Clinical Observations on 46 Cases of Globus Hystericus Treated with Modified Banxia Houpu Decoction

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Objective: To observe the therapeutic effect and mechanism of modified Banxia Houpu decoction on globus hystericus. Methods: The 95 patients with globus hystericus were randomly divided into a treatment group of 46 cases treated with modified Banxia Houpu decoction and a control group of 49 cases treated with Manyanshuning (Granula for Clearing the Throat). In addition, a normal group of 24 healthy people was set up. SCL-90 scale was adopted to observe the therapeutic effect, evaluate the psychological state of patients and build a database on combination of four diagnoses. Results: The effect of the modified Banxia Houpo decoction was better than that of the control group in relieving depression, anxiety and improving the psychological state (P<0.05 or P<0.01). Conclusion: Modified Banxia Houpu decoction has definite therapeutic effect on globus hystericus. Its mechanism may be related to its function in relieving depression and anxiety and regulating the psychological state. Key words: modified Banxia Houpu decoction; globus hystericus; SCL-90 scale

Globus hystericus, a subjective symptom of abnormal sensations in the throat, is generally referred to as ball-blocking sensation, itching sensation, burning sensation, ant-crawling sensation and other abnormal sensations in the throat with no difficulty in swallow. The disease, called imagined plum pit in the throat in TCM, is generally caused by functional pathological change. The recipe of modified Banxia Houpu decoction was prescribed by REN Da-ran, a late famous physician in Jiangsu, to treat globus hystericus. The authors treated 46 cases of globus hystericus with granules made from the recipe from June 2005 to June 2007. The study is reported as follows.

CLINICAL MATERIALS

General Data

The 95 outpatients of Northern Jiangsu People's Hospital affiliated to Yangzhou University and Taixing People's Hospital were randomly divided into a treatment group and a control group. Among 46 cases in the treatment group there were 15 males and 31 females aged 19–60, 46.80±11.96 on average, 11 cases with illness course less than 3 months, 15 cases with illness course from 3 to 12 months and 20 cases with illness course more than 12 months, 23.59±27.68 months on average. Among 49 cases in the control group there were 16 males and 33 females aged 20–65, 47.34±10.80 on average, 13 cases with illness course less than 3 months, 14 cases with illness course from 3 to 12 months and 22 cases with illness course more than 12 months, 26.00±30.83 months on average. There was no statistic difference (P>0.05) in sex, age and illness course between the two groups, hence comparability. In addition, among

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This study was supported by a grant from High-tech Project of Science & Technology Department of Jiangsu Province (No. 30772839, No.30873302)
24 healthy people who were willing to take part in the normal group, 9 were males and 15 females aged 19–63, 46.12±15.82 on average.

**Standard for Diagnosis**

1. Standard for diagnosis in Western medicine

On the basis of Rome II standard, the following symptoms appear for at least 12 weeks in the past 12 months, but it is unnecessary for them to be successive: 1) The patient continuously or intermitently feels as if a foreign body is blocking the throat. 2) The sensation is felt between two meals. 3) There is no difficulty or no pain in swallow. 4) There is no pathological adverse flow in the stomach and esophagus, no achalasia of cardia and no other dynamic diseases, such as sclerodermal esophagus.

2. Standards for diagnosis and syndrome differentiation in traditional Chinese medicine

Standard for diagnosis is worked out in reference to the “Principle for Guiding Clinical Research into New Chinese Drugs”: 1) Patients often have clear or unclear emotional disorder. 2) Patients often feel as if their throat is being blocked by a foreign object, which can neither be spitted out nor swallowed in. The sensation becomes severer during empty swallow but without hindering while taking meals or even milder during intake of food. The onset of the disease and the change in symptoms are often closely related to emotional state. 3) No abnormality or inflammation is discovered in examination of throat. 4) No organic, especially malignant, pathological change is found in the throat, adjacent organs and the whole body. Standard for syndrome differentiation is drawn up in reference to 1991 Standard of National TCM Association of Ear-nose-throat Department in the Standard for Diagnosing TCM syndromes and Determining Therapeutic effect.

