Clinical study on the treatment of non-small cell lung cancer (NSCLC) with a combined therapy of Kanglaite Injection and chemotherapy

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**[Key Words]** Kanglaite; NSCLC; Control study

Non-small-cell lung cancer (NSCLC) is difficult to be diagnosed at early stage. About 85-90% of the patients, when the disease is confirmed, have already been at mid or advanced stage and lost the opportunity for surgery. Therefore, for stage III-IV patients, the only suitable treatment is a comprehensive therapy. From June 1998 to May 2001 we employed Kangalite Injection (produced by Zhejiang Kangalite Pharmaceutical Co., Ltd.) for intravenous infusion. At the same time we also employed a first-line MVP chemotherapy protocol plus a treatment based on basic theory of TCM - diagnosis and treatment based on overall analysis of the symptoms, signs and patient's physical conditions. We compared this treatment group to the control group employing MVP +TCM drugs and verified that the former group was superior over the latter group in terms of short-term efficacy, protective effect to chemotherapy and the influence on patient’s quality of life.

Data and Methods

Clinical data

A total of 64 cases were randomly divided into treatment group 34 cases and control group 30 cases. All cases have been confirmed by CT and pathologic examinations of whom male 44 cases and female 20 cases. Age: 39-78 with average as 52. Duration of disease: 2 months-3.5 years. Among them adenocarcinoma 45 cases and squamous carcinoma 19 cases.

1. Treatment group
   (1) Kanglaite Injection 200ml for intravenous infusion, d₁-d₂;
   (2) MVP regime: MMC 10mg/m², d₁; VDS 4mg/m², d₁, d₈; DDP 100mg/m², d₁, plus hydration and antiemetic therapy, repeated the treatment 4 weeks later;
   (3) Treatment based on the basic theory of TCM - diagnosis and treatment based on overall analysis of the symptoms, signs and patient’s physical conditions with the following basic prescription. *Radix Pseudostellariae, Radix Adenophorae, Radix Glehniae, Rhizoma Atractylodis Macrocephalae, Poria, Radix Astragali, Bulbus Lili, Pericarpium Citri Reticulatae, Rhizoma Pinelliae Praeparata, Herba Salviae Chinensis, Spica Prunellae, Herba Houttuyniae, Tianlong, Radix Glycyrrhizae.* The ingredients of this prescription could be added or reduced according to what type of symptom complex the patient belongs to. There were 5 types of symptom complex i.e. deficiency of both qi and yin, insufficiency of the spleen with phlegm-dampness, deficiency of yin with interior heat-syndrome, accumulation and abundance of noxious heat and stagnancy of qi and blood stasis. The ingredients of the prescription were made into a decoction taken orally one dose qd and 30 doses as a treatment course.
2. Control group

(1) MVP protocol;

(2) Treatment according to the basic theory of TCM mentioned above. The dosage and duration of the chemotherapy as well as TCM treatment were the same as the treatment group.

After two cycles of the above treatment WHO criteria for evaluation of therapeutic effect was applied for processing statistic data.

Results

The short-term efficacy, the protective effect to the chemotherapy and influence on patient’s quality of life in the two groups were listed in Tab.1-3.

Tab. 1  Comparison of the short-term efficacy between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of cases</th>
<th>CR (%)</th>
<th>PR (%)</th>
<th>NC (%)</th>
<th>PD (%)</th>
<th>Effective rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>34</td>
<td>1 (2.94)</td>
<td>18 (52.94)</td>
<td>11 (32.35)</td>
<td>4 (11.76)</td>
<td>55.58</td>
</tr>
<tr>
<td>Control</td>
<td>30</td>
<td>1 (3.33)</td>
<td>8 (26.66)</td>
<td>10 (33.33)</td>
<td>9 (30.0)</td>
<td>29.99</td>
</tr>
</tbody>
</table>

Comparison between the two groups: CR, NC tested by $X^2$, P>0.05, CR+PR<0.05

Tab. 2  Comparison of the protective effect on chemotherapy between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>G.I. reactions</th>
<th>Bone marrow inhibition</th>
<th>Hepatic &amp; renal impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I</td>
<td>II</td>
<td>III</td>
</tr>
<tr>
<td>Treatment</td>
<td>0</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Control</td>
<td>5</td>
<td>9</td>
<td>11</td>
</tr>
</tbody>
</table>

Comparison between the two groups: G.I. reactions, WBC, PLT and hepatic & renal functions: (P<0.05)

Tab. 3  Comparison of the quality of life (KPS) between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of cases</th>
<th>Decline</th>
<th>Stable</th>
<th>Elevation (point)</th>
<th>Ave. per capita</th>
<th>Rate of elevation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>20</td>
<td>30</td>
<td>40</td>
<td>50</td>
</tr>
<tr>
<td>Treatment</td>
<td>34</td>
<td>0</td>
<td>6</td>
<td>4</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Control</td>
<td>30</td>
<td>2</td>
<td>10</td>
<td>13</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Comparison between the two groups: the average points per capita P<0.01

Discussion

1. Efficacy in the treatment of NSCLC

As a first-line regime for the treatment of lung cancer, the remission rate of MVP in treating NSCLLC is only about 20%.

The TCM treatment usually has good synergistic and toxicity-reducing effect to chemotherapy and embodies important value in improving patient’s quality of life and extending survival period. The authors have conducted a comparative study between the group using Kanglaite + chemotherapy + treatment based on the basic theory of TCM and the
group using chemotherapy + treatment based on the basic theory of TCM. The study have proven that the short term therapeutic effect of the former group was more stable than that of the latter group, indicating that the biphasic regulating action of Kanglaite Injection could significantly raise therapeutic effect. The therapy of Kanglaite+ chemotherapy + treatment based on the basic theory of TCM has a bright prospect.

2. Protective effect to chemotherapy
Kanglaite can not only inhibit and kill cancer cells but also reduce such side effects as bone marrow inhibition, G.I. reactions and hepatic and renal function impairment, etc. caused by chemotherapy. It is also helpful to the improvement of the insufficiency of energy resulted from G.I. reactions of chemotherapy. Kanglaite presents good protective effect in adjuvant cancer treatment and chemotherapy.

3. Influence on improvement of quality of life
Improving quality of life is of great importance to the prolongation of patient survival period. The treatment principle of “strengthening body’s resistance and suppressing cancer cells” has become the guiding ideology of TCM doctors in treating patients with advanced cancer [1]. The above study demonstrated that Kanglaite could improve patient quality of life and relieve the contradiction between the elimination of pathogenic factor and the inevitable injury of body’s immunity. This is in conformity with the ideology and practice of “strengthening body resistance and suppressing cancer” of TCM and is worthy to be widely adopted by clinicians.

References