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Comparison of the Clinical Effect of Collagenase Lysis with Different Administration Routes in Treating Lumbar Disc Herniation

Junhong Liu

Department of Pain, Liuzhou People's Hospital Affiliated to Guangxi Medical University, Liuzhou 545006, Guangxi, China

Abstract: *Objective:* To observe and discuss the clinical effect of collagenase lysis in the treatment of lumbar disc herniation through different administration routes. *Methods:* Sixty patients with lumbar disc herniation admitted to Liuzhou People's Hospital from February 2023 to February 2024 were selected, including 31 males and 29 females. They were divided into A and B groups according to the random number table method. Group A was injected through sacral hiatus route combined with intervertebral foramen safety triangle route (n = 30), and Group B was injected only through sacral hiatus route (n = 30). The VAS score, ODI index, and the efficacy of Macnab were observed before operation, 3 days, 1 month, and 3 months after operation, and the results were summarized and compared. Results: Compared with Group B (only through the sacral hiatus route), the VAS score, ODI index, and the efficacy evaluation of Macnab in Group A (through the sacral hiatus route combined with the intervertebral foramen safety triangle route) were significantly better, and the differences were statistically significant ($P < 0.05$). *Conclusion:* Multi-path collagenase lysis is more effective than single-path collagenase lysis.

Keywords: Puncture; Collagenase; Clinical observation; Lumbar disc herniation

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1. Introduction

Lumbar disc herniation (LDH) is commonly encountered in clinical pain departments and is generally considered a degenerative spinal disease. Epidemiological surveys indicate that LDH is highly prevalent among middle-aged and elderly populations, with low back pain and sciatica being its most common concurrent symptoms, significantly impacting the daily lives of elderly patients and thereby drawing considerable attention from scientific research in geriatric medicine, geriatric nursing, and other geriatric healthcare fields [1]. As times change, the demographic most affected by LDH is gradually becoming younger, no longer limited to the middle-aged and elderly. Moreover, patients discharged after treatment

for lumbar disc herniation often face a lengthy treatment cycle and incur substantial costs during treatment, posing a considerable burden on the social healthcare system [2]. Collagenase chemonucleolysis (CCNL) is a minimally invasive interventional treatment commonly used in clinical settings for LDH patients who do not respond well to conventional conservative treatments. Since its introduction in 1968, CCNL has garnered widespread attention due to its minimal invasiveness, effectiveness, and relatively low cost. However, due to the development of new technologies and commercial competition, its application has gradually decreased abroad. In contrast, in China, continuous research and improvement of this method have led to its widespread use as a common treatment for LDH in clinical practice [3]. Depending on the injection route, CCNL can be classified into various types. This study takes the injection of collagenase chemonucleolysis through sacral hiatus route combined with intervertebral foramen safe triangle route as an example. By comparing the clinical effects of combined injection and the sacral hiatus route alone, we explore the impact of different injection routes on the clinical efficacy of CCNL.

2. Materials and methods

2.1. General information

This study selected 60 patients with LDH admitted to Liuzhou People's Hospital from February 2023 to February 2024, comprising 31 males and 29 females, aged between 50 and 70 years. They were divided into two groups, A and B, using a random number method. Patients in Group A underwent catheter injection surgery via the sacral hiatus route combined with the intervertebral foramen safe triangle route (n = 30), while patients in Group B underwent catheter injection surgery via the anterior space approach through sacral hiatus puncture (n = 30). The physical conditions of the two groups of patients were similar, with no significant differences in various data ($P > 0.05$), indicating comparability. See **Table 1**.

This study has been approved by the Ethics Committee of Liuzhou People's Hospital, and all patients fully understood the research content and signed informed consent forms.

Table 1. General information of the two groups of patients

Group	Number of cases	Age (years)	Male/Female	Body mass index (kg/m^2)	ASA grade ratio (I/II)	Operation time (min)	Medical history (years)	Lesion location	
								L5–S1	L4–5
A	30	59.6 ± 5.3	16/14	21.27 ± 2.4	9/21	48.5 ± 7.0*	14.5 ± 3.2	5	25
B	30	60.1 ± 5.3	15/15	22.0 ± 2.2	1/2	35.4 ± 4.5	14.6 ± 2.5	6	24
t	/	-3.65	/	-1.24	/	8.65	-0.18	/	/
P	/	0.716	/	0.220	/	<0.01	0.859	/	/

2.2. Diagnostic indicators

Based on the *Guidelines for Diagnosis, Treatment, and Rehabilitation Management of Lumbar Disc Herniation* [4], pain scores and various indicators were recorded and compared before surgery, as well as 3 days, 1 month, and 3 months after surgery. The indicators to be compared include: the Oswestry Disability Index (ODI), Visual Analog Scale (VAS), and the modified Macnab criteria for evaluating therapeutic efficacy.

