Effect observation on intravenous drip of Kanglaite Injection combined with ultrasound thermal therapy in the treatment of patients with advanced hepatic carcinoma

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[Abstract] Objective: To observe effect of intravenous drip of Kanglaite Injection combined with ultrasound thermal therapy in treating patients with advanced hepatic carcinoma. Methods: 60 cases admitted at the same period with stage III hepatic carcinoma were divided into two groups. 30 cases in treatment group received treatment of Kanglaite Injection (KLT) plus ultrasound thermal therapy while 30 cases in control group had combined medicinal treatment. Short term effect between two groups was observed. Results: Elimination of cancerous pain, remission of other symptoms, inhibition of tumor growth, and prolongation of survival period in treatment group were better than those in control group (P<0.01). Conclusion: Short term effect of KLT plus ultrasound thermal therapy in treating advanced hepatic carcinoma was confirmed.

[Key words] Hepatic carcinoma; Kanglaite Injection; Ultrasound thermal therapy

Materials and methods
1. General information
In line with enrollment criteria proposed from National Conference of Liver Cancer Prevention, Treatment & Research held in Shanghai in Dec. 1997, 30 patients admitted between Dec. 1997 and Oct. 2000 with stage III hepatic carcinoma entered treatment group on personal voluntary or family relative agreement basis to accept treatment of Kanglaite Injection (KLT) plus ultrasound thermal therapy. Another 30 cases with stage III hepatic carcinoma and admitted at the same period but once applied other treatment methods due to various reasons were randomly enrolled in control group. In treatment group: male 25 cases, female 5 cases, age 36-65 years; In control group: male 28 cases, female 2 cases, age 38-63. Comparison on patients between the two groups had no significant difference in terms of gender and age (P>0.05).

2. Treatment methods
In treatment group KLT (manufactured by Zhejiang Kanglaite Pharmaceutical Co., Ltd.) was applied at dose: 100ml, iv drip, once a day, 21 days as a course while ultrasound thermal therapy was concomitantly applied at tumor location, 45~60min per time, 3 times per week, 3 weeks as a treatment course. Patient with stable condition used this combination therapy and severe cases were infused with energy support formulation and accepted other emergency measures. General medicinal comprehensive treatment was used for patients in control group including liver protection and anticancer drugs and symptomatic supportive treatment with a
course of 3 weeks.

3. Observation methods
Indexes in 4 aspects were observed before, during and after treatment i.e. elimination of cancerous pain, remission of other symptoms (including psychosis, inappetence, abdominal distension, and ascites), inhibition of tumor growth (tumor mass shrank or not expanded), and prolongation of survival period.

4. Criteria of therapeutic effect
Criteria of therapeutic effect were based on that from literature [1]: 1) Conformation with one of the following criteria was evaluated as effectiveness. Elimination of cancerous pain: Cancerous pain was disappeared after treatment or apparently relieved with appetite and sleep not affected. Remission of other symptoms: Abdominal distension and inappetence got disappeared after treatment or apparently relieved while ascites was eliminated or notably relieved. Shrinkage of tumor mass without expansion: Tumor mass was shrunken without expansion after treatment (confirmed by ultrasound and CT examination). Extension of survival period: Patient’s survival was longer than 3 months and above after treatment. 2) Non-effectiveness: Disagreement with the above criteria was counted as non-effectiveness.

5. Statistical method
Data were tested with $X^2$.

Results
1. Comparison on short term effect between the two groups
In treatment group elimination rate of cancerous pain, symptom relief rate, inhibition rate of tumor mass and survival rate (prolongation of survival period) were significantly better than those in control group ($P<0.01$). See Tab.1.

<table>
<thead>
<tr>
<th>Group</th>
<th>Case</th>
<th>Pain eliminated</th>
<th>Other symptom relieved</th>
<th>Tumor mass shrunken &amp; no expansion</th>
<th>Survival period prolonged</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Case</td>
<td>%</td>
<td>Case</td>
<td>%</td>
</tr>
<tr>
<td>Treatment</td>
<td>30</td>
<td>26</td>
<td>86.7</td>
<td>24</td>
<td>80.0</td>
</tr>
<tr>
<td>Control</td>
<td>30</td>
<td>6</td>
<td>20.0</td>
<td>7</td>
<td>23.3</td>
</tr>
</tbody>
</table>

$X^2$ value: 26.78, 19.28, 7.20, 6.66

$P$ value: $<0.01$, $<0.01$, $<0.01$, $<0.01$
2. Toxic side reaction of drugs

After applying KLT in treatment group there was no other toxic side reaction except that individual cases had transient symptoms like slight dizziness, nausea or low fever. Ultrasound thermal therapy itself had no side reaction.

Discussion

Kanglaite Injection (KLT) is a novel biphasic broad spectrum anticancer drug with substance extracted from TCM coix seed by modern advanced technology. Major ingredient is coix seed oil. Pharmacological and clinical research showed that KLT has inhibitive action on various cancers and is able to kill cancer cells and concomitantly improve immunological function in addition to provide nutrition [2]. In treatment group 12 cases had tumor mass shrunk or not expanded and 10 case had survival extended. This echoed the observation result of Wu Jingyu el al [3] to verify KLT had effect to control tumor growth, prevent metastasis, elevate body immunological ability, and prolong survival period.

Most patients at advanced stage of hepatic carcinoma have pain in different degrees of whom 70% and above have pain as major symptom. Among 30 cases in treatment group 27 cases had pain as major symptom at admittance, accounting for 90%. KLT can not only control tumor growth but have remarkable effect to relieve pain. Coixol in KLT presents analgesic function to treat muscular soreness and arthritic pain and its strength is not weaker than aminopyrine. In addition coix seed can reduce muscular spasm and relieve fatigue so as to control pain and alleviate invasion and oppression in tissue and nerve [4]. In treatment group 26 cases has pain completely removed thus verifying pharmacological action of KLT.

Ultrasound thermal therapy can make temperature of tumor mass up to 42.5°C to trigger lipid peroxidation, damage membrane structure of tumor cells to inhibit and kill cancer cells. In treatment group 12 cases had tumor mass shrunk or not expanded while 10 cases had survival period extended, indicating that this thermal therapy had anticancer function. Yao Herui [5] used high strength focused ultrasound thermal therapy to treat 42 cases with effective rate as 33% and median survival period as 22 weeks. This showed that high strength focused ultrasound thermal therapy had certain effect in treating hepatic carcinoma. Therefore, short term effect of KLT plus ultrasound thermal therapy to treat advanced hepatic carcinoma is affirmative and this combination shall be recommended to be used at basic hospitals.
[Reference]


