ORIGINAL ARTICLE

Clinical Study on Treatment of Hyperuricaemia by Retention Enema of Chinese Herbal Medicine Combined with Allopurinol

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ABSTRACT  Objective: To study the effect of retention enema of Chinese herbal medicine combined with allopurinol in treating hyperuricaemia (HUE). Methods: Seventy-eight patients with HUE were assigned to two groups, the 40 patients in the treated group were treated with retention enema of Chinese herbal medicine combined with oral intake of allopurinol, and the 38 patients in the control group were treated with allopurinol alone. The therapeutic course for all was 6 weeks. The clinical efficacy, changes of symptoms, blood levels of uric acid and lipids, renal function, and 24 h urinary micro-albumin were observed. Results: The total effective rate was 92.5% in the treated group, which was significantly higher than that in the control group (68.4%, P<0.05). After treatment, the score of symptoms in the treated group decreased from 9.43 ± 1.15 scores to 3.25 ± 0.85 scores, significantly lower than that in the control group (9.75 ± 1.43 scores vs 9.25 ± 0.82 scores, P<0.01). Moreover, the post-treatment improvements in blood uric acid, blood lipids, renal function and 24h urinary micro-albumin in the treated group were all better than those in the control group (P<0.05 or P<0.01). Conclusion: Retention enema with Chinese herbal medicine combined with allopurinol could obviously reduce the uric acid level in blood, improve patients' renal function and lipid metabolism, and alleviate the clinical symptoms in patients with HUE.

KEY WORDS  Chinese herbal medicine, retention enema, hyperuricaemia

Hyperuricaemia (HUE) is a metabolic disease caused by purine metabolic disturbance leading to excessive production of uric acid, which is the pathogenetic basis for gout, and could damage the kidney directly. Lots of current reports prove that it is highly correlated with such diseases as coronary heart disease, hypertension, diabetes mellitus and hyperlipidemia, forming the common soil for producing arteriosclerosis(1-5). Therefore, to actively intervene and treat the disease is a thing of extraordinary necessity. In this study, HUE patients were treated by retention enema of Chinese herbal medicine in combination with oral administration of allopurinol by the authors, and good effect has been obtained.

METHODS

Diagnosis Standard

In reference to the diagnostic standard of HUE in "Endocrinology"(6), patients were diagnosed as suffering from HUE when their serum uric acid > 416 μ mol/L (in male) or > 357 μ mol/L (in female), with all other serum and uric influencing factors excluded.

Patients diagnosed as HUE and belonging to Chinese medicine wind-damp with heat accumulation syndrome type were enrolled, who manifested no symptoms of acute joint pain, but revealed the following symptoms and signs: dizziness, lassitude, chest stuffiness, thirsty and preference to drink, vexation and restlessness, yellow urine, red tongue proper with yellow coating, and slippery and quick pulse.

General Materials

The 78 subjects enrolled in the trial were the in- or out-patients who visited the authors' hospital from October 2006 to December 2007, and assigned, according to the sequence of visiting, to two groups. The 40 patients in the treated group were 37 males and 3 females; aged 38-68 years, 51.5 ± 3.4 years on average; with illness course of 5-7 years, 5.4 ± 1.7 years on average; among them, 16 were complicated with hypertension, 18 with hyperlipidemia, 12 with coronary heart disease, 6 with cerebral infarction, 37 with gout, 4 with kidney dysfunction and 4 with other diseases. The 38 patients in the control group were 36 males and 2 females; aged 36-69 years, 51.6 ± 3.3 years on average; with illness course of 4-8 years,

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5.2 ± 1.9 years on average; among them, 10 were complicated with hypertension, 15 with hyperlipidemia, 11 with coronary heart disease, 5 with cerebral infarction, 25 with gout, 3 with kidney dysfunction and 2 with other diseases. The two groups were not different significantly in sex, age, clinical symptoms, and illness course ($P>0.05$).

