

Meta-analysis of Xiehuang Powder as a Basic Formula for the Treatment of Oral Ulcers

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Abstract: This study aims to evaluate the effectiveness of Xiehuang Powder as a basic formula for treating oral ulcers. We systematically searched the relational clinical randomized controlled trials (RCTs) conducted in the CNKI, VIP, WFPD, and CBM databases, focusing on the use of Xiehuang Powder as a basic formula for treating oral ulcers (oral ulcer, OU). Strict inclusion and exclusion criteria were applied to select relevant studies, and data were extracted. The data were analyzed using RevMan 5.3 software. Resultly, fifteen articles involving 1,167 patients were included in the meta-analysis. All articles reported the overall clinical effectiveness rate, seven articles reported the recurrence rate, eight articles reported adverse reactions, three articles reported the healing time of oral ulcers, and two articles assessed changes in inflammatory factors. The meta-analysis results showed that the overall clinical effectiveness rate of Xiehuang Powder as a basic formula for treating oral ulcers was higher than that of conventional Western medicine treatment (RR=1.27, 95% CI: 1.21-1.34, P<P<0.00001). The recurrence rate was lower in the Xiehuang Powder group compared to the conventional Western medicine group (RR=0.35, 95% CI: 0.26-0.49, P<0.00001). There was no significant difference in the incidence of adverse reactions between the two groups (RR=0.57, 95% CI: 0.17-1.93, P=0.37). Furthermore, the healing time was shorter in the Xiehuang Powder group than in the conventional Western medicine group (MD=-4.42, 95% CI: -8.17 to -0.8, P=0.02). Thus it can be seen that Xiehuang Powder, as a basic formula, demonstrates effective treatment for oral ulcers, reducing the recurrence rate, alleviating inflammatory reactions, and accelerating the healing time of oral ulcers, thereby improving patients' quality of life. However, the number of high-quality trials available for analysis is limited, and further validation through more high-quality and high-level clinical studies is warranted.

1. Introduction

Oral ulcers are a prevalent and common clinical condition occurring within the oral cavity. In China, the incidence of oral ulcers is as high as 20% and predominantly affects adolescents and young adults. These ulcers often occur during periods of high stress and are also more common in females around the menstrual cycle. There is a certain genetic predisposition to this condition [1]. Oral ulcers

manifest as variable-sized, shallow or deep ulcers located on the oral mucosa, inner lips, tongue, or soft palate. They typically present as round or oval-shaped lesions with a red surrounding area and a grayish-white pseudomembrane covering. Pain, particularly during eating, is a common symptom, and the ulcers often exhibit periodic episodes [2]. In Traditional Chinese Medicine, this condition is referred to as "Kou Jian" or "Kou Cuan." Common pathological mechanisms include excessive gastric heat, damp-heat accumulation, spleen deficiency leading to stagnant heat, yin deficiency with excessive heat, and yang deficiency with flaring heat [3]. In recent years, Chinese herbal decoctions have become the most commonly used intervention method due to their rapid efficacy and precise therapeutic effects. However, the efficacy of these interventions has not yet been systematically evaluated through standardized assessments. Therefore, the objective of this meta-analysis is to assess the clinical effectiveness of Xiehuang Powder as a basic formula or in combination with conventional Western medicine for the treatment of oral ulcers. The aim is to provide reference evidence for the clinical application of traditional Chinese medicine in the management of oral ulcers.

2. Materials and methods

The literature selected for this study consisted of randomized controlled trials (RCTs) conducted in China and published in academic journals. The trials investigated the clinical treatment of oral ulcers using Xiehuang Powder as a basic formula or in combination with conventional Western medicine.

2.1. Inclusion criteria

The title and abstract of each article were first evaluated by two independent investigators. A full-text screening of the studies was then performed based on the following inclusion criteria: (1) Participants: patients that met the diagnostic criteria of OU (diagnosis of OU confirmed by a clinician or patient's condition meets the diagnostic criteria for OU in Oral Mucosal Pathology); (2) Study design: RCTs; (3) Intervention: Xiehuang Powder alone or in combination with routine treatment, such as oral vitamin B and vitamin C; (4) Outcome indicators: Primary outcome indicator - overall efficacy rate; Secondary outcome indicators - incidence of adverse reactions, recurrence rate, changes in inflammatory factors, and comparison of ulcer healing time.

