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Efficacy of Acupuncture in Clinic Treatment of Generalized Anxiety Disorder

--A Meta-Analysis

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Abstract: Objective: Evaluate the clinical effect of acupuncture on generalized anxiety disorder. Methods: Nine databases, including CNKI, Wanfang, Web of Science, and PubMed, were searched for this study. A randomized controlled trial (RCT) of acupuncture for generalized anxiety disorder was selected for inclusion in the study. Hamilton Anxiety Scale, self-Assessment Scale of Anxiety, and clinical treatment effects were Meta-analysed using the dedicated statistical analysis software RevMan version 5.3. Results: According to the comparison of Self-Anxiety Scale scores and Hamilton Anxiety Inventory of treatment in the acupuncture and medication groups, acupuncture was more effective than medication in the clinical treatment of generalized anxiety disorder. Discussion: Although the limited amount of included literature and the high level of bias affected the quality of the analysis, this study could still provide evidence that acupuncture plays a prominent role in the clinical treatment of generalized anxiety disorder.

Keywords: acupuncture, generalized anxiety disorder, meta-analysis, clinical efficacy

1. Introduction

1.1. Theoretical Basis

1.1.1. GAD

Generalized anxiety disorder (GAD) is the primary sub-type of anxiety disorder and is defined in the DSM-III as the presence of generalized, persistent anxiety (lasting one month or more). Generalized anxiety disorder usually presents with three or more of the four symptoms of motor tension, autonomic hyperactivity, apprehensive expectation, vigilance, and scanning [1]. GAD is characterized by a long duration, a tendency to relapse, and the need for long-term intensive supportive treatment, which places high demands on the effectiveness and tolerability of treatment. Currently, chemically synthesized anxiolytics have dominated the mainstream psychiatric field, but their adverse effects have always been a concern [2]. Therefore, the search for an alternative to pharmacological treatment that is less side-effective, more effective, and easier to administer has become a matter of concern.

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1.1.2. Acupuncture

Chinese medicine has different advantages compared to chemically synthesized drugs. Acupuncture is one of the essential treatment methods of traditional Chinese medicine. Modern scientific research on acupuncture techniques began in the late 1950s and has been refined and innovated over the years as complementary and alternative medicine accepted worldwide [3]. Acupuncture treatment in Chinese medicine is characterized by its specificity in treatment, flexibility in theory and prescription, and safety in efficacy. It has shown its unique advantages in current clinical applications [4].

1.2. Research Purpose

With the development of modern medicine, there has been an increase in the number of studies on the treatment of GAD with Chinese medicine, the results of which are superior to those of anxiolytic drugs while significantly reducing the side effects of the drugs. Therefore, it is of great interest to investigate the clinical efficacy of acupuncture in GAD at this stage. However, clinical studies in this area have shown small sample sizes and high randomization. A meta-analysis, as high-level evidence in evidence-based medicine, has the advantage of quantitatively synthesizing the results of multiple small sample studies on the same topic and improving the statistical validity of the initial results [5]. This paper aims to systematically review the results of randomized controlled trials of acupuncture for GAD, having obtained more comprehensive and objective effect estimates.

2. Methods

2.1. Research Retrieval Process

2.1.1. Source of Data

A total of nine databases were selected for this study. CNKI, Wanfang, Wanfang Medicine and Wipu in Chinese. Web of Science, Proquest, PubMed, Cochrane, and Embase in English.

2.1.2. Retrieval Strategies

Literature was searched using the title or abstract “generalized anxiety disorder,” “GAD,” or “generalized anxiety,” and the title or abstract “acupuncture.”

2.2. Criteria for Selection of Studies

2.2.1. Inclusion Criteria

This study included studies that meet the following five indicators,

(1)The study participants are patients with generalized anxiety disorder.

(2)The intervention is acupuncture.

(3)The comparative measure is a positive control, and the control group is chemically synthesized anxiolytics.

(4)The outcome indicators are the Self-Assessment Scales for Anxiety (SAS), the Hamilton Anxiety Inventory (HAMA), and clinical efficacy.

(5)The type of study is a clinical randomized controlled trial.

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2.2.2. Exclusion Criteria

Articles will be excluded when,

(1)Full-text articles excluded.

(2)The same experiment was republished.

(3)Absence of important information.

2.3. Data Extraction and Management

The literature for this study was managed using NoteExpress 3.7. Data were extracted from the literature by the investigator and populated into specially designed forms. Data were extracted from each included clinical trial for the author, year, location, age, gender, sample size, intervention, type of control, outcome indicators, random method, reports of side effects, and duration. Where necessary, missing information will be obtained by contacting the original author.

2.4. Included Literature Quality Assessment

The Cochrane Reviewers Handbook was consulted for this study to evaluate the included literature against the following six criteria for assessing the quality of randomized controlled trials.

