Clinical Guidelines and Practice: A Commentary on the Complexity of Tinnitus Management

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Abstract

Subjective tinnitus is an enigmatic and chronic condition that is predominantly managed as symptomatic. Little high-level evidence exists for the efficacy and specificity of the various tinnitus management strategies currently used, and this is reflected in documents that aim to guide clinicians. As a consequence, there are clear gaps in evidence-based practice linking diagnosis to the most effective management strategies as well as a general lack of consensus about which are appropriate strategies for assessment and management. Several guidelines have been produced from research efforts and from expert opinion. All recommend standardization of assessment and a range of management options but do not yet provide a means to link the

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two. The authors call for clinicians, scientists, and policy makers to work together to address this barrier to good practice.

Keywords

department of health, practice guidelines, standardization, tinnitus management, tinnitus research initiative

In the United Kingdom, there have been many changes in audiological services in the last decade. The Modernizing Hearing Aid Services project (Department of Health, 2000) set out several key objectives including the introduction of standard service protocols, the increase of available resources to reduce referral-to-treatment time, the introduction of leading-edge digital hearing-aid technology, and the delivery of measurable benefits (Phillips, Knight, Caldwell, & Warrington, 2007). Most significantly for tinnitus, a Good Practice Guide (GPG) for the provision of adult tinnitus services was released by the Department of Health in 2009, with the express aim of promoting equity of services throughout the United Kingdom for individuals with troublesome tinnitus.

For most medical complaints, patients presenting to medical or allied clinical professionals might expect to be assessed and treated according to a standardized protocol, the execution of which varies little from one clinician to another. In the case of subjective tinnitus, however, such a model for diagnostic assessment and choice of treatment has yet to be established, if indeed it is at all possible. The subjective tinnitus sound is not accessible to objective measurement and there is no definitive diagnosis of etiology. The main role of the clinician therefore is to help the patient manage their symptoms, not “cure” their tinnitus.

Current tinnitus management options include hearing aids, sound generators, cognitive behavioral therapy (CBT), music therapy, tinnitus retraining therapy (TRT), relaxation therapy, or may involve pharmacotherapy for associated problems such as insomnia, anxiety, or depression (for a review see Han et al., 2009). There is no Food and Drug Administration (FDA)- or European-approved drug specifically for the treatment of subjective tinnitus, however (Langguth, Salvi, & Elgoyhen, 2009). The choice of treatment is largely in the hands of the clinical professional, perhaps influenced also by patient preference and local resource limitations. But some degree of standardization in practice is essential (a) to ascertain key standards of best practice for tinnitus, that is, the most effective forms of management to prescribe, given particular symptoms, (b) to facilitate clinical audit (quality or

cost-benefit) and inform commissioners of services, (c) to define equal patient access to treatments, and (d) to perform meta-analyses and quantitatively compare new management strategies before their adoption into clinical practice (i.e., to provide high-level evidence of efficacy).

Certainly the need for standardized practices is widely accepted. Recent literature targeting researchers and clinicians at a national and international level is spotted with terms such as “equity,” “consistency,” “conformity,” and “uniformity” when describing how tinnitus care should be delivered (Biesinger et al., 2010; Department of Health 2009; Henry, Zaugg, & Schechter, 2005a, 2005b; Langguth et al., 2007). Here, we discuss how two guideline documents (GPG and Tinnitus Research Initiative [TRI]) have addressed issues of standardization by asking what assessments and what interventions are recommended, and what are the decision criteria linking diagnosis to choice of intervention.

At a national level, the GPG document (Department of Health, 2009) is targeted at the U.K. National Health Service. At the international level, the TRI document (Biesinger et al., 2010) is targeted more generally. The Tinnitus Clinic Network, a division of the TRI, agreed a consensus list of recommended measures for patient assessment and outcome evaluation (Langguth et al., 2007) and has recently produced an algorithm for the assessment and management of tinnitus patients (Biesinger et al., 2010). Other guidelines exist in the form of peer-reviewed journal articles (e.g., Henry et al., 2005a, 2005b), but these are different in kind to the aforementioned guidelines which were developed from broad collaborative efforts.

