MEDS Chinese Medicine (2024)
Clausius Scientific Press, Canada

DOI: 10.23977/medcm.2024.060305
ISSN 2616-1753 Vol. 6 Num. 3

A systematic review and meta-analysis of the clinical efficacy of Needle warming moxibustion in the treatment of ulcerative colitis

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Keywords: Needle warming moxibustion, ulcerative colitis, meta-analysis

Abstract: The randomized controlled trial of warm acupuncture in the treatment of ulcerative colitis was searched by computer using China Journal Full-Text Database (CNKI), Wan fang Data Knowledge Service Platform (Wan fang), VIP Chinese Journal Service Platform (VIP) and PubMed. The search time was from the establishment of the database to January 8, 2024. RevMan5.4.1 was used to evaluate the quality of this study and evaluate its clinical role. The results indicated that the total effective rate, TCM syndrome effect and modified Mayo score of warm acupuncture and moxibustion group were significantly higher than the traditional treatment methods of the control group, indicating that warm acupuncture and moxibustion had high clinical value in the treatment of UC patients and was worth promoting.

1. Introduction

Ulcerative colitis (UC) is a common chronic nonspecific inflammatory bowelitis. The sigmoid colon, rectum, and even in the colon are more common, and often recur. Epidemiological surveys have shown that worldwide, the incidence of inflammatory bowel disease is increasing every year, with a national infection rate of 11.6 per 100,000[1]. The main symptoms are diarrhoea, mucus, pus, bloody stools, abdominal pain, tenesmus, and various systemic symptoms, and the course of the disease is usually more than 4 to 6 weeks[2].Because the cause of the disease is not known, therapies have previously been directed at clinical symptoms, such as inducing remission. At present, the treatment of this disease is mainly based on early intervention, from the alleviation of clinical symptoms to mucosal repair, so as to improve the quality of life and prevent the occurrence of complications[3].As a simple and easy method of combining acupuncture and moxibustion, warm acupuncture can play a role in warming the meridians, replenishing qi and blood, etc., to achieve the purpose of treating ulcers[4]. In this paper, the efficacy of randomized controlled trials in ulcerative colitis was analyzed by meta-analysis, which provided a more reliable basis for clinical application.

2. Information and Methodology

2.1 Inclusion Criteria

(1)The diagnostic criteria for ulceration are based on the Consensus on the Diagnosis and Treatment of Inflammatory Bowel Disease[5]or the Consensus on the Diagnosis and Treatment of Ulcerative Colitis with Integrated Traditional Chinese and Western Medicine (2017)[6]. (2) the treatment group was treated with warm needles or warm needles combined with other therapies (traditional Chinese medicine, enema, etc.), while the control group was treated with other comprehensive or monotherapy without warm needles; the original literature should include the treatment group and the control group, rather than a case study;(3) Outcome observation indicators: primary indicators: total effective rate, secondary indicators: efficacy of TCM syndromes, modified Mayo scores,Adverse reactions. Include any of the above items.

2.2 Exclusion Criteria

(1) non-randomized control of the original literature trial, (2) no control group in the original literature,(3) The Needle warming moxibustion group was the control group,(4) republished literature, (5) conference reports, (6) literature review, (7) animal testing, (8) experience summaryand ,(9) literature that could not provide valid data for meta-analysis.

2.3 Search Methods

A computerized search was conducted for published randomised controlled trials of the clinical efficacy of Needle warming moxibustion in the treatment of ulcerative colitis. The databases searched included: China Journal Full-text Database (CNKI), Wanfang Data Knowledge Service Platform (Wan fang), VIP Chinese Journal Service Platform (VIP), and PubMed. The search term is:"Needle warming moxibustion","Ulcerative Colitis","Idiopathic Proctocolitis","Colitis Gravis"," Inflammatory Bowel Disease, Ulcerative Colitis Type". The retrieval methods are: "Needle warming moxibustion" and "ulcerative colitis", "Needle warming moxibustion" and " Idiopathic Proctocolitis", "Needle warming moxibustion" and "Colitis Gravis","Needle warming moxibustion" and "Inflammatory Bowel Disease, Ulcerative Colitis Type". The retrieval time is from the establishment of the database to January 8, 2024.

