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Comparing verum and sham acupoint catgut embedding for adults with obesity

A systematic review and meta-analysis of randomized clinical trials

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Abstract

Background: Previous clinical trials have reported that acupoint catgut embedding (ACE) is a useful modality for weight loss. However, no study has specifically investigated the effectiveness and safety of comparing verum and sham ACE in adults with obesity. Thus, this study aimed to evaluate the effectiveness and safety of comparing verum and sham ACE in obese adults.

Methods: A comprehensive literature search was conducted in the electronic databases of PUBMED, EMBASE, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wanfang, China Science and Technology Journal Database, and China Biomedical Literature Service System from inception to April 1, 2022. Randomized clinical trials that focused on evaluating the effectiveness of comparing verum and sham ACE in adults with obesity were included. The primary outcomes included reduction in body weight, body mass index, hip circumference, and waist circumference. The secondary outcomes consisted of a decrease in body fat percentage and the occurrence rate of adverse events. The methodological quality of the included randomized clinical trials was evaluated using the Cochrane Risk-of-bias tool. Statistical analysis was performed using RevMan 5.4 software.

Results: Six trials involving 679 adults with obesity were included in this study and entered in the data analysis of systematic review and meta-analysis. Results of the meta-analysis revealed significant reduction in body weight (mean difference [MD] = –1.68, 95% confidence intervals (CI) [–2.34, –1.01], I^2 = 51%, P < .001), body mass index (MD = –0.51, 95% CI [–0.81, –0.21], I^2 = 74%, P < .001), hip circumference (MD = –1.11, 95% CI [–1.67, –0.55], I^2 = 0%, P < .001), waist circumference (MD = –2.42, 95% CI [–3.38, –1.45], I^2 = 68%, P < .001), and decrease in body fat percentage (MD = –0.83, 95% CI [–1.30, –0.36], I^2 = 16%, P < .001) in comparing verum and sham ACE. However, no significant difference was identified in AEs (odds ratio = 1.53, 95% CI [0.80, 2.95], I^2 = 0%, P = .20) between the 2 groups.

Conclusion: ACE is effective in the treatment of obesity in adults with safety profile. Further studies with higher quality and larger sample size are warranted to confirm the current findings.

Abbreviations: ACE = acupoint catgut embedding, BFP = body fat percentage, BMI = body mass index, CI = confidence intervals, EA = electroacupuncture, MD = mean difference, ORAE = occurrence rate of adverse events, RCTs = randomized controlled trials.

Keywords: acupoint catgut embedding, loss weight, meta-analysis, obesity, systematic review

JY, XL, YZ, and GY contributed equally to this work.

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

This study is a secondary literature review based on currently available clinical trials. No ethical approval is needed for this study. This study is expected to be published in a peer-reviewed journal.

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1. Introduction

Obesity is a chronic metabolic disorder characterized by abnormal or excessive lipid accumulation in adipose tissue, which exceeds the body consumption level.[1–3] According to the latest data from the World Health Organization in 2022, there are more than 1 billion people with obesity around the world, including 650 million adults, 340 million teenagers, and 39 million children.[4] Furthermore, it is been estimated that approximately 167 million people will become ill by 2025.[4] Compared to the normal weight population, people with obesity are more likely to have an increased risk of cardiovascular disease, insulin resistance, type 2 diabetes mellitus, hypertension, and dyslipidemia.[5–8] Therefore, timely prevention and treatment of obesity with effective treatment modalities are particularly necessary.

Currently, the treatment modalities for obesity include pharmacotherapy, exercise, yoga, and complementary and alternative therapies.[9–17] Although pharmacotherapy is a common treatment for obesity, it relieves symptoms with easy relapse after drug cessation. In addition, long-term use of such drugs also has serious side effects, such as nausea, vomiting, headache, diarrhea, nasopharyngitis, abdominal pain, eructation, dizziness, and back pain.[9] In this regard, complementary and alternative treatments are among the most promising candidates for an increasing number of obese patients owing to their promising effects, safety, and low cost.[11–17] Of these, acupoint catgut embedding (ACE) is one of the most popular modalities.[17]

ACE is an integrative modality that uses acupuncture and modern technology. It is applied by implanting absorbable catgut sutures into the acupoint in accordance with the meridian and collateral theory.[18] It has been reported to effectively treat obesity because it causes continuous acupoint stimulation when the catgut is absorbed. A previous study has also reported that ACE can improve weight loss by improving leptin resistance.[19]

Although previous systematic reviews have addressed the effectiveness of ACE, acupuncture, and electroacupuncture (EA) in the management of obesity,[20–25] no study has specifically assessed the effectiveness and safety of comparing verum and sham ACE in adults with obesity. Thus, this systematic review and meta-analysis specifically investigated the effectiveness and safety of comparing verum and sham ACE in the treatment of obese adults.

