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Beneficial effects of auricular acupressure on preventing constipation in breast cancer patients undergoing chemotherapy: evidence from systematic review and meta-analysis

Original article

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Abstract: **Objective:** To evaluate the available evidence from randomized controlled trials (RCTs) of auricular acupressure (AA) therapy for preventing constipation in breast cancer patients undergoing chemotherapy.

Methods: The following databases were searched from their inception until August 2017: Ovid Medline, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), and Allied and Alternative Medieine (AMED). We also searched four Chinese databases: Chinese BioMedical Database (CBM), China National Knowledge Infrastructure (CNKI), WANFANG Data, and Chinese VIP Database. Only the RCTs related to the effects of AA therapy on preventing constipation in breast cancer patients undergoing chemotherapy were included in this study. Quantitative syntheses of data from RCTs were conducted using RevMan 5.3 software. Study selection, data extraction, and validation were performed independently by two authors. Cochrane criteria for risk of bias were used to assess the methodological quality of the trials.

Results: Four RCTs met the inclusion criteria, and most were of low methodological quality. Study participants in the AA plus routine care group showed significantly greater improvements in the response rate (risk ratio [RR] = 1.27, 95% confidence interval [CI] [1.14, 1.42], $P < 0.01$) with low heterogeneity ($\chi^2 = 2.31$, $P = 0.31$, $I^2 = 14\%$). In addition, when compared with routine care alone, one RCT suggested favorable statistically significant effects of AA plus routine care on Constipation Assessment Scale (CAS; mean difference [MD] = -5.07, 95% CI [-6.86, -3.28], $P < 0.01$). Furthermore, when compared with routine care alone, one RCT suggested positive statistically significant effects of AA plus routine care on Patient Assessment of Constipation-Quality of Life (PAC-QOL; MD = -1.26, 95% CI [-1.59, -0.93], $P < 0.01$).

Conclusions: Overall, as a potential safety therapy, only weak evidence can support the hypothesis that AA can effectively prevent constipation in breast cancer patients undergoing chemotherapy.

Keywords: *auricular acupressure therapy • constipation • chemotherapy • breast cancer • systematic review • meta-analysis*

1. Introduction

Breast cancer (BC) is ranked as the second most common malignancies in women worldwide.[1] Recently, in population-based studies, the prevalence of BC in Asian regions is reported to be almost 10% and it significantly rapidly increased from 1999 to 2013 at a 5.7% average annual rate.[2]

To date, most BC patients may receive chemotherapy after they have undergone mastectomy. Chemotherapy, as an aggressive treatment, may make a great contribution to extending life for BC patients. However, it is often accompanied by chemotherapy-induced constipation. BC patients who suffered from chemotherapy-induced constipation may impair the normal quality of life and result in the severe psychological symptoms such as anxiety and stress.[3] Moreover, untreated constipation may progress to fecal impaction, intestinal obstruction, and even sepsis.[4] So far, oral and/or rectal

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laxatives may be the first-line choices to manage the chemotherapy-induced constipation. Unfortunately, these laxatives are often associated with some risk of serious adverse events (AEs) involving the electrolyte and mineral imbalances, severe dehydration, and laxative dependence.[5]

As a major integral part of traditional Chinese medicine (TCM), auricular acupressure (AA) is described as a technique that involves Semen vaccariae (*wang bu liu xing*) seeds, Semen raphani (*lai fu*) seeds, Semen sinapis Albae (*bai jie*) seeds, or magnetic pellets with an adhesive tape on certain acupuncture points of ears.[6] Based on meridian theory in China, the ear is associated with 12 meridians, and continuously stimulating the ear can improve vital energy (Qi) and remove the blood stasis.[7] Nowadays, numerous systematic reviews have investigated the effects of AA on insomnia[8], postoperative pain[9], and in vitro fertilization[10]. Nevertheless, there was no systematic review specifically focusing on the efficacy of AA for preventing constipation in BC patients undergoing chemotherapy. Therefore, the aim of this study was to update and critically evaluate the evidence from randomized controlled trials (RCTs) that have tested the efficacy and safety of AA in preventing constipation in BC patients undergoing chemotherapy.

