Background: The aim of this study was to examine whether the effects of acupotomy therapy were beneficial for the treatment of protrusion of lumbar intervertebral disc.

Methods: The number of patients \((n = 80)\) were equally assigned into treatment group and control group. Treatment group was given acupotomy therapy twice a week, and control group was given acupuncture 3 times a week, for 4 weeks. The beneficial effect and changes in score of the Japan Orthopedic Association (JOA) for low back pain were observed.

Results: Among 40 cases in the treatment group, there were 25 (62.5%) with an excellent effect, 13 (32.5%) with good effect, 1 (2.5%) with a medium effect and 1 (2.5%) with poor effect, with the total experiencing an excellent/good effect of 95.0%. Among 40 cases in the control group, there were 11 (27.5%) with an excellent effect, 17 (42.5%) with good effect, 10 (25.0%) with a medium effect, and 2 (5.0%) with poor effect, with an excellent/good rate of 70.0%. The result of the rank sum test showed \(Z = -4.923, p < 0.05\) in the comparison, indicating a significantly better outcome following acupotomy compared with acupuncture. JOA scores increased in both groups after treatment \((p < 0.05)\), which was more significant in the acupotomy treatment group \((p < 0.05)\).

Conclusion: Acupotomy therapy has a beneficial effect on protrusion of lumbar intervertebral disc.
youngest was 20 years and the oldest was 62 years, with an average of (44.60 ± 12.07) years; the shortest course of the disease was 4 days, and the longest was 8 months, with an average of (32.78 ± 47.59) days.

There was no significant difference between the 2 groups regarding gender, age, course of condition/disease and JOA scores for lower back pain before treatment (p > 0.05). These results indicate that the 2 groups were comparable.

There is not an IRB system in China, so there was no IRB number assigned to this study.

**Diagnostic criteria**

**The diagnostic criteria of Western medicine**

The diagnostic criteria of LDH refer to the “Criteria of diagnosis and therapeutic effect of diseases and syndromes in traditional Chinese medicine [1].”

1. Have a history of lumbar trauma, chronic strain or cold and damp. Most patients have a history of chronic lower back pain before the onset of the condition/disease.
2. Often occurs in young adults.
3. Lower back pain radiates to the buttocks and lower limbs. When the abdominal pressure increased (such as coughing and sneezing), the pain was aggravated.
4. Scoliosis, the physiological curvature of the lumbar spine disappears, tenderness near the vertebrae of the lesion, and radiation to the lower extremities, and limitation of waist movement.
5. The nerve innervation area of the lower limbs is hypersensitive or insensitive, and muscle atrophy may have occurred if the patient is elderly. The straight leg-raising test or Bragard sign positive. The knee and Achilles tendon reflexes are weakened or have disappeared, and the extension of the back of the thumb is weakened.
6. X-ray examinations reveal scoliosis, disappearance of lumbar physiological lordosis, the diseased intervertebral disc may become narrow, and adjacent edges have osteophyte hyperplasia. A CT or MRI scan can show the location and degree of disc herniation.

**Traditional Chinese medicine syndrome diagnosis criteria**

The syndrome differentiation of blood stasis syndrome of LDH refers to the “Criteria of diagnosis and therapeutic effect of diseases and syndromes in traditional Chinese medicine [1]:” the pattern of blood stasis can manifest as fixed pricking pain and rigidity in the lower back and legs, which limits pitch rotation, and is aggravated during the night and with pressure, presents with a dark, purplish tongue with possible petechia and a wiry, rough pulse.

**Inclusion criteria**

1. Meet the diagnostic criteria of LDH, and age of ≥ 18 ≤ 65 years, regardless of gender.
2. Able to accept and adhere to acupotomy and acupuncture treatment, and willing to cooperate with the researchers to complete clinical observation.

**Exclusion criteria**

1. Pregnant women or lactating women.
2. Those who have diabetes, severe skin disease, and blood system disease.
3. Those who combined with severe cardio-cerebral disease, liver, and kidney function disease, and unclear mental consciousness.
4. History of lumbar surgery or lumbar tumor, or tuberculosis.
5. Complicated compression fracture, spondylitis, and pyogenic conditions/diseases around the spine.
6. Prominent nucleus pulposus, severe neurological dysfunction (sensory disturbance in the saddle area), and compression of cauda equina nerve.
7. Those who had other therapy at the same time.

**Discontinuation and exclusion criteria**

1. During the course of treatment, those who requested to discontinue treatment or withdraw by themselves.
2. During the treatment, those who did not receive acupotomy or acupuncture as planned, or did not follow the doctor’s instructions, or received other methods of treatment.

**Study withdrawal criteria**

1. Those who failed to complete the treatment and observation as required due to various reasons, resulting in incomplete treatment.
2. Those who were lost to the follow-up observation.
3. Those who have serious adverse events or reactions, deterioration of the condition, and other patients who were not suitable for further treatment during the study.

**Research methods**

**Grouping method**

Numbers 1-80 were imputed into the Excel table, and a random function was used to renumber and reorder the 80 numbers in ascending order of the random numbers, arranged as the first 40 numbers. These numbers were the acupotomy treatment group and the last 40 numbers were the general acupuncture control group.

**Blind method**

Researchers, operators, and statisticians were blinded to the specifics. The researcher did not know the specific treatment plan of a certain subject in advance, The operator was the doctor who carried out the clinical treatment according to the treatment plan determined by the random number table method. The patients did not know which treatment schemes were available in advance. The statisticians were unaware of the groups, treatments, and significance, to ensure the authenticity and objectivity of the collection, and analysis of experimental data.

