

# Meta-analysis of Clinical Studies on the Efficacy of Acupuncture and Moxibustion in the Treatment of Orthostatic Hypotension

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## Abstract

Hypotension is a condition in which the pressure in the body's circulating arteries is below normal. Hypotension is generally considered to be lower than 12/8kpa (90/60mmHg) in the upper limb arteries of adults. It can be divided into physiological and pathological hypotension according to etiology, and acute and chronic hypotension according to the form of onset. Postural hypotension is a type of chronic hypotension. The occurrence of hypotension in some patients is related to postural changes (especially in the upright position), which is called postural hypotension. Postural hypotension was defined as a drop in systolic blood pressure >20mmHg or diastolic blood pressure >10mmHg within 3 minutes of changing position to upright, accompanied by hypoperfusion symptoms, including dizziness, blurred vision, fatigue, nausea, cognitive dysfunction, palpitations, and neck and back pain. The World Health Organization also has a clear standard for the diagnosis of hypertension, but there is no unified standard for the diagnosis of hypotension. Acupuncture and moxibustion has been accepted by more and more patients and medical staff at home and abroad because of its high safety and accurate efficacy. This study is to through the acupuncture treatment of orthostatic hypotension randomised controlled trials (RCTs randomised controlled trials) and Meta analysis study of quality, evaluate the related curative effect in order to make up for the defect of relevant clinical evidence.

## Keywords

Hypotension; Orthostatic Hypotension; Postural Hypotension; Acupuncture; Acupuncture Points; Electroacupuncture; Traditional Chinese Medicine; Meta-analysis.

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## 1. Introduction

Hypotension is a condition in which the pressure in the body's circulating arteries is below normal. Hypotension is generally considered to be lower than 12/8kpa (90/60mmHg) in the upper limb arteries of adults. It can be divided into physiological and pathological hypotension according to etiology, and acute and chronic hypotension according to the form of onset. Postural hypotension is a type of chronic hypotension. The occurrence of hypotension in some patients is related to postural changes (especially in the upright position), which is called postural hypotension. [1] postural hypotension was defined as a drop in systolic blood pressure >20mmHg or diastolic blood

pressure >10mmHg within 3 minutes of changing position to upright, accompanied by hypoperfusion symptoms, including dizziness, blurred vision, fatigue, nausea, cognitive dysfunction, palpitations, and neck and back pain. The World Health Organization also has a clear standard for the diagnosis of hypertension, but there is no unified standard for the diagnosis of hypotension.[2] Acupuncture and moxibustion has been accepted by more and more patients and medical staff at home and abroad because of its high safety and accurate efficacy.[3] this study is to through the acupuncture treatment of orthostatic hypotension randomised controlled trials (RCTs randomised controlled trials) and Meta analysis study of quality, evaluate the related curative effect in order to make up for the defect of relevant clinical evidence.

## 2. Organization of the Text

### 2.1 Data and Methods

#### 2.1.1 Literature Retrieval

The literatures of acupuncture treatment for orthostatic hypotension in PubMed, Cochrane Library (CENTRAL), Chinese Journal Full-text Database (CNKI), Wanfang Academic Full-text database (Wanfang), VIP Chinese Scientific and Technical Journal Full-text database (VIP) and SinoMed Chinese Biomedical literature database (SinoMed) were analyzed Comprehensive search. Chinese with "hypotension", "postural hypotension", "acupuncture", "acupuncture", "moxibustion", "moxibustion", "electric acupuncture" as the main inscription, English is tested with "hypotension" "Orthostatic hypotension" "Postural hypotension" "acupuncture" "acupuncturepoints" "electroacupuncture" as the main theme Search, retrieval time from database construction to August 1, 2021.

