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A Systematic Review and Meta-analysis of Dane Fukang Decoction and Gestrinone for Treatment of Endometriosis

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Abstract

Endometriosis is a chronic gynecological condition influenced by hormones that frequently causes severe pelvic pain and other concerning symptoms such as heavy or irregular menstrual bleeding, painful intercourse, fatigue, nausea, and infertility. While surgery is often required, the rates of recurrence after surgery remain high. Objective. This systematic review and meta-analysis aimed to determine the efficacy of Dane Fukang decoction and Gestrinone for treating endometriosis after surgery. A literature search was conducted in the primary electronic databases, with studies published from inception until January 2024. The analysis included in randomized controlled trials (RCTs) that compared Dane Fukang decoction to Gestrinone for endometriosis treatment after surgery. Meta-analyses were conducted using random-effects models, calculating pooled odds ratios (OR) and 95% confidence intervals (CI). A total of six RCTs involving 658 patients were included. The meta-analysis showed that Dane Fukang decoction significantly improved effectiveness compared to gestrinone treatments. The random effect model analysis yielded an odds ratio of 2.72 (95% CI: 1.13 to 6.54, p=0.05) with an I2 value of 56%, suggesting moderate heterogeneity among the included studies. No serious adverse events were reported with either intervention. This systematic review and meta-analysis provide evidence supporting the superior efficacy of Dane Fukang decoction over gestrinone as a post-operative treatment for endometriosis to improve overall clinical outcomes.

Keywords: Meta-analysis, random-effects model, heterogeneity assessment, treatment effectiveness.

1. Introduction

Endometriosis is a prevalent chronic gynecological condition where tissue similar to the uterine lining grows abnormally outside the uterus, affecting an estimated 176 million women worldwide. About one in ten women of reproductive age suffer from endometriosis, experiencing severe menstrual cramps, pelvic pain, and infertility, with approximately 20-40% of adolescent girls missing school due to severe period pain, and two out of five reporting negative impacts on

academic performance. Despite available treatments, endometriosis often recurs, with around 10% of cases relapsing yearly and 50% recurring within five years after initial surgery. The condition causes a range of painful symptoms from mild to severe. It includes chronic pelvic pain during periods, ovulation, and intercourse. This diminishes quality of life for those affected. Infertility also commonly affects 30-40% of women with endometriosis. It is linked to ovarian damage, fallopian tube damage, uterine damage, adhesions, inflammation, and ovarian cyst issues. Interestingly, the severity of pain may not directly correlate with the extent of the condition present.

Conventional endometriosis treatments such as hormonal therapies and surgery provide symptom relief, but often come with significant drawbacks including high costs, side effects, tolerability challenges, and incomplete resolution of symptoms. One such alternative method that is becoming popular is using herbal formulations derived from traditional Chinese medicine (TCM). The Dane Fukang decoction is a multi-herbal TCM formulation comprised of Salvia miltiorrhiza, Rhizoma Curcumae, Rhizoma Sparganii, Radix Bupleuri, Angelica sinensis, Glycyrrhiza uralensis, Rhizoma Corydalis, Radix Paeoniae Rubra, and Rhizoma Cyperi. The majority of its bioactive phytochemical constituents are absorbed into systemic circulation via the hepatic portal system. Research suggests the decoction's therapeutic mechanisms include regulating qi and blood flow, promoting blood circulation to alleviate blood stasis, and exerting analgesic and anti-inflammatory effects by inhibiting inflammatory cytokine production. Furthermore, the herbal formulation may possess hormone-regulating properties that could aid in reducing endometriotic lesions. In contrast, the synthetic gestrinone suppresses ovarian function and reduces estrogen levels but carries risks of androgenic side effects. While laparoscopic surgery can provide benefits for endometriosis, post-surgical complications such as adhesions and incomplete cyst wall removal increase the risk of symptom recurrence, particularly when cyst fluid leak.

