

## SYSTEMATIC REVIEW

**Meta-analysis on integrative medicine for the treatment of malignant ascites: a comparative study**

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**Abstract**

**OBJECTIVE:** To compare the efficacy of integrated Chinese and Western Medicine with that of only Western Medicine for the treatment of malignant ascites.

**METHODS:** All randomized controlled trials (January 2004 to March 2013) from the China National Knowledge Infrastructure Database, Chinese Biomedical Literature Database, and Wanfang Database were searched with keywords. Meta-analysis was conducted by combining the odds ratios of the individual studies. Review Manager 5.0 was used for the analysis.

**RESULTS:** One thousand one hundred and fifty-six patients from 19 randomized controlled trials were included. Of them, 630 patients were treated with integrated Chinese and Western Medicine (the integrative group), and 526 patients were treated with Western Medicine alone (the control group). The Meta-analysis showed that the total effective rate was 78.73% in the integrated group, and 59.13% in the control group. The effective percentage was sig-

nificantly higher in the integrative group than that of the control group [OR = 2.85, 95% CI (2.16, 3.74),  $P < 0.01$ ].

**CONCLUSION:** The short-term curative effect in the integrative group was better than that in the control group. Integrative medicine may be beneficial for malignant ascites.

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**Key words:** Ascites; Integrative medicine; Treatment outcome; Meta-analysis

**INTRODUCTION**

Malignant ascites is a common complication of late malignant tumors. Ascites is a symbol of advanced cancer, and seriously affects patient quality of life. Patients in poor physical condition have numerous clinical symptoms, and often cannot tolerate chemotherapy or radiotherapy. Moreover, patients in the late stages of cancer are usually not sensitive to chemotherapy, radiotherapy, or other anti-tumor strategies, and survival time is usually only 3-6 months. Therefore, malignant ascites is a major problem in clinical oncology.

Many studies have investigated the treatment of malignant ascites with Traditional Chinese Medicine (TCM). Therefore, therapeutic principles and effective prescriptions of Chinese medicine have been established. TCM plays an increasingly important role in treating malignant ascites. In the present study, we searched randomized controlled trials (RCTs) (published from January 2004 to March 2013 in China) for studies investigating TCM treatment of malignant ascites. In this Meta-analysis, we assessed the disease entities, syndrome differentiation, therapeutic principles and methods, and curative effects.

## MATERIALS AND METHODS

### *Literature selection strategy*

We searched articles from the China National Knowledge Infrastructure Database, Chinese Biomedical Literature Database, and Wanfang Database from January 2004 to March 2013. Medical keywords used were: "cancerous ascites," "cancerous abdominal effusion," "malignant ascites," "malignant abdominal effusion," "Traditional Chinese Medicine," "Chinese herbal medicine," and "Integrated Chinese and Western Medicine." We reviewed all retrieved articles to find relevant statistics and analysis.

### *Inclusion criteria*

Studies were included if: (a) they could be defined as controlled trials; (b) the patients in the study were diagnosed to have malignant ascites by cytology or pathology; (c) the general data between the groups in age, gender, stages, and pathological types were comparable.

### *Exclusion criteria*

We excluded any non-controlled trials, theoretical discussions, literature reviews, and studies in which the data could not be used or was not in accordance with the inclusion criteria.

### *Therapeutic methods for malignant ascites*

In the control group, only Western Medicine treatment was adopted, including abdominocentesis, ascites drawing, and cisplatin and/or interleukin 2 (IL-2) peritoneal perfusion. In the integrative group, conventional Western Medicine treatment was used plus TCM treatment. TCM treatments included decoctions for oral administration, external application, and peritoneal perfusion.

### *Criteria for short-term curative effect*

Ascites was assessed by ultrasound in reference to Response Evaluation Criteria in Solid Tumors. Complete response: disappearance of ascites, confirmed at  $\geq 4$  weeks; partial response:  $\geq 50\%$  decrease from baseline, confirmed at  $\geq 4$  weeks; progressive disease:  $\geq 25\%$  increase from baseline; stable disease: met neither PR nor PD criteria, confirmed at  $\geq 4$  weeks. The total response rate was CR + PR.

### *Data extraction and statistical analysis*

The following information was extracted from each of the eligible included publications: disease entities, TCM syndrome types, TCM therapeutic principles and methods, and curative effect. We performed a systematic review following recommendations of the Cochrane Collaboration (Higgins 2011)<sup>1</sup> using Review Manager 5 (RevMan 2011),<sup>2</sup> produced and updated by Cochrane Collaboration. The between-study heterogeneity was assessed using the Cochran's *Chi*-square test, if  $P > 0.05$ , a fixed-effect model was used; if  $P < 0.05$ , a random-effect model was used. The Meta-analysis was conducted by combining the odds ratios of the individ-

ual studies and followed the sensitivity analysis. Funnel plots were used to assess the potential publication bias.

### *Data synthesis*

Data synthesis involved number of the patients, TCM syndrome types, Chinese herbal medicines used, and therapeutic effects.

## RESULTS

### *Results of literature retrieval*

Sixty-four references were collected initially, and 19 papers met all the inclusion criteria.<sup>3-21</sup> All non-controlled trials were excluded, and TCM theoretical research, reviews, animal experiments, case reports, and nursing research were also excluded. A total of 1156 patients were reported in 19 studies, including 526 patients treated with Western Medicine (the control group) and 630 patients treated with integrated Chinese and Western Medicine (the integrative group). The control group was treated with abdominocentesis and ascites drawing, followed by IL-2 and/or cisplatin intraperitoneal injection. The integrative group was treated with Western Medicine and at the same time given Chinese herbal medicines for oral administration or external application.

### *Disease entity*

Disease entities of the patients included liver cancer (426 cases), ovarian cancer (238 cases), colorectal cancer (154 cases), gastric cancer (145 cases), pancreatic cancer (32 cases), lung cancer (22 cases), breast cancer (11 cases), cervical cancer (5 cases), small intestinal cancer (3 cases), esophageal carcinoma (3 cases), bile duct carcinoma (2 cases), and other types of cancer (33 cases). Disease entities were not presented in one study that included 45 patients. Thirty-seven gastrointestinal cancer cases were reported in another study.

### *TCM syndrome types*

No unified standards were used for differentiation of the TCM syndrome types. There were no TCM syndrome types listed in nine papers, especially for study of externally used Chinese herbs. The TCM syndrome types are generally: *Qi* stagnancy and toxin stasis syndrome (192 cases), *Qi* deficiency and blood stasis syndrome (185 cases), *Qi* deficiency and water retention syndrome (170 cases), spleen-kidney *Yang* deficiency syndrome (120 cases), deficiency of *Yin* and water-heat accumulation syndrome (80 cases), and damp obstruction because of spleen deficiency (61 cases).

### *Publication bias*

The symmetry of the reversed funnel plot indicates no publication bias (Figure 1).

The funnel plot is produced with *OR* as the X-axis, which represents the short-term effective rate of the integrative group versus the control group, and with  $\log [OR]$  as the Y-axis. The included studies present a symmetrical funnel plot, indicating no publication bias.

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