Clinical Trial/Experimental Study

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The effect of ultrasound-guided acupotomy and Juanbi decoction on lumbar disc herniation

A randomized controlled trial

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Abstract

Background: Acupotomy as well as Juanbi decoction has been used in the treatment of lumbar disc herniation. However, there is no study on ultrasound-guided acupotomy combined with Juanbi decoction in the treatment of lumbar disc herniation.

Method: This study was supported by the Sichuan Provincial Administration of Traditional Chinese Medicine [grant number: 2020LC0163] and the Science and Technology Department of Sichuan Province [grant number: 2022YFS0418]. This study was 3 center, open, randomized, controlled trial, and was carried out from December 2020 to December 2022. A total of 60 eligible patients with LDH were split into group A and group B at random. The group B received Juanbi Decoction 3 times daily for 2 weeks along with an acupotomy assisted by ultrasound. The acupotomy was administered once a week. The same protocol was used with the group A, but the Juanbi Decoction was replaced with normal saline.

Observation index: Visual analogue scale (VAS) score on 1 day and 1 week after treatment, VAS score, Japanese orthopedic association low back pain score(JOA) rate, Oswestry Disability Index (ODI), and low back outcome scale (LBOS) at 1, 3, 6, and 12 months after treatment in 2 groups.

Results: There were no significant differences in general information, VAS score before treatment, JOA, ODI, and LBOS between the 2 groups ($P > .05$). Intra-group comparison: VAS score, JOA rate, ODI, and LBOS were compared before and after treatment in both groups, and the differences were statistically significant ($P < .05$). There were significant differences in VAS and LBOS between the 2 groups at 3 and 6 months after treatment, and there were statistically significant differences in ODI and JOA rates at 3, 6, and 12 months after treatment between the 2 groups.

Conclusion: Acupotomy aided by ultrasound combined with Juanbi Decoction significantly relieves lumbar pain and can improve lumbar function in patients with LDH, and the clinical efficacy lasts for about 6 months.

Abbreviations: JOA = Japanese orthopedic association low back pain score, LBOS = low back outcome scale, LDH = lumbar disc herniation, ODI = Oswestry Disability Index, VAS = visual analogue scale.

Keywords: acupotomy, juanbi decoction, lumbar disc herniation, ultrasound

1. Introduction

One key cause of low back pain is lumbar disc herniation,[1,2] which accounts for about 21.31 percent of patients with low back pain in outpatient departments.[3] A systematic analysis in China shows that the prevalence rate of low back pain in adults is 7.21% to 39.0%, 20.88% to29.88% annually, and 6.11% to28.5% in real-time.[4] The prevalence of low back pain is higher than that of diabetes and hypertension, and it has become a public health concern in China. As a result, many manual workers lose their ability to work, causing a severe economic burden to individuals, families, and societies. Noninvasive treatments currently in use do not provide long-term pain relief. While extensive treatments such as endoscopic therapy can relieve pain, surgical complications, recurrence after surgery, and high costs discourage its patronage. Acupotomy, based on anatomy and acupuncture theory, was firstly introduced in China in 1976 by Zhu Hanzhang. It has been applied for treating chronic pain via incising the synechia and removing the attached tissue with a flat-head bladed needle.[5]Acupotomy is a treatment method for lumbar disc herniation (LDH),[6] but it has some disadvantages such as accidental injury of blood vessels and nerves, and inaccurate operation and positioning. Musculoskeletal ultrasound has been

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The datasets generated during and/or analyzed during the current study are publicly available.

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widely used in the rehabilitation, orthopedics department and other fields for puncture localization and real-time guidance in recent years.[7]Juanbi Decoction, from the Book "Medical Mind Understanding" written by Cheng Guopeng in the Qing Dynasty, is a common prescription for the treatment of lumbago in China. It was listed in the first batch of the Catalogue of Ancient Classic Prescriptions released by the National Administration of Traditional Chinese Medicine. Not a lot of studies has been done on acupotomy aided by ultrasound combined with Juanbi Decoction in the treatment of LDH. This study, therefore, was aimed at assessing the effect of treating LDH with acupotomy aided by ultrasound and combined with Juanbi Decoction.

2. Method

2.1. Participants and study design

This study was designed following the Helsinki Declaration, approved by the Ethics Committee of Qionglai Hospital of Traditional Chinese Medicine [grant number: MR51-21-005688], and registered at the Chinese Clinical Trial Registry [registration number: ChiCTR2100051712]. This study was 3 center, open, randomized, controlled trial, and was carried out from December 2020 to December 2022. All participants were open to the group allocation and required to provide a prior written informed consent. Participants were recruited through the social media networking tool WeChat. Although participants received no financial rewards during the trial, the treatment and examinations were both free for all.

All participants were confirmed by physical examination and magnetic resonance imaging with LDH at L4 to 5 or L5 to S1. Patients were either or not selected on the following basis:

2.1.1. Inclusion criteria.

(1) A confirmed diagnosis of the lumbar herniated disc of L4 to 5 or L5 to S1 by magnetic resonance imaging within the past year.
(2) Clinical symptoms of lumbago and pain in 1 side of the lower limb.
(3) Age <65 years.
(4) Ability to independently sign the informed consent and comply with the study protocol.

