

Meta-analysis of Chinese medical therapy for treating patients with Hysteromyoma

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Introduction. To systematically evaluate the effect of nursing patients with syndrome of Chinese medicine.

Methods. Computer retrieval of CNKI, Wanfang, VIP, EMBase, Scopus, Web of Science, PubMed and Cochrane Library databases, collecting randomized controlled trials related to the application of nursing patients with syndrome of Chinese medicine, and tracking the references included in the literature, the retrieval time limit is from the establishment of the database to January 2024. After the selection of trials, data extraction and evaluation of methodological quality by 2 evaluators independently, RevMan 5.3 software was used for Meta analysis, and the Cochrane system was used to evaluate the quality of evidence.

Results. 8 studies were included, with a total of 694 subjects. They were randomly divided into test group and control group. There was no statistically significant difference between the two groups before treatment (all $P > 0.05$). After nursing, the indicators of the test group were significantly better than those of the control group, with statistically significant differences ($P < 0.05$).

Conclusion. Nursing patients with syndrome of Chinese medicine can improve symptoms quickly, and is conducive to the reduction of various risk indicators. However, due to the lack of high-quality literature, large-sample double-blind randomized trials are still needed in the future.

Abbreviations. TCM= Traditional Chinese Medicine, CI = Confidence interval, MD=Mean Difference.

Keywords. Hysteromyoma; Zheng Jia; Traditional Chinese Medicine; Meta-analysis; Health

INTRODUCTION

Hysteromyoma longs to the category of “mass in the abdomen” in Chinese medicine^[1], and its clinical manifestations mainly include abnormal menstruation, lower

abdominal mass and pressure sensation, which may be accompanied by frequent urination and urinary urgency, leucorrhoea, constipation, and even infertility. The concept of mass in the abdomen is unique to traditional Chinese medicine, and was first mentioned in Shennong's Classic of the Materia Medica (General Introduction), which states that “error drinking custom, addictive eating bias, accumulation, and mass in the abdomen”. The concepts of ZhengJia and accumulation are intertwined. Song dynasty “sheng ji zong lu” said: “the obstruction in the abdomen fetish knot, accumulation of synonyms.” Ming Dynasty, Zhang Jingyue said: “The disease of obstruction in the abdomen is an alias of accumulation.” With the development and progress of medicine, the definition of obstruction and accumulation was gradually clarified by the later medical doctors. In the Qing Dynasty, Ye Tianshi, a doctor of warm disease, recorded “accumulation” and “ZhengJia” in his “Guide to Medical Cases”, and discussed respectively "Accumulation, on the 'HuangMo' agglomeration, to the part of the meridian, belonging to the viscera for the yin, the yin is static, static and firm, belonging to the viscera for the yang, yang is active, moving and moving and uncertainty. Zheng, attributes to blood and food obstruction, tangible signs, certain and immobile; Jia is immaterial, agglomeration of Viscera qi, no form, push to move."

Modern medical doctors have reached a consensus that both include fixed and movable masses in the abdominal cavity, but accumulation refers to masses in the upper abdomen and obstruction refers to masses in the lower abdomen.

For a long time, the Chinese medicine has researched a large number of Chinese medicine programs with strong relevance in the process of regulating the obstruction in the abdomen. Therefore, in this study, we collected data from clinical trials on the adjuvant treatment of Hysteromyoma (zheng Jia) in patients with Chinese medicine, and objectively evaluated the adjuvant treatment effect of Chinese medicine on patients with Hysteromyoma by using Meta-analysis, in the hope of providing reliable medical evidence for future clinical adjuvant treatment.

1 INFORMATION AND METHODOLOGY

1.1 Sources

1.1.1 Literature Inclusion Criteria ① The literature is about the Randomized Controlled Trials (RCT) on the Chinese medicine therapy to adjuvant Hysteromyoma patients, and the literature is complete; ② The literature reports the diagnostic methods and bases of the obstruction of the abdomen; ③ The test group and the control group are comparable.

