Observation on the Effect of Kanglaite Injection Combined with Chemotherapy in the Treatment of Gastric Cancer

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Abstract

In order to further investigate the effect of KLT injection combined with chemotherapy in the treatment of gastric cancer, we randomly divided 114 patients who got final diagnosis pathologically after operation into trial group (n=57) and control group (n=57). The trial group was subject to the treatment of KLT combined with chemotherapy and the control group with mono-chemotherapy, both adopting scheme of FAM. Based on the standard of therapeutic effect on solid tumors formulated by WHO, CR rate of trial group was 50.88%, PR was 35.88%. In the control group 36.84% had complete response(CR) and 31.58% partial response( PR). Total response rate in trial group was 87% and that in control group was 69% with significant statistic difference between the 2 groups (P< 0.05).

Key words: stomach tumor, TCM therapy, drug therapy, combination, randomly controlled trial

Presently, operation remains the first choice for treatment of gastric cancer. However postoperative adjuvant chemotherapy has played more important role in the colligation treatment of gastric cancer. The report presented here describes our clinical study using Kanglaite Injection (KLT) to combine with chemotherapy in the treatment of gastric cancer.

1. Clinical Data

1.1 Standard for patients selected

All patients got final diagnosis pathologically after operation and their behavior got scored. The hepatic, cardiac and renal functions were normal and the estimated survival period was over 6 months. During the period from March 1998 to March 2000 in hospital 114 patients including 93 males and 21 females met with the above criteria and their age ranging from 39 to 64. All patients were randomly divided into trial group (n = 57) and control group (n = 57).

1.2 Therapeutic methods

Trial group: chemotherapy scheme FAM (5-FU 500mg/m^2) d_1, d_8, intravenous drip; ADM 30-50mg/ m^2, d_1, intravenous injection; MMC 8-10mg/ m^2, d_1,d_8, intravenous drip; KLT 200ml, once daily, intravenous drip, 2~4 weeks as a cycle of treatment. Control group: only chemotherapy with the same scheme.

1.3 Observation index and statistical process
Blood routine, hepatic and renal functions were analyzed for the evaluation of therapeutic effect based on the WHO standards. The total response rate = CR+PR using chi-square test and t-test.

1.4 Results

1.4.1 Blood routine change

All patients had blood routine re-examination once a week after chemotherapy. The result showed no significant difference in WBC change before and after chemotherapy between the 2 groups (Table 1).

<table>
<thead>
<tr>
<th>Group</th>
<th>Type</th>
<th>Day before chemotherapy</th>
<th>Day of chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1\textsuperscript{st}</td>
<td>7\textsuperscript{th}</td>
</tr>
<tr>
<td>Control</td>
<td>WBC</td>
<td>6.1</td>
<td>4.90</td>
</tr>
<tr>
<td></td>
<td>LC</td>
<td>1.24</td>
<td>0.80</td>
</tr>
<tr>
<td>Trial</td>
<td>WBC</td>
<td>5.7</td>
<td>5.20</td>
</tr>
<tr>
<td></td>
<td>LC</td>
<td>1.25</td>
<td>1.31</td>
</tr>
</tbody>
</table>

1.4.2 Hepatic and renal function change: Hepatic and renal functions were re-examined before and after each chemotherapeutic course in 2 groups. No evident change was observed in trial group. But the hepatic function of patients in control group appeared declined after chemotherapy which showed elevation in glutamic-pyruvic transaminase (GPT) and bilirubin, thus the smooth proceeding of treatment was affected.

1.4.3 Comparison of therapeutic effect between 2 groups: CR in trial group was 50.88% (29/57), PR was 35.88% (20/57); CR in control group was 36.84% (21/57), PR was 31.58% (18/57). The total response rate in trial group was 87% and in control group was 69% with significant difference between the 2 groups (P < 0.05).

2. Discussion

KLT Injection is made from traditional Chinese herb "semen coicis" through modern scientific technology. Previous investigations \cite{1} revealed that the anti-tumor mechanism of KLT was the retardation of the cell division at G\textsubscript{2}/M stage and the reduction of DNA synthesis. The clinical trials carried out in many domestic hospitals\cite{2-4} indicated that KLT had effects of inhibiting tumor growth, preventing tumor metastasis, providing high nutrition, enhancing immunity and improving body activity and living quality. It also had effect in relieving cancerous pain. The incidence of gastric cancer is very high in China with a high mortality. The cure rate of gastric cancer has been greatly increased in recent years with constant rise of diagnostic level and practice of colligation treatment. However the total rate remains at about 50%. The major reason is that certain limitation is existed in postoperative treatment such as to improve sensitivity of chemotherapeutic drugs, to enhance strength of chemotherapy, to reduce adverse effects of chemotherapy and the presence of malnutrition in patients, etc. Therefore KLT Injection has been applied in combination with chemotherapy in the treatment of gastric cancer to
evaluate its therapeutic effect.

The study demonstrated that KLT had certain protective effect on blood picture of patients during chemotherapy.

Table 1 showed that KLT could raise the level of WBC and platelets which made chemotherapy carried out smoothly.

No evident change in hepatic and renal function was observed in trial group before and after chemotherapy. But the hepatic function of patients in control group appeared declined after chemotherapy and this could affect the treatment.

The key point of the study was to evaluate the anti-tumor effect of KLT. The result showed that the treatment method of KLT Injection used in combination with chemotherapy could improve therapeutic effect of chemotherapy. The total response rate in trial group and control group was 85.96% and 68.42% respectively with significant difference (P< 0.05).

It was demonstrated in this study that KLT not only had effect of providing body with nutrition but also had anti-tumor effect which was the most important. So the combination of KLT with chemotherapy in the treatment of gastric cancer could be a good program to enhance the effect of postoperative chemotherapy and prolong survival period for patients.

References


