Journal of Pain Research

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ORIGINAL RESEARCH

The Effectiveness and Safety of Acupuncture for Mammary Hyperplasia: A Systematic Review and Meta-Analysis

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Objective: This study aims to systematically evaluate the effectiveness and safety of acupuncture in treating mammary hyperplasia.

Methods: A comprehensive search was conducted in various databases, including PubMed, Web of Science, Cochrane Library, Embase, SinoMed, China National Knowledge Infrastructure (CNKI), Wanfang, and VIP Database, from their inception until July 2023. Only randomized controlled trials (RCTs) researching the use of acupuncture for mammary hyperplasia were included. Quality assessment and data analysis were performed using RevMan 5.3 software.

Results: Eight RCTs, comprising 573 patients, were included in this analysis. The meta-analysis revealed that in the acupuncture group, the experimental group was better than the control group in improving breast pain, breast lump extent, and the texture of breast lump (P=0.0007, I^2=61%; P=0.02, I^2=0%; P=0.0002, I^2=0%). We found that both could be improved, but after statistical analysis, there was no significant advantage in the acupuncture group compared with the patent Chinese medicine group (p>0.05).

Conclusion: Acupuncture appears to be an effective and safe treatment for mammary hyperplasia, providing pain relief and reducing mass volume, texture, and extent. However, the insufficient quality of the available evidence indicates the need for further methodologically rigorous and convincingly designed studies to determine the efficacy and safety of acupuncture in the treatment of breast hyperplasia.

Keywords: acupuncture, mammary hyperplasia, efficacy, meta-analysis, review, safety

Introduction

Mammary hyperplasia, a condition marked by the proliferation of both epithelial and fibrous breast tissue alongside an imperfect degeneration of the ducts and lobules due to endocrine disorders, is increasingly becoming a significant health concern.[1] Approximately 25.5% of women of reproductive age reportedly suffer from mammary hyperplasia, with the age of onset declining, making it the most prevalent breast disease.[2,3] The pathogenesis of mammary hyperplasia is similar to that of breast cancer, with cancer rates fluctuating between 1.25% to 50%.[4,5] It primarily manifests as unilateral or bilateral breast pain and lumps, often associated with the menstrual cycle and emotional state. For treatment, pharmacological ingredients such as Oenothera biennis oil are regularly utilized.[6] In cases of suspicious nodules, puncture or surgical excision is employed to get tissues for pathological examination to prevent misdiagnosis and missed diagnosis.[7] While drug therapy has proven effective, it also presents drawbacks, such as gastrointestinal side effects, including abdominal pain and indigestion.[8] In contrast, acupuncture, a traditional medicine treatment modality, has emerged as a widely accepted alternative and complementary therapy in clinical practice.[9] Thus, the aim of this review is to systematically analyze the existing literature and perform a meta-analysis to assess the efficacy and safety of acupuncture as a treatment for mammary hyperplasia.

Received: 28 January 2024
Accepted: 8 May 2024
Published: 17 May 2024

Methods

Protocol Registration

This review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for performing and reporting systematic reviews and meta-analyses (Supplementary Table 1).

Search and Screening Strategy

Relevant studies were sourced from eight databases: PubMed, Web of Science, Cochrane Library, Embase, SinoMed, China National Knowledge Infrastructure (CNKI), Wanfang database, and VIP Database. The search focused on randomized controlled clinical trials investigating the use of acupuncture in the treatment of mammary hyperplasia. The search period extended from each database's inception until October 2023. The keywords used included ("Acupuncture" OR "Needling" OR "Electroacupuncture") AND ("Mastalgia" OR "Mammary hyperplasia" OR "Breast hyperplasia" OR "Hyperplasia of mammary glands" OR "Fibrocystic changes of the breast" OR "Mastopathy" OR "Fibroadenosis" OR "Benign mammary dysplasia" OR "Sclerosing adenosis") AND ("Randomized controlled trial", and "RCT"). There were no restrictions on language, population, or country of publication. The specific search protocol was modelled on PubMed's search format (Supplementary Table 2). For the remaining seven databases, according to their unique search strategy, we searched the literature separately.

Study Selection

The study was considered eligible if it satisfied all of the subsequent inclusion criteria: (1) Study Design: A randomized controlled trial wherein the intervention group only received acupuncture, and the control group received any of the following: acupuncture, medicinal treatment, sham acupuncture, placebo therapy, or no treatment. (2) Participants: Patients with a definitive diagnosis of breast hyperplasia. (3) Intervention: Either manual acupuncture or electroacupuncture stimulation of acupoints. (4) Primary Efficacy Outcome: Score of breast pain. (5) Secondary Efficacy Outcome: Score of breast lump, which could include factors such as breast lump size, hardness (texture), and extent (As for the secondary efficacy measures, one of the above is sufficient). Adverse events were also recorded.

The exclusion criteria were: (1) Protocols, clinical trial registrations, announcements, and animal experimental studies. (2) Alternative forms of acupuncture, such as laser acupuncture, floating acupuncture, and needle knife.

Two evaluators (Jifeng Li and Dongxiao Zhang) independently screened all article titles and abstracts. The first 100 recorded decisions were compared to check for methodological consistency, which resulted in seven different decisions but a 93% agreement rate. Due to the low barrier of entry to the next stage, the remaining titles and abstracts were screened by a single examiner (Jifeng Li). Both reviewers performed full-text screening of potentially relevant records. Data extraction was carried out by the first reviewer (Jifeng Li), and the accuracy was verified by the second reviewer (Dongxiao Zhang). Any disagreements were resolved through discussions with a third reviewer.