(1)Whether the randomization method of the study was correct.

(2)Whether the investigator subjects were aware of the specific grouping and experimental content.

(3)Whether the measurement was blinded to the method used.

(4)Whether there were cases of missed interviews or withdrawals, and if so, whether deliberate analysis was used.

(5)Whether variables declared throughout the process were reported in the article.

(6)Whether there were other bias issues, such as falsified data, small sample sizes, etc.

2.5. Data Synthesis and Statistics

Statistical analysis for this study was performed using Revman 5.3. Count data were expressed using the ratio of ratios (OR). Measures were expressed as weighted mean differences (WMD) using 95% confidence intervals (CI). Also, if there is significant heterogeneity in the test results, the Meta-analysis will use a random-effects model. Conversely, the fixed-effects model will be used.

3. Results

3.1. Literature Search Results

Based on the retrieval strategies, 425 articles were retrieved in English or Chinese.

As the PRISMA flowchart (Fig. 1) shows, 321 articles remained after removing the duplicate. Two hundred ninety-three were excluded by reading the titles, abstracts, and full text. Eleven articles were then excluded after full-text reading. The reasons were: (1) full text could not be found; (2) duplicate publications; and (3) missing essential data. In the end, 17 articles were included in the qualitative analysis. The quantitative research did not have one piece because it lacked HAMA and SAS indicators.

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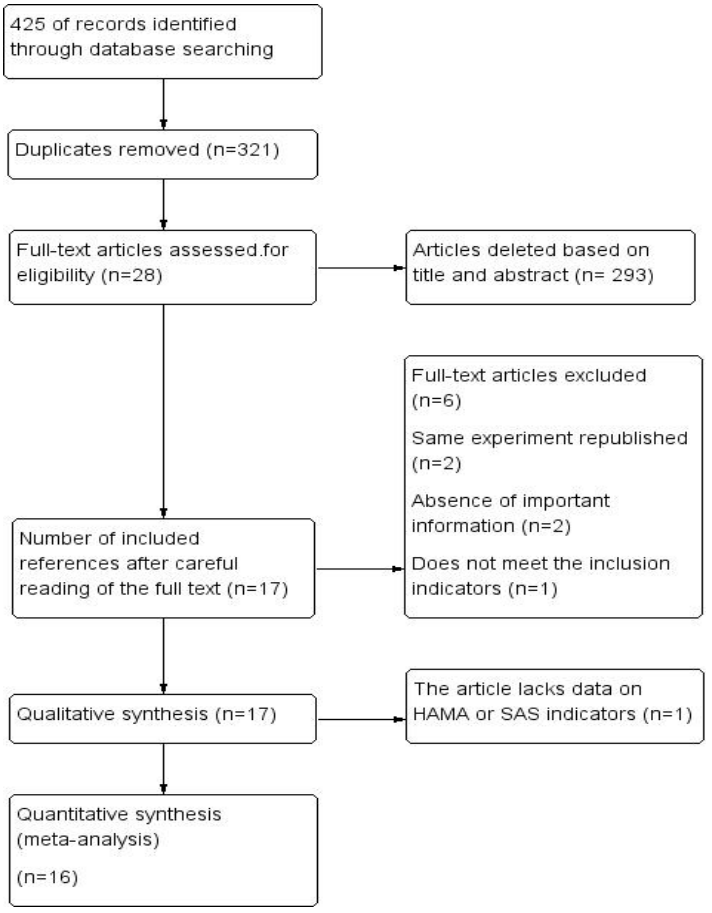

Figure 1: Study screening flow chart.

3.2. The Basic Information for the Inclusion Study

Table 1 shows the details of the characteristics of the included studies. All included studies [6-22] were in the Chinese literature, and the experimental subjects were patients with generalized anxiety disorder. In terms of outcome indicators, 13 studies [6-9,11,13-19,21] used the Zung Self-Assessment Scale for Anxiety (SAS), and 15 studies [6-13, 15-17,19-22] used the Hamilton Scale scale (HAMA). In terms of interventions, 12 studies [6,8-12,15,16,18-20,22] used acupuncture as an intervention, three studies [13,14,17] used acupuncture in combination with traditional Chinese medicine, 1 study [7] used acupuncture in combination with auricular pressure pills, and 1 study [21] used acupuncture in combination with music. In terms of the type of chemically synthesized drugs in the control group, four studies [8,15-17] chose oral flupirtine melittin tablets, five studies [6,7,13,19,21] chose oral paroxetine, two studies [11,20] chose oral buspirone hydrochloride tablets, one study [9] determined oral alprazolam, 1 study [10] chose oral lorazepam, 1 study [22] chose oral clonazepam, and the remaining studies [12,14,18] chose a combination of multiple drugs for treatment. Regarding reporting side effects, six studies [6,12,15,16,19,20] declared the use of the TESS (Traumatic Exposure Severity Scale) scale. In terms of the duration of the trials, four studies [8,9,15,16] had observations lasting four weeks, two studies [11,17] lasted 30 days, eight studies [6,7,10,12,19-22] lasted six weeks, 1 study [14] lasted eight weeks, 1 study [18] lasted 60 days, and 1 study [13] lasted three months.

