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A Meta-analysis of Tianma Gouteng Decoction Combined with Qiju Dihuang Pills in the Treatment of Essential Hypertension

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Abstract

Objective: A Meta-analysis was used to systematically evaluate the efficacy and safety of Tianma gouteng decoction and Qiju dihuang pills in the treatmennt of essential hypertension (EH). **Methods:** Randomized controlled trials (RCTs) associated with the treatment of EH via the Tianma gouteng gecoction combined with Qiju dihuang pills were searched on VIP, CNKI, Wanfang, PubMed, Cochrane Library databases from the clinical trials published from 2012 to October 2020. After the quality evaluation of literatures, the valid data from the literatures were extracted and Meta-analysis was carried out by using Review Manger 5.4 software. **Results:** There were 23 Chinese articles, including 2339 EH patients. The results of a Meta-analysis showed that, compared with western medicine treatment, traditional Chinese medicine combined with western medicine has better clinical [OR=4.48, 95%CI(2.72, 7.37), P<0.00001], In addition, solely traditional Chinese medicine treatment in contrast to western medicine improved the total clinical effective rate [OR = 9.73,95% CI(5.90, 16.06), P<0.00001]. **Conclusion:** Tianma gouteng decoction combined with Qiju dihuang pills have a positive effect on the treatment of EH, and also show less toxic. Yet, considering the quality limitation of the literatures included, further high-quality clinical trials are needed be carried out to validate this conclusion.

Keywords

Tianma Gouteng Decoction and Qiju Dihuang Pills, Essential Hypertension; Meta-Analysis

1. Introduction

The incidence of Essential Hypertension (EH) is on the rise year by year, and the continuous increase of blood pressure will lead to systemic vascular diseases, which is one of the important factors for cardiovascular terminal events. The disclosure rate and treatment rate of patients are generally low [1, 2]. EH diagnosis is made according to the Chinese Guidelines for the Prevention and Treatment of Hypertension (2018 Revision) [3]. Conventional western medicine treatment of EH, mainly has diuretic, calcium channel blockers, beta blockers, angiotensin converting enzyme inhibitors (ACEI) and angiotensin II receptor blockers(ARB), etc. [4], is usually a joint, long-term clinical application. TCM classifies EH into the categories of “vertigo” and “headache”, etc., and the “Simple Question. The Most important Theory” records that “dizziness in wind all belongs to the liver”, and “deficiency of kidney means heavy head shaking, insufficient medullary sea means brain turning to tinnitus”, suggesting that this disease is closely related to the liver and kidney organs [5]. This study comprehensively collected the existing clinical research literature, objectively evaluated the efficacy and safety of Tianma gouteng decoction combined with Qiju dihuang Pills in the treatment of EH, and provided the basis for the clinical treatment of EH.

2. Materials and methods

2.1 Retrieval strategy

Retrieval of VIP, CNKI, Wanfang, PubMed, Cochrane Library and other databases was conducted from the beginning and end of the database construction to April 2020.

Keywords: essential hypertension, gastrodia elata uncaria decoction and Qiju rehmannia pill; English retrieval words included Essential hypertension, Tianma gouteng decoction with Qiju dihuang decoction.

2.2 Inclusion and exclusion criteria

2.2.1 Inclusion Criteria

(1) Subjects: EH patients;

(2) Research type: RCTs;

(3) Intervention measures: The experimental group was given additional treatment with Tianma gouteng decoction combined with Qiju dihuang pills, or conventional treatment with Tianma gouteng decoction combined with Qiju dihuang pills western medicine; The control group received symptomatic treatment with basic western medicine.

(4) Outcome indicators: total clinical efficiency, Systolic blood pressure, Diastolic blood pressure, Adverse reactions.

2.2.2 Exclusion criteria

animal experiment, cell experiment, mechanism research, experience summary, case report, review, etc; Duplicate publication; publication; Conference papers; Outcome indicators are incomplete; The selected cases were combined with other serious organic lesions.

2.3 Efficacy criteria

Outcome indicators of this study include: total clinical effective rate; Systolic blood pressure; Diastolic blood pressure; Adverse reactions.