2.3. Inclusion criteria

(1) Meet the diagnostic criteria for mild to moderate lumbar disc herniation with radiculopathy as confirmed by MRI examination [5];
(2) Aged between 50 and 70 years old;
(3) Able to communicate normally with medical staff and accurately describe pain and symptoms;
(4) Able to actively cooperate with treatment and complete all measures in the study;
(5) No severe allergic reactions to medications used in surgery and acceptable for collagenase chemonucleolysis treatment;
(6) Informed consent obtained from both the patient and their family for participation in this study.

2.4. Exclusion criteria

(1) Patients with sudden worsening of symptoms and signs, presenting with motor dysfunction and cauda equina syndrome;
(2) Patients with other major diseases such as cancer, hypertension, coronary heart disease, etc.;
(3) Patients who have previously received other spinal interventional treatments;
(4) Patients with infections or organ failure leading to organ dysfunction;
(5) Patients with abnormal blood coagulation function who cannot undergo surgery;
(6) Patients who withdraw from the study for various reasons.

2.5. Instruments and medications

2.5.1. Instruments

(1) Medical angiography X-ray machine (DSA, Siemens Healthineers, Arsis One);
(2) 18-gauge epidural needle (BD, USA, State Food and Drug Administration Import License No. 2005-3153190).

2.5.2. Medications

(1) Collagenase for injection (Yuanda Life Sciences Co., Ltd., National Medical Products Administration Approval No. H10960178);
(2) 1% lidocaine hydrochloride injection (Hubei Tiansheng Pharmaceutical Co., Ltd., National Medical Products Administration Approval No. H42021839);
(3) Dexamethasone sodium phosphate for injection (Cisen Pharmaceutical Co., Ltd., National Medical Products Administration Approval No. H37021969);
(4) Hismanal (Loratadine tablets; Chengdu Yongkang Pharmaceutical Co., Ltd., National Medical Products Administration Approval No. H20051618);
(5) Iodotrren injection (contrast agent; Yangtze River Pharmaceutical Group Co., Ltd., National Medical Products Administration Approval No. H10970358);
(6) Betamethasone sodium phosphate for injection (Ma'anshan Fengyuan Pharmaceutical Co., Ltd., National Medical Products Administration Approval No. H20060968).

2.6. Surgical methods

Group A: Catheter injection surgery via the sacral hiatus pathway combined with the safe triangle pathway of the intervertebral foramen;

Group B: Catheter injection surgery with catheter placement in the anterior epidural space via the sacral hiatus puncture approach.

2.6.1. Preoperative preparation

Both groups underwent the same preoperative preparation, including routine examinations to ensure normal vital signs and suitability for surgery. Patients received an intravenous injection of 5 mg dexamethasone before surgery.

2.6.2. Procedure

Group A: (1) Puncture point localization: The patient was placed in a prone position. Under DSA guidance, the optimal puncture point was identified, and the puncture angle and depth were calculated and marked. (2) Local anesthesia with 1% lidocaine was administered. Using an 18-gauge epidural needle, under DSA guidance, the needle was inserted at the predetermined optimal puncture point, adjusting the angle as needed to reach the predetermined depth. (3) 2 ml of contrast agent was injected, and anteroposterior and lateral vertebral canal angiography images were taken to confirm catheter position (see **Figure 1**). (4) After confirming that the needle tip was located in the anterior epidural space, a catheter was placed (or the puncture needle was oriented towards the intervertebral foramen with its spoon-shaped side facing it). 3 ml of 1.3% lidocaine was injected, and the patient's response was observed for 10–15 minutes. If no spinal anesthesia occurred, collagenase for injection (4 ml of collagenase diluent dissolving 1,200 U of collagenase powder) was injected (see **Figure 2**). (5) After observing for 1 hour postoperatively for no allergic reactions or other complications, the patient was instructed to maintain a supine position for approximately 8 hours, with the body slightly tilted forward and the affected side down. Absolute bed rest was required for at least 24 hours.