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Table 1: The basic information for the inclusion study.

Author, Year	Location	Age of treatment (Mean±SD)	Age of control (Mean±SD)	Gender of treatment (M/F)	Gender of control (M/F)	Number of subjects (T/C)	Intervention methods	Type of control	Outcome measures used	Random method	Report of side effects	Duration
Shen 2022 [6]	China	49.43±5.230	51.73±5.982	12/18	14/16	90/90	acupuncture	oral flupentixol melitracine tablets	HAMA SAS SLEFI	random number table	TESS	Four weeks
Fan 2021 [7]	China	54.18	54.54	72/56	68/60	30/30	acupuncture combined with auricular point pressure pill	oral Paxil orally	HAMA SAS	random number table		Six weeks
Liu 2020 [8]	China	53.41±8.53	51.24±8.37	8/21	9/20	128/128	acupuncture combined with TCM	oral Paxil orally	HAMA SAS	random number table		Three months
Li 2019 [9]	China	46.97±9.35	48.83±9.64	12/18	10/20	29/29	acupuncture	oral buspirone hydrochloride tablet	HAMA SAS	random number table		30 days
Gu 2019 [10]	China	42.59±8.17	43.31±7.96	20/35	23/36	30/30	acupuncture	oral flupentixol melitracine tablets	HAMA SAS SLEFI	random number table		Four weeks
Zhao 2018 [11]	China	43.2±7.8		32/48		53/59	acupuncture	oral buspirone hydrochloride tablet	HAMA SLEFI	random number table	TESS	Six weeks

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Table 1: (continued).

Che 2015 [12]	China	67±6.4	69±8.7	15/6	17/7	40/40	acupuncture	oral Paxil orally	HAMA SAS		TESS	Seven weeks
Li 2015 [13]	China	42.31±8.44	41.59±7.89	11/19	13/17	21/24	acupuncture	oral Loralazepam	HAMA			Eight weeks
Zhao 2014 [14]	China	39±14	40±14	13/17	12/18	30/30	acupuncture	oral Paxil orally	HAMA SAS	random number table	TESS	Nine weeks
Zheng 2013 [15]	China	38±8	38±10	16/24	18/22	30/28	Mongolian acupuncture combined with music therapy	oral Paxil orally	HAMA SAS	random number table		Ten weeks
Zhou 2013 [16]	China			32/39		40/40	acupuncture	oral Clonazepam	HAMA Brain wave changes	random order of visit		11 weeks
Xiong 2013 [17]	China	41.00±10.72	43.87±12.56	11/19	6/24	36/35	acupuncture	oral Flupentixol melitracine tablets and glutamate	SAS			60 days
Li 2011 [18]	China	47.66±10.74	43.46±11.29	9/20	11/17	28/28	acupuncture	oral Alprazolam	HAMA SAS SLEFI	opaque envelope		Four weeks

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Table 1: (continued).

Shi 1 2010 [19]	China			23/37		29/28	acupuncture	oral fluphenazine melitracine tablets	HAMA SAS	random order of visit	TESS	Four weeks
Shi 2 2010 [20]	China	37.23 ±12.93	37.11 ±12.18	12/28	12/26	30/30	acupuncture combined with TCM	oral fluphenazine melitracine tablets	HAMA SAS			30 days
Shen 2007 [21]	China	38.48 ±15.80	36.48 ±12.80	11/18	12/17	40/38	acupuncture combined with TCM	oral Doxepin hydrochloride tablets and alprazolam, supplemented by psychotherapy	SAS	random order of visit		Eight weeks
Liu 2007 [22]	China	38.48 ±15.80	36.48 ±12.80	11/18	12/17	27/26	acupuncture	oral Doxepin hydrochloride tablets and alprazolam were taken orally, supplemented by psychotherapy	HAMA CGI	random number table	TESS	Six weeks

3.3. Risk of Bias in Included Studies

The risk of bias for the included studies is shown in Figure 2. Nine studies [7-9, 11, 13, 15, 19, 21]

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reported the appropriate randomization method. Four studies [12, 14, 16, 20, 22] stated the specific way, but the randomization method was incorrect, and a further four studies [6, 10, 17, 18] did not write about the particular randomization method. All studies [6-22] did not discuss how implementation and measurement biases were prevented. Regarding attrition bias, most articles [6-11, 13-22] had no missing data, or only a few visits were missing, but these sheddings were documented. Only one study [12] had a high risk of follow-up bias. Regarding reporting bias, four studies [11, 12, 15, 20] did not exhaustively report the previously mentioned variables, and the remaining studies [6-10, 13, 14, 16-19, 21,22] had only a low risk of bias. In addition, one study [10] had a small sample size, and two studies [21, 22] had non-uniform data decimal places, which were classified as other biases. The summary of the risk of bias for the included studies is presented in Figure 3.