#### 2.1.2 Inclusion Criteria

- (1) Research type: RCTs, language: Chinese or English.
- (2) Subjects: Patients aged 18-80 years old, clinically diagnosed as postural hypotension, with no limitation on gender, disease course and cases.
- (3) Intervention measures: the intervention group and the control group were in line with the following two conditions: ① Acupuncture and moxibustion + conventional treatment in the intervention group, and simple conventional treatment or sham acupuncture and moxibustion + conventional treatment in the control group; ② The intervention group received acupuncture + Traditional Chinese medicine + conventional treatment, and the control group received traditional Chinese medicine + conventional treatment. Conventional treatment refers to basic treatments such as fasting, gastrointestinal decompression, correction of electrolyte acid-base balance disorder, nutritional support and anti-infection after radical treatment of postural hypotension. Avoid using morphine, anisodamine and other drugs that affect smooth muscle contraction. Acupuncture and drug therapy both began at the onset of postural hypotension, and drug administration was limited to oral administration.

#### 2.1.3 Exclusion Criteria

- (1) Non-randomized controlled trials were used;
- (2) Repeated findings or published studies;
- (3) the study of acupuncture treatment in the experimental group and the control group;
- (4) studies with incorrect or unknown experimental data and unable to contact the authors for confirmation;
- (5) No literature on outcome indicators was available.

#### 2.1.4 Literature Screening and Data Extraction

The retrieved literatures were imported into Endnote9.1 software for management. Literature screening was conducted by two investigators separately according to inclusion and exclusion criteria. The two researchers first read the titles and abstracts of the literatures independently, and initially

excluded irrelevant literatures. Then read the full text and screen out the literature that meets the requirements; Finally, the valid data in the included literature were extracted one by one. During the screening process, the exclusion reasons of relevant literature were recorded for the convenience of review and further evaluation. In case of disagreement during the screening process, a final decision will be reached through discussion with a third investigator.

### 2.1.5 Literature Quality Evaluation

The quality of the included literature was assessed using the Cochrane Risk assessment of bias tool, which was performed independently by two investigators. Cochrane bias risk assessment tools include randomized sequence generation, allocation concealment, subject and investigator blind implementation, outcome evaluator blind implementation, data integrity, selective reporting, and other biases. The quality of the original study was assessed on the risk scale of high (unsatisfactory) and unclear (insufficient information). For literature that is difficult to determine quality, the third party researcher should negotiate to solve the problem.

### 2.1.6 Statistical Methods

Meta-analysis was performed using Revman5.4 software provided by the Cochrane collaboration. Dichotomous variables and continuity variables were used as measurement indexes, RR (relative risk) and WMD (weighted mean difference) were used as statistics, respectively, and were expressed with 95% confidence interval (Confidence interval CL). Chi-square test was used to test the results. When  $P < 0.1$  and  $I^2 > 50\%$ , it indicated that there was considerable heterogeneity among the included studies. In the case of heterogeneity, sources of heterogeneity were first searched for article by article, and then random effects model was used for combined analysis without clinical or methodological heterogeneity. In the case of heterogeneity, fixed effects model was used for analysis without data.  $P < 0.05$  was considered statistically significant; otherwise, there was no statistical significance. If there were sufficient literatures, the existence of publication bias was tested by funnel plot.

## 2.2 Results

### 2.2.1 Literature Retrieval Results

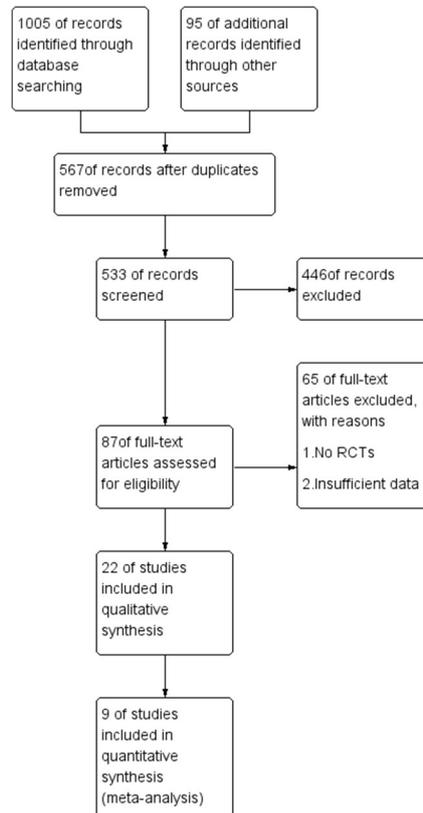


Figure 1. Literature screening process

According to the retrieval strategy, 1100 literatures meeting the inclusion criteria were retrieved, 567 literatures were obtained and excluded through the initial screening by reading titles and abstracts, and the remaining 533 literatures were screened through detailed reading of the full text according to the inclusion and exclusion criteria. Finally, 9 RCTs studies [4-12] were included, including 557 patients. All the literatures were in Chinese, the research sites were all in China, and the included research baselines were basically the same. The results of literature screening process are shown in Figure 1.