1.1.2 Exclusion Criteria ① The source of the research subjects mentioned in the literature is not clear; ② the result data in the literature is incomplete and the reason is not explained; ③ the same literature in different databases.

1.2 Methodology

1.2.1 Search strategy Using Hysteromyoma, Traditional Chinese Medicine, Nurse, Randomized controlled trial, RCT as the English search terms, and Zheng Zheng, Hysteromyomas, Chinese medicine adjuvant treatment, randomized controlled trial as the Chinese search terms, the combination of subject words and free words were used for the search. The search was performed by combining subject words and free words. The computer searched the major domestic and international academic literature databases CNKI, Wanfang, VIP, PubMed, EMBase, Scopus, Cochrane Library, and Web of Science to find RCTs on the application of TCM adjuvant treatment for patients with Hysteromyomas and to track the references of the included RCTs, and the timeframe for the literature search was from the establishment of the database to January, 2024

1.2.2 Screening the literature and extracting information The initial screening was conducted by two researchers: each read the titles and abstracts of the literature independently, excluded duplicates, excluded literature that did not meet the inclusion criteria, and read the full text of the literature that met the inclusion criteria. The two researchers checked the results of the included literature with each other, carried out

quality assessment, and if there was any disagreement, a third researcher was consulted to reach a consensus. Data were extracted on: time of publication; inclusion and exclusion criteria; general information about the members of the trial and control groups; interventions; and test indicators. If the included RCTs had incomplete late outcome data, the reason for data loss should be found in the original article.

1.2.3 Literature quality evaluation Two researchers will evaluate the quality of RCTs that are screened and decided to be included in the analysis by referring to the "Cochrane Collaboration's Risk of Bias Assessment Criteria". Specific content should include: random allocation method, masking of allocation scheme, blinding, blinding evaluation of outcomes, completeness of outcome data, and selective reporting of studies.

1.2.4 Conclusion indicators ① Complication rate; ② Satisfaction with adjuvant therapy; ③ Time to first anal defecation; ④ Anxiety score (Hamilton Anxiety Scale, HAMA); ⑤ Depression score (Hamilton Depression Scale, HAMD)

1.3 Statistical analysis Meta-analysis was performed using RevMan 5.3 software. Measurement data were evaluated by mean difference (MD), and count data were evaluated by relative risk (RR), and heterogeneity was determined by I^2 test, $I^2 < 25\%$ for no heterogeneity, $25\% < I^2 < 50\%$ for mild heterogeneity, all indicating that the difference was not statistically significant, and Meta analysis applied fixed effect model; $50\% < I^2 < 75\%$ for moderate heterogeneity, $I^2 > 75\%$ for severe heterogeneity, all indicating statistically significant differences, Meta-analysis applying a random-effects model, and if feasible, sensitivity analyses, and subgroup analyses should be performed to explain the source of heterogeneity. Meta-analysis applying a funnel plot to identify publication bias.

2 RESULTS

2.1 Literature search results A total of 367 papers were initially examined, and after excluding duplicates and papers that did not meet the requirements for inclusion, and reading the title, abstract and body in order, a total of 8 papers were finally included. There were a total of 694 patients, including 347 cases in the control group and 347

cases in the test group. The process of literature screening is shown in Figure 1, and the basic information of inclusion analysis is shown in Table 1.

