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Traditional Chinese Medicine symptom patterns in patients with colorectal carcinoma☆☆☆

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ABSTRACT

Objective: To observe the symptom patterns (or syndromes) according to Traditional Chinese Medicine (TCM) theory in patients with various stages of colorectal cancer, and to observe the dynamic evolution process of these TCM patterns.**Methods:** A prospective and cross-sectional questionnaire-based investigation was performed. Clinical data on TCM symptom patterns in patients with colorectal cancer in the perioperative period (210 cases) and adjuvant treatment period (160 cases) were collected. EPIData 3.1 together with frequency statistics and cluster analyses were performed to identify the TCM patterns based on symptom characteristics in patients with colorectal cancer, and to assess the dynamic changes in these patterns.**Results:** In the perioperative period, from the first day of perioperative care to postoperative days 3, 7, and 10, the TCM pattern showed a process of dynamic change from blood deficiency to deficiency of both *Qi* and *Yin* and the pattern of dampness and hot accumulative knotting. In the adjuvant treatment period, the TCM pattern changed from *Qi* deficiency and *Yin* deficiency inner-heat with dampness to a deficiency pattern, primarily including *Yin* deficiency of the liver and kidney, deficiency of *Qi* and blood, and spleen deficiency.**Conclusion:** Our study confirmed that variations in the dynamic evolution of TCM symptom patterns exist in patients with colorectal cancer during different treatment periods. This information is of great value in the individualized management of colorectal cancer.

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1. Introduction

Cancer treatment involves a comprehensive treatment protocol including surgery, chemotherapy, radiotherapy, targeted therapy, biotherapy, and immunotherapy, together with the use of Traditional Chinese Medicine (TCM). Colorectal cancer is the third most common cancer in the world, and it accounts for over 9% of all

cancer incidences [1]. The 5-year survival rate in patients with colorectal carcinoma in China is approximately 40% based on data published in 2018 [1]. In China, herbal medicine has been used to treat diseases, including cancer, for more than 2000 years. Due to the improvement of physical, mental and emotional symptoms, the role of TCM in cancer care is widely recognized around the globe [2].

Although TCM is commonly used in Chinese patients with colorectal cancer [3–5], epidemiological studies on TCM patterns (or syndromes) in colorectal cancer patients have not yet been reported. The identification of TCM patterns is a TCM theory-based summary of patients' signs and symptoms gathered through four diagnostic methods: inspection, auscultation and olfaction, inquiry, and palpation. TCM pattern identification guides the establishment of TCM therapeutic principles, and thus the treatment plan. As the patients' symptoms evolve, the TCM pattern and the corresponding treatment plan are expected to change. Based on more than 30 years of clinical practice and experiences, our group proposed that

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TCM cancer treatments should follow a four-stage protocol according to the following periods: perioperative, adjuvant treatment, follow-up, and palliative treatment [6]. However, specific classifications of the TCM pattern in each of the four stages have not been reported. To better classify patient symptoms and signs and thus guide the management of colorectal cancer using TCM, we aimed to use modern mathematical statistics to explore the classification and the dynamic evolution of TCM patterns in patients with colorectal cancer in the perioperative period and the adjuvant treatment period.

2. Methods

2.1. Diagnostic criteria

The diagnosis of colorectal cancer was confirmed by surgery and pathology. Postoperative pathological stages were diagnosed according to the American Joint Committee on Cancer (2010), NCCN Clinical Practice Guidelines in Oncology: Colon Cancer (2011.V1), and NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer (2011.V1) for staging of Tumor Node Metastasis (TNM) [7,8]. TCM pattern identification was performed according to the GB/T 16751.2-1997 TCM patterns in terms of the national standard (GB) [9].

2.2. Patient selection

Included patients met all of the following criteria: pathological diagnosis of colorectal cancer; expected acceptance radical operation with stages I–III in the perioperative period; expected acceptance adjuvant chemotherapy using the oxaliplatin/capecitabine (XELOX) or oxaliplatin/leucovorin/5-Fu (mFOLFOX) [7,8] regimen after radical operation in the adjuvant treatment period; no previous chemotherapy, radiation, or TCM therapy before study commencement. Patients with any of the following criteria were excluded from the study: history of primary and serious illnesses of the cardiovascular, cerebrovascular, hepatic, renal, and hematopoietic systems; did not undergo radical operation after study inclusion; could not complete the full chemotherapy course; received Chinese herbal intervention.