Data Extraction, Quality and Validity Assessment

Two reviewers independently examined studies that met the inclusion criteria, each calculating a modified Jadad score based on four distinct criteria: the description of randomization sequence, concealment of randomization, blinding, and withdrawals. The possible scores ranged from 0 to 7.[10,11] Given the inherent difficulty of blinding patients and acupuncturists, the implementation of sham acupuncture in the control group was considered to effectively blind patients. If the outcome evaluator was blinded, the blinding criterion was awarded one point. The two reviewers reached a consensus on all the modified Jadad scores. Beyond the data related to the Jadad score, other data, including sample size, interventions for both test and control groups, types of study and trial design, primary and secondary efficacy outcomes, adverse events, and others, were extracted from the selected papers. This data was then presented graphically within this review. For those who cannot get the complete data research, we make every effort to via Email to follow up with the original author.

Data Analysis

The data analysis was conducted utilizing Review Manager statistical software (RevMan version 5.4). The synthesis of data was carried out in accordance with primary and secondary efficacy outcomes. Metrics such as breast pain scores, lump sizes, extents, and texture scores were also evaluated.

The extraction of data varied based on whether the variables were continuous or dichotomous. For continuous variables, the mean (MD) and standard deviation (SD) from the RCT groups were extracted, along with the total sample size. If the results were reported in the literature as standard errors (SEx), these were converted to SD. When necessary, MD and SD were estimated from the charts. In cases where data were expressed as median (M) and quartile spacing (Q), these were converted to MD and SD as required.[12] For dichotomous variables, the number of positive cases and the total sample size for each group were extracted. The effect was assessed by MD and a 95% confidence interval (CI) or odds ratio (OR), depending on whether the data was continuous or dichotomous, respectively.

For assessing heterogeneity, we used the following classification system: 0–30% indicated no significant heterogeneity; 30–50% denoted moderate heterogeneity; 50–90% signified substantial heterogeneity; and 90–100% represented extreme heterogeneity.[13] A fixed-effects model was employed if the included Randomized Controlled Trials (RCTs) were homogeneous. Conversely, in instances of substantial heterogeneity (I2 > 50%), a random-effects model was utilized. Given that different treatment methods can influence the outcome of mammary hyperplasia, a comprehensive analysis of the therapeutic effects of various treatment methods was undertaken. Treatments were categorized into acupuncture vs acupuncture (employing different acupoints) and acupuncture vs Chinese patent medicines based on the treatment modality. Furthermore, a safety evaluation was conducted using a chi-square test analysis by extracting the total sample size and the number of adverse events with the help of SPSS 26.0 software.

Results

Study Description

Initially, we identified a total of 379 publications from eight databases, comprising 371 from Chinese databases and 8 from English databases. By thoroughly screening the titles and abstracts, we excluded those that did not meet the predetermined inclusion criteria. For instance, we removed protocols, clinical trial registrations, animal experiments, and studies focusing on other acupuncture modalities like laser acupuncture, floating acupuncture, or acupuncture knife, among others. By reading the full articles, we further excluded 13 articles with a modified Jadad score below 5. Eventually, eight articles satisfied all the specified criteria and were included in our study (Figure 1).

In regard to ethical considerations, ethical approval was explicitly described in two trials,[14,15] whereas six trials did not provide this information.[16–21] Concerning sample size estimation, it was described in three studies,[15–17] whereas it was not mentioned in five trials.[14,15,18–21] When considering the control group setting, two studies[14,18] employed a Chinese patent medicine as a control, one trial utilized a sham acupuncture control, specifically minimal penetration sham acupuncture,[15] and the remaining five trials employed acupuncture as controls.[16,17,19–21]In terms of study centers, seven studies were performed in single-center settings,[14–16,18–21] while one study was conducted in two centers.[17] All eight trials utilized parallel control designs in their trial design.[14–21] For acupoint selection in the trial groups, three trials based their selection on Chinese medical theory;[16,20,21] one trial utilized both Chinese medical theory and statistical analysis for acupoint selection;[18] two studies relied on standard acupuncture textbooks,[14,19] and the last two studies based their acupoint selection on the practitioner's experience.[17,19] Regarding the type of acupuncture applied in the test group, manual acupuncture was utilized in three trials,[15,19,21] while electroacupuncture was employed in five studies.[14,16–18,20] All trials provided detailed descriptions of the specific acupuncture operations used in the trial group methods.[14–21] In relation to adverse events, these were reported in four studies,[15,16,20,21] while the remaining four did not provide this information.[14,17–19] Lastly, concerning post-treatment follow-up, three studies included follow-ups: two after one month[14,21] and one after three months.[15] However, the other five studies did not include follow-ups[16–20] (Table 1).

