Clinical Study on Kanglaite Injection in the Treatment of Malignant Pleural Effusion

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Abstract

Objective: To study the clinical application of KLT in the treatment of malignant pleural effusion. Methods: 60 malignant pleural effusion patients were randomly divided into KLT treatment group (n=30) and control group (n=30). The KLT group was treated with KLT intrathoracic perfusion and the control group with DDP perfusion. Results: The treatment group had evident advantages over the control group in therapeutic effect, immunological function before and after treatment, survival period and toxic and adverse reactions. Conclusion: KLT could effectively control malignant pleural effusion, enhance immunity, prolong survival and improve life quality.

Key words: KLT, intrathoracic perfusion, therapy, malignant pleural effusion

Malignant pleural effusion is the common complication of advanced malignant tumors. Patients have short survival time and very poor life quality. Intrathoracic drug perfusion has become a main therapeutic measure. Compared with the routine intrathoracic perfusion of cisplatin we have administered KLT by intrathoracic perfusion for the treatment of malignant pleural effusion since 1999. The study report is presented as follows.

1. Materials and Methods

1.1 Patients selected

60 patients were selected for this study with 42 male and 18 female. Their ages ranged from 22~73 with average of 55. Among them had lung cancer, 10 had mammary cancer, 8 had malignant pleural mesothelioma, 5 had gastric cancer and 2 had hepatic cancer. All cases were with medium or large amount of pleural effusion confirmed by pathology or cytology examination. Patients' KPS should be more than 50 scores and they did not receive other therapy at the same time.

1.2 Random division of groups

The patients were randomly divided into KLT treatment group (n=30) and cisplatin control group (n=30).

1.3 Methods of treatment

Treatment group: Aspirate pleural fluid as completely as possible then perfuse KLT 200ml into the pleural cavity, twice a week. Control group: Aspirate the pleural fluid as completely as possible, then perfuse cisplatin 60mg into the pleural cavity, once or twice a week. The therapeutic effects were
evaluated after one month. The treatment would be terminated if there were patients whose pleural effusion got disappeared. The control group should receive hydration, diuresis, leukogenic and antiemetic treatment at the same time.

2. Results

2.1 Determination of therapeutic effects

Complete response (CR): Pleural fluid got decreased or was not increased after one puncture and intrathoracic drug perfusion. The remission of symptoms lasted for more than 4 weeks. Partial response (PR): Pleural effusion got controlled after 2 punctures and drug perfusion. The remission effect lasted for more than 4 weeks. No change (NC): Pleural effusion could not be controlled with symptoms worsened after 2 punctures and drug perfusion. See Table 1.

<table>
<thead>
<tr>
<th>Group</th>
<th>CR (n)</th>
<th>PR (n)</th>
<th>NC (n)</th>
<th>RR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>12</td>
<td>14</td>
<td>4</td>
<td>86.7</td>
</tr>
<tr>
<td>Control group</td>
<td>7</td>
<td>13</td>
<td>10</td>
<td>66.7</td>
</tr>
</tbody>
</table>

2.2 Immune function

CD$_4$, CD$_8$ and CD$_4$/CD$_8$ values in the two groups before and after treatment were shown in Table 2.

<table>
<thead>
<tr>
<th></th>
<th>Treatment Group (n=30)</th>
<th>Control Group (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td>After treatment</td>
<td>Before treatment</td>
</tr>
<tr>
<td>CD$_4$</td>
<td>39.35±8.52</td>
<td>40.76±8.65</td>
</tr>
<tr>
<td>CD$_8$</td>
<td>31.24±6.13</td>
<td>28.47±6.32</td>
</tr>
<tr>
<td>CD$_4$/CD$_8$</td>
<td>1.28±0.54</td>
<td>1.44±0.39</td>
</tr>
</tbody>
</table>

2.3 The median survival period

14 months for treatment group and 6 months for control group.

2.4 Toxic reactions and side effects

The treatment group had no side effects while the control group had symptoms of chest pain, reaction of digestive tract and bone marrow depression, etc.

3. Discussion

Based on Traditional Chinese Medicine, the character of coix seed is sweet in taste and non-toxic. It enters the lung and the spleen channels with function of invigorating the spleen, replenishing qi,
minimizing tumor and resolving mass [1]. As a dual-function broad-spectrum anticancer preparation, KLT was extracted from coix seeds through scientific technology. The mechanism of the dual-function effect was that it could directly inhibit and kill tumor cells and elevate general immune function of the body. It could make cancer cells stagnated at G2+M stage, inhibit proliferation and induce apoptosis of cancer cells [2]. Japanese scholars had reported that they isolated two components from coix seeds extract which could inhibit the Ehrlich ascites carcinoma in mice. The first function was to make protoplasm degenerated and the second was to induce karyokinesis stagnated at metaphase. The clinical trial had demonstrated that KLT had a definite therapeutic effect in the treatment of malignant pleural effusion and ascites. It could regulate the cytokine level, improve the body immunity and resist cachexia. Malignant pleural effusion was caused by direct invasion or metastasis of tumors and could induce deterioration of disease and death if not treated positively. The overall prognosis of solid tumor combined with malignant pleural effusion was relatively bad with a mean survival period of only 6 months [3]. We made a comparative study in patients receiving KLT intrathoracic perfusion and cisplatin perfusion respectively before and after treatment. Through analysis we found that KLT treatment group had evident advantages over the control group in therapeutic effect, immune function before and after treatment, survival period and adverse reaction. It suggested that KLT could effectively control the malignant pleural effusion, improve the life quality of the patients with advanced cancer, enhance immunity and prolong survival period.

References:

