Review Article

Evaluating the Efficacy and Adverse Effects of Clearing Heat and Removing Dampness Method of Traditional Chinese Medicine by Comparison with Western Medicine in Patients with Gout

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Objective. In China, the method of clearing heat and removing dampness medicine of Chinese traditional medicine has been widely used on gout. However, the clinical effects are various and not summarized systematically. Methods. In this study, a large number of randomized controlled clinical trials were reviewed and analyzed and the clinical efficacy and adverse reactions of traditional Chinese medicine with clearing heat and removing dampness effects for the treatment of gout were systematically evaluated. A comprehensive search of databases including PubMed, China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database, Wanfang Data, and SinoMed was performed. Results. There are 69 randomized controlled trials with 5915 sample sizes meeting the criteria in the study. The results of the meta-analysis indicate that the effects of clearing heat and removing dampness medicine were slightly better than western medicine in the treatment of gout based on the following parameters: serum uric acid (standardized mean difference (SMD): -62.14, 95% confidence interval (CI): -78.12 to -46.15), C reactive protein (SMD: -4.21, 95% CI: -6.19 to -2.23), erythrocyte sedimentation rate (SMD: -6.23, 95% CI: -8.39 to -4.06), and overall clinical response (relative risk (RR): 1.11, 95% CI: 1.08 to 1.15) and, in the profile of adverse drug reactions, the clearing heat and removing dampness medicine showed less adverse reactions than traditional Western medicine (RR: 0.18, 95% CI: 0.10 to 0.32). Conclusions. Through a systemic evaluation of the clinical efficacy of the clearing heat and removing dampness medicine of traditional Chinese medicine and western medicine on gout, the clearing heat and removing dampness medicine and western medicine possessed similar clinical efficacy, but traditional Chinese medicine treatments are superior to western medicine in controlling adverse reactions.

1. Introduction

With the change of lifestyle and dietary factor, gout has been the global burden [1], mainly because of its high incidence in not only elderly people but also younger people [2]. Gout is a crystal deposition disease which results from local uric acid supersaturation as a consequence of systemic uric acid overload, leading to the formation of monosodium urate (MSU) crystals in the around joints, which caused severe pain and had a strong impact on quality of life. The most common clinical manifestation of gout is recurrent attacks of acute arthritis involving one joint at a time [3]; in some cases, joint injury and renal insufficiency will even occur in patient with gout.

In clinical, western medicines including corticosteroids, allopurinol, and NSAIDs are widely used in treating acute attack of gout [4]. But they all possessed various degrees of side-effect such as gastrointestinal tract reaction, tissue and organ damage, and other adverse reactions. In recent years, IL-1R antagonists appeared and was used for the patients who have contraindications to colchicine and nonsteroidal anti-inflammatory drugs and hormones (oral or injection)
[5]. However, the mechanism was unclear and the side effect was also not mentioned. Traditional Chinese medicine (TCM) has been used for preventing and treating gout with unique clinical effects since 200AD in China [6]. Clearing heat and removing dampness is a special medical method for treating patients with gout based on the theory of Chinese traditional medicine, which indicated that the pathogenesis of gout disease is closely related to the heat evil and wetness evil attacking [7]. Many randomized controlled trials (RCTs) in clinical published have selected heat and removing dampness method of Traditional Chinese Medicine to treat gout, and most have clearly shown that Traditional Chinese Medicine have achieved positive results in treating gout.

Meta-analysis, which is the statistical synthesis of relative literature to develop evidence-based conclusions, is able to systematically evaluate and summarize the consistency of multiple studies on the same topic [8]. To the best of our knowledge, there is no meta-analysis of the treatment of gout with heat and removing dampness method of Traditional Chinese Medicine. We need to have a clearer understanding of the application of heat and removing dampness method of Traditional Chinese Medicine in the treatment of gout and to evaluate its effectiveness of in the treatment of gout. The efficacy and side effect of clearing heat and removing dampness medicine and western medicine in the treatment of gout were compared using meta-analysis method in this study. The results will lay a foundation for the treatment of gout with clearing heat and removing dampness methods.

2. Methods

2.1. Experimental Design. The clinical designs in all reports selected in this study were clinical randomized controlled trials (RCTs). Based on the intervention method, the trials were divided into experimental and control groups, oral administration of Chinese herbal decoction and disposition with other methods of traditional Chinese medicine were included in the experimental group, while oral administration of western medicine was regarded as the control group. The publication time was restricted to the period from January 2000 to May 2017, and the journals’ languages were restricted in Chinese and English.

2.2. Subjects. According to the diagnostic criteria created by the 1977 American College of Rheumatology classification criteria and Guidelines for the diagnosis and treatment of primary gout established by the Chinese Rheumatology Association, etc., all subjects selected in the study were diagnosed with primary gout in the phase of acute arthritis. Subjects with other comorbidities were excluded.

2.3. Database Search Strategy. The titles of “Clearing heat and removing dampness” and “hyperuricemia” or “Clearing heat and removing dampness” and “gout” were searched from the databases including PubMed, China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database, Wanfang Data, and China Biology Medicine disc during the period from January 2000 to May 2017.

2.4. Data Analysis. Three investigators who participated in the study extracted data from all publications selected in this study. The information of the first author, the year of publication, the number of cases in the experimental group and the control group, the intervention method, the end point evaluation index, and the Jadad score were included. One investigator did the first data extraction, the second investigator reviewed the literatures and confirmed the results afterwards, and the third investigator participated in the discussion when the disagreement occurred and reached a consensus with the other two finally.