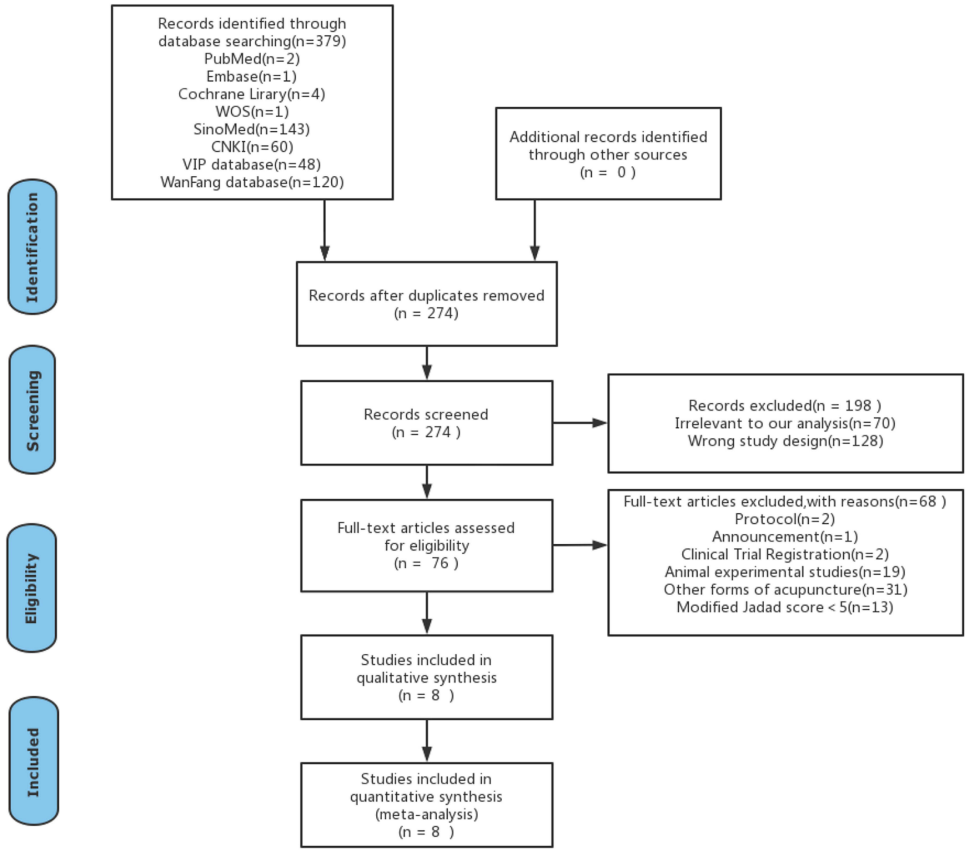

Figure 1 Flowchart of study screening.

Methodological Quality

Four studies achieved Jadad scores of 5,[14,15,17,21] while four additional studies achieved scores of 6[16,18–20] (Table 2). The methodological quality of these trials varied from moderate to high. In terms of randomization: All eight studies delineated the generation methods for random sequences. Specifically, four of these studies utilized random number tables,[18–21] while the remaining four studies employed computer-generated random numbers.[14–17] Regarding allocation concealment: Seven studies implemented the envelope method;[14–18,20,21] however, one study merely indicated the use of random numbers without specifying the concealment approach, thus earning a score of one.[19] As for blinding procedures: Four studies elaborated on their blinding strategies.[16,18–20] Out of these, two trials blinded patients,[16,20] one trial blinded outcome evaluators,[18] and one trial blinded both patients and outcome evaluators.[19] Unfortunately, the remaining four trials did not provide details on their blinding procedures.[14,15,17,21] In the context of dropout and excluded aspects: All eight trials provided detailed descriptions of patients who either dropped out or were lost to follow-up.[14–21]

Outcomes

Trial Group Acupuncture Vs Control Group Acupuncture

A meta-analysis was conducted on four indicators: breast pain, lump size, lump extent, and lump texture. Both the trial and control groups employed acupuncture therapy, but the selection of acupoints varied. Six studies reported breast pain scores,[15–17,19–21] while four studies investigated lump, extent, and texture.[16,17,20,21] Among the six studies that compared breast pain scores,[15–17,19–21] one study utilized a comparison with sham acupuncture. We classified this control group as an acupuncture group due to its similar acupuncture methodology to the trial group, except the needle depth was 0.1 inch, and the acupoints were 0.1 inch beside the accurate points.

In our analysis, the efficacy of acupuncture treatment was significantly higher in the trial groups as compared to the control groups in alleviating breast pain (P=0.0007, I^2=61%, Figure 2). Still, there was a substantial degree of

Table 1 Basic Information on the Randomized Controlled Trials of Acupuncture in Patients with Mammary Hyperplasia

Literature(Ref)	EAP	SSE	TG(FOI)	CG(FOI)	RCTY	TDF	Principle of TG Point Selection	EG Specific Needling Operation	Adverse Events	Follow-up (time)
Zhang DX 2022[14]	Passed	No	EA	CPM	Single	PC	Medical textbooks	Description	No	Yes (one month)
Liu GQ 2016[16]	Not described	Yes	EA	EA	Single	PC	Chinese medicine Theory	Description	Yes	No
Zhou TX 2018[17]	Not described	Yes	EA+HA	EA	Double	PC	Clinical experience	Description	No	No
Xu LX 2017[18]	Not described	No	EA	CPM	Single	PC	Summary of Chinese medicine theory and data statistics	Description	No	No
Li PF 2009[19]	Not described	No	MA	MA	Single	PC	Clinical experience	Description	No	No
Guo X 2018[20]	Not described	No	EA	EA	Single	PC	Chinese medicine theory	Description	Yes	No
Sun MY 2018[15]	Passed	Yes	MA	SAT	Single	PC	Medical textbooks	Description	Yes	Yes (three months)
Luo JJ 2016[21]	Not described	No	MA	MA	Single	PC	Theory of Chinese Medicine	Description	Yes	Yes (one month)

Abbreviations: EAP, Ethical Approval; SSE, Sample Size Estimation; TG, Trial Group; CG, Control Group; FOI, Form(s) of intervention; RCTY, Research Center Type; TDF, Trial Design Form; EA, Electroacupuncture; HA:Head Acupuncture; MA, Manual Acupuncture; CPM, Chinese Patent Medicine; SAT, Sham Acupuncture Treatment; PC, Parallel Comparison.

