Clinical observation on Kanglaite Injection combined with chemotherapy in treating elderly patients with NSCLC

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[Abstract] Objective To compare the therapeutic effect, adverse reactions and influence on immunity of Kanglaite Injection (KLT) combined with chemotherapy (treatment group) with those of simple chemotherapy (control group) in treating elderly patients with non-small cell lung cancer (NSCLC). Methods In the treatment group, KLT together with NVB+DDP treatment, 100ml of KLT was given intravenously once daily for 21 consecutive days, while in the control group, only chemotherapy (NVB+DDP) was given. Results The response rate in the treatment group and the control group was 44.4% and 36.1% respectively, without significant difference between two groups, P>0.05. But the PD rate, blood adverse reaction, digestive tract reaction and decrease of immunity in the treatment group were all markedly lower than those in the control group with significant difference, P<0.05. The improvement in KPS scores in the treatment group was higher than that in the control group, P<0.05. Conclusion Kanglaite Injection combined with chemotherapy in treating elderly patients with non-small cell lung cancer could lower the influence on immunity and adverse reactions of chemotherapy, and improve patients’ quality of life.


[Key words] Carcinoma, Non-small cell lung/drug therapy; Antineoplastic drug (TCM)/therapeutic use; Injection; the Aged

72 cases of hospitalized elderly NSCLC patients (Jan. 1999- Sep. 2002) were randomly divided into simple chemotherapy group and KLT+ chemotherapy group. The following is the report of observation on T lymphocyte subgroups changes before and after treatment, clinical efficacy and toxic & adverse reactions.

1. Clinical data
   1.1 General information
   All the 72 cases have been confirmed by cytology or pathology were randomly divided into the treatment group (KLT+ chemotherapy) and control group (simple chemotherapy) with 36 cases in each group. In treatment group, 27 cases were male, 9 cases were female, their age ranged from 60 to 78 with the average of 68.5 years old. In control group, 28 cases were male, 8 cases were female, their age ranged from 60 to 77 with the average of 67.9 years old. All patients were not suitable for or refused surgery because of advanced age, physical weakness or other illnesses. They had measurable focus, normal liver & kidney functions and blood routine before treatment. KPS scores were all >50, expectant survival time >3 months.

   1.2 Treatment methods
   NP regimen (NVB+DDP) in the control group: NVB 25mg/m², i.v. d1,d8; DDP 100 mg/m², i.v. d1. 21 d as one treatment course.
   Treatment group: on the basis of NP regimen, added KLT 100ml/d, i.v. once daily, for 21 consecutive days.

   1.3 Observation indexes and efficacy standard
   According to the unified evaluation standard issued by WHO in 1981, the efficacy was classified into complete response (CR),
partial response (PR), no change (NC) and progress of disease (PD). Toxic reactions were classified into 0-IV degrees \[^1\]. Life quality should be evaluated in accordance with KPS scores 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. Adverse reactions should be recorded in details during treatment, evaluation should be conducted based on the summaries of 2 doctors in accordance with the standard for toxic reactions of anticancer drug issued by WHO.

1.4 Results

1.4.1 Short-term efficacy

In the treatment group, CR 1 case, PR 15 cases, NC 18 cases, PD 2 cases. In control group, CR 0, PR 13 cases, NC 15 cases, PD 8 cases. The response rate (CR+PR) in the treatment group and control group was 44.4% and 36.1% respectively, without significant difference, \(P>0.05\). PD rate in the treatment group and control group was 5.6% and 22.2% respectively, with significant difference, \(P<0.05\).

1.4.2 Quality of life

In the treatment group, improved 55.6%, stable 36.1%, reduced 8.3%. while in the control group, improved 25%, stable 38.9%, reduced 36.1%. There was significant difference in improved rate and reduced rate between the two groups, \(P<0.05\).

1.4.3 T lymphocyte subgroups changes

There were no significant decreases in \(CD_3, CD_4, CD_8, CD_4/CD_8\) in the treatment group, \(P>0.05\). While significant decreases were found in the control group, \(P<0.05\). See Table 1.

