Clinical and Experimental Studies on Treatment of Asthma with Juanxiao Tablet (蠲哮片)

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ABSTRACT
Objective: To evaluate the therapeutic effect of Juanxiao Tablet (JXT) in treating asthma.

Methods: Clinical observation on 447 cases of asthma was done in double- or single-blinded control method, and the therapeutic effect and safety of JXT were analysed. The effect of JXT in anti-asthma, expectorant, antiseptic, hypoxia tolerance was studied, and its acute and chronic toxicity was also examined. Results: The clinical control rate in patients treated with JXT was 38.2%, the markedly effective rate 31.2% and the total effective rate 93.49%, whereas in patients treated with Oleum Vitex Negundo, the respective rates were 13.3%, 20.0% and 68.5%. Results of pulmonary function and IgE measurement were consistent with clinical effect. Experimental study showed that JXT has the actions of anti-asthma, expectorant, antiseptic and hypoxia tolerance enhancement, with its LD₅₀(40.48 ± 5.17) g/kg. Conclusion: JXT is a new Chinese herbal preparation of good effect, with less toxic-side effect for asthma treatment.

KEY WORDS Juanxiao Tablet, bronchial asthma, asthma relieving, expectorant, bacteriostasis

Juanxiao Tablet (蠲哮片, JXT) is a third class Chinese herbal preparation developed by Jiangzhong Pharmaceutical Factory from the experienced recipe used by Dr. HONG Guangxiang. From October 1993 to June 1994, 317 patients of asthma treated with JXT were observed clinically in Xiyuan Hospital of China Academy of TCM, Jiangxi Provincial Hospital, the First and the Second Affiliated Hospitals of Jiangxi Medical College and Nanchang Municipal Hospital of Integrated Traditional Chinese and Western Medicine. And experimental studies of pharmacology and toxicology on JXT were conducted in the Division of Pharmacology, Basic Courses Department, Jiangxi College of TCM. The results were reported as follows.

CLINICAL STUDY

Clinical Materials
All the 447 patients of asthma, with their diagnosis conforming to the diagnostic and efficacy evaluation standard(¹) put forward in the “Guidance on Principles of Clinical Research on New Drugs”, were enrolled in this study, 124 out-patients and 323 in-patients, and randomized by single or double blinded method into the JXT group and the control group. The 317 cases in the JXT group were 190 males and 127 females, aged 18 - 65 years, 46.74 ± 14.69 years in average, with their average course of disease as 13.03 ± 8.70 years. The 130 cases in the control group were 89 males and 41 females, aged 18 - 65 years, 46.86 ± 14.33 years in average, with their average course of disease as 12.59 ± 9.18 years. Data of the two groups showed no significant difference in statistical analysis.

Treatment
The JXT group was treated with JXT, which was produced by Jiangzhong Pharmaceutical Factory, batch No. 930111, consisting of Semen Lepidii seu Descurainiae 10 g, Pericarpium Citrus Reticulata Viride 10 g, Pericarpium Citrus Reticulata 10 g, Fructus Viticis Negundinis 15 g, Semen Arecae 10 g, Radix et Rhizoma Rhei 6 g and Rhizoma Zingiberis Recens 10 g, each tablet containing 0.3 g of crude drugs. It was administered

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Table 1. Comparison of the Pulmonary Function and IgE between Groups ($\bar{x} \pm s$)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>FEV$_1$ (ml)</th>
<th>PEFR (L/s)</th>
<th>IgE (u/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>JXT Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Treatment</td>
<td>317</td>
<td>1440.6 ± 486.7</td>
<td>1.8 ± 0.5</td>
<td>340.3 ± 134.2</td>
</tr>
<tr>
<td>Post-Treatment</td>
<td>187</td>
<td>1511.2 ± 483.8</td>
<td>2.5 ± 0.6</td>
<td>331.0 ± 104.8</td>
</tr>
<tr>
<td>Differential Value</td>
<td>430.6 ± 342.3</td>
<td>0.7 ± 0.6</td>
<td>159.0 ± 98.8</td>
<td></td>
</tr>
<tr>
<td>Cont. Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-Treatment</td>
<td>130</td>
<td>1450.6 ± 186.3</td>
<td>1.7 ± 0.6</td>
<td>352.6 ± 145.6</td>
</tr>
<tr>
<td>Post-Treatment</td>
<td>166</td>
<td>1669.9 ± 170.8</td>
<td>2.1 ± 0.7</td>
<td>252.3 ± 115.9</td>
</tr>
<tr>
<td>Differential Value</td>
<td>219.3 ± 277.5</td>
<td>0.4 ± 0.5</td>
<td>104.9 ± 103.5</td>
<td></td>
</tr>
</tbody>
</table>

Notes: * $P < 0.001$, compared with pre-treatment of the same group; ** $P < 0.05$, *** $P < 0.01$, compared with the control group.

orally 8 tablets each time, three times a day. The control group was treated with Oleum Vitex Negundo Capsules (OVNC, produced by Jiangzhong Pharmaceutical Factory, batch No. 930701), 2 capsules each time orally, three times per day. All the patients in both groups were also given the placebo in tablet or capsule form with the same appearance as that of the drug used in the opposite group. The therapeutic effect was evaluated after 7 days treatment. No other drug was given to the patients in both groups in the observation period. The symptoms, signs, chest film, electrocardiogram (ECG), pulmonary function, IgE level, routine examination on blood and urine, liver and renal functions in patients were observed before and after treatment.

Statistical Analysis
Measurement data were treated with $t$-test, enumeration data with $\chi^2$ test and rank materials with Ridit test.

Therapeutic Effect Evaluation
The standard in the "Guidance on Principles of Clinical Research of New Drugs"(1) was adopted.

Comprehensive Therapeutic Effect
After treatment, of the 317 patients in the JXT group, 121 had their condition clinically controlled, accounting for 38.2 %, 99 (31.2%) were markedly effective, 76 (24.0%) effective and 21 (6.6%) ineffective, the total effective rate being 93.4%. While of the 130 patients in the control group, 18 (13.8%) had their condition clinically controlled, 26 (20.0%) were markedly effective, 45 (34.6%) effective and 41 (31.5%) ineffective, the total effective rate being 68.5%. The total effective rate in the JXT group was significantly higher than that in the control group ($P < 0.01$).

Therapeutic Effect on Symptoms
Ridit test showed that the improvement occurred in all items of the symptoms in the JXT group were better than that in the corresponding items in the control group ($P < 0.01$). Analysis of the therapeutic effect revealed in patients treated in different hospitals showed no significant difference ($P > 0.05$), indicating that the sources of data were reliable.

Therapeutic Effect on Pulmonary Functions and IgE Level
After treatment, the pulmonary functions, including forced expiratory volume in one second (FEV$_1$) and peak expiratory flow rate (PEFR), in the JXT group were all higher than those before treatment ($P < 0.001$). They were also better than those in the control group after treatment ($P < 0.01$). The improvement of IgE in the JXT group after treatment was better than that in the control group. The recovery rate in the JXT group was 75.0% and that in the control group 31.6%, with significant difference shown between them ($P < 0.05$). See Table 1.

Side-Effect
There were 79 cases in the JXT group revealed diarrhea 3 - 5 times a day, and 6 among them were accompanied by slight abdominal pain. But since the side-effect would be cured automatically as the condition of disease got im-