Thirty Cases of the Blood-Stasis Type Prolapse of Lumbar Intervertebral Disc Treated by Acupuncture at the Xi (cleft) Point plus Herbal Intervention Injection

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Objective: To observe the clinical therapeutic effects and explore the mechanism of acupuncture at the xi (cleft) points combined with herbal intervention injection for treatment of prolapse of the lumbar intervertebral disc with TCM symptoms and signs of blood stasis. Methods: The 60 cases in this series were randomly divided into a treatment group and a control group, 30 cases in each group. The patients in the treatment group were treated by acupuncture at Jiaji L4-S1, Waiqiu (GB 36), Weizhong (BL 40) and Xiaxi (GB 43) plus intervention injection of Gegensu Zhusheye (葛根素注射液 Puerarin Injectio). The patients of the control group were given the routine acupuncture combined with injection of Gegensu Zhusheye (葛根素注射液 Puerarin Injectio) into the Ashi points. The changes in interleukin-6 (IL-6) and hemodynamics were observed before and after treatment in both the two groups. Results: The total therapeutic effect in the treatment group was obviously better ($P<0.05$) and the treatment course was obviously shorter than that of the control group ($P<0.01$). After the treatment, the total score, the visual analog scale (VAS) pain-evaluating score, and the score in straight-leg raising test were obviously improved in both the two groups, in which the improvement in the treatment group shown by the score in straight-leg raising test and the total score superior to that of the control group ($P<0.05$). The IL-6 level, red blood cell ratio, K value of blood sedimentation equation, and whole blood high shearing specific viscosity were improved in both the two groups, but the treatment group showed better improvement than that of the control group in the red blood cell ratio, K value of blood sedimentation, and IL-6 level ($P<0.05$ or $P<0.01$). Conclusions: The treatment group was superior to the control group in improvement of the symptoms and signs, the daily life ability, and in pain alleviation. The mechanism is possibly related with the improvement in the IL-6 level and hemodynamic indexes, which may promote the subsidence of inflammation of the nerve roots.

CLINICAL DATA

All the 60 cases in this series were in- and outpatients of the Department of Acupuncture and Moxibustion, the First Affiliated Hospital of Guangzhou University of TCM. Of them, 48 cases were male, and 12 female, ranging in age from 20 – 65 years. They were all conformed to the diagnostic criteria for Prolapse of the Lumbar Intervertebral Disc, ¹ with the diagnosis confirmed by lumbar vertebral CT or MRI. According to TCM differentiation, the syndrome they
had all belonged to the blood stasis type. 1 The
criteria for exclusion: 1) those with a history of the
condition over 2 months; 2) those aged over 70 years;
3) those with complication of lumbar vertebral tumor,
tuberculosis, and fracture; 4) those with severe
central-type prolapse of the lumbar intervertebral disc;
5) those with sciatica due to other causative factors; 6)
those with severe insufficiency of the heart, lung and
liver; and 7) those allergic to Gegensu Zhusheye (葛
根素注射液 Puerarin Injectio). Single-blind random
control study was taken. The cases were divided
randomly into a treatment group and a control group,
30 cases in each group. Comparisons between the
two groups in the quantitative score of the symptoms
and signs, in the pain score and the score in straight
leg raising test showed no significant differences
\( P > 0.05 \).

**METHODS**

1. The treatment group were treated by acupuncture
combined with intervention injection of Gegensu
Zhusheye (葛根素注射液 Puerarin Injectio, produced by Guangdong Yantang Biochemical
Pharmaceutical Co., Ltd., Guangdong Approval
Certificate No. 161006, 1996). The patient was asked
to lie on the healthy side. After routine skin
sterilization and routine local anesthesia at the
injection point (6-8 cm lateral to the spinous process
of the affected intervertebral disc) with 2 ml 2% procaine (2-3 ml lidocaine for those with skin
allergy), a No.7 lumbar puncture needle was inserted
into the injection point, with the injection point and
the sagittal plane of the body trunk forming an angle
of 50°– 60°. The needle was slowly inserted nearby
the intervertebral foramen. The needle tip should be
avoided to touch the nerve root, and the patient
would not have electric-shock-like sensation and
aggravated pain. If the needle tip is made to touch the
nerve root, the patient would have the electric-
shock-like sensation, when the insertion angle and
depth of the needle tip should be changed. When
there showed no blood upon pulling back the stylet, 4
ml Gegensu Zhusheye (葛根素注射液 Puerarin
Injection) was slowly injected, after which the needle
was retained for 1 min before slowly drawn out. After
the injection, the patient was asked to have bed rest
for 1-2 days. The patients with no obvious
improvement of the symptoms 10 days after the
injection could have the second injection treatment. 3
such injection treatments formed one therapeutic
course. Simultaneously, the patient received
acupuncture treatment. The points selected were
Weizhong (BL 40), Waiqiu (GB 36), Xiaxi (GB 43)
and Jiaji L₄-S₁. For the Jiaji points, the needle was
inserted 2-3 cun deep; In the first needling, Xiaxi
(GB 43) was pricked to caused bleeding of 3-5 drops
of blood. Then, Weizhong (BL 40) and Waiqiu (GB
36) were needled with 1-2 cun filiform needles,
followed by qi-inducing manipulation for 1-2 min
upon the arrival of qi. Afterwards, the needles were
connected to a G6805 type electroacupuncture meter,
with an irregular wave given at a frequency of
10-20/per min for 15 minutes, after which the dense
wave was used at a frequency of 80-100/per min for
5 min. These two waves could produce the
anti-inflammation and pain-checking effects. The
intensity was kept within the patient’s endurance. In
the first to the third treatment, blood-letting and
cupping were adopted at Weizhong (BL 40) after
withdrawal of the needle, with the cup retained for
3-5 min. The above treatment was given once every
other day, 15 treatments constituting one therapeutic
course.