Conventional Western medicine offers a range of medications, including Gonadotropin-releasing hormone (GnRH) analogs and antagonists. These medications effectively control pain but may cause side effects such as hot flashes and bone loss. Progestins, such as dienogest, norethindrone acetate, and levonorgestrel intrauterine devices, are considered first-line therapies due to their ability to induce anovulation, reduce endometrial atrophy, and exert anti-inflammatory effects. Combined oral contraceptives containing estrogen and progestin are use in small trials used, with high-quality evidence for their effectiveness in endometriosis treatment is limited. Danazol, a testosterone-derived drug, is effective but has androgenic side effects, restricting its use.

A meta-analysis comparing Dane Fukang decoction and Gestrinone specifically could be warranted because gestrinone is a well-established synthetic medication used for post-surgical endometriosis management, serving as a suitable comparator to evaluate the efficacy of the Dane Fukang decoction. By directly comparing these two treatments, the meta-analysis can provide evidence on whether the herbal approach is a viable option compared to the conventional pharmaceutical treatment. A quantitative synthesis using a meta-analysis is required to determine the overall scale and statistical significance of treatment effects and investigate potential sources of heterogeneity or bias across studies. The systematic review and meta-analysis aimed to evaluate the effects of Dane Fukang decoction and gestrinone as post-operative treatments on overall clinical outcomes in women with ovarian endometriosis who underwent laparoscopic surgery.

2. Methods

This systematic review used the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) statement to benefit authors, editors, and peer reviewers of systematic reviews.

The review followed the guidelines outlined in the Cochrane Handbook for Systematic Review of Interventions.

2.1. Eligibility criteria

The systematic review and meta-analysis followed the PICO framework. The population (P) comprised reproductive-age women diagnosed with ovarian endometriosis requiring laparoscopic surgical treatment. The intervention (I) was the therapeutic use of the Dane Fukang decoction for endometriosis. The comparison (C) evaluated the effectiveness of gestrinone in managing endometriosis. The primary outcome (O) measured changes in therapeutic efficacy, assessed by patient-reported outcomes.

Included were randomized controlled trials (RCTs) without language or publication year restrictions. Non-randomized studies, observational reviews, opinion pieces, and other non-experimental designs were excluded. Participants were females with ovarian endometriosis who underwent laparoscopic surgery, with an average age range of 29-36 years across studies. While endometriosis staging was not consistently reported, some studies included participants with stages I-IV. Information on infertility status was limited.

Postoperatively, the treatment group received the Dane Fukang decoction orally, typically 10g twice daily for 2-7 months. This herbal medicine contained Salvia miltiorrhiza, Curcuma zedoary, and Cyperus Rotundus. The control group received oral gestrinone, a synthetic progestin, at a typical dose of 2.5mg twice weekly for 2-7 months. Studies compared the effectiveness of these two post-operative interventions combined with initial laparoscopic surgery.

The primary outcome, " total effective rate" , categorized patients into four levels based on symptom relief: complete resolution, significant improvement, moderate improvement, or no improvement/worsening. Patients were deemed "Get well" or "markedly effective" if all significant symptoms of dysmenorrhea, dyspareunia, menstrual disorders, and pelvic masses/ nodules were completely resolved after treatment. The " effective" category included patients who experienced significant improvement, with 2-3 major symptoms relieved but not fully resolved and reduced pelvic mass size. Those termed "quite effective" only showed improvement in 1-2 symptoms, while others persisted. Patients were labelled " ineffective" if there was no change or worsening of symptoms post-treatment. The total effective rate was calculated by combining the proportions of cured, effective, and partially effective patients. It was determined by taking the sum of the number of cured patients, the number of effective patients, and the number of partially effective patients divided by the total number of patients. A higher total effective rate indicated better overall symptom relief and clinical efficacy for that particular treatment regimen in managing endometriosis.

2.2. Search strategy

Electronic databases, including PubMed, Embase, Scopus, Cochrane Library, Base, Google Scholar, and CNKI (China National Knowledge Infrastructure), were searched from their inception to January 31, 2024. The search strategy was constructed based on the PICO framework (Population, Intervention, Comparator, and Outcome), taking guidance from a previous related systematic review. The primary outcome of interest was the odds ratio for treatment efficacy, calculated as the number of patients cured, significantly improved, or improved divided by the total number of patients. Database alerts were also set up to identify any newly published studies meeting the criteria during this period.

