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Reported Hearing Outcome Measures Following Stereotactic Radiosurgery for Vestibular Schwannoma: A Scoping Review

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Abstract

Background Evidence on hearing outcome measures when assessing hearing preservation following stereotactic radiosurgery (SRS) for adults with vestibular schwannoma (VS) has not previously been collated in a structured review.

Objective The objective of the present study was to perform a scoping review of the evidence regarding the choice of hearing outcomes and other methodological characteristics following SRS for adults with VS.

Methods The protocol was registered in the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) and reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension guidelines for scoping reviews. A systematic search of five online databases revealed 1,591 studies, 247 of which met the inclusion criteria.

Results The majority of studies ($n = 213$, 86%) were retrospective cohort or case series with the remainder ($n = 34$, 14%) prospective cohort. Pure-tone audiometry and

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speech intelligibility were included in 222 (90%) and 158 (64%) studies, respectively, often summarized within a classification scheme and lacking procedural details. Fifty-nine (24%) studies included self-report measures. The median duration of follow-up, when reported, was 43 months (interquartile range: 29, 4–150).

Conclusion Evidence on hearing disability after SRS for VS is based on low-quality studies which are inherently susceptible to bias. This review has highlighted an urgent need for a randomized controlled trial assessing hearing outcomes in patients with VS managed with radiosurgery or radiological observation. Similarly, consensus and coproduction of a core outcome set to determine relevant hearing and communication outcome domains is required. This will ensure that patient priorities, including communication abilities in the presence of background noise and reduced participation restrictions, are addressed.

Introduction

Vestibular schwannomas (VSs) are the World Health Organization Grade 1 tumors arising from the vestibular component of the eighth cranial nerve, with a lifetime incidence of ~1/500.[1] The vast majority of these tumors are unilateral and arise sporadically but may also arise as part of tumor predisposition syndromes leucine-zipper-like transcription regulator 1 and neurofibromatosis type 2 (NF2)–Schwannomatosis.[2] These tumors present most often with audiological symptoms, typically hearing loss and tinnitus.[3] Even in patients with functional hearing at diagnosis, the vast majority progress to severe hearing loss within 5 years.[4]

Two therapeutic options are currently employed in an effort to attenuate the progressive hearing loss experienced by the majority of patients with VS: hearing preservation surgery and stereotactic radiosurgery (SRS).[5] SRS is an attractive option because it entails a single outpatient treatment session without general anesthetic and is associated with a low risk of complications such as facial nerve palsy.[6,7] Indeed, some SRS practitioners argue that SRS should be considered an "upfront" treatment at diagnosis for VS patients with serviceable hearing, citing excellent tumor control rates and improvement in the rates of hearing preservation compared with natural history.[8–12] However, the data on hearing outcomes following SRS for VS are largely based on single-center case series or matched cohort studies, with all of the biases and limitations this study design entails.[11,13] Large cohort studies of patients with conservatively managed VS also report similar or better hearing outcomes and a recent propensity-matched cohort study of patients managed with SRS or observation reported no difference in rates of serviceable hearing preservation during a median follow-up period of 38 months.[4,14–16] It is therefore unclear if SRS is associated with better hearing outcomes compared with untreated tumors.

A further limitation in study design is the lack of focus on issues of importance to patients, likely to include hearing difficulty when communicating in the presence of background noise, a common symptom of sensorineural hearing, particularly when asymmetric, and is associated with limited social interaction and increased isolation.[17–19] Community-based digits-in-noise tests revealed that 1 in 10 United Kingdom adults has some difficulty understanding speech in background noise,[20] and those with unilateral hearing loss have a particular difficulty in these listening environments.[21] In addition, the two most widely used hearing classification systems for patients with VS, the Gardner–Robertson (GR) scale and the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) scale, do not assess speech intelligibility in background noise.[22,23] Therefore, the degree to which the full range of issues arising from hearing loss is assessed is unclear, and was an area of particular focus for this review.

