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Unilateral Cochlear Implants for Severe, Profound, or Moderate Sloping to Profound Bilateral Sensorineural Hearing Loss
A Systematic Review and Consensus Statements

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IMPORTANCE Cochlear implants are a treatment option for individuals with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss (SNHL) who receive little or no benefit from hearing aids; however, cochlear implantation in adults is still not routine.

OBJECTIVE To develop consensus statements regarding the use of unilateral cochlear implants in adults with severe, profound, or moderate sloping to profound bilateral SNHL.

DESIGN, SETTING, AND PARTICIPANTS This study was a modified Delphi consensus process that was informed by a systematic review of the literature and clinical expertise. Searches were conducted in the following databases: (1) MEDLINE In-Process & Other Non-Indexed Citations and Ovid MEDLINE, (2) Embase, and (3) the Cochrane Library. Consensus statements on cochlear implantation were developed using the evidence identified. This consensus process was relevant for the use of unilateral cochlear implantation in adults with severe, profound, or moderate sloping to profound bilateral SNHL. The literature searches were conducted on July 18, 2018, and the 3-step Delphi consensus method took place over the subsequent 9-month period up to March 30, 2019.

MAIN OUTCOMES AND MEASURES A Delphi consensus panel of 30 international specialists voted on consensus statements about cochlear implantation, informed by an SR of the literature and clinical expertise. This vote resulted in 20 evidence-based consensus statements that are in line with clinical experience. A modified 3-step Delphi consensus method was used to vote on and refine the consensus statements. This method consisted of 2 rounds of email questionnaires and a face-to-face meeting of panel members at the final round. All consensus statements were reviewed, discussed, and finalized at the face-to-face meeting.

RESULTS In total, 6492 articles were identified in the searches of the electronic databases. After removal of duplicate articles, 74 articles fulfilled all of the inclusion criteria and were used to create the 20 evidence-based consensus statements. These 20 consensus statements on the use of unilateral cochlear implantation in adults with SNHL were relevant to the following 7 key areas of interest: level of awareness of cochlear implantation (1 consensus statement); best practice clinical pathway from diagnosis to surgery (3 consensus statements); best practice guidelines for surgery (2 consensus statements); clinical effectiveness of cochlear implantation (4 consensus statements); factors associated with postimplantation outcomes (4 consensus statements); association between hearing loss and depression, cognition, and dementia (5 consensus statements); and cost implications of cochlear implantation (1 consensus statement).

CONCLUSIONS AND RELEVANCE These consensus statements represent the first step toward the development of international guidelines on best practices for cochlear implantation in adults with SNHL. Further research to develop consensus statements for unilateral cochlear implantation in children, bilateral cochlear implantation, combined electric-acoustic stimulation, unilateral cochlear implantation for single-sided deafness, and asymmetrical hearing loss in children and adults may be beneficial for optimizing hearing and quality of life for these patients.

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Hearing loss is one of the leading causes of disability worldwide, occurring in 466 million people (6% of the total population).[1] Hearing loss substantially alters people's lives, resulting in (but not limited to) communication difficulties,[2] social isolation,[3] depression,[4] falls,[5] and increased health care use.[6]

Sensorineural hearing loss (SNHL) is associated with dysfunction of the cochlea, auditory nerve, or central auditory pathways. In many cases, SNHL in adults is attributed to presbycusis,[7-9] and its cause can be genetic or environmental.[10] The estimated prevalence of SNHL in adults ranges from 0.07% to 5.2% across different countries and increases with age.[11-13]

Cochlear implants are the most successful neuroprosthesis used across health care.[14] They can provide benefit to individuals with severe, profound, or moderate sloping to profound bilateral SNHL who receive little or no benefit from hearing aids[15] by directly stimulating the auditory nerve, bypassing injured hair cells of the cochlea, and providing salient coded information for better speech perception.[16]

International guidelines on adult cochlear implantation candidacy are limited, and country-specific guidelines vary and are associated with disparate levels of access and systemic underuse across the world.[7,17-19] Barriers to access include low awareness and understanding of the benefits associated with cochlear implantation in individuals with SNHL, little knowledge of the surgical candidacy criteria among health care professionals, and a lack of defined care pathways.[20,21]

An international group of clinical experts in the fields of otology, audiology, and hearing science who have extensive clinical and scientific experience of cochlear implantation were brought together to form a Delphi consensus panel. The aim of the group was to use a modified Delphi method to develop a series of consensus statements regarding the use of unilateral cochlear implants to treat severe, profound, or moderate sloping to profound bilateral SNHL. The objectives of our article are to describe the findings of this international Delphi consensus study on cochlear implant use in adults and to present the resulting consensus statements agreed on by the Delphi consensus panel.