Table 2 Jadad Score of Randomized Controlled Trials of Acupuncture in Mammary Hyperplasia Patients

Literature (Ref.)	Random Sequence	Concealment	Blind Method	Dropout and Exclusion	Total Score
Zhang DX 2022[14]	2	2	0	1	5
Liu GQ 2016[16]	2	2	1	1	6
Zhou TX 2018[17]	2	2	0	1	5
Xu LX 2017[18]	2	2	1	1	6
Li PF 2009[19]	2	1	2	1	6
Guo X 2018[20]	2	2	1	1	6

Notes: Random sequence, concealment, and blind scores all ranged from 0–2; Dropout and exclusion scores ranged from 0–1; The maximum total score of the four items was 7.

heterogeneity in the comparison of the two acupuncture groups. In terms of lump size reduction,[16,17,20,21] both acupuncture groups demonstrated a decrease; however, there was no significant difference between the two groups (P=0.07, I^2=1%, Figure 3). With respect to the lump extent score,[16,17,20,21] the trial groups' acupuncture showed a more significant effect in reducing the extent of breast lumps than that of the control groups (P=0.02, I^2=0%, Figure 4). In terms of lump texture,[16,17,20,21] the results indicated that the trial groups' acupuncture treatment was more successful in softening the lumps compared to the control groups (P=0.0002, I^2=0%, Figure 5).

Acupuncture Vs Chinese Patent Medicine

In addition to the six papers mentioned above, two other studies utilized acupuncture in trial groups and Chinese patent medicines in control groups.[14,18] A meta-analysis was performed on each of the four aforementioned indicators. As for the breast pain score,[14,18] the effectiveness of acupuncture did not significantly surpass that of Chinese patent medicine in alleviating breast pain (P=0.53, I^2=76%, Figure 6). Similarly, with respect to the lump size score,[14,18] acupuncture did not present a significant advantage over Chinese patent medicine either (P=0.18, I^2=43%, Figure 7). In the domain of the lump extent score,[14,18] acupuncture did not prove to be superior to Chinese patent medicine (P=0.60, I^2=78%, Figure 8). Lastly, considering the lump texture score,[14,18] both acupuncture and Chinese patent medicine exhibited similar effectiveness, with no statistically significant disparity between the two groups (P=0.46, I^2=76%, Figure 9).

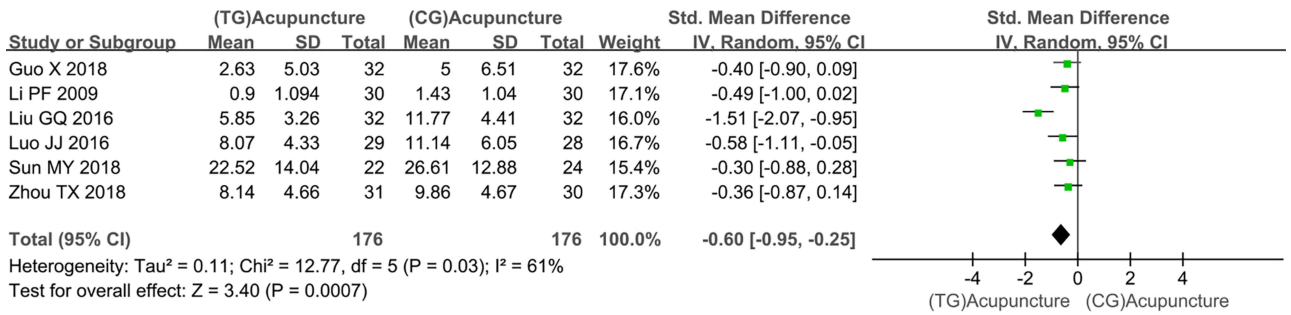

Figure 2 Forest plot of breast pain score for trial group acupuncture vs control group acupuncture.

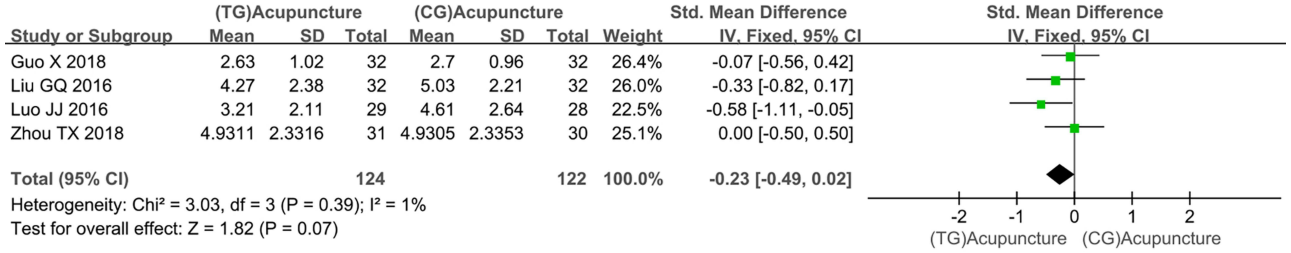

Figure 3 Forest plot of lump size score for trial group acupuncture vs control group acupuncture.