Previous systematic reviews and meta-analyses have reported the hearing outcomes following SRS for VS. However, they have not assessed what, when, and how best to measure hearing outcomes, mostly relying on reductive hearing classifications.[24–26] It is also unclear if minimal differences in outcome that are meaningful to the patient have been determined. The overarching aim of the present review was to scope the literature and identify knowledge gaps regarding domains, timing and choice of outcomes, and the reporting of minimal important differences (MIDs). For this reason, this evidence synthesis used a scoping review methodology. This information is required as a precursor to a systematic review as well as informing the choice of hearing outcome measures in future studies. A secondary aim involved documenting additional study characteristics including experimental design.

Methods

This scoping review was registered in the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY 2021120067). The methods were reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for scoping reviews.[27]

Eligibility Criteria

The eligibility criteria for the review were developed based on the PICOS elements (participant, intervention, comparator, outcome, and study design).[28]

- *Participant*: The participants of interest were adults who have been diagnosed with sporadic VS. Studies performed

with children or adults primarily diagnosed with NF2–schwannomatosis-associated VS were excluded.
- *Intervention*: The intervention of interest was SRS; other surgical and nonsurgical (e.g., fractionated radiotherapy) treatments for VS were excluded. Studies that combined SRS with other treatment methods were included.
- *Comparator*: There was no comparator of interest for this scoping review.
- *Outcome*: Hearing and tinnitus outcomes (e.g., hearing thresholds, speech recognition thresholds, and self-reported listening ability scores) were included; other audiovestibular outcomes, including vertigo, were excluded, as were studies that measured only generic outcomes (e.g., quality of life [QoL]).
- *Study design*: All peer-reviewed primary research publications were eligible for inclusion. Book chapters, dissertations, conference proceedings, and white papers were excluded. Non-English publications were excluded.

Information Sources
The following databases were systematically searched (on December 8, 2021) to identify relevant studies: PubMed, PsycINFO, EMBASE, EMCare, Web of Science, and Cochrane Library. No search restrictions were imposed in terms of age, sex, publication date, or status. However, when necessary, nonhuman studies were filtered out.

Search Strategy
The search strategy was developed by a medical information scientist, in consultation with the review team. Where appropriate, both controlled vocabularies (e.g., medical subject headings) and free text words were used to develop a comprehensive search protocol. The search protocols used are reported in Supplementary Content 1.

Selection Process
The titles and abstracts of all retrieved references were screened for inclusion by two independent reviewers, who then reviewed the full text of all studies passing the screening stage. On rare occasions (<5% of screened titles/abstracts and <2% of full texts), disagreements were resolved by discussion between the two reviewers.

Data Collection Process, Data Items, and Data Synthesis
Data were extracted by two reviewers, and 10% of extracted data were verified by a third independent reviewer. Discrepancies (accounted for <1%) were resolved by discussion. All extracted data were aggregated and reported narratively. As this evidence synthesis used a scoping review methodology, no formal critical appraisal of quality was conducted.[29]

Results

Following our literature search and removal of duplicates, 1,591 studies were screened with, 1,344 excluded, leaving 247 for inclusion in the scoping review (►**Fig. 1**). The number of retrieved records from each database is reported in Supplementary Content 2.

Study Design
None of the studies was randomized controlled trials (RCTs). The majority (213/247, 86%) were retrospective cohort studies or case series, with the remainder (34/247, 14%) composed of prospective cohort studies.

Hearing Outcomes
►**Table 1** summarizes the proportion of studies reporting hearing outcomes categorized as hearing sensitivity, speech intelligibility, and self-report outcomes (full details in Supplementary Content 3). Out of 247, 222 (90%) studies included pure-tone audiometry (PTA) as a measure of hearing sensitivity, most commonly as part of the GR, AAO-HNS, and/or 2003 consensus meeting in Tokyo classifications (181/247, 73%). However, details of the audiometric frequencies used were reported in only 44/247 (18%) studies, and summary statistics of the hearing thresholds (e.g., mean and range) were reported in 60/247 (24%). A smaller proportion of studies (158/247, 64%) assessed speech intelligibility, again most commonly as part of the GR or AAO-HNS classification. However, few studies (27/247, 11%) reported summary statistics of the speech intelligibility results, and even fewer (5/247, 2%) described the test procedure with respect to stimuli and presentation level. No study specifically mentioned speech intelligibility in background noise.

