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Safety and Efficacy of Herbal Medicine for Symptom Management After HIFU Treatment in Adenomyosis: A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Formal screening of search results against eligibility criteria.

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 21 March 2025 and was last updated on 21 March 2025.

INTRODUCTION

Review question / Objective This study aims to evaluate the safety and efficacy of Herbal Medicine in managing symptoms and enhancing recovery after HIFU treatment in patients with adenomyosis.

Rationale There are several studies evaluating the efficacy of herbal medicine for adenomyosis. However, research on herbal medicine for symptom management after HIFU treatment remains limited. A meta-analysis by Li (2023), which included studies published as of May 2022, incorporated only five RCTs (excluding grey literature), making it difficult to draw definitive conclusions regarding efficacy. Since the publication of that study, several randomized controlled trials (RCTs) have been conducted, which are expected to provide a stronger evidence base for more conclusive findings.

Condition being studied Adenomyosis (AM) is an estrogen-dependent condition characterized by the infiltration of endometrial tissue into the myometrium, leading to symptoms such as menorrhagia and progressively worsening dysmenorrhea. Currently, hysterectomy is the only definitive treatment, but it is not suitable for women who wish to preserve their uterus or maintain fertility. Therefore, effective, minimally invasive treatment options with fewer side effects and lower recurrence rates are being actively explored, with High-Intensity Focused Ultrasound (HIFU) emerging as a recommended approach in clinical guidelines. HIFU is a non-invasive technique that induces coagulative necrosis in targeted tissues through thermal energy, offering advantages such as high efficacy, minimal adverse effects, and rapid recovery. It is suitable for patients who have fertility planning and desire to conserve the uterus. However, due to the deep infiltration of AM lesions, HIFU alone often leaves residual lesions, which may contribute to symptom recurrence, posing a major challenge in long-term disease management.

Herbal medicine has shown promising efficacy in managing AM, and combining it with HIFU is being explored to enhance treatment outcomes. This study aims to compare HIFU alone with HIFU combined with herbal medicine in terms of uterine and lesion volume reduction, symptom relief, recurrence rate reduction, and overall safety. A systematic review and meta-analysis of existing studies will be conducted to provide evidence-based insights into the clinical benefits of herbal medicine with HIFU for AM treatment.

METHODS

Search strategy We will search electronically on English databases, Chinese databases and Korean databases. We used the search terms " adenomyosis " and "herbal medicine," which were adapted to suit the language specifications of each database.

Participant or population
[Inclusion Criteria]
Patients diagnosed with adenomyosis according to the diagnostic criteria outlined in Obstetrics and Gynecology

[Exclusion Criteria]
Patients with contraindications to ultrasound ablation.
Patients requiring surgical treatment or those with severe gynecological diseases (such as malignant tumors).
Patients with severe hepatic or renal impairment, cardiovascular diseases, or other serious systemic conditions.
Pregnant or lactating women.

Intervention The experimental group received HIFU combined with herbal medicine (with no restrictions on the specific type of herbal medicine used, such as oral, external application, and enema formulations). The control group received HIFU treatment alone. Conventional Western medicine was allowed, provided that both groups received the same treatment.

Comparator The control group received HIFU treatment alone. Conventional Western medicine was allowed, provided that both groups received the same treatment.

Study designs to be included All the randomized controlled trials (RCTs) were included.

Eligibility criteria All randomized controlled trials (RCTs) on the efficacy of HIFU combined with herbal medicine in the treatment of adenomyosis (AM) were included. Non-RCTs, RCT protocol, animal studies, case reports, thesis, survey and reviews were excluded.

Information sources We will electronically search 11 following databases. Three English databases (MEDLINE via PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), three Chinese databases(China National Knowledge Infrastructure, Wanfang data, and VIP), and five Korean databases (such as Oriental Medicine Advanced Searching Integrated System, Korean studies Information Service System, Korea Citation Index, Research Information Sharing Service, and Korean Medical database) without any language restrictions.

Main outcome(s)
1)Uterine volume (or Lesion volume) assessed by transvaginal ultrasound.
2)CA125 in peripheral blood.
3)Dysmenorrhea assessed by visual analogue scale.

Additional outcome(s)
1)Total effective rate
2)Menstrual bleeding volume assessed by pictorial blood loss assessment chart
3)Adverse events.

Quality assessment / Risk of bias analysis Quality assessment will be performed using Risk of bias (Rob2) tool from the Cochrane Handbook for Systematic Reviews of Interventions. The tool includes bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, and bias in the selection of reported results.

Strategy of data synthesis The data will be synthesized using Review Manager 5.4 software. Dichotomous outcomes will be summarized using Risk Ratios (RR) with 95% Confidence Intervals (CI). Continuous outcomes will be presented as the standard mean difference (SMD) or mean difference (MD) with 95% CI. Heterogeneity was evaluated using the Higgins I2 index, with I2 ≥ 50% indicating potential heterogeneity, and I2 ≥ 75% indicating significant heterogeneity.

Subgroup analysis If the meta-analysis shows significant heterogeneity, subgroup analyses will be conducted. Subgroup analyses will also be performed based on the compositions of herbal medicines, both with and without conventional treatment, provided that a sufficient amount of data is available.

Sensitivity analysis A sensitivity analysis was performed by excluding one study at a time to assess the robustness of the meta-analysis results.

Language restriction No language restriction.

Country(ies) involved Republic of Korea.

Keywords adenomyosis; high intensity focused ultrasound; herbal medicine; Systematic review; Meta-anaylsis.

Dissemination plans adenomyosis; high intensity focused ultrasound; herbal medicine; Systematic review; Meta-anaylsis.

Contributions of each author

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