All search results from the electronic databases were imported into Endnote reference management software and deduplicated. Titles and abstracts were screened to exclude irrelevant studies. Full texts of the remaining studies were independently assessed to determine final inclusion or exclusion, with any disagreements resolved through discussion.

A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram was prepared to summarise the search, screening, and selection decisions made during this process. Additionally, reference lists of included studies and relevant articles were manually screened to identify any additional eligible studies that may have been missed in the electronic database searches.

2.3. Study selection and quality appraisal

The retrieved studies were screened for eligibility according to predefined inclusion criteria. An initial screening involved reviewing the study titles and abstracts to identify those meeting eligibility criteria, which then advanced to the next stage for a critical assessment of the full-text articles. During this full-text review, it was determined whether the studies investigated the desired interventions and reported on relevant outcomes of interest. Additionally, the methodology and quality of each study were evaluated. In cases of disagreement on a study' s eligibility or methodological quality, a third party was consulted to resolve the differences.

The data extraction process follows a standardized form provided by Cochrane to ensure consistent extraction of relevant details from each included study. This process covers information such as author, publication year, sample size, average age of participants, average disease duration, post-surgery staging, clinical curative effects, treatment methods, and treatment durations. To ensure accuracy, any discrepancies in the extracted data will be resolved through consultation with an additional party to reach a consensus.

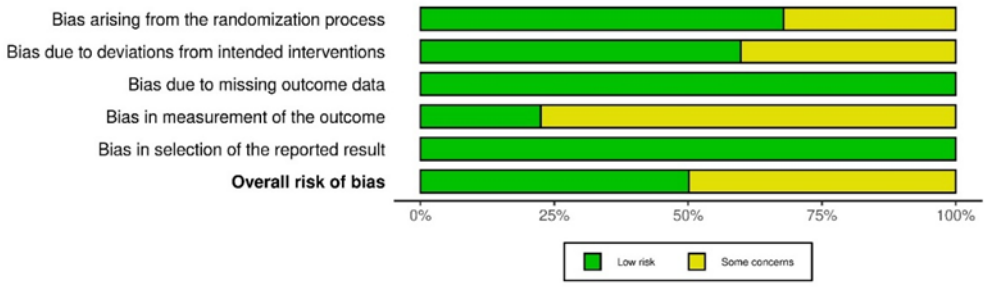

Figure 1. The risk of bias graph post-surgery treatment

The quality assessment process employed the Cochrane Collaboration's Risk of Bias tool, version 2.0 (RoB 2.0), to critically appraise the included randomized controlled trials. This comprehensive tool evaluates five key domains: randomization process, deviations from the intended intervention, missing outcome data, outcome measurement, and selective reporting. Each domain was assessed and scored as having a high, low, or unclear risk of bias. Any discrepancies in the assessment were resolved through discussion among the review team. Studies were classified as "high quality" if all domains demonstrated a low risk of bias, while those with high-risk ratings across all domains were considered "low quality". In cases where information was insufficient to make a definitive judgment, the study was classified as having an "unclear risk of bias". The assessment revealed that most studies exhibited a low risk of bias for the domains of missing

outcome data and selective reporting (green circles). However, some studies raised concerns regarding the randomization process, deviations from intended interventions, and outcome measurement, highlighting the need for caution in interpreting their results.