**Therapeutic method**

**The acupotomy treatment group**

Patients lay prone on the treatment bed, and were marked to indicate the needle insertion points. After routine disinfection, the Chinese Medicine Doctor placed on a disposable cap, mask and a pair of sterile gloves to carry out the acupotomy. A 0.8 mm × 80 mm acupotomy knife needle was selected and its edge was parallel to the longitudinal axis of the spine. Then, the knife needle was quickly inserted into the needle points of the skin vertically. The procedure in detail are as follows [2].

1. Treatment point of the interspinous process: the supraspinous ligament and interspinous ligament was loosened which caused a soreness after which the needle was withdrawn.
2. The treatment points of ligamentum flavum and lateral
Basic security indicators

(1) The pulse, respiration, blood pressure, and heart rate were measured and recorded before and after treatment.

(2) Adverse reactions such as massive bleeding, dizzy needle, shock were recorded during the treatment. None of the cases included in this study had adverse reactions before or after operation. In this study (except for 1 patient in the acupotomy group who did not complete the treatment because of fear of acupotomy), there were no adverse reactions before and after treatment.

The Japanese Orthopaedic Association (JOA) scores for low back pain

(1) JOA scores were recorded before and after treatment, and the total scores were calculated according to the evaluation scores of clinical symptoms, signs, and daily activities.

(2) JOA scores for pain severity and frequency were recorded for gluteus medius and quadriceps femoris. Improvements in the results were recorded.

Statistical methods

The data were analyzed using SPSS (Version 17.0) statistical software and measurement data that belonged to a normal distribution were represented as $\bar{x} \pm s$, and used in an independent sample $T$ test. The measurement data which was not normally distributed were represented by median ($m$), quartile spacing ($p_{25}-p_{75}$), and the nonparametric test rank sum test was used for ranking data $p < 0.05$ was considered statistically significant.

Results

Efficacy criteria

Clinical efficacy was judged according to the JOA score for low back pain [3]. The improvement rate of score after treatment = $[(\text{score after treatment} - \text{score before treatment}) / (29 - \text{score before treatment})] \times 100\%$. After treatment, a score improvement rate $\geq 75\%$ was recorded as excellent, $50-74\%$ was recorded as good, $25-49\%$ was recorded as medium, 0-24% was recorded as poor.

Comparison of the clinical efficacy of the 2 groups

Among the 40 cases in the treatment group, the improvement after treatment was excellent in 25 cases (62.5%), good in 13 cases (32.5%), medium in 1 case (2.5%), and poor in 1 case (2.5%). The total number of patients with an improvement rate of excellent and good was 95% after treatment. Among the 40 patients in the acupuncture control group, the improvement was 11 cases (27.5%) after treatment, good in 17 cases (42.5%), medium in 10 cases (25%), poor in 2 cases (5%). The total number of patients with the improvement rate as excellent and good after treatment was 70.0%.

Comparison of the efficiency of the 2 groups, after rank sum test, $z = -4.923$, $p < 0.05$, the difference was statistically significant, indicating that the clinical effect of the acupotomy treatment group was better than the acupuncture control group (Table 1).

Comparison of JOA scores for low back pain between groups

JOA scores for low back pain after treatment was significantly higher in both groups ($p < 0.05$). After treatment, the acupotomy group was significantly higher than the acupuncture group, with the difference before and after treatment statistically significant ($p < 0.05$). The JOA scores were significantly better in the acupotomy treatment group than the control group (Table 2).
**Discussion**

LDH is one of the diseases of lumbago in traditional Chinese medicine, with other names including “lumbago spine pain” and “bi syndrome.” The main external causes of LDH include a sudden strain or contusion of a muscle, or pathogenic cold and dampness leading to stagnancy of meridians and qi and blood. Therefore, most causes of LDH are due to blood stasis.

Western medicine has 4 theories on the mechanism of pain caused by LDH [4]: mechanical compression, inflammatory reaction of nerve root, blood supply disorder of surrounding tissue, and autoimmunity.

In this study, acupotomy therapy was applied to patients with LDH. It was combined with the 4 theories of pathogenesis and anatomical features of the waist to loosen the soft tissue on both sides of the lumbar spine (depending on its unique effect), help restore the biomechanical balance inside the spine, and relieve the pressure above and below the lumbar disc. In addition, touch-stimulation of spinal nerves of Ren and Ren [5] was applied in the direction of the nerves to activate the endogenous analgesia system, and cause a strong stress “escape” from the nerves. Thus, acupotomy treatment, through neural touch-stimulation, relaxed waist muscle tension and promoted local repair, and relieved the inflammatory adhesion between nerves and the surrounding tissue. However, acupotomy loosening presents certain risks without detailed knowledge of human anatomy and clinical experience of acupotomy and may cause nerve and blood vessel injury. The clinical operator must understand human anatomy, be proficient in acupotomy operations, and give targeted loosening and neural stimulation to different anatomical sites to achieve the ideal therapeutic effect. Acupotomy loosening, and metabolism and degradation of allogenic substances around the nerve roots were effectively promoted in this study, and with inflammatory stimulation, pain was reduced. However, there are still deficiencies in this trial. 1) The sample size was small, the observation time was short, and the long-term efficacy was not established. 2) The evaluation criteria of LDH adopted some subjective indicators, which may make the "good" rating of this group subjective. Therefore, further studies are needed.

**Conflicts of Interest**

The authors have no conflicts of interest to declare.

**References**


