



Five commonly used traditional Chinese medicine formulas in the treatment of ulcerative colitis: A network meta-analysis

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Abstract

BACKGROUND

Currently, traditional Chinese medicine (TCM) formulas are commonly being used as adjunctive therapy for ulcerative colitis in China. Network meta-analysis, a quantitative and comprehensive analytical method, can systematically compare the effects of different adjunctive treatment options for ulcerative colitis, providing scientific evidence for clinical decision-making.

AIM

To evaluate the clinical efficacy and safety of commonly used TCM for the treatment of ulcerative colitis (UC) in clinical practice through a network meta-analysis.

METHODS

Clinical randomized controlled trials of these TCM formulas used for the adjuvant treatment of UC were searched from the establishment of the databases to July 1, 2022. Studies that met the inclusion criteria were screened and evaluated for literature quality and risk of bias according to the Cochrane 5.1 standard. The methodological quality of the studies was assessed using ReviewManager (RevMan) 5.4, and a funnel plot was constructed to test for publication bias. ADDIS 1.16 statistical software was used to perform statistical analysis of the treatment measures and derive the network relationship and ranking diagrams of the various intervention measures.

RESULTS

A total of 64 randomized controlled trials involving 5456 patients with UC were

included in this study. The adjuvant treatment of UC using five TCM formulations was able to improve the clinical outcome of the patients. Adjuvant treatment with Baitouweng decoction (BTWT) showed a significant effect [mean difference = 36.22, 95% confidence interval (CI): 7.63 to 65.76]. For the reduction of tumor necrosis factor in patients with UC, adjunctive therapy with BTWT (mean difference = -9.55, 95%CI: -17.89 to -1.41), Shenlingbaizhu powder [SLBZS; odds ratio (OR) = 0.19, 95%CI: 0.08 to 0.39], and Shaoyao decoction (OR = -23.02, 95%CI: -33.64 to -13.14) was effective. Shaoyao decoction was more effective than BTWT (OR = 0.12, 95%CI: 0.03 to 0.39), SLBZS (OR = 0.19, 95%CI: 0.08 to 0.39), and Xi Lei powder (OR = 0.34, 95%CI: 0.13 to 0.81) in reducing tumor necrosis factor and the recurrence rate of UC.

CONCLUSION

TCM combined with mesalazine is more effective than mesalazine alone in the treatment of UC.

Key Words: Network meta-analysis; Traditional Chinese medicine; Ulcerative colitis; Mesalazine; Treatment

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Core Tip: This study aimed to evaluate the clinical efficacy and safety of commonly used traditional Chinese medicines (TCM) for the treatment of ulcerative colitis (UC), in clinical practice, through a network meta-analysis. A network meta-analysis of the five types of TCM formulas can provide a rational and personalized plan for the selection and use of TCM as clinical adjuvant therapy for UC. TCM formulas combined with mesalazine exhibit a better effect in treating UC compared to using mesalazine alone. The adjuvant treatment of UC with TCM formulas can improve clinical efficacy, repair the intestinal mucosa, improve the immunity of the body and the quality of life of patients, and reduce the probability of disease recurrence.

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INTRODUCTION

Traditional medicines, such as traditional Chinese medicine (TCM) and Ayurveda, have been used for hundreds to thousands of years and possess unique theoretical benefits, making them invaluable to clinical practice[1]. Traditional medicine has significant advantages over modern medicine in the treatment of certain diseases, such as diabetes, hypertension, cardiovascular diseases, cancer, digestive disorders, and mental disorders[2]. Additionally, some modern pharmaceuticals are limited in their clinical application due to their side effects. Moreover, traditional medicines play an important role in preventing the onset and progression of diseases[3].

Ulcerative colitis (UC) is a chronic, nonspecific, continuous, intestinal inflammatory bowel disease observed mainly in the colorectal mucosa and submucosa[4]. It gradually spreads to the whole colon and can damage the ileocecum. The primary clinical manifestations are chronic or subacute diarrhea, mucus, pus, blood in the stool, and abdominal pain. The incidence and prevalence of UC have been increasing worldwide[5]. Colectomy is required in approximately 15% of the patients with the condition[6]. The etiology of UC remains unclear, and the disease course is long and prone to recurrence. Currently, amino salicylic acids, glucocorticoids, and immunomodulatory and biological drugs are commonly used in the clinical treatment of UC. However, long-term or high-dose use of these drugs can cause serious adverse reactions, such as increased abdominal pain, kidney damage, liver toxicity, and blood disorders[7-9].

In recent years, basic and clinical research on the adjuvant treatment of UC with TCM formulations has demonstrated remarkable curative effects. TCM improves the clinical efficacy of the treatment, repairs the state of the intestinal mucosa, and increases the body's immunity to prevent recurrence. Currently, TCM is widely used for the treatment of UC in clinical practice in China[10]. In this study, the five most commonly used TCM formulas for the treatment of UC [Baitouweng decoction (BTWT), Shenlingbaizhu powder (SLBZS), Xi Lei Powder (XLS), Shaoyao decoction (SYT), and Chang-yan-ning (CYN)] were screened through sorting of relevant literature, data mining, and statistical analyses to re-evaluate their clinical efficacy. All five herbal remedies are approved by the Chinese State Drug Administration for the treatment of UC. UC is clinically similar to "Li Ji" in TCM in terms of clinical symptoms. The primary treatment methods involve clearing heartburn and draining dampness, tonifying the qi of the spleen and stomach, eliminating dead and regenerating novel tissues, and regulating the qi and harmonization of the blood. BTWT originated from the "Treatise on Exogenous Febrile Disease." It clears heat burn, removes toxins, cools the blood, and stops diarrhea[11]. SLBZS originated from the "Taiping Imperial Pharmacy in the Song Dynasty." It supplements the qi, strengthens the spleen, drains dampness, and stops diarrhea[12]. XLS originated from the "Golden Chamber Wing." It clears the heat required to detoxify the system as well as eliminate dead tissues and regenerate novel tissues[13]. SYT was obtained from the "Suwen Pathological Qi Proper Life Preservation Collection." It clears heat, eliminates dampness, and regulates and harmonizes

the qi and blood[14]. CYN is widely used in modern Chinese medicine. It can reduce body heat, remove toxins, stop bleeding, and promote the regeneration of novel tissues[15]. No systematic network evaluation of the clinical efficacy of these five TCM formulas has been carried out for the adjuvant treatment of UC, even though their pharmacological effects have been investigated by researchers[16-20]; this provides a theoretical basis for our study on the clinical efficacy of the five commonly used TCM formulas in the treatment of UC.

This study aimed to compare the efficacy of five TCM formulas as adjuvant treatments for UC using a network meta-analysis (NMA). According to the efficacy indicators, the treatment measures with the best clinical effects should be sorted and screened to provide reliable evidence-based medical interventions for clinical use. The team obtained an international registration number, CRD42022360996, from PROSPERO for this study. The names of the herbs mentioned in the article have been verified in Medicinal Plant Names Services (<http://mpns.kew.org>) and Chinese Medicinal Material Images Database (<https://Library.hkbu.edu.hk/electronic/Libdbs/mmd/>).

MATERIALS AND METHODS

Inclusion criteria

Type of study: A randomized controlled trial (RCT) of five commonly used Chinese herbal formulas for the treatment of UC was carried out. The languages were limited to Chinese and English.

Research objective: The patients conformed to the "Consensus Opinions on the Diagnosis and Treatment of Inflammatory Bowel Disease (2018 Beijing)"[21], and the age, sex, and race of the patients were not restricted.

Interventions: The control intervention was mesalazine or mesalazine + placebo. Based on the control group, the experimental group was treated with TCM. The route of administration was either oral or through enema.

Outcomes: The primary outcome measures were evaluated as follows:

Clinical effect: The clinical effect of the two groups of patients was evaluated according to the Consensus on the Diagnosis and Treatment of Inflammatory Bowel Disease (Beijing, 2018)[21]. The clinical effect was mainly divided into three grades: particularly effective: symptoms disappeared after colonoscopy, and colonic mucosa returned to normal; effective: colonoscopy showed notable improvement in colonic mucosal symptoms with mild inflammation; and ineffective: no remarkable improvement in symptoms or colonoscopy results. Total efficiency = [(Particularly effective + effective)/total number of cases] × 100%.