<table>
<thead>
<tr>
<th>Group</th>
<th>(CD_3)</th>
<th>(CD_4)</th>
<th>(CD_8)</th>
<th>(CD_4/CD_8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Before treatment</td>
<td>54.9±2.89</td>
<td>36.8±3.12</td>
<td>31.5±2.65</td>
<td>1.17±0.18</td>
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<tr>
<td>After treatment</td>
<td>54.4±3.08</td>
<td>36.7±2.52</td>
<td>30.8±1.89</td>
<td>1.19±0.17</td>
</tr>
<tr>
<td>P value</td>
<td>(P&gt;0.05)</td>
<td>(P&gt;0.05)</td>
<td>(P&gt;0.05)</td>
<td>(P&gt;0.05)</td>
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<tr>
<td>Control group</td>
<td></td>
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<tr>
<td>Before treatment</td>
<td>57.4±2.69</td>
<td>36.9±2.53</td>
<td>30.4±2.28</td>
<td>1.21±0.23</td>
</tr>
<tr>
<td>After treatment</td>
<td>45.8±2.22</td>
<td>25.6±2.15</td>
<td>27.8±1.16</td>
<td>0.92±1.13</td>
</tr>
<tr>
<td>P value</td>
<td>(P&lt;0.05)</td>
<td>(P&lt;0.05)</td>
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1.4.4 Toxic & adverse reaction

There were 6 cases (16.7%) in the treatment group and 20 cases (55.6%) in the control group who had degree III-IV WBC declines, with significant difference, \(P<0.05\). There were 11 cases (30.6%) in the treatment group and 25 cases (69.4%) in the control group who had degree I-IV digestive tract reactions, with significant difference, \(P<0.05\).

2 Discussion

Chemotherapy is the major therapy in treating advanced NSCLC. NVB is a new semisynthesized VLB anticancer drug with broad spectrum. Its single therapy in treating NSCLC is quite effective, which was reported by Pan Qichao\[^2\] that the RR could reach about over 30%. The combined therapy of NVB+DDP could improve the anticancer activity without increasing the
toxicity, with total RR 30%-50%[3]. In this study, the response rate in simple chemotherapy group was 33.3%, which conformed to previous report. While the patients had especially severe bone marrow depression and digestive tract reactions which were the major toxic reactions in NP regimen. Morikawa[4] thought the importance of protecting immunity should be regarded as same as killing cancer cells during cancer treatment. One of the directions for current cancer research should be searching for a drug by which the efficacy of chemotherapy and body’s immunity could be improved while the toxic & adverse reactions could be reduced simultaneously. Studies indicated that KLT is a dual-functional anticancer drug with broad spectrum, which has the actions of inhibiting and killing cancer cells, improving immunity and reducing the toxic and adverse reactions of chemotherapy, providing high-energy nutrition and improving life quality of patients[5]. In this study, although the response rate (44.4%) in the treatment group was higher than that (33.3%) in the control group, there was no significant difference between the two groups. While there was significant difference in PD rate between the two groups thus indicating KLT could prolong patients’ survival time. There was no significant difference in CD3,CD4,CD8,CD4/CD8 in the treatment group between before and after treatment, while those indexes in the control group were significantly decreased after treatment. It indicated KLT has the action of immunity protection. The cases with WBC declines in the treatment group were evidently less than those in control group, which indicated that KLT could reduce bone marrow depression and increase WBC. Life quality in the treatment group was obviously higher than that in the control group, this might be related to KLT’s action of improving immunity and enhancing tolerance to chemotherapy.

KLT combined with chemotherapy could not only improve the efficacy, but also significantly reduced the toxic & adverse reactions of chemotherapy, improve life quality. In this way, KLT could prolong the survival time and enhance tolerance to chemotherapy in treating elderly patients with physical debility and other illnesses.

References