**Treatment**

Applied on all patients was strict alimentary therapy with low purine: restriction of foods containing high purine, such as animals' pluck, crab, oyster, pilchard, pigeon's meat, etc.; abstinence from stimulants, particularly beer; no smoking; protein intake restricted to about 1 g/kg weight body per day; sufficient water supply to make the daily volume of urine maintain at 2 000-3 000 mL, and avoidance of excessive labor and spiritual tension.

Allopurinol tablet (product of Guangzhou Baiyunshan Pharmaceutical Factory, China) was given to both groups in the dosage of 100 mg three times a day. Other treatments for relieving symptoms were administered to patients in both groups, e.g. Lotensin 10-20 mg per day was given to patients complicated with hypertension for depressing blood pressure.

Besides, to patients in the treated group, additional retention enema of Chinese herbal decoction was implemented once a day. The decoction used for enema consisted of crude rhubarb 30 g, calcined oyster shell 50 g, waterplantain rhizome 30 g, red sage root 15 g, sophora flower 30 g, aconite root 15 g, and scullcap root 30 g. It was boiled down to 500 mL of decoction. In enema, 150 mL of the decoction was used each time for high enema (20-30 cm) and reserved there for over 60 min. The therapeutic course for both groups was 6 weeks.

**Item and Methods of Observation**

**Clinical Symptoms**

Clinical symptoms were estimated before and after treatment by scoring, 0 score for none, 1 for mild, 2 for moderate, and 3 for severe for none.

**Laboratory Indices**

Laboratory indices were detected before and after treatment, including blood levels of uric acid (SUA), urea nitrogen (BUN), creatinine (SCR), creatinine clearance (CCr) and blood lipids using Hitach 7600 automatic biochemical analyzer, as well as the 24 h urinary micro-albumin (24 h U-mAlb).

**Safety Monitoring**

To indicate safety of the treatment, routine tests of blood, urine and stool, and liver/renal function were monitored.

**Efficacy Evaluation Criteria**

In reference to the "Guiding Principle of Clinical Research on New Drugs of Traditional Chinese Medicine" and relative literature, the efficacy of treatment was graded into three grades, i.e. markedly effective was defined as disappearance of symptoms and signs, SUA decrease to normal level; effective was defined as apparent alleviation of symptoms and signs, SUA decrease to < 410 μmol/L, and renal function restored to definite extent or turning normal; ineffective was defined as no improvement in symptoms, signs, and laboratory indexes, or even aggravation.

**Statistical Analysis**

SPSS 14.0 software was used to manage all the data, measurement data were expressed as mean ± standard deviation and analyzed by $t$-test; enumeration data were analyzed by $\chi^2$ test; $P<0.05$ was regarded as of statistical meaning.

**RESULTS**

Observation was completed in all patients enrolled, with no case dropped out.

**Comparison of Clinical Efficacy**

As shown in Table 1, the total effective rate in the treated group was obviously better than that in the control group ($P<0.01$).

<table>
<thead>
<tr>
<th>Group</th>
<th>Case</th>
<th>Markedly effective (%)</th>
<th>Effective (%)</th>
<th>Ineffective (%)</th>
<th>Total effective rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated</td>
<td>40</td>
<td>19 (47.5)</td>
<td>18 (45.0)</td>
<td>3 (7.5)</td>
<td>92.5*</td>
</tr>
<tr>
<td>Control</td>
<td>38</td>
<td>10 (26.3)</td>
<td>16 (42.1)</td>
<td>12 (31.6)</td>
<td>68.4</td>
</tr>
</tbody>
</table>

Note: *$P<0.01$, compared with the control group*

**Comparison of Improvement of Symptom Scores**

In the treated group, the score of symptoms decreased from 9.43 ± 1.15 scores before treatment to 3.25 ± 0.85 scores after treatment, showing a significant difference ($P<0.01$); while in the control group, it changed from 9.75 ± 1.43 scores to 9.25 ± 0.82