2.4 Literature screening, data extraction and quality evaluation

There were conducted independently by two evaluators according to inclusion and exclusion criteria, and the third researcher assisted in the judgment of conflicting or difficult literatures; The Cochrane Systematic Review Manual bias risk assessment tool was used.

2.5 Statistical methods

Meta analysis was conducted with the Review Manger 5.4 software provided by The Cochrane Collaboration. Dichotomous variables were represented by 95%*CI* and the advantage ratio OR was used for all counting data. A continuous variable was analyzed using a combined mean difference MD or standard mean difference STD. MD using measurement data. I^2 test was used to evaluate the heterogeneity between similar studies. If $I^2 < 50\%$, the heterogeneity between studies was less likely. Fixed-effect model was used. If $I^2 >$ is 50%, it indicates inter-study heterogeneity, and a random effect model is used.

3. Results

3.1 Literature screening process

63 literatures were initially examined, and 23 literatures were finally included in strict accordance with inclusion and exclusion criteria and outcome indicators [6-28]. The literature screening flow chart is shown in Figure 1.

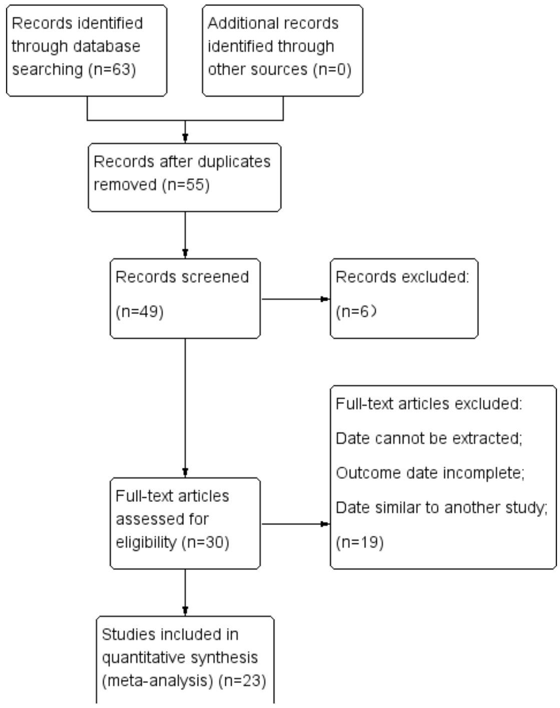

Figure 1. Literature screening flow chart.