2.5. Endpoint Indicators. The evaluations of effective and ineffective were reached artificially based on the indicators of measurement data, such as Serum uric acid (SUA), C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR). And the evaluations of SUA, CRP, and ESR were collected after the period of gout attack. The reducing of blood uric acid, ESR, and CRP and the relieving of the clinical symptoms were regarded as effective. On the contrary, it was ineffective. The respective measurement data of blood uric acid, ESR, and CRP were also regarded as the primary indicators.

2.6. Assessment of Methodological Quality. Assessment of methodological quality is based on the validated Jadad scale by two reviewers (XN and CH) and the Jadad scale has three scoring points. The first is if the study was described as randomized, and with detailed descriptions. The second is if the blind method was adopted in the study and with detailed descriptions. And the third is if there was a description of withdrawals and dropouts. A paper reporting could therefore receive a Jadad score from 0 to 7, in which the scores with 1-3 and 4-7 were considered as low and high quality, respectively.

2.7. Statistical Methods. The measurement data were evaluated using the mean difference (MD) and 95% confidence interval (CI), or the relative risk (RR) and 95% confidence interval. If the heterogeneity of the study was within the acceptable range (I² ≤ 50%), the fixed effect model was used. Otherwise, the random effects model was used. The collected data in clinical research were analyzed by RevMan 5.0 software.