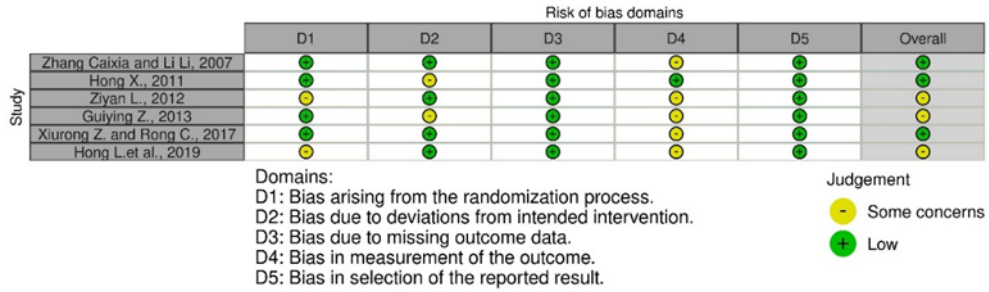

Figure 2. The Risk of Bias summary post-surgery treatment

2.4. Data synthesis and analysis

The study's eligibility for inclusion in the meta-analysis was evaluated through a systematic review process, with any disagreements resolved through team discussion and consensus. Following established meta-analytic approaches for randomized studies, categorical variables were analyzed using odds ratios (ORs) to increase the precision of the conclusions and detect treatment effects with greater power than single studies. The statistical synthesis methods were based on current practice in meta-analysis of binary outcomes, carefully considering systematic review principles to identify and summarize findings from all relevant studies. Statistical analyses were performed using R 4.2.1. Results were presented narratively if data analysis was not feasible due to insufficient data or significant heterogeneity across studies. The heterogeneity among the included studies was assessed using I-squared statistics and chi-squared tests, following guidelines from the Cochrane Handbook for Systematic Reviews of Interventions. When substantial heterogeneity was anticipated, a random-effects model was employed to pool effect sizes; otherwise, a fixed-effects model was used without significant heterogeneity. The funnel plot was examined to assess potential small-study effects and publication bias.

3. Results

3.1. Study screening

The screening involved removing duplicates, screening titles/abstracts, assessing full texts, and excluding studies that did not meet the eligibility criteria related to the interventions, outcomes, study design, etc. This sequential screening process yielded six studies that were ultimately included in the meta-analysis.

Initially, 298 records were identified through database searching from Pubmed, Embase, Scopus, Cochrane Library, BASE, Google Scholar, and CNKI. After duplicate records were removed, 283 records remained. These 340 records were screened, and 351 were excluded from screening titles and abstracts using inclusion and exclusion criteria. The remaining 32 full-text articles were assessed for eligibility. Among these, 32 full-text articles were further excluded for the following reasons: only pregnancy outcome (n=1), only recurrence rate (n=1), only adverse reactions (n=1), animal studies (n=5), incomplete outcome (n=4), non-surgery treatment (n=14). Ultimately,

six articles were included in the meta-analysis after this screening process. The flowchart is labelled as Figure 3. PRISMA Flow Diagram.