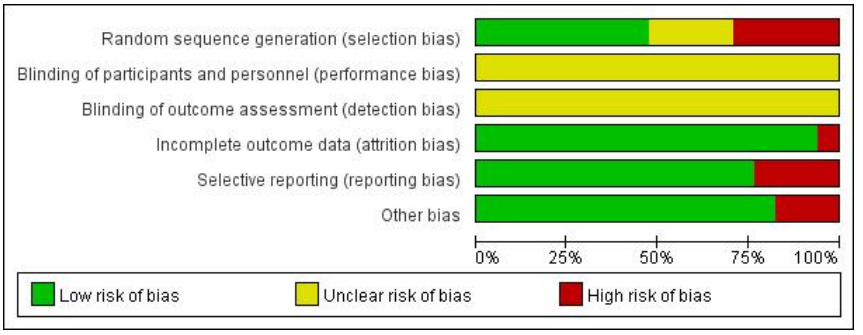

Figure 2: Risk of bias graph.

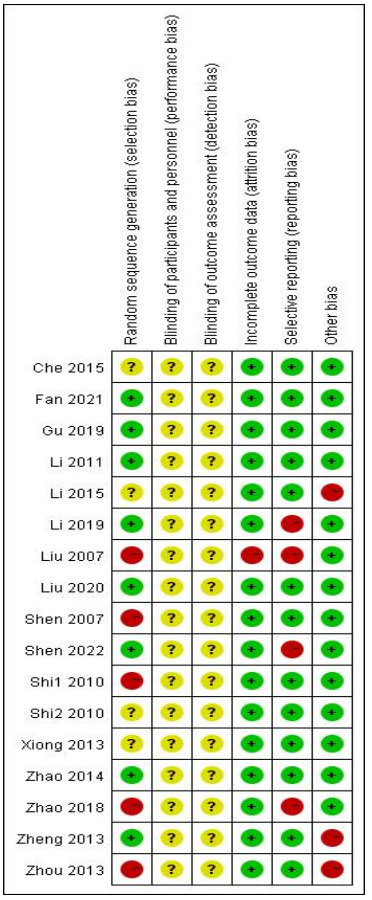

Figure 3: Risk of bias summary.

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3.4. Meta-analysis Results

In this study, separate meta-analyses were done on the SAS indicators, HAMA indicators, and clinical outcomes included in the study, the results of which are presented below.

3.4.1. Results of Self-rating Anxiety Scale (SAS)

As shown by Figure 5, 13 studies [6-9,11,13-19,21] were included in the meta-analysis of SAS scores. One thousand one hundred thirty-four samples were included, 570 in the observation group and 564 in the control group. A random effects model was used as the heterogeneity test, resulting in P<0.00001 and I^2 =94%, with high heterogeneity in the data. The difference was statistically significant as WMD=-0.57, 95% CI=[-1.08, -0.05],P=0.03.

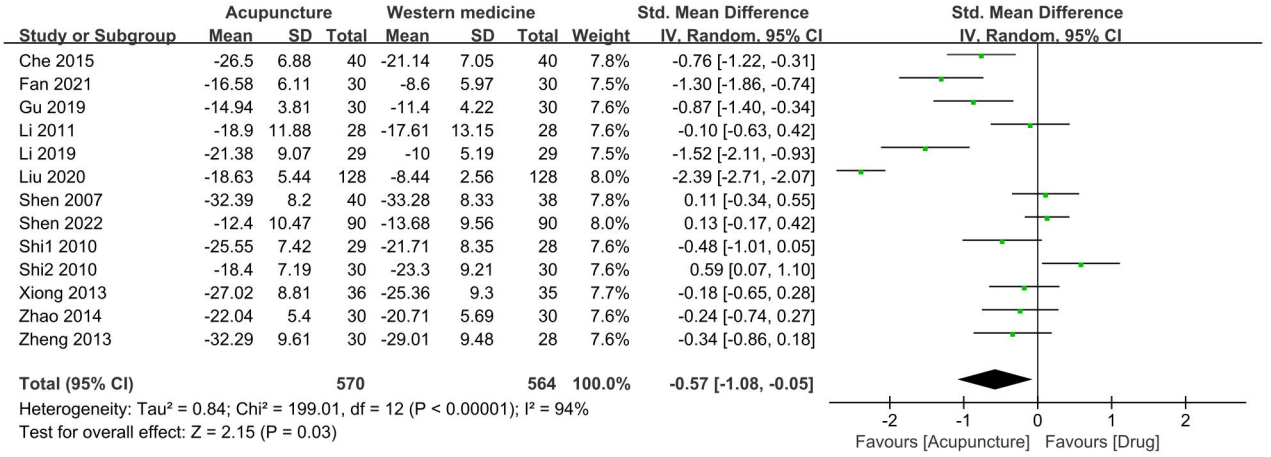

Figure 4: Forest plot of SAS.