Key Points

Question How can we improve awareness about the potential advantages of cochlear implants in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss?

Findings A Delphi consensus panel of 30 international specialists voted on statements about cochlear implant use, informed by a systematic review of the literature and clinical expertise. This vote resulted in 20 evidence-based consensus statements that are in line with clinical experience.

Meaning The consensus statements provide recommendations on the use of unilateral cochlear implants in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss; they could inform the development of clinical practice guidelines, which could increase access to cochlear implantation worldwide and improve hearing and quality of life in eligible adults.

Methods

Overview

This study involved a modified Delphi consensus process that was informed by a systematic review (SR) of the literature and clinical expertise. We carried out a 3-step Delphi consensus method, which was modified to include 2 rounds of email questionnaires and a face-to-face meeting of panel members at round 3 (eFigure 3 in the Supplement), which took place over a 9-month period from July 18, 2018, to March 30, 2019. The Delphi consensus panel consisted of 30 international specialists who voted on consensus statements about cochlear implantation.

The face-to-face meeting allowed for discussion of the consensus statements and subsequent consensus statement refinement, as needed. The process was also modified to include an SR of evidence relevant to adults with severe, profound, or moderate sloping to profound bilateral SNHL to support consensus statement development.

Delphi Consensus Panel, Chair, and Steering Committee

The Delphi consensus panel comprised clinical experts in cochlear implantation from the fields of otology, audiology, and hearing science, who contributed to the development of the consensus statements (eMethods in the Supplement). Four clinical experts (1 audiologist [R.H.G.] and 3 otolaryngologists [D.S.H., T.L., and G.O.]) were identified by the chair (C.A.B.) to form the steering committee of the Delphi consensus panel.

The steering committee was responsible for identifying candidates to complete the Delphi consensus panel, who were representative of different geographic regions and practice types (5 audiologists [A.B., M.H., J.L., H.T., and T.Z.] and 21 otolaryngologists [O.A., R.J.B., M.L.C., P.D., C.L.D., H.W.F., B.J.G., R.K.G., M.R.H., E.K., M.K., E.A.M.M., J.T.R., S.R.S., H.S., P.H.S., M.S., P.H.V., C.V., H.W., and T.Y.]) and were selected to achieve a mix of male and female Delphi consensus panel members. The steering committee was also responsible for designing and finalizing the Delphi consensus protocol and approving the SR areas of interest.

All members of the steering committee and the Delphi consensus panel (except the chair) were able to vote in the consensus process. Voting on the draft consensus statements took place over 3 rounds (eFigure 1 and eMethods in the Supplement).

SR of the Literature

Search Strategy

An SR was performed to identify studies relevant to at least 1 of 6 key areas of interest. These areas included (1) level of awareness of cochlear implantation, (2) best practice clinical pathway from diagnosis to surgery, (3) best practice guidelines for surgery, (4) best practice guidelines for rehabilitation, (5) factors that change cochlear implant performance and outcomes, and (6) cost implications of cochlear implantation.

The literature searches (eTable 1 in the Supplement) were conducted on July 18, 2018, in 3 electronic databases. These databases included (1) MEDLINE In-Process & Other Non-Indexed Citations and Ovid MEDLINE (1946 to present); (2) Embase (1974 to present); and (3) Cochrane Library, comprising Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of

Effects (DARE), Cochrane Central Register of Controlled Trials (CENTRAL), National Health Service Economic Evaluation Database (NHS EED), the Health Technology Assessment (HTA) database, and the American College of Physicians (ACP) journal club. Consensus statements on cochlear implantation were developed using the evidence identified.

The SR protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO).[22] It is fully adherent to the 2009 Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guideline.

Eligibility Criteria, Data Extraction, and Consensus Statement Development

The title and abstract of the identified publications were screened manually against prespecified eligibility criteria (eTable 2 in the Supplement). The literature searches were limited to human studies published in English and conducted in Australia, Canada, China, Europe, India, Japan, the United Kingdom, and the United States. Systematic reviews of observational studies, prospective and retrospective studies, and cross-sectional and longitudinal studies were included. Full-text versions of all publications meeting the eligibility criteria at initial screening were reviewed to confirm eligibility. Key exclusions included studies with the following characteristics: studies with sample sizes smaller than 20; case studies, case series, and narrative reviews; studies published before 2005 (so that only studies on new-generation technology were included); studies limited to pediatric populations; studies of hearing preservation; and studies on bilateral cochlear implantation, electroacoustic stimulation or hybrid hearing, and single-sided deafness with tinnitus suppression.

