Efficacy of acupuncture for tinnitus: an umbrella review

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Background: Tinnitus is a condition characterized by an annoying auditory phantom sensation with a heterogeneous etiology, often associated with an impairment of health-related quality of life. This umbrella review aims to determine whether acupuncture can be a useful remedy for the symptomatic management of patients with tinnitus.

Methods: PubMed, EMBASE, Web of Science, Cochrane Library, and Google Scholar were systematically searched up to May 9th, 2020 for relevant systematic reviews and meta-analyses on the topic. The quality of included studies was evaluated with a dedicated NIH assessment tool. Then, retrieved evidence was summarized and critically discussed.

Results: After the article screening process, six systematic reviews were included. Overall, results of included studies suggested that acupuncture might have an integrative role in the symptomatic management of tinnitus, but available evidence is limited and conflicting. In general, acupuncture, when administered by an expert practitioner following all hygienic rules, was considered a well-tolerated practice, although safety data are quite scant. The overall methodological quality of included reviews was judged as fair-to-good, but the quality of primary studies comprised in analyzed reviews was reported to be low.

Conclusions: To date, on the basis of available scientific evidence, it is not possible to affirm that acupuncture is effective for the treatment of tinnitus. However, it is not excluded that there might be some efficacy of intervention (especially manual acupuncture plus moxibustion) in the symptomatic management of specific subtypes of tinnitus (neurogenic tinnitus). The actual state of research requires a joint effort by Chinese and Western centers to conduct at least one high-quality multicenter randomized controlled trial to draw firm conclusions on the topic.

Keywords: Acupuncture; traditional Chinese medicine (TCM); integrative medicine; tinnitus; review

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Introduction

Tinnitus is usually defined as an "auditory phantom sensation (ringing of the ears) experienced when no external sound is present" (1), which is frequently associated with hearing impairment (2). In particular, it is possible to distinguish objective and subjective tinnitus, the former indicating an abnormal and annoying perception of a real sound produced by blood flowing into cerebro-cervical vessels or by contractions of head and neck muscles, whereas the latter describing the false perception of a sound

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in absence of any external or internal acoustic stimulus (2). The clinical etiology of tinnitus is quite heterogeneous, including otologic, neurologic, infectious, and drugrelated causes for subjective tinnitus, while ranging from pulsatile (vascular-based) to neuromuscular causes for objective tinnitus (2). When no specific clinical cause can be identified, tinnitus is usually referred to as "idiopathic" (3). From a pathophysiological point of view, it is hypothesized that tinnitus can be related to a downregulation of intracortical inhibition induced by cochlear damage, regardless of its specific etiology (1). Epidemiologically, it is estimated that, in the USA, one out of ten adults suffers from tinnitus, with some occupational and individual risk factors such as high-noise exposure being related to its more frequent occurrence (4). Additionally, rising prevalence of chronic tinnitus has been likely attributed to an increased longer-living population. In fact, aging has been demonstrated to result in functional impairment of both peripheral sensorineural epithelium and central auditory afferent pathways (1).

Considering the prevalence of tinnitus in the general population, its etiology (sometimes difficult to precisely determine and cure), and its impact on the patient's quality of life, many treatments have been proposed to date for the symptomatic management of this health condition, ranging from medicinal drugs to physical, psychological and surgical therapies (3). Among these treatments, acupuncture has been studied as a potential remedy for the improvement of tinnitus (5-7) with limited and conflicting evidence on its actual efficacy for this specific condition (8,9). In particular, acupuncture is an ancient therapeutic practice, deeply rooted in the heart of ancient Traditional Chinese Medicine (TCM), which implies the manual insertion of fine needles into specific trigger points (sometimes called "acupoints") on the body surface (10). Traditionally, acupuncture is believed to rebalance and improve the patient's vital energy (called "Chi") (10), thus acting both as a therapeutic and as a preventive practice. More recently, emerging scientific evidence indicates that acupuncture can be a valid integrative strategy for the management of various symptoms, including nausea, anxiety, pain and pain-related conditions (5).