3.4.2. Results of the Hamilton Anxiety Scale (HAMA)

As shown by Figure 4, 15 studies [6-11,13,15-17,19-22] were included in the analysis results. A total of 122 samples were included in this analysis. Of these samples, 608 were in the observation group and 614 in the control group. A random effects model was used as the heterogeneity test, resulting in P<0.00001 and I^2 =83%, with high heterogeneity in the data. WMD=-0.34, 95% CI=[-0.63, -0.05],P=0.02, the difference was statistically significant.

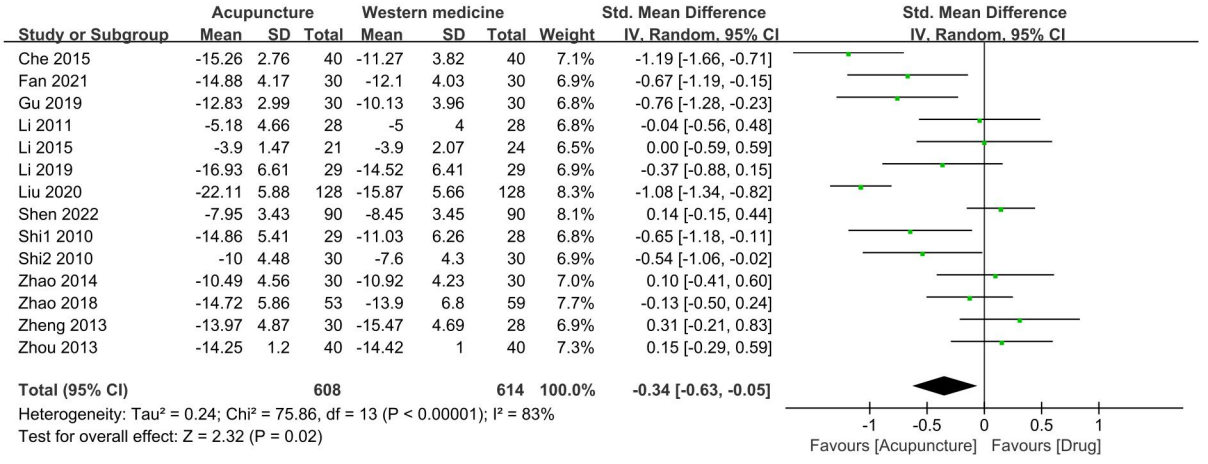

Figure 5: Forest plot of HAMA.

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3.4.3. Effective Meta-analysis

As shown in Figure 6, 14 studies [6-9,11,12,14-21] were included in the clinical effectiveness analysis. A total of 1048 samples were included, of which 524 were in the observation and control groups. p=0.72, I^2=0. There was no heterogeneity, so a fixed effects model was used. OR=1.55, 95% CI=[1.11,2.15], p=0.009, the difference was statistically significant. The confidence interval lies to the right of the null line (OR=1), indicating that the study factors are positively associated with the outcome event.