Data relevant to the 6 key areas of interest were extracted manually from the included studies. Consensus statements were drafted based on the findings.

Quality Assessment of the Evidence

Quality assessment (QA) was conducted on all included studies at the full-text review stage using a modification of the method described by Eubank et al.[23] This method has previously been used in a Delphi consensus study[23] and includes assessment criteria for a wide range of study types. The literature was rated on the basis of study design. Each study was assigned a numerical score from 1 to 5, with 1 being the highest-quality evidence and 5 being the lowest-quality evidence (eTable 3 in the Supplement).

The method by Eubank et al[23] was adapted to include survey-based studies, which were ranked as level 5 because they generate databases on expert opinion. The method was also modified to include economic-based studies and to differentiate between retrospective prognostic studies (level 2) and retrospective therapeutic studies (level 3), as described by Wright et al.[24] The QA rating for the evidence supporting each consensus statement was made available to the Delphi consensus panel at each voting stage.

Results

All voting members of the Delphi consensus panel participated in at least one round of voting. Details are given in the eResults in the Supplement. In total, 6492 articles were identified in the searches of the electronic databases (eFigure 1 in the Supplement). After removal of duplicates, 74 articles fulfilled all of the inclusion criteria and were used to create the 20 evidence-based consensus statements. Some of these articles were relevant to more than 1 category (eTable 4 in the Supplement).

The 74 articles selected for inclusion underwent QA (eTable 3 in the Supplement). Four studies were categorized as level 1 (highest quality), 29 studies as level 2, 32 studies as level 3, 7 studies as level 4, and 2 studies as level 5 (lowest quality). All references are outlined in the Supplement.

In total, 21 consensus statements were developed based on the evidence identified in the SR and were included in the Delphi voting rounds (eFigure 2 and eTable 5 in the Supplement). After 3 voting rounds, 20 consensus statements were agreed on and endorsed by the Delphi consensus panel (**Table**).

The evidence identified as being associated with the SR categories *best practice guidelines for rehabilitation* and *factors that affect cochlear implant performance and outcomes* was used to develop consensus statements associated with 3 key area subtopics. These included (1) clinical effectiveness of cochlear implants, (2) factors associated with postimplantation outcomes, and (3) association between hearing loss and depression, cognition, and dementia. Therefore, the 20 consensus statements on the use of unilateral cochlear implants in adults with SNHL were relevant to the following 7 key areas of interest: level of awareness of cochlear implantation (1 consensus statement); best practice clinical pathway from diagnosis to surgery (3 consensus statements); best practice guidelines for surgery (2 consensus statements); clinical effectiveness of cochlear implantation (4 consensus statements); factors associated with postimplantation outcomes (4 consensus statements); association between hearing loss and depression, cognition, and dementia (5 consensus statements); and cost implications of cochlear implantation (1 consensus statement).

Level of Awareness of Cochlear Implantation

Statement 1: Awareness of cochlear implantation among primary and hearing health care clinicians is inadequate, leading to underidentification of eligible candidates. Clearer referral and cochlear implantation candidacy pathways would help increase access to cochlear implants.

As expected, the SR identified few published articles addressing awareness of cochlear implantation. To develop this consensus statement, the Delphi consensus panel supplemented the data identified in the SR with their understanding and experience of awareness of cochlear implantation among health care clinicians.

According to evidence found in the SR, the duration of hearing loss before an individual receives a cochlear implant has been increasing over time; this practice is thought to be primarily associated with a low general awareness of cochlear implantation and little knowledge about candidacy criteria for the procedure.[25] Cohen et al[26] reported that a large proportion of primary care physicians do not routinely screen for hearing loss in adults, and only one-quarter of physicians had referred patients for implant evaluation, which most commonly were attributed to uncertainties about where to refer and identification of patients who were potential candidates.