Colonoscopy: The colonoscopy scores and pathological changes in the two groups before and after treatment were evaluated using Baron's four-point scale[19]: (1) Normal: the mucosa was normal; (2) Mild abnormalities: colonoscopy showed unclear mucosal vascular texture and congestion, without bleeding; (3) Moderate abnormality: the mucous membrane was granular and bled easily when exposed; and (4) Severe abnormality: mucosal ulceration and spontaneous bleeding.

The levels of tumor necrosis factor (TNF) in the serum are used to reflect the inflammatory activity within the body.

The Inflammatory Bowel Disease Questionnaire (IBDQ)[22] is a scale used to evaluate the quality of life.

Recurrence rate: The probability of the disease recurring within 1 year after the patient has undergone treatment and discontinued medication.

Incidence of adverse reactions: Adverse reactions refer to any unfavorable and unintended medical occurrences that arise in patients following drug therapy, vaccination, or other medical interventions. Based on the literature, we classified the adverse reactions into common adverse reactions and rare adverse reactions. Common adverse reactions included pain, headache, diarrhea, frequent urination, vomiting, nausea, decreased appetite, and dizziness, whereas rare adverse reactions included hepatotoxicity, pancreatitis, profound leukopenia, cardiac toxicity, and respiratory symptoms[23,24].

Exclusion criteria

The exclusion criteria included: (1) UC with serious complications; (2) Severe underlying diseases, mental diseases, and patients with allergies to the drugs used in this study; (3) Full text not available or duplicate publications; or (4) Conference papers, gray literature, and master's degree papers.

Document retrieval

Literature search strategy: The China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Scientific Journal Database (VIP), Chinese Biomedical Literature Database (SinoMed), PubMed, Cochrane Library, and Web of Science databases were searched using a computer. The retrieval period was from the establishment of the database to July 1, 2022. The search methods included: (Ulcerative Colitis) AND (Mesalazine) AND (Baitouweng decoction or Shaoyao decoction or Shenling Baizhu or Xi Lei powder Changyanning) AND (clinical). The retrieval method for each database was adjusted according to its characteristics. For example, the CNKI advanced search included: Academic Journal [Subject: Ulcerative Colitis (Precise)] AND [Subject: Mesalazine (Precise)] AND [Excerpt: Clinical (Precise)] AND [Excerpt: Baitouweng decoction + Shaoyao decoction + Shenling Baizhu + Xi Lei powder + Changyanning (Exact)]. The English search terms included: "ulcerative colitis," "UC," "mesalazine," "tcm," "Chinese medicine," and "TCM." For example, the PubMed advanced search included: {[(UC) OR (ulcerative colitis)] AND [(TCM) OR (TCM) OR (Chinese

medicine)] AND (mesalazine)}. A specific search formula is provided in the [Supplementary material](#).

Data extraction: Literature was retrieved according to the established literature retrieval strategy, and the retrieved literature bibliography was imported into NoteExpress 3.5 software; duplicate literature was deleted using the software's duplicate-checking function. The remaining literature was selected according to the established inclusion and arrangement standards, and unqualified literature was deleted by reading the titles and abstracts of the literature. The full texts of the remaining studies were downloaded and filtered. This study was performed independently by two researchers. If there were any disagreements, discussions were carried out with a third researcher to decide whether to include the relevant literature. An Excel sheet was created to extract information such as the author(s), publication time, publication journal, age, sex, sample size, intervention measures, course of treatment, outcome indicators, and number of corresponding cases.

Quality evaluation: The Cochrane Risk-of-Bias Assessment Tool was developed by the Cochrane Collaboration. Seven aspects of the literature were evaluated, namely random allocation methods, allocation scheme concealment, blinding of subjects and intervention providers, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias[25].

Statistical analysis

The methodological quality of the included studies was assessed using ReviewManager (RevMan) version 5.4, and funnel plots were constructed to test for publication bias. ADDIS 1.16 statistical software packages were used for the statistical analyses of the treatment measures, and network relationship and ranking diagrams of the various intervention measures were created simultaneously. The software is based on the Bayesian Markov Chain-Monte Carlo algorithm[26] and convergence assessment of the data results for random effects models. Four chains were used for the simulation analysis; the initial value was 2.5, the refinement iteration step was 10, the number of adjustment iterations was 20000, and the number of simulation iterations was 50000. Statistical significance was considered at $P < 0.05$, and a 95% confidence interval (CI) was considered as the standard of statistical difference. For the enumeration data, the odds ratio (OR) was used as the efficacy analysis statistic. The mean difference (MD) and standardized MD were used for data measurement. Heterogeneity was assessed using the Cochrane Q test (with the significance level set at $P < 0.05$) and I^2 statistics ($I^2 > 50\%$)[27]. A sensitivity analysis was performed using a one-by-one elimination method. Each effect size was expressed as a 95% CI. A node-split model was used for inconsistency testing. No statistical difference between studies in the subgroup ($P > 0.05$) indicated that the included studies had minute heterogeneity; therefore, the consistency model was used for analysis. Otherwise, the inconsistency model was used for analysis ([Supplementary Figure 1](#)). The potential scale reduction factor reflects convergence; when the value is close to or equal to 1, a good convergence performance is achieved, and the results obtained by the consistency model analysis are more credible[28].

RESULTS

Literature search results

A total of 1698 articles were initially identified. After reading the titles, abstracts, and full texts, 64 RCTs were included. The specific literature screening process and results are shown in [Figure 1](#).

Basic characteristics and risk of bias assessment results of the included studies

A total of 64 RCTs[24,29-91], involving 5456 patients with UC, were included. The interventions in the experimental group were mesalazine combined with herbal formulae, which were BTWT in 19, SLBZS in 20, CYN in 7, SYT in 10, and XLS in 8 patients. The interventions in the control group were all mesalazine treatments, with the same dosages and methods in the two groups of chemical drugs. Fifty-eight studies were randomized, and the grouping methods of six studies[24,42,72-75] were not mentioned. Referring to the specific randomization method, one study[30] had case dropouts, and another study[81] used a double-blind method. The basic characteristics of the included studies are shown in [Table 1](#), and the risk-of-bias assessment is shown in [Figure 2](#). The results are presented in [Supplementary Figure 2](#).

Consistency analysis and NMA

Sensitivity analyses for the three outcome indicators were conducted with $I^2 > 50\%$ ([Supplementary Figure 3](#)). All the studies were two-arm studies, and a consistency analysis was performed on the following five indicators of clinical response rate: Colonoscopy Baron score, TNF, IBDQ, and recurrence rate ([Figure 3](#) and [Supplementary Figure 3](#)). The analysis revealed that the PSFR parameters ranged between 1 and 1.1, indicating good convergence; therefore, an NMA was carried out as a result of the consistent model. The size of the nodes is related to the number of participants in that intervention type, and the thickness of the lines between interventions is related to the number of studies for that comparison.