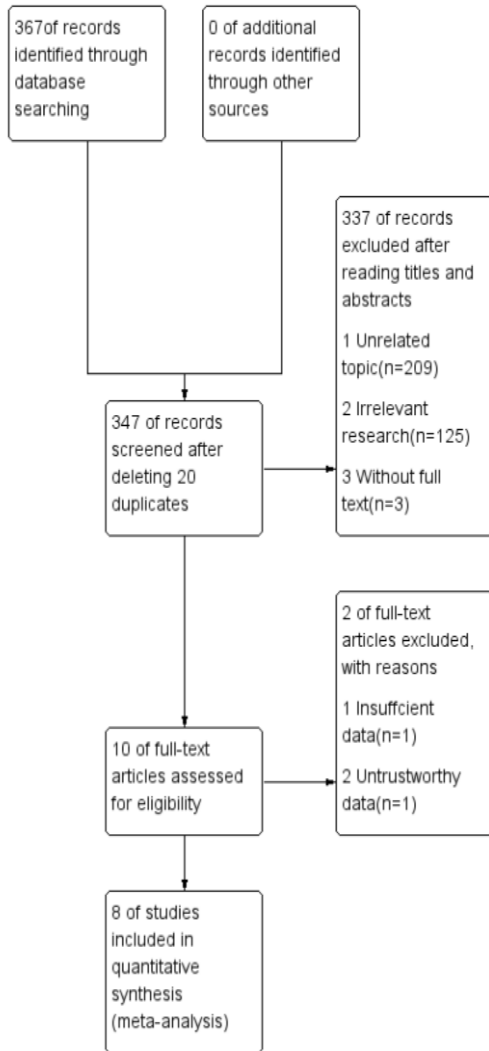


Figure 1 Literature screening process

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
曹玲 2017	+	?	+	+	+	+	+
朱卫平 2021	+	?	+	+	+	+	+
李明清 2018	+	?	+	+	+	+	+
李路路 2023	+	-	-	-	+	+	+
王夕文 2022	?	?	?	?	+	+	+
甘丰妹 2021	+	?	+	+	+	+	+
胡寿涓 2018	+	?	+	+	+	+	+
陈生梅 2015	+	?	+	+	+	+	+

Figure 2 Risk of bias assessment for each study

Table 1 Basic characteristics of the eight studies included in the efficacy Meta-analysis

first author	Year of publication	integrate into number of examples		Age (years)		intervention		conclusion norm
		test group	control subjects	test group	control subjects	test group	control subjects	
Hu	2018	46	46	32 - 54	30-55	support of Chinese medicine	regular therapy	①②
				43.2 ± 5.3	43.5 ± 5.5	emotional adjuvant therapy in Chinese medicine	Routine perioperative adjuvant interventions	②④⑤
Zhu	2021	40	40	36.95±4.3	37.19±4.9	+ routine perioperative adjuvant interventions	Routine perioperative adjuvant interventions	①②
				9	56	Traditional Chinese Medicine specializing in adjuvant stem Pre + perioperative routine adjuvant interventions		
Li	2023	47	47	40.42±5.14	40.38 ± 5.12	Chinese holistic therapy + comfort therapy	Comfort therapy	③
				48.1±3.7	46.2±4.5	Perioperative Chinese medicine adjuvant therapy	regular therapy	③
Wang	2022	48	48	35.09 ± 4.14	35.12 ± 4.28	Conventional adjuvant + Chinese medicine adjuvant	regular therapy	③
				42	42			
Gan	2021	42	42	40.56±3.35	40.62±3.41	General adjuvant intervention +Chinese Medicine Emotional and Spiritual Support	General adjuvant intervention	②④⑤
				40	40			
Cao	2017	40	40					

				40±5.23	44±4.12	Conventional adjuvant + regular therapy	①
Chen	2015	34	34			TCM adjuvant intervention	

Note: ① Complication rate; ② Satisfaction with adjuvant therapy; ③ Time to first anal defecation; ④ HAMA score; ⑤ HAMD score

2.2 Literature Quality Evaluation The quality of the eight included literature^[2-9] was evaluated and the results of the quality evaluation are shown in Figure 2.