Best Practice Clinical Pathway From Diagnosis to Surgery

Statement 2: Detection of hearing loss in adults is important; pure-tone audiometry screening methods are considered the

Table. Results for Each Consensus Statement in Voting Rounds 1, 2, and 3

Consensus statement[a]	Voting round 1	Voting round 2	Voting round 3
Statement 1: Awareness of cochlear implantation among primary and hearing health care clinicians is inadequate, leading to underidentification of eligible candidates. Clearer referral and cochlear implantation candidacy pathways would help increase access to cochlear implants.	Consensus statement reached ≥75% agreement (95.5%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 2: Detection of hearing loss in adults is important; pure-tone audiometry screening methods are considered the most effective. The addition of a questionnaire or interview to the screening can improve the detection of SNHL.	Consensus statement reached ≥75% agreement (86.4%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by the majority of the Delphi consensus panel (87.5%)
Statement 3: Preferred aided speech recognition tests for cochlear implant candidacy in adults include monosyllabic word tests and sentence tests conducted in quiet and noise. Further standardization of speech recognition tests is needed to facilitate comparison of outcomes across studies and countries.	Consensus statement reached ≥75% agreement (81.8%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 4: Age alone should not be a limiting factor to cochlear implant candidacy because positive speech recognition and QOL outcomes are experienced by older adults as well as younger adults.	Consensus statement reached ≥75% agreement (100%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by the majority of the Delphi consensus panel (95.8%)
Statement 5: Both curved (perimodiolar) and straight electrodes are clinically effective for cochlear implantation, with a low rate of complications.	Consensus statement reached ≥75% agreement (95.5%), with no feedback for rewording	NI	NI
Statement 6: When possible, hearing preservation surgery can be beneficial in individuals with substantial residual hearing.	Consensus statement reached ≥75% agreement (86.4%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 7: Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with severe, profound, or moderate sloping to profound bilateral SNHL; these gains in speech recognition are likely to remain stable over time.	Consensus statement reached ≥75% agreement (95.5%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 8: Both word and sentence recognition tests should be used to evaluate speech recognition performance after cochlear implantation.	Consensus statement reached ≥75% agreement (90.9%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 9: Cochlear implants significantly improve overall and hearing-specific QOL in adults with severe, profound, or moderate sloping to profound bilateral SNHL.	Consensus statement reached ≥75% agreement (95.5%), with feedback for rewording	NI	NI
Statement 10: Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize postimplantation speech recognition.	Consensus statement reached ≥75% agreement (100%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 11: Where appropriate, individuals should use hearing aids with their cochlear implant to achieve bilateral benefits and the best possible speech recognition and QOL outcomes.	Consensus statement reached ≥75% agreement (100%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 12: Many factors impact cochlear implantation outcomes; further research is needed to understand the magnitude of the effects.	Consensus statement reached ≥75% agreement (77.3%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by the majority of the Delphi consensus panel (95.8%)
Statement 13: Long durations of unaided hearing loss do not rule out potential benefit of cochlear implants: individuals who receive an implant in an ear that was previously unaided for more than 15 y have been shown to experience improvements in speech recognition.	Consensus statement reached ≥75% agreement (81.8%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 14: Adults who have undergone cochlear implantation should receive programming sessions, as needed, to optimize outcomes.	Consensus statement reached <75% agreement (36.4%) and was revised based on feedback	Consensus statement reached ≥75% agreement (77.8%), with feedback for rewording	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)

(continued)

most effective. The addition of a questionnaire or interview to the screening can improve the detection of SNHL.

Methods for hearing loss detection in adults are heterogeneous, are based on region-level and country-level practices, and may

Table. Results for Each Consensus Statement in Voting Rounds 1, 2, and 3 (continued)

Consensus statement[a]	Voting round 1	Voting round 2	Voting round 3
Statement 15: Adults with hearing loss can be substantially affected by social isolation, loneliness, and depression; evidence suggests that treatment with cochlear implants can lead to improvement in these aspects of well-being and mental health. Longitudinal studies are needed to obtain further knowledge in this area.	Consensus statement reached ≥75% agreement (95.5%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by the majority of the Delphi consensus panel (95.8%)
Statement 16: There is an association between age-related hearing loss and cognitive or memory impairment.	Consensus statement reached ≥75% agreement (77.3%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 17: Further research is required to confirm the nature of cognitive impairment in individuals with hearing loss and its potential reversibility with treatment.	Consensus statement reached ≥75% agreement (100%), with no feedback for rewording	NI	NI
Statement 18: The use of cochlear implants may improve cognition in older adults with bilateral severe to profound SNHL.	Consensus statement reached ≥75% agreement (100%), with no feedback for rewording	NI	NI
Statement 19: Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia.	Consensus statement reached ≥75% agreement (77.3%), with feedback for rewording	NI	The consensus statement was reworded after Delphi consensus panel discussion, and the revised wording was voted for by all of the Delphi consensus panel (100%)
Statement 20: Unilateral cochlear implantation in adults is cost-effective compared with no implant or no intervention at all and is associated with increased employment and income.	Consensus statement reached ≥75% agreement (95.5%), with no feedback for rewording	NI	NI
Statement 21: Some evidence suggests that the risk of social isolation and depression is higher in women with hearing loss than in men with hearing loss; while this should not affect referral decisions, it should be taken into account when offering counseling to cochlear implantation candidates.[b]	Consensus statement reached <75% agreement (59.1%) and was revised based on feedback	Consensus statement reached <75% agreement (70.4%) and was revised based on feedback	Consensus statement reached <75% agreement (16.7%) and was not endorsed by the Delphi consensus panel