2.1.2. Exclusion criteria.

(1) Complications of lumbar instability, spondylolisthesis, tumor, or infections.
(2) Disc protrusion to the posterior middle or accompanied by symptoms of cauda equina injury such as abnormal bowel and urine function and hypesthesia in the saddle area.
(3) LDH caused by trauma.
(4) Medical conditions that advise against the use of local anesthesia.
(5) History of surgery to treat the lumbar.

2.1.3. Sample size, randomizationand masking. The sample size was calculated by PASS software (Power Analysis & Sample Size 2020), and a total of 60 patients with LDH were enrolled in this study according to the inclusion and exclusion criteria. The random numbers generated were placed in an opaque sealed envelope using a random number table, and the envelopes were drawn sequentially based on the order in which the patients were seated and randomly divided into group A and group B accordingto a 1:1 ratio. For the group B, 30 patients were treated with acupotomy aided by ultrasound combined with Juanbi Decoction. For the group A, the other 30 patients were treated with acupotomy aided by ultrasound combined with normal saline. The operators were not blindly offering treatments, but blind to the grouping allocation. However, participants, outcome evaluators, and statisticians were all unaware of the grouping allocation.

2.2. Treatment

2.2.1. Acupotomy treatment points, position, and preparation. Acupotomy treatment points were as follows: Medial articular process, below the base of L4 to S1 transverse process, and GB30 point. The patients were each placed face-down on a pain management table, which was initially aseptically prepared and draped. The convex array low-frequency probe was wrapped with an aseptic sheath.

2.2.2. Medial point of the articular process. The convex array low-frequency probe was positioned under showing until a "cat face" sign first appeared (Fig. 1), and about 1% lidocaine was used to perform dermatomic infiltration anesthesia at the located point. The assistant then fixed the probe, and the operator inserted the acupotomy of 1.2 × 80 mm into the target point in the plane from the side of the probe. The insertion was stopped until the tip reached the bone surface of the inferior articular process. The operator slightly raised acupotomy by 1 to 2 mm to make the tip slip from the medial edge of the inferior articular process into the ligament flavum. The operator had a blunt sense of cutting tendinous tissue after sliding through the medial edge of the articular process and controlled the cutting range of 4 to 5mm 4 to 5 times. Ligamentum flavum penetration was denoted by a subtle change of resistance. The release was stopped immediately the numbness radiated to the lower extremities, showing that the tip of the acupotomy had touched the nerve root. The schematic diagram of acupotomy operation of medial articular process and lower base of transverse processes was shown in Figure 2A.

2.2.3. The lower base of L4 to L5 transverse processes. Convex array low-frequency probe was positioned under showing until "Hump sign" first appeared (Fig. 3), and 1% lidocaine was used to perform dermatomic infiltration anesthesia at the located point. Then, the assistant fixed the probe, and the operator inserted the acupotomy of 1.2 × 80mm into the target point in the plane from the side of the probe. The insertion was stopped until the tip of the acupotomy reached the lower transverse process. The acupotomy was slightly lifted to make the tip about 2 mm away from the lower transverse

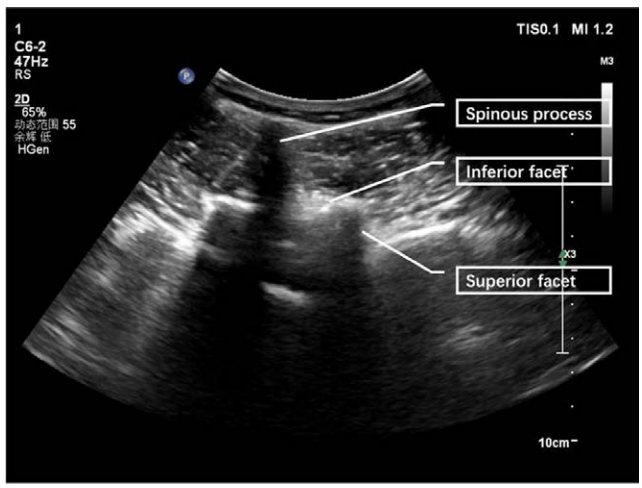

Figure 1. The "cat face" sign. (Showed by the musculoskeletal ultrasonography of lumbar).