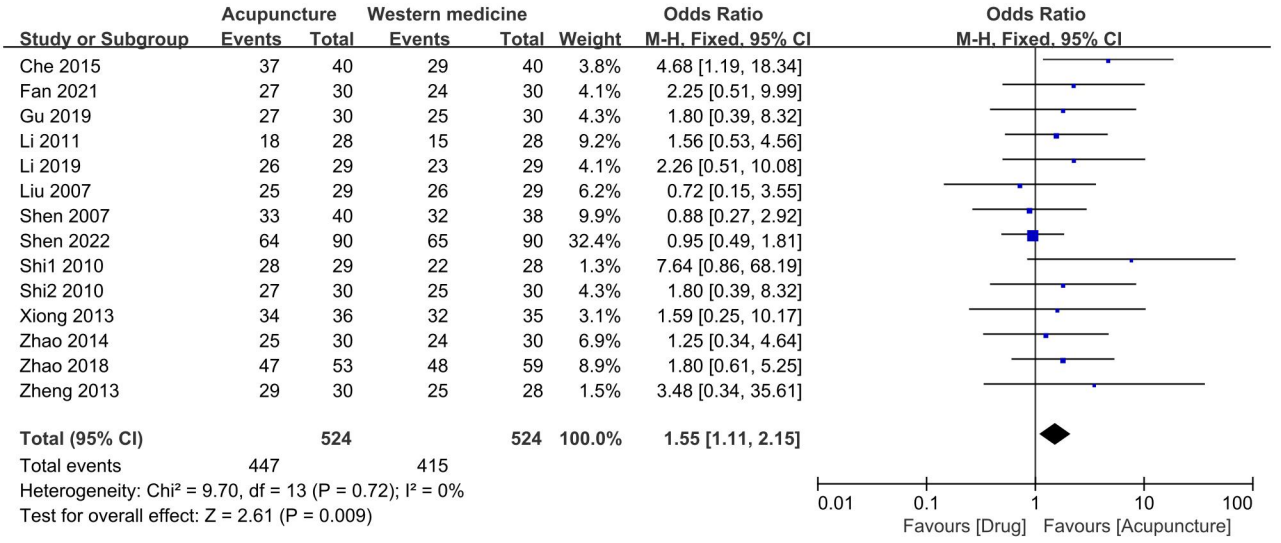

Figure 6: Forest plot of efficacy.

3.4.4. Results of Publication Bias

Regarding reporting bias, it can be seen that the funnel plots for all three (Figure 7, Figure 8, and Figure 9) show an essential symmetry. Visual assessment of the funnel plots supports that the publication bias is unlikely to influence the overall results of this meta-analysis.

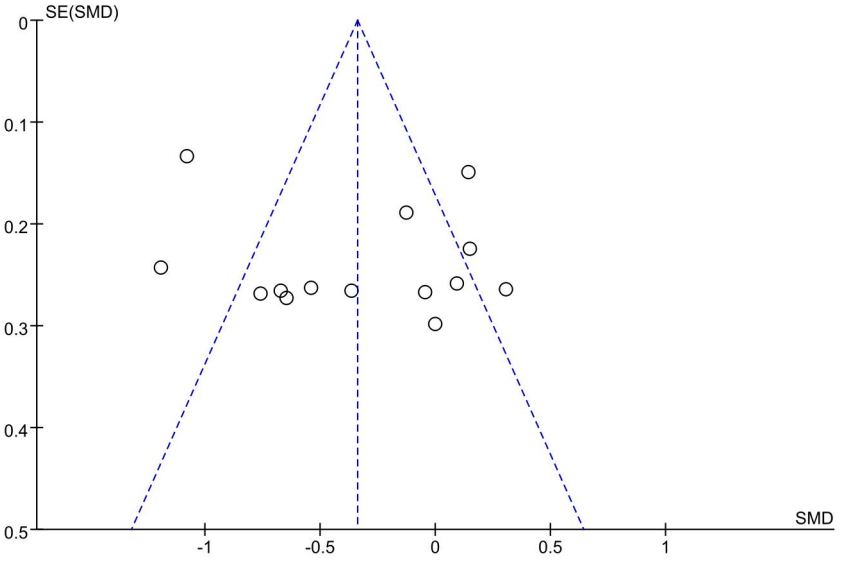

Figure 7: Funnel plot of HAMA.

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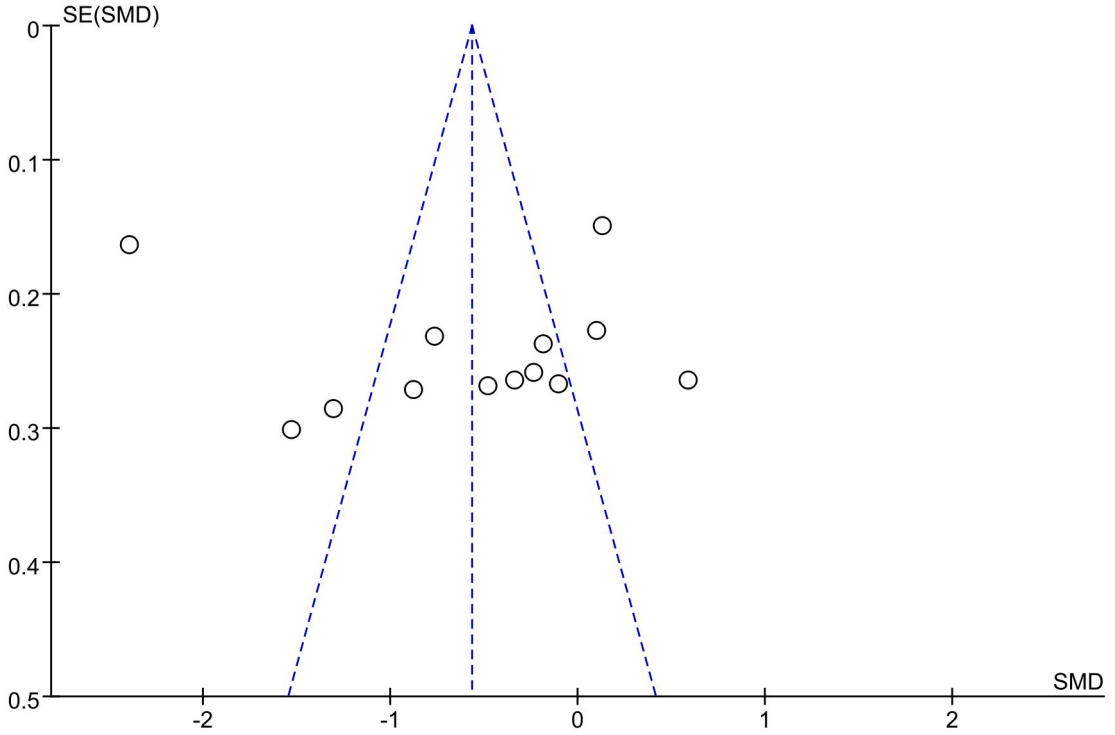