2. The control group was given the routine
acupuncture treatment combined with point injection.
The herbal injection and the dose used for point
injection were the same as those used for the
treatment group. After routine skin sterilization, a
No.7 injection needle was inserted 1-2 cm deep into
the Ashi point lateral to the affected intervertebral
disc. When no blood was shown upon pulling back of
the stylet, 4 ml Gegensu Zhusheye (葛根素注射液 Puerarin
Injectio) was slowly injected. The injection
was given once every 10 days, 3 sessions constituting
one therapeutic course. The point selection and the
operation method of the routine acupuncture
treatment were conducted in referring to the
procedures described in the Acupuncture Therapeutics (针灸治疗学). The point selected were the Ashi, Dachangshu (BL 25), Ciliao (BL 32), Huantiao (GB 30), Weizhong (BL 40), Yanglingquan (GB 34), and Geshu (BL 17). Blood-letting and cupping were done at Weizhong (BL 40), and deep needling for Huantiao (GB 30), with the routine needling techniques for the other points. Upon the arrival of qi, electric stimulations were added in the same way as that of the treatment group. The needles were retained for 15 min. In the first to the third treatment, blood-letting and cupping were adopted for Weizhong (BL 40), with the cup retained for 3-5 min. The treatment was given once every other day, 15 treatments constituting one therapeutic course.

The clinical symptoms and signs were evaluated respectively once before and after the treatment by a special physician. The visual analog scale (VAS) method was adopted for evaluation of pain. The interleukin-6 (IL-6) level and the hemodynamic indexes were tested by the experimental centre of the First Affiliated Hospital of Guangzhou University of TCM, which were done respectively once before and after the treatment.

3. The statistical methods: The therapeutic effects were analyzed by the Ridit method; t test was adopted for determination of the average course of treatment and the quantitative score of symptoms and signs; and the SPSS 10.0 statistical software was used for processing of the data obtained.

Criteria for therapeutic effects

The most closely related symptoms and signs with Prolapse of the Lumbar Intervertebral Disc, such as the functional activities of the lower limbs, the clinical signs and the daily life abilities, were quantitatively scored. The possible full score was 60. The evaluation score for patients was calculated with the following formula: the real total scores the possible full score × 100%, indicating the condition of the illness and the state of the motor function. The higher the percentage was, the poorer the motor function and the severer the condition would be. With 0 – 10% for the normal to a mild decrease of the motor function (grade V), 11% – 40% for a mild to moderate decrease of the motor function (grade IV); 41% – 60% for a severe decrease of the motor function (grade III); 61% – 80% for loss of the motor function (grade II); and 81% – 100% for the laid-up patient (grade I).

Cured: Disappearance of the symptoms and signs, with a grade V motor function after the treatment. Markedly relieved: Basic disappearance of the symptoms and signs, with an over two-grade improvement of the motor function. Improved: Amelioration of the symptoms and signs, with a one-grade improvement of the motor function. Failed: No improvement was found in the symptoms and signs, and in the motor function.

RESULTS

Comparison of the total therapeutic effect between the two groups

As shown in Table 1, after one course of the treatment, the total therapeutic effect in the treatment group was obviously superior to that of the control group (P<0.05). The average course of treatment was 23.93±3.08 days in the treatment group, which was much shorter than that of the control group 28.23±3.48 days.