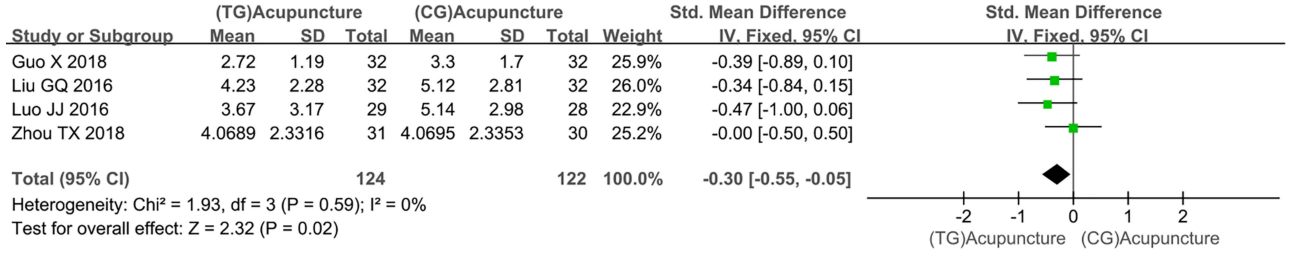

Figure 4 Forest plot of lump extent score for trial group acupuncture vs control group acupuncture.

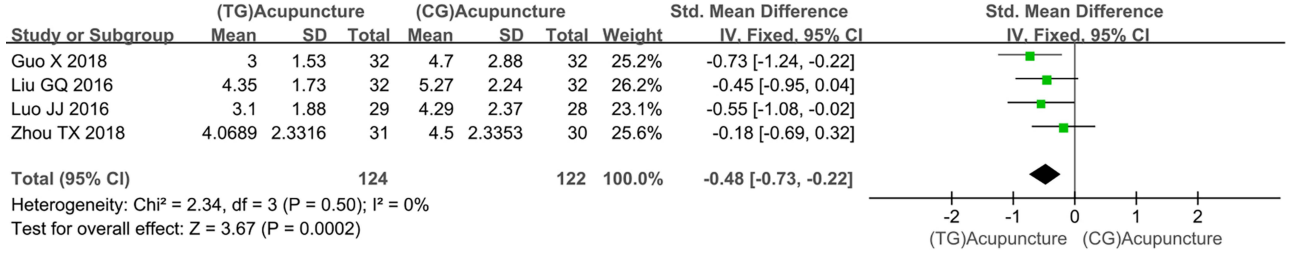

Figure 5 Forest plot of lump texture for trial group acupuncture vs control group acupuncture.

In the group administered with Chinese patent medicine, no adverse events were reported, resulting in an incidence rate of 0%. Conversely, five cases of adverse events were observed in the acupuncture groups, yielding an incidence rate of 1.106% (Table 3). The adverse events recorded in the acupuncture groups were as follows: one patient experienced dizziness, two patients had needle stagnation during the acupuncture procedure, one patient reported bleeding subsequent to the removal of the needle, and another patient developed a subcutaneous hematoma (Table 4).

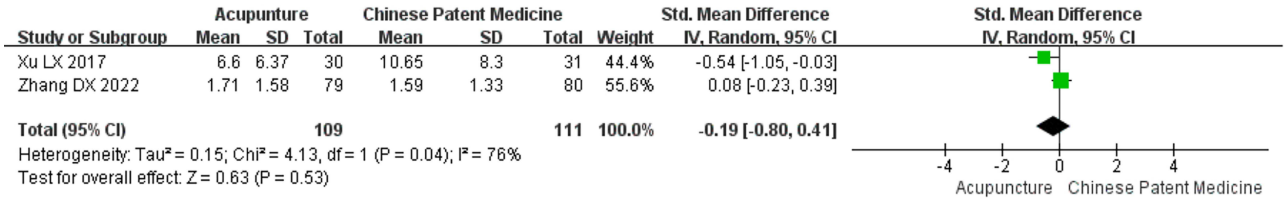

Figure 6 Forest plot of breast pain scores for acupuncture vs Chinese patent medicine.

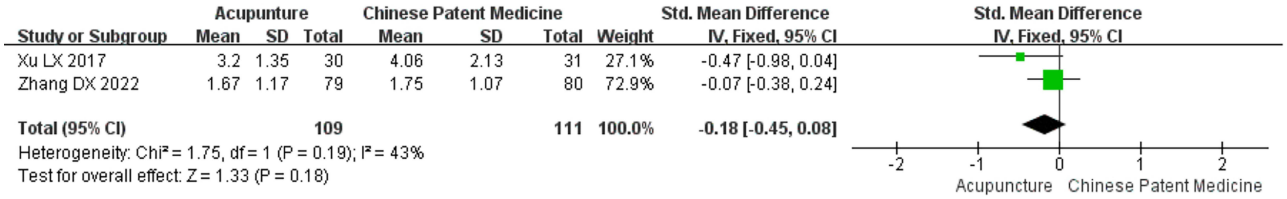

Figure 7 Forest plot of lump size scores for acupuncture vs Chinese patent medicine.