**Inclusive Standard**

Patients conform to standard for diagnosis in Western medicine and standards for diagnosis and syndrome differentiation in traditional Chinese medicine, and are willing to take part in clinical experiment and persist in completing treatment course.

**Exclusive Standard**

Patients have organic diseases of throat, esophagus, stomach, liver, gallbladder and pancreas, diabetes, diseases of connective tissue and nervous system, mental disorder, other complications which can influence observation of therapeutic effect, and diseases that should not be treated with the experimental drug. Patients excessively drink wine. Patients are unsuitable for the experiment.

**METHODS**

**Method of Treatment**

The recipe of modified Banxia Houpu decoction consists of Ban Xia (半夏 Rhizoma Pinelliae) 30g, Fo Shou (佛手 Fructus Citri Sarcodactylis) 15g, Hou Pu (厚朴 Cortex Magnoliae Officinalis) 15g, Fu Ling (茯苓 Poria) 30g, Sheng Jiang (生姜 Rhizoma Zingiberis Recens) 15g and Zi Su Ye (紫苏叶 Folium Perillae) 15g. The granule made from modified Banxia Houpu decoction is produced by Tianjiang Pharmaceutical Factory and has won a national patent of invention. Patients in the treatment group orally took the granule one pack each time, 3 times a day. Patients in the control group orally took Manyanshuning (舒柠 Granula for Clearing the Throat) (produced by Shanxi Guilong Pharmaceutical Co. Ltd.) 5g a pack each time, 3 times a day. Patients in both groups were treated for one week as a course of treatment. The therapeutic effect was observed at the end of 3 courses of treatment.

**Indexes and Method of Observation**

Investigation was carried out on illness cause, illness course, TCM syndromes and relapse condition of the 95 patients. Psychological determination was conducted with SCL-90 scale on patients before and after treatment. The scale comprises 90 items and 10 factors to determine 10 psychological states (namely physioneurosis, compulsion, interpersonal relationship, depression, anxiety, hostility, horror, paranoia, mental disease and others). After withdrawal, patients visited the clinic or physicians paid monthly follow-up visits by phone for 12 months.
Standard for Evaluating Therapeutic Effect

In reference to “Standards for Diagnosing TCM Syndrome and Evaluating Therapeutic effect” in the “Standard for TCM Industry of the People’s Republic of China,” the standard for evaluating therapeutic effect is divided into 4 grades: Being cured means that the foreign body sensation of the throat and other symptoms disappear and no relapse is observed in 1-year follow-up visit. Being obviously effective means that the foreign body sensation of the throat and other symptoms disappear and no relapse is observed in half-a-year follow-up visit. Being effective means that the foreign body sensation of the throat and other symptoms are alleviated. Ineffectiveness means that there is no obvious change in the foreign body blocking sensation of the throat.

Statistic Method

SPSS10.0 software is used to statistically analyze data. $\chi^2$ test is used for numerical data and $t$ test for measurement data.

RESULTS

Comparison of Therapeutic Effects between the Two Groups

As shown in Table 1, there was no statistic difference ($P>0.05$) in curative rate, effective rate and total effective rate between the two groups. However, the obvious effective rate in the treatment group was much better than that in the control group ($P<0.05$).

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Cured</th>
<th>Obviously effective</th>
<th>Effective</th>
<th>Ineffective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>46</td>
<td>7 (15.2)</td>
<td>23 (50.0)</td>
<td>12 (26.1)</td>
<td>4 (8.7)</td>
</tr>
<tr>
<td>Control group</td>
<td>49</td>
<td>6 (12.2)</td>
<td>14 (28.5)</td>
<td>21 (42.8)</td>
<td>8 (16.3)</td>
</tr>
</tbody>
</table>

Analysis of Illness Cause

1) 48 patients (accounting for 50%) were related to mental factors, mainly depression, anxiety, irritability and long-term nervousness, among which anxiety was mostly seen. 2) 28 patients (accounting for 29.5%) were related to climatic factors, most obviously manifested in seasonal change and sudden change in atmospheric temperature, among which the disease is easily induced in spring, autumn and when the atmospheric temperature suddenly drops. 3) 25 patients (accounting for 26.3%) were related to dietary factors, mainly pungent food. 14 patients (accounting for 14.7%) were related to fatigue factors. Among the 95 patients, 31 cases (accounting for 32.6%) suffered from the disease induced by 2 or more factors, indicating that globus hystericus is caused by multiple factors.