Figure 8: Funnel plot of SAS.

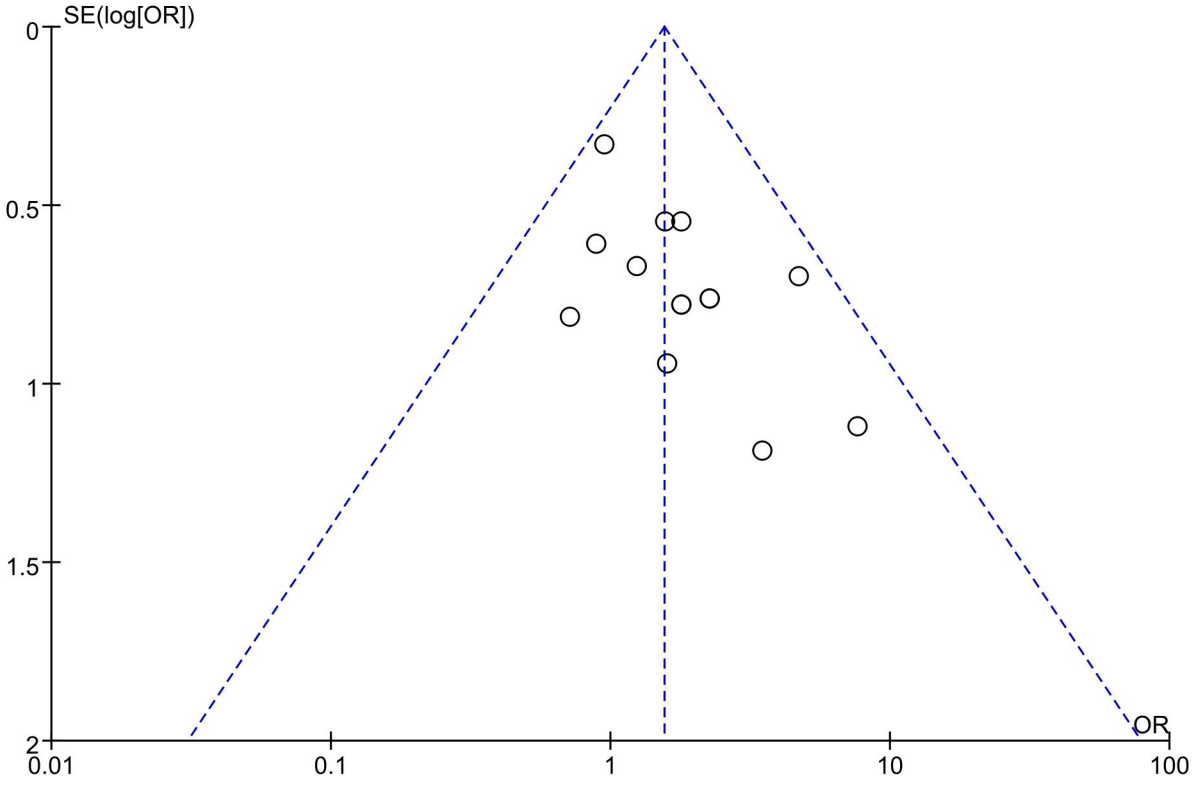

Figure 9: Funnel plot of efficacy.

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3.5. Results of Side Effects

A total of 9 studies reported side effects [6-8,10,12,14,15,19,20]. Seven of these studies [6-8,14,15,19,20] reported specific cases and symptoms. Figure 10 shows a sample of 630 patients, with 313 points in the experimental group and 317 issues in the control group. Analysis of heterogeneity showed that P=0.42 and I^2 =1%. There was no heterogeneity, so a fixed effects model was used. OR=0.17,95% CI=[0,10,0.29], P<0,00001, the difference was statistically significant. The confidence interval was to the left of the null line (OR=0). Therefore, acupuncture was negatively associated with the development of side effects.