3. Results

3.1. Selection of Studies. 971 articles about the treatment of gout using clearing heat and removing dampness medicine of Chinese traditional medicine were retrieved from five electronic databases, in which 442 duplicated publications articles were excluded. Then two reviewers independently screen the full texts of the remaining 529 articles. 109 non-RCT articles, 8 articles based on animal experiments, 88 articles had inconformity to inclusion standard but included the experimental group or the control group, 19 articles without diagnostic criteria, 143 articles about review and experience summary, and 93 articles about other directions. Finally, 69 articles were included in this study [9–77] (Figure 1). The characteristics of these studies were shown in Tables 1 and 2.
| Author, year | Sample size | Age | Intervention methods | Duration treatment | Effective number | Jadad scale |
|--------------|-------------|-----|----------------------|--------------------|-----------------|-------------|
| Yan Zhang, 2016 | 27 | 25 | 47.04±12.92 | 47.72±8.69 | Qingrelishi side | Low purine diet + meloxicam | 14 | 14 | 25 | 23 | 3 |
| Fang Zuo, 2001 | 36 | 30 | N/A | N/A | BaiHuGuiZhi Decoction+ Simiaoa Powder | allopurinol | 14 | 14 | 52 | 22 | 1 |
| Yihui Yan, 2006 | 46 | 46 | N/A | N/A | BiNing Decoction | allopurinol | 28 | 28 | 33 | 28 | 1 |
| Xubin Zhao, 2014 | 25 | 25 | N/A | N/A | Blood-letting puncture and cupping+ Microwave therapy | Colchicine + Diclofenac Sodium Sustained Release Capsules | 3–7 | 1–7 | 25 | 23 | 1 |
| Li Cheng, 2009 | 32 | 30 | N/A | N/A | Danghuiniantong Decoction | Meloxicam | 7 | 7 | 31 | 29 | 1 |
| Guicai Sun, 2007 | 65 | 65 | N/A | N/A | Compound xiqiancao capsule | Voltaren+ allopurinol | 21 | 21 | 58 | 54 | 1 |
| Yuhong Zhang, 2003 | 45 | 43 | N/A | N/A | Modified Sanmiao Powder Simiaoa Powder+ Xinhuang Tablet(external) | Colchicine | 14 | 14 | 33 | 18 | 1 |
| Shengyun Wu, 2017 | 34 | 34 | 35.9±6.1 | 35.9±6.1 | Modified Simiaoa Powder+ Xinhuang Tablet (external) | Colchicine | 7 | 7 | 49 | 44 | 3 |
| Qingsheng He, 2016 | 50 | 50 | 34.5±4.7 | 32.7±3.2 | Modified Simiaoa pill | Colchicine | N/A | N/A | 67 | 33 | 1 |
| Lixin Wang, 2001 | 69 | 35 | N/A | N/A | Modified Simiaoa pill | Colchicine | N/A | N/A | 15 | 55 | 27 | 1 |
| Zhonghua Yang, 2007 | 60 | 30 | N/A | N/A | Jianpi qingrelishi Tongluo Decoction JunHu analgesic powder(external)+ acupuncture treatment | colchicine | 3 | 3 | 44 | 38 | 1 |
| Wenping Cao, 2008 | 44 | 43 | N/A | N/A | Lizhuodingtong decoction | Nimesulide | 30 | 10 | 34 | 32 | 1 |
| Yanhong Zou, 2010 | 40 | 40 | N/A | N/A | Niantongxiaofeng prescription | colchicine | 15 | 15 | 52 | 43 | 1 |
| Jincheng Cai, 2006 | 54 | 46 | N/A | N/A | Qingrechushi prescription | Etoricoxib Tablets Didlofenac Sodium Sustained Release Tablets+ Benzbromarone Tablets | 14 | 14 | N/A | N/A | 1 |
| Wei Li, 2016 | 58 | 58 | N/A | N/A | Discriminate treatment of Chinese medicine by clearing away heat and resolving turbid | Didlofenac Sodium Sustained Release Tablets | 31 | 31 | 31 | 27 | 1 |
| Yingxu Wang, 2014 | 33 | 31 | 46.97±9.65 | 41.16±9.72 | Compound Chinese medicine decoction of Clearing heat-toxin and eliminating dampness method | Etoricoxib Tablets Didlofenac Sodium Sustained Release Tablets | 14 | 14 | 30 | 29 | 3 |
| Author, year | Sample size | Age | Intervention methods | Duration treatment | Effective number | Jadad scale |
|--------------|-------------|-----|----------------------|--------------------|----------------|-------------|
| Feng Yue, 2005 | 30 30 | N/A | Clearing heat-toxin and eliminating dampness method+ Gold paste(external) | colchicine | 7 7 | 30 30 | 1 |
| Yanming Ren, 2007 | 60 30 | N/A | Acid fat clear capsule | colchicine | 7 7 | 52 27 | 1 |
| Huilian Wang, 2012 | 40 40 | 48.4±12.8 49.1±13.1 | Gouty granule Nimesulide | 10 10 | 34 33 | 1 |
| Wei Jin, 2013 | 32 32 | C | Self-prepared gout recipe+ Jiawei Jinhuang powder colchicine | 7 7 | 30 24 | 1 |
| Hong Tu, 2015 | 30 30 | 44.9±9.1 45.1±8.1 | Gout clear granules Didofenac Sodium Sustained Release Tablets Ibuprofen+ Probencid52 | 10 10 | 49 33 | 1 |
| Binchu Wang, 2000 | 52 38 | N/A | Gout decoction | allopurinol | 30 30 | 67 69 | 1 |
| Haileng Li, 2012 | 73 80 | 45.6±10.1 47.2±12.4 | Xuanbide decoction | Indomethacin | 7 7 | 18 16 | 3 |
| Hongtao Yan, 2006 | 20 20 | N/A | Xuanbide decoction | allopurinol | 7 7 | 54 32 | 1 |