2. Methods and analysis

2.1. Eligibility criteria

In this study, the eligibility criteria followed the Participants, Intervention, Control, Outcome, Study design principles as follows.[26]

2.1.1. Type of participants. All adult participants (adults aged 18 years or older) were diagnosed with obesity, regardless of sex and type of obesity.

2.1.2. Type of intervention and comparison. All patients in the treatment group received ACE alone. All patients in the control group underwent sham ACE alone (no catgut implanted). Studies with combined any other types of associated modality, such as drug, acupuncture, EA, diet and no treatment were excluded.

2.1.3. Type of outcomes. Primary outcomes included reduction in body weight, body mass index (BMI), hip circumference, and waist circumference. Secondary outcomes consisted of decrease in body fat percentage (BFP) and the occurrence rate of adverse events (ORAE).

2.1.4. Type of studies. This study only included published randomized controlled trials (RCTs) investigating verum ACE in comparison with sham ACE for the management of obese adult participants. Studies of duplicates, animal studies, laboratory studies, reviews, case reports, conference summaries and others, combined therapy, wrong comparison, non-RCTs, quasi-RCTs (it utilizes quasi-random method of allocating participants to different interventions, such as allocation by date of birth, day of the week, medical record number, month of the year, and so on), and incomplete information were excluded.

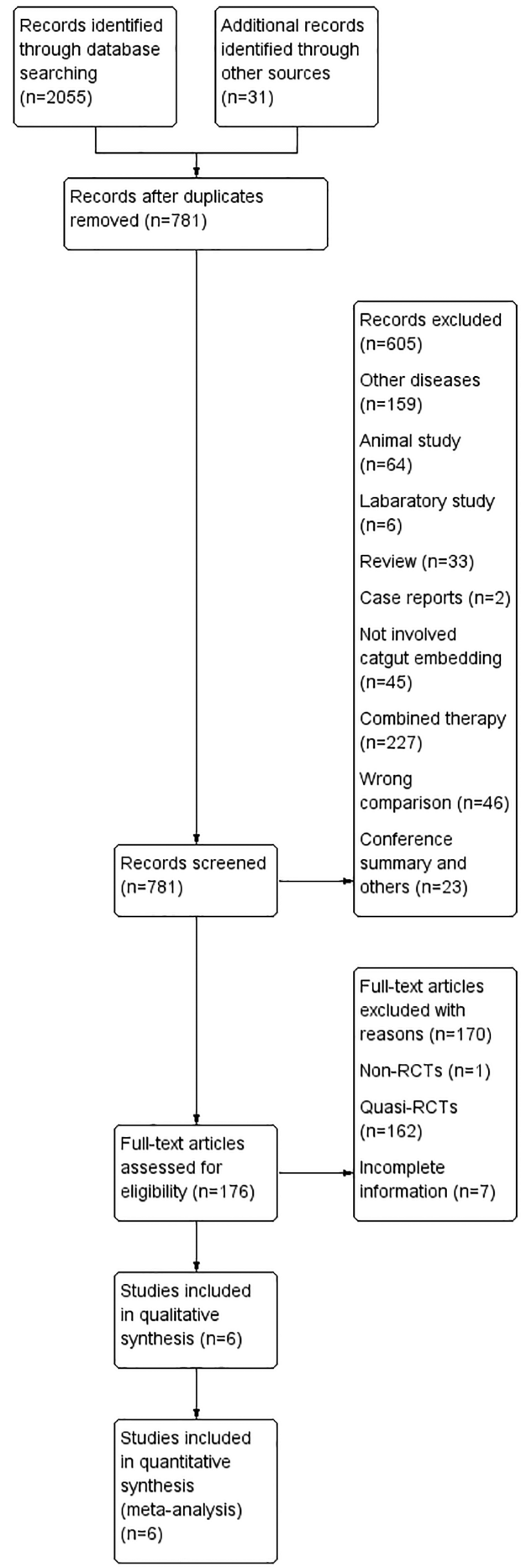

Figure 1. Flow diagram of study selection.

2.2. Data sources and search strategy

2.2.1. Electronic database search. A comprehensive literature search was carried out from inception up to April 1, 2022, in the PUBMED, EMBASE, Cochrane Library, Web of Science, China National Knowledge Infrastructure, Wanfang, China Science and Technology Journal Database, and China Biomedical Literature Service System databases. The combination search terms of obesity, overweight, ACE, and catgut implantation were used to search for potential RCTs comparing verum and sham ACE for the management of obesity. The language used was limited to Chinese and English.

2.2.2. Other data sources. Apart from the electronic database sources, reference lists of associated reviews, dissertations and theses were also identified to avoid missing potential trials.

