanism of ozone in the treatment of lumbar disc protrusion, it is generally believed that ozone has an oxidative effect, anti-inflammatory effect, analgesic effect, and immunosuppression effect⁽¹¹⁾. Ozone, as a potent oxidant, can oxidize the nucleus pulposus in the lumbar disc by dehydrating the proteoglycan, thereby decreasing the pressure inside the lumbar disc by shrinking the nucleus pulposus, finally reducing the protruded lumbar disc into the original place⁽¹²⁻¹⁴⁾. The shrinkage or retraction of the lumbar disc may mitigate the suppression of the nerve root while increasing the reflux of venous blood, thereby augmenting the local blood supply, which can improve the hypoxia-sensitive pains of the nerve root. Besides, oxygen can promote the expression of anti-oxidative enzymes and inhibit the generation of inflammatory factors, thus dilating the vessels and eliminating the absorbance of the inflammatory mediator, so as to mitigate the pains⁽¹⁵⁾. CT guidance for the injection of drugs at the targeted site in the protruded lumbar disc can help the physicians to deliver the drugs to the target site precisely, which can benefit the absorbance of the lumbar disc and relieve the inflammation in the nerve root.

The results of this study showed that the total effectiveness rate in the short-term treatment in the observation was superior to that of the control group ($P < 0.05$), suggesting that this strategy benefits the recovery of patients by improving the clinical efficacy. Furthermore, after treatment, patients in the observation group had better performance in the joint range of motion when bending forward or backward the lumbar disc, BI index and Fugl-Meyer scores than their counterparts in the control group ($P < 0.05$), with a lower Oswestry score ($P < 0.05$), indicating that this strategy, by introducing the advantages of different protocols, improves the waist functions and limb function, and mitigates the functional disturbance of patients^(16,17). However, patients should perfect the relevant examinations before treatment, and guarantee to comply with the treatment protocol. However, patients with the calcified protruded lumbar disc or with spinal canal stenosis are not eligible for this strategy.

In conclusion, targeted injection of betamethasone surrounding the protruded lumbar disc in combination with the ozone performs well

in short-term efficacy, conducive to improving the lumbar disc function and limb function, and alleviating function disturbance. Thus, this strategy is worthy of being promoted in clinical practice.

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