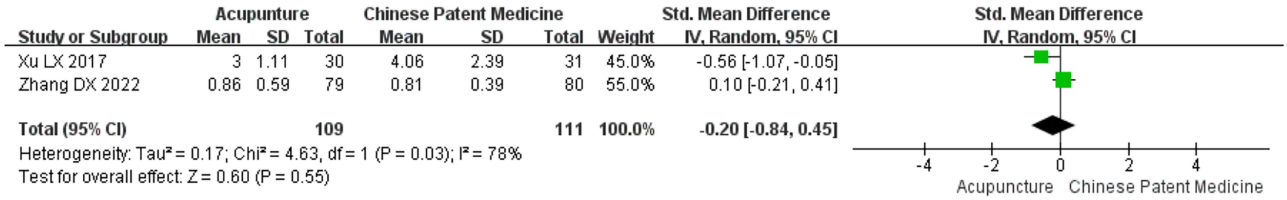

Figure 8 Forest plot of lump extent scores for acupuncture vs Chinese patent medicine.

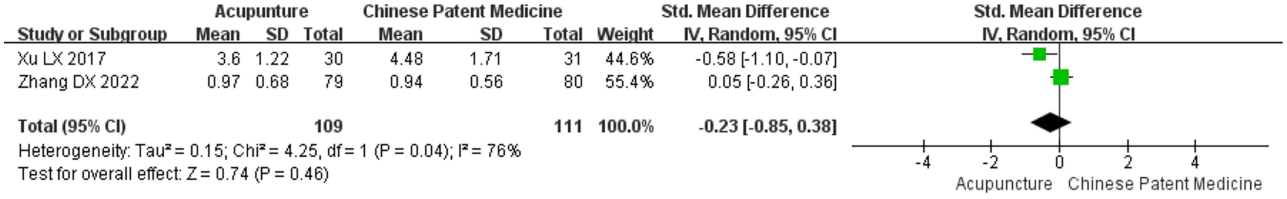

Figure 9 Forest plot of lump texture scores for acupuncture vs Chinese patent medicine.

Discussion

This systematic review scrutinizes the efficacy of acupuncture in relieving mammary hyperplasia. A critical evaluation was carried out on eight randomized controlled trials (RCTs) of relatively high quality. The findings from these trials have provided substantial evidence supporting the effectiveness and safety of acupuncture as a treatment modality for mammary hyperplasia. These results prompt an analysis to determine whether acupuncture is indeed the optimal treatment choice for this condition.

Table 3 Security Analysis

Group	N	Number of Adverse Events	Incidence (%)	Cardinality	P
Acupuncture Chinese Medicine	452 121	5 0	1.106 0	1.350	0.589 0

Table 4 Specific Adverse Events in the Acupuncture Groups

Literature (Year)(Ref.)	Dizziness During Acupuncture	Stagger Needle	Bleeding from a Needle Puncture	Subcutaneous Hematoma
Liu GQ 2016[13]	1	0	0	0
Sun MY 2018[19]	0	0	1	0
Luo JJ 2016[20]	0	2	0	1

Despite initially identifying 379 RCT articles examining acupuncture as a treatment for mammary hyperplasia, only eight studies with Jadad scores of 5 or higher were ultimately included after rigorous screening. Although the quality of the literature in this field appears to be low in general, the studies included in this review are of moderate to high quality and provide persuasive arguments. Thus, the overall quality of evidence provided in this review is reliable despite the limited number of included studies. In regard to the reported methodologies of these eight studies, it was noted that two studies implemented blinding for both patients and outcome evaluators,[19,20] one study blinded patients,[16] and one study blinded outcome evaluators,[18] while the remaining four trials[14,15,17,21] did not employ any blinding method. Allocation concealment was reported in seven trials,[14–18,20,21] with one trial omitting this detail. Insufficient blinding and allocation concealment can potentially lead to exaggerated treatment effects, thereby compromising the reliability of the study.[22,23] This might explain why none of the trials achieved the maximum Jadad score of 7. Sample size estimation, which enables a minimum number of observed cases based on a scientifically reasonable evaluation, was reported in three out of the eight studies.[15–17] Appropriate sample size is crucial as it enhances the validity of the test, ensures the reliability of the results and conclusions, and accurately reflects the overall effect of the study.[24] Only two trials reported receiving ethical approval.[14,15] Ethical approval guarantees the protection and rights of the subjects, acts as a form of disciplinary guideline for the researchers, and enhances adherence to the study protocol.

Furthermore, it ensures the scientific and ethical quality of clinical research.[25] Three studies conducted post-treatment follow-ups.[14,15,21] Post-treatment follow-up is essential to evaluate the long-term effectiveness of the therapy. Although most drugs (Chinese or Western) can alleviate the pain of mammary hyperplasia in the short term, the recurrence rate remains high. As such, acupuncture therapy has shown superiority over drug therapy in both short-term and long-term efficacy. The long-term effectiveness of acupuncture, as evidenced by the follow-up results, can be a deciding factor in determining whether acupuncture is the best treatment for mammary hyperplasia.