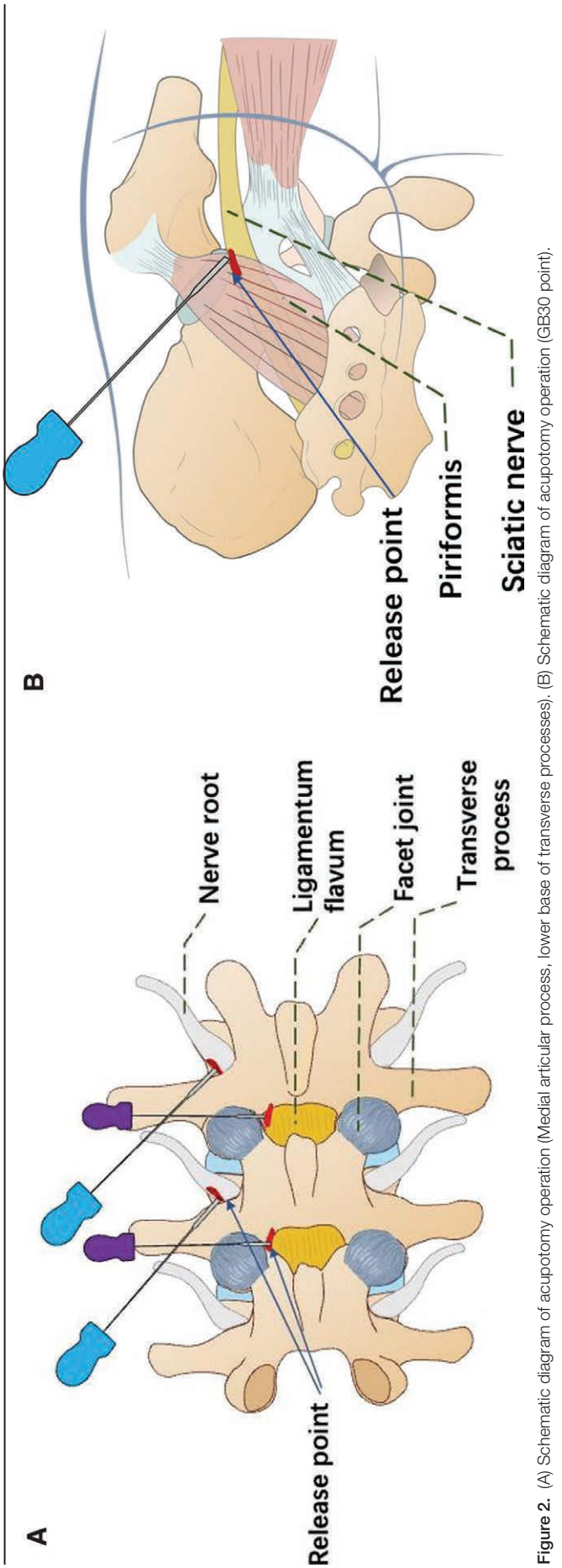

Figure 2. (A) Schematic diagram of acupotomy operation (Medial articular process, lower base of transverse processes). (B) Schematic diagram of acupotomy operation (GB30 point).

process. Then the operator redirected the acupotomy to slide under the lower transverse process and performed the release range of 4 to 5mm, 4 to 5 times. Next, the operator slowly made the acupotomy touch the nerve root. The touch was stopped until the numbness inductance radiated to the lower extremities indicating that the nerve root had been touched. The nerve root touch was repeated 3 times.

2.2.4. GB30 point. About 1% lidocaine was used to perform dermatomic infiltration anesthesia at GB30 point. The acupotomy of 1.0x80mm was used to slowly pierce the GB30 point. When the numbness radiated to the lower extremities, which gave an indication that root of the nerve has been touched, the insertion was stopped immediately and held for 3 seconds. The acupotomy was then slightly raised by 1 to 2mm, and the longitudinal release was made 4 to 5 times. The preceding steps were then repeated 3 times. The schematic diagram of acupotomy operation of the GB30 point was shown in Figure 2B.

2.2.5. Juanbidecoction. The Juanbi Decoction, composed of QiangHuo (Notopterygii Rhizoma seu Radix), Du Huo (Radix angelicaepubescentis), Rou Gui (Cinnamon), Qin Jiao (Fraxinus bungeana), Dang Gui (Angelica sinensis), Chuan Xiong (Ligusticum wallichii), Gan Cao (Liquorice), Hai Feng Teng (Kadsura pepper stem), Sang Zhi (Ramulus mori), Ru Xiang (Frankincense), and Mu Xiang (Radix vladimiriae), was administered 100mL once, 3 times a day, for 14 consecutive days.

2.3. Primary outcomes

(1) Visual analogue scale (VAS) was used to evaluate the improvement of lumbar pain.
(2) Japanese orthopaedic association low back painscore(-JOA) Evaluation Scale was used to assess the lumbar function before treatment and at 1, 3, 6, and 12 months after treatment. The treatment improvement rate was calculated as follows:

$$\text{Rate} = [(\text{post} - \text{treatment score} - \text{score of pre} - \text{treatments}) \div (29 - \text{score of pre} - \text{treatments})] \times 100\%, \text{ divided into four grades: excellent } (\geq 75\%), \text{ good } (50\% - 74\%), \text{ medium } (25\% - 49\%), \text{ poor } (\leq 24\%).$$

(3) The Oswestry Disability Index (ODI) questionnaire, with 10 items each rating between 0 to 5, was used. The calculations were then made as follows:

$$\text{ODI} = \text{actual score} / (\text{highest possible score}) \times 100\%.$$

ODI was used to evaluate the dysfunction of the lumbar before treatment and at 1, 3, 6, and 12 months after treatment, and a higher score indicates higher dysfunction.