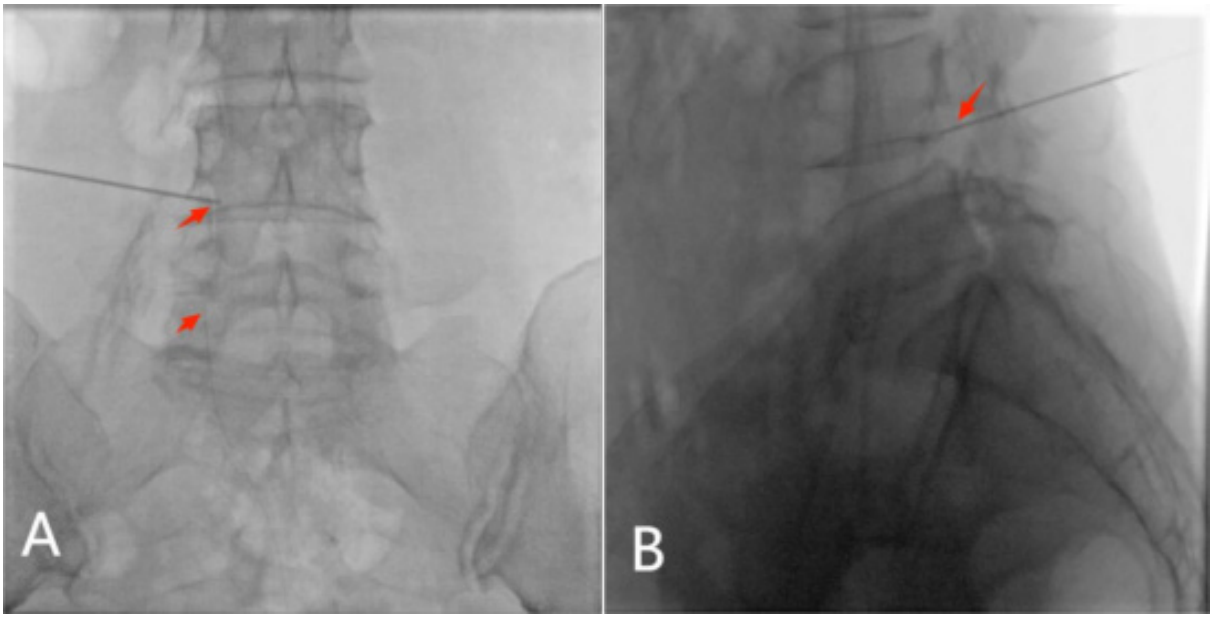

Figure 1. Sacral hiatus route combined with intervertebral foramen safety triangle route

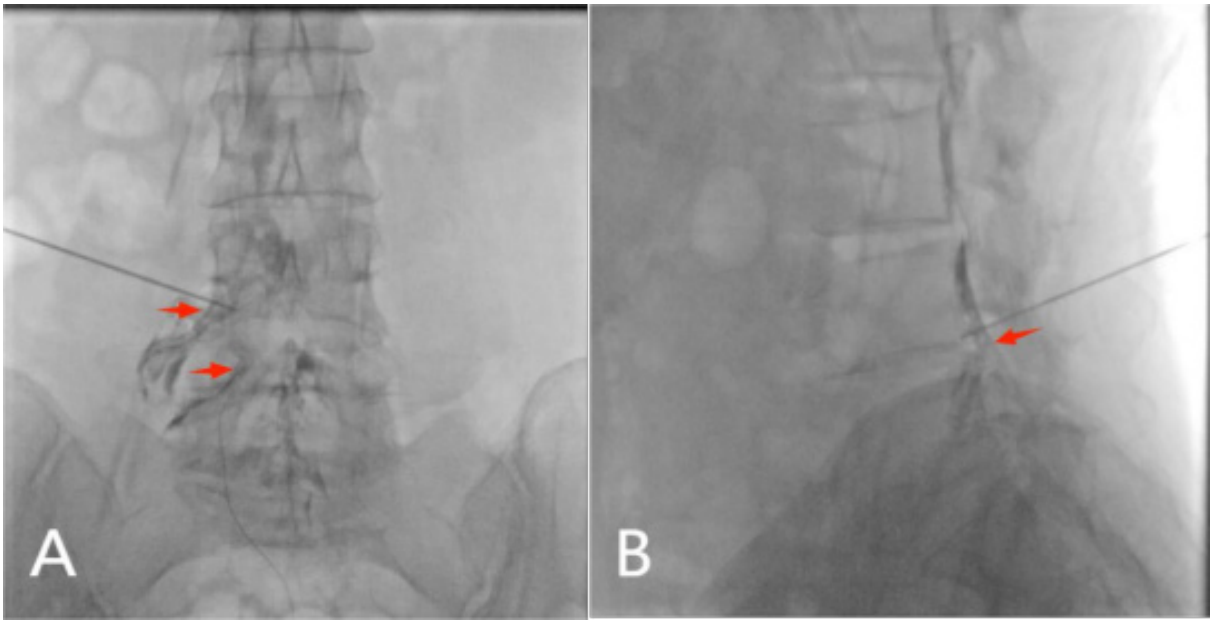

Figure 2. Intraoperative imaging (A: Puncture needle to target, nerve root development; B: Anterior epidural space imaging)

Group B: (1) Puncture point localization: Under DSA guidance, identified the puncture point at the sacral hiatus, calculated the puncture angle and depth, and marked them accordingly; (2) Disinfected the skin at the affected area and draped it with a sterile towel. Using an 18-gauge beveled intradiscal needle, punctured through the sacrococcygeal ligament to reach the periosteum. The needle was initially inserted perpendicular to the skin at a 90° angle, then adjusted to tilt caudally, forming a 15–30° angle upwards with the skin. The needle was inserted approximately 5–7 cm into the skin, with the puncture depth exceeding the plane of the posterior. See **Figures 3** and **4**.

