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Research paper

Tinnitus Functional Index: Development, validation, outcomes research, and clinical application

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ABSTRACT

The Tinnitus Research Consortium (TRC) issued a Request for Proposals in 2003 to develop a new tinnitus outcome measure that would: (1) be highly sensitive to treatment effects (validated for "responsiveness"); (2) address all major dimensions of tinnitus impact; and (3) be validated for scaling the negative impact of tinnitus. A grant was received by M. Meikle to conduct the study. In that observational study, all of the TRC objectives were met, with the final 25-item Tinnitus Functional Index (TFI) containing eight subscales. The study was published in 2012, and since then the TFI has received increasing international use and is being translated into at least 14 languages. The present study utilized data from a randomized controlled trial (RCT) that involved testing the efficacy of "telephone tinnitus education" as intervention for bothersome tinnitus. These data were used to confirm results from the original TFI study. Overall, the TFI performed well in the RCT with Cohen's *d* being 1.23. There were large differences between the eight different subscales, ranging from a mean 13.2-point reduction (for the Auditory subscale) to a mean 26.7-point reduction (for the Relaxation subscale). Comparison of TFI performance was made with the Tinnitus Handicap Inventory. All of the results confirmed sensitivity of the TFI along with its subscales.

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1. Introduction

Based on epidemiology studies, 10–15% of adults experience chronic, persistent tinnitus (Heller, 2003; Hoffman and Reed, 2004; Shargorodsky et al., 2010). For about 20% of these individuals, the tinnitus is "bothersome," disrupting sleep and concentration, and causing negative emotional reactions (Jastreboff and Hazell, 1998; Davis and Refaie, 2000; Krog et al., 2010; Cima et al., 2011). Although a cure for tinnitus is actively being sought, currently there is no proven means of eliminating tinnitus, or even of reducing its loudness (Henry et al., 2014). Patients with bothersome tinnitus must learn management techniques, and numerous behavioral methods exist for this purpose (Cima et al., 2014; Hoare et al., 2014). The method with perhaps the strongest evidence, based on randomized controlled trials (RCTs), is cognitive-behavioral therapy (CBT) (Martinez-Devesa et al., 2010; Tunkel et al., 2014).

Research is ongoing to evaluate the effectiveness of existing behavioral methods and to develop new methods. These methods are not designed to reduce or change the perception of tinnitus, but are intended to reduce reactions to tinnitus and thereby improve quality of life. A separate line of research focuses on "treatments" for tinnitus that are intended primarily to reduce the loudness (intensity or magnitude) of tinnitus (Schmidt et al., 2014). Such

Abbreviations: BPVAMC, Bay Pines VA Medical Center; CBT, cognitive-behavioral therapy; CC, Cleveland Clinic; HSI, Hearing and Speech Institute; IC, immediate care; JAHVA, James A. Haley VA Hospital; OHSU, Oregon Health & Science University; POQ-VA, Pain Outcomes Questionnaire-VA; PTM, Progressive Tinnitus Management; RCT, randomized controlled trial; TFI, Tinnitus Functional Index; THI, Tinnitus Handicap Inventory; TTE, telephone tinnitus education; TRC, Tinnitus Research Consortium; VA, Veterans Affairs; WLC, wait-list control

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treatments include pharmaceutical drugs, specialized acoustic protocols, and various alternative methods such as electrical and magnetic stimulation (Folmer et al., 2014). By reducing the loudness of tinnitus, it is expected that reactions to tinnitus would also be reduced (Schmidt et al., 2014).

Prior to the year 2000, there were at least nine well-known questionnaires, each of which was statistically validated for intake assessment (Meikle et al., 2012). None, however, was validated for assessing outcomes, which would have required being prospectively designed and tested to maximize responsiveness to change in outcomes related to intervention. Further, these questionnaires did not cover all dimensions of tinnitus functional impact, and each differed with respect to formatting, scaling, and wording of individual items. These differences made it difficult to compare outcomes between clinics and between clinical trials, thus resulting in a lack of available systematic reviews, which are important to determine the clinical effectiveness of different interventions (Kamalski et al., 2010).

Some explanation is needed as to why none of these questionnaires was validated for responsiveness. The importance of measurement sensitivity and responsiveness was not fully recognized by researchers until the 1980s and 1990s. Lipsey (1990) provided guidance for selecting measures that would be sensitive to change in intervention studies. Lipsey and Cordray (2000) reported "the characteristics that make a measure sensitive to individual differences on a construct of interest are not necessarily the ones that make them sensitive to change on that construct over time" (p. 355). These concepts were not familiar to the tinnitus researchers who developed these original questionnaires. Since then, responsiveness and measurement sensitivity for intervention studies has been extensively researched.