2.3 Meta-analysis results

2.3.1 Comparison of complication rates after adjuvant treatment Three RCTs were included ^[2,4,9] involving a total of 254 patients (127 patients in the test group and 127 patients in the control group); Meta-analysis of complication rates after adjuvant treatment, using a fixed-effect model, showed that there was no heterogeneity among studies ($I^2=0\%$, $P=0.96$); the complication rate in the test group was 4% (5/127) and that in the control group was 20% (26/127). Test group was lower than that in the control group and the difference was statistically significant [$RR=0.19$, 95% CI: (0.08-0.48, $P=0.0005$)], as shown in Figure 3.

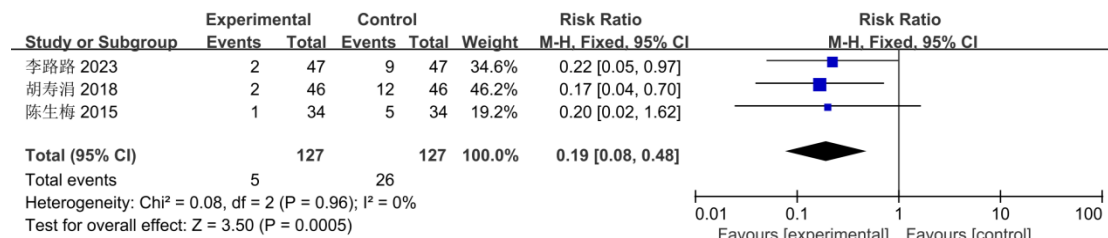


Figure 3 Meta-analysis comparing the complication rate after adjuvant therapy in the two groups of patients

2.3.2 Comparison of adjuvant satisfaction The four included RCTs^[2-4,8] involved a total of 346 patients (173 patients in the test group and 173 patients in the control group); Meta-analysis of adjuvant satisfaction, using a fixed-effects model, showed that there was no heterogeneity between studies ($I^2 = 0\%$, $P=0.83$); the satisfaction rate was 96% (166/173) in the test group and 76% (132/173) in the control group, and the

test group had higher satisfaction than the control group with statistically significant differences [RR=1.26, 95% CI: (1.15-1.37, P<0.83)]. 173), the satisfaction of the test group was higher than that of the control group and the difference was statistically significant [RR=1.26, 95% CI: (1.15-1.37, P<0.0001)], as shown in Figure 4.

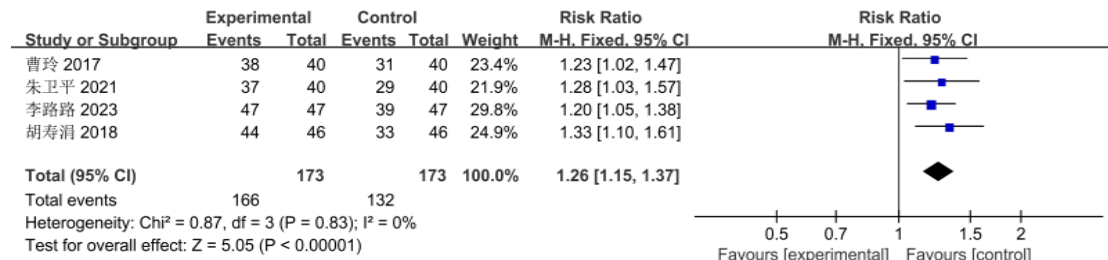


Figure 4 Meta-analysis comparing the satisfaction of adjuvant therapy between the two groups of patients

2.3.3 Comparison of the time to first anal defecation after adjuvant treatment The three RCTs^[5-7] included involved a total of 280 patients (140 patients in the test group and 140 patients in the control group); Meta-analysis of the comparison of the time to first anal defecation after adjuvant treatment in the two groups, there was a high degree of heterogeneity between the studies (I² = 92%, P<0.0001), and a random-effects model was used; the time to first anal defecation after adjuvant treatment in the two groups was statistically significance [MD=-13.42,95%CI:(-16.52 to -10.32,P<0.0001)], as shown in Figure 5.