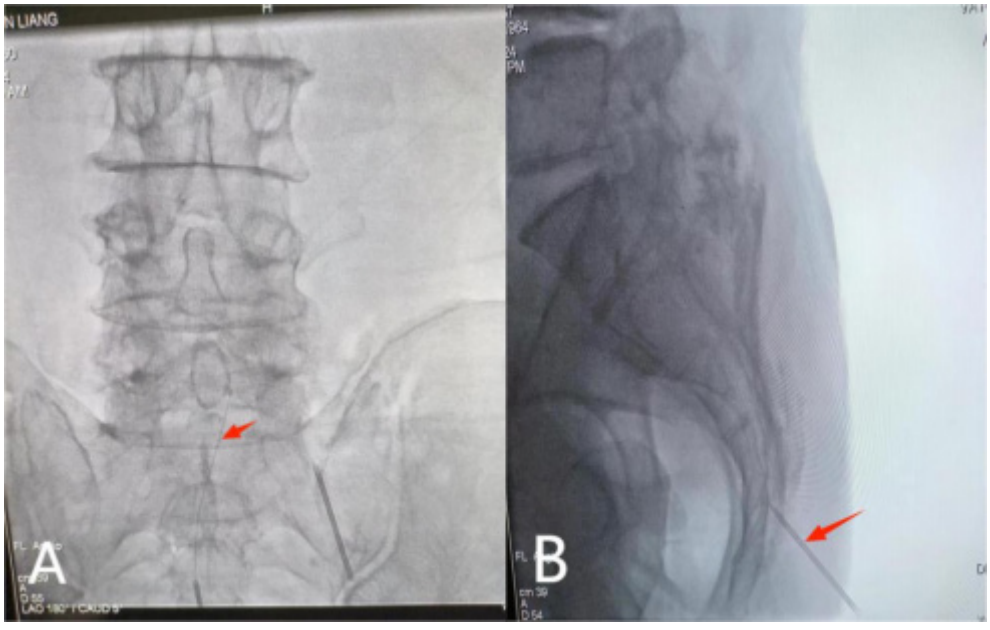

Figure 3. Gap before sacral hiatus puncture approach (A: Right position; B: Lateral position)

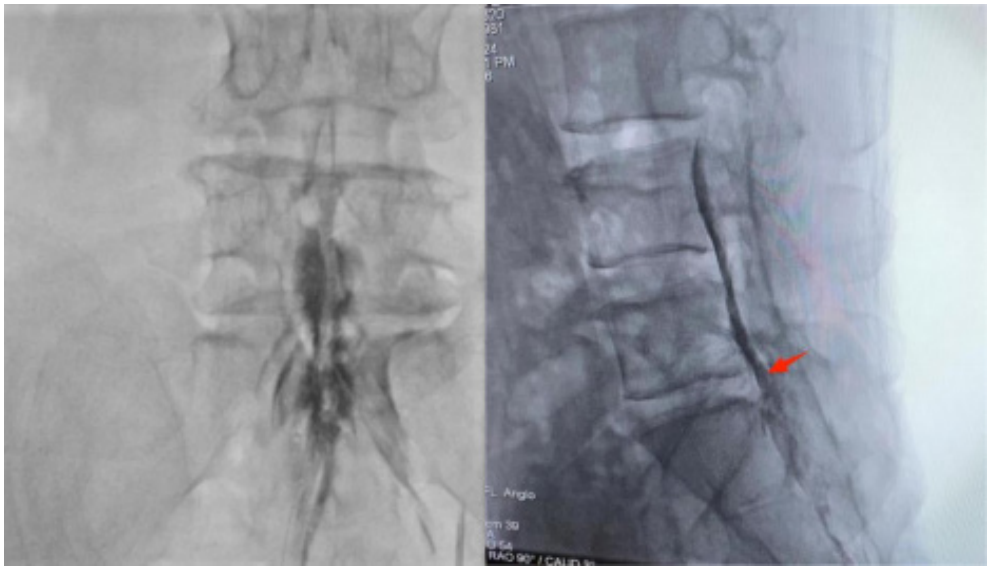

Figure 4. Puncture imaging of sacral hiatus (lumbar L5/S1)

2.6.3. Prevention and emergency management of complications

Early prevention: After CCNL surgery, complications such as nervous system edema, intervertebral space infection, and deep vein thrombosis of the lower extremities are prone to occur [6]. To ensure the safety of the surgery, it is necessary to strictly control the patient's diet before the operation and provide relevant bowel training. Studies have shown that the patient's psychological state has a certain impact on postoperative recovery, so professional psychological counseling should be provided before surgery. The patient's vital signs should be closely monitored during the puncture process. After surgery, infrared radiation should be applied locally while keeping the affected area clean and dry. Medications should be administered strictly according to medical advice to prevent postoperative infection, and patients should be assisted in performing functional exercises safely and correctly [7].

