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REVIEW ARTICLE (META-ANALYSIS)

Systematic Review of Patient-Reported Outcome Measures in Clinical Vestibular Research

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Abstract

Objective: To identify the most commonly used patient-reported outcome (PRO) measures in clinical vestibular research, and to assess their test characteristics and applicability to the study of age-related vestibular loss in clinical trials.

Data Sources: We performed a systematic review of the PubMed, Cumulative Index to Nursing and Allied Health Literature, and PsycINFO databases from 1950 to August 13, 2013.

Study Selection: PRO measures were defined as outcomes that capture the subjective experience of the patient (eg, symptoms, functional status, health perceptions, quality of life). Two independent reviewers selected studies that used PRO measures in clinical vestibular research. Disparities were resolved with consensus between the reviewers. Of 2260 articles initially found in the literature search, 255 full-text articles were retrieved for assessment. Of these, 104 met inclusion criteria for data collection.

Data Extraction: PRO measures were identified by 2 independent reviewers. The 4 most commonly used PROs were evaluated for their applicability to the condition of age-related vestibular loss. Specifically, for these 4 PROs, data were collected pertaining to instrument test-retest reliability, item domains, and target population of the instrument.

Data Synthesis: A total of 50 PRO instruments were identified. The 4 most frequently used PROs were the Dizziness Handicap Inventory, Activities-specific Balance Confidence scale, Vertigo Symptom Scale-short form, and visual analog scale. Of these 4 PROs, 3 were validated for use in patients with vestibular disease and 1 was validated in community-dwelling older individuals with balance impairments. Items across the 4 PROs were categorized into 3 domains based on the *International Classification of Functioning, Disability and Health*: activity, participation, and body functions and structures.

Conclusions: None of the most commonly used PRO instruments were validated for use in community-dwelling older adults with age-related vestibular loss. Nevertheless, the 3 common domains of items identified across these 4 PRO instruments may be generalizable to older adults and provide a basis for developing a PRO instrument designed to evaluate the effectiveness of interventions targeted toward age-related vestibular loss. Archives of Physical Medicine and Rehabilitation 2015;■:■■■-■■■

Age-related vestibular loss is the reduction in vestibular function associated with the aging process. Studies suggest that age-related vestibular loss is a prevalent condition among community-dwelling older adults, particularly in individuals aged ≥80 years.[1,2] The 1-year prevalence of vestibular vertigo in adults 60 to 69 years old and adults ≥80 years old was reported as 7.2% and 8.8%, respectively.[2] A study using data that assessed balance function using the modified Romberg test demonstrated that 35% of U.S. adults ≥40 years old had balance dysfunction.[1] Age was positively associated with balance impairment, with nearly 85% prevalence of balance dysfunction in adults aged ≥80 years.

Older adults who are otherwise healthy have been shown to have an age-related decrease in vestibular response,[3] but the pathophysiology of age-related vestibular loss remains unclear, and age-related vestibular loss does not appear to be caused by a specific or known vestibular pathology.[4] The main clinical features of age-related vestibular loss include disequilibrium and dizziness, and age-related vestibular loss has also been associated with an increased risk of falling.[1,5] Very few studies have evaluated the potential for vestibular interventions to improve age-related

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vestibular loss.[6] Studies have largely focused on the benefit of vestibular interventions (eg, vestibular rehabilitation [VR]) for specific vestibular diseases (eg, Meniere disease, vestibular neuritis, unilateral deafferentation).

Objective outcome measures of vestibular function typically include computerized dynamic posturography, electronystagmography, and angular vestibuloocular reflex testing. However, studies suggest that these objective measures often do not concord with a patient's subjective experience and therefore may not fully capture the effect of an intervention on the quality of life of the patient with vestibular impairment.[7-9] The design of large-scale studies to evaluate the effectiveness of vestibular interventions for age-related vestibular loss will require the identification of appropriate outcome measures validated for use for this specific condition (age-related vestibular loss) and in this specific population (older adults).