Out of 247, 59 (24%) studies included postoperative self-reported hearing loss or tinnitus; however, only 4/247 (2%) used a validated scale such as Tinnitus Handicap Inventory.[30] None of the studies demonstrated evidence of having calculated minimal clinically important differences for any hearing outcome.

Follow-up Duration
The mean/median follow-up duration varied between studies, with some reporting lengths as short as 1 month and as long as 252 months. The median follow-up of included studies was 43 months (interquartile range: 29, 4–150) (►**Fig. 2**).

Discussion

This scoping review of more than 240 studies is important because the argument is increasingly being made that SRS at the time of VS diagnosis in patients with preserved hearing may offer an improvement in long-term hearing outcomes compared with the natural history of hearing loss associated with these tumors.[8,10] However, it remains unclear if the outcome domains and measures adequately reflect: (1) functional impairment, (2) limitations in abilities, and (3) restricted participation following SRS for VS. The review highlights the reliance on PTA as a measure of functional impairment, often provided within a classification scheme without a summary statistic, and lacking a description of test methods, such as which test frequencies have been included. Around two-thirds of studies reported speech intelligibility,[1]

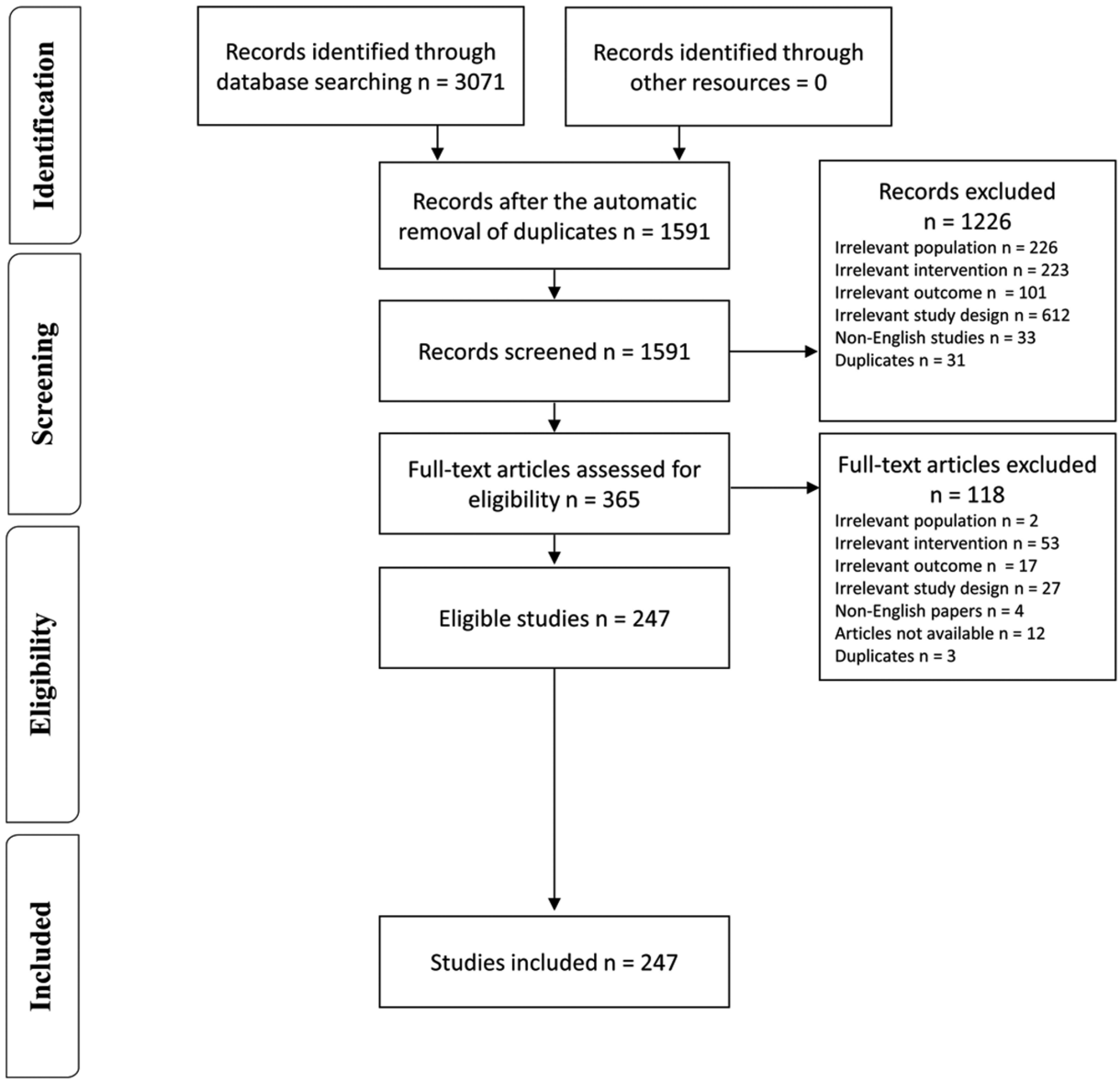

Fig. 1 Flow diagram of the selection process based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. Note: *n*, number of studies.

again without summary statistics or a description of the test methods.

With respect to study design, we did not identify any prospective RCT reporting hearing outcomes following SRS for VS. The majority (86%) were retrospective cohort studies; therefore, the current evidence on hearing disability after SRS for VS is based on low-quality, class 3 studies which are inherently susceptible to selection bias and loss to follow-up.[31] There is an urgent requirement for an RCT to investigate whether SRS influences progression of hearing loss following diagnosis of VS. We note that the "vestibular schwannoma-radiosurgery or expectation" study which compared these two treatment strategies in patients with newly diagnosed VS and included the assessment of GR hearing class as a secondary outcome has completed and the results are awaited.