In terms of side effects symptoms, the side effects in the experimental group were needle sickness in 4 cases [6, 19, 20], mild hematoma in 6 patients [6, 19, 20], pain until the next day in 1 issue [20], drowsiness in 3 cases [7, 14], vertigo in 2 patients [7], headache in 1 case [7] and gastrointestinal symptoms in 4 points [14]. The side effects in the control group were insomnia in 7 patients [6, 15, 19, 20], dizziness in 21 cases [6, 7, 8, 14, 19, 20], diarrhea in 1 issue [6], constipation in 15 patients [6, 8, 14, 15], drowsiness in 16 cases [7, 14], emotional instability in 2 cases [7], hyperexcitability in 4 patients [7], headache in 3 cases [7], dry mouth in 21 cases [8,14,15,19, 20], bloating in 2 cases [8], loss of appetite in 4 patients [8, 19, 20], gastrointestinal symptoms in 3 cases [14], excessive sedation in 1 issue [15], sweating in 4 points [19, 20] and nausea in 1 patient [20].

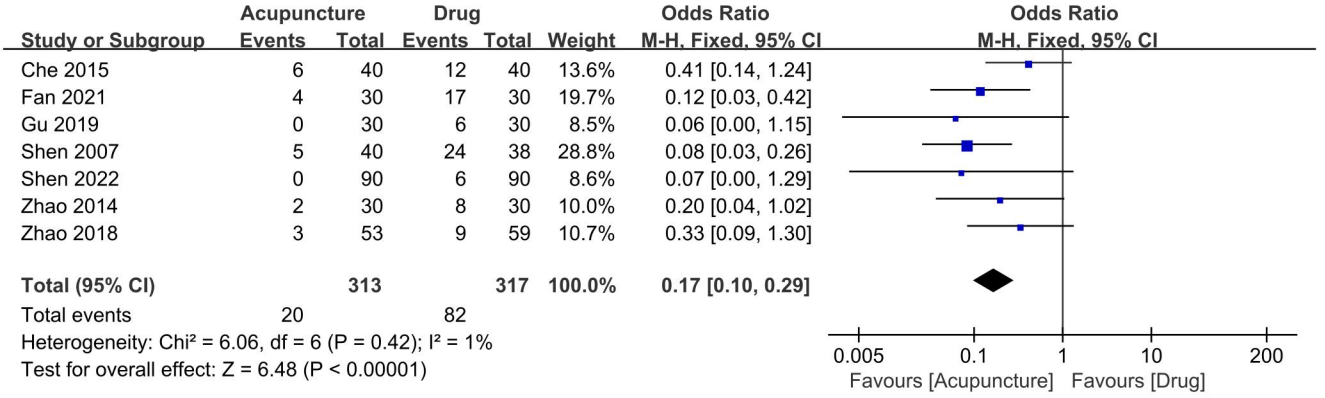

Figure 10: Forest plot of side effects.

4. Conclusion

4.1. General Interpretation of the Results

The results of the Meta-analysis showed that acupuncture had better results in treating generalized anxiety disorder than medication in SAS scores, HAMA scores, and clinical efficacy. Moreover, studies of side effects showed that the probability and severity of side effects from acupuncture therapy were much lower than those from the western drug group. The study's results demonstrate the safety and effectiveness of acupuncture in treating generalized anxiety disorder.

4.2. Limitations

Unfortunately, only 17 papers were included in this study, reducing the reliability of the study's findings. Also, none of the included literature was blinded, leading to more severe implementation bias and measurement bias, which affects the reliability of the results to some extent.

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4.3. Research Significance

Traditional Chinese medicine theory holds that the human body is closely related to its natural environment. The tendons, bones, and organs are linked together through meridians to form a whole. Therefore, no matter which part of the body is diseased, it is closely related to the full. Acupuncture stimulates the body's acupuncture points to regulate yin and yang, meridians and qi, and blood to achieve a therapeutic effect. In traditional Chinese medicine, there is no such concept as "anxiety." Chinese medical theory classifies anxiety in modern medicine as "liver qi stagnation". Acupuncture can unblock the flow of qi and blood to achieve the effect of unblocking liver qi stagnation [23]. Although the small sample size affects the reliability of the study, this study can still show that acupuncture is safe and effective in the clinical treatment of generalized anxiety disorder. In the future, it is promising that acupuncture will be active as an alternative therapy in the clinical treatment of GAD.

In addition, in terms of study methodology, experimental designs should be large samples and high quality. Proper randomization groups, allocation concealment schemes, and scientific and appropriate blinding should be adopted and documented in detail to increase the credibility of the trial design. At the same time, experimental data should be appropriately recorded throughout the experiment, and all affirmed variables should be reported exhaustively and practically to ensure that the results are accurate and credible.

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