Abbreviations: NI, not included in the voting round; QOL, quality of life; SNHL, sensorineural hearing loss.

[a] Consensus statement wording included in the Table is the final endorsed version of the consensus statement.

[b] Statement 21 did not reach the agreement threshold at voting round 3 and was not endorsed by the Delphi consensus panel.

be applied to the general population or only to high-risk groups. The evidence identified as part of the SR suggested that screening for hearing loss in adults is important for identification of potential candidates for cochlear implantation[27] and cost-effective.[28] However, some of these data only apply to occupational screening in individuals who are at high risk of hearing loss owing to high noise levels in the workplace.[27] The Delphi consensus panel noted that it is important to identify adults with hearing loss who could benefit from cochlear implantation even in those regions without routine hearing screening and that the addition of questionnaires may be beneficial.

Statement 3: Preferred aided speech recognition tests for cochlear implant candidacy in adults include monosyllabic word tests and sentence tests conducted in quiet and noise. Further standardization of speech recognition tests is needed to facilitate comparison of outcomes across studies and countries.

The evidence identified in the SR highlighted inconsistencies in the word and sentence recognition tests used to assess cochlear implantation candidacy between regions, countries, and clinics.[29,30] The most commonly used assessments were reported to be the Consonant-Vowel Nucleus-Consonant (CNC) word test,[31] the AzBio sentence test,[32] and the Hearing in Noise Test.[33] Less commonly used tests were reported to include the Bamford-Kowal-Bench Speech-in-Noise Test[34-36] and the City University of New York sentences.[29]

Each test has a place in identifying adult cochlear implantation candidates; however, the Delphi consensus panel noted that standardized speech recognition tests (word and sentence) using 60-dB sound pressure level presentation and recorded speech would improve consistency in the assessment of cochlear implantation candidacy. It should also be noted that scoring below the threshold on a speech recognition test does not necessarily mean that the individual would benefit from a cochlear implant as discussed in statements 4 and 12. It is important that aided speech recognition tests using appropriately verified hearing aids are completed by adults who are not receiving adequate benefit to identify those who may be candidates for cochlear implantation.

Statement 4: Age alone should not be a limiting factor to cochlear implant candidacy because positive speech recognition and quality-of-life (QOL) outcomes are experienced by older adults as well as younger adults.

Four studies[37-40] reported that there are improvements in hearing performance and QOL observed in older age groups (>65 years, >70 years, and ≥75 years) after implantation compared with before implantation, and the performance of older and younger individuals was comparable over 12 months of cochlear implant use. Furthermore, 3 studies[37,39,41] reported recommendations that age must not be a limiting factor in assessing cochlear implantation candidacy.

Seven studies[37-40,42-44] reported that age was associated with speech recognition or QOL outcomes after cochlear implantation, with younger individuals experiencing better outcomes than older individuals. However, this finding does not negate the justification for cochlear implantation in older adults because positive outcomes have been reported in these individuals as well, particularly over long follow-up periods.[37-39] The Delphi consensus panel noted that although older age alone must not be a limiting factor to cochlear implantation candidacy, other comorbidities commonly associated with older age, such as dementia, should be taken into consideration.

Best Practice Guidelines for Surgery

Statement 5: Both curved (perimodiolar) and straight electrodes are clinically effective for cochlear implantation, with a low rate of complications.

Ten studies[38,42,45-52] were identified in the SR that were relevant to this consensus statement. One of these studies[46] reported no difference in speech recognition in those receiving straight electrodes compared with those receiving curved electrodes. Four studies[45,48,51,52] reported that in adults with residual hearing before cochlear implantation, hearing preservation was variably achieved with both straight and perimodiolar electrodes. Both curved and straight electrodes are commonly used for cochlear implantation, and selection of the electrode should be made on an individual basis by the surgeon.

Statement 6: When possible, hearing preservation surgery can be beneficial in individuals with substantial residual hearing.