2.2. Exclusion criteria

The following exclusion criteria were used: (1) Treatment group receiving non-pharmacological interventions in addition to Xiehuang Powder modification; (2) Unclear diagnostic criteria or outcome evaluation indicators; (3) Clinical case reports, literature reviews, animal experiments, conference papers, expert opinions, and non-statistically analyzed descriptive studies without a control group; (4) self-controlled before-and-after randomised controlled trials; (5) Duplicate studies in which the same data have been published by different centers; (6) Studies involving complications or comorbidities of oral ulcers.

2.3. Literature search

The Chinese search terms and search strategy used in the CNKI, VIP, WFPD, and CBM databases are as follows: Search terms: "Xiehuang Powder", "Oral ulcer", "Recurrent aphthous ulcer", "Recurrent oral ulcer", "Stomatitis", "Recurrent stomatitis", "Oral mucosal ulcer", "Oral erosion". Search strategy (using WFPD as an example): Title or Keywords =Xiehuang Powder AND (Title or Keywords = "Oral ulcer" or "Recurrent aphthous ulcer" or "Recurrent oral ulcer" or "Stomatitis" or

"Recurrent stomatitis" or "Oral mucosal ulcer" or "Oral erosion" AND Any Field = "Random" or "Randomized control". The search strategy is the same for other databases such as CNKI, VIP, and CBM. The time range is set from the inception of each database until January 20, 2023.

2.4. Data extraction and evaluation

Two evaluators independently screened and extracted data from the selected literature based on the predetermined inclusion and exclusion criteria. In cases of disagreement, a third party was consulted for consensus. Methodological evaluations of the included literature were conducted using the Cochrane Collaboration's risk of bias assessment criteria. Key evaluation criteria included randomization methods, allocation concealment, blinding methods, completeness of outcome data, and selective reporting of study results.

2.5. Statistical methods

Data analysis was performed using RevMan 5.3 software provided by the Cochrane Collaboration. The combined effect size for count data was expressed as relative risk (RR) with a 95% confidence interval (CI). Heterogeneity was assessed using the Q test and I^2 test. If $P > 0.1$ and $I^2 < 50\%$, indicating low heterogeneity among the studies, a fixed-effects model was selected for analysis. If $P < 0.1$ and $I^2 > 50\%$, indicating high heterogeneity among the studies, a random-effects model was used. Individual studies that could not be included in the meta-analysis were analyzed separately based on the reported clinical outcomes. Forest plots were used to present the results of the analysis, and funnel plots were used to assess potential publication bias.

3. Results

3.1. Literature search results

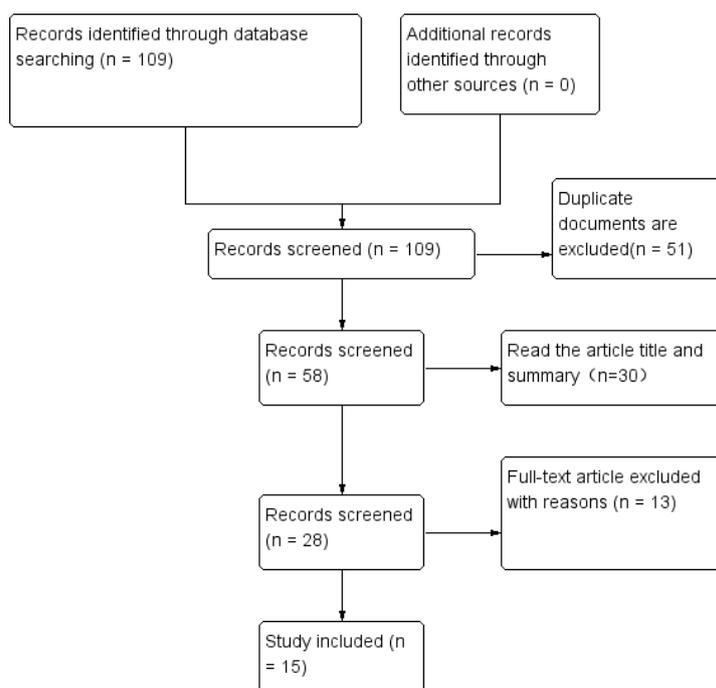


Figure 1: PRISMA flow diagram of included and excluded articles

According to the search plan, a total of 109 articles were obtained, and the bibliography was