We therefore compare National U.K. recommendations with those of the International Network. Based on our own research, we also comment on the evidence for standard practices and evidence-based practice in the management of subjective tinnitus across English audiological department.

Background to the GPG and the TRI Documents

The GPG document was created from a broad-ranging multidisciplinary effort involving U.K.-based academics and medico-surgical specialists in neuro-otology, hearing therapy, audiology, general practice, ear, nose, and throat (ENT) nursing, clinical psychology, and relevant charities. In contrast, 11 of 14 contributors to the TRI document were medico-surgical specialists in neuro-otology with the remainder being audiologists and a project manager, practicing in a number of different countries. Contrasts between the philosophies of the two guidelines perhaps reflect these differences in authorship. Most notably, the TRI document focuses heavily on a medical

model of tinnitus management, while the GPG is more representative of a patient-centered approach. The GPG places more emphasis on holistic, individual care than on standardization and starts with the proposition that patients take some responsibility for their own tinnitus, by engaging where possible in self-management. From the primary care setting, the GPG recommends that General Practitioners refer a subset of tinnitus patients directly to local audiology services (typically staffed by audiologists and specialists in hearing rehabilitation). This is entirely at odds with the TRI proposition that management of all tinnitus patients should begin with examination by a neuro-otological specialist.

Standardization of Assessment

Both documents propose similar protocols for diagnostic assessment. Recommendations include clinical history taking and examination, identification of psychological or psychiatric conditions (using validated measures of tinnitus severity and intrusiveness, and measures of anxiety and depression), and psychoacoustic measures of tinnitus (using minimum masking level and loudness matching). From a clinical research perspective, a valid measure of treatment outcome (is there a reduction in tinnitus severity or intrusiveness?) is crucial if an intervention is to be demonstrated as efficacious and if new interventions are to be evaluated and introduced, either as adjunct or as alternatives to current practice.

For classification of tinnitus severity, both guidelines point to the Tinnitus Handicap Inventory ([THI] Newman, Jacobson, & Spitzer, 1997) which is a discriminative scale useful for comparisons between patients (Meikle, Stewart, Greist, & Henry, 2008). While the GPG does not justify its recommendation of this measure, the TRI's rationale is predominantly that it has been validated in many languages. The THI questionnaire is a weak outcome measure, however, because it is not very sensitive to change (Meikle et al., 2008). A more sensitive measure of treatment outcome is the Tinnitus Handicap Questionnaire (Kuk, Tyler, Russell, & Jordan, 1990). This questionnaire is mentioned in the TRI document but not in the GPG, but even in the TRI document it is not the preferred tool. Surprisingly to us, the GPG document does not explicitly call for the need to assess tinnitus management outcome.

Standardization in Choice of Treatment

The GPG recommends that subjective tinnitus is managed with information-based advice, hearing aids, relaxation therapy, CBT, good sleep hygiene,

sound enrichment, and combinations of strategies that provide habituation therapy (Department of Health, 2009). The GPG cites limited primary sources, randomized controlled trials (RCT), or meta-analyses. As such it is not and does not profess to provide an evidence base but offers “suggestions” for effective care.

The TRI document proposes a similar set of management options and also recommends combining therapies for greater efficacy, to include information-based advice, or CBT-based therapy, with the express aim of patient empowerment. The document was generated largely from a literature search completed in 2008, although it is unclear whether this literature search was systematic. It cites studies of very-low to moderate levels of evidence (below the level of RCT, and without details of postintervention follow-up) for a number of management practices including masking, other passive sound stimulation, and hearing aids. It cites numerous “possibilities” for treatment such as habituation with music and neurobiofeedback. It also refers to “emerging treatments” such as auditory training but again refers to small-scale experimental studies that we have judged to provide, at best, moderate quality evidence of efficacy (Hoare, Stacey, & Hall, 2010). While it is important to disseminate emerging research directions and findings to clinicians, details of novel interventions that have only received limited testing in small-scale studies do not have a place in a treatment algorithm.