This umbrella review aims to determine whether acupuncture can be a useful remedy for the symptomatic management of patients with tinnitus. We present the following paper in accordance with a validated checklist for review articles (the authors have completed the review reporting checklist: see the supplementary material for

further details).

We present the following article in accordance with the PRISMA reporting checklist (available at http://dx.doi.org/10.21037/lcm-20-21).

Methods

The PRISMA guidelines were followed for the conduction of this review of the scientific literature (11). Additional useful recommendations for umbrella reviews were taken into account to improve the quality of this research work (12).

Eligibility and exclusion criteria (PICOS)

All systematic reviews and meta-analyses about the efficacy of acupuncture in the management of tinnitus were included. Reviews without any description of research methods were excluded. Articles withdrawn by the editors or with an irretrievable full-text version were excluded as well. Intervention was defined as the professional administration of acupuncture (or electro-acupuncture), alone or in combination with other treatments, for any number of sessions. All studies were included regardless of comparison or control group type. All relevant clinical outcomes were considered, including any change in tinnitus severity and persistence, and any improvement in health-related quality of life. No language restrictions were applied during the article selection process.

The following list summarizes the applied PICOS criteria for inclusion and exclusion of studies in the present overview:

- P (Population): patients with tinnitus caused by any known (secondary) or unknown (idiopathic) clinical etiology.
- ❖ I (Intervention): administration of acupuncture (or electro-acupuncture), alone or in combination with other treatments, for any number of sessions and performed by a health professional.
- ❖ C (Comparison): any type of comparison (sham acupuncture, conventional drug-based care, other treatments, or no control).
- ❖ O (Outcomes): any change in tinnitus severity and persistence, along with any improvement in reported quality of life. All scales ranging from the Visual Analogue Scale (VAS) to the more specific Tinnitus Handicap Inventory (THI) were considered. Essential safety data were collected as a secondary outcome.

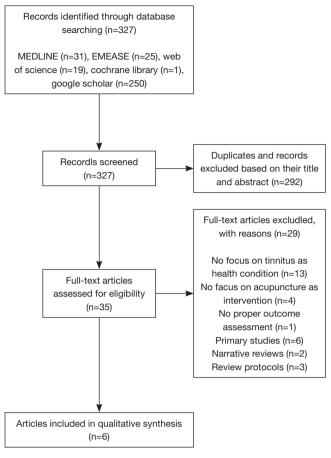


Figure 1 Flow diagram describing the article screening and selection process (adapted from the PRISMA statement).

S (Study design): systematic reviews and metaanalyses. When methods were not reported, reviews were excluded.

Information sources

Considering general recommendations about optimal database combinations for literature searches (13), Medline (through PubMed), EMBASE, Web of Science, Cochrane Library, and Google Scholar were systematically searched for relevant reviews and meta-analyses.

Search

Databases were searched up to May 9th, 2020. The following search strategies were used:

❖ PubMed (31 items): (acupuncture[Title/

Abstract] OR acupoint*[Title/Abstract] OR electroacupuncture[Title/Abstract] OR electroacupuncture[Title/Abstract] OR meridians[Title/Abstract]) AND (tinnitus[Title/Abstract] OR (ear[Title/Abstract] AND (buzz*[Title/Abstract] OR ring*[Title/Abstract] OR roar*[Title/Abstract] OR click*[Title/Abstract] OR pulse*[Title/Abstract]))). Filters applied: Meta-Analysis, Review, Systematic Reviews.