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Cured</th>
<th>Markedly relieved</th>
<th>Improved</th>
<th>Failed</th>
<th>Total effective rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>30</td>
<td>13 (43.33%)</td>
<td>10 (33.33%)</td>
<td>6 (20.00%)</td>
<td>1 (3.33%)</td>
<td>96.67%</td>
</tr>
<tr>
<td>Control</td>
<td>30</td>
<td>6 (20.00%)</td>
<td>10 (33.33%)</td>
<td>10 (33.33%)</td>
<td>4 (13.33%)</td>
<td>86.67%</td>
</tr>
</tbody>
</table>

Comparison of the hemodynamic indexes and IL-6 between the two groups

It can be seen from Table 2 that after treatment, the red blood ratio, value of blood sedimentation equation, whole blood high shearing specific viscosity and IL-6 were obviously improved in both
the two groups \((P<0.05\) or \(P<0.01\)), except that the level of whole blood low shearing specific viscosity raised obviously in the control group after the treatment. And the treatment group showed a better improvement in the red blood cell ratio, value of blood sedimentation equation and IL-6 than that of the control group \((P<0.05\) or \(P<0.01\)).

**Comparison of the VAS s pain core, the straight leg-raising score, and the total score**

Table 3 showed that after treatment both the two groups were significantly improved in the total score, VAS pain score and straight leg-raising score \((P<0.01)\). And the treatment group showed a better improvement in the total score and the straight leg-raising score than that of the control group \((P<0.05)\).

<table>
<thead>
<tr>
<th>Group</th>
<th>Time</th>
<th>(n)</th>
<th>VAS score</th>
<th>Straight leg-raising</th>
<th>Total Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treat.</td>
<td>Bef. treat.</td>
<td>30</td>
<td>8.07±0.94</td>
<td>4.05±0.95</td>
<td>45.73±3.09</td>
</tr>
<tr>
<td></td>
<td>Aft. treat.</td>
<td>30</td>
<td>8.03±1.13</td>
<td>4.11±0.89</td>
<td>45.68±3.15</td>
</tr>
<tr>
<td>Contr.</td>
<td>Bef. treat.</td>
<td>30</td>
<td>4.90±2.01*</td>
<td>2.85±1.25**</td>
<td>23.87±10.63**</td>
</tr>
<tr>
<td></td>
<td>Aft. treat.</td>
<td>30</td>
<td>4.75±1.30**</td>
<td>2.50±1.30**</td>
<td>21.30±9.12**</td>
</tr>
</tbody>
</table>

Note: Intragroup comparison, \(*P<0.05\), \(**P<0.01\); intergroup comparison, \(\Delta P<0.05\), \(\Delta\Delta P<0.01\).

**DISCUSSION**

At present, there are three main theories on pathogenesis for prolapse of the lumbar intervertebral disc, namely, the theory of mechanical pressure, the theory of chemical radiculoneuritis, and the theory of autoimmunity. The theory of chemical radiculoneuritis has provided the basis for treatment of this disease without surgical operation, especially for the cases at the acute stage, which can be treated by eliminating inflammation of the nerve root. The Chinese herbal drugs with the action of promoting blood circulation by removing blood stasis can produce significant effects for subsidence of the nerve root inflammation. 7, 8 Purarin is the extract of Ge Gen (Radix Puerariae), which has the effect of dilating the blood vessels, improving the microcirculation, and inhibiting the release of 5-HT in the blood platelet. 9 It has been demonstrated by experimental study that puerariae injectio can eliminate inflammation of the nerve root, 8 showing the effect of promoting circulation of blood in the collaterals, and relaxing muscles and tendons. The present study shows that the intervention injection of purarin near the affected spinous foramen can yield better effects than the point injection at the Ashi point.

The Xi (cleft) points may show the actions of relaxing the muscles and promoting the circulation of blood, and dredging the collaterals to check pain, which are mostly used for clinical treatment of the acute
diseases with painful syndrome; 2 which the ying (spring) points are mostly used for the excess syndrome, the heat syndrome and the blood stasis syndrome. 2 Therefore, we selected the ying (spring) point Xiaxi (GB 43) and xi (cleft) point Waiqiu (GB 36), combined with the use of Weizhong (BL 40) and Jiaji L₄-S₁ for relaxing the muscles and tendons and promoting blood flow, and dredging the collaterals to check pain. The present study has proved that acupuncture at the xi (cleft) points can help to improve the clinical symptoms and signs and enhance the ability of daily life, with better effects than that of the routine acupuncture treatment (P<0.05).

The present study has also demonstrated that the patients with prolapse of the lumbar intervertebral disc may have abnormal hemodynamic indexes; and that acupuncture combined with the herbal intervention injection can improve several hemodynamic indexes and lower the level of IL-6, which is probably the mechanism for the treatment of prolapse of the lumbar intervertebral disc.

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