### 2.2.2 Included Studies

**Table 1.** Basic features of the included literature

Study	Sample Number		design	intervention		Course	safety Report	Blind	allocation hidden
	acupuncture group	control group	RCT	acupuncture group	control group			None	None
Ma Shuaitiong [1]	30	30	RCT	Acupoint moxibustion	rehabilitation treatment	4 weeks	no adverse reactions	None	None
Xu Mingxia et al.[2]	24	23	RCT	acupuncture and acupoint embedding	drug treatment	1 month	I:3 cases fell off due to personal reasons	None	None
Wang Yahui et al[3]	15	15	RCT	Abdominal acupuncture, moxibustion	drug treatment	4 weeks	not mention	None	None
Zhang Guangyong and Yu Man [4]	9	9	RCT	moxibustion and Oral Chinese medicine	midodrine hydrochloride	4 weeks	I: 2 giddiness	None	None
Yao Xiaofei [5]	45	45	RCT	Acupoint moxibustion	drug treatment	1 month	not mention	None	None
Wu Di[6]	50	50	RCT	Acupoint moxibustion	drug treatment	1 month	No adverse reaction	None	None
Chen Rui [7]	19	17	RCT	Acupoint moxibustion	drug treatment	1 month	not mention	None	None
Liu Xiaoli et al.[8]	46	41	RCT	Acupoint moxibustion	Tension socks, oral Midodrine hydrochloride tablets	1 month	I: local scald 1 case, elastic sock intolerance 9 cases	None	None
Zhao xiaohua and gao wenli [9]	45	44	RCT	Acupoint moxibustion	drug treatment	1 month	None	None	None

In Table 9, the sample size was 557 cases in total, 9 literatures reported the total effective rate of acupuncture in the treatment of orthostatic hypotension, 2 literatures reported significant efficiency [4-12], and 2 literatures reported effective rate [4-12]. Basic features of the included literature are shown in Table 1.