2. Methods

The detailed reporting items for this study were based on the (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) PRISMA for systematic review (PRISMA chart; http://www.prismastatement.org).

2.1. Types of studies

Only the RCTs related to the effects of AA for preventing constipation in BC patients undergoing chemotherapy were included in this study. Trials published in the form of dissertations were also selected as eligible studies. No language restrictions were imposed.

2.2. Types of participants

BC patients aged >18 years who experienced constipation after chemotherapy were included. BC patients who suffered from degenerative neurological condition, lesions on both ears, and abdominal operation in the past 6 months were excluded in this study.

2.3. Types of interventions

2.3.1. Control interventions

A sham AA/placebo or routine care as controls was included. The routine care involved appropriate physical and psychological interventions as well as dietary modification.[11] If BC patients undergoing chemotherapy experience constipation, laxative therapies would be administered. Studies were excluded if the control group treatments were not relevant to routine care, or other TCM therapies were used as an adjunct treatment in conjunction with the routine care.

2.3.2. Experimental interventions

Studies were included if AA was used as an adjunct therapy in conjunction with routine care for preventing constipation among BC patients undergoing chemotherapy. In addition, we excluded studies in which other TCM therapies were utilized as an adjunct treatment in conjunction with the routine care.

2.4. Types of outcome measures

2.4.1. Primary outcomes

(1) Response rate: Bristol Stool Form (BSF) was an internationally used validated questionnaire to determine the form of feces. A higher BSF score indicated soft feces. Response rate, also known as improved effectiveness according to the Guiding Principles of Clinical Research on New Drugs criteria (GPCRND constipation), was defined as the number of patients who achieved BSF Scale score over 3 after intervention in our study.

(2) Constipation Assessment Scale (CAS): CAS score was used to assess patients with constipation in the clinical settings.[12] This questionnaire included eight items. For each item, we had three possible response options: no constipation, some problem, and severe problem. The equivalent scores were 0, 1, and 2, respectively. The total CAS score ranged from 0 to 16, and higher scores can indicate higher degrees of constipation.

2.4.2. Secondary outcomes

(1) Patient Assessment of Constipation-Quality of Life (PAC-QOL): It was a valid and reliable measurement containing 28 items in four dimensions (physical discomfort, four items; worries and concerns, 11 items; psychosocial discomfort, eight items; and satisfaction, eight items). Each item was rated using a 5-point Likert scale from 0 (not at all) to 4 (extremely). Higher score indicated a more severe effect of constipation.[13]

(2) AEs: The incidence and severity of AEs from AA, the proportion of patients requiring discontinuation of AA.

2.5. Data sources and search methods

The following electronic databases were searched from their inception to the current date: Ovid Medline, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), and AMED. We also searched four Chinese databases: Chinese BioMedical Database (CBM), China National Knowledge Infrastructure (CNKI), Wan-Fang Data, and Chinese VIP Database. Experienced researchers helped the study team to develop a search strategy to identify the relevant articles. The Ovid Medline search strategy can be seen in "Online Supplementary A."

2.6. Study selection

The results of the searches were exported to the Endnote referencing software, and duplicates were removed. Studies were selected by two independent reviewers (Zheng and Yan). In most cases, disagreements were resolved by discussion between the two reviewers. If disagreement remained after discussion, a third reviewer (Xu) was consulted before taking the final decision on the disagreements. A flowchart depicting the trial selection process was shown in the PRISMA flow diagram.