2.4 Data Extraction

Literature data were collected, including authors, year of publication, sample size, interventional interventions, treatment duration, outcome observations, effect sizes, and literature quality assessment. Sort the collected data into Excel, check and check it, and if you find any problems, ask another researcher to help with them.

2.5 Quality evaluation

This review was assessed according to the risk of bias assessment tools provided by the Cochrane Collaboration. The former included random sequence generation, concealment of randomized protocols, blinding of implementers and participants, blinding of outcome assessors, outcome data integrity, selective reporting, and other biases, and then low-risk, unclear, and high-risk of the included studies were subsequently assessed based on the results of these assessments. The quality assessment of the paper is discussed by two people, and if there is a disagreement, a third party is

consulted.

2.6 Statistical Methods

The collected literature was collated and analysed using RevMan 5.4.1 from the Cochrane Collaboration. Heterogeneity was first examined, and in the case of dichotomous variables, the relative risk ratio (RR) was chosen, and conversely, in the case of continuous variables, the standardized mean difference (SMD) was used, both yielding 95% effect intervals. The indicators that affect the selection of the model are the result of heterogeneity. When I2 < 50%, the heterogeneity of the data is within the acceptable range, and a fixed effect model is chosen, and if I2 > 50%, the heterogeneity of the data is not acceptable, then the reasons for this phenomenon must be analysed, and if it cannot be ruled out, random effects are chosen. Evaluate the risk of publication bias using a funnel plot.

3. Results

3.1 Literature search results

A computerized search resulted in a total of 305 entries in the four databases, of which only 230 were excluded from duplicates. After initial screening and re-screening, 26 studies were included in the final studies. The process is shown in Figure 1.

3.2 Results of the methodological quality assessment of the included studies

A total of 26 articles were included in this study, and the overall status of the included studies was relatively balanced, and the baselines were well comparable. The characteristics of the included trials are shown in Table 1 and the risk of bias is shown in Figure 2.

