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Shenqi Fuzheng Injection combined with chemotherapy for gastric cancer: An overview of systematic reviews and meta-analyses

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 September 2023 and was last updated on 13 September 2023.

INTRODUCTION

Review question / Objective We evaluated the efficacy and safety of SFI for gastric cancer through the overview of SMs/MAs, providing a reliable basis for its clinical application.

Condition being studied Gastric cancer (GC) is one of the most common malignancies of the digestive system. Global cancer statistics indicate that GC ranks fifth in terms of incidence and fourth in terms of mortality among malignant tumors. In China, GC is a major concern, with 480, 000 new cases and 370, 000 deaths, accounting for 44.04% and 48.05% respectively. Moreover, 80% of GC patients in China are diagnosed at an advanced stage, resulting in poor treatment outcomes and an overall 5-year survival rate of less than 50%. Although immunotherapy and targeted therapy are advancing rapidly, chemotherapy (CT) remains the primary treatment option for GC. However, CT is associated with side effects such as gastrointestinal reactions, neurotoxicity, and bone marrow suppression, which are intolerable to patients and limit its use, thus severely impacting the physical and mental health of patients. Consequently, there is an urgent need to find a safe and effective adjuvant treatment in clinical practice.

METHODS

Participant or population Gastric cancer patients.

Intervention The test group received treatment with SFI combined with CT.

Comparator The control group received CT alone, with no restrictions on the CT regimen.

Study designs to be included Systematic reviews and meta-analysis.

Eligibility criteria 1) Study type: We selected SRs/MAs based on randomized controlled trials (RCTs) as they are considered the gold standard for evaluating clinical evidence. 2) Subjects: Patients with confirmed GC through histopathology or cytology, regardless of gender, age, course of disease, and other factors. 3) Intervention measures: The test group received treatment with SFI combined with CT, while the control group received CT alone, with no restrictions on the CT regimen. 4) Outcome indicators: The outcome indicators included the objective response rate (ORR), disease control rate (DCR), Karnofsky Performance Status (KPS), CD4+/CD8+ levels, gastrointestinal reactions, neurotoxicity, and others.

Information sources In our research, we utilized two independent reviewers, Jing Xu and Xiao Li, to conduct a comprehensive search across various databases including PubMed, Embase, Cochrane Library, CNKI, Wanfang, VIP, and SinoMed. Additionally, we conducted a secondary search of all references cited in the included literature.

Main outcome(s) The outcome indicators included the objective response rate (ORR), disease control rate (DCR), Karnofsky Performance Status (KPS), CD4+/CD8+ levels, gastrointestinal reactions, neurotoxicity, and others.

Quality assessment / Risk of bias analysis The ROBIS tool was used to assess the bias risk included in the SRs/MAs analysis.

Strategy of data synthesis RevMan 5.4 is employed for quantitative analysis of RCTs, including SRs/MAs, to provide a clearer understanding of the effectiveness and safety of SFI for GC. Relative risk (RR) is utilized for binary classification outcome measures, while standardized mean difference (SMD) is employed for continuous outcome indicators. Heterogeneity assessment is determined using I^2. If the $P > 0.1$ and $I^2 \leq 50\%$, the fixed-effect model is applied; otherwise, the random-effect model is adopted. In cases of significant heterogeneity, subgroups or sensitivity analysis may be conducted to lessen heterogeneity, and funnel plots can be utilized to assess publication bias in the included studies.

Subgroup analysis If the clinical heterogeneity is significant, subgroup or sensitivity analysis can be used to reduce the heterogeneity, and funnel plots can be used to determine whether there is publication bias in the included studies.

Sensitivity analysis Heterogeneity assessment is determined using I2. If the $P > 0.1$ and $I2 \leq 50\%$, the fixed-effect model is applied; otherwise, the random-effect model is adopted.

Country(ies) involved China.

Keywords traditional Chinese medicine, shenqi fuzheng injection, gastric cancer, overview, meta-analyses, systematic review.

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