2.3. Study selection and data collection

2.3.1. Study selection. After excluding duplicate studies, 2 researchers independently scanned the research records according to titles and abstracts, and irrelevant records were eliminated. Then, full-text articles were carefully read against the eligibility criteria. Any divergence was resolved by a third researcher and a consensus was reached after discussion.

2.3.2. Data extraction. Two researchers independently extracted data from the included RCTs using a previously designed data extraction sheet. The extracted data included eligible trial characteristics (e.g., title, first author, year of publication), participant data (e.g., age, sex, eligibility criteria), details of study design (randomization, allocation concealment, blinding), information on intervention and control (dosage, frequency, etc), primary and secondary outcomes (reduction in body weight, BMI, hip circumference, and waist circumference; decrease in BFP and ORAE), results, and findings. Any disagreement was resolved by a third researcher through discussion, and a consensus was reached after discussion.

2.4. Risk of bias assessment

Two researchers independently assessed the risk of bias of all included RCTs using the Cochrane Risk of Bias Tool.[27] It covers 7 fields: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessments, incomplete outcome data, selective reporting, and other sources of bias. Each aspect was further ranked as low, unclear, or high risk of bias. Any discrepancy was resolved by a third researcher through adjudication or discussion and a final consensus decision was reached.

2.5. Statistical analysis

RevMan 5.4 software (Cochrane Collaboration, Copenhagen, Denmark) was used to perform the statistical analysis. Discontinuous data are presented as odds ratios and 95% confidence intervals (CI), and continuous data are presented as the mean difference (MD) and 95% CI. In terms of continuous data, we calculated the mean change by subtracting pretreatment from post-treatment and standard deviation change by pretreatment and post-treatment in accordance with Cho formula.[28] Heterogeneity across included RCTs was utilized by I^2 statistic. A P value of $I^2 \leq 50\%$ indicates reasonable heterogeneity, and a fixed-effects model was used to pool the data. A P value of $I^2 > 50\%$ signifies substantial heterogeneity, and a random-effects model was used to synthesize the data. Subgroup analysis was performed to explore potential factors influencing heterogeneity whenever it was significant.

3. Results

3.1. Study selection

In this study, 2086 associated records were searched in both electronic databases and other sources (Fig. 1). After removing duplicates, titles and abstracts of 781 articles were scanned, and 605 irrelevant records were eliminated. A total of 176 full-text articles were assessed against the eligibility criteria, and 170 articles were excluded because of non-RCTs, quasi-RCTs, and incomplete information. Finally, 6 RCTs involving 679 patients were included in this study. The study selection process is illustrated in Figure 1.

3.2. Study characteristics

The general characteristics of the 6 RCTs included in this study are presented in Table 1. We summarized the first author, year of publication, region, sample size, age, sex, details of intervention and comparison, and outcomes. All the studies were conducted in China. The intervention and comparison arms were the verum ACE and sham ACE, respectively.

3.3. Risk of bias assessment

The risk of bias assessment of the 6 included trials is shown in Figure 2. All 6 RCTs provided sufficient information on

Table 1

General characteristics of eligible trials.

Study	Country	No. of patients (T/C)	Age (yr, T/C); range (yr)	Gender (male; T/C)	Intervention (ACE)	Control (sham ACE)	Outcomes	Follow-up
Chen 2018[29]	China (Taiwan)	40/40	T:39.9 ± 9.8; C:43.7 ± 9.3 Range: 20–65	0/0	Once weekly for 6 wk	Once weekly for 6 wk	① ② ③ ④ ⑥	6wk
Chen 2022[17]	China	108/108	T:31.66 ± 6.55; C:30.75 ± 6.71 Range: 18–45	28/23	Once per 2wk for 16 wk	Once per 2wk for 16 wk	① ② ③ ⑤ ⑥	16 wk
Lin 2015[30]	China	29/27	T:36.38 ± 10.08; C:34.30 ± 10.13 Range: 18–60	14/19	Once per 2 wk for 8 wk	Once per 2 wk for 8 wk	① ② ④ ⑤	8 wk
Tan 2016[31]	China	58/54	T:42.14 ± 11.83; C:39.13 ± 11.13 Range: 22–65	5/3	Once weekly for 4 wk	Once weekly for 4 wk	① ② ④	4 wk
Wan 2022[32]	China	68/63	T:34 ± 4; C:34 ± 4 Range: 18–50	28/23	Once per 2 wk for 12 wk	Once per 2 wk for 12 wk	② ④ ⑤ ⑥	12 wk
Zhang 2019[33]	China	42/42	T:33.05 ± 6.60; C:36.17 ± 9.71 Range: 18–60	14/19	Once per 10 d for 12 wk	Once per 10 d for 12 wk	① ② ③ ④ ⑥	12 wk

① body weight; ② body mass index; ③ hip circumference; ④ waist circumference; ⑤ body fat percentage; ⑥ occurrence rate of adverse events.
ACE = acupoint catgut embedding, C = control group, T = treatment group.