On the topic of acupoint selection, all eight studies offer detailed descriptions of the principles guiding the selection of points.[14–21] These principles draw from various sources, including Chinese medical theory,[16,20,21] a combination of Chinese medical theory and statistical data,[18] Chinese medical textbooks,[14,21] and personal clinical experience.[17,19] The rationale behind this approach is fourfold: 1. Acupuncture, being rooted in Chinese medicine and operating on the principle of meridians, naturally lends itself to acupoint selection based on Chinese medical theory. 2. Chinese medical textbooks, encapsulating the essence of millennia-old Chinese medical texts and distilled from practice, provide a reliable reference for the most effective acupoints for specific conditions.[26] 3. The integration of traditional experience and intelligent technology presents a novel approach. By inputting all acupoints with reported therapeutic effects into software, optimal treatment acupoints for conditions like mammary hyperplasia can be computed. These derived acupoints are then cross-referenced with traditional Chinese medical theory to formulate a range of optional points. 4. Personal clinical experience, founded on theoretical knowledge and years of clinical practice, also contributes to the selection of acupoints. This experience gives rise to treatment plans that not only align with the principles of traditional Chinese medicine but also bear the unique characteristics of the individual practitioner. In light of the aforementioned, the selection of acupuncture points in these studies can be deemed reasonable and well-founded.

The sensation experienced post-needling, referred to as "De-Qi", was reported in six trials,[14,15,17–20] while two other trials[16,21] omitted this detail. "De-Qi" denotes a specific acupuncture experience encompassing sensations such as soreness, numbness, swelling, and pain. The recognition of this needling sensation dates back over 2000 years. Contemporary literature[27–29] suggests that the clinical efficacy of acupuncture is enhanced when this sensation is achieved, compared to when it is not. Consequently, the obtaining of this sensation is a critical factor in the therapeutic

effect of acupuncture. A majority of acupuncture practitioners concur that patients who experience this sensation often yield better therapeutic outcomes compared to those who do not.

For the effectiveness, the meta-analysis results indicate that the trial group, which received acupuncture, had significantly better outcomes than the control group in terms of pain relief, lump size reduction, and lump texture softening (all P< 0.05). However, when comparing acupuncture therapy with Chinese patent medicine for the treatment of mammary hyperplasia in this review, there was no significant difference in the two groups (P>0.05). Both methods were found to have therapeutic effects on breast pain, lump size, extent, and texture.

What are the similarities and differences between the trial and control acupuncture groups in our study? We have carefully read these five articles[16,17,19–21] and come to the following conclusions: Similarities: they all use manual acupuncture, and the acupuncture points are accurate and the technique is standard and the same, so they all belong to the real acupuncture technology;[16,17,19–21] Differences: The difference between them is the difference of some acupuncture points. Specifically, in the four studies, the main acupuncture points of the experimental group and the control group were the same, and the key was that the experimental group had more points than the control group.[16,17,20,21] In two studies, the matching points were based on syndrome differentiation.[16,17] In the other two studies, acupoints were selected according to the menstrual cycle.[20,21] In another study, the acupoints selected by the experimental group were different from those selected by the control group, and the acupoints of the experimental group were empirical points summed up by years of clinical experience, while the acupoints of the control group were commonly used in clinical treatment[19] (Table 5).

The potential reasons for acupuncture's effectiveness in relieving symptoms of mammary hyperplasia and why acupuncture in the trial group is superior to acupuncture in the control group are multifaceted: firstly, acupuncture may promote analgesia by impacting analgesic signaling molecules, such as opioid peptides, glutamate and 5-hydroxytryptamine. It can also stimulate mast cells to activate nerve receptors for analgesic purposes.[30–32] Secondly, acupuncture can enhance the nutrition of hyperplastic local tissues and facilitate blood circulation and metabolism, aiding in reducing or even eliminating the mass.[33] Thirdly, as mammary hyperplasia is linked with the menstrual cycle, different acupuncture points are chosen to modulate hormones based on the three distinct phases of the menstrual cycle, namely the follicular

Table 5 Specific Information on Randomized Controlled Trials of Acupuncture in Patients with Mammary Hyperplasia

First Author (Year)(Ref.)	Trial Group (Acupoints)	Control Group (Acupoints or Medicine)	Sample Size (Drop Out)	Key Outcome
Zhang DX 2022[14]	CV17,ST15,ST18,ST40,SP6,LR14	Ruxiankang Capsule	TG:80(1) CG:80	(1) Breast pain score, (2) Breast lump size, extent, and texture score
Liu GQ 2016[16]	ST40,LR3,ST15,ST18,LR14,EX-HN1,GV20,GV29,GV24,GB13	ST40,LR3,ST15,ST18,LR14	TG:33(1) CG:33(1)	(1) Breast pain score, (2) Breast lump size, extent, and texture score
Zhou TX 2018[17]	MS4,LR14,GB21,CV17,SP6,SP9,ST36,LR3,PC6	LR14,GB21,CV17,SP6, SP9,ST36,LR3,PC6	TG:35(4) CG:35(5)	(1) Breast pain score, (2) Breast lump size, extent, and texture score
Xu LX 2017[18]	CV17,ST15,ST18,ST36,LR3,SP6	XiaoYao pill	TG:33(3) CG:33(2)	(1) Breast pain score, (2) Breast lump size, extent, and texture score
Li PF 2009[19]	Bizhong	ST18	TG30 CG:30	(1) Breast pain score
Guo X 2018[20]	Main Acupuncture Points:ST18,CV17,ST36,LR3,SP6 Selection of acupuncture points according to the menstrual cycle: Menstrual period:CV3, SP8,SP10; Follicular phase:CV4,BL23,KI3; Ovulation period: SP8,SP10, EX-CA1; Luteal phase:GV4,CV4,BL23	ST18,CV17,ST36,LR3,SP6	TG:34(2) CG:34(4)	(1) Breast pain score, (2) Breast lump size, extent, and texture score
Sun MY 2018[15]	CV17,ST15,ST18,ST36,LR14	CV17,ST15,ST18,ST36, LR14.Both beside 1 inch to the right points	TG:22(3) CG:24(4)	(1) Breast pain score
Luo JJ 2016[21]	Main Acupuncture Points:CV17,ST15,ST18,ST36,LR1 Selection of acupuncture points according to the menstrual cycle: Pre-menstrual:LI4,LR3,ST40; During menstruation: KI3,GV4,CV4; Post-menstrual:SP6,KI3,SP10	CV17,ST15,ST18,ST36, LR14	TG:30(1) CG:30(2)	(1) Breast pain score, (2) Breast lump size, extent, and texture score