Table 1. Baseline characteristics of included literature

Articles Author/year	Age(year)		Sample size		Intervention	Control	Treatment duration (Day)
	Ex	Co	Ex	Co	Traditional Chinese and Western medicine	Western medicine	
Chu et al, 2020 [6]	63.17±2.19	63.49±2.31	40	40	Con+ TM GT decoction and QJ DH Pills	WM	42D
Li et al, 2020 [7]	58.2±3.5	58.2±3.5	30	30	Con+ TM GT decoction and QJ DH Pills	WM	28D
Zhou et al, 2019 [8]	60.37±2.66	60.56±2.71	75	75	Con+ TM GT decoction and QJ DH Pills	WM	-
Li et al, 2019 [9]	65.88±8.14	65.36±8.11	49	48	Con+ TM GT decoction and QJ DH Pills	WM	30D
Huang et al, 2018 [10]	49.18±2.49	49.21±2.57	47	47	Con+ TM GT decoction and QJ DH Pills	WM	30D
He et al, 2018 [11]	61.9±11.3	61.5±10.3	50	50	Con+ TM GT decoction and QJ DH Pills	WM	30D
Li et al, 2017 [12]	62.12±2.13	62.28±2.09	73	73	Con+ TM GT decoction and QJ DH Pills	WM	-
Yi et al, 2019 [13]	47.5±6.5	48.5±6.5	80	80	TM GT decoction and QJ DH Pills	WM	40D
Yang et al, 2019 [14]	59.7±5.2	59.6±5.1	30	30	TM GT decoction and QJ DH Pills	WM	60D
Wu et al, 2019 [15]	50.46±11.3	50.26±11.2	35	35	TM GT decoction and QJ DH Pills	WM	30D
Song et al, 2019 [16]	54.3±5.7	54.1±5.9	28	28	TM GT decoction and QJ DH Pills	WM	35D
Lu et al, 2019 [17]	69.8± 6.4	69.7±5.9	39	39	TM GT decoction and QJ DH Pills	WM	28D
Zheng et al, 2018 [18]	53.11± 6.25	54.25±6.42	47	47	TM GT decoction and QJ DH Pills	WM	40D
Li et al, 2018 [19]	43.3±13.6	45.2±12.8	67	67	TM GT decoction and QJ DH Pills	WM	40D
He* et al, 2018 [20]	28-71	28-73	30	30	TM GT decoction and QJ DH Pills	WM	28D
Guo et al, 2018 [21]	52.57±4.65	52.55±4.54	45	45	TM GT decoction and QJ DH Pills	WM	30D
Chen et al, 2018 [22]	62.31±7.16	62.13±7.11	40	40	TM GT decoction and QJ DH Pills	WM	28D
Xia et al, 2017 [23]	53.96±3.66	53.82±3.71	49	49	TM GT decoction and QJ DH Pills	WM	180D
Weng et al, 2017 [24]	54.1±11.2	53.5±10.4	50	50	TM GT decoction and QJ DH Pills	WM	28D
Shen et al, 2017 [25]	55.43±0.65	55.87±0.48	46	46	TM GT decoction and QJ DH Pills	WM	28D
Han et al, 2016 [26]	55.42±6.59	55.39±6.53	52	52	TM GT decoction and QJ DH Pills	WM	-
Jiang et al, 2012 [27]	41.2±5.1	41.2±5.1	70	70	TM GT decoction and QJ DH Pills	WM	30D
Gao et al, 2012 [28]	28-70	39-64	137	59	TM GT decoction and QJ DH Pills	WM	40D

Abbreviations: TCM=Traditional Chinese Medicine; WM=Western Medicine; TM GT decoction=Tianma gouteng decoction; QJ DH Pills=Qiju Dihuang Pills.

3.2 Features of included literature

Among the 23 RCTs included, literature published from 2012 to October 2020, a total of 2,339 EH patients were included, including 1,209 patients in the experimental group and 1,130 patients in the control group. The basic features of the included literatures are shown in Table 1.

3.3 Quality evaluation of the included literature

Into 23 articles, 1[6] to research carried out in accordance with the "law of the double chromospheres" grouping, 1 study [21] shall be carried out in accordance with the "coin" grouping, 1 study [26] shall be carried out in accordance with the "lottery law" group, 2 study [18, 25] shall be carried out in accordance with the "order" in hospital group, 2 study [10,19] according to the "admission number even method" grouping, 3 study [11, 13, 22] in accordance with the "random number table method", 5 study [9, 14, 20, 23, 24] to research carried out in accordance with the "treatment" group, eight studies [7, 8, 12, 15-17, 27, 28] only mentioned "randomization" without specifying specific methods, and did not mention the literature allocation concealment scheme or the use of blind method. The result of bias risk is shown in Figure 2.

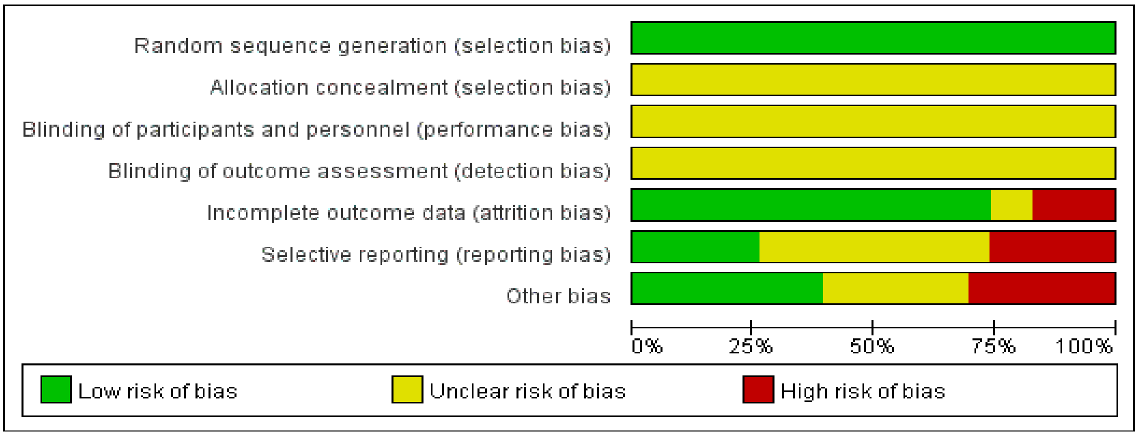

Figure 2. Summary of bias risk.