random sequence generation, incomplete outcomes, selective reporting, and other bias.[17,29–33] Three trials provided sufficient details regarding allocation concealment.[17,30,32,33] Four studies reported essential details on blinding for participants and researchers,[17,29–31] and 2 RCTs recorded sufficient information of blinding to outcome assessment.[17,33]

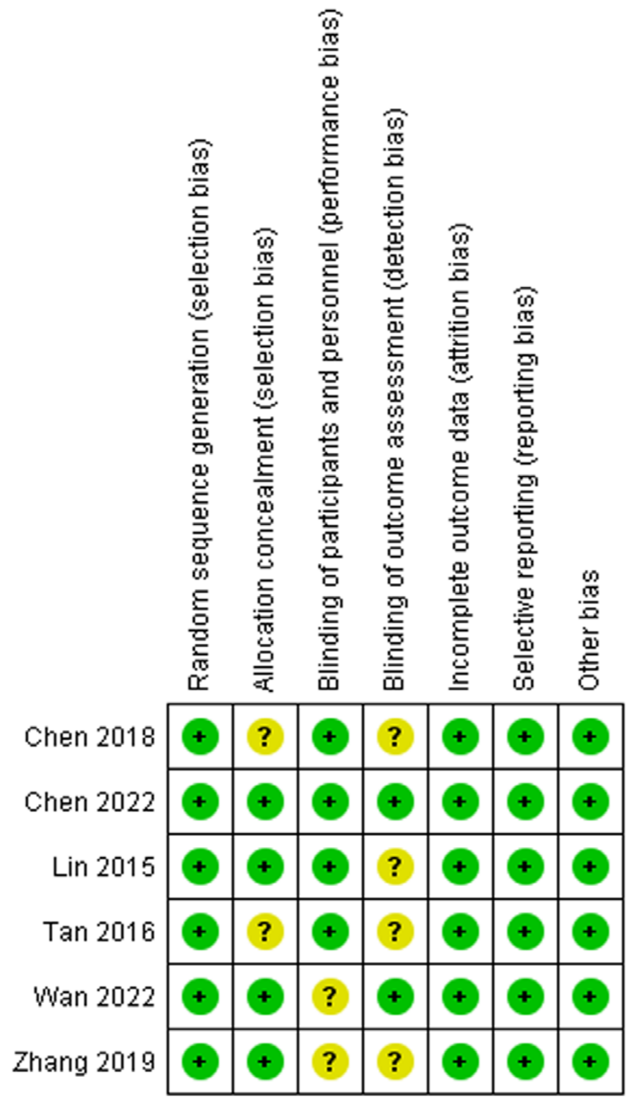

Figure 2. Risk of bias summary.

3.4. Meta-analysis of ACE on obesity

3.4.1. Body weight reduction. Five studies involving 548 subjects evaluated body weight reduction.[17,29–31,33] The meta-analysis results showed that there were significant differences in body weight reduction between the 2 groups (MD = –1.68, 95% CI [–2.34, –1.01], I^2 = 51%, P < .001; Fig. 3).

3.4.2. Decrease in BMI. Six studies involving 679 participants assessed BMI decrease. There were not significant differences in BMI decrease between the 2 groups (MD = –0.98, 95% CI [–2.30, 0.34], I^2 = 99%, P = .14)[17,30–33] (Fig. 4). However, subgroup analysis results showed significant difference in BMI reduction (MD = –0.51, 95% CI [–0.81, –0.21], I^2 = 74%, P < .001)[17,29–31,33] (Fig. 4).

3.4.3. Reduction in hip circumference. Three RCTs involving 380 participants assessed the hip circumference[17,29,33] (Fig. 5). Meta-analysis results showed significant reduction in hip circumference (MD = –1.11, 95% CI [–1.67, –0.55], I^2 = 0%, P < .001).

3.4.4. Reduction in waist circumference. Five studies involving 463 participants checked the waist circumference[29–33] (Fig. 6). Meta-analysis results showed substantial difference in waist circumference (MD = –3.00, 95% CI [–4.65, –1.35], I^2 = 95%, P < .001). Subgroup analysis after excluding 1 study still exerted significant difference in waist circumference (MD = –2.42, 95% CI [–3.38, –1.45], I^2 = 68%, P < .001).

3.4.5. Decrease in BFP. Three studies involving 403 participants assessed BFP[29,30,32] (Fig. 7). Meta-analysis results did not show significant difference in BFP (MD = –2.99, 95% CI [–7.98, 2.00], I^2 = 100%, P = .24). However, subgroup analysis after excluding 1 study showed significant difference (MD = –0.83, 95% CI [–1.30, –0.36], I^2 = 16%, P < .001).