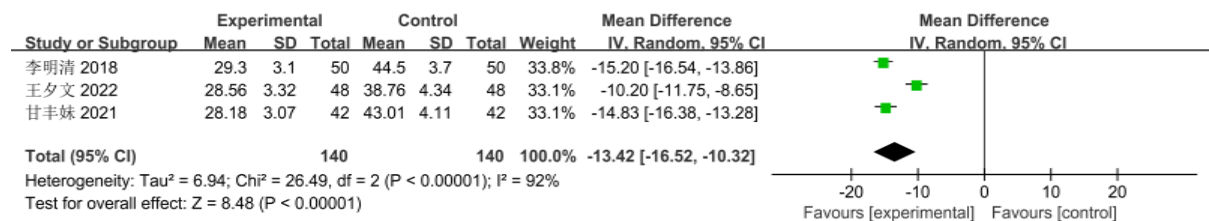


Figure 5 Meta-analysis of time to first exhaustion after adjuvant therapy in both groups of patients

2.3.4 Comparison of HAMA scores before and after adjuvant treatment The 2 RCTs^[3,8] included involved a total of 160 patients (80 patients in the test group and 80 patients in the control group); Meta-analysis of the comparison of HAMA scores before adjuvant treatment, using a fixed-effect model, there was no heterogeneity

between studies ($I^2 = 0\%$, $P=0.33$); the difference in the HAMA scores of the two groups before adjuvant treatment was not statistically significant [MD=-0.12 ,95%CI:(-1.16 to 0.92, $P=0.82$)], as shown in Figure 6. Meta-analysis comparing the HAMA scores after adjuvant treatment between the two groups, using a fixed-effects model, ($I^2 = 50\%$, $P=0.16$); the difference between the two groups of patients after adjuvant treatment, was statistically significant [MD=-4.67, 95%CI:(-5.49 to -3.85, $P<0.0001$)], as shown in Figure 7.

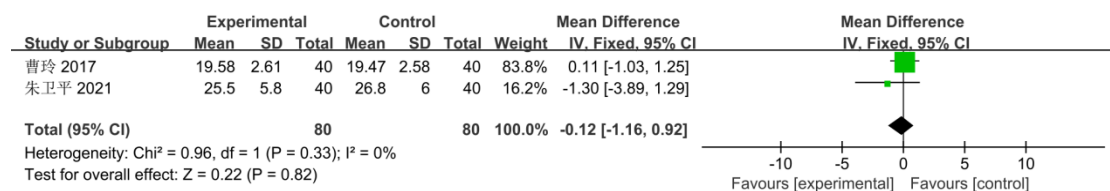


Figure 6 Meta-analysis of the comparison of HAMA scores before adjuvant treatment between the two groups of patients

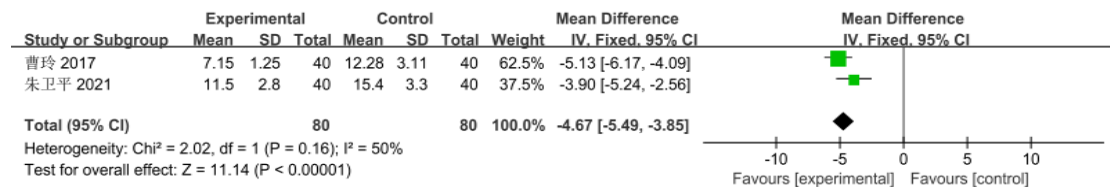


Figure 7 Meta-analysis comparing HAMA scores after adjuvant treatment in the two groups of patients

2.3.5 Comparison of HAMD scores before and after adjuvant treatment The 2 RCTs^[3,8] included involved a total of 160 patients (80 patients in the test group and 80 patients in the control group); Meta-analysis of the comparison of HAMD scores before adjuvant treatment was performed with a fixed-effects model, and there was no heterogeneity between the studies ($I^2 = 0\%$, $P=0.58$); the difference in the pre-adjuvant HAMD scores of the two groups was not statistically significant [MD=0.28, 95%CI:(-1.13 to 1.69, $P=0.70$)], as shown in Figure 8. Meta-analysis of the comparison of HAMD scores between the two groups after adjuvant therapy, using a fixed-effect model, ($I^2 = 0\%$, $P=0.91$); the difference between the two groups of patients after adjuvant therapy, was statistically significant [MD=-4.71, 95%CI:(-5.73 to -3.68, $P<0.0001$)], as shown in Figure 9.