2.2.3 Methodological Quality

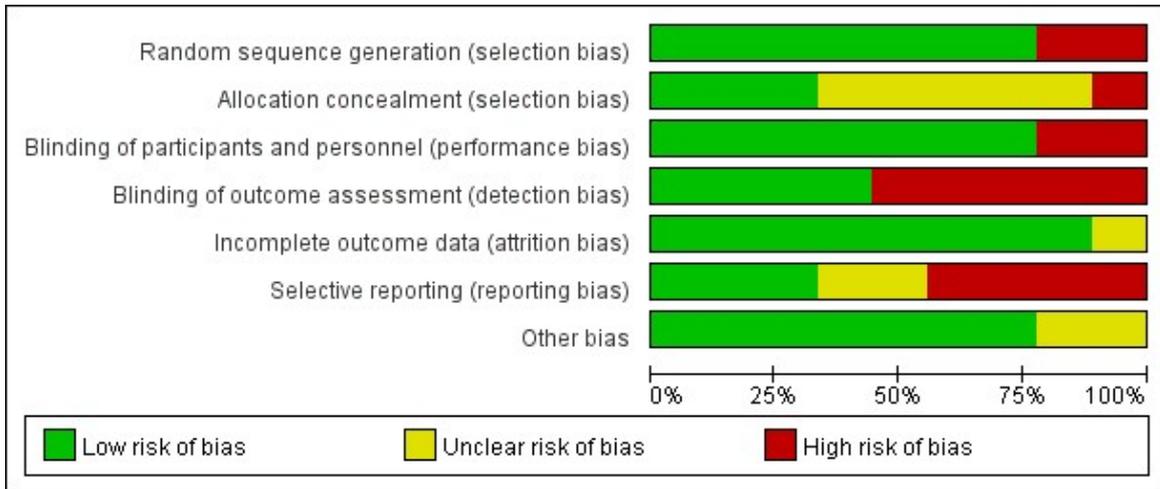


Figure 2. Proportion of bias risk for included studies

	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
Chen Rui 2005	+	+	+	-	+	?	+
Liu Xiaoli, Chen Yidan, SHU Qinfeng 2018	+	?	-	+	+	+	+
Ma Shuaitong, FENG Xiaodong, Song Lin 2017	-	?	+	+	+	-	+
WANG Yahui, HAO Shuqin, ZHAO Baoli 2019	+	?	+	+	+	-	+
Wu Di 2017	+	?	+	-	+	+	?
Xu Mingxia, Qiu Mingyue, LIU Qingping 2018	+	+	-	+	?	+	?
Yao Xiaofei 2015	+	+	+	-	+	-	+
Zhang Gunagyou, Yu Man 2019	+	-	+	-	+	?	+
Zhao Xiaohua, GAO Wenli 2018	-	?	+	-	+	-	+

Figure 3. Summary of bias risk for included studies

Evaluation of included Studies Included literature quality evaluation None of the 9 included literatures reported the hidden situation of research protocol, sample size estimation, blind method and random allocation. Two articles were grouped by random number table [4-12], two articles were grouped according to the order of medical treatment [4-12], and the other five articles only mentioned randomized controlled trials [4-12], without reporting specific randomized regimens. The overall quality assessment of the included studies is shown in Figure 2 and Figure 3.

### 2.2.4 Meta-analysis Results

Total effective rate Meta-analysis Twelve RCTS reported the total effective rate of acupuncture in the treatment of orthostatic hypotension, heterogeneity test  $P=0.60$ ,  $P > 0.1$ ;  $I^2=0\%$ ,  $I^2 < 50\%$ , indicating low heterogeneity, so the fixed-effect model was used, and the combined effect value  $RR=1.46 > 1.00$ ,  $95\%CI 1.30-1.65$ ,  $P < 0.00001$ . As shown in Figure 4, the rhombus did not intersect with the invalid line, and all fell on the side of acupuncture for orthostatic hypotension, indicating that the total effective rate of acupuncture for orthostatic hypotension was better than that of the conventional treatment group.

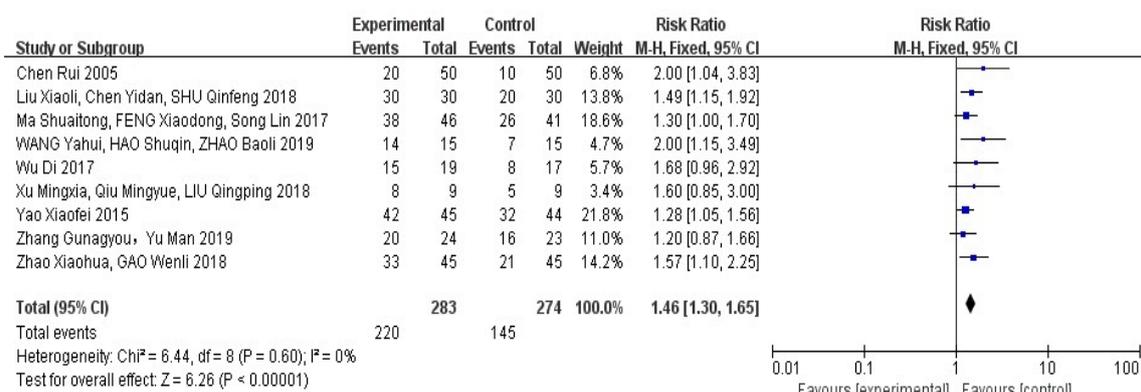


Figure 4. Forest diagram of total effective rate of acupuncture and conventional treatment of Western medicine