(4) The low back outcome scale(LBOS) questionnaire, consisting of 13 items with a total of 75 points, was used to assess the outcome of treatment of low back pain 1, 3, 6, and 12 months after treatment, with a lower score indicating worse effect.

2.4. Safety assessment

The expected adverse events of the acupotomy and Juanbi decoction are local pain from the treated area, local bleeding from the treated area, infections, localized infection symptoms (redness, swelling, and/or local pain), nausea, vomiting, and dizziness. Patients were observed for the occurrence of adverse reactions during treatment, recorded and dealt with immediately.

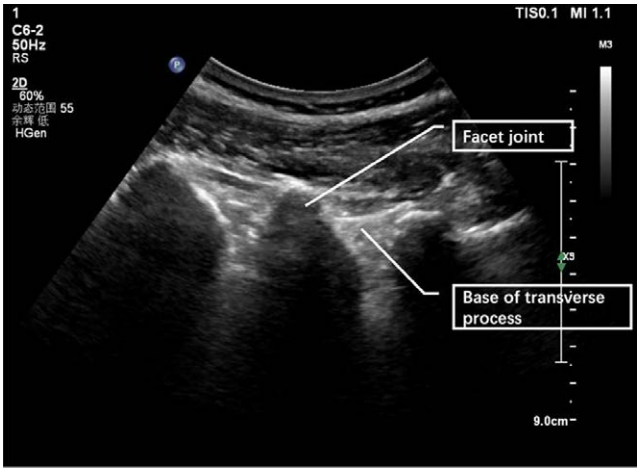

Figure 3. The "Hump sign" sign. (Showed by the musculoskeletal ultrasonography of lumbar).

2.5. Suspension and dropout

(1) Violations of the study protocol by investigators or participants.
(2) Emergence of serious adverse events, or challenging in trial continuation due to adverse events.
(3) A participant legal representative demands for discontinuing the trial because of unsatisfactory therapeutic effect.
(4) Withdrawal of participant's agreement to the study.
(5) During the trial, the medications which may influence on the outcomes assessment were used without the investigators' permission, such as the nonsteroidal anti-inflammatory drug.
(6) Patient's condition of LDH worsened.
(7) Loss to follow-up.

2.6. Statistical analysis

Statistical Product and Service Solutions (SPSS) statistical software version 26.0 (IBM, Armonk, NY) was used for data analysis, with test level $\alpha = 0.05$. Count data between the groups were tested by the χ^2 test. The T test was also used for measurement data conforming to normal distribution. An independent sample group T test was used for measurement data between groups and paired T test was used for intra-group comparison before and after treatment. $P < .05$ was statistically significant.

3. Results

All patients have successfully gone through the trial without adverse events observed.

3.1. Baseline information

This study included 60 patients with LDH, including 30 cases in the group A and 30 cases in the group B. This basic information(gender, age, time of operation) was no significant difference in the general data between the 2 groups ($P > .05$), as given in Table 1 and 2.

3.2. Efficacy

3.2.1. Intra-group comparison.

1. VAS for pain in the group A and group B in different periods.
   (Group A): the mean and standard deviation of VAS for pain between preoperative and postoperative assessments in 6 time periods (after 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months) were shown in Table 3. There were significant differences between means of VAS for pain in preoperative assessment (4.87) and postoperative assessments in 6 time periods (1.36,1.63,1.7,2.33,2.47 and 3.67 respectively) ($P < .05$).
   (Group B): the mean and standard deviation of VAS for pain between preoperative and postoperative assessments in 6 time periods (after 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months) were shown in Table 4. There were significant differences between means of VAS for pain in preoperative assessment (4.8) and postoperative assessments in 6 time periods (1.4,1.53,1.57,1.6,1.8 and 3.43respectively) ($P < .05$).
2. ODI in group A and group B in different periods
   (Group A): the mean and standard deviation of ODI between preoperative and postoperative assessments in 4 time periods (1 month, 3 months, 6 months, and 12 months) were shown in Table 5. There were significant differences between means of ODI in preoperative assessment and postoperative assessments in 4 time periods ($P < .05$).
   (Group B): the mean and standard deviation of ODI between preoperative and postoperative assessments in 4 time periods (1 month, 3 months, 6 months, and

Table 1

The mean differences of time and age between 2 groups.

Variable	Group A	Group B	*P*
Time (min)	19.7 ± 0.43	19.8 ± 0.41	.759
Age (yr)	49.6 ± 5.84	48.8 ± 7.48	.632

Table 2

The gender comparison between the 2 groups.

	Gender				
Group	Male	Female	Total	X^2	*P*
Group A	17	13	30	0.601	.438
Group B	14	16	30		
Total	31	29	60		

Pearson chi-square, $P = .438$.

12 months) were shown in Table 6. There were significant differences between means of ODI in preoperative assessment and postoperative assessments in 4 time periods ($P < .05$).

3. LBOS in group A and group B in different periods

(Group A): the mean and standard deviation of LBOS between preoperative and postoperative assessments in 4 time periods (1 month, 3 months, 6 months, and 12 months) were shown in Table 7. There were significant differences between means of LBOS in preoperative assessment and postoperative assessments in 4 time periods ($P < .05$).

