
Tinnitus: The Complexity of Standardization

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Abstract

Tinnitus is a heterogeneous disorder that causes significant impairment in many patients. Treatment is elusive and there is a need for more comprehensive guidelines for diagnosis and management of tinnitus. However, different standardization approaches should be differentiated according to their specific purpose. Standardization of assessment methods and outcome measurements are useful for the performance of clinical trials, for comparison of results across centers, for clinic audits, and for epidemiological studies. In contrast, clinical guidelines are the best approach for the standardization of the clinical management of tinnitus patients. In the development of these clinical guidelines, the heterogeneity of tinnitus should be considered. Tinnitus can be a symptom of a severe underlying disease. Also, there are specific subforms of tinnitus for which curative treatment options are available. Therefore, medical diagnosis is necessarily the first step in tinnitus management.

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Treatment guidelines should not be restricted to recommendations that are supported by high-level evidence. They should also contain treatment recommendations that have shown clinically highly relevant effects in case series of specific tinnitus subgroups.

Keywords

assessment, clinical guidelines, outcome measurement, standardization, tinnitus

We want to thank Hoare et al., to draw the attention to the important topic of the current practice of tinnitus management and the need for evidence-based patient management protocols. Tinnitus is a frequent disorder. About 15% of the population is affected (Shargorodsky et al., 2010) and in about 10% of them, tinnitus severely impairs the quality of life (Axelsson & Ringdahl, 1989). With an even higher prevalence of tinnitus in expanding demographics, including aging individuals and recent war veterans (Department of Veterans Affairs, 2008; Henry, Dennis, & Schechter, 2005), efficient management of tinnitus is of growing concern.

Despite its high prevalence, there are only few specialized treatment centers, evidence levels for most diagnostic and therapeutic procedures are relatively low, and the few existing recommendations for treatment are only rarely fulfilled in clinical practice (Hoare, Gander, Collins, Smith, & Hall, 2010). Current diagnosis and treatment of tinnitus patients is highly variable not only across and within disciplines (audiology, ENT, psychology/psychiatry) but also across and within countries. We therefore agree with Hoare et al. that there is an urgent need for more comprehensive guidelines for diagnosis and management of tinnitus. At the same time, standards should always be developed in order to reach a specific goal and therefore we advocate that the claim for guidelines is differentiated from the standardization of assessment methods and also from systematic outcome measurement for evaluating specific treatment procedures.

Clinical guidelines should provide orientation in the diagnosis and therapy of the individual patient. A standardized core set of different instruments for qualitative and quantitative assessment of different aspects of the tinnitus of the patient can be useful in this context. However, the goal in this case is an exact description of all clinical features of the tinnitus in a given patient based on reliable and validated assessment instruments. In turn, a good and reliable clinical characterization of the tinnitus is a prerequisite for finding the exact diagnosis in each patient, which in a second step then

enables to select the appropriate treatment. Thus, in a chronic patient with the main complaint of tinnitus-related concentration difficulties, other assessment instruments are appropriate than in a patient who is suffering from an acute pulsatile tinnitus. Also, for the assessment of the outcome in the individual patient, it is important whether the treatment resulted in improvement in those aspects and symptoms, which were most relevant for the patient himself, suggesting the need for individualized assessment. In contrast, standardized assessment methods are needed for the comparison of results across centers, for clinic audits, and for epidemiological studies. Finally, for the analysis of efficacy of specific therapeutic approaches interventions, either clinical trials or systematic clinical observations have to be performed, involving specific therapeutic interventions and standardized tinnitus assessment at defined time-points before, during, and after the intervention. We are well aware that there may be some overlap between the different needs of standardization. On the other hand, different approaches will be needed to fulfill the different purposes of standardization. As an example, a specific standardized questionnaire can be very useful in the context of diagnostic assessment but inappropriate for the use as outcome measurement (Meikle et al., 2007).

The Tinnitus Research Initiative (TRI) has adopted different strategies for improving standards of both clinical management and clinical research. These activities started with a consensus for trial methodology. There was consensus among experts that there exist several validated Tinnitus Questionnaires and that one of these should be used as primary outcome measurement in clinical trials. The additional use of the THI was recommended in order to enable comparison across trials. The THI has been chosen as comparator, because it is easily applicable, most widely used, and most widely translated (Langguth et al., 2007).

A higher level of standardization of clinical trial methodology has been achieved with the establishment of the TRI database (Landgrebe et al., 2010). Performing clinical trials according to standardized methodology and pooling the data in a database should facilitate both clinical subtypization of different forms of tinnitus, and identification of promising treatments for different types of tinnitus. This would be an important step toward the goal of individualized treatment of tinnitus.

In order to standardize and improve the clinical management of tinnitus patients, a project for developing an algorithm for diagnostic and therapeutic management of tinnitus has been initiated. As pointed out in the commentary of Searchfield, this project is intended to be a living and growing document and is in its current form available at the TRI website (http://www.tinnitusresearch.org/en/projects/flowchart_en.php).

As mentioned correctly by Hoare et al. the TRI algorithm is based on a medical model. The algorithm has been developed by a multidisciplinary team involving otolaryngologists, neuro-otologists, audiologists, neurologists, psychiatrists, and a neurosurgeon. It is characterized by the belief that tinnitus is a symptom that can result from a large variety of different underlying pathologies. Considering the facts that some of these pathologies can be life threatening, if left untreated (e.g., carotid dissection, acousticus neurinoma, suicidality), and that some of the underlying pathologies can be causally treated (e.g., ear wax, microvascular compression), we strongly advocate a comprehensive medical diagnostic workup of every tinnitus patient as the basis for all therapeutic decisions—similar like in most other areas of medicine. We consider it as inappropriate and dangerous to recommend self-management without diagnosis.

We agree with Hoare et al. that clear links between results from diagnostic tests and therapeutic recommendation would be desirable. In the development of the TRI algorithm, we try to provide guidance about indications for advanced diagnostic tests and therapeutic interventions based on the findings in the basic assessment. Currently, there are only low levels of evidence for establishing most of these links, indicating the need for further research efforts.

We also want to further underscore Searchfield's position to include recommendations with low evidence levels in a flowchart. Evidence based on clinical studies and clinical relevance for the treatment of the individual patient are not identical. If a specific intervention has been demonstrated to have a small benefit in several controlled studies involving large samples, it is considered the highest level of evidence. However, this small benefit may be clinically completely irrelevant in a specific patient. In contrast, if an intervention has been shown to stop tinnitus in case series of a specific rare subform of tinnitus (e.g., carbamazepine treatment in "type-writer-tinnitus"), it is only considered as a recommendation of relative low evidence, but it has a huge clinical relevance for the affected patient.

Thus, we agree to the need of more standardization in tinnitus research and treatment. At the same time we advocate the development of different standardization approaches for the different purposes clinical research and patient management. In view of the complexity of tinnitus, these are challenging tasks that will require a step-wise approach.

Declaration of Conflicting Interests

The authors declare no conflict of interest with respect to the authorship and/or publication of this commentary.

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