Analysis on immunological indexes of 95 cases with primary bronchogenic carcinoma treated by Kanglaite Injection

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Primary bronchogenic carcinoma (lung cancer) was a commonly encountered primary lung malignancy. The morbidity and mortality of lung cancer in the world were gradually increasing since half century. A survey of our country on the death of neoplasm showed that lung cancer ranked No.1 in men and No.3 in women. Kanglaite Injection (KLT) was extracted from a Traditional Chinese Medicine-“Semen Coisis” with modern technology by Zhejiang TCM Hospital. Through the proof by plenty of clinical trials, it could effectively inhibit and kill cancer cells, prevent metastasis and improve immunological function\(^1\) and thus it is a relatively ideal anticancer new drug with broad spectrum\(^2\). From March 1997 to April 2000 a clinical study on KLT in treating 97 cases of primary lung cancer was conducted in our hospital. The results indicated that KLT could significantly enhance the activity of NK cells, levels of IL-2, CD\(_4^+\), CD\(_8^+\) and ratio of CD\(_4^+\)/CD\(_8^+\), raise immunological function and body’s anticancer function, relieve clinical symptoms and improve quality of life.

Materials and methods

1 Clinical data
Male:90 cases, female:56 cases, male:female:1.71:1. Treatment group: 95 cases, control group: 51 cases. No significant difference in the ratio of male to female in the two groups (\(P>0.05\)). Age ranged 29~74 with an average of 57.3.

2 Treatment methods
All the 146 cases were in-patients, which were divided into 2 groups: 1. KLT treatment group. 2. Simple chemotherapy group.

2.1 Treatment group
KLT 200 ml/d, i.v drip, once daily, 21 days as one treatment course.

2.2 Simple chemotherapy group
MMC 6-8 mg/m\(^2\), i.v infusion, d1; VDS 3mg/m\(^2\), i.v infusion, d1,8; PDD 50mg/m\(^2\), i.v infusion, d1; VDS 3mg/m\(^2\), i.v infusion, d1,8; PDD 50mg/m\(^2\), i.v drip, d3,4. Six weeks as one course. No combination with other anticancer therapy and special immunodepressing agent used during medication period in the two groups.

2.3 Observation indexes
The major indexes observed were tumor size, TCM symptoms and signs, body weight, changes of immunological functions, liver & kidney functions, and hemogram before and after treatment.

(1) Tumor size: Check X-ray films (PA & lateral films), once a month before and after treatment.

(2) Immunological function: The activity of NK cell, IL-2, T-lymphocytes and other subgroups (CD\(_4^+\), CD\(_4^+\), CD\(_8^+\), CD\(_4^+\)/CD\(_8^+\)) were checked once a month before and after treatment.
3. Results

3.1 Objective efficacy on tumor

The response rate (RR) in the treatment group (95 cases) was 12.36%, while 13.72% in the control group (51 cases), without significant difference between the 2 groups (P>0.05) (See Tab.1).

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>CR</th>
<th>PR</th>
<th>NC</th>
<th>PD</th>
<th>RR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>KLT group</td>
<td>95</td>
<td>0</td>
<td>12</td>
<td>75</td>
<td>8</td>
<td>12.36</td>
</tr>
<tr>
<td>Chemotherapy group</td>
<td>51</td>
<td>1</td>
<td>6</td>
<td>32</td>
<td>12</td>
<td>13.72</td>
</tr>
</tbody>
</table>

3.2 Changes of immunological function before and after treatment

3.2.1 Changes of the activity of NK cell

In KLT group, there was significant difference in NK cell activity between before and after treatment (P<0.05), while no significant difference in chemotherapy group (P>0.05). There was most noticeable difference in NK cell activity after treatment between the two groups (P<0.01), which indicated that KLT could significantly enhance the activity of NK cell and which was superior to that of chemotherapy group (see Tab.2).

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Before treatment (x±s)</th>
<th>After treatment (x±s)</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>KLT group</td>
<td>95</td>
<td>18.11±3.24</td>
<td>27.54±7.85</td>
<td>6.36</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Chemotherapy group</td>
<td>51</td>
<td>18.79±3.33</td>
<td>18.05±3.20</td>
<td>0.12</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

3.2.2 Changes of IL-2

There was significant improvement of the ability of lymphocytes to produce IL-2 after KLT treatment (P<0.05) with significant difference between the two groups (P<0.05). It indicated that KLT could improve the level of IL-2 (see Tab.3).

<table>
<thead>
<tr>
<th>Group</th>
<th>Cases</th>
<th>Before treatment (x±s)</th>
<th>After treatment (x±s)</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>KLT group</td>
<td>95</td>
<td>18.77±14.15</td>
<td>32.06±15.17</td>
<td>1.69</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Chemotherapy group</td>
<td>51</td>
<td>18.79±13.19</td>
<td>24.57±12.56</td>
<td>1.12</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

The normal value of IL-2 should be 15~80pg/ml, after treatment in KLT and chemotherapy group:t:2.19, P<0.05.

3.2.3 Changes of T-lymphocytes and subgroups

There was significant improvement of CD3+, CD4+ and CD8+ after KLT treatment (P<0.05), while no significant difference on CD3+, CD4+ and CD8+ before and after treatment in chemotherapy group. After treatment, CD3+, CD4+ and CD8+ in KLT group were all significantly improved compared to those in control group (see Tab.4 and Tab.5).

<table>
<thead>
<tr>
<th>Item</th>
<th>Cases</th>
<th>Before treatment (x±s)</th>
<th>After treatment (x±s)</th>
<th>t</th>
<th>P</th>
</tr>
</thead>
</table>
Comparison between KLT and Chemotherapy group: CD3⁺: t=3.42, P=0.001; CD4⁺: t=4.99, P=0.001

4 Discussion
The genesis and development of tumor in human body are closely correlated with the imbalance of immune system. NK cells are a group of heterogenic and multifunctional cells. It has the functions of anticancer, anti-infection and immunoregulation, etc. It was the first line of defense in immune surveillance system. CD3⁺, CD4⁺ and CD8⁺ are the subgroups with function of counter-suppression. They can restore the auxiliary activity of TH and enhance immune response. The response rate of KLT to primary bronchogenic carcinoma was 12.63%. The immunological test results showed that KLT could significantly raise the activity of NK cell, improve IL-2 level, CD4⁺ / CD8⁺ value and immunological function. At the same time the increase in the expression of CD3⁺, CD4⁺ and CD4⁺ / CD8⁺ would be beneficial to their being induced, and would play an important role in the restoration of immunological function. The main adverse reactions in this study were fever, nausea, vomiting and phlebitis, they would generally last for 1 week, the symptoms, except fever that needed symptomatic treatment, would be relieved by themselves. So KLT is currently a rather ideal TCM product in treating lung cancer

References