Linking Assessment to Choice of Treatment

Crucially, neither the TRI nor the GPG specify clear links between the findings of the diagnostic assessment and the subsequent management decision. This is something that should emerge from a comprehensive diagnostic assessment. A lack of clarity suggests the course of first-line management is decided upon by personal judgments based on experience, trial and error, what resources are available, or what the patient regards as preferable. The GPG entirely lacks guidance on which management strategy (or combination thereof) to choose in the first instance. More usefully, the TRI document provides indication and contraindication for some of the management strategies it recommends. However, these too are based on varied levels of evidence. For example, CBT is recommended, particularly for patients diagnosed as having severe tinnitus, and this is supported by reference to a systematic review of six independent trials. In contrast, the recommendation of hearing-aid fitting is only supported by anecdotal evidence.

Lack of Standardization in Clinical Practice in England: An Example

We recently surveyed all audiology and hearing therapy staff in England, who we had identified as being involved in tinnitus patient care, with a 39% response rate (Hoare, Gander, Collins, Smith, & Hall, 2011). The aim of this survey was to gauge current practice and limitations in light of the GPG. From the responses received, it appears that formal aspects of tinnitus assessment are nonstandardized, even though 83% of respondents reported being open to some level of standardization. Less than half of responding clinicians ever use a tinnitus-specific questionnaire (the THI) and fewer than 20% of respondents ever collect psychoacoustic measures of tinnitus.

Respondents made clear that they considered the potential of psychological comorbidities in their patients, but less than 5% screen for anxiety or depression using a validated questionnaire. While it may be beyond the scope of practice of some audiological clinicians to address such psychological issues, the GPG specifically advises use of the Beck Anxiety and Depression Inventories or the Hospital Anxiety and Depression Scale questionnaire. The limited practical use of these questionnaires in England, may in part reflect the absence of appropriate referral possibilities. For example, only one third of respondents reported having the option to refer their tinnitus patients to a clinical psychologist. Whatever the issues underlying the under-use of validated measures, it does imply inequity in the approach to tinnitus care in England. In terms of management, almost all respondents offer information-based advice, hearing aids, sound generators, and some form of TRT. Other practices, such as the delivery of psychological counseling, are far more variable. Evaluation of treatment outcome is generally unstructured and not standardized within departments. For example, only one third use a tinnitus questionnaire at this stage. Given that a lot of tinnitus management practices are essentially “experimental” (the outcome is largely unknown), measuring change, however subtle, should be a priority and this should be done using an appropriate tool. As such, this is a point of practice where a clear standardized protocol would be of real immediate benefit to the advancement of tinnitus care and research.

Conclusion

Unlike many health services, tinnitus care is not prescribed or delivered in a standard way using a well-defined, accepted protocol. The current shortage

of high-level evidence for the efficacy of many approaches to tinnitus management means that clinicians and patients alike cannot make informed decisions as to the most likely effective form of management to take. This highlights the need for some degree of standardization in practice to ensure patients receive comparable management from different clinicians. According to the respondents of our survey, the lack of standardization in practice predominantly reflects local demand or limited resources, or is the product of personal experience, but we conclude that it will always have drawbacks in terms of clinical audit and equal patient access to care. The vast majority of clinicians are open to some degree of standardization, and the priority therefore should be to confirm what components of tinnitus management best provide the necessary evidence of efficacy for advancements in tinnitus patient care. Therapeutic uncertainties have no place in practice guidelines. At this time therefore, rather than striving for an all inclusive model of tinnitus care, basic elements of practice that will measure patient benefit in a valid and meaningful way should be standardized, and a solid evidence base for the efficacy or lack thereof, of current and emerging practices in tinnitus management can be established.

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