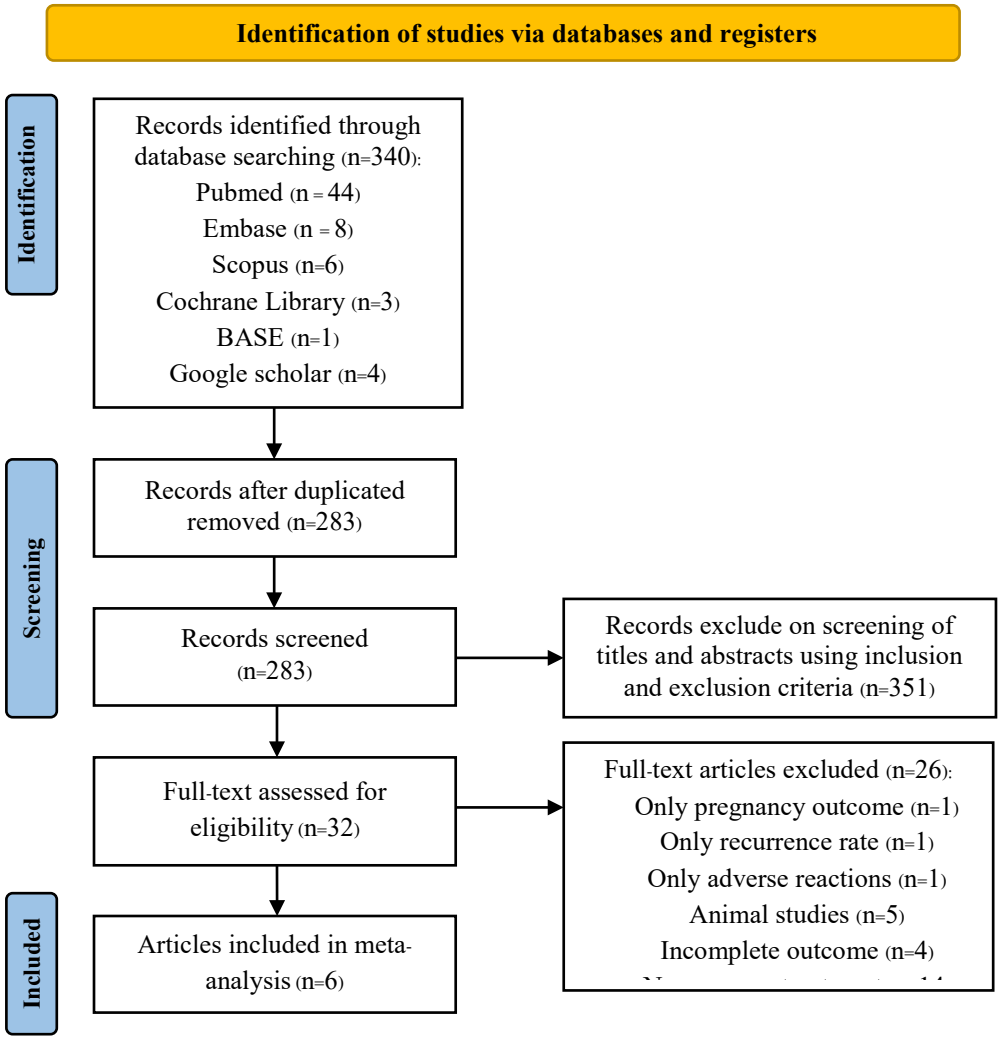

Figure 3. PRISMA flow diagram

3.2. Study characteristics

The data summarizes several studies examining surgical and herbal treatments for endometriosis. The surgical studies included are by Caixia and Li (2007), Hong (2011), Ziyan (2012), Guiying (2013), Xiurong and Rong (2017), and Hong et al. (2019). Each surgical study details the sample size of endometriosis patients, their age, disease duration, and, in some cases, post-surgery staging data, categorising patients into different disease severity levels after treatment. Across these studies, the patient characteristics such as sample size, average age, disease duration, and post-surgical staging showed no statistically significant differences.

Table 1. Baseline characteristics of participants in post-surgery studies included in the meta-analysis

No.	Author	Sample size (I/C)	Average age (I/C; months)	Average disease (I/C; months)	Post-surgery staging (I/C)	Clinical curative effect (I/C)			
						Get well	Significant improvement	Effective	Invalid
1	Caixia and Li (2007)	40/35	33.0±2.7 /34.0±5.4	not reported	I: II=18, III-IV=22, infertility=10; C: II=20, III-IV=15, pregnancy=7		25/13	13/12	2/2
2	Hong (2011)	87/71	36.21±5.25 /36.95±5.31	not reported	not reported	55/43	11/11	7/8	14/9
3	Ziyan (2012)	47/47	36.6	16.9	II=37, III=19, IV=16, infertility=22		33/18	10/14	4/15
4	Guiying (2013)	75/75	35.9±3.98 /36.7±6.8	17.9±3.4; 18.4±4.1	not reported		51/40	17/13	5/8
5	Xiurong and Rong (2017)	50/50	36.19±4.84	16.14±2.25	not reported		34/19	11/15	5/16
6	Hong et al. (2019)	40/40	29.3±1.4 /29.4±1.3	not reported	not reported		30/22	7/7	3/11

Table 2. Characteristics of efficiency outcome, treatment methods, and treatment course of post-surgery eligible studies included in the meta-analysis

