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SYSTEMATIC REVIEW

Effect of Aidi injection plus chemotherapy on gastric carcinoma: a Meta-analysis of randomized controlled trials

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Abstract

OBJECTIVE: To conduct a Meta-analysis of studies on the effect of Aidi injectioncombined with chemotherapy versus chemotherapy alone in the treatment of gastric cancer (GC).

METHODS: Nine electronic databases and six gray literature databases were comprehensively searcheduntil April 20, 2013. Two reviewers independently selected and assessed included trialsaccording to the inclusion and exclusion criteria. The risk of bias tool from the Cochrane Handbook version 5.1.0 was used to assess trial quality. All calculations were performed using Review Manager 5.0.

RESULTS: Thirty-two studies including 1927 participants met the inclusion criteria, most of which were low quality. Compared with chemotherapy alone, Aidi injection plusthe same chemotherapy significantly improved the effective rate [*OR* = 1.52, 95% *CI* (1.24, 1.86), *P* < 0.0001], clinical beneficial rate [*OR* = 1.77, 95% *CI* (1.33, 2.36), *P* < 0.0001], and quality of life [*OR* = 3.02, 95% *CI* (2.39, 3.82), *P* < 0.000 01]. There was a significant improvement in nausea and vomiting incidence [*OR* = 0.34, 95% *CI* (0.24, 0.47), *P* < 0.000 01], diarrhea [*OR* = 0.47, 95% *CI* (0.33, 0.69), *P* < 0.000 01], leukopenia (Ⅲ-Ⅳ) [*OR* = 0.34, 95% *CI* (0.23, 0.51), *P* = 0.05], hemoglobin decrease (Ⅲ-Ⅳ) [*OR* = 0.42, 95% *CI* (0.18-1.00), *P* = 0.05], thrombocytopenia (Ⅲ-Ⅳ) [*OR* = 0.46, 95% *CI* (0.22, 0.96), *P* = 0.04], and damage to liver function [*OR* = 0.36, 95%*CI* (0.24, 0.54), *P* < 0.000 01].

CONCLUSION: Aidi injection combined with chemotherapy significantly improved the clinical effect of chemotherapy, reducing the incidence of adverse events. Use of the CONSORT statement for randomized controlled trials is recommended for stricter reporting.

Key words: Drug therapy; Stomach neoplasms; Review; Randomized controlled trial; Aidi injection

INTRODUCTION

Gastric carcinoma (GC) is one of the common malignant carcinomas. GC is the fourth most frequent malignant cancer and the second most common cause of death, with an incidence of 989 600 cases and 738 000 deaths worldwide in 2008.[1] More than 70% of new cases and deaths occur in underdeveloped countries.[2] In China, there were 464 000 new gastric carcinoma cases and 352 000 deaths in 2008, accounting for 16.5% of allcancer cases and 18.0% of cancer-related deaths.[3]

Therefore, GC is a large worldwide public health burden. Surgical therapies, radiotherapies, and chemotherapies arethe three mainstays of treatment. Unfortunately, almost half of the patients that present with middle-to-advanced stage gastric cancer are inoperable, with a median survival time (MST) of 6-10 months. Therefore, comprehensive chemotherapy treatment programs aremost commonly used for GC.[4] However, chemotherapy has adverse short- and long-term side effects,[5] because the selectivity of chemotherapy is low for normal cells. Traditional Chinese medicinal herbs combined with chemotherapy could significantly improve quality of life, relieve symptoms, remove toxins, increase immune function, and act as anticancer agents.[6]

Aidi injection is made from an extraction of Renshen (*Radix Ginseng*), Huangqi (*Radix Astragali Mongolici*), Ciwujia (*Radix et Caulis Acanthopanacis Santicosi*), and Banmao (*Mylabri*).The injection can clear heat and toxins, remove blood stasis, inhibit tumor growth, induce apoptosis, decrease the side-effects of radiotherapy and chemotherapy, and increase immune function.[7,8] Aidi injection combined with chemotherapy could improve the effect of chemotherapy, increase drug tolerance, and improve quality of life.[7]

We aimed toconduct a Meta-analysis of 32 randomized controlled trials (RCTs) to assess the efficacy and safety of Aidi injection combined with chemotherapy in GC patients.