imported into the "Medical Literature King V6" software, and duplicates were removed using the duplicate check function, resulting in 58 remaining articles. After reviewing the titles and abstracts, 30 articles that clearly did not meet the research criteria were excluded, leaving 28 articles for further evaluation. The full texts of these articles were then assessed based on the inclusion and exclusion criteria, resulting in the exclusion of 13 articles. Finally, a total of 15 articles were included in the analysis. The flowchart of the literature search process and results are presented in Figure 1.

3.2. Basic characteristics of included studies

Table 1: General characteristics of the included studies

Author	Age	Sample Size		Age (years)		Intervention measures		Duration	Outcome
		T	C	T	C	T	C		
Guofu Liu [4]	2010	30	30	34.5±12.6	32.5±13.7	XHP	Vc+Vb2	3 days/month, Total 2 months	(1)(2)(3)
Min Wu [14]	2016	42	40	33.6±4.3	35.2±5.8	XHP+TFC+BPP	TFC+BPP	4 weeks	(1)(4)
Wanying Huan [11]	2015	30	30	42.0±0.5	42.5±0.5	XHP	Vc+Vb2	3 days/month, Total 2 months	(1)(2)
Yan Li [5]	2018	40	40	49.4 ± 3.1	49.3 ± 3.1	XHP+Vc+Vb2	Vc+Vb2	7 days	(1)(2)(3)(5)
Dongsheng Li [15]	2019	52	52	34.1 ± 0.9	33.4±1.2	XHP+TFC+DABS+Vb2	TFC+DABS+Vb2	2 weeks ~6 months	(1)(4)
Yingxiao Li [16]	2016	60	58	32.6	38.2	XHP+HUS+Vc+Vb	HUS+Vc+Vb	/	(1)
Guimei Liang [12]	2013	37	37	36.5±3.2	38.6±4.1	XHP	Vc+Vb2	3 days/month, Total 2 months	(1)(2)
Yushan Fan [6]	2019	30	30	37.0±6.0	35.2±6.2	XHP+Vc+Vb	Vc+Vb	14 days	(1)(2)(3)
Hong Wu [7]	2020	29	29	53.7±8.1	53.5±8.2	XHP+CWMT	CWMT	/	(1)(3)
Hongguang Wang [13]	2012	40	40	21.0~64.0	24.0~65.0	XHP	Vc+Vb2	3 days/month, Total 2 months	(1)(2)
Ziyun Zhao [8]	2019	30	31	37.3±11.9	34.8±9.2	XHP	Vc+Vb2	14 days	(1)(2)(3)(5)
Zhiming Chen [9]	2014	50	50	51.1±7.8	53.7±9.3	XHP	CWMT	7-14 days	(1)(2)(3)(5)
Chunhui Chen [10]	2022	50	50	7.2±1.6	7.1±1.6	XHP+CWMT	CWMT	14 days	(1)(3)
Lan Gao [17]	2012	35	35	42.8	41.9	XHP	Vb2+Yike paste	2 weeks ~ 6 months	(1)
Jialou Li [18]	2008	42	18	1.8~10.0	2.0~10.0	XHP	CWMT	5 days	(1)

Note: T: treatment group; C: control group; XHP: Xiehuang powder plus or minus; TFC: transfer factor capsules; BPP: Bingpeng power; DABS: Dexamethasone acetate bonded sheet; HUS: Homemade ulcer spirit; CWMT: Conventional western medicine treatment; (1) Overall clinical

symptom effective rate; (2) Incidence of adverse reactions; (3) Recurrence rate; (4) Changes in inflammatory factors; (5) Comparison of ulcer healing time.

A total of 15 studies involving 1,167 patients were included in the analysis. Among them, the treatment group consisted of 597 patients, while the control group consisted of 570 patients. All included studies reported the overall clinical efficacy. Seven studies [4-10] reported on the recurrence rate, and eight studies [4-6, 8-9, 11-13] reported on adverse reactions. Three studies [5, 8-9] provided information on the healing time of oral ulcers, and two studies [14-15] examined the changes in inflammatory factors. The basic characteristics of the included studies are summarized in Table 1.