Percentage of TCM Syndromes among the 95 Patients with Globus Hystericus

There were 29 patients (accounting for 30.5%) with disharmony between the liver and stomach, 3 patients (accounting for 3.1%) with heat accumulated in the liver and stomach, 36 patients (accounting for 37.9%) with stagnation of the liver and deficiency of spleen, 10 patients (accounting for 10.5%) with deficiency of spleen and stagnation of dampness, 6 patients (accounting for 6.3%) with yang deficiency of the spleen and kidney, 5 patients (accounting for 5.2%) with deficiency of spleen yang, 2 patients with deficiency of kidney yang, 2 patients with deficiency of the heart and spleen, and 2 patients with sinking of qi in the middle-jiao. 68 patients (accounting for 71.6%) were related to the liver, indicating that globus hystericus is closely related to the liver. 59 patients (accounting for 62.1%) were related to the spleen, 8 patients (accounting for 8.4%) to the kidney, and 2 patients (accounting for 2.1%) to the heart. There were 32 patients (accounting for 33.7%) with excess syndrome, 17 patients (accounting for 17.9%) with deficiency syndrome and 46 patients (accounting for 48.4%) with the syndrome of deficiency complicated with excess. It can thus be seen that globus hystericus is mainly caused by syndrome of deficiency complicated with excess.

Illness Course and Relapse Condition

There were 42 of the 95 patients suffered from the disease for more than one year. Among them there
were 9 cases with their illness course over 10 years. The 32 patients visited hospital twice or more. The disease was self-cured without any treatment in 13 patients (accounting for 14.4%), among whom 6 cases had their illness self-cured within one week and 7 cases within 3 weeks. The disease relapsed in 38 patients (accounting for 40%) with the average relapse time 6.25±6.69 months. The syndrome of deficiency complicated with excess, mainly stagnation of the liver and deficiency of the spleen, relapsed more easily than other syndromes.

**Comparison of Psychological Condition between Globus Hystericus Patients and Healthy People**

As shown in Table 2, the average scores for physioneurosis, depression and anxiety as well as the total average score in the globus hystericus group of 65 cases were much higher than those in the normal group of 24 cases ($P<0.01$), indicating that globus hystericus patients obviously suffer from psychological depression and anxiety.

**Comparison of SCL-90 Scores for Depression and Anxiety Before and After Treatment in the Two Groups**

As shown in Table 3, there was no statistic difference ($P>0.05$) in scores for psychological condition before treatment in the two groups. However, statistic differences ($P<0.05$ or $P<0.01$) were observed in average scores for depression and anxiety before and after treatment in the treatment group, indicating that the therapeutic effect on depression and anxiety of globus hystericus patients in the treatment group is better than that in the control group.

### Table 2. Comparison of scores for psychological condition between globus hystericus group and normal group (points, $\bar{X} \pm s$)

<table>
<thead>
<tr>
<th>Item</th>
<th>Globus hystericus group (65 cases)</th>
<th>Normal group (24 cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physioneurosis</td>
<td>1.84±0.50*</td>
<td>1.25±0.25</td>
</tr>
<tr>
<td>Compulsion</td>
<td>1.62±0.47</td>
<td>1.56±0.36</td>
</tr>
<tr>
<td>Interpersonal relation</td>
<td>1.44±0.48</td>
<td>1.37±0.36</td>
</tr>
<tr>
<td>Depression</td>
<td>1.65±0.46*</td>
<td>1.29±0.25</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1.84±0.53*</td>
<td>1.28±0.24</td>
</tr>
<tr>
<td>Hostility</td>
<td>1.38±0.53</td>
<td>1.23±0.25</td>
</tr>
<tr>
<td>Horror</td>
<td>1.32±0.42</td>
<td>1.21±0.35</td>
</tr>
<tr>
<td>Paranoia</td>
<td>1.41±0.50</td>
<td>1.24±0.29</td>
</tr>
<tr>
<td>Mental disease</td>
<td>1.19±0.40</td>
<td>1.18±0.18</td>
</tr>
<tr>
<td>Others</td>
<td>1.83±0.58*</td>
<td>1.27±0.21</td>
</tr>
<tr>
<td>Total average score</td>
<td>1.66±0.37*</td>
<td>1.30±0.19</td>
</tr>
</tbody>
</table>

Note: *$P<0.01$ as compared with the datum of the same item in the normal group.