- * EMBASE (26 items): (acupuncture:ti,ab,kw OR electroacupuncture:ti,ab,kw OR 'electro acupuncture':ti,ab,kw OR acupoint*:ti,ab,kw OR meridians:ti,ab,kw) AND (((((tinnitus:ti,ab,kw OR ear) AND buzz:ti,ab,kw OR ear) AND ring:ti,ab,kw OR ear) AND roar:ti,ab,kw OR ear) AND click:ti,ab,kw OR ear) AND pulse:ti,ab,kw. Publication type: Review.
- Web of Science (19 items): TOPIC: (acupuncture) AND TOPIC: (tinnit*). Refined by: DOCUMENT TYPES: (REVIEW). Timespan: All years. Indexes: SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, ESCI.
- Cochrane Library (1 item): "acupuncture" in Title Abstract Keyword AND "tinnitus" in Title Abstract Keyword - in Cochrane Reviews, Cochrane Protocols (Word variations have been searched).
- Google Scholar (limited to the first 250 items): "acupuncture" AND "tinnitus" AND "systematic review".

Study selection and data collection process

Study selection was performed by the two authors (MA and DD) independently and disagreements were discussed until consensus was reached. Details of the screening process were summarized in a flowchart (*Figure 1*). Data were manually extracted from included studies, collected in a table and then critically appraised. EndNote X4 ProgramTM was used for the article screening process.

Data items

Data items extracted from selected reviews were the etiology of tinnitus, the characteristics of intervention and control, all relevant analyzed outcomes, safety data, the authors' conclusions, and the overall quality of primary studies comprised in included reviews.

Risk of bias in individual studies and across studies

The overall quality of included studies was assessed by two authors (MA and DD) following the criteria of an NIH dedicated tool (14). Disagreements were resolved with discussion until consensus was reached. The NIH tool provides an 8-item methodological checklist for the quality assessment of systematic reviews and meta-analyses. Reviews are assessed individually and their overall quality, ranging from a minimum of 0 to a maximum of 8, is judged as "poor" if 3 or less items are positive, "fair" if 4 or 5 items are positive, and "good" if at least 6 items are positive. Results of the overall quality assessment were reported in a specific column of *Table 1*. Since no meta-analysis was feasible, the risk of bias across studies was only qualitatively assessed.

Synthesis of results

Results of included reviews were summarized, properly evaluated, and then discussed to obtain a critical qualitative synthesis.

Results

Scientific database searches yielded 327 results and, after screening and selection of retrieved articles, six systematic reviews were considered eligible for inclusion in this work (check the flowchart reported in *Figure 1* for further details) (8,9,15-18). The main characteristics of included studies were summarized in *Table 1*.

Study population was mostly composed of patients with tinnitus due to a wide range of poorly specified causes, even associated with hearing loss (8,9,15-18). In all reviews, intervention comprised manual or electro-acupuncture, alone or in combination with other treatments. In particular, only studies investigating the efficacy of electroacupuncture were included in one review (16), in another review only trials regarding manual acupuncture were analyzed (8), whereas in the remaining research works intervention also comprised acupuncture in combination with other treatments, including conventional drug-based care (9,15,17,18). Across included reviews, primary studies adopted various acupuncture protocols, either based on traditional indications or determined by more standardized approaches, but in the majority of trials the following acupoints were involved: Yi feng (TE-17), Er meng (TE-21), Ting gong (SI-19), and Ting hui (GB-2) (9,15). Control was quite heterogeneous too, thus including sham acupuncture or conventional care. In some cases, the efficacy of electroacupuncture was compared with manual acupuncture, the latter forming an intervention administered to the comparison group (9,16). The main efficacy outcome was clinically assessed in various ways, ranging from qualitative approaches (medical interview) to more quantitative methods (a generic 10-point VAS or the more specific THI) (8,9,15-18). The secondary safety outcome was reported in all but one review (8). All included studies were systematic reviews of the scientific literature, and three of them also included a meta-analytic synthesis of retrieved data (9,15,18).

