INPLASY PROTOCOL

To cite: Xing et al. Efficacy and safety of Suzi Jiangqi Decoction in patients with acute exacerbation of chronic obstructive pulmonary disease A protocol for systematic review and meta analysis. Inplasy protocol 202180035. doi: 10.37766/inplasy2021.8.0035

Received: 09 August 2021

Published: 09 August 2021

Corresponding author:
Lei Xing

xinglei789@163.com

Author Affiliation:
First Clinical Medical College, Nanjing University of Chinese Medicine.

Support: **JSTCMD.**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
None declared.

Efficacy and safety of Suzi Jiangqi Decoction in patients with acute exacerbation of chronic obstructive pulmonary disease A protocol for systematic review and meta analysis

Xing, L[1]; Guo, HM[2]; Wang, ZQ[3].

Review question / Objective: **Background: Chronic obstructive pulmonary disease (COPD) is characterized by chronic respiratory symptoms. The respiratory symptoms of patients with acute exacerbation of COPD (AECOPD) worsen rapidly. At present, traditional western medicine treatment can not effectively alleviate the symptoms and attack frequency of patients. Suzi Jiangqi decoction(SZJQ) has a good clinical effect in the treatment of AECOPD. Due to the lack of evidence-based medicine, it can not provide an effective systematic evaluation for the treatment of AECOPD with Suzi Jiangqi decoction. Therefore, it is necessary to provide high-quality evidence evaluation for the clinical efficacy and safety of Suzi Jiangqi Decoction in the treatment of AECOPD. Methods: Two researchers independently retrieved randomized controlled trial (RCT) and quasi-RCTs of SZJQ in the treatment of AECOPD from databases including PubMed, Web of science, the Cochrane Library, CBM, CNKI, Sinomed, VIP and WanFang.The included studies were evaluated for quality according to the RCT quality assessment method provided by Cochrane Reviewer's Handbook 5.3.Review Manager 5.3 software provided by the Cochrane collaboration was used for meta-analysis. Results: This study will provide systematic review on the efficacy and safety of SZJQ as adjuvant therapy in patients with AECOPD by rigorous quality assessment and reasonable data synthesis. Conclusions: This systematic review will provide the good evidence currently on SZJQ as adjuvant therapy in patients with AECOPD.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 August 2021 and was last updated on 09 August 2021 (registration number INPLASY202180035).

INTRODUCTION

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rapidly. At present, traditional western medicine treatment can not effectively alleviate the symptoms and attack frequency of patients. Suzi Jiangqi decoction(SZJQ) has a good clinical effect in the treatment of AECOPD. Due to the lack of evidence-based medicine, it can not provide an effective systematic evaluation for the treatment of AECOPD with Suzi Jiangqi decoction. Therefore, it is necessary to provide high-quality evidence evaluation for the clinical efficacy and safety of Suzi Jiangqi Decoction in the treatment of AECOPD. Methods: Two researchers independently retrieved randomized controlled trial (RCT) and quasi-RCTs of SZJQ in the treatment of AECOPD from databases including PubMed, Web of science, the Cochrane Library, CBM, CNKI, Sinomed, VIP and WanFang.The included studies were evaluated for quality according to the RCT quality assessment method provided by Cochrane Reviewer's Handbook 5.3.Review Manager 5.3 software provided by the Cochrane collaboration was used for meta-analysis. Results: This study will provide systematic review on the efficacy and safety of SZJQ as adjuvant therapy in patients with AECOPD by rigorous quality assessment and reasonable data synthesis. Conclusions: This systematic review will provide the good evidence currently on SZJQ as adjuvant therapy in patients with AECOPD.

Condition being studied: A large number of clinical studies show that Suzi Jiangqi Decoction (SZJQ) combined with conventional western medicine can significantly improve the clinical efficacy of AECOPD prevention and treatment[5, 6].There are still some limitations since most research were based on single case, and others were scattered or defected with limited sample numbers. In this case, the introduction and popularization of evidence-based medicine create a new research field in clinical efficacy evaluation of on traditional Chinese medicine (TCM), which elicits some novel research strategies and becomes one of the major driving forces for clinical investigations TCM. Since there were no systematic reviews or evidence-based medicine meta-analysis on SZJQ so far, we conducted a systematic review on SZJQ in treating AECOPD. According to Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) published in 2019, our study might provide more evidence-based medicine basis for clinical application of SZJQ.

METHODS

Participant or population: Patients who were diagnosed as COPD were included. The diagnostic criteria complied to the guidelines for the management of chronic obstructive pulmonary disease (revised version in 2021[8]), which was drawn up by Respiratory Society of Chinese Medical Association, as well as other diagnostic criteria for AECOPD.Participants were older than 40 years old.The following cases were excluded: (1)patients with stable COPD;(2)severe respiratory failure, liver and kidney insufficiency and other lung diseases;(3)repetitive publications; (4)documents, reviews and conference papers that cannot obtain full text or extract effective data.