3.3. Quality assessment of included literature

The quality of the studies was assessed using the Cochrane bias assessment tool. All the included literature met the requirements of controlled trials, but none of them reported detailed trial protocols or implementation processes. It was unclear whether allocation concealment and blinding methods were employed. Among the included studies, three articles [4, 8, 10] explicitly mentioned the use of random number table method, while the remaining 12 articles [5-7, 9, 11-18] described randomization in text but did not specify the specific implementation method. All the included studies had complete outcome data without selective outcome reporting. No evidence of reporting bias or other biases was found in any of the included literature. The quality assessment indicated that the included studies had a low quality, and the risk of bias assessment results for the included literature are shown in Figure 2 and Figure 3.

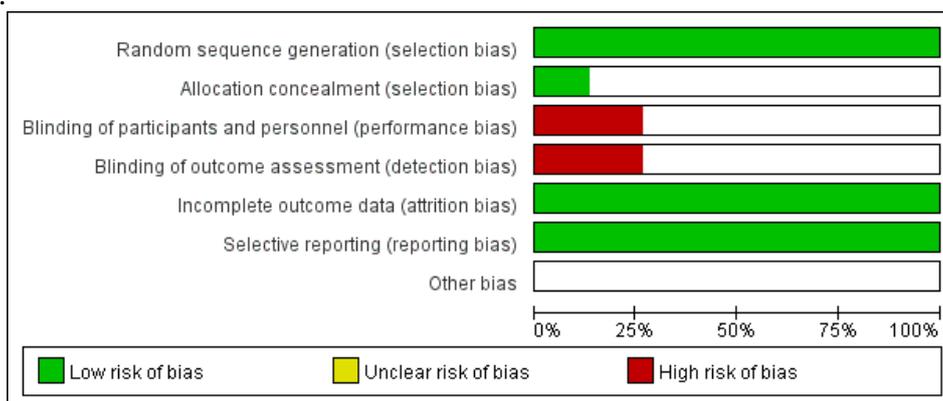


Figure 2: The risk of bias graph

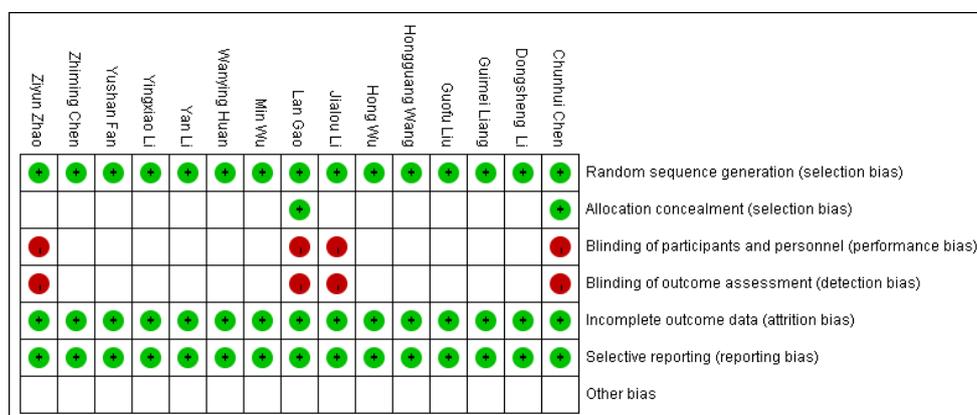


Figure 3: The risk of bias summary

3.4. Outcome Measure Analysis

3.4.1. Overall Effective Rate

All included studies reported the overall effective rate. Heterogeneity analysis shows that the traditional Chinese medicine group with Xiehuang powder addition and subtraction is compared with the conventional western medicine group, and there is homogeneity among the studies ($I^2=9\%$, $P=0.35$); therefore, a fixed-effects model was employed. The results showed that Xiehuang Powder as the basic treatment for oral ulcers had a higher overall effective rate compared to the conventional Western medicine group, and the difference was statistically significant ($RR=1.27$, 95% CI [1.21, 1.34], $P<0.00001$). Please refer to Figure 4 for the results.