3.4.6. ORAE. A total of 4 studies reported ORAE[17,29,32,33] (Fig. 8). Meta-analysis did not show significant difference in ORAE (odds ratio = 1.53, 95% CI [0.80, 2.95], I^2 = 0%, P = .20) between 2 groups.

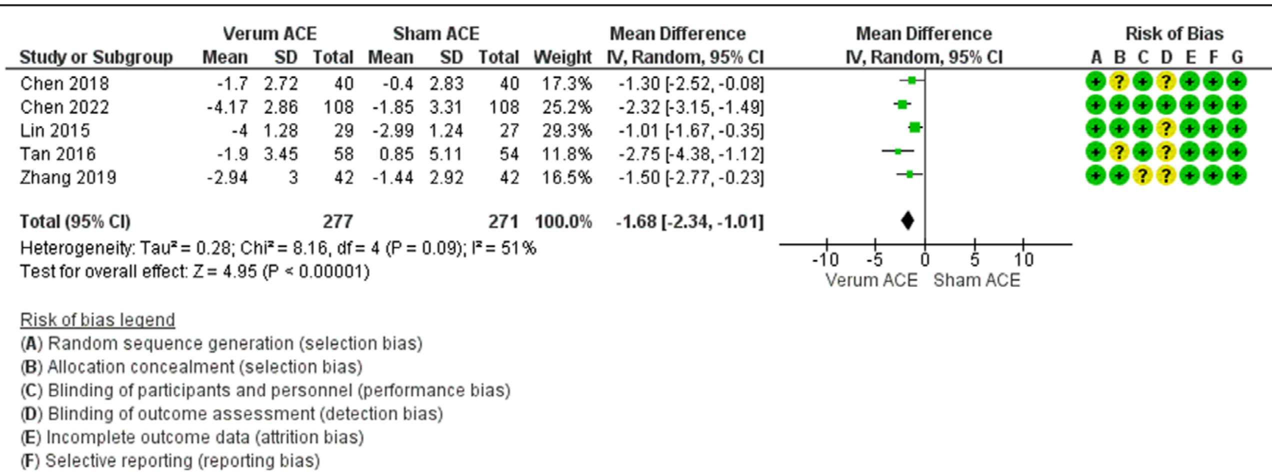

Figure 3. Meta-analysis of body weight.