| Weigang Zeng, 2010 | 55 50 | N/A | Yushantongfeng decoction 2 | allopurinol | 7 7 | 118 108 | 1 |
| Weigang Zeng, 2007 | 120 116 | N/A | Yushantongfeng decoction | colchicine | N/A N/A | 118 108 | 1 |
| Jiang Wu, 2015 | 36 36 | 51.34±6.28 52.46±7.4 | Acupuncture+Sanyen decoction and Sijunzi decoction | Didofenac Sodium Sustained Release Tablets Colchicine+ allopurinol Ibuprofen Sustained-release Capsules | 7 7 | 33 30 | 1 |
| Jing Chen, 2017 | 61 55 | 52.1±1.2 51.5±1.4 | Chinese medicine and acupuncture | Colchicine+ allopurinol Ibuprofen Sustained-release Capsules | 7 7 | 58 47 | 1 |
| Minghai Zhou, 2014 | 20 20 | N/A N/A | Simiao powder and acupuncture | Meloxicam | 7 7 | 55 56 | 1 |
| Guangheng Cui, 2011 | 60 60 | N/A N/A | Hovenia acer balindl Tongfeng Decoction Compound decoction of Chinese herbal medicine | Colchicine+ allopurinol Allopurinol+ Sodium Bicarbonate Tablets(oral)+ Qingpeng Paste(external) | 7 7 | N/A N/A | 1 |
| Yangang Wang, 2005 | 35 35 | 45.0±6.5 46.0±5.7 | Oral administration of Chinese medicine decoction+Rebiqing granules(oral)+Chinese medicine(external) | Colchicine Tablets | 7 7 | 29 25 | 2 |
| Hai Lu, 2013 | 30 30 | N/A N/A | Simiao pill and Gouty ointment | Allopurinol+Celecoxib | 31 31 | 39 29 | 1 |
| Bo Duan, 2016 | 54 54 | 40.26±10.98 42.31±11.77 | | | 7 7 | 47 46 | 2 |
| Author, year | Sample size | Age | Intervention methods | Duration treatment | Effective number | Jadad scale |
|-------------|-------------|-----|----------------------|--------------------|-----------------|-------------|
| Min Dai, 2015 | 39 39 | 35±2.5 35±2.5 | Atractylodes rhizome, Achyranthes bidentata, Smilax glabra, Cortex Phellodendri, honeysuckle vine, liquorice, 2 Corydalis tuber, astragalus root and coix seed | Didofenac Sodium Sustained Release Tablets | 14 14 | 36 29 | 1 |
| Xiaohong He, 2008 | 28 26 | 42.5±7.7 46±11.8 | Simiao powder+Shuang powder Self-made prescription: Mountain arrowhead, clematis, peach, Atractylodes, Poria, Alisma, Adenophora, Polygonum cuspidatum, rice, Bixie | Colchicine | 3 3 | 27 20 | 1 |
| Xiaoxia Wang, 2010 | 30 30 | 48.5±15.5 49.1±13.7 | Self-made prescription: Mountain arrowhead, clematis, peach, Atractylodes, Poria, Alisma, Adenophora, Polygonum cuspidatum, rice, Bixie | Colchicine | 10 10 | 28 29 | 1 |
| Hujuan Yao, 2010 | 56 54 | N/A N/A | Modified Guizhi Shao Yao Zhi Hu decoction | Colchicine | 10 10 | 51 52 | 1 |
| Lei Zhang, 2016 | 37 37 | 44.43±11.29 45.02±12.1 | Oral administration of Bixie decoction Clearing heat and damp elimination tongluo + Relieving stasis and pain Clearing heat and damp elimination prescription | Didofenac Sodium Sustained Release Tablets | 7 7 | 33 31 | 1 |
| Bo Shi, 2010 | 45 40 | 49±16 48±14 | Oral administration of Bixie decoction Clearing heat and damp elimination tongluo + Relieving stasis and pain Clearing heat and damp elimination prescription | Colchicine | 10 10 | 38 25 | 1 |
| Liping Yan, 2012 | 38 31 | N/A N/A | Self-made prescription: Mountain arrowhead, clematis, peach, Atractylodes, Poria, Alisma, Adenophora, Polygonum cuspidatum, rice, Bixie | Colchicine | 7 7 | 35 23 | 1 |
| Yueqi Wang, 2013 | 32 32 | N/A N/A | Clearing heat and removing dampness and activating blood circulation method | Dicofenac acid enteric coated tablets | 7 7 | 30 29 | 1 |
| Rong Li, 2014 | 75 75 | 50.24±12.37 49.15±13.06 | Bixi shen shi decoction and Taohongsiwu decoction | Celecoxib+ Sodium Bicarbonate Tablets | 10 10 | 69 62 | 1 |
| Shanshan Yu, 2008 | 40 40 | 48.2±8.6 46±9.7 | Dampness detoxification method | Nimesulide tablets | N/A N/A | 38 34 | 1 |
| Weidong Qian, 2007 | 60 40 | N/A N/A | Xitong Granule Qingrelishi Tongluo Decoction Stiffness and pain relieving prescription | Colchicine | 7 7 | 53 34 | 1 |
| Zheng Huang, 2013 | 32 30 | N/A N/A | Self-made Clearing heat and damp elimination tongluo prescription | Nimesulide tablets | 10 10 | 28 27 | 1 |
| Chongyu Tan, 2013 | 52 46 | N/A N/A | Self-made Clearing heat and damp elimination tongluo prescription | Colchicine+ Fenbid | 7 7 | 48 34 | 2 |
| Chun Kang, 2012 | 30 30 | 70.2±5.3 69.9±6.1 | Clearing heat and damp elimination tongluo decoction | Ibuprofen Sustained-release Capsules+ Sodium Bicarbonate Tablets | 7 7 | 28 24 | 2 |
| Xiaowu Fan, 2013 | 50 48 | N/A N/A | Clearing heat and damp elimination tongluo decoction | Fenbid | 7 7 | 48 38 | 2 |
Table 1: Continued.

