Therapeutic observation of Kanglaite Injection (KLT) in supporting intervention therapy to liver cancer – 38 cases reports

LU-Dezheng, ZHAO-Chongyu
The Tumor Department, Guangdong Provincial Nongken Central Hospital, Guangdong 524002, China

[ABSTRACT] Purpose To study the effects of Kanglaite Injection to quality of life and immunity function of liver cancer patients by supporting intervention therapy. Method 76 cases of liver cancer patients after intervention therapy were included in our group and randomly divided into treatment group and control group (38 cases each). The control group was applied with common supportive and symptomatic treatment. The treatment group was applied with KLT 200ml, iv drip once daily, 21 days as a treatment course. To observe clinical symptoms, QOL score, immunity variation and adverse reactions before and after treatment. Result Remission rate for clinical symptoms (pain relief 61%, abdominal distension relief 53%, hypodynamia relief 70%) in the treatment group after treatment was higher than those of the control group (43%, 37% and 50% respectively), P<0.01. QOL score increased: 23 cases (61%) in treatment group and 12 cases (32%) in control group, P<0.01. Cluster of T lymphocyte differentiation 3 (CD3), CD4 and T lymphocyte transformation rate in treatment group were all increased sharply after treatment [(61±4)%, (41±4)%, and (61±11)% respectively], excelling those in control group [(50±5)%, (30±4)%, and (48±3)% respectively], P<0.01, P<0.05, P<0.05. Conclusion KLT supportive treatment can remarkably enhance QOL and immunity of liver cancer patients after intervention therapy and is therefore good to improve the comprehensive therapeutic effects for advanced liver cancer patients. [KEY WORDS] Kanglaite Injection; Liver cancer; Advanced; Intervention therapy; Quality of life; immune function

[New Medicine, 2004, 7(35): 415-416]

1. Introduction
Intervention therapy has been a major and effective method for comprehensive treatment of advanced primary hepatic carcinoma (liver cancer) [1]. However, the physical constitutions of patients after the therapy often get worse and are unbearable to the second or third cycle of intervention therapy. Therefore, to improve the symptoms and enhance QOL and immunity of patients after intervention therapy is the key to a continuous effective treatment. In our group, 38 cases of advanced liver cancer patients accepted KLT treatment and received good response.

2. Subject and method
2.1 Case selection
78 cases of advanced liver cancer patients after intervention therapy were included in Guangdong
Provincial Nongken Central Hospital from November 2001-November 2003. All cases were diagnosed, typed and staged according to relevant standards prepared by State Association on Liver Cancer Prevention Study and were divided randomly into treatment group and control group (38 cases each). Treatment group: male 30 cases, female 8 cases, age 24-70, median age 49; stage II 27 cases, stage III 11 cases; type: sclerosis 28 cases, inflammation 8 cases and single type 2 cases. Control group: male 31 cases, female 7 cases, age 25-69, median age 49; stage II 28 cases, stage III 10 cases; type: sclerosis 29 cases, inflammation 8 cases, single type 1 case. The two groups accepted intervention therapy for the first time (super-selective right hepatic, left hepatic or proper hepatic artery catheterization by percutaneous vascular catheterization technology, inject emulsified suspension drug prepared of ultra-iodized oil and anticancer drugs like epirubicin slowly under X-ray control).

2.2 Treatment method
The control group was applied with common supportive and symptomatic treatment. While the treatment group was applied additionally with KLT 200ml, iv drip once daily, based on the control treatment. Treatment course (21 days) and the comprehensive treatment regimen are the same in both groups.

2.3 Clinical index
To observe symptoms of liver pain, abdominal distension, appetite, hypodynamia, poor sleep and lassitude before and after treatment, and QOL score, immune function test, cluster of T lymphocyte differentiation 3 (CD3), CD4, CD8, CD4/CD8 and T lymphocyte transformation rate. QOL scores were evaluated on 11 items of appetite, mental status, sleep, fatigue, pain, family support, colleague support, patients’ understanding of cancer, attitudes towards treatment, daily life, adverse reactions and facial expression etc. There are 1-5 grades on each item, full score 60: <20 score as very poor, 21-30 score as poor, 31-40 score as median, 41-50 score as good, 51-60 score as very good.

2.4 Criteria for efficacy evaluation
To compare the cases with clinical symptoms improved after treatment to those before treatment and calculate the response rate. Criterion for QOL evaluation: score increased >10 after treatment as QOL improved, decreased >10 as reduced, and less than 10 in increase or decrease as stable.

2.5 Statistical analysis
Counted by $X^2$ test and measured by t test with ($\bar{x} \pm s$).

3. Result
3.1 Comparison of clinical symptoms improvement
Major clinical symptoms before treatment like liver pain, abdominal distension, fatigue, anorexia, poor sleep and lassitude were similar in two groups. Symptoms improved after treatment in treatment
group was better than that of the control group. There was statistical significance, $P<0.01$. See Table 1.