Emergency management: Accidental entry into the subarachnoid space is an emergency that may occur during the collagenase dissolution treatment process. Experiments have shown that accidental entry into the subarachnoid space carries a certain risk of spinal cord injury, leading to lower limb paralysis and causing serious consequences. Therefore, once it occurs, the following emergency measures should be taken immediately: (1) The characteristic of accidental entry into the subarachnoid space is that the cerebrospinal fluid in the cavity is pink or bloody. If the puncture point is selected at or below the collagenase injection level and this characteristic appears, a diagnosis can be made. First, withdraw 10 ml of cerebrospinal fluid, then inject 10 ml of normal saline, wait for 2 minutes, and repeat the above operation until the cerebrospinal fluid becomes clear. The replacement can be repeated once after 24 hours, generally replacing more than 50 ml. (2) Factors such as advanced age with spinal stenosis, high-level herniation causing obstruction, cerebrospinal fluid leakage, and arachnoid adhesion may all prevent cerebrospinal fluid replacement. If relevant situations occur, replacement can be performed under CT guidance. The patient should lie prone on the diagnostic bed, and the needle should be inserted at the L3–4; L4–5 ligamentum flavum area, with the needle tip placed in the center of the dural sac. At this time, fluid overflow can be seen at the needle tip, confirming entry into the subarachnoid space. Inject 10 ml of normal saline with a syringe, remove the

syringe, wait for about 10 ml to automatically overflow, continue to inject 10 ml of saline, and repeat the above operation 5–6 times.

2.6.4. Postoperative follow-up and observation

Patients were followed up after surgery, and their indicators and recovery status were recorded at three time points: 3 days, 1 month, and 3 months after surgery.

2.7. Observation of treatment efficacy and safety

2.7.1. Efficacy evaluation

(1) The Visual Analog Scale (VAS) is used to assess the degree of pain. Patients mark their pain intensity on a scale according to their own perception, with scores ranging from 0 to 10, increasing from painless to severe pain. The higher the score, the more severe the pain. A score of 0 is considered painless, and 10 is the highest level of unbearable pain. A mean score of 2.57 ± 1.54 is considered mild, 5.18 ± 1.41 is considered moderate, and 8.41 ± 1.35 is considered severe.

(2) The modified Macnab method is used to evaluate the efficacy, which is divided into four grades: excellent, good, fair, and poor, based on the degree of pain relief and recovery of daily life activities. "Excellent" means that the patient can resume normal life without medication and has no pain symptoms; "good" means significant improvement, with the patient's life basically returning to normal; "fair" means that symptoms have improved but still affect life to a certain extent; "poor" means no significant improvement. Poor results are considered ineffective treatment. The results are summarized and the proportion is calculated.

(3) The Oswestry Disability Index (ODI) is used to evaluate functional impairment. Patients fill out a test form with a maximum possible score of 50, with 5 points for each question. The ODI index is calculated using the formula (actual score/maximum possible score) × 100% (if any questions are left unanswered, the maximum possible score should be reduced by the score of the unanswered questions). The higher the score, the more severe the functional impairment [8].

2.7.2. Safety observation

(1) Observe whether the patient experiences any discomfort in the digestive system, nervous system, immune system, etc., after surgery, and whether the vital signs are normal.

(2) Observe whether the patient develops complications such as infection or adverse reactions such as allergies after surgery.

2.8. Statistical analysis methods

Data were processed using SPSS 27.1 statistical software. Measurement data were tested using the two independent sample t-test and expressed as mean ± standard deviation (SD). Count data were tested using the χ^2 test, with a test standard of $\alpha = 0.05$. If $P < 0.05$, the difference was considered statistically significant.

3. Results

3.1. Pain status

The preoperative *P*-value of 0.250 > 0.05 for the two groups of patients indicates no significant difference

in preoperative VAS scores. The VAS scores of both Group A and Group B on the 3rd day, 1 month, and 3 months after surgery were significantly lower than those before surgery ($P < 0.05$). The VAS scores of both groups dropped below 3 at 3 months after surgery, indicating that both groups had effective treatment with good results. Comparing the VAS scores of Group A and Group B, the preoperative average score of Group A was 8.6 ± 0.3, which dropped to 1.5 ± 0.3 at 3 months after surgery; the preoperative average score of Group B was 8.5 ± 0.3, which was 1.9 ± 0.3 at 3 months after surgery. The improvement rate of postoperative scores in Group A was slightly higher than that in Group B (see **Table 2**).

