Clinical Observation of Lumbrokinase Capsules and Compound Danshen Injection to Prevent Reoccurrence of Cerebral Infarction
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[ABSTRACT] OBJECTIVE: To observe the efficacy of lumbrokinase in prevention of recurrence of cerebral infarction. METHOD: 233 outpatients with cerebral infarction were randomly divided into three groups: lumbrokinase treatment group: 72 patients, administered lumbrokinase; Danshen treatment group: 77 patients, administered compound Danshen injection; control group: 84 patients, conventional treatment. RESULTS: Within one year, lumbrokinase treatment group’s cerebral infarction recurrence rate was 19.44%, while the Danshen group and the control group were 37.60% and 32.29% (P<0.01, P<0.05) respectively. CONCLUSION: The efficacy of lumbrokinase is determined to prevent recurrence of cerebral infarction, no obvious side effects.

Keywords cerebral infarction/TCM therapy; lumbrokinase capsule; compound Danshen injection/therapeutic use

Since 2004-2006, comparative study of lumbrokinase and compound Danshen (Radix Salviae Miltiorrhizae) injection to prevent recurrence of cerebral infarction in 149 patients was conducted, report was as followed:

1. DATA & METHOD
1.1 General Information In 2004 -2006, 233 outpatients with cerebral infarction were selected. Patients met the diagnostic criteria for cerebrovascular disease set by the Fourth National Cerebrovascular Disease Conference [1]. CT or MRI confirmed that patients had no history of liver disease, kidney disease, gastrointestinal bleeding or diabetes, and blood pressure did not exceed 160/90 mmHg.

1.2 Method Selected patients were randomly divided into treatment group, 72 patients, given lumbrokinase 2 capsules 3 times daily, to be taken 30 min before meals. Danshen treatment group: 77 patients, given compound Danshen injection 20mL, once daily, 15d for a treatment course, two treatment courses in one year. The control group had 84 patients with conventional treatment. Observe the recurrence of cerebral infarction.

1.3 Treatment Efficacy Assessment of efficacy before and after treatment was to be determined according to the neurological deficit score standards in patients with cerebral infarction set by the Fourth Annual Conference on Cerebral disease in 1995. Overall recovery: neural deficits reduced by an average of 90%-100%, and disability level at 0; markedly improved: neural deficits reduced by an average of 46%-89%, and disability level at 1-3; improved: neural deficits reduced by an average of 16%-45%; non-responsive: neural deficits reduced less than 15% or increased [2].

1.4 Recurrence Evaluation Patients were observed for one year from the starting date of taking the medicine. CT or MRI was used to confirm new brain lesions. If patient’s symptoms and signs corresponds to the new lesions on CT/MRI, it was considered a recurrence.

2. RESULTS
2.1 Comparison of neurological deficits between two groups before and after treatment. See table 1.

2.2 Comparison of cerebral infarction recurrence within one year of the three groups. See table 2.
Table 1 Comparison of neurological deficits between two groups before and after treatment. (x ± s)

<table>
<thead>
<tr>
<th>Group</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbrokinase</td>
<td>18.02 ± 8.62</td>
<td>16.52±10.75</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Danshen</td>
<td>16.32 ± 9.45</td>
<td>15.96 ± 9.33</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

Table 2. Comparison of cerebral infarction recurrence within one year of the three groups

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Recurrence within 1 yr</th>
<th>Recurrence rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbrokinase</td>
<td>72</td>
<td>13</td>
<td>19.44**</td>
</tr>
<tr>
<td>Danshen</td>
<td>77</td>
<td>29</td>
<td>37.66*</td>
</tr>
<tr>
<td>Control</td>
<td>84</td>
<td>32</td>
<td>39.29</td>
</tr>
</tbody>
</table>

Note: compared with control * P<0.05, **P<0.01

3. DISCUSSIONS

Table 2 showed Danshen intravenous infusion did not significantly reduce the recurrence rate of cerebral infarction, and when compared with the control group, there was no significant difference. To avoid recurrence of cerebral infarction, many patients would have Danshen injection in spring and autumn each year; yet, it failed to prevent recurrence. In the lumbrokinase treatment group, the recurrence rate compared with the control group were significantly different, P<0.01. However, there was no difference when compared the degree of recovery of neurological defects between lumbrokinase and Danshen groups, and there was no significant improvement in these two groups before and after treatment [3]. This proved that a simple treatment of lumbrokinase or Danshen injection cannot improve the existing neurological deficit symptoms. Both treatment groups did not have cerebral hemorrhage or other bleeding parts, no damage to liver, kidney and other organs. Lumbrokinase is a kind of bio-active ingredient extracted from a group of earthworm protease. It is used to activate the fibrinolytic system; hence, lowers fibrinogen and reduces platelet aggregation; lowers blood viscosity and thus prevents recurrence of cerebral infarction. Danshen injection and other injections given to clear the blood vessel, promoting blood circulation theoretically may have a role in treatment of cerebral vascular diseases [4]. However, through clinical observation and practical work, the preventive role was not evident, and the infusion itself can increase the chances of infection and infusion reactions. The process of infusion may cause vascular endothelial injury, and the damage can lead to atherosclerosis; consequently, this may cause the formation of a new infarct.

Author believed that in the prevention of recurrence of cerebral infarction should do the following: (1) Adhere to drug therapy. In a long term run and under the guidance of a doctor, patients should take less of the anti-platelet aggregation drugs, defibrase drugs and medicines that posed to improve vascular function. (2) Treat the early symptoms of relapse; give adequate attention especially to the TIA onset. (3) Eliminate the underlying factors of recurrence, such as hypertension, diabetes, heart disease, high blood lipids, and etc., especially keep control of hypertension and diabetes and adhere to medication to avoid large fluctuations in blood pressure and blood sugar. (4) Avoid relapse triggers; be emotional stable, avoid over exertion, stop smoking and alcohol consumption and have a peaceful state of mind. (5) Establish healthy living and eating habits. A balanced diet, limiting the intake of high fat foods, eat more of fruits and vegetables, control weight, have healthy life patterns, and enhance physical exercise.
4. REFERENCE