A total of 210 patients were observed in the perioperative period. These patients usually had an average hospital stay of 10 d, and were observed at each of four timepoints: 1 d before surgery, 3 d after surgery, 7 d after surgery, and 10 d after surgery.

A total of 160 patients were observed in the adjuvant chemotherapy period. The distinction of these patients over a total process of 6 months and patient turnover meant that not all of these patients' pattern-related data were completely collected at the four timepoints (before receiving adjuvant chemotherapy, in the early period of adjuvant chemotherapy, in the mid period of adjuvant chemotherapy, and at the end of adjuvant chemotherapy). Based on the inclusion and exclusion criteria, we investigated 100 patients in the period before receiving adjuvant chemotherapy, 120 patients in the early period of adjuvant chemotherapy, 114 patients in the mid period of adjuvant chemotherapy, and 110 patients at the end of adjuvant chemotherapy.

2.3. Sample size calculation

Analysis of multiple factors required the observation of at least 5–10 times the number of variables; this study set used 18 variables. The total number of patients enrolled in the study meets the requirements of sample size calculation.

2.4. Questionnaire development

Based on the existing literature and preliminary study results [10–12], the 'perioperative stage colorectal cancer TCM pattern questionnaire' and 'adjuvant stage colorectal cancer TCM pattern questionnaire' were developed. Questionnaire content include the following aspects: (a) general condition; (b) treatment situation; (c) tumor situation; (d) tumor stage and patient's Karnofsky performance status; (e) past medical history, family history, and individual habits; (f) TCM symptoms, tongue and pulse condition; (g) other supplementary symptoms. Investigators were postgraduate students and doctorate students majoring in medical oncology using combined TCM and Western Medicine. Prior to conducting the survey, all investigators received standardized training for the present study.

2.5. Statistical analysis

The collected data were assigned and quantified using EpiData 3.1 database management software (EpiData Association, Odense, Denmark). The database was imported into a SAS 9.2 (SAS Institute, Cary, NC, USA) statistical analysis software package. After the removal of symptoms with a frequency of less than 5%, the remaining symptoms were considered as variables. The statistical analysis results contain data from tongue and pulse presentations, TCM pattern classifications acquired from the experts' experience in TCM pattern identification, and statistics and analysis of the number of cases in each TCM pattern. The tongue body and tongue coating as well as pulse patterns based on TCM diagnosis were used only for TCM pattern dialectical analysis by experts, and were not included in the frequency analysis; this is because during the process of pattern identification, the tongue body, tongue coating, and pulse condition were not differentiated by only presence or absence.

3. Results

This was a prospective, multi-center, large-scale, cross-sectional study. A total of 370 patients with colorectal cancer were recruited from July 2008 to November 2013 in three different hospitals in Hangzhou City, Zhejiang Province, China. The study protocol was approved by the institutional review board, and all patients provided written informed consent prior to study participation.

Of the 370 included patients, 210 (56.7%) were patients who were hospitalized in the First Affiliated Hospital of College of Medicine, Zhejiang University and Zhejiang Cancer Hospital from July 2009 to October 2011 to undergo radical resection for colorectal cancer. The remaining 160 (43.2%) were patients who were hospitalized in the Second Affiliated Hospital of College of Medicine, Zhejiang University and the First Affiliated Hospital of College of Medicine, Zhejiang University from July 2008 to November 2013 after completion of radical resection for colorectal cancer.

3.1. Clinical characteristics of participants

A total of 430 patients with colorectal cancer were assessed for study eligibility, of which 60 patients were excluded. Detailed reasons for study exclusion are provided in Fig. 1. A total of 370 patients were included. Of these 370 patients, 210 (56.7%) were hospitalized patients in the First Affiliated Hospital of College of Medicine, Zhejiang University and Zhejiang Cancer Hospital from July 2009 to October 2011 who were scheduled to undergo radical resection for colorectal cancer (perioperative patients); the other 160 (43.2%) were hospitalized patients in the First and Second Affiliated Hospitals of College of Medicine, Zhejiang University from July 2008 to November 2013 who had undergone radical resection

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