The authors of included reviews drew different conclusions with regard to the clinical efficacy of acupuncture in the management of tinnitus. In particular, in two reviews it was stated that acupuncture was unlikely to provide a significant beneficial effect for tinnitus (8,15), in two other reviews evidence was considered too limited to draw any conclusion on the topic (16,17), whereas in the remaining reviews acupuncture was judged as effective in improving tinnitus, with the combination of acupuncture and moxibustion being evaluated as the most efficacious (9,18). In half of included reviews, acupuncture was considered as a safe and well-tolerated treatment, with no report of severe adverse events following its administration (9,15,17). In two reviews, authors stated that there is insufficient evidence to precisely determine whether acupuncture can be considered a safe practice (16,18), while in one review safety outcomes were not reported (8).

The overall quality of included reviews, evaluated with the NIH assessment tool, was generally quite high and was rated as good (A level) for four reviews (9,15-17) and fair (B level) for two reviews (8,18), as reported in *Table 1*. The authors of all included reviews acknowledged that primary studies on the topic were often characterized by a poor methodological quality, thus often lacking essential information regarding proper randomization or allocation concealment processes. Additionally, some concerns about appropriate blinding were also raised.

Discussion

After examining all retrievable systematic reviews and metaanalyses about the use of acupuncture for the treatment of tinnitus, some considerations can be made with respect to the whole picture. Unfortunately, available evidence basis

Table 1 Characteristics of systematic reviews about the efficacy of acupuncture for tinnitus

Reference	Reference Health condition Intervention	Intervention	Control	Outcomes (N of RCTs per outcome)	Study design (N of RCTs)	Efficacy for tinnitus Safety	Safety	Review quality
Chen <i>et al.</i> Sudden [2019] sensorin	Sudden sensorineural hearing loss	MA+CM	CM	Clinical improvement (2 RCTs) and changes in auditory threshold (20 RCTs)	SR + meta- analysis (20 RCTs)	No (improvements only for audiometry parameters)	Safe (no severe adverse events)	∢
He <i>et al.</i> [2016]	Tinnitus (subjective EA or idiopathic)	EA	MA, SA or CM	Clinical improvement and changes in auditory threshold (5 RCTs)	SR (5 RCTs)	Unclear (too limited evidence)	Unclear (too limited evidence)	∢
Kim e <i>t al.</i> [2012]	Tinnitus (any cause)	MA or EA	SA or CM	Clinical and QoL improvement SR (9 RCTs) (THI) (9 RCTs)	SR (9 RCTs)	Unclear (conflicting evidence)	Safe (no severe adverse events)	⋖
Liu <i>et al.</i> [2016]	Tinnitus (any cause)	MA, MA+CM or EA	SA or CM	Clinical and QoL improvement SR + meta-(THI) (18 RCTs) analysis (18	SR + meta- analysis (18 RCTs)	Yes (only in some patients)	Unclear (too limited evidence)	В
Pang e <i>t al.</i> [2019]	Tinnitus (neurogenic)	MA or MA+CM, EA or EA+CM, MA/EA+MB	CM (or MA if intervention was EA or MA+MB)	Clinical improvement measured with any scale (40 RCTs)	SR + meta- analysis (40 RCTs)	Yes (MA+MB seems the most effective among others)	Safe (no severe adverse events)	∢
Park <i>et al.</i> [2000]	Tinnitus (any cause)	MA	SA or CM	Clinical and QoL improvement, mostly with a VAS (5 RCTs)	SR (6 RCTs)	No (lack of high- quality evidence in support of MA)	Not reported	В

Caption: Review quality was assessed with the dedicated 8-item NIH tool. A=good quality; B=fair quality; C=poor quality. CM, conventional medicine (mostly drugbased therapy); EA, electro-acupuncture; MA, manual acupuncture; MB, moxibustion; QoL, quality of life; RCTs, randomized controlled trials; SA, sham acupuncture; SR, systematic review; THI, Tinnitus Handicap Inventory; VAS, Visual Analogue Scale.