For the best possible postoperative outcomes, it is important that hearing preservation is considered as a goal in those with preoperative residual hearing. Residual hearing is important in individuals receiving an implant for postoperative use of combined electric-acoustic hearing. Although this practice involves the use of unilateral cochlear implants, the data identified in this SR were specifically associated with hearing preservation in adults with severe, profound, or moderate sloping to profound bilateral SNHL receiving unilateral implants alone.

Five studies[45,48,51-53] were identified in the SR that examined hearing preservation after standard cochlear implanation surgery; preservation of low-frequency residual hearing was observed in 22% to 7% of individuals during a follow-up of 4 to 33 months after surgery. Differences in reporting methods in addition to variable length of follow-up may account for some of the wide variation in outcomes.

Clinical Effectiveness of Cochlear Implants

Statement 7: Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with severe, profound, or moderate sloping to profound bilateral SNHL; these gains in speech recognition are likely to remain stable over time.

Eighteen studies[30,38,40,41,44,49,52-63] reported increases in speech recognition scores after cochlear implantation compared with before implantation in quiet or noise or in conditions that were not stated. Six of these studies[30,44,52,62,63] demonstrated increases in speech recognition scores after cochlear implantation compared with before implantation in noise. One study[43] showed that improvements in speech recognition observed in the first 24 months after surgery were maintained when assessed at 120 months, with no change or deterioration. Evidence from the literature and real-world experience reported by the Delphi consensus panel corroborated the evidence from these studies, suggesting that improvements in speech recognition scores are likely to be maintained over time.

Statement 8: Both word and sentence recognition tests should be used to evaluate speech recognition performance after cochlear implantation.

The SR identified 2 studies[30,38] that reported mixed results on the use of word and sentence recognition tests. One study[30] demonstrated that sentence scores reached a ceiling effect after 3 months, but word scores continued to improve over longitudinal assessments, which suggests that word scores may be more suitable for measuring long-term performance. However, Chen et al[38] found improvement in AzBio sentence test scores at 1 month after cochlear implantation and further improvement over 24 months, indicating that this test could be useful for measuring speech recognition performance. No other studies were identified that made recommendations for or compared the usefulness of word vs sentence tests.

The Delphi consensus panel believed that both word and sentence recognition tests could be used when evaluating speech recognition performance after cochlear implantation. There are regional differences in which test is used and different advantages and disadvantages of each test. For example, word recognition tests are less likely to reach ceiling effects than sentence recognition tests when used in quiet conditions, and cognition can have greater implications for sentence recognition performance than for word recognition performance when used in noise conditions. Therefore, 1 test is not consistently recommended over another.

Statement 9: Cochlear implants significantly improve overall and hearing-specific QOL in adults with severe, profound, or moderate sloping to profound bilateral SNHL.

The SR identified 14 studies[30,40,41,44,49,55,56,59,61,62,64-67] that reported improvements in overall QOL after cochlear implantation compared with before implantation. Six of these studies[30,55,56,59,62,67] demonstrated improvements in hearing-specific QOL after cochlear implantation compared with before implantation. Five of these studies[55,56,59,62,67] used the Nijmegen Cochlear Implant Questionnaire, which was the only published questionnaire specifically designed for measuring QOL associated with cochlear implantation at the time of the SR. Other general QOL questionnaires that were used included the Health Utilities Index Mark 2,[56] the Health Utilities Index Mark 3,[30] the 36-Item Short Form Health Survey,[67] and the World Health Organization Quality of Life Questionnaire in Older Adults.[62]

Statement 10: Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize postimplantation speech recognition.

Seven studies[37-40,42-44] demonstrated an association between age at implantation and speech recognition scores after implantation, with younger individuals scoring higher than older individuals. Three studies[38,44,46] showed that the duration of hearing loss before cochlear implantation is associated with postimplantation speech recognition scores, with individuals who had a shorter duration of hearing loss before cochlear implantation scoring higher than those who had a longer duration of hearing loss. However, 2 studies[49,57] did not find any association between age and postimplantation speech recognition. Furthermore, 3 studies[42,43,49] found no association between the duration of hearing loss before cochlear implantation and speech recognition scores.

In the Delphi consensus panel's experience, individuals who are candidates for cochlear implantation should undergo the procedure as soon as possible to maximize benefit. However, as highlighted in Statement 4, individuals of any age may benefit from a cochlear implant.

Factors Associated With Postimplantation Outcomes

Statement 11: Where appropriate, individuals should use hearing aids with their cochlear implant to achieve bilateral benefits and the best possible speech recognition and QOL outcomes.