[32] Although this RCT will deliver high-quality evidence to inform the management of newly diagnosed VS, it was not powered to detect a change in hearing outcomes between both groups and its use of the GR scale to assess hearing outcomes means that the evidence it will provide with respect to hearing outcomes that are of particular relevance to patients with VS may be limited.

It is not surprise that the ubiquitous PTA was reported in 90% of studies. However, there was a considerable lack of consistency and reporting on how the pure-tone hearing thresholds were averaged. Hearing preservation rates may be over- or underestimated based on averaged audiometric frequencies as some frequencies tend to deteriorate more severely than others following irradiation. Such variation in calculation methods could limit the usefulness of comparing, pooling, and analyzing data from different studies. In addition, we know hearing threshold levels are not good predictors of some aspects of hearing, especially the common task of listening to speech in the presence of background

Table 1 Proportion of studies reporting measures of hearing sensitivity, speech intelligibility, and self-reported outcomes

		Number of studies (%)
Total number of studies		247 (100%)
Hearing sensitivity	Measured hearing sensitivity	222 (89.8%)
	Reported the tested audiometric frequencies and those used to calculate PTAs	44 (17.8%)
	Reported hearing thresholds (e.g., actual PTAs, mean, and ranges)	60 (24.3%)
	Reported the tested side(s)	13 (5.2%)
Speech intelligibility	Tested speech intelligibility	158 (63.9%)
	Reported the used procedure (e.g., stimuli, presentation level and scoring procedure)	5 (2%)
	Reported speech ineligibility findings (e.g., actual, mean, and ranges)	27 (11.3%)
	Reported testing in background noise	0 (0%)
Self-reported	Reported using a self-reported outcome	59 (23.8%)
	Reported using a validated tool to measure self-reported outcome	4 (1.6%)
Used GR, AAO-HNS, and/or 2003 consensus meeting in Tokyo classifications		181 (73.2%)
Measured minimal clinical important difference		0 (0%)