(Group B): the mean and standard deviation of LBOS between preoperative and postoperative assessments in 4 time periods (1 month, 3 months, 6 months, and 12 months) were shown in Table 8. There were significant differences between means of LBOS in preoperative assessment and postoperative assessments in 4 time periods respectively ($P < .05$).

4. JOA in group A and group B in different periods

(Group A): the mean and standard deviation of JOA between preoperative and postoperative assessments in 4 time periods (1 month, 3 months, 6 months, and 12 months) were shown in Table 9. There were significant differences between means of JOA in preoperative assessment and postoperative assessments in 4 time periods. ($P < .05$).

(Group B): the mean and standard deviation of JOA between preoperative and postoperative assessments in 4 time periods (1 month, 3 months, 6 months, and 12 months) were shown in Table 10. There were significant differences between means of JOA in preoperative assessment and postoperative assessments in 4 time periods. ($P < .05$).

3.2.2. Comparison between the 2 groups.

1. Clinical treatment results between the 2 groups

The clinical efficacy of JOA between the 2 groups was presented in Figure 4. In the group B, the maximum effective rate was 90% 3 months after treatment, and the clinical efficacy remained satisfactory half-year, which was 86.67%. The curative effect decreased significantly 1 year after treatment, with a value of 16.67%. In the group A, the highest effective rate was 76.67% 1 month after treatment. With time, the clinical efficacy decreased, and the effective rate was 6.67% after 1 year.

As shown in Figure 5 on the comparison of LBOS between 2 groups, there was no statistically significant difference at 1 month and 12 months after treatment, but there was a statistically significant difference at 3 months and 6 months after treatment.

2. Comparison of pain between the 2 groups

There was no statistically significant difference at the first day, 1 week, 1 month, and 12 months after treatment ($P > .05$), but

Table 3

The mean differences of VAS between preoperative and postoperative assessments in 6 time periods (Group A).

Study variable	Assessment periods	N	Mean	SD	*P* value
VAS	Preoperative	30	4.87	0.57	<.05
	1d	30	1.36	0.49	
	1 wk	30	1.63	0.49	
	1 mo	30	1.7	0.47	
	3 mo	30	2.33	0.48	
	6 mo	30	2.47	0.51	
	12 mo	30	3.67	0.48	

SD = standard deviation, VAS = visual analogue scale.

Table 4

The mean differences of VAS between preoperative and postoperative assessments in 6 time periods (Group B).

Study variable	Assessment periods	N	Mean	SD	*P* value
VAS	Preoperative	30	4.8	0.61	$P < .05$
	1d	30	1.4	0.49	
	1 wk	30	1.53	0.51	
	1 mo	30	1.57	0.50	
	3 mo	30	1.6	0.50	
	6mo	30	1.8	0.55	
	12 mo	30	3.43	0.73	

SD = standard deviation, VAS = visual analogue scale.

Table 5

The mean differences of ODI between preoperative and postoperative assessments in 4 time periods (Group A).

Study variable	Assessment periods	N	Mean	SD	*P* value
ODI	Preoperative	30	66.20	2.91	<.05
	1mo	30	18.20	3.29	
	3 mo	30	25.07	3.31	
	6 mo	30	33.87	4.13	
	12 mo	30	50.93	5.79	

ODI = Oswestry Disability Index, SD = standard deviation.

there was a statistically significant difference at 3 months and 6 months after treatment, as shown in Figure 6.

3. Comparison of lumbar function between the 2 groups

Comparison of ODI: the difference was not statistically significant at 1 month after treatment, while the difference was statistically significant at 3, 6, and 12 months after treatment ($P < .05$), as shown in Figure 7. JOA improvement rate: there was no statistical significance in 1 month after treatment ($P > .05$), but there was statistical significance at 3, 6, and 12 months after treatment ($P < .05$), as shown in Figure 8.

Table 6

The mean differences of ODI between preoperative and postoperative assessments in 4 time periods (Group B).

Study variable	Assessment periods	N	Mean	SD	*P* value
ODI	Preoperative	30	66.8	4.80	<.05
	1 mo	30	17.67	3.68	
	3 mo	30	18.2	3.34	
	6 mo	30	27.4	5.23	
	12 mo	30	47.4	6.22	

ODI = Oswestry Disability Index, SD = standard deviation.

Table 7

The mean differences of LBOS between preoperative and postoperative assessments in 4 time periods (Group A).

Study variable	Assessment periods	N	Mean	SD	*P* value
LBOS	Preoperative	30	24.57	2.67	<.05
	1mo	30	61.63	4.69	
	3 mo	30	48.9	5.38	
	6 mo	30	45.3	3.33	
	12 mo	30	29.4	3.94	

LBOS = low back outcome scale, SD = standard deviation.

Table 8

The mean differences of LBOS between preoperative and postoperative assessments in 4 time periods (Group B).

Study variable	Assessment periods	N	Mean	SD	*P* value
LBOS	Preoperative	30	24.06	2.24	<.05
	1 mo	30	63.20	4.87	
	3 mo	30	65.87	3.51	
	6 mo	30	59.6	4.31	
	12 mo	30	30.67	4.96	

LBOS = low back outcome scale, SD = standard deviation.