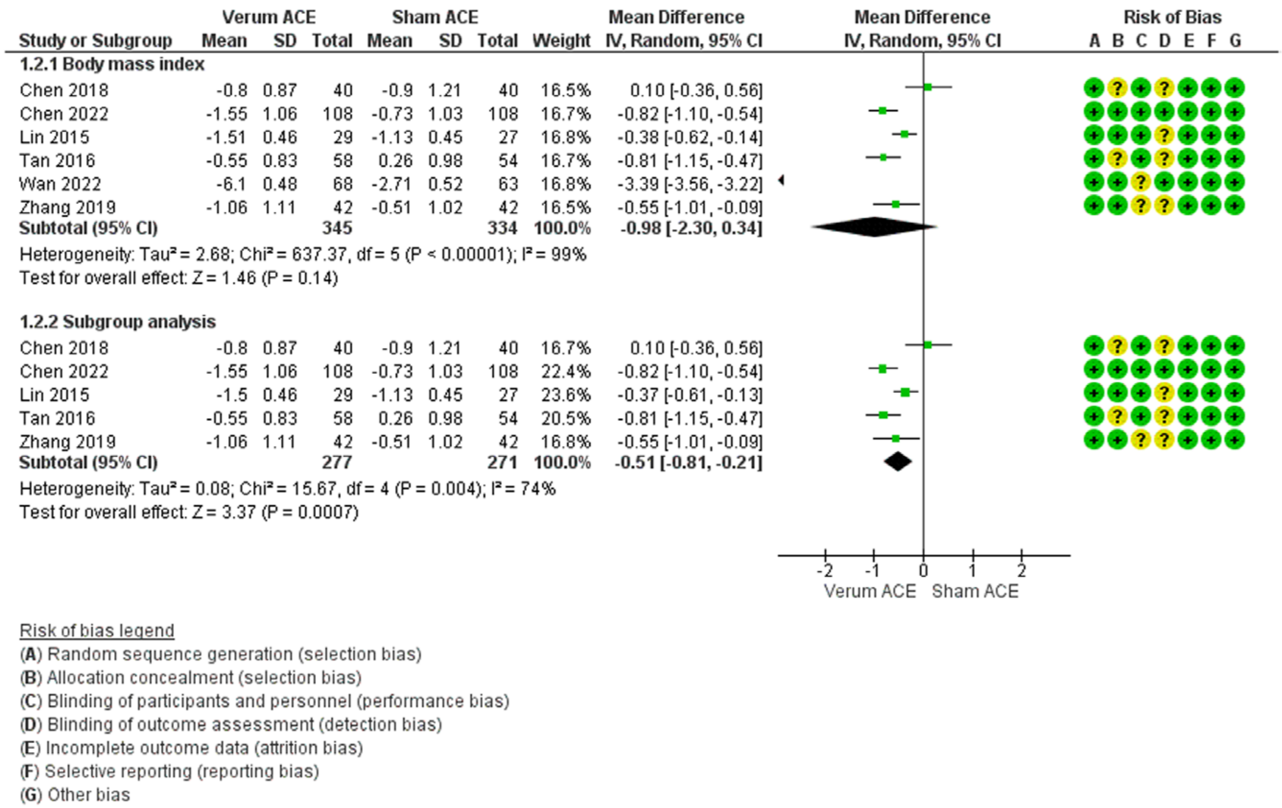

Figure 4. Meta-analysis of body mass index.

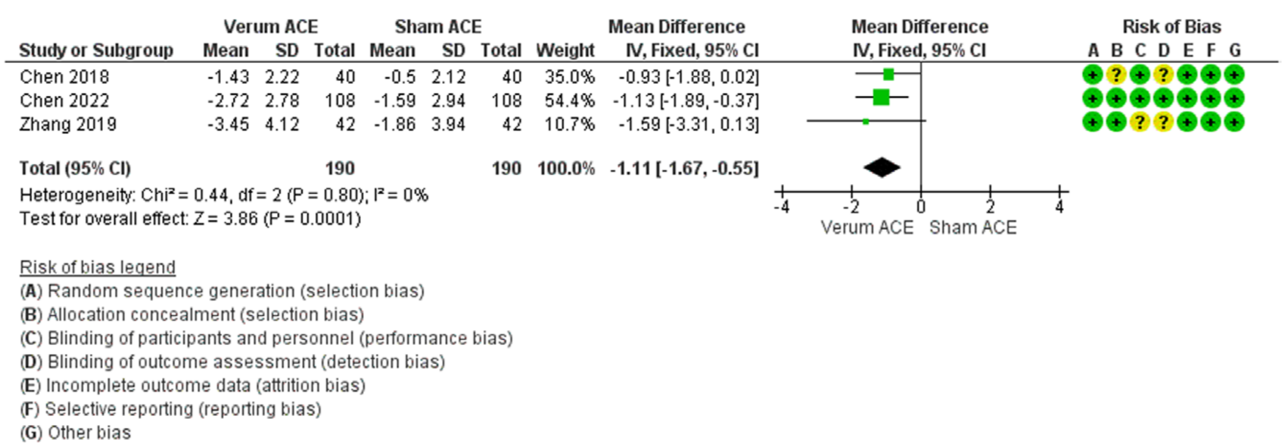

Figure 5. Meta-analysis of hip circumference.

4. Discussion

This systematic review and meta-analysis summarize the latest clinical evidence to assess the effectiveness and safety of comparing verum and sham ACE in obese adults. Six trials, involving 679 participants, were included in the analysis. The methodological quality of the trials is acceptable.

Previous similar studies investigated the effectiveness and safety of ACE alone or in combination with other modalities in patients with different types of obesity.[20–25] Two studies reported as the protocol of ACE for obesity, and no results or findings were presented.[20,21] The other 4 studies compared ACE alone or in combination with acupuncture, EA, or other management strategies to the different controls.[22–25] One study included RCTs that used ACE, ACE plus acupuncture, or EA to treat abdominal obesity.[22] The results showed that ACE exerted equal effects on other types of acupuncture.[22] However, the clinical effect of ACE plus EA is superior to that of EA alone in abdominal obesity.[22] Another study investigated the effectiveness and safety of ACE alone or in combination with a control modality in comparison to drugs, acupuncture, EA, cupping, sham ACE, or others for obesity.[23] The findings showed a tendency of equal or superior effects to other treatments with fewer side effects.[23] Two other studies systematically evaluated the effect of ACE compared to acupuncture and EA for simple obesity.[24,25] The results also showed that ACE was superior to the control modalities for simple obesity.[24,25] However, these studies have several disadvantages. First, the overall quality of the included studies was low, which may have affected their findings. Second, all those studies applied ACE alone or with other modalities in