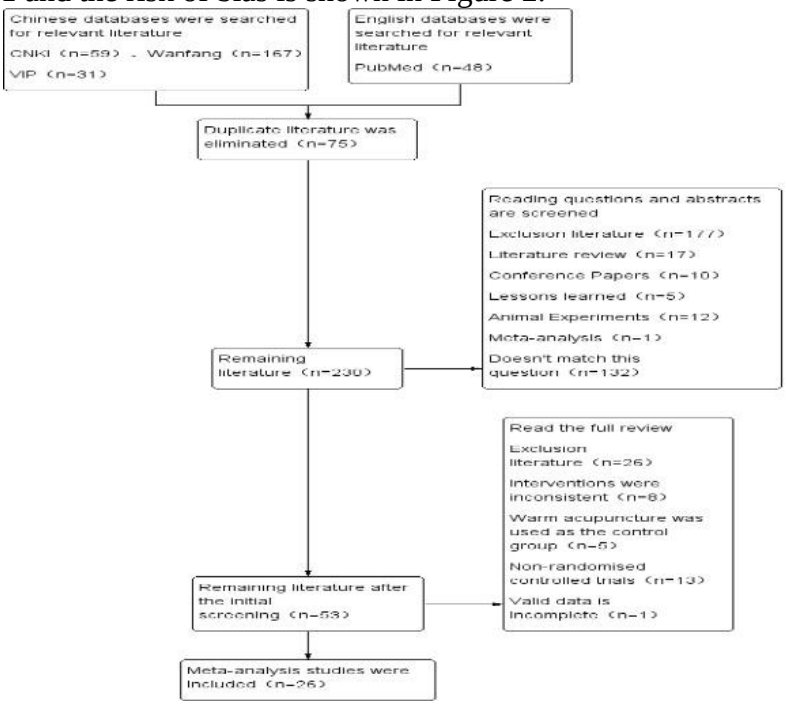

Figure 1: The process and results of each included test

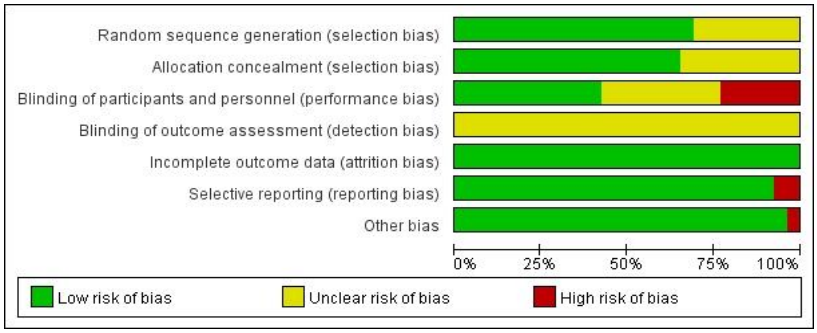

Figure 2: Risk of bias of included literature

Table 1: Includes basic information on the trials.

Into literature	group	Interventions	Sample size	Course	Final eindex
Zang Liang et al.2022[7]	Treatment group	Warm acupuncture + mesalazine	32	Acupuncture 10 times Western medicine 14d	①③
	Control group	Ordinary acupuncture + mesalazine	32		
Li Hongwei 021[8]	Treatment group	Warm acupuncture + mesalazine Enteric-coated tablets	54	8w	①
	Control group	Mesalazine enteric-coated tablets	54	8w	
Zhang Yanjun et al. 2021[9]	Treatment group	Warm acupuncture + tonic and deficiency formula+ Mesalazine enteric-coated tablets	52	2m	①
	Control group	Mesalazine enteric-coated tablets	50	2m	

Continued from Table 1

Zhou Li et al 2021[10]	Treatment group	Warm acupuncture + Shenling Baizhu powder+ Mesalazine enteric-coated tablets	47	4w	①②
	Control group	Mesalazine enteric-coated tablets	46	4w	
Wang Fei et al 2020[11]	Treatment group	Warm acupuncture + warm yang antidiarrheal soup + sulfasalazine enteric-coated tablets	40	4w	①④
	Control group	Sulfasalazine enteric-coated tablets	40	4w	
Zhao Yan et al 2020[12]	Treatment group	Warm acupuncture + mesalazine	28	8w	①④
	Control group	Mesalazine	28	8w	
Fang Xian et al 2019[13]	Treatment group	Warm acupuncture + kudzu root and qin soup Add or subtract retention enema	30	acupuncture30d Enema 6w	①③④
	Control group	Mesalazine enteric-coated tablets	30	6w	
Zheng Lihong et al 2018[14]	Treatment group	Warm acupuncture + intestinal suppository	24	4w	①④
	Control group	Sulfasalazine suppositories	24	4w	
Li Guangqing 2017[15]	Treatment group	Warm acupuncture + spleen and intestinal pills	30	2m	①
	Control group	Sulfasalazine tablets	30	2m	

Li Bing 2016[16]	Treatment group	Warm acupuncture	29	20d	①②
	Control group	Ordinary acupuncture	27	20d	③
Liu Fangfang 2016[17]	Treatment group	Warm acupuncture + mesalazine Sustained-release granules	8	45d	①②③
	Control group	Mesalazine extended-release granules	8	45d	④
Eurasia, etc 2014[18]	Treatment group	Warm acupuncture	35	60d	①
	Control group	Ordinary acupuncture	35	60d	
Li Wenying 2014[19]	Treatment group	Warm acupuncture + spleen and intestinal pills	41	2w	①④
	Control group	Spleen and intestinal pills	41	2w	
Wang Zhong 2013[20]	Treatment group	Warm acupuncture	25	Not reported	①
	Control group	Sulfasalazine + metronidazole	25		
Zhang Hong et al 2013[21]	Treatment group	Warm acupuncture + Bazhen soup enema	50	1m	①
	Control group	Sulfasalazine tablets	48	1m	
He Bangguang 200905[22]	Treatment group	Warm acupuncture	30	60d	①
	Control group	Ordinary acupuncture	30	60d	