Table 9

The mean differences of JOA between preoperative and postoperative assessments in 4 time periods (Group A).

Study variable	Assessment periods	N	Mean	SD	*P* value
JOA	Preoperative	30	11.23	1.61	<.05
	1mo	30	21.63	2.37	
	3 mo	30	19.97	1.75	
	6 mo	30	19.67	1.42	
	12 mo	30	16.83	2.60	

JOA = Japanese Orthopedic Association low back pain score, SD = standard deviation.

Table 10

The mean differences of JOA between preoperative and postoperative assessments in 4 time periods (Group B).

Study variable	Assessment periods	N	Mean	SD	*P* value
JOA	Preoperative	30	11.43	1.65	$P < .05$
	1mo	30	22.17	2.21	
	3 mo	30	23.03	2.01	
	6 mo	30	22.27	1.99	
	12 mo	30	18.67	1.79	

JOA = Japanese Orthopedic Association low back pain score, SD = standard deviation.

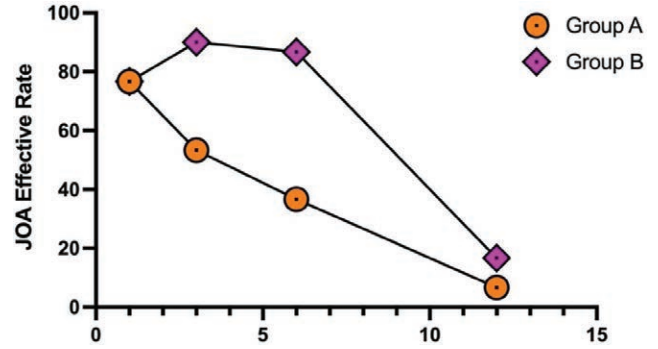

Figure 4. The comparison of clinical efficacy of JOA between the 2 groups. JOA = Japanese orthopedic association low back pain score.

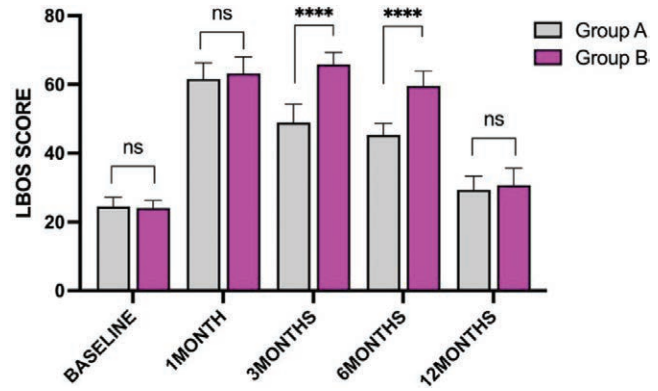

Figure 5. The comparison of LBOS between the 2 groups. ns: $P > .05$, ****: $P < .0001$, LBOS= low back outcome scale.

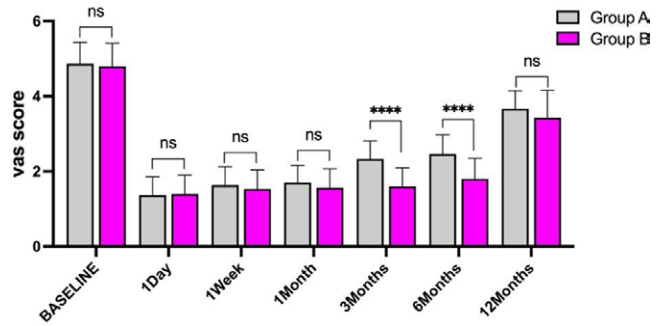

Figure 6. The comparison of VAS between the 2 groups. ns: $P > .05$, ****: $P < .0001$, VAS = visual analogue scale.

4. Discussion

4.1. Mechanism of LDH

Disc degeneration, a major cause of diseases like disc herniation, is a gradual and progressive aging process. Intervertebral disc degeneration is influenced by mechanical load, autoimmunity, inflammatory factors, and related pathways. There are many inflammatory factors associated with intervertebral disc degeneration, among which tumor necrosis factor alpha (TNF-α), interleukin, matrix metalloproteinases, and other factors play an important role,[8] and these factors often affect the degeneration of nucleus pulposa through the activation of NF-κ Bsignaling pathway.[9] Wei et al[10] showed that the expressions of TNF-α, interleukin-1, matrix metalloproteinases, and prostaglandin in degenerative intervertebral

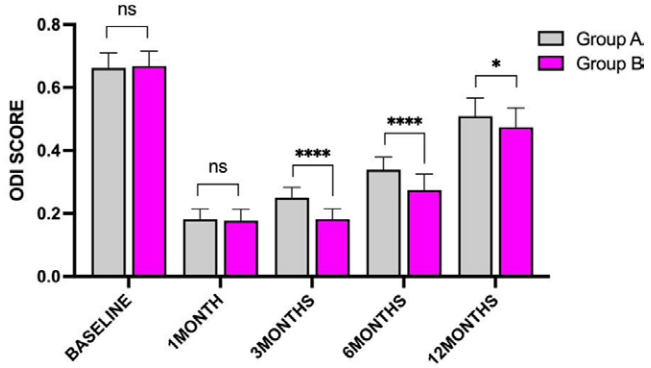

Figure 7. The comparison of clinical efficacy of ODI between the 2 groups. ns: $P > .05$, *: $P < .05$, ****: $P < .0001$, ODI = Oswestry Disability Index.