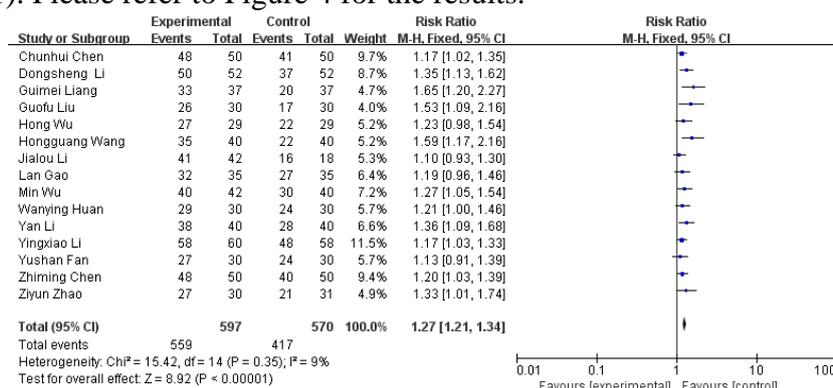


Figure 4: Forest Plot of Overall Effective Rate

3.4.2. Comparison of recurrence rate

Seven studies [4-10] reported the incidence of recurrence. The Q-test and I^2 test indicated low heterogeneity among the studies ($P=0.04$, $I^2=53\%$), therefore a fixed-effects model (FE) was used for analysis. The results showed that Xiehuang Powder as a basic formula for treating oral ulcers had a lower recurrence rate compared to the control group ($RR=0.35$, 95% CI [0.26, 0.49], $P<0.00001$), as shown in Figure 5.

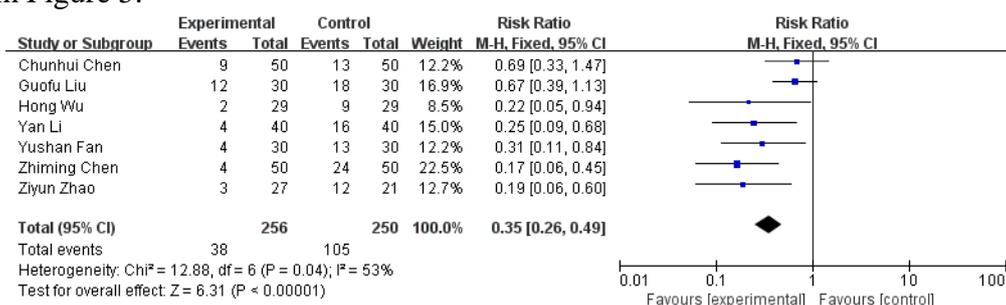


Figure 5: Forest plot of recurrence rate

3.4.3. Incidence of Adverse Reactions

Among the 15 included studies, 1 study [11] only mentioned no significant adverse reactions without providing detailed descriptions, 3 studies [5-6,8] reported no adverse reactions, and 4 studies [4,9,12-13] reported sub specific adverse reactions, mainly gastrointestinal reactions such as diarrhea. Q-test and I^2 -test showed low heterogeneity among the studies ($P=0.33$, $I^2=13\%$), and a fixed-effects model (FE) was selected for analysis. The results indicated that there was no significant difference in the incidence of adverse reactions between Xiehuang Powder and conventional Western medicine for

the treatment of oral ulcers (RR=0.57, 95%CI (0.17, 1.93), P=0.37), as shown in Figure 6.