2.7. Data extraction and quality assessment

The complete text of each included article was read by two independent reviewers (Zheng and Yan) who extracted relevant data and conducted quality assessment of the RCTs based on a data extraction form (Excel). The following data were extracted from the original articles: (1) author, year, and country; (2) sample size; (3) experimental interventions (duration of treatment, auricular acupuncture points choosing); (4) control interventions (routine care interventions, types of laxatives, dose, methods of administration, and the duration of treatment); (5) follow-up; (6) main outcomes; (7) AEs. In addition, when reported data are insufficient, we would try our best to retrieve the missing information from the corresponding authors. The risk of bias was assessed using the "Risk of bias" tool from the Cochrane Handbook V.5.1.0, which included random sequence generation, allocation concealment, blinding of the participants and personnel, blinding of the outcome assessments, incomplete outcome data, selective reporting, and other sources of bias.[14] For the assessment of results, the study bias was classified as either "unclear," "low risk," or "high risk." Disagreements were resolved by discussion between the two reviewers. If consensus was not reached, the third reviewer (Xu) was consulted for a final decision.

2.8. Data collection and synthesis

In our study, meta-analysis was performed using software RevMan 5.3 (Review Manager [RevMan; Computer program], Version 5.3, Copenhagen: The Nordic Cochrane Center, the Cochrane Collaboration, 2014). For dichotomous data, we presented results as risk ratio (RR) with 95% confidence intervals (CIs). For continuous data, mean difference (MD) was included in the meta-analysis. If outcome variables were measured on different scales, standard MD (SMD) analysis with 95% CIs was included in the meta-analysis. In each meta-analysis, the χ^2 and I^2 tests were used to evaluate statistical heterogeneity.[15] Given $I^2 < 50\%$ and $P > 0.1$, the studies were considered to be homogeneous, and a fixed-effects model was applied. On the other hand, if $I^2 \geq 50\%$ and $P < 0.1$, the trials were considered to be heterogeneous, and a random-effects model based on Mantel–Haenszel (MH) or inverse variance (IV) statistical approach was selected.[15]

2.9. Sensitivity analysis

If the test for heterogeneity *P*-value was <0.1 after performing the subgroup analysis, the sensitivity analysis was conducted to evaluate the robustness of our results. The meta-analysis was repeated after omitting the low-quality studies. Moreover, we also assessed whether the statistical model (random-effects vs fixed-effects model) will affect the current results.

2.10. Assessment of reporting biases

If a sufficient number of studies were available (at least 10 studies), we attempted to assess publication bias using a funnel plot.[16]

3. Results

3.1. Trial flow and study characteristics

The literature search of databases generated 180 citations. After excluding the duplicate manuscripts, titles, and abstract, we analyzed 30 full-text articles. Of these 30 articles, 26 were excluded as they did not satisfy the inclusion criteria, leaving four eligible RCTs[17-20] involving 322 participants for the systematic review (Figure 1). Four included RCTs originated in China and had relatively small sample size. All included trials compared a co-intervention of AA and routine care with a control

of routine care alone. Moreover, the duration and frequency of the interventions was mostly 25 minutes and three times/day, respectively. The acupuncture points of AA varied according to TCM theory and the view of Nogier's theory for all included RCTs. Details regarding the four eligible RCTs[17-20] included in our meta-analysis are summarized in Table 1.

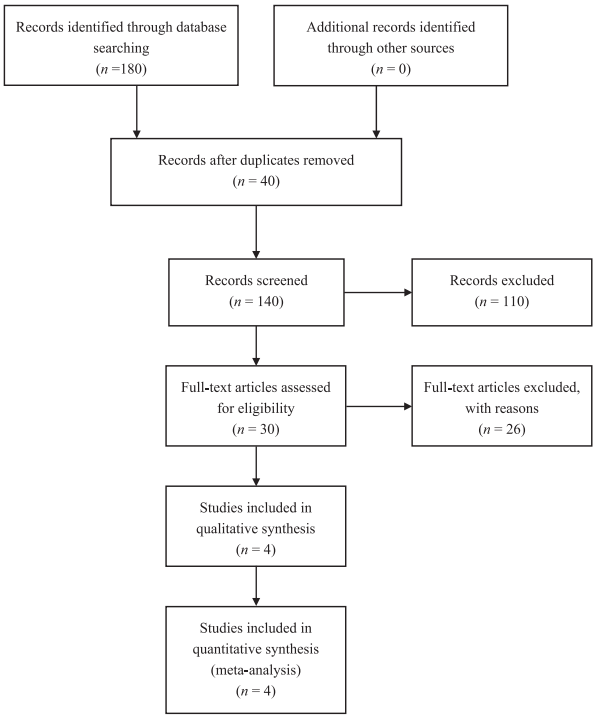

Figure 1. Flowchart of the trial selection process.