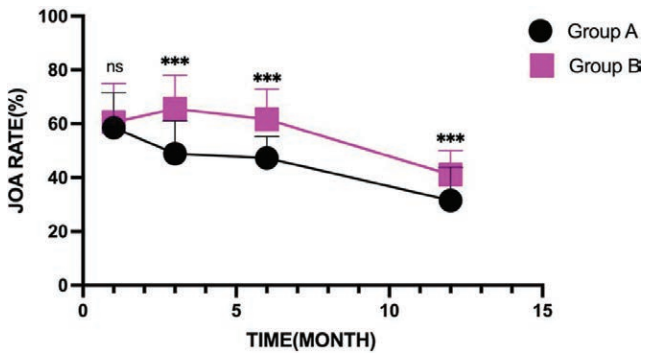

Figure 8. The comparison of JOA rate between the 2 groups. ns: $P > .05$, ***: $P < .001$. JOA = Japanese Orthopedic Association low back pain score.

discs increased, while the expressions of the extracellular matrix such as proteoglycan and type II collagen decreased.

4.2. Acupotomy in treatment of LDH

Acupotomology believes that the force imbalance of the human bowstring mechanics anatomy system is an important cause of LDH. In the treatment of LDH, acupotomy can destroy the original pathological framework by releasing the corresponding lesion site, regulating the force balance of local soft tissue, improving local microcirculation, promoting the release of inflammatory reaction and energy supplement, and ultimately achieving the purpose of relieving spasm, pain, and symptoms.[11,12]

The therapeutic point and depth of acupotomy are important factors that affect the therapeutic effect of acupotomy. Ma Jinming et al[13] treated LDH by releasing the sites of the supraspinous ligament, interspinous ligament, origin of the sacrospinous muscle, articular process, and transverse process of L3 to S1, with high clinical cure rate. In this study, acupoints and anatomy were combined to select acupotomy treatment sites, namely the medial facet of the articular process, below the base of the transverse process of L4 to S1, and GB30 acupoint, which achieved good analgesic effects. Acupotomy in each treatment point serves a different purpose, along with the depth and direction of insertion. On the medial side of the facet, the ligamentum flavum is mainly released to relieve pressure on the disc space. The depth, therefore, reaches the medial bone of the facet joint. LIN et al[14] showed that the clinical effect of ultrasound-guided acupotomy to release ligamentum flavum in the treatment of LDH was due to traditional acupotomy. At the lower part of the transverse process base of L4 to S1 and the treatment point of GB30 acupoint, the nerve root is stimulated by acupotomy to

produce nerve stimulation responses, relieving pain and improving function by releasing the trapped nerve and reducing the pain-causing factors.[15] Xiang Lin et al[16] compared the clinical efficacy of traditional acupuncture and acupotomy stimulation and found that acupotomy stimulation can significantly improve the symptoms and signs of patients. The mechanism of acupotomy therapy has not been fully clarified, but current studies show that it is related to relieving compression, inhibiting the release of chemical inflammatory factors, regulating autoimmune function, affecting the synthesis and secretion of central pain-related transmitters, regulating human electrophysiology, and other aspects.[11,17,18] FENG et al[19] showed that acupotomy therapy can play an analgesic effect by downregulating the expressions of glutamate (Glu), substance P (SP), hypothalamus β-endorphin (β-EP), and serum interleukin-1β(IL-1β) in spinal cord dorsal horn.

