



# How to define level of evidence for tinnitus treatment by acupuncture?

Ektor Tsuneo Onishi<sup>^</sup>

Tinnitus and Sound Intolerance Study and Research Group Prof. Yotaka Fukuda, Discipline of Otolaryngology and Otoneurology – Federal University of São Paulo (UNIFESP), São Paulo, Brazil

*Correspondence to:* Ektor Tsuneo Onishi. Rua Botucatu, 821. 9o andar. São Paulo, SP, 04023-061. Brazil. Email: ektor.onishi@unifesp.br.

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In order to answer this question, the authors of the article “Efficacy of acupuncture for tinnitus: an umbrella review” analyzed systematic reviews published until mid-2020, but unfortunately it has not yet been possible to confirm the effect of this therapy (1). Not because of the lack of effectiveness of acupuncture as a therapeutic tool, but because of difficulties in analyzing the data, also described on published papers, such as low quality of studies, type of intervention (manual or electrical stimuli), among others (2,3).

In order to understand these findings, some points must be identified and analyzed. Most of medical knowledge was obtained from observing the phenomena related to the pathologic process, the natural history of disease. Thousands of years ago, only the enviable ability to identify and interpret these phenomena combined in the so-called patterns of disharmony was able to constitute one of the fundamental pillars of Traditional Chinese Medicine (TCM). For the description of patterns of disharmony used for diagnosis, TCM considers sometimes vague and nonspecific symptoms not valued by the Cartesian point of view of Western Medicine.

Perhaps one of the biggest challenges for ENT doctors is dealing with tinnitus, a sensation of sound in the absence of external sound stimulus with many possible causes. Even the classic concept of tinnitus—“auditory phantom sensation”—emphasizes the difficulty to explain

the symptom and to identify causes besides hearing loss. Due to these characteristics and similarities of its pathophysiological mechanism, tinnitus has often been compared to chronic pain or phantom limbs (4). Previous studies have demonstrated that central nervous system structures related to emotions (limbic system) and reaction to sound (autonomic nervous system) play a fundamental role in determining the degree of discomfort (5) and can be modulated by acupuncture with evidence by functional image exams (6). Many drugs and therapies are used in common (7). The good results obtained with the use of acupuncture for pain treatment justify its application in patients with tinnitus (4,6,7).

The study of TCM organs physiology (Zang Fu) makes it possible to identify two main causes of tinnitus with very different characteristics: the Kidney (Shen) Deficiency syndrome and the Liver (Gan) Excess. The clinical characteristics of Kidney (Shen) deficiency tinnitus are low-frequency tinnitus with a history of insidious, gradual onset, memory difficulties, low back pain, dizziness and hearing loss in older patients. Tinnitus due to the Liver (Gan) excess has a sudden high frequency onset, in younger individuals and related to emotional tension, irritability and headache (8). These psychoacoustic characteristics of tinnitus have been ignored for a long time by otorhinolaryngologists, but recent studies indicate that in some patients they may be related to their handicap and prognosis (9).

<sup>^</sup> ORCID: 0000-0003-1501-8409.

As each MTC organ disharmony has a specific treatment, including the choice of acupuncture points, only studies with well-defined inclusion and exclusion criteria that distinguish the pattern of disharmony will be able to define the real effect of acupuncture in tinnitus patients. We should not expect individuals with such distinct characteristics to respond adequately to a predetermined treatment common to all patients. In addition to being methodologically wrong, it goes against the idea of grouping individuals in well-defined cohorts to compare different interventions or procedures.

The definition of scientific level of evidence depends on the quality of studies on a given subject (prospective, randomized, double-blind). Systematic reviews have been used as instruments for decision and conduct definition in evidence-based medicine, but they depend on well-designed studies, with adequate method and statistics. Research acupuncture to treat tinnitus needs a specific design, with classification by Zang Fu disharmony syndromes and different treatment proposal.

Problems in defining the control / sham group, choosing the type of stimulus (manual, electroacupuncture), choosing of acupuncture points, number of sessions and criteria for assessing the clinical outcome will continue as problems to be solved by the researchers (10,11).

Despite all the facts presented, the absence of scientific evidence does not necessarily mean scientific evidence of no beneficial effect of a particular treatment or intervention.

Donelli *et al.* paper corroborates our opinion that it will not be possible to conclude about the effectiveness of acupuncture to treat patients with tinnitus until well-designed randomized controlled trials, with strict inclusion and exclusion criteria and that consider the homogeneity of the groups (in relation to etiology/cause/energetic disorder) are carried out in different centers. Researchers familiar to ENT and TCM shall be expected to develop scientific surveys that fulfill these criteria and, in this way, could be evaluated by systematic reviews methodology.

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