Table 2. Comparison of VAS scores before and after surgery in the two groups of patients (mean ± SD)

Group	Number of cases	Preoperative	3rd day postoperative	1 month postoperative	3 months postoperative
A	30	8.6 ± 0.3	2.7 ± 0.3	1.8 ± 0.3	1.5 ± 0.3
B	30	8.5 ± 0.3	3. 1 ± 0.2	2.2 ± 0.3	1.9 ± 0.3
t	/	1.161	-7.198	-5.541	-8.591
P	/	0.250	<0.01	<0.01	<0.01

*$P < 0.05$ compared with preoperative values

3.2. Functional impairment status

The preoperative *P*-value of 0.937 > 0.05 for the two groups of patients indicates no significant difference in preoperative ODI scores. The ODI scores on the 3rd day, 1 month, and 3 months after surgery were significantly lower than those before surgery in both groups ($P < 0.05$). The ODI scores of both groups dropped below 45 at 3 months after surgery, indicating that both groups had effective treatment with good results. Comparing the ODI scores of Group A and Group B, the preoperative average score of Group A was 76.4 ± 6.8, which dropped to 20.6 ± 2.3 at 3 months after surgery; the preoperative score of Group B was 76.6 ± 6.1, which decreased to 23.4 ± 2.3 at 3 months after surgery. The improvement rate of postoperative scores in Group A was slightly higher than that in Group B (see **Table 3**).

Table 3. Comparison of ODI scores before and after surgery in the two groups of patients (mean ± SD)

Group	Number of cases	Preoperative	3rd day postoperative	1 month postoperative	3 months postoperative
A	30	76.4 ± 6.8	34.5 ± 3.3	23.8 ± 3.8	20.6 ± 2.3
B	30	76.6 ± 6.1	40.5 ± 3.0	26.5 ± 2.8	23.4 ± 2.3
t	/	-0.80	-6.937	-3.216	-4.853
P	/	0.937	<0.01	<0.05	<0.01

*$P < 0.05$ compared with preoperative values

3.3. Modified Macnab efficacy assessment

At the 3-month postoperative Macnab efficacy evaluation, Group A had 0 cases classified as “poor,” with an excellent and good rate of 100%; Group B had 1 case classified as “poor,” with an excellent and good rate of 76.7%. Furthermore, compared with Group B, Group A had a higher number of cases rated as “excellent” and “good,” indicating a more favorable treatment outcome in Group A (see **Table 4**, **Figures 5** and **6**).

Table 4. Efficacy evaluation of the two groups of patients at 3 months postoperatively

Group	Number of cases	Excellent	Good	Fair	Poor	Excellent and good rate (%)
A	30	20	10	0	0	100
B	30	15	8	6	1	76.7
χ^2	/	/	/	/	/	10.643
P	/	/	/	/	/	<0.05