4.3. Juanbidecoction in the treatment of LDH

Juanbi Decoction is commonly used for the treatment of waist and leg pain in China, with clinical drugs including Qiang Huo (Notopterygii Rhizoma seu Radix), Du Huo (Radix angelicae-pubescentis), Rou Gui (Cinnamon), Qin Jiao (Fraxinus bungeana), Dang Gui (Angelica sinensis), Chuan Xiong (Ligusticum wallichii), Gan Cao (Liquorice), Hai Feng Teng (Kadsura pepper stem), Sang Zhi (Ramulus mori), Ru Xiang (Frankincense), and Mu Xiang (Radix vladimiriae). Yuan Dong et al[20]found that Juanbi Decoction could inhibit the proliferation and differentiation of intervertebral disc cells and resist the erosive effect of inflammatory factors such as TNF-α on intervertebral disc joint tissue. In studies on animals, Wang et al[21] showed that Juanbi Decoction could directly inhibit the production of pro-inflammatory cytokines interleukin-6 (IL-6) and IL-8, and play a therapeutic role by regulating the NF-κB signaling pathway to inhibit the release of inflammatory substances. Studies have shown[22] that Du Huo and Qiang Huo can regulate apoptosis by regulating multiple target-genes such as CASP3, JUN, CASP8, and AR. It can also inhibit inflammatory responses by regulating signaling pathways such as ESR, P53, IL-17, and AGE-RAGE. Hai Feng Teng plays an anti-inflammatory and analgesic role by acting on inflammatory cytokines such as IL-2, IL-4, COX, and other inflammatory signaling pathways.[23] Mulberry branch can effectively reverse the upregulation of the expression levels of pro-inflammatory cytokines such as TNF-α, IL-8, IL-6, and COX-2.[24,25] Gentiana officinalis inhibits inflammatory responses by regulating NF-κB/IκB and JAK2/STAT3 pathways to achieve anti-inflammatory and analgesic effects.[26,27] Angelica promotes autophagy of nucleus pulposus cells by inhibiting the activation of the AKT/mTOR signaling pathway. It also inhibits apoptosis of nucleus pulposus cells by blocking the mitochondrial apoptosis pathway.[28] Chuan Xiong inhibits interleukin-induced degeneration of intervertebral disc endplate chondrocytes.[29] Sharma et al[30] found that hydroethanolic extracts of Rou Gui can significantly reduce joint swelling and IL-β and TNF-αlevels in rats with CFA-induced arthritis. Cinnamon can also play a role in increasing the anti-inflammatory factors IL-10 and TGF-β.[31] Frankincense has an analgesic effect,[32] as Prabhavathi et al[33] found it related to the improvement of pain threshold, pain tolerance, and tolerance time. By lowering serum C-reactive protein, IL-1, and IL-6, TNF-α, total oxidation capacity, and increasing total antioxidant capacity, Mu Xiang can enhance the immune and antioxidant responses in adjuvant-induced arthritis rats, according to TAGHM et al.[34] Licorice, commonly used in Traditional Chinese medicine, has a variety of pharmacological effects, such as anti-inflammatory and neuroprotective effects.[35]Juanbi Decoction may therefore play a therapeutic role through multi-target and multi-pathway anti-inflammatory, analgesic, antioxidant, and nerve protection.

4.4. Ultrasound used in acupotomy operation

Even for skilled and experienced physicians, acupotomy treatment can still result in injury to nerves and blood vessels in the treatment of acupotomy without any guidance,[36] especially in the waist, shoulder, and back.[37] The pain experienced by patients who must re-insert needles as a result of incorrect insertion points may also get worse at the same time. Ultrasound is used as a navigation tool for the acupotomy operation, as it can distinguish among soft tissues such as blood vessels, muscles, and ligaments, thus reducing complications. Although in the lumbar spine, ultrasound displays specific ultrasound images of the facet allowing direct localization of the facet and reducing risks of injury to the dural sac, nerve roots, and peritoneum, there are some shortcomings. Some tissues could not be detected clearly because of the acoustic shadow of bone. It therefore cannot be used in obese patients satisfactorily because of the influence of adipose tissue on ultrasound imaging.

This study shows that the effect of acupotomy combined with Juanbi Decoction in the treatment of LDH is better than that of acupotomy, indicating that Juanbi Decoction can improve clinical efficacy. Acupotomy can have synergistic effects with Juanbi Decoction in relieving lumbago and improving lumbar function. Acupotomy aided by ultrasound improves the accuracy of needle insertion, thereby avoiding dural and nerve root injury. The treatment of acupotomy aided by ultrasound combined with Juanbi Decoction is convenient, and it can be carried out in general outpatient departments. It also has little effect on the integrity of the intervertebral disc and tissues around the facet joint. There is also little possibility of iatrogenic facet joint degeneration, so it does not affect the subsequent surgical treatment.

4.5. Limitation

First, double blinding is impossible because participants can comprehend the intervention they receive based on the taste of Juanbi decoction. Instead, assessors and investigators were all unaware of the grouping allocation and the intervention. Second, because observation indexes in this study are all paper mass scales, the results are subjective. Therefore, we could objectively respond to the changes around the disc and facet joint before and after treatment by the modern medical imaging technology, and conduct further research on the mechanism in a later study. In addition, a total of 60 patients with LDH were enrolled in this study, so we may be unable to get the intended results. Given that this is a pilot trial, we are planning to conduct a further large-scale confirmatory clinical trial based on the results of this study.

5. Conclusion

Acupotomy aided by ultrasound combined with Juanbi Decoction significantly relieves lumbar pain and improves lumbar function in patients with LDH, and the clinical efficacy lasts for about 6 months.

Author contributions

Ye-hui Wang designed this study, Yi Zhou generated the random allocation sequence, Ye-hui Wang enrolled participants, and Yi-zhou Xie assigned participants to interventions.
Conceptualization: Ye-hui Wang.
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Methodology: Ye-hui Wang, Yi Zhou.
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Data curation: Xing Wei, Wan-qiang Liang, Ting Zhang.
Software: Yi-zhou Xie, Ye-hui Wang.
Writing – original draft: Ye-hui Wang.
Writing – review and editing: Xiao-hong Fan.

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