Continued from Table 1

Wang Shuliang 2008[23]	Treatment group	Warm acupuncture	54	45d	①
	Control group	Sulfasalazine + saline enema	54	45d	
Zhang Yanjun et al. 2022[24]	Treatment group	Warm acupuncture + Chinese herbal enema	39	4w	①
	Control group	Chinese herbal enema	39	4w	
He Bangguang 200903[25]	Treatment group	Warm acupuncture	30	60d	①
	Control group	Ordinary acupuncture	30	60d	
Xia Shujie 2019[26]	Treatment group	Yu recruited acupuncture and acupuncture	30	60d	①
	Control group	Ordinary acupuncture	30	60d	
Zhang Dongdong et al. 2022[27]	Treatment group	Warm acupuncture + mesalazine nteric-coated tablets	47	8w	①
	Control group	Mesalazine enteric-coated tablets	47	8w	
Liang Shijiao 2009[28]	Treatment group	Warm acupuncture	30	4w	④
	Control group	Ordinary acupuncture	30	4w	
Sun Yunting et al. 1998[29]	Treatment group	Warm acupuncture + Chinese herbal enema	45	6w	①
	Control group	Chinese herbal enema	43	6w	
Li et al., 2021[30]	Treatment group	Warm acupuncture + Fuzheng Ping ulcer soup+ Mesalazine enteric-coated tablets	44	4w	④
	Control group	Mesalazine enteric-coated tablets	44	4w	
Wu Changyan 2023[31]	Treatment group	Warm acupuncture + Shenling Baizhu powderPlus or minus + mesalazine enteric-coated tablets	27	8w	①②③④
	Control group	Mesalazine enteric-coated tablets	27	8w	
Li Mengchao 2023[32]	Treatment group	Warm acupuncture + Yiyuan decay The decoction retains the enema	30	8w	②④
	Control group	Mesalazine enteric-coated tablets	30	8w	

Notes: ① total clinical effective rate ② efficacy of TCM syndrome ③ modified Mayo score ④ adverse reactions

3.3 Results of meta-analysis

3.3.1 Total clinical response rate

Twenty-two [7-27,29,31] studies (1645 patients in total) reported total clinical response rates. Because the efficacy rate of the experimental group and the control group in the 2022 study by Zang Liang et al.[7] was the same, which was 100%, the heterogeneity analysis of the remaining 22 studies was [Chi2=19.59, df=21, P=0.55; I2=0%], so a fixed-effect model was used for pooled analysis. The result was [RR=1.25, 95%CI (1.19, 1.31), P<0.00001], there was a significant difference between the two groups, and the overall effective rate of the treatment group was higher than that of the control group, as shown in Figure 3.

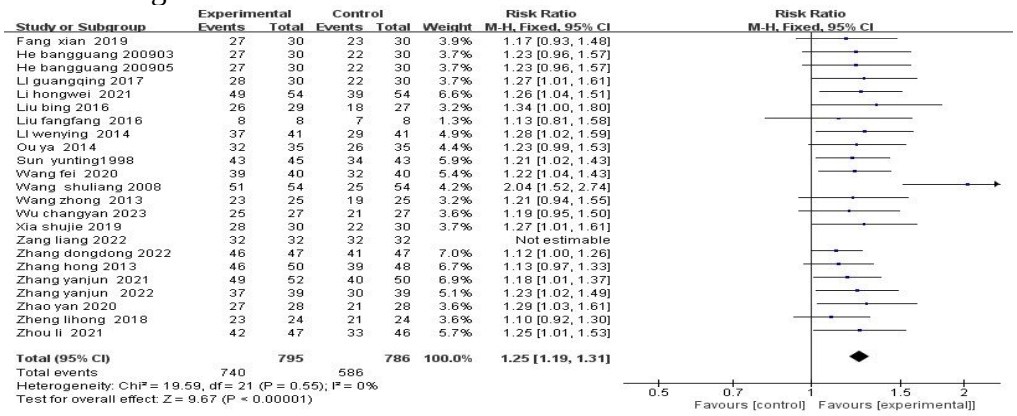

Figure 3: Forest plot of total clinical effective rate of Needle warming moxibustion in the treatment of UC patients

3.3.2 Efficacy of TCM syndromes

A total of 5 trials[10,16-17,31-32] in the literature mentioned the efficacy of TCM syndromes, and the heterogeneity analysis was [Chi2=2.59, df=4, P=0.63;I2=0%], so there was a statistically significant difference between the two groups [RR=1.16, 95%CI (1.05, 1.27), P=0.003].Therefore, it can be considered that the treatment group is better than the control group in terms of TCM syndrome efficacy, as shown in Figure 4.