Abbreviations: AAO-HNS, American Academy of Otolaryngology-Head and Neck Surgery; GR, Gardner–Robertson; PTA, pure-tone average.
Note: The majority of studies refer to "discrimination score" but throughout the review, we use "intelligibility score" to differentiate the common clinical speech task of repeating individual words presented in quiet from discrimination tasks that involve resolving differences in speech sounds (e.g., /da/ /ba/) at suprathreshold presentation levels.

noise (the latter often disproportionately affected by neural hearing loss).[19,33] This is because the impaired auditory system not only results in decreased audibility, as revealed by elevated hearing thresholds, but also poorer discrimination.[34] The significance of this is that even when speech and noise have different frequencies, the brain is unable to untangle the speech from the noise. Speech intelligibility was reported in two-thirds of studies. The specifics of the test procedure were rarely described, which is a limitation because performance is critically dependent on multiple aspects, including the presentation level (threshold vs. suprathreshold), presentation methods (recorded vs. live voice), type of test materials (sentences vs. words), and scoring techniques (phoneme vs. word). For example, it has been found that performance is higher for sentences than words and both higher than syllables, for a given presentation level or signal-to-noise ratio (e.g., Amlani et al, 2002).[35] Despite the primary complaint of people with sensorineural hearing loss often having difficulty understanding speech in background noise[20] (e.g., digits-in-noise tests), no study reported this outcome. Furthermore, this outcome can easily and accurately be recorded remotely, given that speech-in-noise tests are less likely to be affected by a lack of transducer calibration and noisy test environments.[36] The antiphasic version of the bilateral digits-in-noise tests can also provide greater insight into the type of hearing loss, as most individuals with unilateral sensorineural and conductive hearing loss lack the binaural antiphasic processing advantage compared with normal hearing listeners.[37]

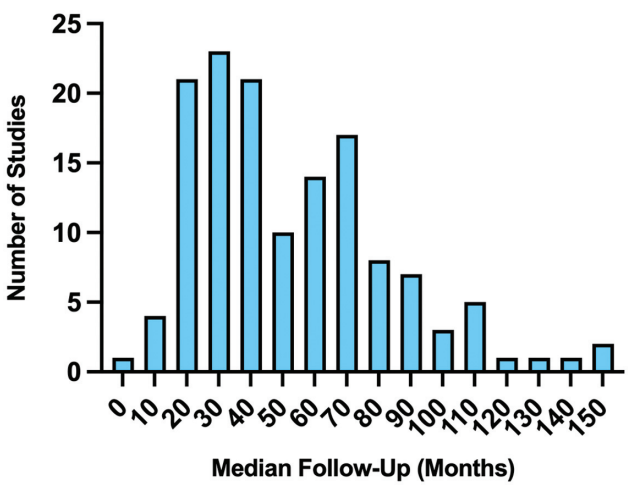

Fig. 2 Histogram demonstrating the frequency distribution of the median follow-up duration of included studies, where reported ($n = 139$). The median follow-up duration was 43 months (interquartile range 29, 4–150).

An additional challenge for patients with asymmetric hearing loss, such as those with a unilateral VS, is the loss of binaural hearing. Without the ability to resolve the signals sent from each ear, it becomes difficult to separate the target signal from competing noise. It also becomes difficult to localize the location from which sounds are generated. This significantly reduces performance compared with binaural hearing. No study specifically reported speech intelligibility on a binaural hearing task or the directional hearing abilities of included patients.

Despite the importance and widespread use of validated self-report measures in other areas of health care, there was limited evidence of their use in VS studies. We know, for example, individuals with sensorineural hearing loss self-report high levels of listening effort and fatigue in everyday

life.[38] The similarity in listening-related effort and fatigue between those with symmetrical and asymmetrical hearing loss suggests that these aspects of listening experience cannot be predicted by hearing threshold levels or speech intelligibility tasks.