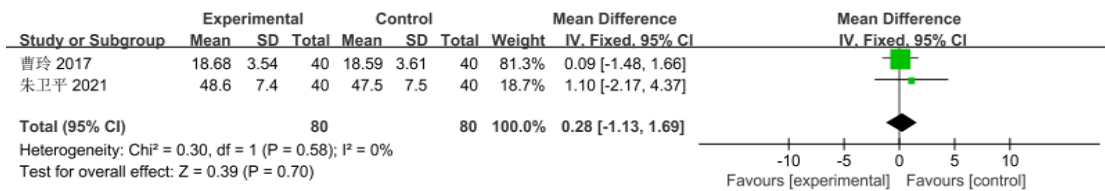


Figure 8 Meta-analysis comparing HAMD scores before adjuvant treatment in the two groups of patients

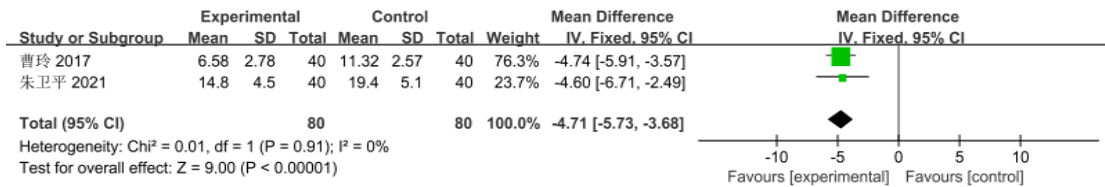


Figure 9 Meta-analysis comparing HAMD scores after adjuvant treatment in the two groups of patients

2.4 Publication bias analysis based on complication rates, adjuvant satisfaction outcomes The distribution of the included studies on both sides of the funnel was basically symmetrical, indicating that the possibility of publication bias was low. As in Figure 10, Figure 11.

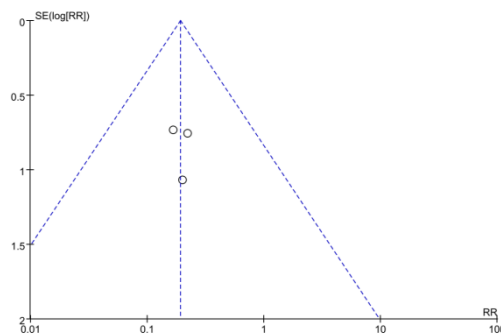


Figure 10 Funnel plot of publication bias test based on complication rate outcome

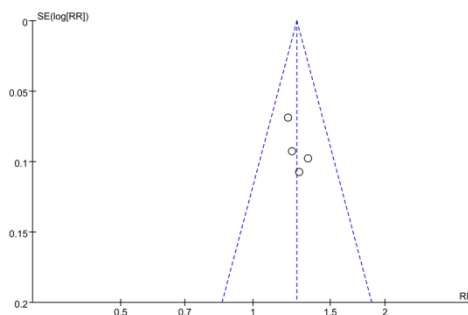


Figure 11 Funnel plot based on the publication bias test for adjuvant satisfaction endpoints