Clinical efficacy: The OR was used as the effect size for the clinically effective rate. Fifteen direct and indirect comparisons were generated in the NMA, and five differences were statistically significant. [Table 2](#) shows the comparison of each intervention with the mesalazine treatment group. BTWT (OR = 3.99, 95% CI: 2.95 to 5.84), Changyanning (OR = 5.58, 95% CI: 3.25 to 10.78), SLBZS (OR = 3.28, 95% CI: 2.50 to 4.39), SYT (OR = 3.66, 95% CI: 2.40 to 6.21), and tin powder (OR = 5.33, 95% CI: 3.12 to 10.66). The five TCM formulas were clinically effective for the adjuvant treatment of UC and

Table 1 Characteristics of included studies

Ref.	Average age in yr		Sample size		Interventions		Course	Outcomes
	T	C	T	C	T	C		
Wei and Mao [39], 2021	44.44 ± 6.78	44.36 ± 6.77	51 (34/17)	51 (32/19)	A (bid)	F	3 mo	(3)
Yu <i>et al</i> [37], 2022	43.6 ± 11.8	24.8 ± 8.6	30 (14/16)	30 (17/13)	A (bid)	F	8 wk	(1) (2) (6)
Chen and Lin [40], 2021	44.97 ± 8.31	42.24 ± 7.85	60 (30/30)	60 (32/28)	A (bid)	F	3 mo	(1) (4) (6)
Ma <i>et al</i> [46], 2019	43.41 ± 8.02	41.68 ± 9.46	42 (22/20)	42 (21/21)	A (bid)	F	3 mo	(1) (4) (6)
Han <i>et al</i> [49], 2018	43.44 ± 11.04	42.71 ± 10.15	32 (17/15)	32 (16/16)	A (bid)	F	1 mo	(1) (4) (6)
Ma <i>et al</i> [44], 2020	41.4 ± 10.8	42.5 ± 9.9	70 (46/24)	70 (44/26)	A (bid)	F	4 wk	(1) (6)
Chen and Yao [53], 2016	46.47 ± 8.92	46.86 ± 9.05	43 (18/25)	42 (19/23)	A (qd)	F	4 wk	(1) (5)
Xu and Ma [47], 2019	56.3 ± 6.8	56.1 ± 7.5	62 (31/31)	62 (30/32)	A (qd)	F	1 mo	(1) (2) (6)
Xue [50], 2018	40.35 ± 6.24	40.59 ± 6.17	61 (30/31)	61 (31/30)	A (qd)	F	1 mo	(1)
Jing <i>et al</i> [41], 2021	34.12 ± 5.17	33.62 ± 5.14	52 (28/24)	50 (27/23)	A (qd)	F	8 wk	(1) (3) (6)
Wei <i>et al</i> [24], 2020	43.51 ± 4.52	43.45 ± 4.56	65 (39/26)	65 (36/29)	A (qd)	F	4 wk	(1) (2) (3) (4)
Wang <i>et al</i> [48], 2019	33.3 ± 3.6	33.6 ± 4.0	34 (20/14)	34 (22/12)	A (bid)	F	4 wk	(1) (6)
Liu [42], 2021	46.53 ± 10.39	46.56 ± 10.41	41 (19/22)	41 (20/21)	A (qd)	F	4 wk	(1)
Liu [54], 2015	41.3 ± 2.5	42.6 ± 3.7	55 (32/23)	52 (27/25)	A (qd)	F	4 wk	(1)
Nie <i>et al</i> [45], 2020	45.27 ± 13.19	44.59 ± 12.87	60 (29/31)	60 (25/35)	A (bid)	F	12 wk	(3) (4) (6)
Lu [43], 2021	32.8 ± 4.5	33.5 ± 4.0	30 (16/14)	30 (18/12)	A (bid)	F	12 wk	(1) (2) (3)
Dai <i>et al</i> [38], 2022	39.69 ± 2.45	41.35 ± 1.94	30 (19/11)	30 (17/13)	A (bid)	F	1 wk	(1)
Gu [51], 2018	45.32 ± 6.13	45.11 ± 6.34	35 (15/20)	35 (16/19)	A (qd)	F	4 wk	(1) (5)
Jin and Li [52], 2018	48.32 ± 4.52	47.88 ± 4.32	40 (23/17)	40 (22/18)	A (bid)	F	4 wk	(1)
Wang <i>et al</i> [88], 2017	34.56 ± 5.58	34.18 ± 5.25	32 (17/15)	32 (16/16)	B (bid)	F	4 wk	(1) (6)
Yao <i>et al</i> [89], 2021	44.1 ± 7.3	45.6 ± 8.0	65 (29/36)	62 (30/32)	B (bid)	F	4 wk	(1) (4)
Zhu <i>et al</i> [86], 2021	43.05 ± 14.53	45.12 ± 13.38	35 (16/19)	35 (18/17)	B (bid)	F	3 mo	(1) (2) (6)
Li <i>et al</i> [90], 2021	38.16 ± 5.43	37.36 ± 6.72	25 (14/11)	25 (16/9)	B (bid)	F	1 mo	(1) (2) (3)
Lei <i>et al</i> [84], 2016	45.1 ± 4.9	45.1 ± 4.9	35 (15/20)	35 (18/17)	B (bid)	F	8 wk	(1) (5) (6)
Wang and Zhou [82], 2017	32.91 ± 4.45	33.14 ± 4.78	49 (26/23)	49 (27/22)	B (bid)	F	6 wk	(1) (3) (6)
Chen <i>et al</i> [91], 2018	38.5	37.9	36 (20/16)	36 (21/15)	B (qd)	F	3 wk	(1) (3)
Sheng <i>et al</i> [83], 2017	34.64 ± 2.98	37.26 ± 2.47	48 (26/22)	48 (23/25)	B (tid)	F	4 wk	(1) (6)
Ding [87], 2019	34.1 ± 3.8	34.5 ± 3.7	38 (20/18)	38 (22/16)	B (bid)	F	8 wk	(1) (2) (6)
Chen and Ye [85], 2014	32.15 ± 4.82	32.84 ± 4.36	39 (21/18)	39 (20/19)	B (bid)	F	6 wk	(1) (3) (6)
Wang [34], 2016	25.6 ± 2.3	26.5 ± 4.1	58 (32/26)	58 (35/23)	C (qd)	F	3 wk	(1) (5) (6)
Meng [33], 2017	54 ± 18	51 ± 17	28 (18/10)	28 (16/12)	C (qd)	F	3 wk	(1) (2) (6)

