Observation on Clinical Effect of Kanglaite Injection (KLT) in the Treatment of Primary Mammary Cancer

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Abstract
As an active anticancer product, KLT injection is made from Traditional Chinese Medicine-coix seed. The experimental study on animals revealed that it had evident effects of inhibiting many kinds of transplanted tumors, activating and enhancing immune functions in animal bodies with slight adverse reaction. From Jan.-Jun.1997, the departments of surgery in our two hospitals treated 21 patients with primary mammary cancer by KLT injection combined with surgical operation. We observed the therapeutic effect and its impact on immune function as well as safety in order to study its value of clinical application.

1. Materials and Methods

1.1 Selection of patients

This study included 21 patients, all female, aged from 35 to 72 years (average 51.2 years). They were all confirmed by definite cytologic diagnosis, with normal heart, liver, kidney and bone marrow function and never received other anticancer therapy. The clinical staging was based on the TNM staging criteria of mammary cancer made by UICC. 14 cases in stage II and 7 cases in stage III were enrolled.

1.2 Treatment scheme

KLT Injection 200ml iv. drip, for 10 days

1.3 Evaluation of safety and therapeutic effect

The evaluation was conducted according to the criteria formulated by WHO for assessment of short-term therapeutic effect on solid tumor and the grading standard for common toxic and adverse reaction.

2. Results

2.1 Short-term therapeutic effect

2.1.1 Clinical therapeutic effect on tumor

According to WHO standard and based on clinical and B-ultrasonic examination, the preliminary evaluation results were as follows. CR (complete response) 1 case, PR (partial response) 5 cases, MR (moderate response) 6 cases, SD (stable disease) 8 cases and PD (progressive disease) 1 case with total response rate: 28.6% (6/21).

2.1.2 Observation of pathomorphology
After operation the microscopic observation on pathological specimens showed 21 patients with mammary cancer had different degrees of degenerative necrosis in cancer cells. Among them 5 cases were relatively evident, one case appeared large areas of degenerative necrosis in cancer tissues with necrosis areas of 75% and the other 4 cases necrosis area was over 25%. The degenerative necrosis of cancer cells showed patchy or focal type distribution and there were large amounts of lymphocytes infiltrating the necrotic cancer cells and various degrees of fibrous tissues proliferation.

2.2 Changes of immune function

The activities of T-lymphocytes subgroups and NK cells were detected before and after treatment in this study. And the results were listed in the following table.

<table>
<thead>
<tr>
<th>Index</th>
<th>Cases (n)</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NK</td>
<td>21</td>
<td>14.62±6.48</td>
<td>16.31±6.32</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>OKT3(%)</td>
<td>21</td>
<td>64.85±4.56</td>
<td>64.92±5.72</td>
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<tr>
<td>OKT4(%)</td>
<td>21</td>
<td>37.22±7.42</td>
<td>40.43±5.74</td>
<td>&gt;0.05</td>
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<tr>
<td>OKT8(%)</td>
<td>21</td>
<td>26.70±3.88</td>
<td>28.21±6.42</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>T4/T8</td>
<td>21</td>
<td>1.39±0.31</td>
<td>1.43±0.34</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

2.3 Evaluation of safety

The 21 patients with mammary cancer treated with KLT had no serious adverse effects. Only one patient appeared grade I abnormal liver function while the others had normal heart, liver and kidney functions. No side effects such as bone marrow depression, gastrointestinal reactions, chill, fever or allergic reaction were observed.

3. Discussion

KLT is a dual-function broad spectrum anticancer drug. The clinical trials in the treatment of lung cancer, hepatic cancer, stomach cancer and esophageal cancer revealed that KLT had an effect of inhibiting tumor growth. It could increase the therapeutic efficacy if combined with chemotherapy and protect bone marrow, liver and kidney from severe side effects caused by chemotherapy. We clinically observed the therapeutic effects on 21 patients with mammary cancer and found out that the short-term effects were remarkable. Six patients had different degrees of decrease in their tumor size with response rate of 28.6%. Although the effects in most patients were not evident the postoperative examination through microscope on tumor specimens also showed that all patients had different degrees of degenerative necrosis in cancer cells including one whose necrotic cancer cells even reached 75%. There were also large amounts of lymphocytes infiltrating the necrotic cancer cells and fibrous tissues proliferation. This indicated that KLT had affirmative effect of inhibiting and killing cancer cells.

The activities of T-lymphocytes subgroups and NK cells were detected before and after treatment in this study. Results showed that T-cell subgroups T3, T4, T8 and NK cells had a tendency to increase after treatment. Although the effect did not reach the level of significant difference it could still indicate that KLT might be effective for restoring and enhancing immune function. Through the observation on 21 patients, administration of KLT by intravenous drip and 200ml per day did not bring about evident toxic and side effect. And this suggested its reliable safety.