Clinical Observation on the Effect of Kanglaiite Injection in the Treatment of Cancerous Pain

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Abstract

Clinical trial with Kanglaiite Injection (KLT) revealed that it had anticancer effect and could relieve cancerous pain as well as improve life qualities in advanced cases. In this study 82 patients with advanced cancerous pain were treated and observed with a total remission rate of 81.71% which suggested that KLT had notable effect on improving life quality of patients with advanced cancer.

Key words: Kanglaiite (KLT), cancerous pain, life quality

The symptom of pain is very common in patients with advanced cancer. About 70%–87% cancer patients suffer from it in different degrees. Therefore the relief of pain is very important in the treatment. We have treated 82 patients suffering from advanced cancerous pain with KLT from August 1996 to August 1998 and our summary is presented as follows.

1. Clinical materials
1.1 Selection of patients
82 patients aged from 20 to 69 years old (median 57) were inpatients of the Dept. of internal medicine among whom 56 were male and 26 were female with diagnosis confirmed by cytological or pathological examinations. Detailed pathological classification is in Table 1. The pains were caused by cancer. All patients were with conscious mind and had objective lesions for evaluation. Physical state KPS ≥ 30 scores, life quality scores ≥ 15 with estimated survival time > 3 months.

<table>
<thead>
<tr>
<th>Table 1. Classification of cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer</td>
</tr>
<tr>
<td>----------</td>
</tr>
<tr>
<td>Case (n)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2. Location of cancerous pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
</tr>
<tr>
<td>------</td>
</tr>
<tr>
<td>Lung cancer</td>
</tr>
<tr>
<td>Mammary cancer</td>
</tr>
<tr>
<td>Gastric cancer</td>
</tr>
<tr>
<td>Esophageal cancer</td>
</tr>
<tr>
<td>Large intestine cancer</td>
</tr>
<tr>
<td>Thyroid Cancer</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
</tr>
<tr>
<td>Hepatic cancer</td>
</tr>
</tbody>
</table>
1.2 According to WHO numeral ranking standard (NRS) the pain could be classified into 3 degrees: 1~3 mild pain, 4~7 moderate pain, 8~10 severe pain.

<table>
<thead>
<tr>
<th>Table 3. Degrees of cancerous pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Lung cancer</td>
</tr>
<tr>
<td>Mammary cancer</td>
</tr>
<tr>
<td>Gastric cancer</td>
</tr>
<tr>
<td>Esophageal cancer</td>
</tr>
<tr>
<td>Large intestine cancer</td>
</tr>
<tr>
<td>Thyroid cancer</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
</tr>
<tr>
<td>Hepatic cancer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 4. Karnofsky scores of cancerous patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case (n)</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>82</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 5. Life quality scores of cancer patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case (n)</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>82</td>
</tr>
</tbody>
</table>

2. Methods of treatment

KLT Injection 100~200ml iv. drip. qd × 20 days

3. Observation index

3.1 Evaluation of pain

3.2 Karnofsky scores

3.3 Life quality evaluation

3.4 WBC changes

3.5 Evaluation of toxic and side effects

4. Results

4.1 See Table 6.
Table 6. Degree of remission of cancerous pain

<table>
<thead>
<tr>
<th>Degree of pain</th>
<th>Case (n)</th>
<th>Degree of pain remission</th>
<th>Remission rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>I</td>
</tr>
<tr>
<td>Mild</td>
<td>22</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Moderate</td>
<td>42</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Severe</td>
<td>18</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>82</td>
<td>15</td>
<td>10</td>
</tr>
</tbody>
</table>

After treatment the mild pain got 100% controlled (22/22), 80.95% (34/42) moderate pain and 61.11% (11/18) severe pain could be relieved. 0 meant no remission as 18.29% (15/82). I ~ III meant partial remission as 48.78% (40/82) and IV indicated complete remission as 32.92% (27/82). Total remission rate was 81.71% (67/82). The pain would be relieved gradually 1-3 days after administration and the effects could continue for over 1~7 days after termination of treatment.

4.2 See Table 7.

Table 7. Remission degree of different cancerous pain

<table>
<thead>
<tr>
<th>Cancer</th>
<th>Remission rate (remission after treatment/ before treatment)</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Total</th>
<th>Remission rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung cancer</td>
<td></td>
<td>6/6</td>
<td>13/14</td>
<td>6/7</td>
<td>25/27</td>
<td>92.59</td>
</tr>
<tr>
<td>Mammary cancer</td>
<td></td>
<td>4/4</td>
<td>7/8</td>
<td>3/4</td>
<td>14/16</td>
<td>87.50</td>
</tr>
<tr>
<td>Gastric cancer</td>
<td></td>
<td>3/3</td>
<td>7/7</td>
<td>0/2</td>
<td>10/12</td>
<td>83.33</td>
</tr>
<tr>
<td>Esophageal cancer</td>
<td></td>
<td>4/4</td>
<td>3/4</td>
<td>0/1</td>
<td>7/9</td>
<td>77.78</td>
</tr>
<tr>
<td>Large intestine cancer</td>
<td></td>
<td>2/2</td>
<td>2/3</td>
<td>0/1</td>
<td>4/6</td>
<td>66.67</td>
</tr>
<tr>
<td>Thyroid cancer</td>
<td></td>
<td>2/2</td>
<td>0/2</td>
<td>0/1</td>
<td>2/5</td>
<td>40.00</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
<td></td>
<td>0/0</td>
<td>1/2</td>
<td>0/2</td>
<td>1/4</td>
<td>25.00</td>
</tr>
<tr>
<td>Hepatic cancer</td>
<td></td>
<td>1/1</td>
<td>0/2</td>
<td>0/0</td>
<td>1/3</td>
<td>33.33</td>
</tr>
</tbody>
</table>