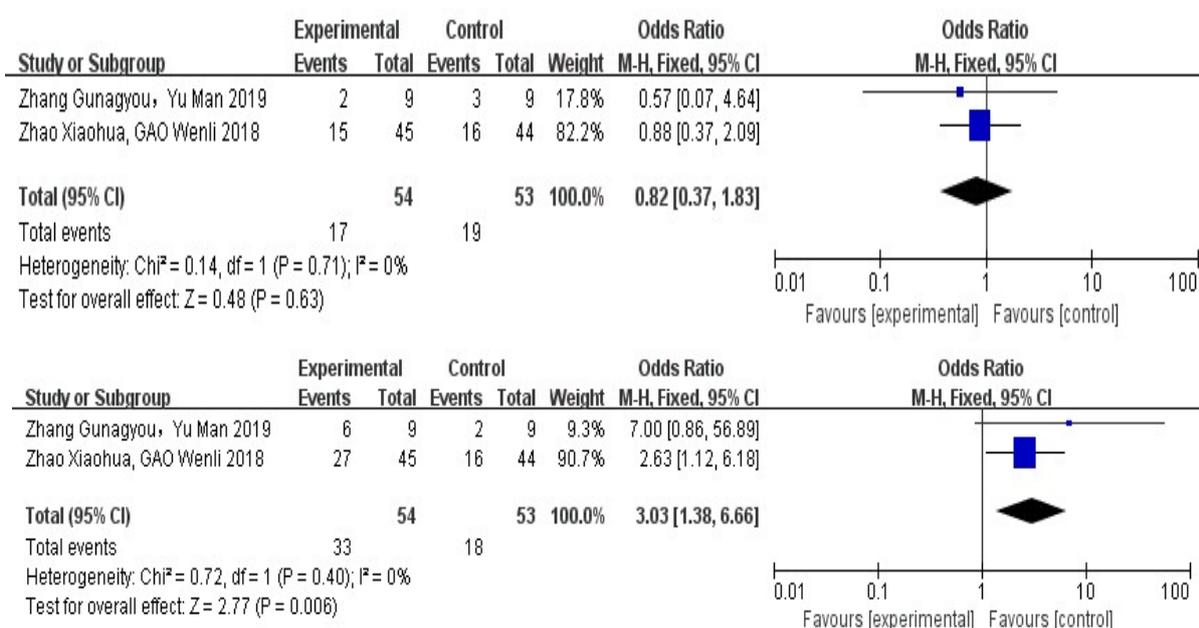
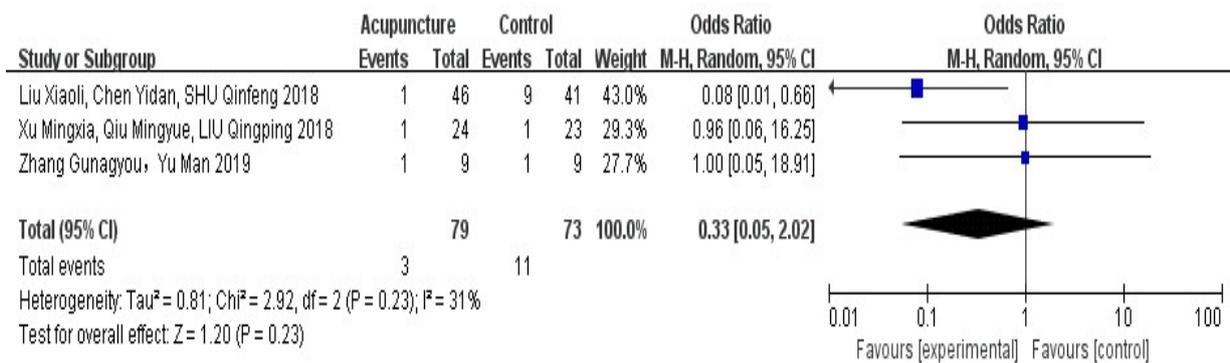


Figure 5. Forest diagram of significant efficiency and effective rate between acupuncture and conventional treatment of Western medicine