| Author, year | Sample size | Age | Intervention methods | Duration treatment | Effective number | Jadad scale |
|--------------|-------------|-----|----------------------|--------------------|-----------------|-------------|
| Jianchong Shen, 2014 | 61 EG 61 CG | 45.78±7.45 46.47±8.35 | Laoshitongfeng prescription + acupuncture | 775 7 4 9 1 | 57 49 | 1 |
| Guiqiong Huang, 2016 | 60 EG 60 CG | 53.82±10.95 54.05±12.31 | Clearing heat and damp elimination tongluo prescription | 55 38 | 1 |
| Xin Ouyang, 2004 | 30 EG 30 CG | 57.77±6.62 56.37±6.74 | Bixiehuadu decoction | 28 25 | 1 |
| Zhimin Qi, 2016 | 105 EG 105 CG | 45.3±9.2 44.1±9.6 | Qingrelishi Zhuyu Decoction | 101 93 | 2 |
| Yaping Chen, 2014 | 45 43 N/A | N/A | Clearing heat and dredging collaterals to clear turbid decoction | 14 | 30 28 22 | 2 |
| Delei Li, 2007 | 40 40 N/A | N/A | Clearing heat and dampness, blood stasis, relieving pain Tongluo Decoction; Qingrelishi Tongluo releasing pain prescription | 38 | 34 | 1 |
| Jun Hao, 2014 | 30 30 | 46±8.03 45.16±7.97 | Gout mixture | 29 | 23 | 1 |
| Chongqing Yang, 2006 | 30 30 N/A | N/A | Gout prescription | 27 | 28 | 3 |
| Lin Wang, 2011 | 29 29 N/A | N/A | Tongbi prescription | 26 | 27 | 4 |
| Ayijiaman, 2012 | 56 44 | 44.3±4.3 44.9±3.9 | Tanreb decoction | 54 | 37 | 1 |
| Chileng Wang, 2014 | 36 36 | 51.7±3.2 52.1±2.9 | Simiao pill | 33 | 30 | 1 |
| Jianping Luo, 2010 | 30 30 N/A | N/A | Modified Simiao Powder | 3 | 3 | 1 |
| Xianzhang Zeng, 2013 | 60 58 N/A | N/A | Modified Simiao Powder | 58 | 51 | 1 |
| Jinfeng Li, 2013 | 28 26 | 43±10.8 44±11.3 | Modified Simiao Powder | 26 | 23 | 1 |
| Xiaozhong Yu, 2013 | 32 30 N/A | N/A | Simiao powder | 31 | 28 | 1 |
| Xianzhang Zeng, 2013 | 35 35 N/A | N/A | Simiaomaqian powder | 34 | 33 | 1 |
Table 2: Outcome of the meta-analyses for the comparison between clearing heat and removing dampness method of Chinese traditional medicine and western medicine, according to study design.