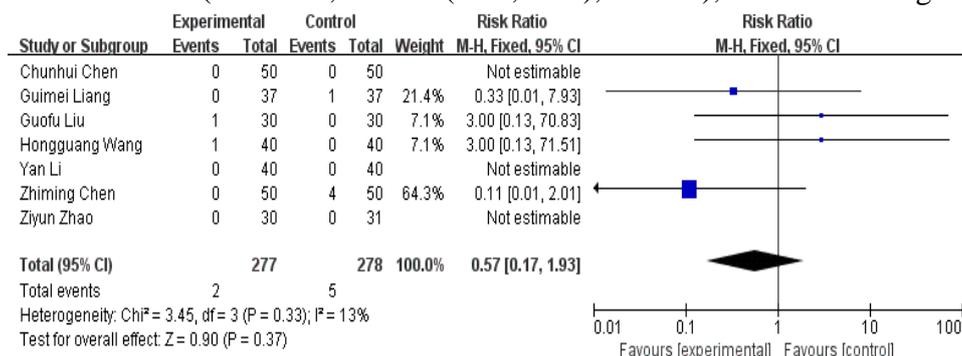


Figure 6: Forest plot of adverse reaction rates

3.4.4. Healing Time of Ulcers

A total of three included studies [5,8-9] reported mean oral ulcer healing time index, data pooled analysis, heterogeneity $\chi^2=101.56$ ($P<0.00001$, $I^2=98\%$), using a random-effects model, MD=-4.42, 95% CI (-8.17, -0.8), pooled effect test $Z=2.31$, and statistically significant differences between the two groups ($P=0.02$). The results showed that the healing time of mouth ulcers in the experimental group was shorter than that in the control group, as shown in Figure 7.

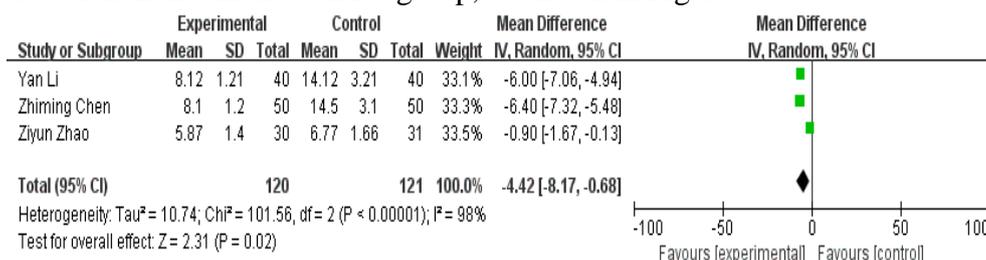


Figure 7: Forest plot of ulcer healing time

3.4.5. Changes in Inflammatory Factors

Two included studies [14-15] examined the changes in inflammatory factors, specifically serum IL-2 and serum IL-4. However, the limited number of studies prevented a meta-analysis from being conducted. The results indicated that treatment with Xiehuang Powder, as a basic prescription of traditional Chinese medicine, significantly increased the expression levels of serum IL-2 and decreased the expression levels of serum IL-4. This effect was associated with promoting ulcer healing and reducing the degree of inflammatory response, and the difference was statistically significant.

3.4.6. Publication Bias

Publication bias analysis was conducted for the overall effective rate of Xiehuang Powder in the treatment of oral ulcers. The funnel plot of the overall effective rate showed some asymmetry, suggesting the presence of publication bias, as depicted in Figure 8.

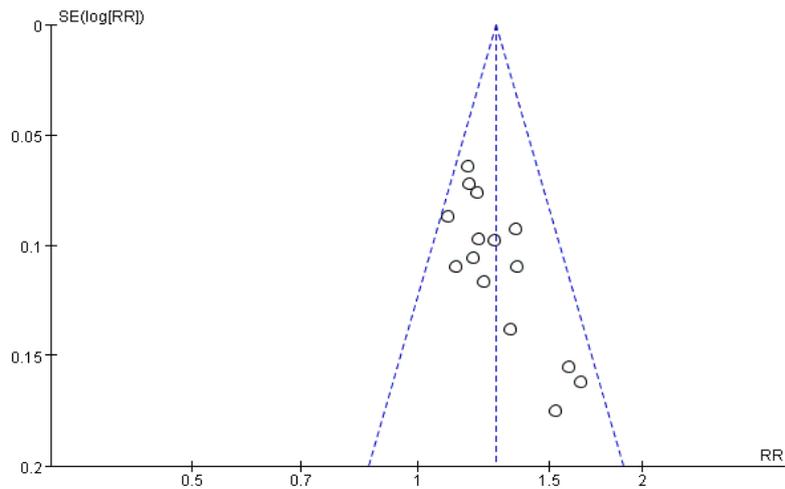


Figure 8: Funnel plot of total effective rate

4. Discussions

The results of this study showed that: (1) compared to conventional Western medicine treatment for oral ulcers, Xiehuang Powder as a basic formula for treating oral ulcers can improve the overall clinical effectiveness; (2) Xiehuang Powder as a basic formula for treating oral ulcers can reduce recurrence rate, lower inflammatory reactions, and shorten the healing time of oral ulcers, suggesting that Xiehuang Powder as a basic formula or in combination with conventional Western medicine treatment may have certain advantages for treating oral ulcers; (3) in the included trials, Xiehuang Powder as a basic formula appears to be a safe medication, although safety data were only mentioned in 8 studies. No life-threatening side effects were observed in the treatment of patients across all studies. Therefore, we conclude that Xiehuang Powder as a basic formula does not pose serious risks to patients.