3.4 Analysis of results

3. 4.1 The total clinical effective rate

TCM combined with Western medicine was compared with western medicine in 7 studies [6-12], which reported the total clinical effective rate of 736 patients included. The meta analysis results were statistically significant [OR=4. 48, 95%CI(2. 72, 7. 37), P<0. 00001], as shown in Figure 3. There were 15 studies comparing Traditional Chinese medicine with western medicine [14-28], reporting the total clinical efficacy, including 1,452 patients. The differences in meta analysis results were statistically significant [OR=9.73, 95%CI (5. 90, 16. 06), P<0. 00001], as shown in Figure 4. It is suggested that the total clinical efficiency of EH can be improved obviously by using Tianma gouteng decoction and Qiju dihuang pill to treat EH.

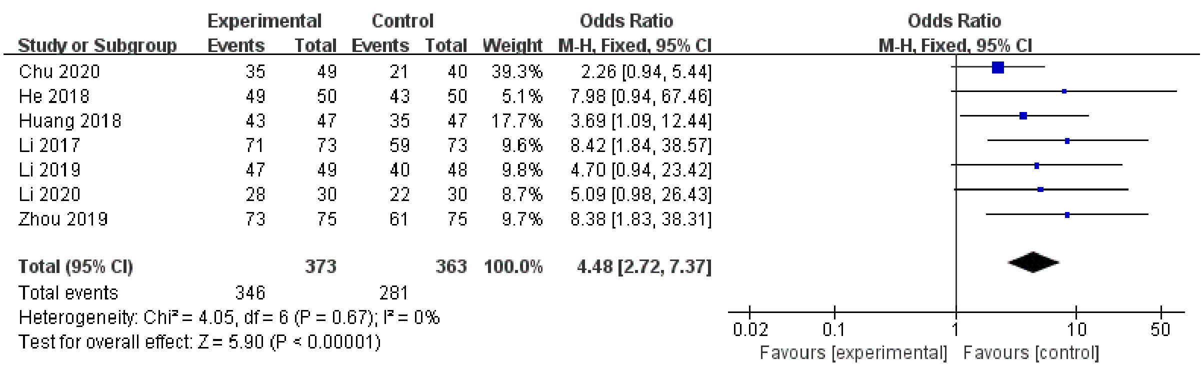

Figure 3. Meta analysis of the total clinical efficacy of TCM combined with Western medicine compared with Western medicine.

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Chen 2018	39	40	28	40	5.0%	16.71 [2.05, 136.08]
Gao 2012	135	137	54	59	7.9%	6.25 [1.18, 33.20]
Guo 2018	44	45	37	45	5.9%	9.51 [1.14, 79.60]
Han 2016	50	52	40	52	11.0%	7.50 [1.59, 35.46]
He* 2018	29	30	23	30	5.5%	8.83 [1.01, 76.96]
Jiang 2012	68	70	61	70	12.5%	5.02 [1.04, 24.13]
Li 2018	66	67	58	67	6.2%	10.24 [1.26, 83.29]
Lu 2019	38	39	24	39	4.4%	23.75 [2.94, 191.59]
Shen 2017	45	46	40	46	6.2%	6.75 [0.78, 58.50]
Song 2019	27	28	22	28	5.6%	7.36 [0.82, 65.83]
Weng 2017	50	50	42	50	3.0%	20.20 [1.13, 360.28]
Wu 2019	33	35	27	35	11.1%	4.89 [0.96, 24.97]
Xia 2017	48	49	39	49	5.7%	12.31 [1.51, 100.37]
Yang 2019	29	30	18	30	4.3%	19.33 [2.31, 161.57]
Zheng 2018	46	47	37	47	5.6%	12.43 [1.52, 101.60]
Total (95% CI)		**765**		**687**	**100.0%**	**9.73 [5.90, 16.06]**
Total events	747		550			