Zhu and Xie[30], 2009			28	27	C (qd)	F	4 wk	(1) (5) (6)
Liu[35], 2015	38.9 ± 3.4	37.4 ± 2.5	30 (14/16)	26 (11/15)	C (qd)	F	8 wk	(1)
Cai <i>et al</i> [32], 2022	30.24 ± 2.17	30.17 ± 2.0	38 (17/21)	38 (19/19)	C (qd)	F	8 wk	(1) (3) (6)
Ma <i>et al</i> [36], 2016	41.2	39.8	26 (14/12)	20 (11/9)	C (qd)	F	3 mo	(1) (5)
Cheng <i>et al</i> [29], 2011	65.3 ± 2.6	65.3 ± 2.6	22	22	C (qd)	F	4 wk	(1) (6)
Xu and Wang [31], 2010	38.4	38.4	42 (29/13)	42 (25/17)	C (qd)	F	4 wk	(1) (6)
Wang[55], 2021	31.5 ± 7.1	31.9 ± 5.4	48 (26/22)	48 (27/21)	D (tid)	F	3 mo	(1)
Li and Wang [57], 2021	47.33 ± 8.52	46.50 ± 7.87	45 (26/19)	45 (25/20)	D (bid)	F	8 wk	(1) (3)
Yin <i>et al</i> [56], 2021	43.6 ± 5.2	42.3 ± 5.6	60 (31/29)	60 (30/30)	D (qd)	F	8 wk	(1) (2) (3) (5) (6)
Liu <i>et al</i> [58], 2021	39.79 ± 10.41	40.28 ± 9.85	58 (36/22)	58 (34/24)	D (tid)	F	3 mo	(1) (6)
Zhu <i>et al</i> [59], 2020	38.5 ± 7.4	40.2 ± 7.8	25 (15/10)	25 (16/9)	D (tid)	F	3 mo	(3)
Liang and Wang [60], 2020	43.02 ± 11.36	44.32 ± 10.63	61 (44/17)	61 (42/19)	D (bid)	F	8 wk	(1) (3) (6)
Tian <i>et al</i> [61], 2019	42.82 ± 10.26	42.74 ± 10.1	66 (35/31)	66 (34/32)	D (tid)	F	12 wk	(1) (3) (5)
Zhang[62], 2018	51.31 ± 14.71	50.00 ± 15.14	16 (8/8)	14 (6/8)	D (tid)	F	12 wk	(1) (5)
Yang and Yan [63], 2018	38.25 ± 7.36	37.85 ± 7.06	43 (26/17)	43 (25/18)	D (tid)	F	12 wk	(1) (3) (6)
Zhou <i>et al</i> [65], 2018	41.68 ± 8.05	42.17 ± 9.12	50 (29/21)	50 (27/23)	D (tid)	F	8 wk	(1) (6)
Zhou and Hu [66], 2017	50.7 ± 14.664	40.87 ± 14.439	30 (14/16)	30 (15/15)	D (tid)	F	24 wk	(1) (5) (6)
Wang[67], 2016	38.87 ± 10.15	38.62 ± 9.97	40 (24/16)	40 (22/18)	D (tid)	F	8 wk	(1)
Zou[68], 2015	41.8 ± 2.1	42.1 ± 1.8	49 (31/18)	48 (30/18)	D (tid)	F	8 wk	(1)
Li[69], 2015	39.5 ± 8.2	40.8 ± 7.6	36 (21/15)	37 (23/14)	D (tid)	F	8 wk	(1) (3)
Xu[64], 2015	34.25 ± 4.56	34.25 ± 4.56	40	40	D (tid)	F	2 mo	(1) (3)
Xin <i>et al</i> [70], 2015	39.5 ± 8.2	40.8 ± 7.6	37 (22/15)	38 (17/21)	D (tid)	F	8 wk	(1) (3)
Xu and Chen [71], 2015	40.3 ± 11.5	41.1 ± 11.7	49 (26/23)	49 (25/24)	D (qd)	F	4 wk	(1) (2) (5) (6)
Chen <i>et al</i> [72], 2013	41.7 ± 8.1	38.2 ± 7.6	48 (24/24)	48 (24/24)	D (tid)	F	2 mo	(1)
Wei <i>et al</i> [73], 2013	18-58	19-60	23 (16/7)	23 (14/9)	D (tid)	F	12 wk	(1) (3)
Chen[74], 2013	42.6 ± 7.2	41.4 ± 8.3	40 (28/12)	40 (30/10)	D (tid)	F	12 wk	(1)
Lu[78], 2021	48.89 ± 2.67	48.21 ± 2.12	35 (25/10)	35 (25/10)	E (tid)	F	8 wk	(1) (3)
Shen[76], 2020	40.38 ± 3.26	40.25 ± 3.79	42 (24/18)	42 (22/20)	E (bid)	F	1 mo	(1)
Luo[77], 2019	40.3 ± 2.0	40.3 ± 2.0	42	42	E (tid)	F	1 mo	(1) (6)
Chen[81], 2019	49.2 ± 5.1	49.3 ± 5.1	50 (31/19)	50 (30/20)	E (bid)	F	8 wk	(1)
Yao[80], 2018	42.3 ± 13.6	41.7 ± 12.8	36 (16/20)	36 (15/21)	E (bid)	F	4 wk	(1) (6)
Zhao <i>et al</i> [79], 2017	43.22 ± 5.92	46.14 ± 6.28	30 (14/16)	30 (15/15)	E (tid)	F	8 wk	(1) (6)
Liu[75], 2014	39.9 ± 7.4	39.7 ± 7.3	45 (21/24)	44 (19/25)	E (bid)	F	1 mo	(1) (6)

A: Baitouweng decoction + mesalazine; B: Shaoyao decoction + mesalazine; C: Xi Lei powder + mesalazine; D: Shenling Baizhu powder + mesalazine; E: Changyanning capsules + mesalazine; F: Mesalazine. Qd: qd-quaque die; bid: bid-bis in die; tid: tid-ter in die. (1) Clinical efficacy; (2) Colonoscopy; (3)

Tumor necrosis factor; (4) Inflammatory Bowel Disease Questionnaire; (5) Recurrence rate; (6) Incidence of adverse reactions.

the differences were statistically significant. No significant differences were observed in the pairwise comparisons of the five interventions (Table 2).

Baron points: Ten studies reported Baron scores for colonoscopy. Using MD as the effect size, 10 direct and indirect comparisons were generated in the NMA; however, the differences were not statistically significant (Table 2).

IBDQ points: Five studies reported the IBDQ on the relevant quality-of-life scale. Using MD as the effect size, the NMA generated three direct and indirect comparisons, with one difference being statistically significant. Table 2 reveals that the adjuvant treatment of UC with BTWT (MD = 36.22, 95%CI: 7.63 to 65.76) improved the quality of life of the patients compared to that using mesalazine treatment alone. The differences were not statistically significant, and other pairwise comparisons were not statistically significant as well (Table 2).

TNF: A total of 22 studies reported related TNF levels. Using MD as the effect size, NMA generated 15 direct and indirect comparisons, 5 of which were statistically significant. Table 2 shows that, compared to the mesalazine treatment alone, the following results were obtained for BTWT (MD = -9.55, 95%CI: -17.89 to -1.41), SLBZS (MD = -13.78, 95%CI: -20.27 to -7.63), and SYT (MD = -23.02, 95%CI: -33.64 to -13.14). Following adjuvant treatment of UC, using these three TCM formulas, the level of TNF in the patients was significantly reduced. In a pairwise comparison of the five interventions, SYT was better than BTWT (MD = 13.47, 95%CI: 0.45 to 27.10) and CYN (MD = 22.08, 95%CI: 0.11 to 44.46) in reducing the TNF levels in patients with UC. Other differences were not statistically significant (Figure 4).

Recurrence rate: Eleven studies reported the recurrence rate of UC. Using OR as the effect size, the NMA generated a total of six direct and indirect comparisons, and three differences were statistically significant. Table 2 shows that each intervention was compared to the mesalazine treatment: BTWT (OR = 0.12, 95%CI: 0.03 to 0.39), SLBZS (OR = 0.19, 95%CI: 0.08 to 0.39), and tin powder (OR = 0.34, 95%CI: 0.13 to 0.81). The adjuvant treatment of UC with these three TCM formulas significantly reduced the recurrence of UC in patients, and the difference was statistically significant. No significant differences were observed in the other pairwise comparisons (Table 2).

Adverse reactions: Thirty studies reported adverse reactions involving the five TCM formulations. Among them, BTWT [39,40,45,47,48] and XLS[31] were combined with mesalazine for the treatment of UC in six studies and no adverse reactions occurred in any group. The major adverse effects of mesalazine in the treatment of UC include inflammatory reactions, pancreatitis, cardiotoxicity, hepatotoxicity, musculoskeletal discomfort, respiratory symptoms, nephropathy, and sexual dysfunction[89]. The major adverse effects of Chinese herbal formulas combined with mesalazine in the treatment of UC include nausea, vomiting, abdominal distension, stomach discomfort, anorexia, headache, and rash. In the literature, no rare adverse reactions have been reported in the control or treatment group; all the reported adverse reactions have been common ones. Therefore, after comparing the incidence rates of adverse reactions, the adverse reactions of the TCM formula combined with mesalazine in the treatment of UC were observed to be lower than those of mesalazine alone. None of the studies were discontinued because of adverse reactions. The rate of adverse reactions in patients with UC treated with mesalazine was 7.3% and that in patients treated with an herbal formula combined with mesalazine was 4.4% ($P = 0.001$, $P < 0.05$). Specific statistical results are presented in Supplementary Figure 4. The results showed that the adjuvant treatment of UC with TCM formulas can effectively reduce the occurrence of adverse events and increase treatment safety.

Probabilistic ordering

A probabilistic ranking of the five interventions was done according to Bayesian statistics. Rank 1 indicated the best clinical efficacy rate and quality of life scale (IBDQ); the higher the value of Rank 1, the better was the clinical efficacy rate. The colonoscopy Baron score, TNF, and recurrence rate were best with Rank 6; the higher the value of Rank 6, the better were these parameters (Table 2 and Figure 5). The order of clinical efficacy was as follows: CYN, (0.52) > XLS (0.41) and > BTWT (0.03) = SYT (0.03) and SLBZS (0.00). The order of the life quality scale (IBDQ) was as follows: BTWT (0.73) > SYT (0.26); the order of the colonoscopy Baron scores was as follows: XLS (0.43), and BTWT (0.31) > SYT (0.17) > SLBZS (0.09), followed by SYT (0.70) > XLS (0.26) > SLBZS (0.03) > CYN (0.01) = BTWT (0.01); the order of recurrence rates was as follows: BTWT (0.70), followed by SLBZS (0.24) > XLS (0.05).