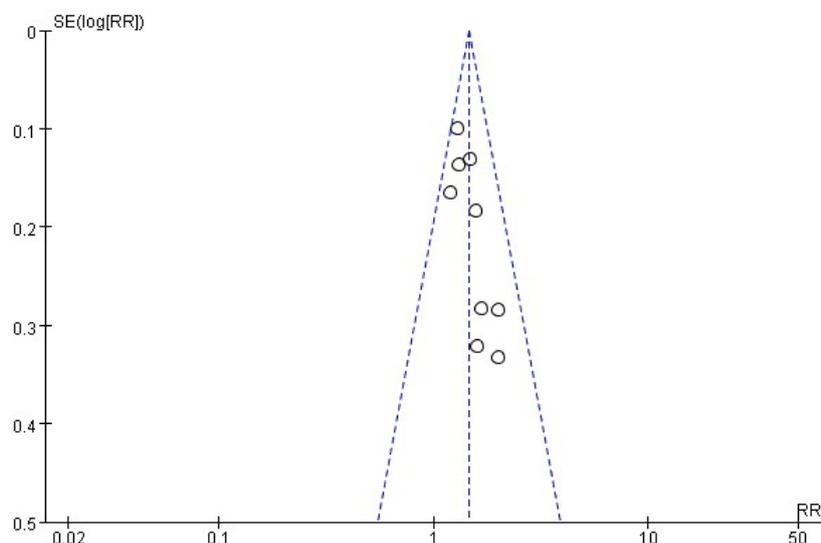
2 RCTS reported the incidence of adverse reactions in the treatment of orthostatic hypotension by acupuncture [5, 10-11], heterogeneity test  $P=0.98$ ,  $P > 0.1$ .  $I^2=0\%$  and  $I^2 < 50\%$  indicated low heterogeneity. Therefore, the fixed effect model was used for analysis, and the combined effect value  $RR=0.11 < 1.00$ , 95%CI 0.03-0.34,  $P=0.0002$ . As shown in Figure 5, the rhombus did not intersect the ineffective line, and all of them fell on acupuncture for orthostatic hypotension, indicating that the incidence of adverse reactions in acupuncture for orthostatic hypotension was lower than that in conventional treatment of western medicine.

Meta-analysis of the incidence of adverse reactions three RCTS reported the incidence of adverse reactions in the treatment of orthostatic hypotension by acupuncture [5,7,11], heterogeneity test  $P=0.24$ ,  $P > 0.1$ .  $I^2=29\%$ ,  $I^2 < 50\%$ , indicating low heterogeneity, so the fixed effect model was used for analysis. The combined effect value  $RR=0.25 < 1.00$ , 95%CI 0.07-0.86,  $P=0.0002$ . As shown in Figure 6, the rhombus did not intersect with the ineffective line, and all fell on the side of acupuncture treatment for postural hypotension, indicating that the incidence of adverse reactions in acupuncture treatment for postural hypotension was lower than that in conventional treatment of western medicine.



**Figure 6.** Forest plot of incidence of adverse reactions between acupuncture and conventional treatment of Western medicine

As shown in Figure 7 and 8, the symmetry of funnel plot of total response rate and recovery rate was low, suggesting a high possibility of bias.



