Clinical Observation on Treatment of Colonic Cancer with Combined Treatment of Chemotherapy and Chinese Herbal Medicine

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ABSTRACT  Objective: To observe the clinical effect of combined chemotherapy and Chinese herbal medicine in treating colonic cancer. Methods: One hundred and sixty-three patients were assigned, according to their will, to two groups, 105 in the traditional Chinese medicine treated group (Group A) and 58 in the combined treatment group (Group B). The Chinese herbal drug Zhao's Weiliao No. 3 (赵氏微调3号方, ZW3) was given to both groups, twice a day, 40 mL each time, 30 days as one cycle, and over 6 cycles applied in total. For patients in Group B, the chemotherapy of OLF protocol (L-OHP+LV+5-FU) was given for 4-6 cycles. The effects of treatment on the main symptoms, tumor mass, patients’ quality of life (QOL) and body weight, changes of carcino-embryonic antigen (CEA), as well as the integral effect and survival rate were observed and compared. Results: The total effective rate in Group A and Group B was 89.52% and 86.21% respectively, on the main clinical symptoms; 86.67% and 93.10% on tumor mass, 82.86% and 77.59% on QOL, 85.71% and 75.86% on body weight and 76.19% and 79.31% on CEA. The integral efficacy of total beneficial rate was 73.33% and 68.97%; and the 3-year survival rate 49.52% and 46.65% in Group A and Group B. These data showed that the effect in Group A was better than in Group B in terms of clinical symptom improvement, QOL, body weight and integral beneficence increase and survival rate, though it was inferior in reducing the tumor mass and CEA level. Conclusion: Chinese drug ZW3 for the treatment of colonic cancer could improve the main clinical symptoms, improve the QOL, increase body weight and prolong the survival time of patients, showing a favorable integral effect.

KEY WORDS  Chinese herbal medicine, chemotherapy, clinical observation

Colonic cancer is one of the commonly encountered malignant tumors, and both its morbidity and mortality in China show an increasing trend. In order to seek effective treatment of colonic cancer, the authors observed, from January 2003 to June 2007, the clinical effect of combined chemotherapy and Chinese herbal medicine on this kind of cancer.

METHODS

Diagnostic Criteria
The diagnosis of colonic cancer in all patients enrolled was made in reference to the “Norm for Diagnosis and Treatment of Malignant Tumor Commonly Encountered in China”(1), and confirmed by pathology or cytology. The stage of the disease was graded in reference to the “Handbook for AJCC Cancer Staging”(2).

Standard of Inclusion
(1) Patients with colonic cancer confirmed by histopathologic or cytologic examination, who refused to receive surgical operation or were unsuitable to have it, or had tumor relapse after excision and showed no indication of re-operation. (2) Who had lesions with measurable bi-radiuses, showing a size by CT of $>10 \text{ mm} \times 10 \text{ mm}$, with initial examination performed 20 days before the first medication in this trial. (3) The patients aged from 36 to 85 years of any sex. (4) Karnofsky score $>30$ scores and predicted survival time $\geq 3$ months. (5) The results of laboratory examination matched the following criteria: WBC count $>4.0 \times 10^9/\text{L}$; hemoglobin $>60 \text{ g/L}$; urea nitrogen $(\text{mmol/L}) \leq 1.25$-fold of the upper limit of the normal range; creatinine $(\mu \text{ mol/L}) \leq 1.25$-fold of the upper limit of the normal range; alanine transaminase (ALT) and aspartate aminotransferase (AST) $< 2.5$-fold of the upper limit of the normal range, with the initial examination performed 8 days before the first medication. (6) Those who had signed on the written

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informed consent for participating in the trial of their own will.

**Standard of Exclusion**

Patients were excluded if they (1) had tumor metastasis to brain or cerebral maninges; (2) had history of other complicated malignant tumors; (3) had severe cardiovascular disease, hepatopathy, nephropathy; complicated with severe diseases or events, including uncontrolled active infection, severe electrolyte disorder, active disseminated intravascular coagulation, or with obvious tendency of bleeding; (4) had the target lesion having already received radiation; (5) in the process of receiving treatment by other Chinese herbal medicines.

**General Materials**

All the 163 subjects enrolled were patients with colonic cancer, whose diagnosis matched the diagnostic standard, hospitalized in the authors’ department from January 2003 to June 2007. They were assigned, according to the patients’ will, to two groups. The 105 patients in the traditional Chinese medicine TCM treated group (Group A) were 48 males and 57 females; aged 36-85 years, 63.07 ± 12.23 years on average. The course of disease was 0.5-2 years. The pathologic type was papillary adenocarcinoma in 45, tubular adenocarcinoma in 20, mucous adenocarcinoma in 18, singnet-ring cell carcinoma in 12 and other types in 10. The TNM stages were stage I in 8, stage II in 9, stage III in 12, and stage IV in 76. All patients in this group were unwilling to receive radiotherapy or chemotherapy, or had quit radiotherapy or chemotherapy due to being uncertainty of their effects or were unable to endure the toxic adverse reaction. The 58 patients in the combined therapy group (Group B) were 24 males and 34 females, aged 36-78 years, 58.62 ± 12.00 years on average with course of disease at 0.5-2 years. The pathologic type was papillary adenocarcinoma in 24, tubular adenocarcinoma in 11, mucous adenocarcinoma in 10, singnet-ring cell carcinoma in 12 and other types in 6. The TNM stages were stage I in 5, stage II in 7, stage III in 10, and stage IV in 36. The two groups were not statistically different in terms of sex, age, illness course, pathological type and TNM stage.

All patients received the Chinese herbal medical treatment voluntarily, and those who received chemotherapy simultaneously had all signed the consent.

**Treatment**

The Chinese herbal medicine used was Zhao's Weitiao No. 3 (赵氏微调3号方, ZW3), a preparation made by the pharmaceutical department of the authors’ hospital, which prescribed in one dose asiabell root 10 g, grifola 30 g, prepared white atractyloides tuber 10 g, Indian bread 10 g, coix seed 15 g, pinellia tuber 6 g, tangerine peel 6 g, and loquat leaf 10 g. It was made into a decoction of 80 mL, taken in two portions every day, 40 mL each time, 30 days as one cycle of the treatment, with over 6 cycles in total administered to all patients.

For patients in Group B, chemotherapy of OLF protocol was given additionally, which consisted of Oxaliplatin (L-OHP) 130 mg/(m$^2 \cdot$ d) through intravenous drip on day 1, LV 200 mg/(m$^2 \cdot$ d) and 5-fluorouracil (5-FU) 300 mg/(m$^2 \cdot$ d) through intravenous drip per day from day 1 to day 5, 3 weeks as one cycle, and 4-6 cycles in total.

Besides, for all patients, the supportive treatment of standardized liquid infusion and corresponding symptomatic management were administered, and complications in patients were managed according to the principles registered in the book "Practical Internal Medicine" (10th edition).

**Items of Observation and Efficacy Assessment**

**Main Clinical Symptoms**

The main clinical symptoms in patients, including poor appetite, weakness, abdominal pain, emaciation, constipation or loose stool, bloody stool, were divided in reference to the “Guiding Principle of Clinical Research on New Drugs of TCM” (3) into 4 grades, i.e. none (expressed by 0); mild grade (+), moderate grade (++) and severe grade (+++), one grade (+) scored as 2 points.

The efficacy of treatment was judged in light of the changes before and after treatment in the total accumulated scores of various symptoms. It was judged as markedly effective if the scores after treatment were reduced by ≥ 70%; as effective if reduced by ≥ 30% but <70%; and as ineffective if reduced by less than 30%, and the percentage of