Publication bias

After comparing the outcome indicators of the included studies and correcting, the funnel plot was found to be slightly asymmetric, indicating small sample effects or publication bias between the studies (Figure 6).

DISCUSSION

According to TCM, UC is located in the intestine and is closely related to the spleen and stomach. Exogenous factors, such as diet and emotions, can affect the transportation and transformation functions of the spleen and stomach. The basic

Table 2 Ranking list of different interventions					
Interventions	Effective	Baron	IBDQ	TNF	Recurrence rate
BTWT	0.03	0.31	0.73	0.01	0.70
CYN	0.52	-	-	0.01	-
SLBZS	0.00	0.09	-	0.03	0.24
SYT	0.03	0.17	0.26	0.70	-
XLS	0.41	0.43	-	0.26	0.05
Mesalazine	0.00	0.00	0.00	0.00	0.00

BTWT: Baitouweng decoction; CYN: Chang-yan-ning; IBDQ: Inflammatory Bowel Disease Questionnaire; SLBZS: Shenlingbaizhu powder; SYT: Shaoyao decoction; TNF: Tumor necrosis factor; XLS: Xi Lei powder.

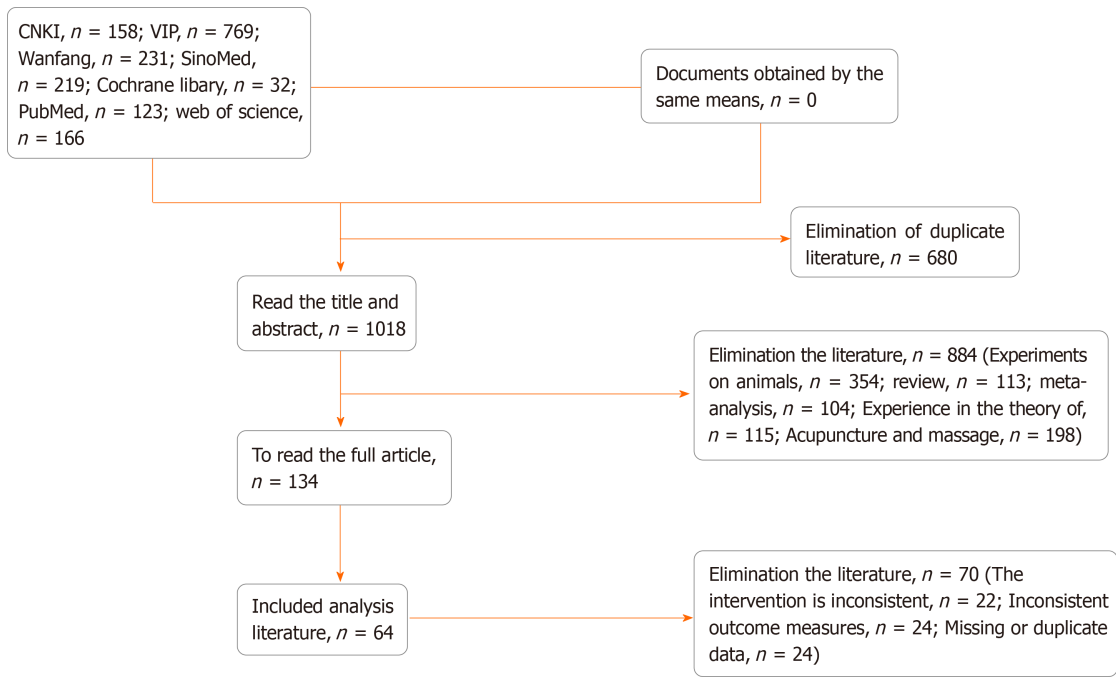


Figure 1 Screening flow diagram of included studies. CNKI: China National Knowledge Infrastructure; PubMed: Publication Database of the National Library of Medicine; VIP: Chinese Scientific Journal Database.

pathogenesis is a pattern of dampness and heat in the intestines and stomach, a pattern of spleen deficiency with dampness and heat, and a pattern of qi and blood disharmony. Therefore, TCM formulas that clear heat, dispel dampness, regulate qi, fortify the spleen, remove toxins to promote tissue regeneration, and regulate and harmonize qi and bleeding are often used in the clinical treatment of UC.

Mesalazine, a commonly used salicylate, releases acetyl acetylde, which has notable anti-inflammatory effects in the colon and terminal ileum. Salicylic acid is effective for the treatment of UC[53]; however, long-term or high-dose use of such drugs can have crucial adverse effects on the body[92]. TCM formulas combined with mesalazine in the treatment of UC can not only effectively exert a synergistic effect between Chinese and Western medicines but also more effectively improve the clinical symptoms and pathological conditions of the disease, improve patients' quality of life, and reduce the disease recurrence rate[93].

The results showed that, in terms of clinical efficacy, CYN was the most effective adjuvant treatment for UC, followed by XLS, BTWT, and SYT. CYN is a commonly used Chinese patent medicine and is mainly composed of *Euphorbia humifusa*, *Elsholtzia ciliata*, *Coptis chinensis*, and *Daemonorops draco* (Willd.) Blume. Modern pharmacological studies have shown that *E. humifusa*, *E. ciliata*, *C. chinensis*, and *D. draco* (Willd.) Blume exhibits anti-inflammatory, antibacterial, and immune-enhancing properties[94-97]. *Coptis chinensis* can regulate intestinal flora and maintain intestinal microecological balance[94], and *D. draco* (Willd.) Blume can alleviate damage to the colonic mucosa in mice, inhibit platelet aggregation, shorten prothrombin time, promote blood circulation, and stop bleeding[94]. TCM combined with mesalazine can effectively treat UC disease symptoms, inhibit the inflammatory response, and promote the recovery of the intestinal mucosa, thereby improving clinical efficacy.

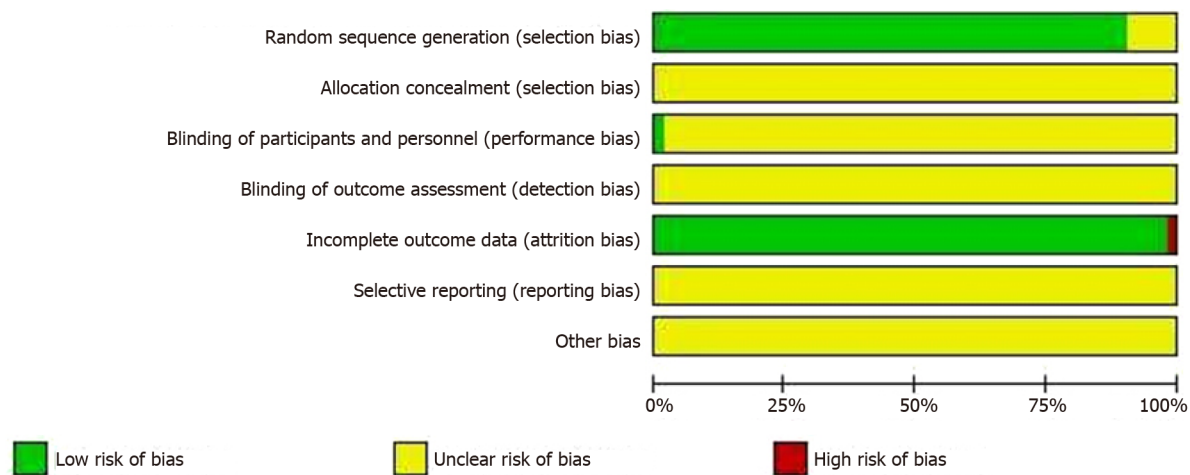


Figure 2 Bias risk assessment of included studies.