No.	Author	Efficiency outcome	Treatment methods		Treatment course
1	Caixia and Li (2007)	pregnancy outcome, side effects	taken during non-menstrual period, 10 g/time, twice a day	start taking 2.5 mg twice a week, from the first day of the first menstrual cycle	3 months
2	Hong (2011)	comparison of serum CA125, improvement of dysmenorrhea symptoms, adverse reactions	start taking it on the 10th day before menstruation, 15 g/time	2.5 mg/time, twice a week	3 months
3	Ziyan (2012)	not reported	10 g/time, twice a day	2.5 mg/time, twice a week	6 months
4	Guiying (2013)	not reported	10 g /time, twice a day, during the menstrual period	2.5 mg/twice a week during non-menstrual periods	7 months
5	Xiurong and Rong (2017)	not reported	10 g/time, twice a day, 1 week after operation, and avoid the ovulation period.	2.5 mg/twice a week after operation	6 months
6	Hong et al. (2019)	indication of estradiol, luteinizing hormone, and follicle-stimulating hormone before and after treatment	10-15 g/time, twice a day	2.5 mg/time, twice a week, 1st day of menstruation, 2nd time three days later	2 months

The surgical studies also compared clinical outcomes, categorizing patients as cured entirely, showing significant improvement, some effect, or no effect from the interventions. Baseline disease severity and numbers of mild, moderate, and severe cases were reported, though some data fields

were incomplete. In addition to surgical management, other studies examined the use of herbal medicine treatments such as Dane Fukang decoction for improving menstrual symptoms and pregnancy rates in endometriosis patients.

3.3. Results of individual studies

To evaluate the efficacy of the treatment, the researchers used the 'Diagnosis and Treatment Standards of Integrated Traditional Chinese and Western Medicine for Endometriosis' as a guideline. The patients were classified into three or four groups based on these standards. The researchers calculated the total effective rate by adding the number of patients who achieved marked effects and those who were successfully treated, then dividing this sum by the total number of cases and multiplying the result by 100%. This rate provides an overall measure of the treatment's effectiveness. A higher total effective rate indicates that the treatment was successful for a more significant percentage of patients. The specific details of the clinical curative effects varied across the different studies.

According to Caixia and Li (2007), the treatment group (Dane Fukang decoction) had 40 cases. Twenty-five cases had dysmenorrhea and irregular abdominal pain disappear, with partial or complete relief of dyspareunia, resulting in an effective rate of 62.5%. Thirteen cases had occasional pain or irregular abdominal pain that was milder than before and showed a trend of reduction over time on the medication, resulting in an introductory effective rate of 32.5%. Two cases had no significant improvement in symptoms, yielding an ineffective rate of 5.0%. The control group (Gestrinone combined therapy) had 35 cases in total. During the medication period, all 35 cases developed amenorrhea and had no dysmenorrhea, with partial or complete relief of dyspareunia. After stopping the medication, 21 cases (60.0%) resumed normal menstruation without dysmenorrhea or dyspareunia. Twelve cases (34.3%) had occasional irregular vaginal bleeding that stopped after increasing the dose and reduced dyspareunia and abdominal pain. Two cases (5.7%) had no improvement in symptoms.

The study by Hong (2011) reported that 55 cases (63.22%) in the treatment group were considered "effective" compared to 43 cases (60.56%) in the control group. There was no statistically significant difference between the groups. Seven cases (8.05%) in the treatment group showed "improvement" compared to 8 cases (11.27%) in the control group. Eleven cases (12.64%) in the treatment group were considered "invalid," compared to 11 cases (15.49%) in the control group. In the treatment group, 80 cases (91.95%) had no adverse reactions and were deemed safe. Seven cases (8.05%) had mild adverse reactions but could continue taking the medication without treatment. After treatment, serum CA125 levels decreased significantly in both groups compared to before treatment ($p<0.05$), but the reduction was more significant in the treatment group compared to control ($p<0.05$). Dysmenorrhea symptoms improved significantly after 1, 2, and 3 menstrual cycles in both groups compared to baseline ($p<0.05$), with the treatment group showing greater improvement than the control group ($p<0.05$).

The study by Ziyan (2012) showed that after six months of treatment, in the treatment group, 33 of 47 cases were effective (70.21%), and 10 cases were in recovery (21.28%), for a total effective rate of 91.49%. The recurrence rate was 8.51% (4 cases relapsed). In the control group, 18 of 47 cases were effective (38.30%), and 14 cases were in recovery (29.79%), for a total effective rate of 68.09%. The recurrence rate was 31.91% (15 cases relapsed).