3.2. Risk of bias

The Cochrane risk of bias is shown in Figures 2 and 3. One of the included trials[17] reported appropriate sequence generation methods for the randomization, whereas the remaining trials[18-20] did not describe the methods of sequence generation. One of the included trials[17] conducted concealment of allocation by sealed envelopes, while one RCT[20] used inappropriate methods, and the remaining trials[18,19] did not describe the methods of sequence generation. In addition, the authors reported that in addition to one RCT[17], none of the included trials employed patient-blinding methods, whereas the assessor blinding was unclear in three RCTs[18-20]. Of all included RCTs, only one RCT[17] stated the risk of bias for dropout or withdrawal participants. Considering other biases, the sources of funding were shown in all included trials. The sources of direct funding were medical university or the Ministry of Health research foundations; these trials were considered to be free from the risk of bias posed by a financial conflict of interest.

3.3. Meta-analysis outcomes

3.3.1. Response rate

Three RCTs[18-20] (involving 270 patients) were identified with the outcome measurement of response rate. The pooled results displayed favorable significant effects of routine care plus AA on response rate when compared with the AA alone (RR = 1.27, 95% CI [1.14, 1.42], $P < 0.01$) with low heterogeneity ($\chi^2 = 2.31$, $P = 0.31$, $I^2 = 14\%$; Figure 4).

Study	Sample size	Intervention group (regimen)	Control group (regimen)	Main outcomes	Acupuncture points	AEs
Shin and Park[17]	52	(A) AA (one session = 20 minutes, three times/day, total 20 days, $n = 26$), plus (B)	(B) Routine care, $n = 26$	CAS PAC-QOL	Rectum, large intestine, lung, and San Jiao	Mild pain, mild discomfort
Wang et al[18]	60	(A) AA (one session = 25 minutes, three times/day, total 18 days, $n = 30$), plus (B)	(B) Routine care, $n = 30$	Response rate	Rectum, large intestine, lung, San Jiao, and subcortex	n.r.
Xu et al[19]	90	(A) AA (one session = 30 minutes, three times/day, total 18 days, $n = 45$), plus (B)	(B) Routine care, $n = 45$	Response rate	Rectum, large intestine, lung, San Jiao, and subcortex	n.r.
Feng et al[20]	120	(A) AA (one session = 30 minutes, three times/day, total 20 days, $n = 60$), plus (B)	(B) Routine care, $n = 60$	Response rate	Rectum, large intestine, lung, San Jiao, and subcortex	n.r.

Table 1. Summary of the RCTs of AA for treating constipation in BC patients undergoing chemotherapy.
Note: AA, auricular acupressure; AEs, adverse events; BC, breast cancer; CAS, Constipation Assessment Scale; n.r., not reported; PAC-QOL, Patient Assessment of Constipation-Quality of Life; RCT, randomized controlled trial.

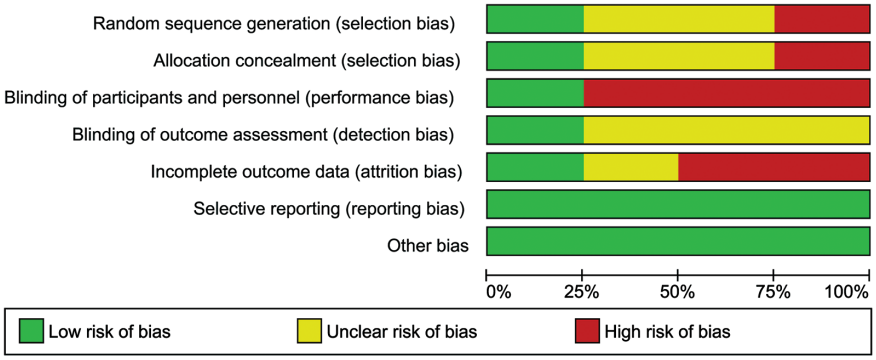

Figure 2. Risk of bias summary: reviewers' judgments about each risk of bias item for each included study.

