Clinical observation on Kanglaite Injection combined CEP regimen in treating NSCLC

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[Key words] cancer; NSCLC/TCM therapy; Anticancer drug(TCM)/ administration and dosage; Injection


The following is a summary in which satisfactory efficacy was obtained by using Kanglaite Injection (KLT) combined with CEP regimen in treating 64 cases of NSCLC.

1. Clinical data
   1.1 Selection of patients
   Among the pathologically confirmed 64 cases of NSCLC, male 38 cases, and female 26 cases; age 41~68, average 59. Of which squamous carcinoma 36 cases, adenocarcinoma 28 cases, stage IIIA 12 cases, stage IIIB 36 cases, and stage IV 16 cases. KPS scores were all beyond 60 points, and they were all newly treated patients.

   1.2 Treatment regimen
   The 64 cases were randomly divided into 2 groups.
   The Trial group 32 cases, CTX 400 mg/m$^2$, i.v. d1; EPI 40 mg/m$^2$, i.v. d1; DDP 40 mg/m$^2$, i.v. d1; KLT 200 mg/d, i.v. d1-d10; 28 d as 1 treatment cycle for 2 consecutive cycles.
   Control group 32 cases, with same chemotherapy regimen as the trial group and without KLT.

   1.3 Observation indexes
   1.3.1 Short-term efficacy
   After 2 cycles of chemotherapy, the tumor size was observed and the efficacy should be evaluated according to the “Evaluation Standard of Short-term Efficacy on Solid Tumor” issued by WHO which classified the efficacy into complete response (CR), partial response (PR), no change (NC) and progress of disease (PD). The response rate (RR) should be CR+PR.

   1.3.2 Toxic and adverse reactions
   After chemotherapy, indexes such as Hb, WBC, PLT, ALT and BUN, etc. should be tested and adverse reactions should be recorded in details. The evaluation on adverse reactions should be conducted in accordance with the “Grading Standard for Acute and Sub-acute Toxic Reactions of Anticancer Drug” issued by WHO which classified the adverse reaction into 0-IV degrees.

   1.3.3 Quality of life
   The life quality before and after treatment should be evaluated in accordance with the “KPS Scores Standard” recommended by WHO. Increase >10 points after treatment was termed as improved and decrease >10 points as reduced and less than 10 points in increase or decrease as stable.
1.4 Results

The short-term efficacies in the two groups were different. In the trial group, CR 2 cases, PR 16 cases, RR 56.3%, while in the control group, CR 0, PR 12 cases, RR 37.5%. There was significant difference between the two groups with \( p < 0.05 \). The toxic and adverse reactions should refer to Table 1, which showed that the toxic and adverse reactions of the trial group was significantly lower than that of the control group with \( p < 0.05 \). As for the life quality changes, 24 cases (75%) in the trial group got improved and stable, 8 cases got reduced. While in the control group, 10 cases (31%) got improved or stable, 22 cases got reduced. Comparison between the two groups showed that \( p < 0.05 \).

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>Trial group</th>
<th>Control group</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>I</td>
<td>II</td>
</tr>
<tr>
<td>Hb</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>WBC</td>
<td>3</td>
<td>7</td>
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<tr>
<td>mPLT</td>
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<td>1</td>
</tr>
<tr>
<td>ALT</td>
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<td>0</td>
</tr>
<tr>
<td>BUN</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nausea &amp; vomiting</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Alopecia</td>
<td>18</td>
<td>4</td>
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<tr>
<td>Arrhythmia</td>
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<td>0</td>
</tr>
</tbody>
</table>

2 Discussion

The results showed that the RR of simple CEP regimen in treating NSCLC was 37.5% while RR of KLT combined with CEP was 56.3%. There was significant difference between the two groups, \( p < 0.05 \). It indicated KLT combined with chemotherapy would have the additive or even synergistic action, which can significantly improve the inhibitory effect of chemotherapeutic drugs on cancer cells.

The effect of most chemotherapy regimens currently applied in treating primary lung cancer, especially NSCLC, was not quite ideal. Their efficacy could be improved with dosage increase, but the toxic and adverse reactions would be also increased accordingly, which were hardly tolerated for the patients. There would be high costs for applying new chemotherapeutic drugs, such as Taxol, Gemzar and Navelbine, which were difficult to be used widely. The clinical administration of KLT combined with CEP regimen in treating NSCLC has revealed that KLT could improve the efficacy of chemotherapy and quality of life while without increasing the toxicity.

The main toxic and adverse reactions of chemotherapy were bone marrow depression, nausea and vomiting, and alopecia. The results showed that the toxic reactions in the trial group were significantly reduced (\( p < 0.05 \)) which indicated KLT could reduce the toxic and adverse reactions of chemotherapy. 75% patients in the trial group got KPS scores improved or stable, which was significantly higher than that of the control group (31%). It indicated that KLT could significantly improve the performance status of the patients, thus greatly improving the overall response rate of lung cancer and prolonging the survival time.

We thought KLT combined with chemotherapy could become one of the effective ways in treating advanced lung cancer.

Reference