Abbreviations: TG, Trial group; CG, Control group; CV3, Zhongji; CV4, Guanyuan; CV17, Danzhong; ST15, Wuyi; ST18, Rugen; ST36, Zusanli; ST40, Fenglong;SP6, Sanyinjiao; SP8, Diji; SP9, Yinlinnngquan; SP10, Xuehai; LR1, Dadun; LR3, Taichong; LR14, Qimen; LI4, Dazhong; GV20, Baihui; GV24, Shenting; GV29, Yintang; GB13, Benshen; GB21, Jianjing;PC6, Neiguan; BL23, Shenshu; GV4, Mingmen; MS4, Epangsanxian; KI3, Taixi; EX-HN1, Sishencong; EX-CA1, Zigong.

phase, ovulatory phase, and luteal phase.[34,35] Fourthly, the occurrence of mammary hyperplasia is associated with stress, anxiety, and emotional factors.[36,37] Long-term exposure to adverse emotions such as tension and anxiety can easily lead to sympathetic nerve excitation and inhibit the hypothalamic-pituitary-ovarian axis (HPO axis), resulting in an increase or decrease in the secretion of estrogen, progesterone, prolactin and other hormones.[38,39] Addtionally, the mammary gland is one of the hormone target organs, which is regulated by a variety of hormones (such as estrogen, progesterone, prolactin, etc.), and the imbalance of various hormones is easy to lead to the proliferation of mammary cells, resulting in the formation of mammary hyperplasia.[40,41] Finally, studies have shown that acupuncture can regulate hormone levels in patients or mice with mammary gland hyperplasia, thus achieving the purpose of treating mammary gland hyperplasia.[42,43] Therefore, acupuncture can improve the symptoms of breast hyperplasia. Fifthly, from the perspective of Traditional Chinese Medicine (TCM), mammary hyperplasia is categorized into different syndromes. Beyond identifying the primary acupoints for the condition, the selection of acupoints is further tailored based on the specific syndrome types. For instance, for Liver Qi Stagnation syndrome, the corresponding acupoints are Gan shu and Nei guan; for Chong and Ren Disharmony syndrome, the acupoints selected include Guan yuan and Shen shu. Various studies have demonstrated that accurate treatment based on syndrome differentiation significantly enhances the efficacy of acupuncture and moxibustion.[44–46] Therefore, customizing the selection of acupuncture points according to the different types of mammary hyperplasia can improve the treatment effectiveness through strategic point selection. Sixthly, Empirical effect points are points selected by clinicians according to their own or others' clinical practice experience and have obvious curative effects on some diseases. It is come out, after many years of clinical practice is a rationality, such as Bi zhong in our study, Rugen.[47]

Based on the above reasons, we understand why acupuncture can improve the mammary hyperplasia, also understand why our group acupuncture is better than that of control group acupuncture.

Regarding the safety of acupuncture, many previous studies have suggested that it is safer than drug therapy.[48–51] Out of the 432 patients who underwent acupuncture in the eight studies, there were only five adverse events, a difference that was not statistically significant compared to the Chinese patent treatment groups (P=0.589). Furthermore, compared to long-term drug therapy, acupuncture caused no severe adverse effects; occasional minor side effects, such as subcutaneous hematoma and needle retention, were less harmful and generally insignificant. Of course, these events remind practitioners of the importance of careful monitoring and appropriate patient care during the application of acupuncture.

In conclusion, the evidence supporting the effectiveness and safety of acupuncture in the treatment of mammary hyperplasia is credible, but the current evidence is insufficient to support acupuncture as the optimal treatment option unequivocally. Generally speaking, the available randomized controlled trials substantiate the effectiveness of acupuncture. However, to conclusively determine whether acupuncture represents the most effective treatment for mammary hyperplasia, further research is needed. This research should encompass large-sample, multicenter studies utilizing rigorous methodologies to ensure the validity and reliability of results.

Funding

This study was supported by Special Project on Traditional Chinese Medicine (TCM) heritage of ancient books, literature, and distinctive techniques (GZY-KJS-2022-035), Young doctor scholar project (2022), Capital research and transformation of clinical diagnosis and treatment technology (Z211100002921020), Research project on education and teaching reform at Capital Medical University (2023JYY326).

Disclosure

The authors declare no conflicts of interest.

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