DATA AND METHODS

Study selection

The study search, study selection, data extraction, and quality assessment were performed independently by two trained reviewers (JCW and LG). Disagreements between reviewers were resolved through consensus or by consulting a third expert adjudicator (KHY).

Inclusion and exclusion criteria

Included studies met the following inclusion criteria: (a) RCTs using Aidi injection combined with chemotherapy for GC patients; (b) participants were confirmed to have GC pathologically or via computed tomography, regardless of age, sex, or nationality; (c) intervention was Aidi injection combined with chemotherapy vschemotherapy alone;and (d) relative risks (RR), odds ratios (OR), or data for calculations were provided.

Studies were excluded if: (a) the patients were not confirmed to have GC; (b) the studies were not RCTs; (c) the control measures did not include chemotherapy; (d) the data could not be extracted; or (e) the study was a review or Meta-analyses, animal study, case report, conference abstracts, or letters to journal editors.

Outcome measures

Efficiency rate was defined as complete response (CR) + partial response (PR), according to the World Health Organization (WHO)[9]criteria for solid tumors.The clinical beneficial rate was defined as complete response (CR) + partial response (PR) + stable disease (SD). Quality of life before and after treatment was assessed using the Karnofsky performance status scale (KPS), with KPS scores increasing by ≥10 points after treatment considered as improving quality of life, KPS scores decreasing by ≥ 10 points after treatment as lower quality of life, and KPS scores increasing or decreasing by < 10 points considered as stable.

According to the WHO grading criteria for acute and sub acute toxicity of anticancer drugs,[10] adverse events were evaluated after treatment,including leukopenia, thrombocytopenia, nausea/vomiting, anemia, and diarrhea. Survival time was calculated from the beginning of chemotherapy to death, withdrawal, or drop out. Immune function was measured with T lymphocyte subsets such as CD3, CD4, CD8, CD4/CD8, and NK cells before and after treatment.

Search strategy

We comprehensively searched the following databases: China Academic Journal Network Publishing Database (CAJD, 1994-2013/4), Chinese Biomedical Literature Database (CBM, 1978-2013/4), Chinese Technological Periodical Full-text Database (VIP, 1989-2013/4), China Online Journals (COJ, 1997-2013/4), Chinese Science Citation Database (CSCD, 1989-2013/4-2013/4), PubMed (1966-2013/4), EMBASE (1974-2013/4), Cochrane Library (inception-2013/4), and Science Citation Index Expanded (SCI-EXPANDED, 2000-2013/4). Grey literature was obtained from the China Proceedings of Conference Full-text Database (CPCD, 1994-2013/4), Academic Conferences in China (ACIC, 1990-2013/4), Chinese-foreign Conference Database (*via* National Science and Technology Library, 1985-2013/4), China Doctoral Dissertations full-text Database (CDFD, 1994-2013/4), China Master's Theses Full-text Database (CMFD, 1994-2013/4), and Dissertations of China (DOC, 1990-2013/4). Searches were composed of a combination of the following terms: stomach neoplasm, gastric neoplasm, stomach cancer, gastric cancer, stomach neoplasms, Aidi zhusheye, Aidi injection, Aidi, and random*. The searches were performed on April 20, 2013. The search strategy was presented as follows:

#1 Stomach Neoplasm
#2 Gastric Neoplasm
#3 Stomach Cancer
#4 Gastric Cancer
#5 Stomach Neoplasm
#6 "Stomach Neoplasms" [Mesh]
#7 #1 OR #2 OR #3 OR #4 OR #5 OR #6
#8 Aidi zhusheye
#9 Aidi injection
#10 Aidi
#11 #8 OR #9 OR #10
#12 Random*