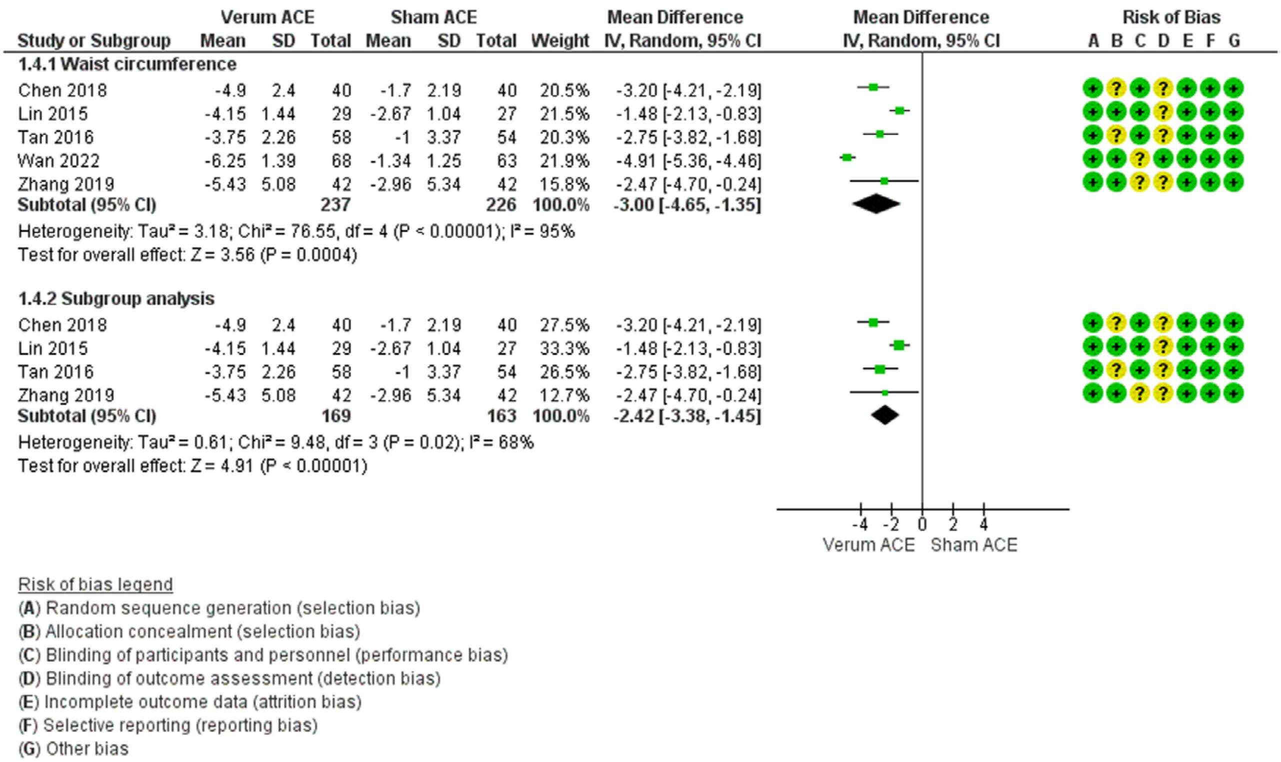

Figure 6. Meta-analysis of waist circumference.