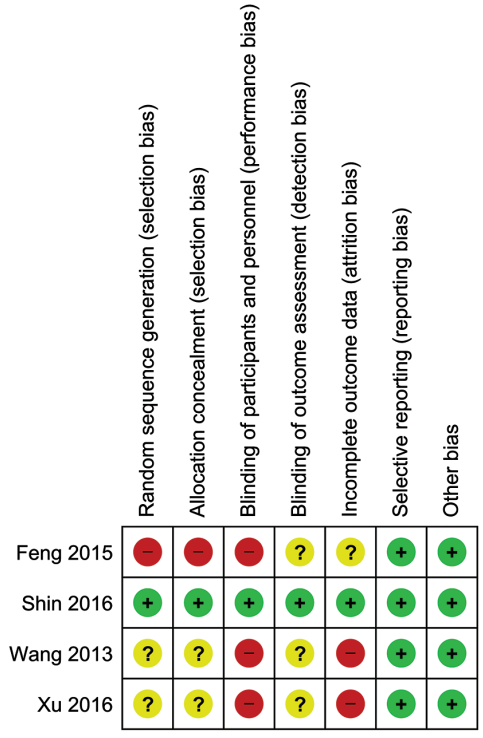

Figure 3. Risk of bias graph: reviewers' judgments about each risk of bias item presented as percentages across all included studies.

3.3.2. CAS

Only one RCT[17] used CAS as the outcome measure. The result of this RCT showed superior effects of routine care plus AA on CAS when compared with the routine care alone (MD = -5.07, 95% CI [-6.86, -3.28], $P < 0.01$).

3.3.3. PAC-QOL

There was only one RCT[17] that used PAC-QOL as an outcome measure for the improvement in chemotherapy-induced constipation. The result of this trial showed superior effects of routine care plus AA on PAC-QOL when compared with the AA alone (MD = -1.26, 95% CI [-1.59, -0.93], $P < 0.01$).

3.4. AEs

In all included trials, only one RCT[17] assessed AEs, while the other RCTs did not.[18-20] Several common adverse outcomes (mild discomfort or pain) from the routine care plus AA therapy group were reported in this trial.

4. Discussion

Overall, our meta-analysis showed that the combined use of routine care and AA was found to be superior to routine care therapy alone in terms of BSF, CAS, and PAC-QOL.

Previously, Luo et al.[21] summarized the current evidence to examine the effect of AA on constipation. Unfortunately, in that systematic review, the author included RCTs only to test the effect of AA for preventing opioid-induced constipation in cancer patients. Their findings are somewhat consistent with our study. Nevertheless, chemotherapy-induced constipation was not included in the previous systematic review.[21] Moreover, the previous systematic review[21] included some RCTs that compared different Complementary and Alternative Medicine (CAM) therapies. We excluded these trials according to our inclusion criteria. To our knowledge, our inclusion criteria gave us a more concrete picture on the role of AA than before. Moreover, compared to Luo et al.'s study,[21] one new RCT from Korea[17] was also included and analyzed in our study. Therefore, it is important to consider that a systematic review and meta-analysis should be updated periodically as new RCTs are published.