Heterogeneity: $Chi^2 = 3.63$, df = 14 (P = 1.00); $I^2 = 0\%$
Test for overall effect: Z = 8.90 (P < 0.00001)

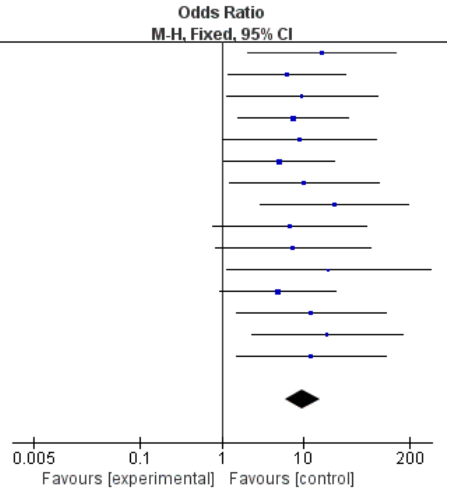

Figure 4. Meta analysis of the total clinical efficiency of Chinese medicine compared with western medicine.

3.4.2 Systolic blood pressure level

There were 6 studies of Chinese herbal medicine combined with Western medicine and Western medicine [6-9, 11, 12], reported patients with systolic blood pressure, including 633 patients, meta analysis results were statistically significant [MD=-17.90, 95%CI (-23.89, -11.91), P<0. 00001], as shown in Figure 5. There were 15 studies comparing Chinese and Western medicines [13-15, 17-28], in which patients' systolic blood pressure was reported and 1,556 patients were included. Meta analysis results showed statistically significant differences [SMD =-2.48, 95%CI (-3.21, -1.75), P<0.00001], suggesting that the combination of Tianma gouteng decoction combined with Qiju dihuang Pills in the treatment of EH can significantly reduce the systolic blood pressure level in EH patients. As shown in Figure 6.

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Chu 2020	132.3	28.7	40	149.2	32.1	40	9.9%	-16.90 [-30.24, -3.56]
He* 2018	133.5	5.7	50	142.6	6.7	50	18.8%	-9.10 [-11.54, -6.66]
Li 2017	140.25	8.56	73	159.41	9.44	73	18.5%	-19.16 [-22.08, -16.24]
Li 2019	125.28	13	49	138.1	15.11	48	16.5%	-12.82 [-18.43, -7.21]
Li 2020	123.76	8.44	30	154.68	9.15	30	17.5%	-30.92 [-35.37, -26.47]
Zhou 2019	141.02	6.92	75	159.33	7.23	75	18.8%	-18.31 [-20.57, -16.05]
Total (95% CI)			**317**			**316**	**100.0%**	**-17.90 [-23.89, -11.91]**

Heterogeneity: $Tau^2 = 48.21$; $Chi^2 = 82.92$, df = 5 (P < 0.00001); $I^2 = 94\%$
Test for overall effect: Z = 5.86 (P < 0.00001)

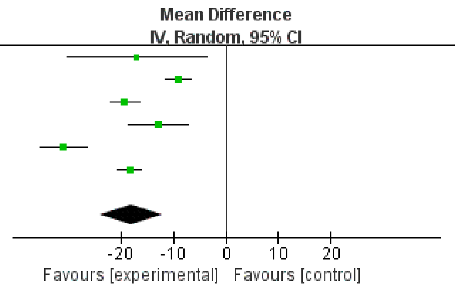

Figure 5. Meta analysis of Traditional Chinese medicine combined with Western medicine versus Western medicine SBP.

Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Chen 2018	131.56	4.67	40	143.76	7.29	40	6.8%	-1.97 [-2.51, -1.43]
Gao 2012	18.2	0.8	137	18.4	0.9	59	7.0%	-0.24 [-0.55, 0.07]
Guo 2018	15.21	0.11	45	18.22	0.37	45	5.1%	-10.93 [-12.62, -9.25]
Han 2016	18.19	0.79	52	20.45	0.93	52	6.8%	-2.60 [-3.13, -2.07]
He 2018	106.2	5.81	30	123.4	5.93	30	6.6%	-2.89 [-3.63, -2.16]
Jiang 2012	17.9	0.7	70	18.1	0.7	70	6.9%	-0.28 [-0.62, 0.05]
Li 2018	18.4	0.9	67	20.9	1.2	67	6.9%	-2.34 [-2.79, -1.90]
Lu 2019	132.6	2.7	39	140.5	2.2	39	6.6%	-3.18 [-3.85, -2.50]
Shen 2017	131.25	13.03	46	140.12	21.12	46	6.9%	-0.50 [-0.92, -0.09]
Weng 2017	120.8	3.6	50	135.6	4.9	50	6.7%	-3.42 [-4.04, -2.79]
Wu 2019	131.2	12.5	35	143.6	13.4	35	6.8%	-0.95 [-1.44, -0.45]
Xia 2017	133.28	7.52	49	141.62	7.83	49	6.9%	-1.08 [-1.50, -0.65]
Yang 2019	132.5	2.6	30	140.4	2.1	30	6.5%	-3.30 [-4.09, -2.51]
Yi 2019	136.12	5.98	80	153.44	5.82	80	6.9%	-2.92 [-3.37, -2.47]
Zheng 2018	136.1	6	47	153.4	6	47	6.7%	-2.86 [-3.44, -2.28]
Total (95% CI)			**817**			**739**	**100.0%**	**-2.48 [-3.21, -1.75]**

Heterogeneity: $Tau^2 = 1.98$; $Chi^2 = 453.53$, df = 14 (P < 0.00001); $I^2 = 97\%$
Test for overall effect: Z = 6.64 (P < 0.00001)

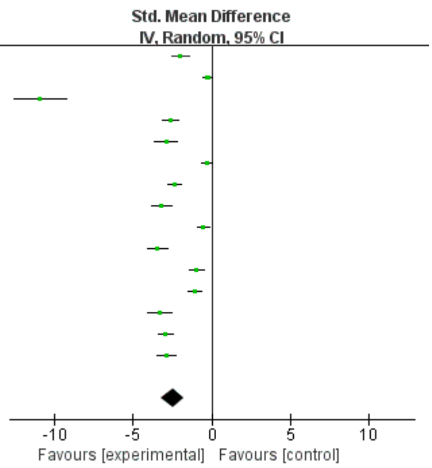

Figure 6. Meta analysis of Traditional Chinese medicine versus Western medicine SBP.

3.4.3 Diastolic blood pressure Level

There were 6 studies on Chinese traditional medicine combined with Western medicine and Western medicine [6-9, 11, 12], reporting diastolic blood pressure, and 633 patients were included. Meta analysis results showed statistically significant differences [MD=-12.57, 95%CI (-15.80, -9.35), P<0. 00001], as shown in Figure 7. A total of 15 studies [13-15, 17-28] comparing Traditional Chinese medicine with western medicine reported diastolic blood pressure in 1,556 patients, and the Meta analysis results showed statistically significant differences [SMD =-1.64, 95%CI (-2.02, -1.26)] (Z=6.27, P<0.00001), as shown in Figure 8. It suggests that the diastolic blood pressure of EH patients can be significantly reduced by the treatment of EH via Tianma gouteng decoction combined with Qiju dihuang Pills.

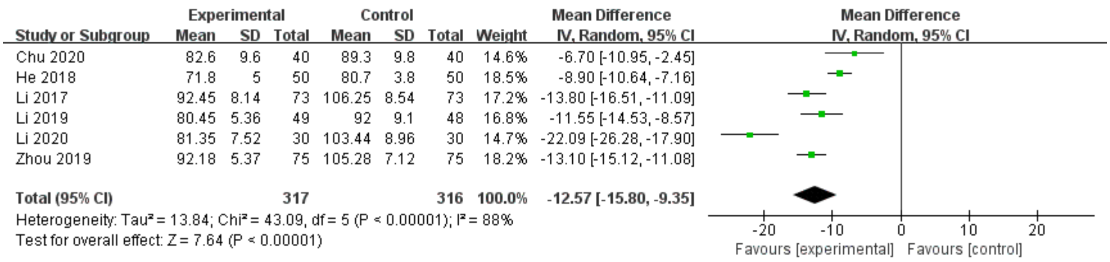

Figure 7. Meta analysis of DBP between Traditional Chinese medicine and Western medicine.