Some adult cochlear implant users may receive additional benefit when using a hearing aid in the contralateral ear (bimodal listening), provided that they have sufficient residual hearing. This benefit is supported by Farinetti et al,[68] who demonstrated that the scores achieved in some QOL domains are higher when using a hearing aid plus cochlear implant vs using an implant alone. This finding is also supported by 2 studies[30,69] that showed higher speech recognition scores when using a hearing aid plus a cochlear implant vs using an implant alone for the following tests: the Freiburg monosyllabic word test in quiet; the Hochmai-Desoyer, Schulz, Moset sentence test in quiet and noise; the Hochmai-Desoyer, Schulz, Moset sentence test with competing speech; and the AzBio sentence test in noise. Sladen et al[30] found that for the CNC word test, speech recognition was also higher in the bimodal condition than in the unilateral condition at 6 months but not at 12 months after implantation.

Statement 12: Many factors impact cochlear implantation outcomes; further research is needed to understand the magnitude of the effects.

Several factors have been found to change cochlear implantation outcomes. Some of the most commonly studied factors shown to be associated with high speech recognition scores after implantation include young age at at the time of the procedure,[37-40,42-44] short duration of hearing loss,[38,44,46] higher educational level,[49,56] and high preimplantation speech recognition scores.[46]

However, some studies failed to associate age[49,57] and the duration of hearing loss[42,43,49] with postimplantation speech recognition. Factors found to be associated with good postimplantation QOL include greater preimplantation QOL[66] and better preimplantation speech recognition.[56]

Although these factors have been shown to change cochlear implantation outcomes, it is challenging to identify the magnitude of the associations owing to different study designs and confounding factors. In addition, factors associated with these outcomes should not be used to identify surgical candidates but may be used to facilitate counseling and supplementary auditory therapy in some circumstances. Specific criteria to identify cochlear implantation outcomes are given in Statement 2 and Statement 3.

Statement 13: Long durations of unaided hearing loss do not rule out potential benefit of cochlear implants: individuals who receive an implant in an ear that was previously unaided for more than 15 years have been shown to experience improvements in speech recognition.

Individuals with long durations of unaided hearing loss may still benefit from cochlear implantation. This finding is demonstrated by 2 studies[41,54] showing that speech recognition scores were not different between individuals who received a cochlear implant in their previously sound-deprived ear and those who received one in their previously aided ear.

Statement 14: Adults who have undergone cochlear implantation should receive programming sessions, as needed, to optimize outcomes.

Following cochlear implant activation after surgery, the recipient should receive implant programming and rehabilitation sessions to optimize performance. However, there are no clear and consistent guidelines on the precise nature, frequency, and number of programming and rehabilitation sessions that should be provided, and substantial evidence gaps in the literature on best practice for rehabilitation after cochlear implantation were identified in the SR.

Four studies[70-73] suggested that frequent fitting and programming sessions immediately after implantation are needed to ensure stabilization of threshold levels and upper stimulation levels, but fewer sessions are required over time because minimal changes in mean lower and upper stimulation levels are expected from 6 months onward.[70,71] The recommendation of the Delphi consensus panel is that programming and rehabilitation programs should be tailored to the individual rather than follow a strict schedule.

Association Between Hearing Loss and Depression, Cognition, and Dementia

Statement 15: Adults with hearing loss can be substantially affected by social isolation, loneliness, and depression; evidence suggests that treatment with cochlear implants can lead to improvement in these aspects of well-being and mental health. Longitudinal studies are needed to obtain further knowledge in this area.

Hearing loss can lead to social isolation, which can alter QOL, as demonstrated in a number of studies[3,4,55,59,66,74-78] identified in the SR. Increased depression, anxiety, stress, social isolation, and loneliness in older adults with hearing loss compared with individuals with normal hearing have been reported,[3,4,74-76] and depression has been identified as a risk factor for hearing loss.[77]

Cochlear implants have been shown to reduce symptoms of depression in 2 studies,[55,59] but 1 study[66] found no improvement in depression after cochlear implantation. Greater loneliness scores in cochlear implant users with severe hearing loss vs hearing aid users with mild hearing loss have also been demonstrated, although it should be noted that loneliness scores are likely to be associated with the degree of hearing loss rather than the treatment method.[78]

The studies[3,4,55,59,66,74-78] identified on this topic in the SR had follow-up periods ranging from 6 months to up to 16 years. Therefore, further longitudinal studies would be beneficial to understand the full association of cochlear implantation with well-being and mental health over a long period.

