Clinical Study on Treatment of Mammary Cancer by Shenqi Fuzheng Injection (参芪扶正注射液) in Cooperation with Chemotherapy

YANG Bo (杨波), LI Hong-sheng (李洪胜), QI Yan-chao (祁岩超), and LU Min-ying (卢敏莹)

ABSTRACT

Objective: To study the effect of Shenqi Fuzheng Injection (参芪扶正注射液, SFI) on cellular immune in patients with mammary cancer (MC) after chemotherapy. Methods: One hundred and ten patients with MC were randomly assigned to two groups. The 58 patients in the tested group were treated with SFI in cooperation with chemotherapy of CAF protocol (Cyclophosphamide, Doxorubicin and Fluorouracil), while the 52 patients in the control group were treated with chemotherapy of the same protocol alone. Changes of the patients' quality of life (QOF), adverse reaction that occurred, peripheral lymphocyte count and killing activity of single karyocyte before and after treatment between the two groups were compared. Results: Patients' QOF elevating rate after treatment in the tested group and the control group was 34.5% and 13.5% respectively; The lowering of peripheral blood cell count of WBC, platelet and lymphocyte as well as that of the killing activity of single peripheral karyocyte on various kinds of MC cells were all milder and recovery sooner than those in the control group. Conclusion: SFI in combination with chemotherapy in treating MC could reduce the occurrence of adverse reaction to chemotherapy, improve clinical symptoms, elevate QOF and enhance immunity in patients with MC.

KEY WORDS  Shenqi Fuzheng Injection, chemotherapy, mammary cancer, cellular immune

Immunological researches on tumor indicated that the immune condition of tumor patients is related with the pathogenesis, development and prognosis of the tumor. It is held in traditional Chinese medicine (TCM) that the malignant tumor is mainly caused by deficiency of vital energy, imbalance of yin-yang and disorder of visceral function, and the treatment of surgical operation, radio- and chemotherapy could further injure vital energy, and so TCM treatment should focus on supporting vital energy, improving the inner environment of organism, alleviating the adverse reaction of radio- and chemotherapy, suppressing the bad effect by surgical operation to immunity, supplementing the congenital and acquired functions to enhance and activate the auto-anti-tumor power of the organism itself. The anti-tumor activity of Chinese drugs is always related with its immunity enhancing effects, as they could not only enhance the immune function of organism, but also inhibit the division of tumor cells, improve the symptoms in patients, raise their quality of life (QOF) and prolong their survival period. From May 2005 to July 2006, 58 patients with mammary cancer (MC) were treated with Shenqi Fuzheng Injection (参芪扶正注射液, SFI) in cooperation with chemotherapy given before surgical operation, and compared with another 52 patients treated with chemotherapy alone. The results are now reported as follows.

METHODS

Subjects

All the subjects enrolled in the study were from the Department of Thoracic Surgery and Department of Integrative Chinese and Western Medicine.

Supported by Integrative Medicine Foundation of State Administration of Guangdong Province (No.1050068), Traditional Chinese Medicine Foundation and Integrative Medicine Foundation of Guangzhou City (No.2005A038), Department of Biomedical Engineering, Affiliated Hospital of Guangzhou Medical College, Guangzhou (510095). Correspondence to: Dr. YANG Bo, Tel: 020-83595032 Ext.3169, E-mail:mammothbo@163.com.

DOI: 10.1007/s11655-007-0037-5
Medicine of the Affiliated Tumor Hospital of Guangzhou Medical College, 110 patients with MC in total. Their age ranged within 32-69 years, with the median age of 48.5 years, and the pathological type of the tumor was infiltrative non-specific carcinoma. Diagnoses of them were all confirmed by pathological examination on biopsy from hallow puncturing, tumor incision or freezing sampling during operation. The 58 patients allocated in the tested group treated with SFI in combination with chemotherapy before surgical operation were of the age of 36-69 years, with the median age of 48 years, and other 52 patients allocated in the control group treated with chemotherapy alone before surgical operation were of the age of 32-68 years, 49 years on average. The general materials of the two groups were insignificantly different (P>0.05), and so they were comparable.

Reagents and Testing Drugs
CaliBRITE four-color standard fluorescent microballoons; MultiTEST four-color test kit, including MultiTEST CD3 FITC/CD8 PE/CD45 PerCP/CD4 APC and MultiTEST CD3 FITC/CD16 CD56 PE/CD45 PerCP/CD19 APC four-color marked monoclonal antibody, Batch numbers: 34725 and 39989; TruCOUNT tube which contained known amount of fluorescent microballoons, and FACS hemolysin were all products of BD Company, USA.

Cyclophosphamide (CTX) was the product of Hengrui Pharmaceutical Co., Ltd., batch numbers: 05052331, 05061522, 06010422, 06025315 and 06041051; Adriamycin (ADM) was the product of Wanle Pharmaceutical Co., Ltd., Shenzhen. Batch numbers: 0505B3, 0507C5, 0601A5, 0603A3, 0604C4; 5-fluorouracil (5-FU) was the product of Jinghua Pharmaceutical Co. Ltd., Nantong, Jiangsu. Batch numbers: 050523, 050815, 060105, 060354, 060411; SFI, the drug for supporting vital energy, consisting of milkvetch root and asiabell root, was the product of Limin Pharmaceutical Plant of Lizhu Group, 250 ml/bottle. Batch numbers: 050510, 050601, 051024, 060208, 060479 and 060615.

Therapeutic Methods
The protocol used for chemotherapy was CAF, i.e. CTX 500 mg/m² by intravenous injection; ADM 50 mg/m² by intravenous injection and 5-FU 750 mg/m² by intravenous dripping, all given at day time, with 3 weeks as one cycle and 2-3 cycles constituting one therapeutic course, 2 courses administered before operation. The modified radical operation was performed 2 weeks after the the second course of chemotherapeutic agents administration when patients’ general condition recovered to normal.

Chemotherapy of the same protocol was given to all the patients, but to those in the tested group, SFI was given additionally, starting from the second day after the end of chemotherapeutic agents administration in the second course, and lasting to the preceding day on which operation was performed. A dose of 250 ml was given by intravenous dripping once a day, for 2 weeks totally.

Items and Methods of Observation
QOF was estimated according to the Karnofsky scoring\(^{(4)}\) and body weight (BW) of patients was measured before and after treatment. QOF of patients was judged as elevated when the Karnofsky score increased after treatment by 10 scores; as lowered when it decreased by over 10 scores, and as stable when it increased or decreased by less than 10 scores. QOF of patients was regarded as elevated when BW increased by 7%, as lowered when it decreased by 7%, and as stable when the increment or decrement was below 7%.

Blood toxic reaction was assessed by the content of hemoglobin and the count of WBC and platelet, which were measured before and after treatment.

Absolute numbers of lymphocyte subsets in peripheral blood including total T-lymphocyte (T, i.e. CD3\(^{+}\)), helper cells (Th, i.e. CD3\(^{+}\)CD4\(^{+}\)), suppresser cells (Ts, i.e. CD3\(^{+}\)CD8\(^{+}\)), natural kill (NK) cells (CD16\(^{+}\)CD56\(^{+}\)) as well as B-lymphocyte (CD19\(^{+}\)), were determined before and after treatment, with 1 ml of venous blood using with flow cytometer.