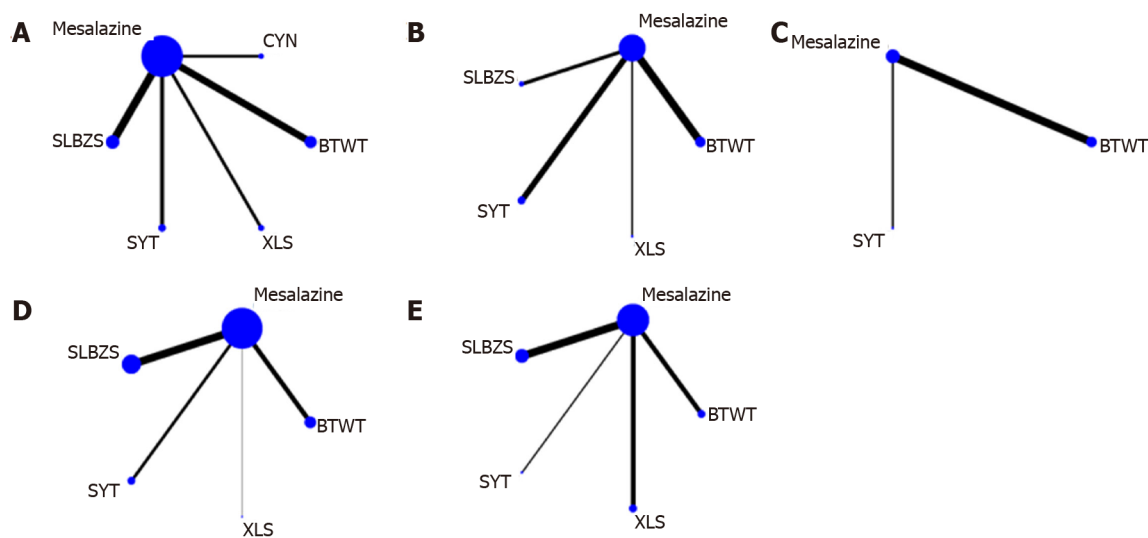


Figure 3 Network meta-analysis. A-E: Network meta-analysis maps of the studies examining the efficacy of five Chinese herbal formulas for adjuvant treatment of ulcerative colitis on clinical efficacy (A), baron points (B), Inflammatory Bowel Disease Questionnaire points (C), tumor necrosis factor (D), and recurrence rate (E). The size of the nodes relates to the number of participants in that intervention type, and the thickness of lines between the interventions relates to the number of studies for that comparison. Chang-yan-ning (CYN), Xi Lei powder, Baitouweng decoction (BTWT), Shenlingbaizhu powder (SLBZS), Shaoyao decoction (SYT) stand for CYN combined with mesalazine, Xileisan combined with mesalazine, BTWT combined with mesalazine, SLBZS combined with mesalazine, and SYT combined with mesalazine, respectively.

In terms of improving the state of the intestinal mucosa in patients with UC, adjuvant treatment with XLS was the most effective, followed by BTWT and SYT. The major components of XLS were *Calcitum*, *Gypsum rubrum*, *Hyriopsis cumingii*, *Dryobalanops aromatica* Gaertn, *Bos taurus domesticus*, and *Gmelin*. It clears heat, removes toxins, and dispels putridity to promote tissue regeneration[98]. Modern pharmacological research has shown that *Calculus bovis* stimulates intestinal peristalsis and acts as a laxative[99], and *D. aromatica* Gaertn has antibacterial and transdermal drug effects[100]. Calcium carbonate is the primary component of *Calcitum* and *Gypsum rubrum*. It exhibits alkaline properties, acid suppression, and inhibition effects after processing[101,102]. In addition, the main clinical route of administration of XLS is through enema, which makes the intestinal tract more conducive to the absorption of the medicinal liquid, and thus, the repair of the intestinal mucosa.

Adjuvant treatment with BTWT had the most significant effect on improving the quality of life of patients with UC. BTWT is mainly composed of *Pulsatilla chinensis*, *C. chinensis*, *Phellodendron amurense*, and *Fraxinus cortex*. All four types of TCM exert the effects of clearing heat, removing toxins, and cooling blood and are commonly used for the treatment of pestilent dysentery. In modern pharmacological research, BTWT has been shown to maintain the intestinal immune balance, regulate intestinal microecology, and prevent the malignant transformation of intestinal tissue[103]. In modern pharmacology, *Pulsatilla chinensis* saponins have the potential to decrease mesenteric blood flow in UC rats, significantly inhibit inflammatory responses, and regulate the intestinal microbiota[104]. *Phellodendrine* can alleviate intestinal injury, promote gastric mucosal healing, and alleviate inflammatory responses[105]. The ethanol extract of *Fraxinus cortex* can influence ion transport in rat jejunum epithelial cells, thereby playing an anti-colitis role[106]. It is supplemented with

