Clinical observation on Kanglaite Injection combined with HAP regimen in the treatment of mid- and late-stage lung cancer

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[Abstract] Objective To compare the therapeutic effect of Kanglaite Injection (KLT) combined with HAP regimen with that of simple HAP regimen in treating mid- or late-stage lung cancer. Methods 48 cases of mid- or late-stage lung cancer were randomly divided into 2 groups: HAP group 22 cases and HAP+KLT group 26 cases. Results The overall response rate and symptomatic marked relief rate in HAP+KLT group and HAP group were 42.3% and 65.4%, and 13.6% and 28.9% respectively, with significant difference between the two groups (P<0.05). Conclusion KLT + HAP regimen can improve efficacy and reduce toxicity in the treatment of mid- or late-stage lung cancer, and is worthy of being further promoted in clinical use.

[Key words] KLT; Lung cancer; Combined chemotherapy

Lung cancer is one of the most commonly encountered malignancies. Limited by various factors most patients, when got diagnosis, have been at their mid- or late-stage and lost the opportunity for surgery, chemotherapy becomes the major treatment method [1]. From March 2001 to Aug. 2002, the author applied KLT+HAP regimen to treat 26 cases of mid- or late-stage lung cancer, and compared with the control group, to which simple HAP regimen was applied, the results are now reported as follows.

1 Materials and methods

1.1 Clinical data
A total of 48 cases (male 42 cases, female 6 cases) were randomly divided into two groups (A and B groups), Group A (22 cases) and Group B (26 cases). The median age, male/female ratio and TNM staging in the two groups were similar. All the cases had been confirmed by pathology or cytology to be mid- or late stage lung cancer. They had measurable focus and no severe dysfunction of heart, liver, kidney and bone marrow.

1.2 Medication methods
Group A: HCPT 10 mg, iv drip, d1-d5; EPI 50-70 mg/m², iv, d1; DDP 40 mg, i.v drip, d1-d3.
Group B: Started simultaneously with chemotherapy, KLT 200ml/d, iv drip, once daily for 21 consecutive days as 1 treatment cycle.
Liver & kidney functions and ECG were re-examined once a month. Routine hydration should be performed when DDP was administered.

1.3 Judgment of efficacy and toxic & side reactions
Judgment could only be performed in patients who had completed more than 2 courses.

① Objective efficacy
According to WHO standard [2], the objective efficacy has been classified into complete response (CR), partial response (PR), no change (NC) and progress of disease (PD), response rate (RR) = CR+PR. Toxicity should be evaluated according to the unified standard issued by WHO which classified the adverse reactions into 0-4 degrees [3].

② Symptomatic relief
Mainly observed the symptoms such as cough, bloody phlegm, short breath, chest pain, etc.

③ Quality of life
Life quality should be evaluated in accordance with KPS system. Increase >10 points after treatment was termed as improved, decrease >10 points as reduced and less than 10 points in increase or decrease as stable.

1.4 Statistics
X² test was applied, P<0.05 with statistical significance.

2 Results
All the cases completed 2 cycles or more, their efficacy and toxic & side reactions could be evaluated.

2.1 Objective efficacy (See Tab.1)
The response rates in group A and B were 13.6% and 42.3% respectively, with significant difference between the two groups (P<0.05), indicating KLT + HAP regimen group had better efficacy

<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>HAP</td>
<td>22</td>
<td>0</td>
<td>3</td>
<td>16</td>
<td>3</td>
<td>3 (13.6)</td>
</tr>
<tr>
<td>KLT + HAP</td>
<td>26</td>
<td>0</td>
<td>11</td>
<td>13</td>
<td>2</td>
<td>11 (42.3)</td>
</tr>
</tbody>
</table>

* P<0.05

2.2 Symptomatic relief (see Tab.2)
The symptomatic relief rates in group A and B were 28.9% and 65.4% respectively, with significant difference between the two groups( P <0.05), indicating KLT+HAP regimen could significantly improve symptoms.

<table>
<thead>
<tr>
<th>Group</th>
<th>Cough</th>
<th>Bloody phlegm</th>
<th>Short breath</th>
<th>Chest pain</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAP</td>
<td>6/22</td>
<td>5/11</td>
<td>6/20</td>
<td>3/18</td>
<td>20/69</td>
</tr>
<tr>
<td>KLT + HAP</td>
<td>20/26</td>
<td>10/14</td>
<td>11/22</td>
<td>12/19</td>
<td>53/81</td>
</tr>
</tbody>
</table>

2.3 Quality of life (See Tab.3)
After 2 courses of treatment, the improvement rates in group A and B were 45.5% and 80.8%6 respectively, with significant difference between the two groups( P <0.05).

<table>
<thead>
<tr>
<th>Group</th>
<th>Improved</th>
<th>Stable</th>
<th>Reduced</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAP</td>
<td>2</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>KLT + HAP</td>
<td>6</td>
<td>15</td>
<td>5</td>
</tr>
</tbody>
</table>
Note: P<0.05, comparison between the two groups

2.4 Toxic & side reactions (See Tab.4)

<table>
<thead>
<tr>
<th>Toxicity &gt;degree II</th>
<th>Hematol toxicity</th>
<th>Phlebitis</th>
<th>Digestive tract reactions</th>
<th>Fever</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAP group</td>
<td>11</td>
<td>0</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>KLT + HAP group</td>
<td>5</td>
<td>1</td>
<td>13</td>
<td>3</td>
</tr>
</tbody>
</table>

2 Discussion

Kanglaite Injection (KLT) is an emulsion prepared by extracting the active components from a Traditional Chinese Medicine-“Semen Coisis” with modern technology by Zhejiang Kanglaite Pharmaceutical Co., Ltd. It is a dual-functional new anticancer drug with broad spectrum. It mainly retards cell cycle at phases G2+M and induces decline of cell percentage of phase S to reduce the mitosis and DNA synthesis, inhibits proliferation of tumor cells and activates relative factors to induce apoptosis⁴. Meanwhile KLT can also activate the activity of NK cells, enhance the secretion of IL-1 and IL-2, enhance the synthesis of macrophage, activate the phagocytosis function of macrophage to improve the general cellular and immune function. It is a unique TCM anticancer injection at home and abroad with functions of anticancer and strengthening body resistance.

Currently the majority of chemotherapeutic regimens had rather poor efficacy on primary lung cancer (especially NSCLC). Increase of dosage could improve the efficacy, but the adverse reactions would also be increased, which could not be tolerated for most patients. The new products (e.g. taxol) were too expensive to be widely administered. The patients of the two groups in this study had similarities in respect of age, gender distribution and clinical staging, which made them comparable. Results showed that KLT+HAP regimen could enhance efficacy and improve life quality while without increasing toxicity. So the development of KLT and its clinical application has provided cancer patients with a safe and effective treatment approach, which has the functions of anticancer, improving general health condition and body’s resistance. It should be worthy of being extensively clinically applied.

References