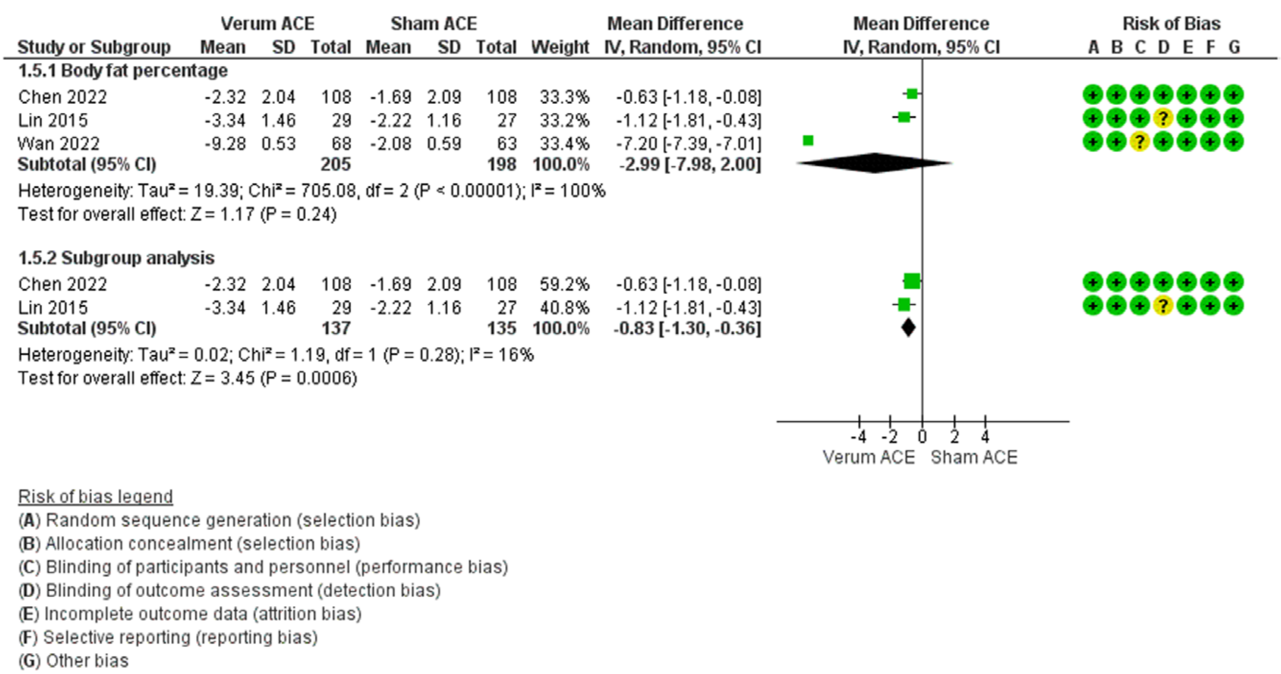

Figure 7. Meta-analysis of body fat percentage.

comparison with different control management strategies. Although their results demonstrated that ACE showed a tendency of equal effects to other kinds of treatments, such as acupuncture and EA, no systematic review and meta-analysis specifically focused on the evaluation of the effectiveness and safety of ACE versus sham ACE. Therefore, this study specifically and systematically assessed the effectiveness and safety of comparing verum and sham ACE in the treatment of adults with obesity. The findings of this systematic review and meta-analysis are partly consistent with previous studies.[22–25]

In this study, the meta-analysis results showed a more promising effectiveness of comparing verum and sham ACE in terms of reduction in body weight, BMI, hip circumference, waist circumference and BFP. It demonstrates that verum ACE is effective for the treatment of obesity in adults. Regarding safety, no significant difference was identified

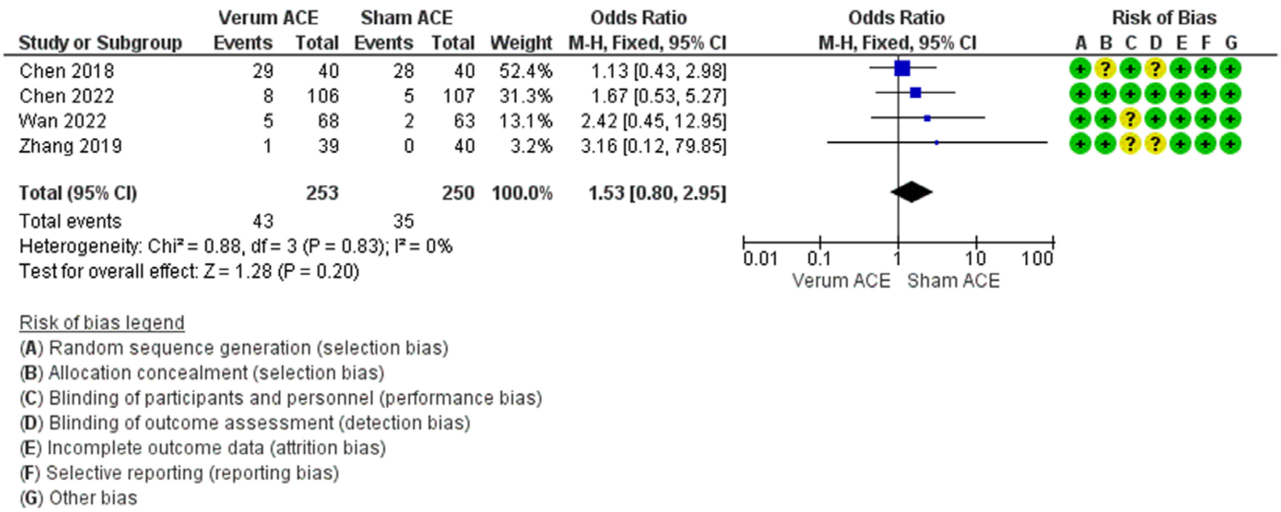

Figure 8 . Meta-analysis of occurrence rate of adverse events.

in ORAE between verum ACE and sham ACE, suggesting that verum ACE has a safety profile in treating adults with obesity.

This study had its own merits. This study comprehensively and systematically investigated the effectiveness and safety of verum ACE compared with sham ACE based on all RCTs, excluding quasi-RCTs. This study also had several limitations. First, the total number of eligible trials was small, which may have affected current findings. Second, most RCTs had quite small sample sizes, which may have restricted their effectiveness and safety. Third, there is some substantial heterogeneity across some meta-analyses, which may not have sufficiently verified the effectiveness and safety of versus ACE in comparison with sham ACE. Fourth, the safety of ACE should be further assessed because of the insufficient data in primary studies. Finally, all included RCTs had relatively short ACE duration and follow-up visits; thus future studies should include long-term follow-ups to further assess its effectiveness and safety.

5. Conclusion

The results of this study demonstrated that verum ACE is effective in the management of adults with obesity. Future studies involving higher-quality RCTs are required to warrant the current findings.

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