Table 7 revealed that KLT had an excellent effect on the pains caused by advanced lung cancer (92.59%) but less effective on thyroid cancer, pancreatic cancer and hepatic cancer. Due to the limit of patient number a further observation should be required.

4.3 See Table 8.

Table 8. Changes in KPS scores after treatment

<table>
<thead>
<tr>
<th>Elevation of KPS (scores) after treatment</th>
<th>Case (n)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>9</td>
<td>10.97</td>
</tr>
<tr>
<td>10</td>
<td>13</td>
<td>15.85</td>
</tr>
<tr>
<td>20</td>
<td>30</td>
<td>36.58</td>
</tr>
<tr>
<td>30</td>
<td>22</td>
<td>26.83</td>
</tr>
<tr>
<td>40</td>
<td>8</td>
<td>9.76</td>
</tr>
</tbody>
</table>

89.02% (73/82) patients had KPS scores raised after KLT treatment among whom 73.17% (60/82) were elevated more than 20 scores.

4.4 See Table 9.
Table 9. Changes in life quality scores after treatment

<table>
<thead>
<tr>
<th>Elevation of life quality (scores) after treatment</th>
<th>0</th>
<th>5</th>
<th>10</th>
<th>15</th>
<th>20</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case (n)</td>
<td>7</td>
<td>14</td>
<td>20</td>
<td>19</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>%</td>
<td>8.54</td>
<td>17.07</td>
<td>24.39</td>
<td>23.17</td>
<td>17.07</td>
<td>9.75</td>
</tr>
</tbody>
</table>

91.46% (75/82) patients had life quality scores elevated after KLT treatment among whom 74.39% (61/82) were elevated more than 10 scores.

4.5 See Table 10.

Table 10. Effect of KLT on peripheral WBC

<table>
<thead>
<tr>
<th>Cases (n) before treatment</th>
<th>$\geq 4.0 \times 10^9$</th>
<th>$\geq 3.0 \times 10^9$</th>
<th>$\geq 2.0 \times 10^9$</th>
<th>$\geq 1.0 \times 10^9$</th>
<th>$&lt; 1.0 \times 10^9$</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>22</td>
<td>20</td>
<td>24</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Cases (n) after treatment</td>
<td>48</td>
<td>30</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Comparison between before and after treatment: $P<0.05$ with significant statistical difference.

4.6 Toxic reactions and side effects

3 patients had nausea, 3 had fever (below 38°C), 1 had dizziness and 2 had slight phlebitis. No adverse effects on cardiac, hepatic and renal function appeared.

5. Discussion

Kanglaite Injection (KLT) was extracted from Chinese herb - *semen coicis* through modern scientific technology. As a dual-function broad-spectrum anticancer drug and confirmed by basic study and clinical trials, KLT had the effects of inhibiting and killing cancer cells, promoting immune function and reducing toxic reactions and side effects induced by radiotherapy and/or chemotherapy. As an emulsion for intravenous administration, KLT could supply the body with high energy nutrition, relieve pain and improve life quality of patients with advanced cancer [3]. The mechanism of KLT in relieving cancerous pain might be due to the properties of *semen coicis* which was a traditional important drug for restoring qi. It was sweet in taste and with the action of strengthening the Spleen and replenishing qi, excreting dampness and promoting pus discharge and was often used in treatment of muscle soreness and joint pain[2]. One of the main ingredients in *coix seed* was coixol which showed analgesic effects in rat tail stimulation test. The animal experiment indicated that *coix-lipid* could reduce muscle contraction, shorten fatigue curve, thus relieve the pain[4,5]. Meanwhile, KLT could make tumor reduce in size or even disappeared, relieve infiltration and pressure on nerves and tissues after administration which was also good for relieving pains. We observed 82 cancerous pain patients in this study. The rate of pain remission reached 81.71% with partial remission rate as 48.78% and complete remission rate as 32.92%. Mild pain could be completely controlled. 80.95% of the moderate pains and 61.11% of the severe pains could also be relieved. KLT had notable effect on improving life quality of advanced cancer patients. 89.02% patients' KPS scores got elevated and 91.46% of them had life quality scores raised. Most of them had peripheral WBC raised to normal level. Clinical observation showed that KLT
had few adverse effects, such as nausea, vomit and phlebitis. It was worth further clinical investigation on its anticancer effect.

References