The results of our study showed that AA may have a beneficial effect on treating constipation in BC patients undergoing chemotherapy. The mechanism of

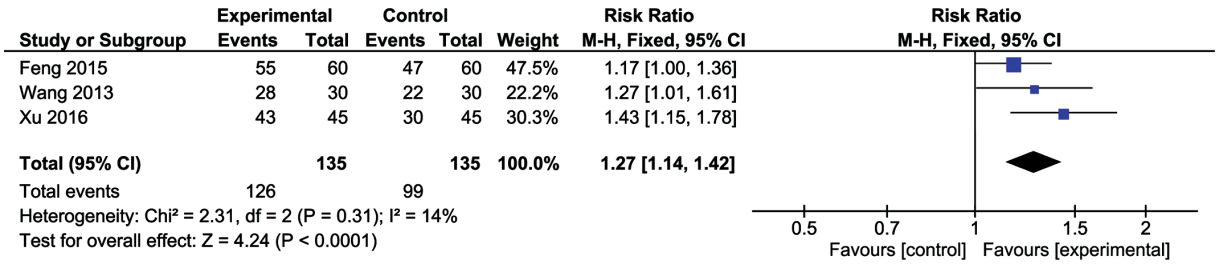

Figure 4. Routine care vs routine care plus AA on response rate. AA, auricular acupressure.

action of AA is interesting for us, and various theories have been proposed. (1) From the TCM perspective, the constipation falls under the heading of *Bian Jie*, which is attributed to "dysfunction of spleen in transportation" and "stomach disharmony." According to the theory of TCM, AA stimulates acupuncture points on ears, which could reinforce *qi* circulation and affect nourishment of the spleen, leading to an improved *Bian Jie* state.[22] (2) The primary modern speculation about AA is somatotopic arrangement theory. Oleson et al.[23] recruited 40 patients with specific musculoskeletal pain condition in a double-blind study to examine whether somatotopic arrangement theory corresponds to parts of the body, and they obtained a 75.2% accuracy rating. Therefore, the ears are the closest organs to the brain, and the application of AA in the auricular reflex points associated with gastrointestinal function may have a beneficial effective on alleviating constipation symptoms.[24] (3) There are various neurophysiological connections between auricular reflex points and the autonomic and central nervous system. Thus, groups of pluripotent cells contain information from the whole autonomic and central nervous system attempt to create regional organization centers representing different parts of the body.[25]

As in all systematic reviews, this study is susceptible to bias. For adequate random sequence generation, high risk of bias was given to 75% of the included studies. For the allocation concealment, the group assignment was adequately concealed in only 25% of the included trials and the remaining trials were given high risk of bias or unclear risk of bias. RCTs with inadequate random sequence generation and inadequate allocation concealment may be subject to selection bias and are more likely to overestimate the results of the outcome measures.[26,27] For the attrition bias, only 25% of included trials adequately reported the incomplete outcome data, which may lead to attrition bias.[28] Finally, although subject blinding is difficult to achieve for AA, assessor blinding is possible. Unfortunately, only one RCT included in the systematic review adopted assessor blinding, which may result in the detection biases[26]. Overall, caution must be taken when attempting to generalize the results of our study owing to the low quality of the included RCT.

This study may have several important limitations. First, based on the assessment of the Cochrane risk of bias, this study had a high risk of bias, which seemed to result in the positive results we found. In the future, to improve the quality of RCT, authors should refer to the Consolidated Standards of Reporting Trials (CONSORT) statement for trials of AA interventions.[29] Second, the sample size of included studies was very small. Thus, the power of our study based on small sample size effects was more likely to be overestimated.[30] Third, compared with other placebos, CAM therapies may include larger placebo effect.[31] AA, as an important integral part of CAM, may enlarge the treatment effect size. Moreover, AA conducted by CAM practitioners may increase doctor–patient face-to face time, and thus a strong placebo effect was often found when CAM practitioners performed AA for their patients. Fourth, due to the limited number of pooled studies, it was not appropriate for us to formally test the asymmetry in the funnel plot. Last but not least, most of the included RCTs originated in China, limiting the results specifically to this subset of Asian populations. In the future, more large-scale, rigorously designed, randomized, placebo-controlled, double-blind trials are still warranted.

5. Conclusions

Overall, as a potential safety therapy, AA can effectively prevent constipation in BC patients undergoing chemotherapy. In the future, more rigorous RCTs must be conducted to overcome the limitations of our existing data and confirm the effect and safety of AA for managing constipation in BC patients undergoing chemotherapy.

Conflicts of interest

All contributing authors declare no conflicts of interest.

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