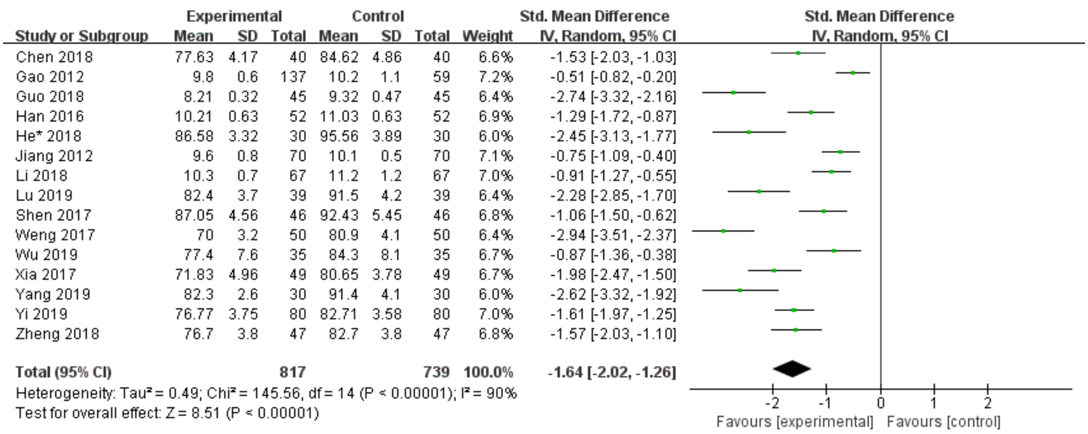

Figure 8. Meta analysis of Traditional Chinese medicine versus Western medicine DBP.

3.4.4 Safety Evaluation

Among the 23 literatures included in this study, 8 literatures [8, 11-14, 17, 22, 24] mentioned specific adverse reactions, including headache, nausea and vomiting, rash and tachycardia, etc. as shown in Table 2. The other literatures did not clearly report adverse reactions. Meta analysis results showed that [OR=0.38, 95%CI (0.19, 0.75), P < 0. 05], indicating that the treatment of EH via Tianma Gouteng decoction combined with Qiju dihuang Pills was superior to pure Western medicine. As shown in Figure 9.

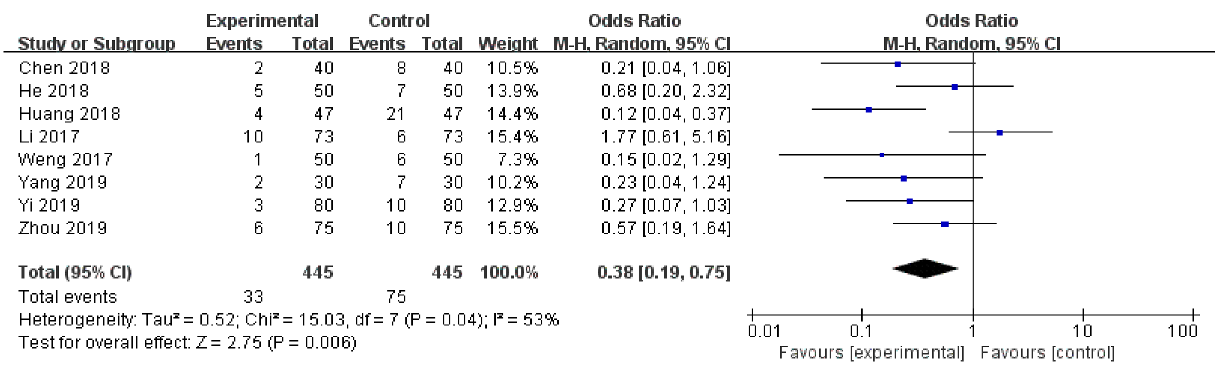

Figure 9. Meta analysis of the occurrence of adverse reactions.