does not still allow to affirm that acupuncture is effective for the treatment of tinnitus. However, this is possibly due to the fact that primary clinical studies on the topic are excessively heterogeneous in terms of study design, population's characteristics, outcome measures, type of intervention and control. As such, it proves very difficult to draw firm conclusions after pooling together results of these studies. Since a broadly accepted and shared definition of tinnitus lacks to date, clinical studies on the topic often involve patients whose main symptomatic condition of interest (tinnitus) is characterized by a heterogeneous (and sometimes poorly specified) underlying etiology, with a different degree of plausibility for a rational and effective use of acupuncture (i.e., neurogenic tinnitus versus vascular tinnitus). The overall quality of primary studies included in analyzed reviews is generally low, thus underscoring poor compliance to research methodological standards and a lack of robust study designs. Besides heterogeneity of underlying pathomechanisms involved in chronic tinnitus, one of the most important limitations in comparing treatment outcomes among different investigations and cohorts is the lack of reliable diagnostic tests objectively evaluating tinnitus features, such as pitch and loudness, and patient's discomfort. Therefore, main outcome measures adopted for the assessment of the efficacy of intervention are often subjective and self-reported, which can increase the risk of biased results. Last but not least, different types of acupuncture, which markedly vary one from another, are considered in included studies (i.e., electroacupuncture versus manual acupuncture and moxibustion, etc.), and the efficacy of these interventions are compared with hard-tostandardize control types. In fact, the challenge of choosing the proper type of control when designing studies aimed at evaluating the clinical efficacy of acupuncture is well-known by the scientific community (19), since the specific nature and characteristics of this intervention make it difficult to select an adequate control type, capable of highlighting any relevant treatment effect by contrast, in a sufficiently sensitive and unbiased way. Another potential source of clinical heterogeneity may be the relationship between the onset of tinnitus and the disease stage (early or late) in which intervention is administered, as observed in trials included in analyzed reviews.

Globally, the high level of observed heterogeneity actually hinders any rigorous and reliable attempt to qualitatively and quantitatively synthesize available clinical data, thus making it necessary to adopt looser PICOS

criteria and "sacrifice" homogeneity between studies in an effort to maximize retrievable evidence on the topic, which would be otherwise too scant and, therefore, meaningless from a clinical point of view if stricter criteria for study eligibility were chosen. As a consequence, it is not surprising that, in the majority of analyzed systematic reviews and meta-analyses, no definitive conclusions about the efficacy of acupuncture for tinnitus are actually outlined. On the other hand, it is understandable why many research groups had difficulties in finding a common ground, especially without having any specific clue about which of the above mentioned—possibly confounding—factors would impact study results the most.

However, some encouraging results come from the recent work by Pang *et al.*, which sheds some light on a possible direction to follow for future research on the topic (9). In fact, manual acupuncture associated with moxibustion seems to be the most promising acupuncture-based intervention for the treatment of tinnitus. Moreover, neurogenic tinnitus appears to be the subtype of this health condition which may better respond to acupuncture treatment.

In conclusion, to date, on the basis of available scientific evidence, it is not possible to affirm that acupuncture is effective for the treatment of tinnitus. The actual state of research requires an effort to conduct at least one high-quality multicenter randomized controlled trial characterized by a rigorous and standardized methodology, trying to reach a large population sample and to minimize potential sources of biases. The scarcity of effective remedies for a quality-of-life impairing condition like tinnitus would justify such research efforts, especially because available studies about acupuncture for the treatment of this health condition show conflicting results and are characterized by a poor overall quality. Useful hints for planning future research on the topic would be to only include patients whose tinnitus is caused by a specific and well-defined etiology, and to adopt an adequate control type for a balanced and proper evaluation of the efficacy of intervention. In the pursuit of this aim, a coordination between Chinese and Western centers is required, in order to combine the best expertise and resources worldwide, and to avoid any dispersion of research efforts which may lead to a multitude of excessively small and heterogeneous studies, useless to draw firm conclusions on the topic and to outline some clinical recommendations.

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Footnote

Reporting Checklist: The authors have completed the PRISMA reporting checklist. Available at http://dx.doi.org/10.21037/lcm-20-21

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi. org/10.21037/lcm-20-21). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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