

• Research Article

Traditional Chinese medicine integrated with chemotherapy for stage IV non-surgical gastric cancer: a retrospective clinical analysis

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ABSTRACT

OBJECTIVE: Traditional Chinese medicine (TCM) is regarded as an important treatment for gastric cancer patients, especially for those in advanced stage. To evaluate the effects of TCM treatment on gastric cancer patients, the authors performed a retrospective study to report the result of the integrated treatment of TCM with chemotherapy for stage IV non-surgical gastric cancer.

METHODS: In this study, 182 patients with stage IV and non-surgical gastric cancer were retrospectively analyzed to evaluate the effects of TCM integrated with chemotherapy. Among the 182 cases, 88 cases received integrated therapy consisting of TCM and chemotherapy, while 94 cases received chemotherapy alone. The overall survival and Karnofsky performance status (KPS) score were measured as the main outcome.

RESULTS: The median overall survival of the integrated therapy group and chemotherapy group were 16.9 and 10.5 months, respectively. The 1-, 3- and 5-year survival rates of integrated therapy group vs. chemotherapy group were 70% vs. 32%, 18% vs. 4%, and 11% vs. 0%, respectively. There was a significant difference between the two groups ($\chi^2 = 42.244$, $P < 0.001$). After six-month treatment, KPS scores of the integrated therapy group and the chemotherapy group were 75.00 ± 14.78 and 60.64 ± 21.39 , respectively ($P < 0.001$). The Cox regression analysis showed that TCM treatment is a protective factor for patients' overall survival.

CONCLUSION: This study demonstrated that TCM integrated with chemotherapy may prolong overall survival and improve survival rate and life quality of patients with stage IV non-surgical gastric cancer.

Keywords: stomach neoplasms; drug therapy, combination; medicine, Chinese traditional; integrative medicine; plants, medicinal

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1 Introduction

Gastric cancer has the highest incidence among all cancers, causing about 70 million deaths each year worldwide. So far, the mortality rate of gastric cancer ranks second globally.^[1-3] In China, the number of new cases of gastric cancer amounts to 405 000 annually, accounting for 42.6% of global gastric cancer. There are about 325 000 deaths from gastric cancer each year in China, and the mortality rate now is up to 0.0219%. Gastric cancer has become a serious health hazard to the residents of China.^[4]

Surgery is currently the preferred method to treat gastric cancer, but the majority of patients with advanced cancer do not have operation chance by the time they are diagnosed.^[5] Chemotherapy is regarded as the main treatment for patients with advanced gastric cancer, which may prolong the median overall survival (OS) of patients, but its effect is limited in disease control, and the average OS extended only from several weeks to several months.^[6,7] Besides, many patients with advanced gastric cancer may give up chemotherapy due to its side effects. Therefore, it is of immediate urgency and importance to find an effective treatment for patients with advanced gastric cancer.^[8]

In China, there has been a long history of using traditional Chinese medicine (TCM) to treat gastric cancer and other malignancies. Compared with modern medicine, TCM lays more emphasis on the overall body adjustment and functional recovery and has achieved good clinical effects in China.^[9,10] So the TCM treatment integrated with modern medicine for advanced gastric cancer has attracted more and more attention. In this study, the authors performed a retrospective study to evaluate the effects of TCM treatment integrated with chemotherapy for stage IV non-surgical gastric cancer.

2 Methods

2.1 Study design and patients

The authors carried out a retrospective study to report the result of the integrated treatment of TCM with chemotherapy for patients with stage IV non-surgical gastric cancer. The OS and Karnofsky performance status (KPS) score were measured as the main outcome.

The inclusion criteria were as follows: (1) gastric cancer confirmed by cytological or histological diagnosis; (2) confirmed clinical TNM staging of IV-gastric cancer, based on 2010 International Union Against Cancer/American Joint Committee on Cancer (UICC/AJCC) staging of gastric cancer (UICC, 2010) without surgery; (3) accepted more than two cycles of

chemotherapy treatment; (4) accepted TCM therapy (including TCM intravenous injection, oral Chinese herbal decoction and oral Chinese patent medicine) more than 3 months, or without any TCM therapy (classified into chemotherapy group); (5) complete clinical data; (6) KPS score ≥ 60 ; (7) more than 6 months of survival time.

The exclusion criteria were as follows: (1) non-epithelial cell origin or association with other malignancies; (2) without standardized medication treatment; (3) patients with severe heart, brain, kidney or other underlying diseases.

Grouping: after inclusion, patients, according to the choice of treatment options, were classified into a chemotherapy group or an integrated therapy group. Patients accepting chemotherapy alone, with more than two cycles, were classified into the chemotherapy group while patients accepting chemotherapy and TCM treatment together, for more than 3 months, were classified into the integrated therapy group.

2.2 Treatment information

The patients in the chemotherapy group all received more than two cycles of chemotherapy, such as DCF, ECF, XELOX, FOLFOX, or FOLFIRI regimens. The patients in the integrated group received not only chemotherapy, but also TCM treatment at the same time, including intravenous injection, oral decoction of Chinese herbs and oral Chinese patent medicine. TCM intravenous injection included Kanglaite injection (State Drug Administration (SDA) approval number: Z10970091, Coix Seed Oil, intravenous infusion of 200 mL, 2 times each day (BID), days 1–7, Zhejiang Kanglaite Pharmaceutical Co., Ltd); Cinobufacini injection (SDA approval number: Z34020274, an aqueous extract from the skin of the toad, used in patients with heat-poison syndrome, intravenous infusion of 20 mL, BID, days 1–7, Anhui Jinchuan Biochemical Co., Ltd); Yadanzi injection (SDA approval number: Z44021325, Javanica oil emulsion injection, used in patients with all types of gastrointestinal tumors, intravenous infusion of 10–30 mL, QD, days 1–7, Zhejiang Jiuxu Pharmaceutical Co., Ltd.); Elemene injection (SDA approval number: H10960114, anti-cancer active ingredients extracted from *Curcuma zedoaria* (Berg.) Rosc, used in patients with all types of gastrointestinal tumors, especially those with phlegm patterns, intravenous infusion of 400–600 mg, QD, days 1–7, Dalian Huali Jingang Pharmaceutical Co., Ltd); and Xiaoaiping injection (SDA number: Z20025868, *Marsdenia tenacissima* (Asclepiadaceae), used in patients of all types of gastrointestinal tumors, especially those of dampness-heat syndrome, intravenous infusion of 20–100 mL,

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