3.4.5 Publication bias

The total clinical efficiency results of the experimental group and the control group were selected for the risk assessment of publication bias. The funnel plot was observed, and the outcome indicators showed incomplete left-right symmetry, suggesting the possibility of publication bias.

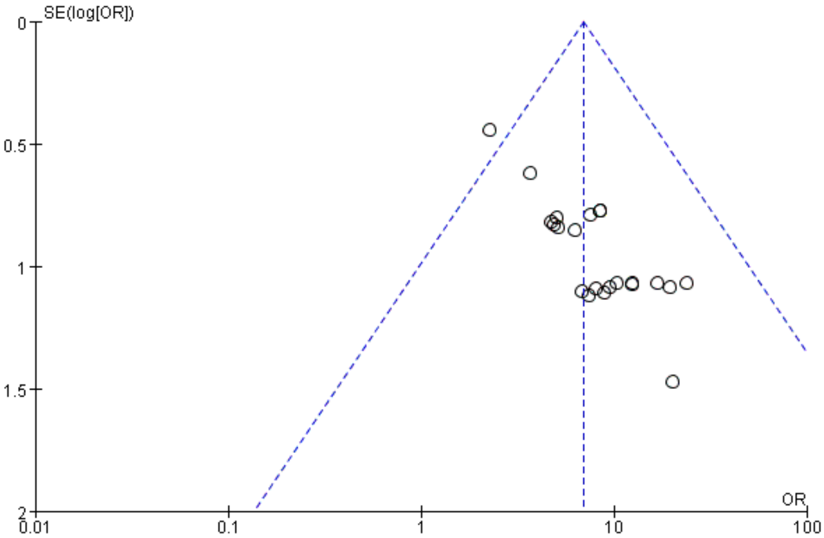

Figure 10. Funnel plot of total clinical effective rate between experimental group and control group.

4. Discussion

In this study, a systematic evaluation was conducted on the treatment of EH via Tianma gouteng decoction combined with Qiju dihuang Pills, and Meta analysis results showed that there are statistical differences in various indicators. Tianma gouteng decoction is a classic prescription for treating liver Yang hyperactivity type EH [29]. It contains Tianma, Gouteng, Shijueming, Niuxi, Duzhong, Sangjisheng, Zhizi, Huangqin, Yimucao, Yejiaoteng, Fushen, and has the functions of calming liver and suppressing wind, clearing heat and activating blood, and nourishing liver and kidney. Qiju dihuang Pills is beginning in the qing dynasty, is made up of Liuwei Dihuang pills and Gouqi, Juhua. Mainly there are Shudi, Shanzhuyu, Shanyao, Mudanpi, Fuling, Zexie, Gouqi, Juhua, who appears to have zi kidney nourishing the liver, the efficacy of clear liver bright eye, both are effective for the treatment of EH, often phase and use, has clear heat, invigorate the circulation of boosting the effect of the liver and kidney. Modern pharmacological studies have confirmed that Tianma gouteng decoction can improve vascular endothelial, function and autonomic nervous system function, and has a protective effect on cardiac muscle and target organs [30]. Qiju dihuang Pills has good antihypertensive and anti-inflammatory effects and can improve vasomotor function [31]. The combination of the both can achieve better antihypertensive effect and prevent EH complications.

To sum up, this study system evaluation Tianma gouteng decoction combined with Qiju dihuang Pills in the treatment of EH total curative effect and adverse reaction. Meta analysis results confirm that Tianma gouteng decoction combined with Qiju dihuang Pills is one of effective method for the treatment of EH. With the widely application of traditional Chinese medicine in clinical, its advantages are obvious. Domestic RCTs quality generally is not high, are not mentioned in this article the traditional Chinese medicine syndrome and syndrome, whether or not to use blind method, and the scheme of the hidden way, therefore, after clinical researchers can provide reference Corchane network of the bias study plan implementation and carry out risk assessment standards, increase the sample size, according to the standardized randomized method, pay attention to the use of blind method and scheme of the hidden, more high-quality RCTs of Tianma gouteng decoction combined with Qiju dihuang Pills in the treatment of EH with more accurate basis, further guide clinical drug use.

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