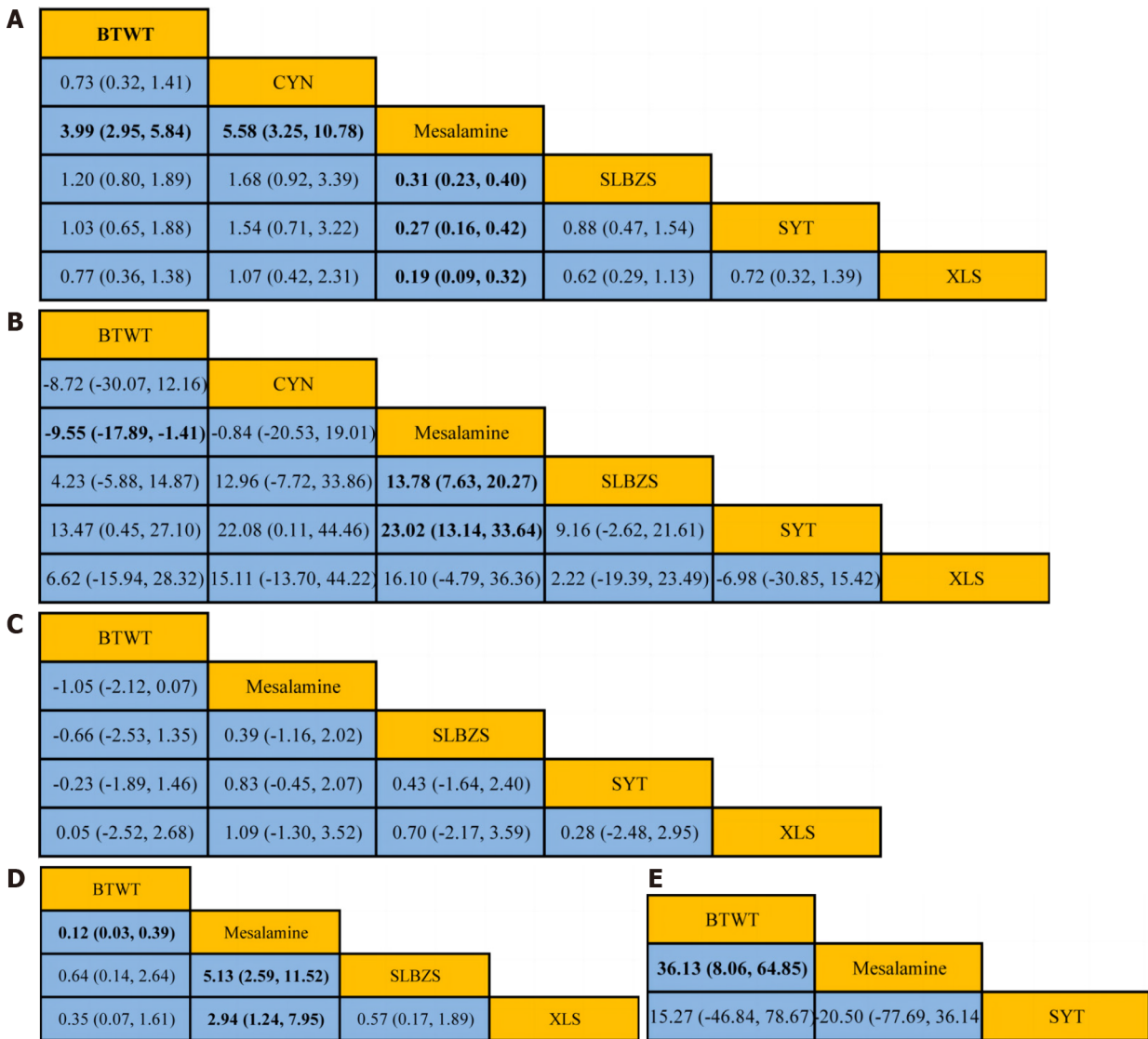


Figure 4 Results of network meta-analysis. Bold font indicates statistical significance ($P < 0.05$). A: Network meta-analysis (NMA) of the clinical efficacy of traditional Chinese medicine (TCM) adjuvant mesalazine in the treatment of ulcerative colitis [UC; OR (95%CI)]; B: NMA of the tumor necrosis factor of TCM adjuvant mesalazine in the treatment of UC [mean difference (MD; 95%CI)]; C: NMA of the Baron points of TCM adjuvant mesalazine in the treatment of UC [MD (95%CI)]; D: NMA of the recurrence rate of TCM adjuvant mesalazine in the treatment of UC [OR (95%CI)]; E: NMA of the Inflammatory Bowel Disease Questionnaire of TCM adjuvant mesalazine in the treatment of UC [MD (95%CI)]. Chang-yan-ning (CYN), Xi Lei powder (XLS), Baitouweng decoction (BTWT), Shenlingbaizhu powder (SLBZS), Shaoyao decoction (SYT) stand for CYN combined with mesalazine, Xileisan combined with mesalazine, BTWT combined with mesalazine, SLBZS combined with mesalazine, and SYT combined with mesalazine, respectively.

Chinese herbs to replenish the qi, soothe the liver, and strengthen the spleen, effectively improving immunity, soothing the patient's mood, and improving their quality of life[23].

SYT adjuvant therapy had a notable effect in reducing TNF in patients with UC, followed by XLS adjuvant therapy. SYT is mainly composed of *Paonia lactiflora*, *Areca catechu*, *Rheum palmatum* root, *Scutellaria baicalensis*, *C. chinensis*, *Angelica sinensis* root, *Cinnamomum cassia*, *Glycyrrhiza uralensis*, and *Aucklandia lappa decne* roots. All types of TCM replenish the qi and regulate blood, clear heat, and dry dampness. Recent studies have shown that SYT can activate Tregs in rats, inhibit Th17 cells, and regulate the Treg/Th17 balance to suppress inflammatory immune responses[107]. *Paonia lactiflora* is sufficient to ameliorate colitis by regulating the intestinal physical barrier, immune responses, and gut microbiota in mice[108]; *Arecoline* can excite the colonic smooth muscle motility *via* the M3 receptor[109]; *Cinnamomum cassia* extract has antioxidant and anti-inflammatory effects[110]; *Rheum palmatum* root extract treats UC by inhibiting inflammatory responses, improving colitis, and enhancing colonic electrical activity[111]; *Angelica sinensis* can enhance the ratio of anti-inflammatory immunocytes M2 and Treg cells, and promote the production of anti-inflammatory cytokines IL-10 and TGF- β [112]; *Glycyrrhiza uralensis* can correct the overall gut microbial dysbiosis and fecal metabolic disorders in colitis mice[113].

Considering that patients with UC are highly prone to disease recurrence, adjuvant BTWT can significantly reduce the possibility of disease recurrence. Modern research has shown that BTWT can regulate intestinal microecology, promote barrier function, and enhance immunity and anti-tumor effects[41], thereby reducing the probability of UC recurrence. In modern pharmacology, *Pulsatilla chinensis* saponins have the potential to decrease mesenteric blood flow in UC rats,

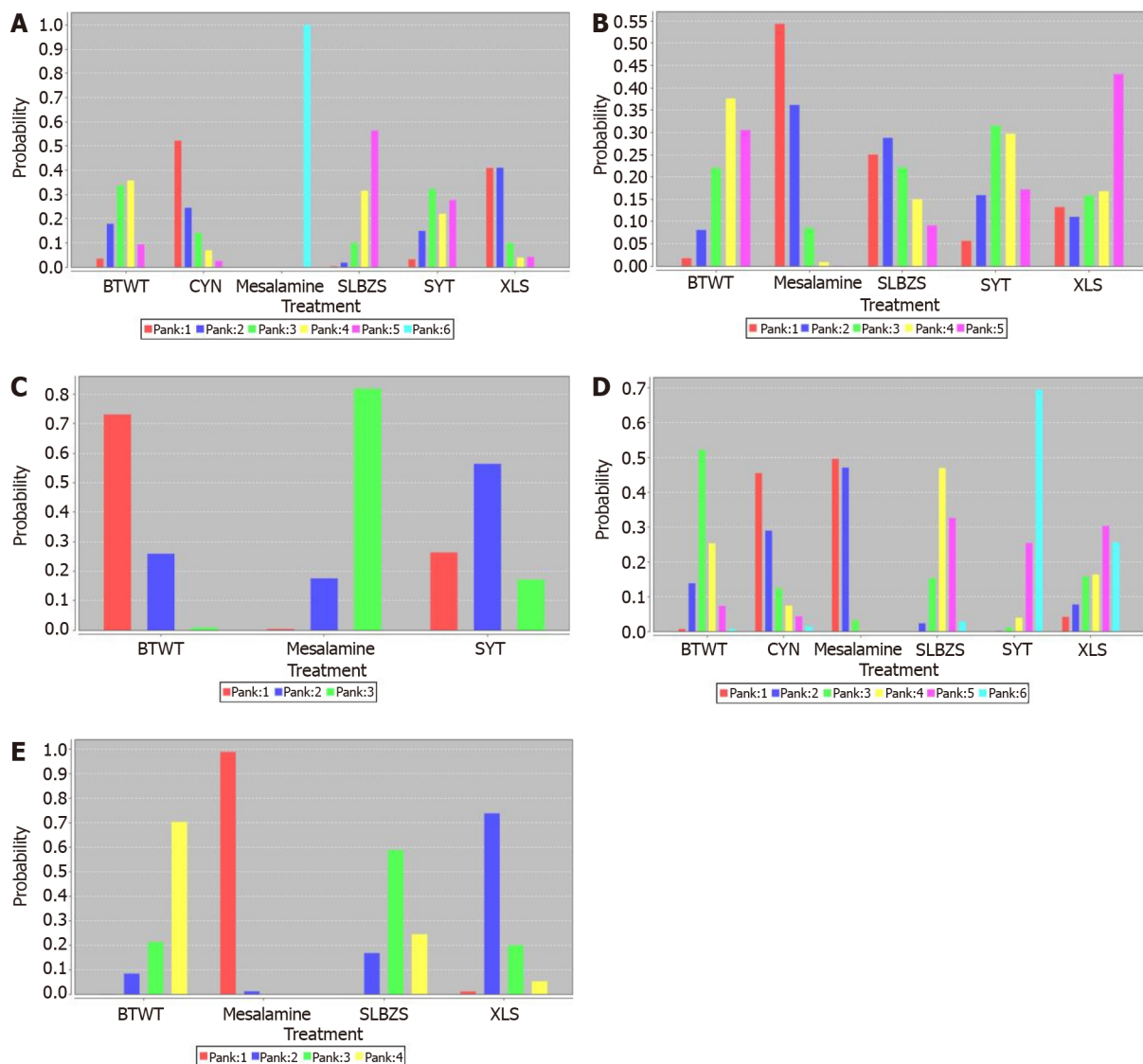


Figure 5 Ranking diagram of outcome indicators for each intervention. A: Clinical efficacy; B: Baron points; C: Inflammatory Bowel Disease Questionnaire points; D: Tumor necrosis factor; E: Recurrence rate. Chang-yan-ning (CYN), Xi Lei powder (XLS), Baitouwen decoction (BTWT), Shenlingbaizhu powder (SLBZS), Shaoyao decoction (SYT) stand for CYN combined with mesalazine, Xileisan combined with mesalazine, BTWT combined with mesalazine, SLBZS combined with mesalazine, and SYT combined with mesalazine, respectively.

significantly inhibit inflammatory responses, and regulate the intestinal microbiota[104]. Phellodendrines alleviate intestinal injury, promote gastric mucosal healing, and alleviate inflammatory responses[105]. SLBZS mainly consists of *Panax ginseng*, *Poria cocos* (Schw.) Wolf, and *Atractylodes macrocephala* (*A. macrocephala*). In modern pharmacological research, ginseng can inhibit colon inflammation and restore the gut microbiota to its original state[114]; *Poria* possesses protective effects against cisplatin-induced intestinal injury by potentially regulating the gut microbiota and metabolic profiles[115]; and *A. macrocephala* can improve gastrointestinal function and immune regulation[116].

