INPLASY PROTOCOL

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Efficacy of traditional Chinese medicine enema for pelvic inflammatory mass

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Review question / Objective: To investigate the efficacy of traditional Chinese medicine enema for pelvic inflammatory mass. The research method used was a RCT.

Condition being studied: Chronic pelvic inflammatory disease is the most common chronic inflammation in women of childbearing age. Because of acute pelvic inflammatory exudate in the pelvic cavity more, it is difficult to completely absorb, and eventually form pelvic inflammatory mass. Longterm inflammatory stimulation, pelvic normal tissue structure is destroyed, local defense function is reduced, pelvic extensive adhesion, fibrous connective tissue hyperplasia, wrapping around organs, antibiotics are not easy to enter, and long-term application of a large number of broad-spectrum antibiotics, bacterial resistance and gastrointestinal reactions. liver and kidney damage, bacterial flora disorders and other adverse reactions, so the application of antibiotics clinical efficacy is not good or ineffective. Traditional Chinese medicine enema delivered through the rectum can direct the drugs to the disease site, reduce the destruction of drug ingredients, and high bioavailability, can promote the local pelvic blood circulation, improve the nutritional status of the tissue, improve metabolism, help inflammatory response to subside, release adhesion, mass dissipation, so as to quickly play a therapeutic role.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 May 2023 and was last updated on 14 May 2023 (registration number INPLASY202350055).

INTRODUCTION

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enema for pelvic inflammatory mass. The research method used was a RCT.

Condition being studied: Chronic pelvic inflammatory disease is the most common chronic inflammation in women of childbearing age. Because of acute pelvic inflammatory exudate in the pelvic cavity more, it is difficult to completely absorb, and eventually form pelvic inflammatory mass. Long-term inflammatory stimulation, pelvic normal tissue structure is destroyed, local defense function is reduced, pelvic extensive adhesion, fibrous connective tissue hyperplasia, wrapping around organs, antibiotics are not easy to enter, and long-term application of a large number of broad-spectrum antibiotics, bacterial resistance and gastrointestinal reactions, liver and kidney damage, bacterial flora disorders and other adverse reactions, so the application of antibiotics clinical efficacy is not good or ineffective. Traditional Chinese medicine enema delivered through the rectum can direct the drugs to the disease site, reduce the destruction of drug ingredients, and high bioavailability, can promote the local pelvic blood circulation, improve the nutritional status of the tissue, improve metabolism, help inflammatory response to subside, release adhesion, mass dissipation, so as to quickly play a therapeutic role.

METHODS

Search strategy: Searching seven electronic databases including PubMed, Cochrane Library, ScienceDirect, Wan-fang database, VIP (Chinese Scientific Journals Database) and CNKI (China National Knowledge Infrastructure). The search time was limited from January 2000 to May 2023. Search terms: "pelvic inflammatory mass", "hydrosalpinx", "pyosalpinx", "pelvic abscess", "Attachment inflammatory mass", "traditional Chinese medicine enema", "traditional Chinese medicine retention enema" and "enema", etc.

Participant or population: Study patients were diagnosed with pelvic inflammatory.

Intervention: ①Patients with pelvic inflammatory mass undergoing ontraditional Chinese medicine enema

②Patients with pelvic inflammatory mass using surgical or medication treatment and traditional Chinese medicine enema.

Comparator: Patients with pelvic inflammatory mass undergoing Routine surgical treatment or medication.

Study designs to be included: RCTs.

Eligibility criteria: (1) human studies; (2) RCTs; (3) studies that include pelvic inflammatory masses; (4) studies with available data can be extracted.

Information sources: Searching seven electronic databases including PubMed, Cochrane Library, ScienceDirect, Wan-fang database, VIP (Chinese Scientific Journals Database) and CNKI (China National Knowledge Infrastructure).

Main outcome(s): The outcomes included abdominal pain, vaginal discharge, gynecological examination and Bultrasound examination of pelvic inflammatory masses outcomes.

Data management: With a pre - designed table, two authors independently performed the data extraction. The disagreement was resolved by another senior researcher. The extracted data includes: lead author, year of publication, country or region, study time, follow-up time, intervention, sample size, age,side effects, outcome indexes (abdominal pain, vaginal discharge, temperature, gynecological examination, and Bultrasound examination of pelvic inflammatory masses outcomes.), etc.

Quality assessment / Risk of bias analysis: According to the literature quality evaluation standards in the "Cochrane Intervention System Evaluation Manual", the first and second authors independently evaluate the quality of the included literature. If there are any differences, they would discuss and resolve them together. If there were still differences, they would discuss with the third author.

Strategy of data synthesis: Statistical analyses were performed with Review Manager 5.3(Cochrane Collaboration, Oxford, UK) and STATA 12.0(StataCorp LP College Station, Texas). Odds ratio (OR) with 95% confidence interval (CI) were used to compare binary variables. The weighted mean difference (WMD) and 95% CI were calculated for continuous outcomes. Based on the method described by Wan et al., the medians and interquartile ranges of continuous data were converted to means and standard deviations . For all meta - analyses , the Cochrane Q p value and I² statistic were applied to check heterogeneity. When p value 50%, there was a significant heterogeneity, a random - effect model was used to merge the results. Otherwise, a fixed - effect model was used . A p value less than 0.05 was considered statistically significant. We performed egger 's test to assess publication bias (only for outcomes including ten or more studies).

Subgroup analysis: NOT.

Sensitivity analysis: The sensitivity analysis was performed using STATA software, and the sensitivity of the articles was determined by the change of the effect size after the deletion of one of the articlesThe sensitivity analysis was performed using STATA software, and the sensitivity of the articles was determined by the change of the effect size after the deletion of one of the articles.

Country(ies) involved: China.

Keywords: pelvic inflammatory mass, Traditional Chinese medicine enema, metaanalysis, systematic review, traditional Chinese medicine.

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