The limited use and reporting of outcomes may be due, at least in part, to a lack of a core outcome set (COS). To date, there is no consensus about which outcome domains should be measured, when they should be measured, and how they should be measured. This review suggests that services have primarily focused on the opinions and expertise of clinicians, rather than patient-centered outcomes, codesigned by stakeholders including patients, carers, health care providers, and researchers. A COS for assessment of hearing rehabilitation in adults with hearing loss, based on the views and consensus from a range of stakeholders, identified the key outcome domains of communication ability, personal relationships, well-being, and reduced participation restrictions.[39]

While outcomes in study trials may yield statistically significant differences between treatment groups, this does not mean the difference is meaningful to the patient. Jaeschke et al (1989) developed the concept of MIDs to aid the interpretation of trial findings.[40] An MID is defined as "*the smallest difference in score in the outcome of interest that patients (or informed proxies) perceive as important, either beneficial or harmful, and which would lead the patient or clinician to consider a change in the management*."[41] To assist with interpretation of VS QoL studies, Carlson et al (2015) reported reference MID data for the Penn Acoustic Neuroma Quality of Life and 36-item Short Form Health Survey.[42] Reference MID data for hearing outcomes in VS studies have yet to be determined.

The GR and AAO-HNS classification schemes are in widespread use, but it is not clear that studies always base classification on the combination of both PTA and speech intelligibility, as intended. Both schemes reduce continuous patient variables into fixed categories, reducing granularity,[24] although this can be addressed by plotting these continuous variables on a scatterplot.[43] However, an underlying limitation to both schemes is the assumption that hearing threshold levels and speech intelligibility in quiet are the primary outcomes of interest to the patient and are related to QoL. Peris-Celda et al revealed that relatively modest elevation of hearing thresholds adversely affects QoL.[17] This suggests the term "hearing preservation" may be being used inappropriately in VS studies. Also, the term "serviceable hearing" commonly used with these schemes is problematic: Peris-Celda et al demonstrated no difference in QoL between patients with classification B and C (serviceable and not serviceable hearing, respectively).[17] In addition, these two classification schemes do not take into account hearing sensitivity at frequencies above 3 kHz, which are the most commonly affected frequencies in patients with VS and tend to deteriorate more severely after irradiation.[44–46]

Of concern is the relatively short duration of follow-up that may prevent meaningful comparison with the natural history. Around half of the studies report a median follow-up duration, and this is typically <4 years. However, we know from national registry studies that hearing loss associated with VS continues for at least 10 years following diagnosis.[4,47] Moreover, it is clear that there is a progressive decline in hearing function after SRS: in a retrospective cohort study of 92 patients who underwent serial audiograms following SRS for VS during a median follow-up period of 106 months, the authors reported a 5-year rate of "serviceable" hearing preservation of 57% that declined to 44% at 10 years.[48] A similar study of 117 patients who underwent the same intervention and were followed up for a median duration of 38 months reported 3-, 5-, and 8-year hearing preservation rates of 55, 43, and 34%, respectively.[49] Therefore, it is unlikely that a study with hearing outcomes <5 years will permit any meaningful conclusions to be drawn. While patient dropout is common in longitudinal studies,[50] using remote hearing tests that are robust against calibration and background noise issues (e.g., digits-in-noise tests and self-report outcomes) may remove the burden of unnecessary clinical visits; hence, improving retention rates and providing greater insight into long-term postirradiation hearing outcomes.[51]

Finally, our review deviated from the preregistered protocol in two areas:

1. The intention was to report dose-related changes in hearing following SRS, but this was ultimately omitted because many of the systematic reviews identified in our search had already partially addressed this question (e.g., Carlson et al, 2018 and Mahboubi et al, 2017), and there were large variations in how studies reported changes in hearing loss.[5,52]
2. We did not track citations or screen reference lists, as our comprehensive search strategy captured numerous papers; the identification of additional references was not felt to be likely to alter the overall conclusion of the review.

Conclusion

Despite numerous studies, there is a dearth of high-quality RCTs reporting on hearing and indeed other outcomes following SRS for VS. In addition, consensus has yet to be reached on what, when, and how hearing outcomes should be measured and reported. A notable omission is a measure of communication in background noise, the primary complaint of adults with sensorineural hearing loss, and likely to be exacerbated in cases of asymmetric hearing loss where binaural cues are disrupted. Finally, minimum important differences that are meaningful to the patient have yet to be established for most hearing outcome measures.

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Conflict of Interest
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