### Table 3. Comparison of SCL-90 scores for depression and anxiety before and after treatment in the two groups (points, $\bar{X} \pm s$)

<table>
<thead>
<tr>
<th>Group</th>
<th>Time</th>
<th>Cases</th>
<th>Depression</th>
<th>Anxiety</th>
<th>Total score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>Before treatment</td>
<td>32</td>
<td>1.66±0.60</td>
<td>1.82±0.48</td>
<td>1.69±0.26</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>32</td>
<td>1.33±0.36*</td>
<td>1.30±0.32</td>
<td>1.69±0.35</td>
</tr>
<tr>
<td>Control group</td>
<td>Before treatment</td>
<td>33</td>
<td>1.69±0.60</td>
<td>1.75±0.30</td>
<td>1.69±0.61</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>33</td>
<td>1.57±0.56</td>
<td>1.62±0.44</td>
<td>1.69±0.51</td>
</tr>
</tbody>
</table>

Note: *$P<0.05$, **$P<0.05$ as compared with the datum before treatment in the same group.
DISCUSSION

It is reported that globus hystericus, a special somatization disorder, is related to diseases in the whole body, most closely to diseases in the digestive tract. Its complicated illness cause, lingering illness course and high relapse rate bring great sufferings to patients. At present, it is mostly regarded as a psychosomatic disease belonging to TCM category of imagined plum pit in throat. The disease is caused by sadness, pensiveness, emotional disorder, qi stagnation and phlegm accumulation in the throat as if the throat is obstructed by a foreign object. Banxia Houpu decoction is an effective recipe used by ZHANG Zhong-jing to treat imagined plum pit in throat. It is clinically reported that Banxia Houpu decoction has a good therapeutic effect on abnormal sensation in the throat. Another article has reported that globus hystericus patients have obvious introverted personality, anxiety and depression, and pay excessive attention to their somatic symptoms. 50% of the 95 patients had their disease caused by psychic factor, coinciding with the report.

SCL-90 scale with very high reliability can comprehensively reflect the psychological state of patients. The result of this research has shown that the average scores for anxiety and depression as well as the total score of globus hystericus patients are obviously higher than those of healthy people, indicating that globus hystericus patients obviously have anxiety, depression and poor psychological state. The therapeutic effect of modified Banxia Houpu decoction on anxiety and depression in the treatment group is much better than that in the control group, indicating that modified Banxia Houpu decoction is effective not only on the throat but also on anxiety, depression and psychological state.

At present, the therapeutic effect of TCM and the combination of TCM with Western medicine on globus hystericus is commonly evaluated by the alleviation of main symptoms. It is generally divided into cure, effectiveness and ineffectiveness. There are some deficiencies in existing standard for therapeutic effect: 1) Clinical symptoms are confined to the throat. The research has shown that globus hystericus patients pay excessive attention to their somatic function, overreact to minor changes in their bodies, and give a general and vague complaint of their somatic discomfort. Therefore, considerations should be given to patients’ psychological factors in the standard for evaluating therapeutic effect, and stress should be put on the special role of life quality on therapeutic effect. 2) Because globus hystericus easily relapses and can be self-cured, there is no definite conclusion in the standard for therapeutic effect on how long the observation should be carried out after withdrawal before the exact therapeutic effect can be determined. This research shows that the period of follow-up visit can be determined at 12 months. How to work out a psychotic scale in consideration of psychological state is to be further studied.

REFERENCES

(Translated by DUAN Shu-min 段树民)
Received July 21, 2009