| Author, year   | Effective number | SUA | CRP | ESR | Adverse reactions |
|----------------|------------------|-----|-----|-----|-------------------|
| Yan Zhang, 2016 | 25               | 23  | N/A | N/A | N/A               |
| Fang, 2001     | 33               | 28  | 487.27±98.88/374.88±95.48 | 469.26±114.81/441.52±102.13 | N/A |
| Yuhu Yan, 2006 | 25               | 23  | N/A | N/A | N/A               |
| Xuhua Zhao, 2014| 31               | 29  | N/A | N/A | N/A               |
| Guice Sun, 2017 | 58               | 54  | 568.61±21.2/397.2±36.7 | 572.5±27.6/385.8±30.2 | N/A |
| Xubin Zhao, 2014| 25               | 23  | N/A | N/A | N/A               |
| Li Cheng, 2009 | 31               | 29  | N/A | N/A | N/A               |
| Guicai Sun, 2007| 58               | 54  | 568.61±21.2/397.2±36.7 | 572.5±27.6/385.8±30.2 | N/A |
| Yuhong Zhang, 2003| 39              | 42  | N/A | N/A | N/A               |
| Shengyu Wu, 2007| 33               | 18  | N/A | N/A | N/A               |
| Qingsheng He, 2006| 49             | 44  | 511±477.7/370±21.56 | 497±50.12/476±19.57 | N/A |
| Lixiu Wang, 2001| 67               | 33  | N/A | N/A | N/A               |
| Zhonghua Yang, 2007| 55             | 27  | N/A | N/A | N/A               |
| Wenping Cao, 2008| 44              | 38  | N/A | N/A | N/A               |
| Yanhong Zou, 2001| 34              | 32  | 442.15±60.12/399.78±38.27 | 438.58±67.45/417.12±41.45 | N/A |
| Jincheng Cai, 2006| 52             | 43  | 585±555/458±162 | 592±425/387±148 | N/A |
| Wei Li, 2016    | N/A              | 536.2±514.6±38.49 | 529.7±522.67±35.39 | 32.9±5.86/12.26±8.49 | N/A |
| Yingui Wang, 2014| 31             | 27  | 605.2±132/474.6±85.4 | 601.16±114.2/454.3±92.2 | N/A |
| Wei Liu, 2016  | 30               | 29  | 548.25±90.31/394.3±32.69 | 544.45±8.31/46 | N/A |
| Feng Yue, 2005 | 30               | 29  | N/A | N/A | N/A               |
| Yiming Ren, 2007| 52               | 27  | 544.36±86.27/341.25±79.34 | 567.74±91.13/387.32±64.64 | N/A |
| Huilai Wang, 2012| 34              | 33  | N/A | N/A | N/A               |
| Wei Jin, 2013   | 30               | 24  | N/A | N/A | N/A               |
| Hong Tu, 2015   | 29               | 24  | N/A | N/A | N/A               |
| Binchu Wang, 2000| 49              | 33  | 489±23.1/345±20.1 | 486±21.35/371±19.1 | N/A |
| Hafeng Li, 2012 | 67               | 69  | 287±55.64 | 426.1±89.2 | N/A |
| Author, year       | Effective number | SUA       | CRP       | ESR       | Adverse reactions |
|-------------------|------------------|-----------|-----------|-----------|------------------|
|                   | EG               | CG        | EG        | CG        | EG               | CG       | EG       | CG       | EG       | EG       | EG       | EG       | EG       | EG       | EG       | EG       | EG       |
| Hongtao Yan, 2006 | 18               | 16        | 537.85±39.72/425.3±16.24 | 558.5±31.27/550.8±25.09 | N/A       | N/A       | 45.30±7.97/40±5.95 | 44.55±8.11/43.95±5.85 | 1       | 8       |
| Weigang Zeng, 2010 | 54               | 32        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Weigang Zeng, 2007 | 118              | 108       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Jiang Wu, 2015    | 33               | 30        | 528.46±178.42/436.14±8.327 | 521.47±80.12/446.72±67.46 | 26.24±12.08/10.37±2.58 | 271.8±11.83/12.43±3.19 | 40.72±13.06/16.87±2.26 | 39.24±13.27/24.35±4.03 | 2       | 6       |
| Jing Chen, 2007   | 58               | 47        | 542.15±3.679/3.840±47.28 | 538.76±42.34/437.21±42.13 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | 0        | 3       |
| Minghai Zhou, 2014| 19               | 15        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Guangheng Cui, 2011 | 55              | 56        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Yangang Wang, 2015| N/A              | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Hai Lu, 2013      | 29               | 25        | 564.4±80.5/326±20.3 | 518±75.4/349.3±34.7 | 36.1±4.3/14.6±5.6 | 34.2±6.8/18.4±3.9 | 65.7±18.5/22.6±7.3 | 19.93±10.08/8.99±6.37 | 19       | 24      |
| Bo Duan, 2016     | 47               | 46        | 673.3±125.26/421.43±58.9 | 666.62±31.54/432.27±70.11 | 3.6±8.6/9.62/15.42±6.94 | 34.56±10.11/17.02±7.78 | 20.52±9.98/8.3±5.83 | 15.5±11.72/9.6±6.9 | 2       | 1       |
| Guoying Han, 2010 | 39               | 29        | 568.6±92.5/412.5±94.7 | 581.7±10.24/483.27±107.6 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Min Dai, 2015     | 36               | 29        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Xiaobing He, 2018 | 27               | 20        | 508.0±63.6/276.1±23.2v | 512.2±576.4/403.3±30.9 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Xiaoxia Wang, 2010| 28               | 29        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Huijuan Yao, 2010  | 51               | 52        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Leizheng, 2016    | 33               | 31        | 546.0±93.4/239.0±62.69 | 542.4±4.3/479.81±71.81 | N/A       | N/A       | 28.59±6.69/17.54±4.74 | 29.59±5.59/23.2±6.08 | 0       | 0       |
| Bo Shu, 2010      | 38               | 25        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Liping Yan, 2012  | 35               | 23        | 573.4±113.6/369.1±117.2 | 587.8±109.7/427.6±121.3 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Yueli Wu, 2015    | 38               | 32        | 573.7±102.4/286.3±122.5 | 582.7±112.5/356.8±117.8 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Yueqi Wang, 2013  | 30               | 29        | 542.36±54.55/351.12±43.92 | 534.99±58.81/424.73±56.79 | 30.90±10.15/6.70±5.11 | 31.45±10.75/12.65±3.26 | 28.90±6.53/7.64±3.14 | 29.45±11.58/7.67±4.11 | 0       | 7       |
| Meng Zhang, 2010  | 65               | 62        | 525.68±11.4/350.8±30.50 | 530.01±12.6/475.60±61.17 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | 1        | 11      |
| Xiaoming, 2008    | 53               | 44        | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Zheng Huang, 2013  | 28               | 27        | 477.16±97.33/430.65±88.97 | 465.32±90.13/451.91±89.48 | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       | N/A       |
| Author, year | Effective number | SUA | CRP | ESR | Adverse reactions |
|-------------|-----------------|-----|-----|-----|------------------|
| Chongyu Tan, 2013 | 48 34 | 56.87±38.29/32.68±38.14 | 573.77±39.87/371.90±38.39 | N/A | N/A | 4 | 16 |
| Chun Kang, 2012 | 28 24 | 485.65±53.11/3.03.22±46.35 | 489.18±52.61/396.43±41.91 | N/A | N/A | N/A | N/A |
| Xiaowu Fan, 2013 | 48 38 | N/A | N/A | N/A | N/A | N/A | N/A |
| Jianchong Shen, 2014 | 57 49 | 495.99±50.73/312.78±54.03 | 485.50±47.58/378.07±50.89 | N/A | N/A | 1 | 5 |
| Guiqiong Huang, 2016 | 55 38 | 547.48±50.93/318.04±54.35 | 546.37±47.58/352.41±51.89 | 26.17±10.28/5.98±1.45 | 25.94±19.65/16.05±1.76 | 35.18±8.82/15.79±4.21 | 3.495±7.88/23.57±4.32 | N/A | 17 |
| Jianping Luo, 2010 | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Ying-Cheng Chien, 2014 | 40 37 | N/A | N/A | N/A | N/A | N/A | N/A |
| Demi Li, 2012 | 38 34 | 496±66.9/266±48.6 | 498.0±68.4/367.5±93.81 | N/A | N/A | 54.6±11.78/23.5±16.71 | 53.10±10.82/32.03±17.42 | 0 | 18 |
| Yanhui Lin, 2013 | 28 22 | 506.57±19.90/352.41±79.93 | 518.70±83.98/402.42±85.53 | 8.15±1.52/4.6±1.07 | 8.52±1.23/6.3±1.09 | 32.6±13.82/17.9±5.2 | 32.40±13.93/26.4±10.87 | N/A | 17 |
| Dehe Li, 2007 | 36 26 | N/A | N/A | N/A | N/A | N/A | N/A |
| Jun Hao, 2014 | 29 23 | N/A | N/A | N/A | N/A | N/A | N/A |
| Chongqing Yang, 2006 | 27 28 | 845.27±98.87/40.4±95.48 | N/A | N/A | N/A | N/A | N/A |
| Lin Wang, 2011 | 26 27 | 498.33±87.25/61.1±86.89 | 498.28±28.18/482.23±116.31 | 29.9±2.06/9.24±1.07 | 52.46±56.82/18.6±28.10 | N/A | 0 | 1 |
| Ayijiaman, 2012 | 54 37 | 591.16±34.9/37.3±52.85 | 552.29±46.15/425.79±48.69 | N/A | N/A | N/A | N/A |
| Chifeng Wang, 2014 | 33 30 | 482.5±51.3/38.3±50.4 | 481.5±50.9/420.2±55.9 | 24.4±3.6/15±2.6 | 24.3±3.7/16±2.9 | 26.3±4.3/3.6±7.2 | 26.2±4.5/15.8±6.8 | N/A | 18 |
| Jianping Luo, 2010 | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Xin Ouyang, 2004 | 28 25 | 492.54±76.03/287.53±93.04 | 498.0±83.46/367.53±93.81 | N/A | N/A | 54.6±11.78/23.5±16.71 | 53.10±10.82/32.03±17.42 | 0 | 18 |
| Guoqiong Huang, 2016 | 55 38 | 547.48±50.93/318.04±54.35 | 546.37±47.58/352.41±51.89 | 26.17±10.28/5.98±1.45 | 25.94±19.65/16.05±1.76 | 35.18±8.82/15.79±4.21 | 3.495±7.88/23.57±4.32 | N/A | 17 |
| Jianping Luo, 2010 | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| Jinjin Jia, 2010 | 26 23 | 488.31±78.4/285.75±75.6 | 490.2±72.5/433.5±77.5 | N/A | N/A | N/A | N/A | 0 | 5 |
| Xiaozhong Yu, 2013 | 31 28 | 556±21.3/216±12.6 | 552±21.8/221±15.2 | N/A | N/A | N/A | N/A | 1 | 15 |
| Jianping Luo, 2010 | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