To address this gap in current tinnitus questionnaires, the Tinnitus Research Consortium (TRC) in 2003 issued a Request for Proposals for a study to develop a new self-report questionnaire they pre-named the Tinnitus Functional Index (TFI). The TRC stipulated criteria for developing the TFI, most importantly that the new questionnaire be validated for use in intake assessment and for being sensitive/responsive to intervention-related changes in the functional effects of tinnitus resulting from intervention. Additionally, the TRC specified that the TFI: (1) employ 10 specific domains of negative tinnitus impact; (2) avoid overly-negative items (i.e., items that "catastrophize"); (3) not use items that refer only to hearing loss (and not tinnitus) or that pertain to more than one domain; (4) use only items having high construct validity for scaling of tinnitus severity; (5) use Likert-type response scales to provide high resolution of responses; and (6) use unambiguous wording that also addresses low health literacy.

In response to the Request for Proposals, Dr. Mary Meikle, tinnitus researcher at Oregon Health & Science University (OHSU) submitted a grant proposal to develop the TFI. Her application (with JAH as Co-Principal Investigator) was approved, and the study was funded in 2004.

The approach of the TFI study was based on the model used by Clark et al. (2003) to develop the Pain Outcomes Questionnaire-VA (POQ-VA). That study addressed the need for Veterans Affairs (VA) hospitals to have available a uniform method of measuring the effectiveness of treatment for chronic pain. The treatment of chronic pain was conceptualized as a complex phenomenon involving multiple domains (behavioral, perceptual, physical, psychosocial) of patient functioning, thus requiring the targeting of treatment to the different domains. The assessment of change within each major domain was preferred over a single outcome score because individuals exhibit different patterns of function/dysfunction across domains. With a single summary score, treatment-related changes in specific outcomes domains would be obscured. At the time the POQ-VA was developed, no pain outcomes instrument was capable of measuring treatment effectiveness within the different domains considered important to a person with chronic pain. As a consequence, pain practitioners used instruments that were developed and validated as clinical pain assessment tools to assess outcomes of treatment for pain. The authors conducted a 5-year study to develop the POQ-VA and to validate its reliability and validity for evaluating the effectiveness of treatment for chronic pain.

The study to develop the POQ-VA was conducted at six VA pain centers to ensure a sufficient number of subjects for valid statistical evaluation (Clark et al., 2003). A total of 957 subjects completed the POQ-VA using a two-stage, iterative process of data collection and analysis to refine the pool of potential items for the final instrument. Treatment was conducted at each center as per usual standard of care. This approach also resulted in more diverse, generalizable data. The project to develop and validate the TFI was similarly conducted at multiple sites, which included: Bay Pines VA Medical Center (BPVAMC), Bay Pines, FL; Cleveland Clinic (CC) Tinnitus Management Clinic, Cleveland, OH; Hearing and Speech Institute (HSI), Portland, OR; James A. Haley Veterans' Hospital (JAHVA), Tampa, FL; and OHSU Tinnitus Clinic, Portland, OR.

The CC Tinnitus Management Clinic and OHSU Tinnitus Clinic were "destination clinics" that were sought out by patients with severe reactions to tinnitus. To evaluate the ability of the TFI to assess the full range of patients with respect to differential reactions to tinnitus, sites were included whose patients would typically have less severe tinnitus: BPVAMC, HSI, and JAHVH. A necessary tradeoff was that the VA sites had mostly male patients.

There were three stages of TFI development: (1) item selection and design (construct Prototype 1); (2) test Prototype 1 to derive Prototype 2; (3) test Prototype 2 to derive final TFI. This collaborative effort required 4 years, and resulted in a publication describing details of TFI development and testing (Meikle et al., 2012). A condensed description of the three stages of work is presented herein, followed by TFI data obtained from an RCT and suggestions for clinical and research application of the TFI.

2. Stage 1: construct prototype 1

Design criteria for constructing the initial prototype included (1) responsiveness (include only items expected to have high sensitivity to treatment-related change); (2) high construct validity (each item should contribute to overall effectiveness in scaling of tinnitus severity); (3) comprehensive coverage (to address the outcomes domains most important to patients); (4) brevity (without compromising comprehensive coverage, limit questionnaire to 25 or fewer items); (5) good resolution for responsiveness—Likert-type 0–10 response scale preferred (Nunnally, 1978); (6) clarity of items – minimal reading difficulty; (7) simple scoring of items and of overall questionnaire; and (8) avoidance of overly negative thoughts in questionnaire items.

Three steps were involved in creating TFI Prototype 1: (1) consultation with measurement experts; (2) selection of items; and (3) construction of Prototype 1. The nine existing tinnitus questionnaires provided the initial pool of 175 items (questions) that were identified as addressing important topics. Selection of items to maximize construct validity followed published recommendations to use multiple expert judges and formalized scaling procedures to quantify their judgments (Haynes et al., 1995). Seventeen tinnitus experts agreed to serve on the Item Selection Panel, of which eight had previously been involved in developing tinnitus questionnaires.

Each Panel member reviewed all 175 items, using a website that was created for this purpose. Items had their own rating pages, which could be viewed in any order (with correction of previous