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Auricular therapy for chronic pain management in adults: A synthesis of evidence

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A B S T R A C T

Objective: To evaluate the efficacy and safety of auricular therapy (AT) on chronic pain.
Methods: A systematic review. Randomized controlled trials investigating AT for chronic pain were retrieved and RevMan 5.3 was used for meta-analysis.
Results: Fifteen trials were included. The overall assessment indicated that AT could be a promising intervention for chronic pain relief. Meta-analyses showed that AT decreased pain intensity, especially for chronic low back pain and chronic tension headache. The lasting effect of AT was not obvious, and it began to diminish 3 months after the completion of treatment.
Conclusions: AT may positively control pain intensity for patients with chronic pain. However, due to the significant heterogeneity and methodological flaws identified in the analyzed trials, the current evidence on AT for chronic pain management is still uncertain. More rigorously designed large-scale randomized controlled trials are required to evaluate the efficacy of AT for patients with chronic pain.
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1. Introduction

Chronic pain is a major health problem worldwide, and it is defined as pain lasting longer than three months [1]. As a heterogeneous condition, chronic pain is associated with a range of diagnoses and symptoms, such as chronic back pain, fibromyalgia, and arthritis [2]. Studies have shown a considerable increase in the prevalence of chronic pain during the past decades [3,4]. Approximately 50% of adults in the US have suffered from chronic pain [5]. In Europe, nearly 20% of adults have experienced moderate to severe chronic pain that seriously affected their working, social lives and emotional functions [6,7].

To control pain, WHO recommends application of both opioid and nonopioid analgesics [8]. The efficacy and safety of opioid medications remain unclear, and the majority of the patients who are administered opioid drugs experience undesirable side effects [9]. In addition, inappropriately using nonopioid medications like NSAIDs may contribute to gastrointestinal and cardiovascular toxicities [10]. Thus, alternatives to these medications, such as non-pharmacological approaches have been recommended. Non-pharmacological interventions refer to various techniques, such as acupuncture, herbal therapies, nutritional supplements, or massage, which are employed to relieve pain as well as to maintain functional status [11].

Acupuncture has been regarded as a promising method in relieving a wide range of chronic pains including chronic pelvic pain and chronic low back pain [12,13]. As an adjunct to acupuncture, auricular therapy (AT) has been used as a therapeutic approach in China since the Han Dynasty. The modern form of the method was developed by Paul Nogier in the late 1950s. The earliest Chinese medical book, *Huang Di Nei Jing*, mentioned that all meridians converge at the ear, and that the ear is closely related to all parts of the body and organs [14]. In modern times, AT is most commonly based on the idea that the outer ear has a somatotopic map with an inverted fetus pattern, and each part of the auricle is corresponding to a specific part of the human body or organ [15]. By stimulating particular ear acupoints, AT may produce a positive impact by rebalancing the central nervous system and alleviating a variety of pathological conditions.

AT has been applied for many conditions including smoking cessation, cocaine dependence, anxiety, or insomnia, but the

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evidence has been mixed [16–19]. Previous studies [20,21] have indicated that AT reduces pain intensity, analgesic intake, and anxiety in patients with both postoperative pain and cancer pain. However, the effect of AT on chronic pain has not yet been clarified. During the past decade, several studies which evaluated the impact of AT on chronic pain showed conflicting results [22–24]. A systematic review, which included 8 studies on perioperative pain, 4 on acute pain, and 5 on chronic pain, revealed a positive impact of AT on postoperative pain. However, the effect of AT on chronic pain is still uncertain [21]. To our knowledge, there have been no systematic reviews to date that have been designed specifically to investigate the efficacy of AT for chronic pain.

Using a wide range of literature databases, this study intended to evaluate the randomized controlled trials (RCTs) on AT for the management of chronic pain. The objective of this review is to evaluate the efficacy and safety of AT for chronic pain management.

2. Methods

2.1. Study design

This study is a systematic review and meta-analysis for evidence synthesis.