Oral ulcer is a common oral mucosal disease in clinical practice, primarily affecting the lips, tongue, floor of the mouth, and soft palate. The main symptom is oral mucosal pain, and in severe cases, it can affect a patient's ability to eat [19]. Modern medical research on oral ulcers is extensive, but the etiology is still unclear and is likely the result of multiple factors, such as the immune system, genetics, endocrine factors, psychological factors, etc. [20]. Conventional Western medicine treatment for recurrent oral ulcers has shown good short-term efficacy, but long-term efficacy is poor, and it does not fundamentally reduce the recurrence rate of the disease [21]. In Traditional Chinese Medicine (TCM), oral ulcers are classified as "Kou chuang," and Xiehuang Powder is a commonly used formula for treating this condition. This formula is derived from the book "Xiao'er Yao Zheng Zhi Jue" and consists of five herbal ingredients: Sheng Shi Gao (gypsum fibrosum), Huo Xiang (Agastache rugosa), Zhi Zi (Gardenia jasminoides), Fang Feng (Saposhnikovia divaricata), and Gan Cao (Glycyrrhiza uralensis) [22]. Xiehuang Powder has been found to have significant analgesic, anti-inflammatory, and ulcer-healing effects based on modern research [14-15, 23]. Pharmacological studies have shown that gypsum fibrosum in the formula can enhance the phagocytic ability of macrophages, promote their maturation, and also has anti-inflammatory, anti-allergic, and diuretic effects [24]. Gardenia jasminoides has antipyretic, analgesic, and antibacterial effects; Saposhnikovia divaricata has antipyretic, analgesic, antibacterial, and anti-inflammatory effects, and can enhance the anti-inflammatory effects of gypsum fibrosum and gardenia jasminoides; Agastache rugosa has preservative, antibacterial, anti-inflammatory, and analgesic effects; Glycyrrhiza uralensis has anti-inflammatory, antibacterial, and antipyretic effects. Therefore, Xiehuang Powder with modifications

has certain clinical value in promoting ulcer healing, reducing inflammatory reactions, and lowering the recurrence rate.

Limitations of this meta-analysis: (1) Publication bias: The included studies were all Chinese-language publications, and there is a lack of foreign-language literature and unpublished studies, which poses a certain risk of bias. Potential publication bias and inclusion of low-quality studies may exaggerate or underestimate the effectiveness of the intervention, and some studies had short treatment and observation periods, and the ratio of subjects in the treatment group to the control group was not always 1:1, which can affect the final results. Therefore, the results of this study should be interpreted with caution, and definitive conclusions about the efficacy of Xiehuang Powder as a basic formula for treating oral ulcers require further clinical trials. (2) Intervention measures: Specific randomization schemes, single-blinding, double-blinding, and allocation concealment were rarely mentioned, which raises doubts about the authenticity of the clinical trial results. (3) Other biases: The outcome measures screened in the literature, such as adverse reactions, were based on patients' subjective symptoms, which introduces a certain degree of subjectivity and affects the objectivity of the outcomes. (4) The number of relevant studies is still limited, so the conclusion that Xiehuang Powder as a basic formula is effective for treating oral ulcers needs further verification through more high-quality clinical trials.

In summary, this study's meta-analysis demonstrated that using Xiehuang Powder as a basic formula for treating oral ulcers can improve the overall clinical effectiveness of patients, reduce recurrence, lower inflammatory reactions, and shorten healing time. It can enhance patients' quality of life and is worth promoting in future clinical practice. However, the number of high-quality trials available for analysis is limited, so caution should be exercised when interpreting the results of this systematic review.

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