Kanglaite Injection combined with TAE in treating mid-late stage hepatic carcinoma

Liang Sumei, Wangjing, Song Jian, Oncological Dept., No.1 Hospital, Xiangfan, 441000, China

[Abstract] Objective: Explore effective therapy in treating mid-late stage hepatic carcinoma. Methods: 56 cases with mid-late stage hepatic carcinoma were randomly divided into 2 groups for the prospective and comparative study. 31 cases in treatment group received Kanglaite Injection (KLT) treatment combined with transcatheter arterial embolization (TAE) and 25 cases in control group took single TAE. Results: Effective rate (CR+PR) in treatment group and in control group was 80.64% and 68% respectively (P<0.05) while progressive rate was 0% and 8% separately (P<0.01). Symptom improvement rate before and after treatment was 84.64% and 64% (P<0.03). In addition, treatment group had apparently less toxic side reaction as compared with that in control group. Conclusion: KLT had synergistic action in combination with TAE with notable therapeutic effect. KLT is worthy to be considered in treatment.

[Key words] Kanglaite Injection; transcatheter arterial embolization; TAE; mid-late stage hepatic carcinoma

Primary hepatic carcinoma is one of the common tumors with high malignancy degree in China with increasing tendency in incidence rate. 80% patients, after confirmation of diagnosis, have entered advanced stage. Various treatment means at present are not satisfactory with poor prognosis. Therefore it becomes an important topic to look for new treatment method and effective therapy mode. We applied KLT combined with TAE for 56 hepatic carcinoma cases in our hospital with the following summary.

1. Clinical data
56 cases in this study, male 44, female 12, age 28~60 years with average 52 years. All cases were confirmed as primary hepatic carcinoma and inoperable mid and late stages hepatic carcinoma based on clinical diagnostic standards. 36 cases in treatment group, male 23, female 8, age 28~70 years with average 50 years, stage II 25 cases, stage III 6 cases; 25 cases in control group, male 20 cases, female 5 cases, age 26~72 years with average 50.5 years, stage II 18 cases, stage III 7 cases.

2. Methods
2.1 Treatment group
TAE was combined with KLT in the treatment. TAE protocol was conducted to be followed by application of KLT for intravenous dripping for 10 days. TAE alone was adopted in control group.
2.2 Evaluation of therapeutic effect
Based on standard of WHO on short term objective therapeutic effect of anticancer drug (1981) i.e. CR, PR, MR, SD, and PD, evaluation was done two months after the administration.

3. Results
3.1 Comparison on therapeutic effect between the two groups
Effective rate (CR+PR) in treatment group: 80.64%, compared with 68% in control group, 
\[ P<0.05 \] while in progressive rate, 
\[ P<0.001 \], see Tab.1.

Tab.1 Comparison on therapeutic effect rate and progressive rate between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>CR</th>
<th>PR</th>
<th>MR</th>
<th>SD</th>
<th>CR+PR</th>
<th>Effective rate (%)</th>
<th>Progressive rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>31</td>
<td>10</td>
<td>15</td>
<td>5</td>
<td>1</td>
<td>25</td>
<td>80.64</td>
<td>0</td>
</tr>
<tr>
<td>Control</td>
<td>25</td>
<td>7</td>
<td>10</td>
<td>5</td>
<td>1</td>
<td>17</td>
<td>68.00</td>
<td>8</td>
</tr>
</tbody>
</table>

3.2 Comparison on symptom improvement before and after treatment between two groups
There was significant difference, 
\[ P<0.05 \], see Tab.2.

Tab.2 Comparison on symptom improvement before and after treatment between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Notable improve.</th>
<th>Partial Improve.</th>
<th>Total improve.</th>
<th>Improve. rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>31</td>
<td>16</td>
<td>9</td>
<td>6</td>
<td>80.64</td>
</tr>
<tr>
<td>Control</td>
<td>25</td>
<td>9</td>
<td>7</td>
<td>9</td>
<td>64.00</td>
</tr>
</tbody>
</table>

3.3 Change in AFP before and after treatment between the two groups
There was significant difference, 
\[ P<0.05 \], see Tab.3.

Tab.3 AFP change before and after treatment between the two groups

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Elevation before treatment (%)</th>
<th>Reduction after treatment (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>31</td>
<td>32.25 (10/31)</td>
<td>80.00 (8/10)</td>
</tr>
<tr>
<td>Control</td>
<td>25</td>
<td>48.00 (12/25)</td>
<td>58.33 (7/12)</td>
</tr>
</tbody>
</table>

3.3 Observation on adverse reaction
Adverse reaction in different degrees occurred in digestive tract after TAE. However, adverse reaction in treatment group was apparently lower than that in control group and got disappeared after symptomatic treatment.
4. Discussion
Mortality rate of hepatic carcinoma has been increased by 41.17% and ranked the 2nd in recent 20 years in China. Hepatic carcinoma has become a serious threat to people’s health and nearly 95% of hepatic carcinoma cases have lost opportunity for operation when diagnosis is confirmed. TAE is a major means of palliative treatment for mid and late stages of hepatic carcinoma to alleviate patient symptoms and shrink the tumor size. The remarkable reduction in AFP can prolong survival period and create opportunity for further treatment. However, chemotherapy can aggravate hepatic damage, inhibit hematopoiesis, and lead to drug resistance of tumor cells to chemotherapy and multi-drug resistance is the main cause of ineffective chemotherapy. Traditional Chinese medicine (TCM) has stable therapeutic effect and can reduce metastasis or postpone metastatic time. Kanglaite Injection (KLT) is manufactured by Zhejiang Kanglaite Pharmaceutical Co., Ltd. with its anticancer active substance extracted from semen coicis. Experimental and clinical studies have verified that KLT is a dual-functional broad spectrum anticancer drug and at the same time, to relieve pain and improve life quality of advanced cancer patient [2]. The combination of western medicine with TCM can react upon each other to enhance effect, minimize toxicity and apparently raise patient survival rate and improve life quality. In this study effective rate (CR+PR) and focus progressive rate in treatment group were remarkably better than those in control group respectively ($P<0.05$, $P<0.001$). AFP change before and after treatment and change of clinical symptom in treatment group were notably higher than those in control group ($P<0.05$). We hold that KLT combined with TAE is an effective, safe protocol with low risk of toxicity in treating mid and late stages hepatic carcinoma. Its clinical application is recommended.

[Reference]