EG: experimental group, CG: control group; SUA: serum uric acid; CRP: C-reactive protein; ESR: Erythrocyte Sedimentation Rate; N/A: not applicable.
971 of records identified through database searching

0 of records identified through other sources

442 of records after duplicates removed

109 non-RCT articles, 8 articles based on animal experiments, 88 articles which the experimental group and the control group do not meet the standard, 19 articles do not have diagnostic criteria, 143 articles which is review and experience summary, 93 articles studies other directions.

529 of records screened

442 of records a/f_ter and duplicates removed

69 of full-text articles assessed for eligibility

Figure 1: Flow diagram of study selection.

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

Low risk of bias
Unclear risk of bias
High risk of bias

Figure 2: Risk of bias summary.

3.2. Risk of Bias. All of the selected trials adopted the method of randomization [9–77], which involved sealed envelopes11, randomized block [9, 10, 12, 13, 15, 17–33, 36–38, 40–51, 53–77], and random number table [14, 16, 34, 35, 39, 52]. Therefore, those trials were considered low risks in terms of selection bias. Only one trial involved the method of blinding [36]. These parameters were considered low risk in terms of incomplete outcome data. Detection bias, reporting bias, and other potential biases were unclear in all studies (Figures 2 and 3).

3.3. Adverse Reactions. Adverse reactions data were provided from twenty-five RCTs, including 2217 patients (1147 cases in the experimental group and 1070 cases in the control group) [11, 20, 23, 24, 27, 30, 32, 34–36, 38–40, 42, 47, 48, 53–59]. The random model was applied finally because of its heterogeneity with \( I^2 = 68\% \) (Figure 4). The results indicated that the adverse reactions rate of patients taking Chinese herb and (or) receiving other traditional Chinese medicine treatment was lower than that of patients who take western medicine (0.18 times), and the difference was statistically significant (\( P < 0.00001 \)).

3.4. Efficacy. The effective rate data were provided from sixty-six RCTs, including 5669 patients (2952 cases in the experimental group and 2717 cases in the control group) [9–13, 15–44, 46–69, 71–77]. The random model was used because of its heterogeneity with \( I^2 = 75\% \) (Figure 5). The results indicated that the effective rate of patients who took Chinese herb and (or) treated with other traditional Chinese medicine methods were higher than that of those who used Western Medicine (1.11 times). The difference was statistically significant (\( P < 0.00001 \)).

3.5. Serum Uric Acid Concentration (\( \mu \)mol/L). The serum uric acid concentration data were provided from forty-one RCTs, including 3549 patients (1834 cases in the experimental group and 1715 cases in the control group) [9–49]. The random model was adopted according to \( I^2 = 98\% \) (Figure 6). Compared with the patients in the control group who only took western medicine, the level of serum uric acid concentration was reduced by 62.14% in patients who took traditional Chinese herb and (or) treated with other traditional Chinese medicine methods. The results were statistically significant (\( P < 0.00001 \)).
Figure 3: Risk of bias graph.
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Figure 4: An analysis of the adverse reactions caused by clearing heat and removing dampness method and western medicine in the treatment of gout.

### 3.6. C-Reactive Protein (mg/L)
The C-reactive protein data was provided from sixteen RCTs, including 1408 patients (704 cases in the experimental group and 704 cases in the control group) [12, 14, 21, 23, 24, 30, 37–42, 44, 50–52]. A random model was adopted according to $I^2 = 98\%$ (Figure 7).

Compared with the patients in the control group who only took western medicine, the level of C-reactive protein was reduced by 4.21% in patients who took traditional Chinese herb and (or) treated with other traditional Chinese medicine methods. They were statistically significant on the difference of two intervention methods to reduce C-reactive protein levels ($P < 0.0001$).

### 3.7. Erythrocyte Sedimentation Rate (ESR) (mm/h)
The Erythrocyte sedimentation rate data was provided from twenty-two RCTs, including 1951 patients (988 cases in the experimental group and 963 cases in the control group) [10–12, 14, 17, 19, 20, 23, 24, 26, 27, 30, 37–41, 44, 50–52]. A random model was adopted according to $I^2 = 95\%$ (Figure 8). Compared with the patients in the control group who only took western medicine, the level of Erythrocyte sedimentation rate was reduced by 6.23% in patients who took traditional Chinese herb and (or) treated with other traditional Chinese medicine methods. There was significant difference between the experimental group and the control group on ESR ($P < 0.0001$).

### 4. Discussion
With the continuous improvement of people’s living standard, the change of dietary structure and the influence of environmental factors, the incidence of gout has been gradually increased every year all over the world. Nowadays, the patient with gout could only be alleviated but not cured with existing clinical treatments; thus searching for a better therapeutic method has been appeared to be very important. Our current study analyzed data from 69 RCTs that aimed to assess the therapeutic effect and safety of heat and removing dampness method of Traditional Chinese Medicine for gouty arthritis.

In respect of adverse reaction rate, clearing heat and removing dampness method with or without other traditional Chinese medicine therapy are better than western medicine treatment ($RR = 0.18$). The adverse reactions often occurred during the process of using drugs, such as abdominal pain, diarrhea, vomiting, and inappetence, and even causing damage of liver and kidney in severe cases. Compared with western medicine, clearing heat and removing dampness method was shown to be more effective to the patients with gout, with less adverse reactions mentioned above at the same time, probably due to the synergistic action of multicomponents and multitargets in the traditional Chinese medicine and the integrity of human body. The clearing heat and removing dampness method which is the unique medical method based on Chinese traditional medicine has
Figure 5: An analysis of the effective of clearing heat and removing dampness method and western medicine in the treatment of gout.
Figure 6: Effects of clearing heat and removing dampness method and western medicine on serum uric acid in the treatment of gout.

Figure 7: Effects of clearing heat and removing dampness method and western medicine on C-reactive protein in the treatment of gout.
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Figure 8: Effects of clearing heat and removing dampness method and western medicine on ESR in the treatment of gout.

