Evaluation on short-term Efficacy and Toxicity of KLT Combined Chemotherapy in Treating Patients with Advanced Carcinoma of Digestive Tract

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Abstract: A non-randomized grouping method was adopted to divide patients with advanced cancer of digestive tract into 2 groups, a combined chemotherapy group 32 cases, and a chemotherapy alone group 35 cases. The clinical short-term efficacy and Toxicity of the two groups were evaluated. Patients in both groups were either relapsed patients or stage IV patients with metastasis who had lost operative indication or had relapse lesion with widespread metastasis after surgery, their performance status was 30-50% according to karnofsk, scale. There was no significant difference in short term efficacy between the KLT combined chemotherapy group and chemotherapy alone group (P>0.05). The quality of life in the KLT combined chemotherapy group was markedly higher than that in the chemotherapy alone group, there was significant difference in toxic and side reactions between the two groups, the chemotherapy alone group was markedly higher than that in the KLT combined chemotherapy group. The results suggested that the KLT combined chemotherapy could reduce the toxic and side effects in the treatment of patients with advanced carcinoma of digestive tract, and the results had also been verified by the clinical observation on patients’ performance status.

Key Words: Tumor of Digestive system/TCM therapy; Anti-tumor Drugs, Multi drug Combined Therapy.

Based upon the original chemotherapy protocol, our department employed a KLT Injection combined therapy in the treatment of 32 cases of patients with advanced tumor of digestive tract, the other 35 cases were treated with the original chemotherapy protocol. A nonrandomized comparison was performed between the above two groups on their short-term efficacy, toxic reactions and other aspects, the results of the observation are reported as follows.

1. Clinical Data
1.1 General Data
Among 67 cases of patients with advanced tumor of digestive tract, male 42 cases, female 25 cases. Age: 30-73 years old, median: 55 years old, sorts of cancer: Esophageal carcinoma 12 cases, Gastric carcinoma 27 cases, Intestinal carcinoma 18 cases, pancreatic carcinoma 10 cases. All of them were relapsed patients after the treatment or Stage IV cancer patients with metastasis. Of which hepatic metastasis 29 cases, peritoneal lymph node metastasis 33 cases, bladder metastasis 4 cases, pulmonary metastasis 7 cases. Among the above patients, metastasis to one viscus 21 cases, metastasis to 2 viscera 35 cases, metastasis to more than two viscera 12 cases.
Chemotherapy alone group 35 cases, of which male 20 cases, female 15 cases, age: 30-69 years old, median: 52 years old.

KLT Combined chemotherapy group 32 cases, of which male 20 cases, female 12 cases; age: 30-73 years old, median: 57 years old, varieties of carcinomas in both groups were: esophageal carcinoma 7 cases and 5 cases, gastric carcinoma 15 cases and 12 cases, intestinal carcinoma 8 cases and 10 cases respectively, and pancreatic carcinoma 5 cases in each group.

All the 67 cases were advanced tumor patients of digestive tract who had lost the operative indication or had recurrent lesion and widespread metastasis after the treatment and their performance status was within 30-50% according to Karnofsky scale.

1.2 Method of Treatment
Chemotherapy alone group: DDP 20-40mg/m² d1-3, MMC 6-8mg/m², d1; 5-FU 50mg/m², d1-5.

Combined chemotherapy group: KLT Injection d1-10 was added on a basis of chemotherapy alone group.

1.3 Indexes of Observation
1.3.1 Short-term Efficacy
In accordance with the evaluation indexes for observing solid tumors, which were formulated by WHO, Complete remission (CR), Partial remission (PR), No change (NC), Progress of Disease (PD), and remission rate = CR+PR.

1.3.2 Quality of Life
In accordance with Karnofsky scale recommended by WHO, patients’ quality of life before and after the treatment could be evaluated, an increase of >10 was defined as “improve” an decrease of >10 was defined as “deteriorated”, an increase or decrease of 10 or less was defined as “stable”.

1.3.3 Indexes of Determinations
Patients in the chemotherapy alone group and combined therapy group were observed on variations of their blood picture.

1.4 Results
1.4.1 Evaluation on Short-term Efficacy
Chemotherapy alone group 35 cases, of which CR 0 cases, PR 10 cases, NC 17 cases, PD 8 cases, total effective rate 28.6%.
KLT combined chemotherapy group CR 0 cases, PR 10 cases, NC 18 cases, PD 4 cases, total effective rate 31.2%, there was no significant difference between the two groups (P<0.05).

1.4.2 Quality of Life
Chemotherapy alone group 35 cases, of which improved 8 cases, stable 12 cases, deteriorated 15 cases.

KLT combined chemotherapy group 32 cases, of which improved 19 cases, stable 9 cases, deteriorated 4 cases, there was a significant difference between the two groups (P<0.05), the KLT combined chemotherapy group was markedly superior to chemotherapy alone group.

1.4.3 Toxic and Side Effects
Chemotherapy alone group 35 cases, of which digestive tract reactions 1st degree 10 cases, 2nd degree 14 cases, 3rd degree 11 cases; hematologic toxic reactions 1st degree 7 cases, 2nd degree 18 cases, 3rd degree 7 cases, 4th degree 3 cases.

KLT Combined chemotherapy group 32 cases, in which digestive tract reactions 1st degree 14 cases, 2nd degree 3 cases, 3rd degree none; hematologic toxic reactions 1st degree 10 cases, 2nd degree 5 cases, 3rd or 4th degree none. The toxic and side effects of the chemotherapy alone group were markedly higher than that of the KLT combined chemotherapy group (P<0.05).

2. Discussion
Kanglaite Injection, an anticancer drug extracted and refined from Coix Seed, has been proved to enhance the immunity of organism, but also has the action against cancer cells(1). Clinical and experimental results have demonstrated that it could inhibit and even kill cancer cells, it also markedly enhanced the immunologic functions of organism, reduced the Toxic and side effects induced by radio and chemotherapy, improved body’s nutritional supply and fight against cachexia(2).

Patients with advanced carcinoma of digestive tract, who had lost operative indication, and weren’t sensitive to radio therapy and could only be treated with a palliative chemotherapy for the aim of remission. The goal of the treatment was not limited to the shrinkage of the tumor, but also paying attention to the improvement of the quality of life. In this paper we reported 67 cases of cancer patients, who all had a history of chemotherapy and a lower performance status according to Karnofsky scale, and had difficulties to tolerate rather strong chemotherapy. A comparative observation and analysis upon the effective rates obtained from both groups following the treatment have shown that there was no significant difference between the two groups and none of complete remission cases appeared. This phenomenon was mainly attributed to the late stage of disease these patients had belonged to, the quality of life in the KLT combined chemotherapy group was markedly improved,
which indicated that KLT Injection could improve patients’ performance status, while there are significant differences in toxic and side effects between the two groups, which suggested that KLT combined chemotherapy group was superior to the chemotherapy alone group. From the above-mentioned results we can reach a conclusion that KLT Injection in combination with chemotherapy has a positive significance to patients with advanced tumor of digestive tract in reducing toxic and side effects of chemotherapy as well as improving patients’ quality of life.

References