The effectiveness rate from the fourth study by Guiying (2013). After seven months of treatment, 51 of 75 cases were effective (68%), and 17 cases were in recovery (22.7%), for a total effective rate of 90.7%. The recurrence rate was 6.7% (5 cases relapsed). In the control group, 40 of

75 cases were effective (58.8%), and 13 cases were in recovery (17.3%), for a total effective rate of 76.1%. The recurrence rate was 10.7% (8 cases relapsed). The recurrence rate was also lower in the treatment group (6.7% vs. 10.7%). The differences between the two groups were statistically significant ($p<0.05$).

In the fifth study by Xiurong and Rong (2017), the treatment group using Dane Fukang decoction had an effectiveness rate of 90.0%, significantly higher than the 68.0% in the control group treated with gestrinone. The recurrence rate was also lower in the Dane Fukang decoction treatment group, at 10.0%, versus 32.0% in the gestrinone control group.

The study by Hong L. et al. (2019) The total effective rate of the group treated with Dane Fukang decoction was 92.5%, higher than the 72.5% in the gestrinone group. The recurrence rate was also lower in the Dane Fukang decoction group at 2.5% compared to 22.5% in the gestrinone group

3.4. Pooled analysis

The odds ratio for the study by Hong (2011) in Figure 4, is 0.76, with a 95% confidence interval ranging from 0.31 to 1.87. An odds ratio of less than 1 suggests that the experimental intervention is less effective than the control. However, the confidence interval for this study crosses the vertical line at the odds ratio of 1, indicating that the result is not statistically significant at the 95% confidence level.

From the above meta-analysis presented in the forest plot, the estimated random effects model odds ratio is 2.72, and the 95% confidence interval is (1.13, 6.54). The overall trend shows that the herbal medicine formulation Dane Fukang decoction demonstrated higher rates of patients achieving significant improvement or complete resolution of symptoms compared to the synthetic hormonal medication gestrinone.

The heterogeneity statistics assess the consistency of the treatment effect across studies. The I^2 value of 56% suggests moderate heterogeneity between the study results. The experimental treatment is superior to the control based on the pooled results from six studies, although there is some heterogeneity in the treatment effect between the individual trials.

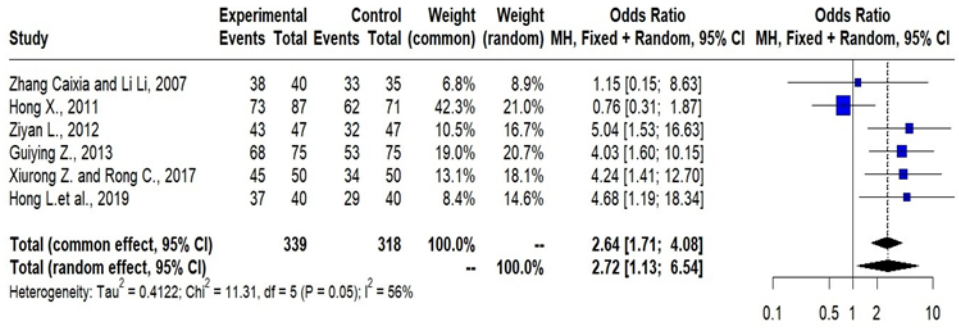

Figure 4. Forest plot

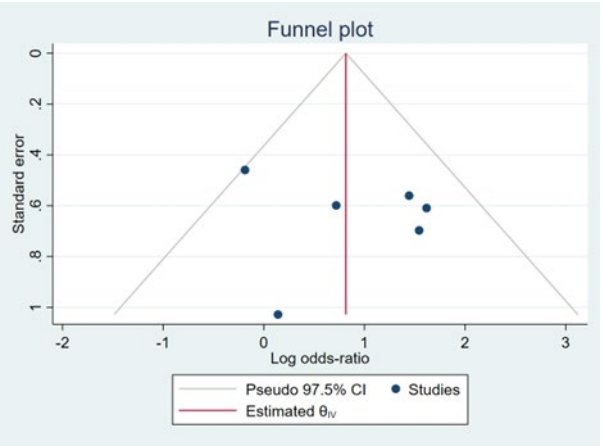

Figure 5. Funnel plot

The funnel shape is not entirely symmetric, suggesting the presence of some potential publication bias or small-study effects.