In terms of the incidence of adverse reactions, neither the control group nor the treatment group experienced rare adverse reactions. The common adverse reactions observed were mild symptoms such as nausea, vomiting, dizziness, and headache indicating that both treatment methods are relatively safe. Moreover, the incidence of adverse reactions in the treatment of UC with TCM prescriptions as an adjuvant therapy to mesalazine was lower than that of mesalazine alone. It can thus be concluded that the adjuvant therapy of TCM prescriptions in the treatment of UC can reduce the probability of adverse reactions and improve the safety of treatment.

Limitations of this study: (1) The Chinese literature included in this study had the largest number of Chinese documents and might have introduced linguistic and geographical bias; (2) The quality of the included studies was generally average. Some studies did not specify the method for generating random sequences and those that mentioned random allocation methods did not provide detailed descriptions of the randomization process. This may have affected the reliability of the results; (3) The patients in the studies had the same syndrome types of TCM; therefore, the efficacy in other syndrome types is unclear; (4) The dose of TCM used in the studies might have differed. This may have affected the efficacy of the TCM. Therefore, further high-quality multi-center, large-sample clinical RCTs should be conducted to verify the results; and (5) The intervention durations in the studies varied, which may have influenced the occurrence of adverse reactions. No study has clearly demonstrated a correlation between the duration of treatment interventions and

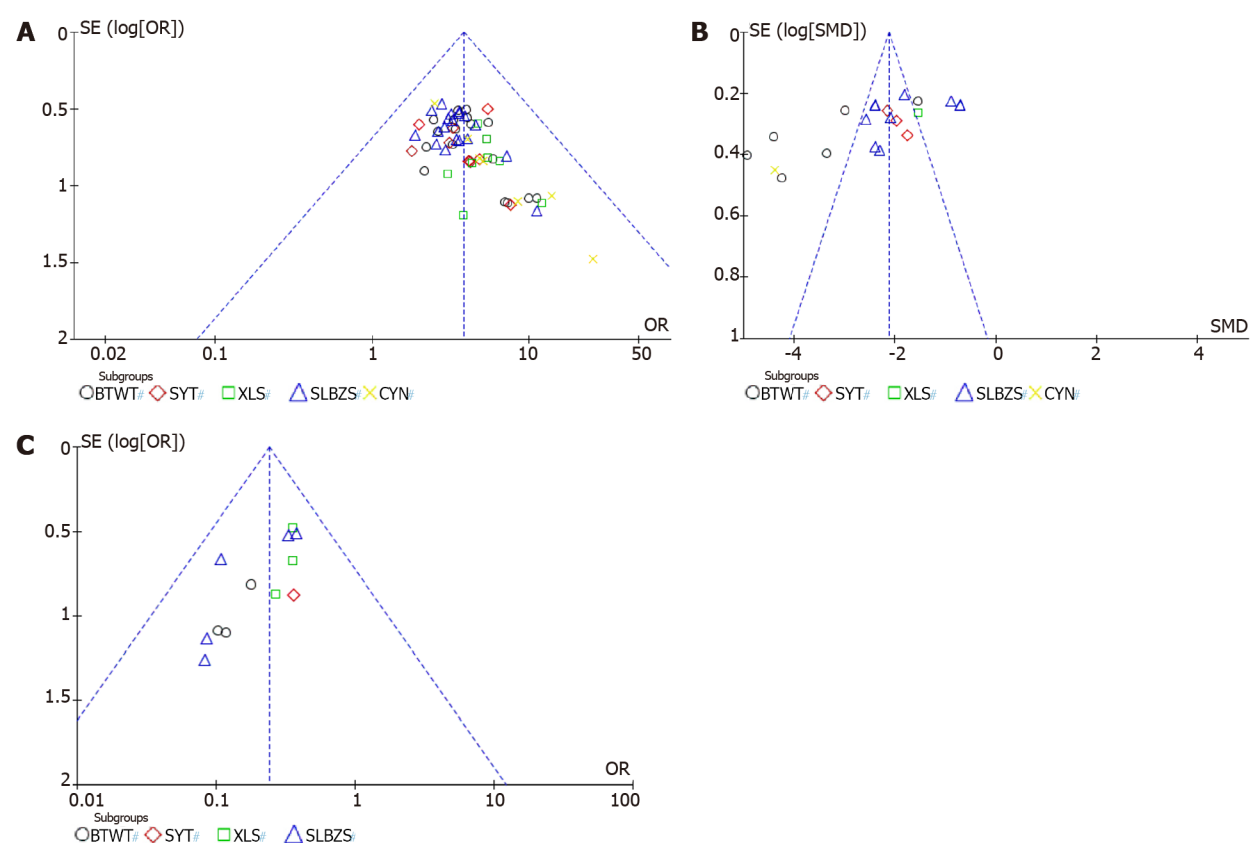


Figure 6 Funnel plot. A-C: Funnel plots for each outcome indicator with clinical efficacy (A), tumor necrosis factor (B), and recurrence (C). Chang-yan-ning (CYN), Xi Lei powder (XLS), Baitouweng decoction (BTWT), Shenlingbaizhu powder (SLBZS), Shaoyao decoction (SYT) stand for CYN combined with mesalazine, Xileisan combined with mesalazine, BTWT combined with mesalazine, SLBZS combined with mesalazine.

the incidence of adverse reactions in patients with UC. Researchers should investigate the correlation between these two factors in patients with UC, thus addressing the gap in this area.

CONCLUSION

In summary, the NMA of the five types of TCM formulas can provide a rational and personalized plan for the selection and use of TCM in the clinical adjuvant treatment of UC. TCM formulas combined with mesalazine have a better effect in treating UC. The adjuvant treatment of UC with TCM formulas can improve clinical efficacy, repair the intestinal mucosa, improve the immunity of the body and the quality of life of patients, and reduce the probability of disease recurrence. Traditional Chinese and Western medicines used in combination for the treatment of UC have better prospects. Modern pharmacological research has focused on the potential mechanisms of action of Chinese medicine monomers, single Chinese medicines, and TCM formulations in the treatment of UC, alleviating the symptoms of UC, controlling the development of intestinal inflammation, and restoring intestinal function through the regulation of key molecular signaling pathways, including PI3K/Akt, NF- κ B, JAK/STAT, MAPK, and Notch[117]. The combination of TCM formulations and mesalazine in the treatment of UC can reduce the probability of adverse reactions and improve the safety of clinical treatment. However, the mechanism by which adverse reactions are reduced during the treatment of UC remains unclear, necessitating further exploration by researchers. The specific symptoms and constitutions of different patients vary, and so do the specific medications and dosages of the TCM formulas. Therefore, the original experimental design research in the future should be objective, standardized, and normalized; large-sample, multicenter, and double-blind RCT trials should be selected for verification. The risk of bias should be avoided to the maximum extent so that the final evaluation results can effectively guide clinical prescription and medication selection, providing a reliable evidence-based basis.

FOOTNOTES

Author contributions: Zhao ZH and Wei YJ contributed equally as co-first authors. Zhao ZH and Jiang XQ designed the research; Zhao ZH, Wei YJ, and Jiang XQ contributed to analytical tools and performed the analysis; Zhao ZH, Wei YJ, and Wang J analyzed the data; Zhao ZH, Dong YH, and Qin WL wrote the paper; Zhang XQ revised the manuscript and provided financial support.

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