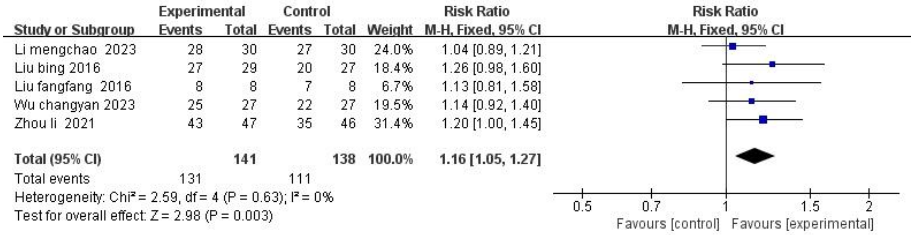

Figure 4: Forest diagram of TCM syndrome efficacy of Needle warming moxibustion in the treatment of UC patients

3.3.3 Improved Mayo score

A total of 5[7,13,16-17,31] trials in the literature reported modified Mayo scores, and their heterogeneity analysis showed that there was homogeneity [Chi2=1.85, df=4, P=0.76; I 2=0%], so the fixed-effect model was used for pooled analysis, and the results were [SMD=0.42, 95%CI (0.16, 0. 67), P=0.001], there was a significant difference between the two groups, indicating that the treatment group had an advantage over the control group for the modified Mayo score, as shown in

Figure 5.

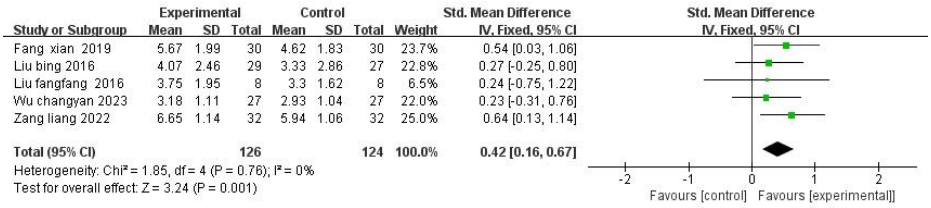

Figure 5: Forest plot of modified Mayo score in patients with UC treated with Needle warming moxibustio

3.3.4 Adverse reaction rate

10 studies explicitly reported adverse effects, 7 [11-14, 17, 19, 32] reported specific adverse effects, and 3[28,30-31] indicates that no significant adverse effects occurred, and the rest are not stated. The heterogeneity results showed that [Chi2=3.58, df=5, P=0.73;I2= 0%], there was homogeneity, [RR = 0.75, 95% CI (0.40 1.42), P = 0.38>0.05], which indicated that there was no statistical significance between the two, and it was not found to lead to an increase in adverse reactions, and the reported adverse reactions were all mild, and did not cause other serious adverse reactions such as liver and kidney damage, as shown in Figure 6.

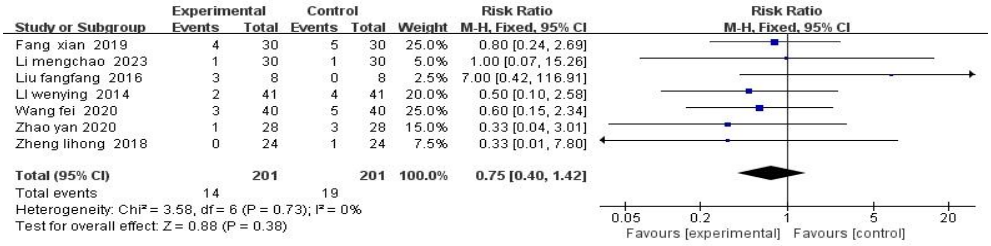

Figure 6: Forest plot of adverse reaction rate in patients with UC treated with Needle warming moxibustion

3.4 Publication bias

As shown in Figure 7, an inverted funnel plot was made based on the selected total clinical effective rate. As can be seen from the graph, the funnel plot is unevenly distributed, some around the vertical line, with more points on the left side of the vertical line than on the right, and a small dot on the outside of the funnel plot that is unevenly distributed, which may be due to the poor methodological quality of the individual studies, or the lack of negative results.