Intervention: SZJQ is the concerned intervention in this study. We will include RCTs comparing SZJQ combined with conventional western medicine therapies(e.g.,anti-infection treatment, anti-asthmatic treatment, improved ventilation, low flow oxygen inhalation). Subjects in control group were only treated with conventional western medicine therapies.The two groups were not allowed to use other Chinese medicine.

Comparator: Subjects in control group were only treated with conventional western medicine therapies.

Study designs to be included: RCTs.

Eligibility criteria: The PICOS (population-intervention-comparative-results-study design) framework are used for the eligibility criteria for the review.

Information sources: Searches will be performed in literature databases of PubMed, Web of science, the Cochrane Library, CBM, CNKI, Sinomed, VIP and WanFang to collect relevant studies, without language restriction. The time frame of the search will be from the inceptions of the databases up to June 30, 2021. The search time frame will be received from the database until June 30, 2021. The terms "acute exacerbation of chronic obstructive pulmonary disease" and "Suzi Jiangqi Decoction", including free text words and medical keywords, will be used to construct the search strategy. An example of search strategy in PubMed is shown in Table 1. We will also search two trial registration platforms, namely Clinical Trials. Gov and Chinese Clinical Trial Registry, as well as references for related reviews and additional studies.

Main outcome(s): The primary outcomes will be estimated Overall effective rate (OR) and pulmonary function index which is including forced expiratory volume in one second (FEV1), forced vital capacity (FVC), peak expiratory flow (PEF) and FEV1/FVC rates.

Additional outcome(s): (1)The following outcomes will also be assessed as the secondary outcomes: Blood gas analysis, including arterial partial pressure of oxygen (PaO2), partial pressure of carbon dioxide (PaCO2); The infection indexes included white blood cell count (WBC) and C-reactive protein (CRP). (2)Qualitative results: according to the recognized classification criteria (such as the guiding principles of clinical research of new traditional Chinese Medicine) for the response to the treatment; (3)Safety results: the incidence of adverse events related to SZJQ.

Quality assessment / Risk of bias analysis: We will evaluate all included studies by using the risk of bias tool in the Cochrane Handbook 5.1.0 for systematic review of interventions[9]. There will be two reviewers independently evaluating the original design. The risk of bias will be obtained through seven evaluation trials: selective reporting (reporting bias), random sequence generation (selection bias), blind method of result evaluation (detection bias), incomplete result data (consumption bias), blind method of participants and personnel (performance bias), allocation concealment (selection bias) and other bias. Each evaluation trial was divided into "low risk", "high risk" or "ambiguous risk". The percentage of each category in each source of bias was described by Rveman 5.3.0 software, and the results were interpreted considering the risk of bias. Further discussion with a third commentator is needed to resolve the disagreement on the risk of bias.

Strategy of data synthesis: The data obtained from the search is imported into Noteexpress for data De duplication. Two reviewers independently screened the literature repeatedly. Firstly, irrelevant literatures are excluded by reading titles and abstracts; Then we will read the full text to determine the final feasibility. Reviewers will cross check the results to solve the differences in the discussion or judgment of the third reviewer.

Subgroup analysis: In this case, we explored the source of heterogeneity through subgroup analysis, meta regression analyses, and sensitivity analyses.If the source of heterogeneity is not known, the synthetic analysis will be abandoned and descriptive analysis will be used.

Sensitivity analysis: We will extract data from single randomized controlled trials through random effect model meta-analysis in Revman version 5.3 (Copenhagen:Nordic Cochran center, Cochran collaboration, 2014). According to its normality, the weighted mean difference (WMD) or standardized mean difference (SMD) was used to measure the impact on the continuity results, and the inverse analysis of variance was used. Mantel-Haenszel method was used to measure the dichotomous results through risk ratio (RR) [10]. A 95% confidence interval (95% CI) will be calculated to represent the estimation accuracy.In meta-analysis,

Cochran Q test will be used to determine whether there is statistically significant heterogeneity between RCTs, and calculate I-square statistics to quantitatively detect the level of heterogeneity. Significant heterogeneity was determined by P value below 0.10 or an I2 higher than 50% in Cochran Q test.

Language: English, Chinese.

Country(ies) involved: China/Jiangsu.

Keywords: Suzijiangqi decoction, protocol, systematic review, acute exacerbation of chronic obstructive pulmonary disease, meta-analysis.

Contributions of each author:

Author 1 - Lei Xing - The author drafted the manuscript.
Email: xingleize@163.com
Author 2 - Hongmin Guo - The author provided statistical expertise.
Email: hongminguo789@163.com
Author 3 - Zhiqian Wang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Email: njsgczyy@163.com