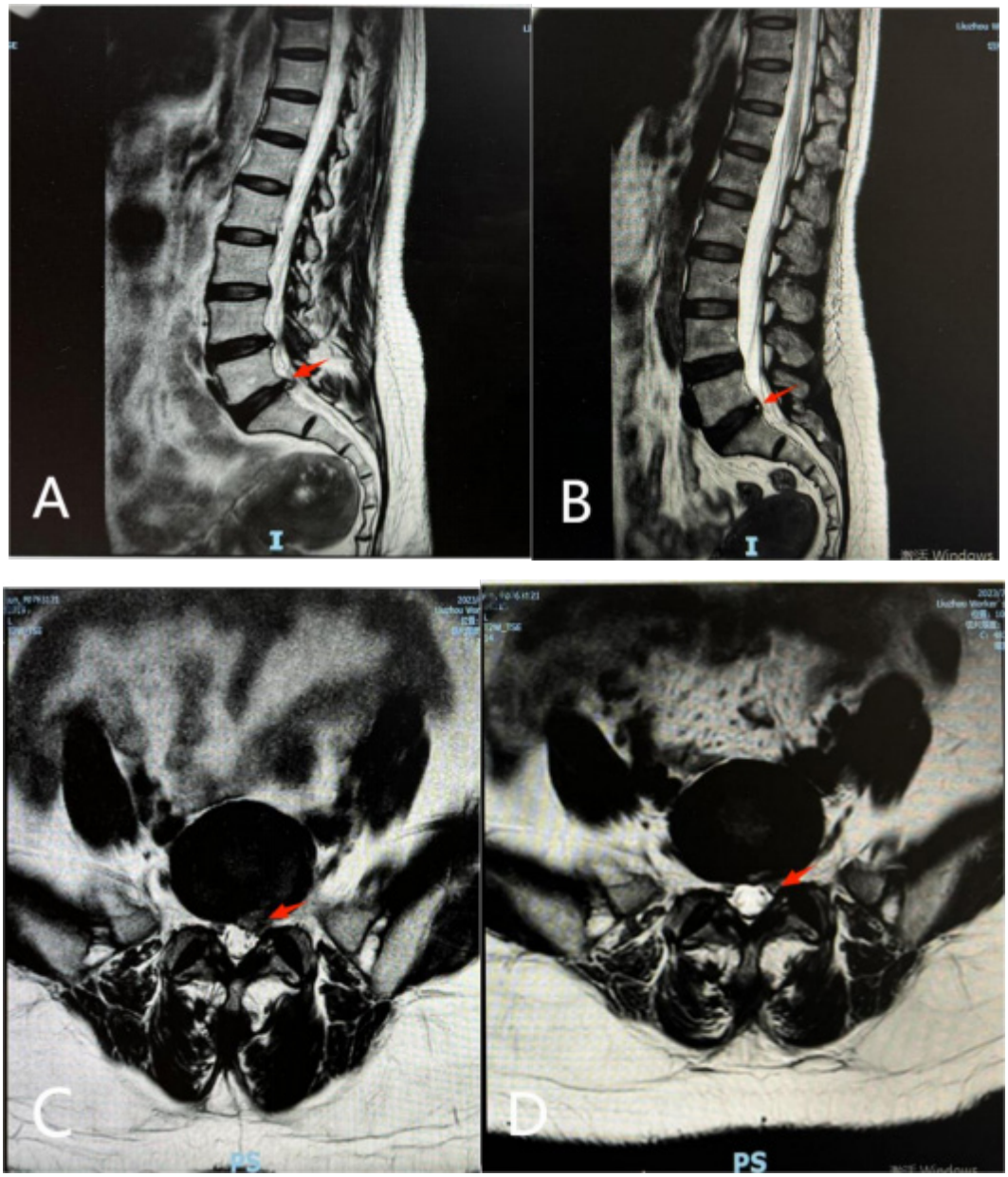

Figure 5. Preoperative and postoperative images of Group A (A, C: preoperative; B, D: 3 months after surgery)