**Figure 7.** Funnel plot of total clinical response rate

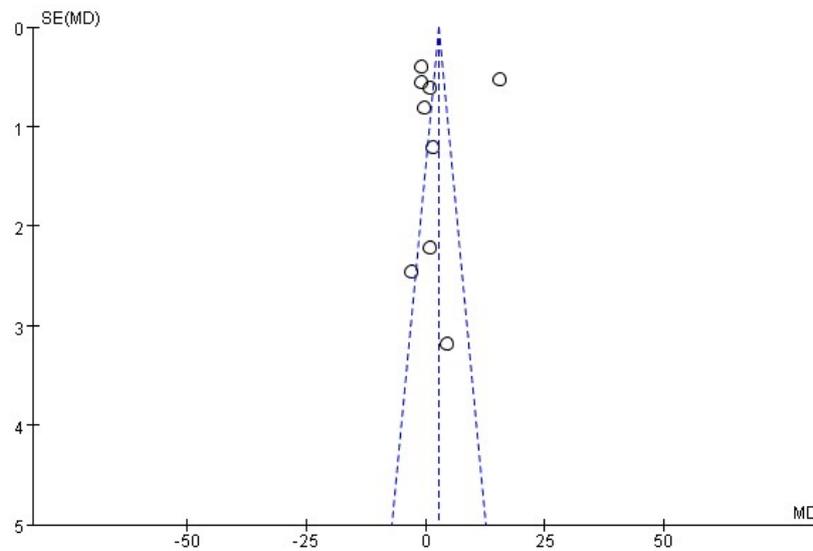


Figure 8. Funnel plot of clinical recovery rate

### 3. Discussion

Postural hypotension often occurs in central nervous system tumors, cerebrovascular accidents, diabetes and other diseases, and there is no specific drug treatment at present.[14] orthostatic hypotension disease is modern medicine disease name, most modern physicians to the disease for traditional Chinese medicine "vertigo" and "headache", "insomnia" category, which is classified according to the low blood pressure in patients with clinical manifestations of the main, these symptoms because of low blood pressure lead to cerebral small artery spasm, then cerebral arteriosclerosis, brain and other pathological changes, so this kind of clinical It's just a part of postural hypotension. Fundamentally, postural hypotension is closely related to the changes of human body position, and fundamentally is a vascular disease, so the etiology and pathogenesis of TRADITIONAL Chinese medicine should also be based on blood vessels.[15][16] According to the theory of meridians and acupoints in Traditional Chinese medicine, which has not been developed by the ancients, it is expected to realize the original innovation of the fundamental theory of acupuncture in the treatment of hypertension and provide theoretical basis for guiding clinical practice.[17] At present, with the improvement of the diagnosis rate of hypotension, the market demand for treatment of hypotension will increase year by year. It has great market potential. Worldwide attention has been paid to the treatment of hypotension research. But the research on acupuncture for postural hypotension is still in its infancy. Acupuncture is generally considered a safe treatment with little risk and few serious side effects. And it has a long history of treating cardiovascular diseases in China.[18] It is noteworthy whether the treatment of hypotension is effective. Since there is no systematic evaluation of acupuncture in the treatment of hypotension, [19] this paper conducted a meta-analysis of clinical studies on the clinical treatment of postural hypotension, which has certain reference significance and value. Limitations of the included clinical studies are as follows :

- 1) Methodological bias exists in the included studies: most of the included literatures did not describe the implementation plan of the specific random assignment scheme and blind method;
- 2) Outcome indicators included in the study were biased: outcome indicators in most literatures were inconsistent and subjective;
- 3) There was bias in the implementation and management of intervention measures: different acupuncture points were included in the intervention measures, and the stimulation methods and parameters were not described in detail, which may lead to bias in the results of the study;

4) Due to the lack of RCT studies on the efficacy of different acupuncture prescriptions for orthostatic hypotension, systematic analysis of acupuncture prescriptions for orthostatic hypotension was not conducted. In this study, the included RCT literatures were analyzed and evaluated from three aspects of total clinical response rate, recovery rate and adverse reactions. However, due to the subjectivity of the assessment of body position change, the evaluation tends to be subjective and there is no objective index basis, which may affect the overall results of meta-analysis. This study showed that acupuncture and moxibustion in the treatment of postural hypotension has certain advantages in terms of safety and effectiveness and clinical significance. However, due to the small sample size, randomization, method and other methodological design, the existing literature evidence is difficult to reflect the characteristics of acupuncture and moxibustion in a timely and effective manner.[20] So future study, should be more normative rigorous clinical testing scheme design, scientific selection in the control group, to show the advantages of orthostatic hypotension and clinical index of reverse to the end of the evaluation, further evaluation analysis of the effectiveness of acupuncture in the treatment of orthostatic hypotension and safety, promotion of acupuncture and moxibustion for clinical treatment of the disease to provide high quality, large sample randomized controlled clinical trials. In conclusion, this study can be used as a reference for the efficacy and safety of acupuncture in the treatment of orthostatic hypotension. However, this study is based on literature data, so the quality and quantity of literature will have a great impact on the results of the study. In the future, a large sample and high-quality randomized controlled clinical trial should be conducted for further verification.

#### 4. Conclusion

clinical randomized controlled trials on the basis of the existing literature found that compared with conventional western medicine, acupuncture and moxibustion treatment of orthostatic hypotension in the clinical curative effect and safety have certain advantages, but due to the low quality into literature, the effectiveness of acupuncture in the treatment of orthostatic hypotension and security evidence on the low side, so, in the clinical application should be combined with the actual situation to use them.

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