2.2. Search methods to identify studies

First, a protocol was formulated, and it was critically reviewed by two experts from the Center of Evidence-based Practice at the Fujian University of Traditional Chinese Medicine. The following 11 databases were searched (from inception to February 28, 2015): PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Science Direct, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, Allied and Complementary Medicine (AMED), China National Knowledge Infrastructure (CNKI), WanFang Data, Chinese Scientific Journal Database (VIP), and Chinese Medical Literature Database (CBM). Mesh terms and key words, including "auricular therapy", "acupuncture, ear", "pain", "chronic pain" and "analgesia" were used in the searching strategies. Additionally, the reference lists of all included studies were searched for further consideration. No language restrictions were used in the electronic database searches. Moreover, we manually retrieved unpublished and published data from our university library (language restricted to Chinese). Two reviewers independently selected the papers according to specified selection criteria, which were defined previously in the protocol. Disagreements regarding study selection were resolved by discussion with strict adherence to the selection criteria. Appendix lists three main searching strategies for this systematic review.

2.3. Selection criteria and outcome measures

The inclusion criteria for this review were as follows: 1) RCTs regardless of blinding; 2) subjects were male or female adults (≥18 years) with any chronic pain syndrome (experienced pain ≥3 months); 3) trials compared AT (auricular acupuncture, auricular acupressure or auricular electro-stimulation, etc.) to one or more of the following: sham AT, waiting-list, standard medical treatment or no treatment. No restrictions were placed on where the therapy was administered or who delivered the therapy. AT trials on migraine were excluded during the stage of study selection because they failed to distinguish the episodic migraine from the chronic migraine, which did not belong to the chronic pain disorders. Studies of cancer pain were also excluded, as the tumor itself and the cancer-related complications can cause additional pain with either acute or chronic onset, which would introduce significantly clinical heterogeneity. The primary outcome for this review was the change in the self-reported pain intensity using validated measures of pain intensity, such as the visual analogue scale (VAS) or the numerical rating scale (NRS). The secondary outcomes were the incidence of adverse events, and satisfaction with AT treatment.

2.4. Data extraction

Data were extracted independently by two reviewers using a standardized data extraction form. The following items were extracted from each of the included trials, when available: 1) study characteristics (design, country of origin, setting, methods, study duration, intervention protocols, controls, and follow-up methods), 2) patient characteristics (pain type and duration, age, sex, and sample size), 3) outcomes and results (self-reported pain intensity or relief, physical function, patients' satisfaction during intervention and at all follow-up time points), and 4) adverse effects associated with AT. Data collection form was piloted. Disagreements were resolved by involving a third review author. Data presented only in figures and charts were extracted whenever possible, and were eligible for inclusion only if the two reviewers independently obtained the same data.

2.5. Assessment of quality of the included studies

The methodological quality and risk of bias of each included RCT was assessed using the "Risk of Bias" assessment tool recommended by the Cochrane Handbook for Systematic Review for Intervention [25] and adapted from items suggested by the Cochrane Pregnancy and Children Group. Eight specific items were evaluated including "random sequence generation" (checking for potential selection bias), "allocation concealment" (checking for potential selection bias), "blinding of participants and personnel" (checking for potential performance bias), "blinding of outcome assessment" (checking for potential detection bias), "incomplete outcome data" (checking for potential attrition bias), "selective outcome reporting" (checking for reporting bias), "other bias" and "size of study". Each item can be categorized as "low risk of bias", "high risk of bias" or "unclear risk of bias", according to the criteria for judging risk of bias in the *Cochrane Handbook for Systematic Reviews of Intervention, Part 2:8.5* [25]. Disagreements were resolved through discussion, and if consensus was not reached, a third reviewer was considered.

2.6. Data analysis

Both qualitative analysis and quantitative synthesis were adopted. Qualitative description was applied for the overall assessment of the treatment effects of AT as significant clinical heterogeneity in the types of chronic pain, types of AT and durations of treatment, etc. were identified in the analyzed studies. To investigate and minimize the clinical heterogeneity, a preliminary subgroup analysis was considered for different study comparisons (sham AT or other comparison), different types of chronic pain, different AT modalities (auricular acupressure, auricular acupuncture or auricular electro-stimulation, etc.), different treatment durations [short-term (0 to <3 weeks), mid-term (≥3 to <6 weeks), and long-term (≥6 weeks)], and different follow-up periods [short-term (≤1 month post-intervention), mid-term (>1 to <3 months post-intervention), and long-term (≥3 months post-intervention)]. All data were analyzed with the RevMan version 5.3, provided by the Cochrane Collaboration. All *P* values were two-sided. The standardized mean difference (SMD) with 95% confidence intervals (95%CIs) was calculated for continuous data, whereas the odds ratios (OR) or risk ratio (RR) was calculated for dichotomous data. A

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