4. Discussion

In the post-surgical treatment setting, a meta-analysis comparing Dane Fukang decoction and gestrinone for the treatment of symptomatic endometriosis yields an estimated random effects model odds ratio of 2.72 (95% CI: 1.13-6.54, p=0.05), indicating that Dane Fukang decoction is associated with higher rates of significant symptom improvement or complete resolution than gestrinone. This finding is supported by the study of Wu SZ 2006a which combined laparoscopic diagnosis with active surgical intervention for both the Chinese Herbal Medicine (CHM) and gestrinone groups. In this study, laparoscopic treatment with either gestrinone or CHM as a post-surgical adjuvant therapy resulted in high symptomatic relief rates for both groups (95.65% for CHM and 93.87% for gestrinone).

4.1. Suggestions for future research

Future research should involve randomized controlled trials to explore Dane Fukang decoction's mechanisms of action, dosage optimization, and long-term efficacy and compare it to newer treatments.

4.2. Strengths and limitations

This meta-analysis demonstrates several methodological strengths in evaluating post-surgical treatments. The comprehensive literature search strategy and strict selection criteria yielded six randomized controlled trials with substantial sample sizes. The comparable clinical characteristics between treatment groups minimized potential confounding factors. The statistical approach, employing restricted maximum likelihood (REML) and random effects modeling, appropriately accounted for between-study variations. The results showed statistical significance with confidence intervals excluding 1 and p-values below 0.05, supporting the superior efficacy of Dane Fukang decoction over gestrinone in post-surgical settings.

However, certain limitations should be considered when interpreting these findings. The moderate heterogeneity observed in post-surgical treatment comparisons (I^2=56%) and the Tau^2 value indicating variability in true effect sizes suggest that treatment benefits may vary across

different contexts. The risk of bias assessment, while systematic, was constrained by the available information in published articles, particularly regarding intervention deviations and outcome measurement methods.

Additionally, the exclusive comparison between Dane Fukang decoction and gestrinone in post-surgical treatment may limit the generalizability of findings. Future research including more post-surgical interventions would better clarify relative treatment efficacy. While our findings support the use of Dane Fukang decoction in post-surgical care, further studies are needed to establish optimal treatment protocols and evaluate long-term outcomes.

5. Conclusion

In conclusion, this meta-analysis provides evidence supporting the role of Traditional Chinese Medicine in post-operative endometriosis care. The results demonstrate that Dane Fukang decoction shows superior efficacy compared to gestrinone during post-surgical treatment, as evidenced by statistical significance and positive odds ratios. These findings are particularly relevant in countries where traditional medicine is integrated into mainstream healthcare delivery systems, such as Thailand.

The results suggest that incorporation of Dane Fukang decoction into post-surgical treatment protocols may improve patient outcomes. However, further research is needed to determine optimal treatment conditions, including timing of intervention, standardization of dosage, and duration of therapy. Studies investigating interactions with conventional post-surgical treatments and long-term follow-up data would enhance our understanding of clinical applications.

The availability and cultural acceptance of Dane Fukang decoction within Asian healthcare settings demonstrates its promise as an effective adjunctive therapy for post-surgical endometriosis management. While these findings support the integration of traditional medicine in surgical care, additional studies are required to elucidate mechanism of action and establish standardized treatment protocols.

Ethical Approval

The study was conducted with ethical considerations for human research participants in accordance with document No. 107/2022, and was approved by the Ethical Review Committee for Human Research at the Faculty of Public Health, Mahidol University.

Registration

The research protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO), with the registration ID CRD42024491428.

Conflict of Interest

The authors declare no conflicts of interest in this systematic review and meta-analysis.

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