Table 1: Clinical symptoms improvement case (%)

<table>
<thead>
<tr>
<th></th>
<th>Treatment group (38 cases)</th>
<th>Control Group (38 cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
</tr>
<tr>
<td>Liver pain</td>
<td>36</td>
<td>22(61)</td>
</tr>
<tr>
<td>Abdominal distension</td>
<td>38</td>
<td>20(47)</td>
</tr>
<tr>
<td>Anorexia</td>
<td>35</td>
<td>16(46)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>37</td>
<td>26(70)</td>
</tr>
<tr>
<td>Poor sleep</td>
<td>34</td>
<td>13(38)</td>
</tr>
<tr>
<td>Lassitude</td>
<td>34</td>
<td>20(59)</td>
</tr>
</tbody>
</table>

Comparison, *$P<0.05$, **$P<0.01$

3.2 Comparison of QOL

See Table 2.

Table 2: QOL evaluation case (%)

<table>
<thead>
<tr>
<th></th>
<th>Case</th>
<th>Improved</th>
<th>Stable</th>
<th>Reduced</th>
<th>Improvement rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>38</td>
<td>23(61)**</td>
<td>10(26)</td>
<td>5(13)**</td>
<td>(87)**</td>
</tr>
<tr>
<td>Control group</td>
<td>38</td>
<td>12(32)</td>
<td>12(32)</td>
<td>14(37)</td>
<td>(63)</td>
</tr>
</tbody>
</table>

Comparison, **$P<0.01$

3.3 Comparison of immune function

See Table 3.

Table 3: Immune function variation ($X \pm s$) %

<table>
<thead>
<tr>
<th></th>
<th>Treatment group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
</tr>
<tr>
<td>CD3</td>
<td>55±5</td>
<td>61±4**</td>
</tr>
<tr>
<td>CD4</td>
<td>35±7</td>
<td>41±4*</td>
</tr>
<tr>
<td>CD8</td>
<td>26±8</td>
<td>24±2</td>
</tr>
<tr>
<td>CD4/CD8</td>
<td>1.38±0.38</td>
<td>1.63±0.18*</td>
</tr>
<tr>
<td>T lymphocyte transformation rate</td>
<td>53±6</td>
<td>61±11*</td>
</tr>
</tbody>
</table>

Intra-group comparison, *$P<0.05$, **$P<0.01$; Inter-group comparison, ***$P<0.01$

3.4 Number of intervention therapy administered in two groups

28 cases in treatment group received more than two times of intervention therapy, among which, twice
21 cases, three times 6 cases, and four times 1 case; while 19 cases in control group received more than two times of intervention therapy, among which, twice 14 cases and three times 15 cases. There was statistical significance, P<0.05.

3.5 Adverse reactions
No adverse reactions to cardiac, hepatic or renal functions in treatment group. No allergic reactions like chill, fever or rash were observed.

4. Discussion
Kanglaite Injection is a novel non-toxic biphasic broad-spectrum anticancer drug extracted from Coix seeds. It relieves toxic & side effects of radio- or chemotherapy, inhibits tumor cells, and improves cachaxia. The anti-tumor mechanism is probably to up-regulate the expression of tumor suppressor gene p53 and down-regulate the expression of tumor promoter gene bcl-2, block cell cycle at stage G2/M, reduce DNA synthesis (stage S), and induce tumor cell apoptosis and necrosis. In our observation, KLT treatment improved symptoms of liver pain, abdominal distention, appetite, fatigue, sleep and lassitude in patients with tumor cachaxia, and enhance their QOL.

Researches in recent years had showed that patients with malignant tumors were in poor immune function whose bodies were hardly response to our treatment. The immunity suppression was due to the existence of tumor. Focal excision was an essential way to remove immunity suppression and rehabilitate immune function. However, liver patients in advanced stage were usually late for surgical operation. Intervention therapy was then taken place. Our long term clinical practice have suggested that patient might have a better therapeutic response and longer survival time if he/she was able to receive more than two times of intervention therapy. The point was that intervention therapy was hard to apply once again if the patient had a poor physical constitute and immune function. Therefore, our task ought to be focus on prompt improvement of patients’ physical constitute and recovery of immune function. In our study, 28 cases in treatment group received more than two times of intervention therapy, and it was 19 cases in control group. There was statistical significance. P<0.05. Some researches revealed: after KLT treatment, the activity of natural killer cell (NK) in peripheral blood of advanced malignant tumor patient was remarkably enhanced as the treatment courses continued and maintained at a high level; the interleukin-2 receptor in blood serum declined sharply and was kept in a low level as the treatment continued. That was to say KLT treatment could improve body immunity and partially eliminate immune suppression caused by tumor. It was found in the immunological assay to treatment group that CD3, CD4, and T lymphocyte transformation rate were all elevated obviously after KLT treatment (superior to those in control group P<0.01, P<0.05, P<0.05), indicating KLT could enhance tumor patients’ immune function and brought little adverse effects to peripheral hemogram or hepato-renal functions, no allergy. In conclusion, KLT, as a supportive measure for intervention therapy in the comprehensive treatment of advanced liver cancer, can promote the
overall effect and enhance QOL.

References