3 CONCLUSION

Hysteromyoma in the abdomen belongs to the category of gynecology in traditional Chinese medicine, which refers to the shaped mass in the pelvis of women, and the typical symptom is a mass in the lower abdomen with distension and pain, which may also cause abnormal menstruation and other symptoms, and it is closely related to Hysteromyoma ,ovarian cancer , and pelvic inflammatory masses in the modern medicine^[10].Hysteromyoma is a common benign tumor of the uterus, and some of its symptoms are similar to those of cervical cancer ^[11]. Chinese medicine believes that benign gynecological tumors are mostly caused by visceral disharmony, qi obstruction, phlegm and stasis. Zhang Xichun pointed out that the cause of women's artwork has two causes: one is due to blood stasis blocked in the Chong Ren, resulting in the disorder of Chong Ren, so the obstruction of the abdomen; the second is due to cold accumulation in the Xia Jiao, resulting in the reversal of the disorder of qi and blood, so the formation of the obstruction of the abdomen. Blood stasis and cold accumulation of disease, once the formation of the mass in the abdomen that is, injuring the positive qi, resulting in weakness, indicating that the positive deficiency and blood stasis is the main pathogenesis of the mass in the abdomen^[12]. Ye Tianshi believes that: the disease of obstruction in the liver and spleen, and the stomach and the eight veins are also responsible for the treatment of the method that is from the meridiansqi deficiency is to tonify the middle to move , qi stagnation is to open the depression in order to promote the passage of blood, blood failure to nourish the camp in order to pass through the blood, blood stasis into the blood in order to attack the paralysis, which is the treatment of the obstruction of the general strategy. Now the principle of treatment is broadly based on the following ideas: dispelling dampness and resolving phlegm, invigorating blood to replenish blood, promoting qi to pass stagnation, and breaking up blood to eliminate the symptoms^[13]. Ancient formulas have a high frequency of medicines for invigorating blood, warming the yang, regulating qi, and cathartic drugs, and the core prescriptions of which are Sizuo Tang and Guizhi Poria Pill ^[14]. Chinese medicine adjuvant treatment is adjuvant

treatment under the guidance of the basic theory of Chinese medicine, there are a variety of special techniques, such as moxibustion, Gua Sha. Moxibustion has a better efficacy of moving qi and warming the meridians to dissipate the cold^[15], and Gua Sha can support the positive to dispel the evil spirits, dissolve the stasis, and dredge the meridians and collaterals^[16], and these adjuvant treatment modalities are widely used in the clinical adjuvant treatment.

4 DISCUSSION

A total of 8 RCTs with a total of 694 patients with Hysteromyomas were included in this Meta-analysis, and the results of the Meta-analysis showed that the improvements in the index levels of the test group after treatment were all significantly better than those of the control group. It indicates that TCM adjuvant treatment for patients with Hysteromyomas can promote recovery faster and possess better overall efficacy. This Meta-analysis of TCM adjuvant treatment is an enhancement and improvement of the original adjuvant treatment, not an abandonment of the original adjuvant treatment.

There was a high degree of heterogeneity in 1 indicator in this study, which was analyzed and could be explained by: (1) differences in the age and gender composition of the patients included in each RCT; (2) some differences in the physical condition of the patients in each RCT; and (3) the presence of combined medications in some RCTs, and differences in therapeutic efficacy.

There are some limitations in this Meta-analysis: (1) the sample size of RCTs is small, which may have some impact on the evaluation of the results; (2) the time of the first exhaustion was mentioned in one RCT, but the unit was days, which was rather general, so it was not discussed; (3) one RCT did not use blinding, so there may be bias in the study; (4) due to the lack of foreign RCTs on the application of Chinese medicine to adjuvant treatment of patients with uterine leiomyosarcoma, the conclusion of Meta-analysis may be controversial.

In conclusion, TCM adjuvant treatment for patients with Hysteromyomas has

good efficacy and is worth applying and popularizing, but it is necessary to design randomized controlled studies with larger samples to provide more high-quality research bases for secondary evaluations, so as to better demonstrate the efficacy of TCM adjuvant treatment for patients with obstruction in the abdomen and to evaluate the value of its popularization.

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