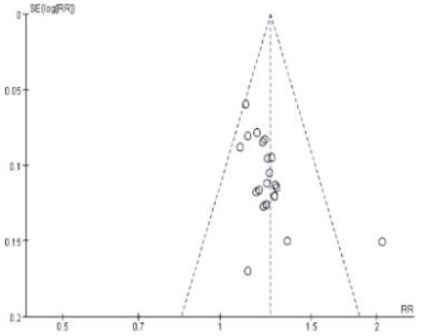

Figure 7: Inverted funnel plot of total effective rate in the included trials

4. Discussion

Ulcerative colitis is considered a difficult disease to cure in medicine, and it tends to recur and is very difficult to treat. The main symptoms are diarrhea, mucus, pus and bloody stools, and tenesmus, which are not clearly recorded in traditional Chinese medicine, and are classified as "diarrhea" and "resting dysentery" according to clinical symptoms[33]. In recent years, it has gradually become a popular clinical treatment method due to its definite efficacy, low recurrence rate, and low toxicity and side effects[34], which mostly uses traditional Chinese medicine oral, enema, acupuncture, and Needle warming moxibustion, all of which have good effects and few side effects[35]. As a combination of acupuncture and moxibustion, Needle warming moxibustion can not only use the power of acupuncture to reach the sick place directly, but also use the warming effect of moxibustion to achieve the purpose of warming the meridians, replenishing qi and blood, and has a good effect on ulcerative colitis[36], which plays an important role in clinical diagnosis and treatment.

This paper uses the method of Meta analysis to analyze 26 articles about the clinical application of warm acupuncture and moxibustion in the treatment of ulcerative colitis patients. Finally, it is found that the clinical total effective rate of the test group is significantly better than that of the control group, $P<0.00001$, the difference is statistically significant; In addition, it was also better than the control group in terms of reducing the efficacy of TCM syndromes and improving Mayo score, $P<0.01$, the difference was statistically significant. Among the 26 articles, 10 articles mentioned the details of adverse reactions, of which 7 articles had no significant difference between the study group and the control group, $P=0.38>0.05$, indicating that warming acupuncture and moxibustion had not yet been found to lead to the increase of its adverse reactions, and the reported adverse reactions were relatively mild, without causing liver and kidney damage and other serious adverse reactions; The other two reports did not show any significant adverse reactions, indicating that this therapy is relatively safe.More trials are needed to validate it. Among them, the literature distributed outside the funnel plot is "Observation on the efficacy of warm acupuncture in the treatment of ulcerative colitis" [23], and after a detailed study of the literature, it was found that the effective rate of the control group was significantly lower than that of the treatment group, and the control group was oral sulfasalazine with sucralfate + metronidazole + procaine saline enema, which may be one of the reasons, and the sensitivity analysis had no effect on the final result, so it was retained.

The studies included in this meta-analysis were at risk of bias and may be biased differently, affecting the results. This study is mainly limited to some studies, although it mentions randomization, but does not elaborate its specific methods, and basically does not report whether there is blinding, resulting in the investigator being unable to make an objective judgment and affecting the accuracy of the final results. Syndrome efficacy, this method is more subjective and will affect the final results, so it is necessary to use the accepted objective indicators as the standard, so as to avoid some biases, and only 4 literature databases were searched, and there were problems such as incomplete data collection, which affected the final results.

5. Conclusion

In summary, compared with traditional treatment methods such as western medicine in the control group, Needle warming moxibustion in the treatment of ulcerative colitis can significantly improve its total clinical effective rate, the efficacy of traditional Chinese medicine syndrome, improve the symptoms of diarrhea, abdominal pain, pus and bloody stool, reduce intestinal inflammatory response, reduce the activity of ulcerative colitis, enhance the repair ability of intestinal mucosa, and improve the quality of life of patients. Since the final result can be affected in many ways, experiments should be conducted using accepted and objective evaluation criteria to reduce bias. Finally, it is expected that more randomized controlled double-blind experiments will provide more evidence for the

treatment of UC patients with Needle warming moxibustion.

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