![Table]

| Study or Subgroup       | Experimental Mean | SD | Total | Control Mean | SD | Total | Weight | Mean Difference IV, Random, 95% CI | Mean Difference IV, Random, 95% CI |
|-------------------------|------------------|----|-------|--------------|----|-------|--------|-----------------------------------|-----------------------------------|
| Bo Duan 2016            | 8.23             | 5.38| 54     | 8.99         | 6.37| 54     | 4.8%   | -0.76 [-1.06, 0.54]                | -                                |
| Chifeng Wang 2014       | 13.6             | 7.23| 16     | 8.15         | 6.88| 36     | 4.6%   | -2.20 [-5.44, 0.04]                | -                                |
| Demei Li 2012           | 21.5             | 12.5| 40     | 30.02        | 7.90| 40     | 4.2%   | -8.70 [-13.28, -4.12]              | -                                |
| GÜlcay Sun 2007         | 17.1             | 4.6 | 65     | 15.43        | 4.35| 65     | 5.0%   | 2.10 [0.57, 3.63]                 | -                                |
| Guipeng Huong 2016      | 15.79            | 4.21| 60     | 23.57        | 4.52| 60     | 5.0%   | -7.78 [-9.34, -6.22]              | -                                |
| Hai Lu 2013             | 22.6             | 7.3 | 30     | 29.6         | 6.9  | 30     | 4.5%   | -7.00 [-10.59, -3.41]             | -                                |
| Halfeng Li 2012         | 21.1             | 5.4 | 73     | 38.3         | 10  | 80     | 4.8%   | -17.20 [-19.72, -14.68]           | -                                |
| Hong Tu 2013            | 14.71            | 8.97| 30     | 24.07        | 12.61| 30     | 3.8%   | -9.56 [-14.90, -3.22]             | -                                |
| Hongtao Yan 2006        | 40               | 5.39| 20     | 49.95        | 5.85| 20     | 4.5%   | -3.95 [-7.44, -0.46]             | -                                |
| Huilian Wang 2012       | 3.9              | 1.2 | 40     | 4            | 2    | 40     | 5.1%   | -0.10 [-0.82, 0.62]               | -                                |
| Jiang Wu 2015           | 16.87            | 2.26| 36     | 24.35        | 4.03| 36     | 5.0%   | -7.48 [-8.99, -5.97]              | -                                |
| Lei Zhang 2016          | 17.54            | 4.74| 37     | 23.22        | 6.08| 37     | 4.8%   | -5.68 [-8.16, -3.20]             | -                                |
| Qingsheng He 2016       | 17               | 6.78| 50     | 21           | 5.91| 50     | 4.8%   | -4.00 [-6.49, -1.51]             | -                                |
| Shengyu Wu 2017         | 14.6             | 9.4 | 34     | 21.8         | 9.2 | 34     | 4.2%   | -7.20 [-11.62, -2.78]            | -                                |
| Wei Li 2016             | 10.26            | 5.35| 58     | 14.86        | 5.47| 58     | 4.9%   | -4.60 [-6.57, -2.63]             | -                                |
| Xiaohong He 2008        | 17.4             | 5.7 | 28     | 30.6         | 8.3 | 26     | 4.4%   | -13.20 [-17.03, -9.37]           | -                                |
| Xin Ouyang              | 23.43            | 16.71| 30     | 32.03        | 17.42| 30     | 4.8%   | -8.60 [-12.74, 0.04]             | -                                |
| Yanhua Zou 2010         | 34.28            | 12.21| 40     | 40.79        | 13.08| 40     | 3.8%   | -6.51 [-10.15, -2.86]            | -                                |
| Yanmin Ren 2007         | 28.37            | 9.36| 60     | 42.72        | 0.24| 30     | 4.8%   | -14.35 [-16.72, -11.98]          | -                                |
| Yanzhi Lin 2016         | 17.9             | 5.2 | 30     | 26.4         | 10.87| 30     | 4.3%   | -8.50 [-12.81, -4.19]            | -                                |
| Youqil Wang 2013        | 6.74             | 3.14| 32     | 7.67         | 4.11| 32     | 4.9%   | -0.93 [-2.72, 0.86]              | -                                |
| Zhimin Qi 2016          | 17.58            | 5.22| 105    | 22.64        | 6.17| 105    | 5.0%   | -4.56 [-6.10, -3.02]             | -                                |
| Total (95% CI)          | 988              | 963 | 100.0%| -6.23 [-8.39, -4.06] | - | - | - | - | - |

Heterogeneity: $I^2 = 23.82; Chi^2 = 454.15; df = 21 (P < 0.00001); I^2 = 95%$

Text for overall effect: Z = 5.04 (P < 0.00001)

a good effect to treat patients with gout, mainly because of the pathogenesis of gout disease which is that the meridian is blocked by a pathogenic factor formed by blending of heat and wetness evils [7].

According to our results, the clearing heat and removing dampness method of Chinese traditional medicine adjuvant treatment of Chinese medicine such as acupuncture and cupping could effectively reduce uric acid, C-reactive protein, and ESR in patients with gout. Different researchers have chosen different modalities of the clearing heat and removing dampness method of Chinese traditional medicine, such as Si Miao San [29–31], Xuan Bi Fang [38, 39], acupuncture and Chinese medicine combination [41, 59, 76], etc. Among them, the types of Chinese medicine, the dose, and the acupoint selection of acupuncture and acupuncture techniques are inconsistent. Therefore, our results cannot get a clear conclusion, we do not know which treatment method has the best effect on gout and the least adverse reactions.

In this study, there are many shortcomings: a lot of randomized controlled trials are not amply described in grouping; it is not sufficient to prove that the randomization program is executed correctly. The overall methodological quality is poor, which limits the value of the effect of the clearing heat and removing dampness method of Chinese traditional medicine in the treatment of gout. Therefore, an indepth investigation and further extensive study were need in the future.

**Disclosure**

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Conflicts of Interest**

The authors declare that they have no conflicts of interest.

**Authors’ Contributions**

Nan Xiao and Hao Chen contributed equally to this work.

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