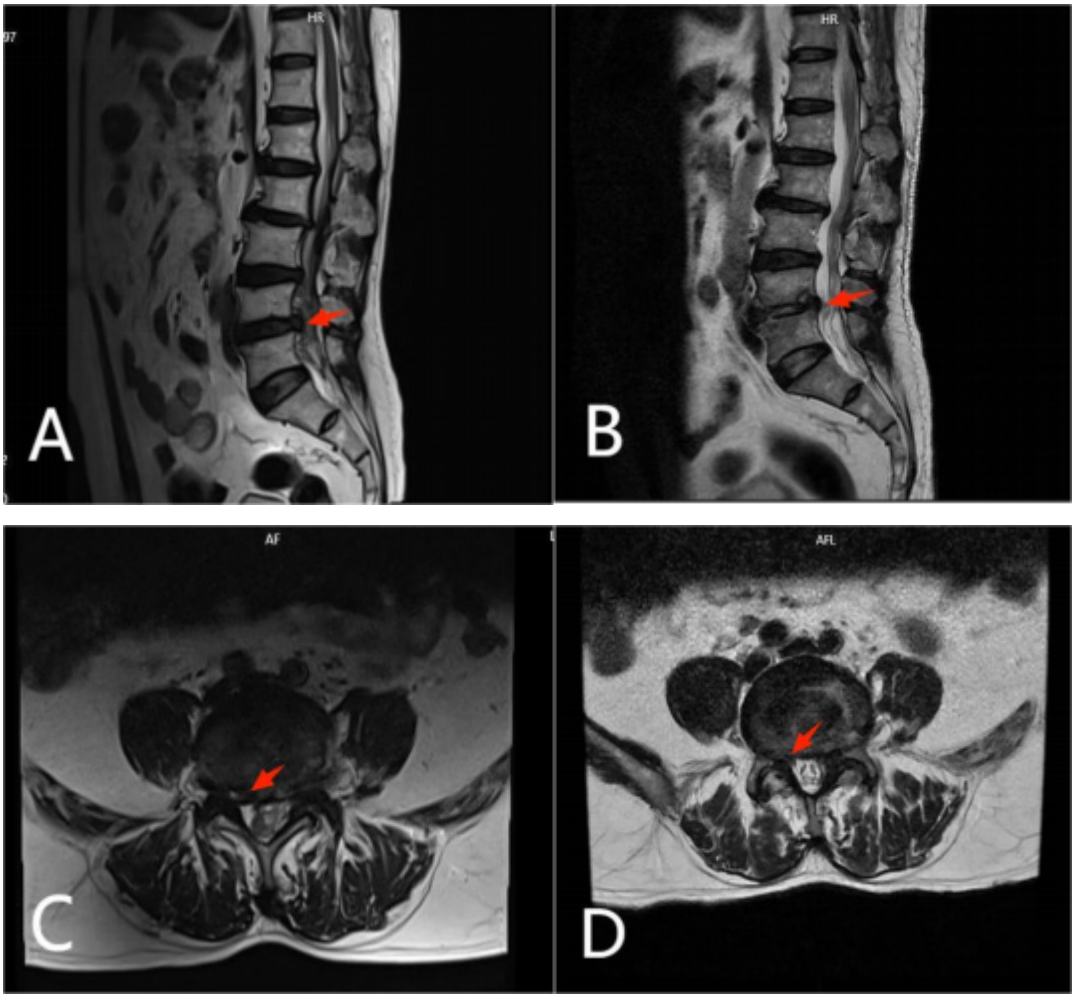

Figure 6. Preoperative and postoperative images of Group B (A, C: preoperative; B, D: 3 months after surgery)

3.4. Safety evaluation

Neither group of patients experienced nerve root injury, neurological edema, intervertebral space infection, deep vein thrombosis of the lower extremities, or other complications. In Group A, only one patient experienced minor bleeding during the operation, which ceased after emergency hemostasis, allowing normal subsequent treatment to proceed. Group B did not experience any bleeding during the operation. Neither group exhibited weakness or numbness in the lower extremities postoperatively. Both groups demonstrated satisfactory safety profiles.

4. Discussion

Collagenase chemonucleolysis involves inserting a puncture needle into the affected area and injecting collagenase, which reaches the herniated site through puncture injection. Activated by proenzyme activators within the intervertebral disc, collagenase disrupts the internal structure, causing the α-chain to break at 3/4 of the distance from the amino acid, ultimately degrading into amino acids that flow into the bloodstream and are neutralized and absorbed by plasma [9]. Additionally, collagenase can inhibit the activity of phospholipase A2, a substance typically associated with tissue inflammation, thereby providing both analgesic and anti-

inflammatory effects at the affected site, resulting in an excellent therapeutic outcome for lumbar disc herniation [10–13]. Theoretically, when the herniation is small and the annulus fibrosus is intact, collagenase can be injected into the intervertebral disc for intradiscal injection [14]. However, this method is prone to causing injury, poses greater challenges in postoperative care, and has a higher recurrence rate compared to extradiscal injection, making extradiscal injection more commonly used in clinical practice [15]. In this study, both groups underwent extradiscal injection.

In this study, both Group A and Group B demonstrated favorable therapeutic effects during the 3-month postoperative follow-up, indicating the superior efficacy of collagenase chemonucleolysis in the clinical treatment of lumbar disc herniation. Since its initial proposal in 1999, the treatment concept of "targeted injection, enzyme dissolution of substrate" has gained widespread acceptance through numerous clinical trials and case observations. Adverse reactions following collagenase surgery have been continuously reduced with the development of treatment methods, while treatment efficacy has improved, with lower costs and minimal trauma. This not only contributes to the conservation of medical resources but also meets the requirements of the Diagnosis-Related Groups (DRG) policy [16].

In this study, Group A, which underwent a combination of sacral hiatus and intervertebral foramen safe triangle approach, showed superior results in terms of VAS score, ODI index, and Macnab efficacy evaluation compared to Group B, which underwent only sacral hiatus approach injection. This suggests that multi-path combined collagenase chemonucleolysis has better clinical efficacy than single-puncture path collagenase chemonucleolysis. This may be because multi-path combined collagenase chemonucleolysis has more puncture targets than single-path methods, covering a larger area on the surface of the herniated lesion, promoting the infiltration of collagenase through weak points to dissolve the herniated lesion compressing the nerve root, thereby enhancing the therapeutic effect [17]. This also suggests that collagenase chemonucleolysis should be performed according to the principles of low dose and multiple targets in actual clinical practice.

5. Conclusion

In summary, the results of this study indicate that multi-path combined collagenase chemonucleolysis has superior clinical efficacy compared to single-path collagenase chemonucleolysis. However, it should be noted that multi-path combined collagenase chemonucleolysis requires injection punctures at more sites than single-path methods, thereby increasing the surgical risk. In actual clinical treatment, a comprehensive consideration of efficacy and safety should be undertaken, taking into account the patient's personal wishes and specific circumstances, to reasonably assess risks and select the appropriate puncture path. This study is a single-center clinical observational study, and due to the selection of samples only from our hospital, it inevitably has the limitation of a small sample size. Additionally, due to time constraints, the follow-up in this study only extended to 3 months postoperatively, which is a relatively short period. To more comprehensively and specifically validate the conclusions, further in-depth studies with larger sample sizes and more comprehensive approaches are needed to refine the conclusions of this study.

Disclosure statement

The author declares no conflict of interest.

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