Patient-reported outcomes (PROs) are an increasingly used category of outcome measure in VR intervention studies. PROs are outcome measures that capture the subjective experience of the patient, independent of external interpretation by assessors (eg, physician, therapist).[10] Types of outcomes that are measured by PROs include symptoms, functional status, health perceptions, and quality of life.[11] PROs may be especially valuable in patients with vestibular dysfunction, given that this disorder can manifest differently and have differential impact across individuals. Therefore, validated PRO instruments can be used to measure how vestibular disease is affecting the patient (ie, a discriminative instrument that can help differentiate patient groups, such as individuals with symptoms versus individuals without symptoms) and assess the effectiveness of vestibular interventions on the patient's subjective experience (ie, an evaluative instrument that is sensitive to changes in function after an intervention).[12] In this study we focus on evaluative PRO instruments, given our longer-term goal of using such an instrument in an intervention trial.

Methods

To identify PROs that may potentially be used in studies of age-related vestibular loss, we completed a systematic review of PRO instruments used in VR intervention studies. VR, given that it is one of the most commonly prescribed vestibular interventions, was the intervention of interest. We selected PROs that were used in >10 clinical trials to assess the effectiveness of VR; there were 4 PROs that met this criterion. The most frequently applied PROs represent the common measures used to compare VR in clinical trials as an intervention. We then evaluated whether these PROs could be applied for clinical effectiveness research for the treatment of age-related vestibular loss.

A literature search was performed using the PubMed, Cumulative Index to Nursing and Allied Health Literature, and PsycINFO electronic databases for publications up to August 13, 2013. *Vestibular rehabilitation* in parentheses was used as the search string. Two trained study team members independently reviewed all titles and abstracts and selected articles for full-text review based on inclusion and exclusion criteria. Inclusion criteria included the following: the authors conducted original research (ie, not a review study), the study population had vestibular disease, VR was used as an intervention, the study contained pre- and postintervention measurements of outcomes, and the outcome assessed was patient reported (ie, based on a patient's subjective experience, elicited through questionnaires, scales, and/or grading systems). The exclusion criteria were as follows: case studies, small case series (N<10), non-English language citations, and nonhuman studies. Discrepancies between reviewers were resolved by discussion between the 2 independent reviewers. Where disagreements could not be resolved, a third author provided input, and the discrepancy was resolved through consensus. A reference check was completed by examination of citations of the articles included and from relevant systematic reviews to ensure a thorough assessment of the literature.

The top 4 most heavily cited PRO instruments with a frequency of ≥10 articles using the outcome were identified. The most frequent PRO measures used in vestibular research likely represent outcomes that are thought to best assess the response of VR. Data from each of the 4 PRO instruments were abstracted, including number of items, methods used to develop the instrument, population in which instrument was validated, and test-retest reliability. Test-retest reliability broadly provides evidence of consistency and therefore may be useful in determining if the PRO studied measures the true effect of the vestibular intervention. Content, construct, and criterion validity were reviewed independently and were undertaken based on original studies reporting the development and validation of each instrument. The unique items in all 4 PRO instruments were identified and categorized into underlying domains according to the World Health Organization's *International Classification of Functioning, Disability and Health* (ICF).[13] The ICF provided a guide for organizing the PRO items into standardized categories. Our criteria for determining whether the PRO was applicable for research in age-related vestibular loss were as follows: Did the process of item generation involve direct surveying of patients through unstructured, qualitative interviews? Did the patients surveyed include older adults without a specific vestibular pathology (ie, older adults with vestibular loss associated only with the normative aging process)?

List of abbreviations:

ABC	**Activities-specific Balance Confidence**
DHI	**Dizziness Handicap Inventory**
ICF	***International Classification of Functioning, Disability and Health***
PRO	**patient-reported outcome**
VAS	**visual analog scale**
VR	**vestibular rehabilitation**
VSS-SF	**Vertigo Symptom Scale-short form**

Results

Study selection process

The initial search (fig 1) yielded 2260 articles. Of these, 85 were removed as duplicates. Analysis of references, including those from 2 systematic reviews,[14,15] identified 3 additional articles.[6,16,17] Screening of 2178 titles and abstracts led to the selection of 255 full-text articles for further assessment. Of these 255 articles, 104 were selected for final inclusion in the qualitative synthesis.

PRO instruments used in vestibular interventional research

Fifty different vestibular-related PRO measures used in clinical trials of VR were identified from these 104 articles (table 1). The 4 most commonly cited PRO instruments were the Dizziness