Statement 16: There is an association between age-related hearing loss and cognitive or memory impairment.

An association between age-related hearing loss and cognitive or memory impairment has been widely observed, with 11 studies[62,74,79-87] identified in the SR demonstrating this association. Individuals with hearing loss are more likely to have cognitive impairment than those with no hearing loss,[75,82,86] and the morbidity of hearing loss is increased in individuals with cognitive impairment.[79,80,84]

An association between performance on neurocognitive tests and the degree of hearing loss in individuals with cognitive impairment has been demonstrated, with individuals with severe hearing loss performing worse than those with mild hearing loss.[81,85] The

Dichotic Sentence Identification auditory test has also been shown to differentiate between individuals with memory impairment and those without memory impairment with 83% accuracy.[79]

Statement 17: Further research is required to confirm the nature of cognitive impairment in individuals with hearing loss and its potential reversibility with treatment.

Only 4 studies[74,78,87,88] were identified that examined the nature of the cognitive impairment that occurs in individuals with hearing loss. Therefore, further research is needed to understand the precise nature and causality of the association and the potential for cochlear implantation to prevent or reverse cognitive impairment.

Impairment in several cognitive domains in individuals with hearing loss has been demonstrated,[74,88] and 1 study[87] reported disruptions to spontaneous neural activity in several regions of the brain that are associated with cognition and speech or language processing in individuals with presbycusis compared with individuals with normal hearing. A decrease in cognitive function has also been demonstrated in the executive function, verbal fluency and processing, and psychomotor speed domains in cochlear implant users with severe or profound hearing loss compared with hearing aid users with mild hearing loss.[78]

Statement 18: The use of cochlear implants may improve cognition in older adults with bilateral severe to profound SNHL.

Völter et al[62] demonstrated improvements in neurocognitive abilities in older adults at 6 months and 12 months after cochlear implantation compared with before implantation. Because that article was the only relevant study identified in the SR, the evidence regarding the association of cochlear implantation with cognition is limited, and this dearth is a key evidence gap that should be addressed with further research.

Statement 19: Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia.

The evidence identified in the SR demonstrated no association between language skills and hearing loss in individuals with dementia.[85] No association was found between hearing thresholds and Alzheimer disease in another study,[84] although Alzheimer disease was found to be associated with central auditory processing disorder.[84] Furthermore, the incidence of dementia was found to be higher in individuals with age-related hearing loss than in those with normal hearing.[89] Combined with the Statement 18 evidence, which suggests that the use of cochlear implants may improve cognition, the treatment of hearing loss could reduce the risk of developing dementia, although further research is required to confirm this hypothesis.

Cost Implications of Cochlear Implants

Statement 20: Unilateral cochlear implantation in adults is cost-effective compared with no implant or no intervention at all and is associated with increased employment and income.

One study[90] reported that, based on the common willingness-to-pay threshold of £30 000 (US $38 371) per quality-adjusted life-year (QALY), unilateral cochlear implants are cost-effective. Two studies[56,90] provided the incremental cost-effectiveness ratios for unilateral implants vs no implant or no intervention, which ranged from £11 440 (US $27 250 at 2017 prices) to £17 625 (US $41 983 at 2017 prices) per QALY in the United Kingdom health care system[90] and from €17 100 (US $25 190 at 2017 prices) to €22 500 (US $33 144 at 2017 prices) per QALY in a Dutch study.[56] Another study[91] demonstrated both an increase in employment rate and an increase in median income after unilateral cochlear implantation in adults.

The Delphi consensus panel noted that the degree of cost-effectiveness will vary depending on the country, the degree of hearing loss, and the age of the individual. Further research is required to demonstrate the cost-effectiveness and economic benefits of cochlear implantation for individuals with hearing loss.

Discussion

There is an urgent need to address the lack of consistent guidelines for and awareness of the benefit of unilateral cochlear implantation for the treatment of bilateral SNHL in adults to increase patient access to treatment and aftercare and improve QOL among adults with hearing loss. To our knowledge, this is the first international Delphi consensus study to be published on unilateral cochlear implantation for hearing loss.

Twenty consensus statements were developed and endorsed by the Delphi consensus panel. These consensus statements examine best practice in diagnosis, surgery, and aftercare; clinical effectiveness of cochlear implantation; and the association between hearing loss and mental health. They mark the first step in raising awareness of the benefits of cochlear implantation in adults and in improving how potential candidates are identified and treated.

Several evidence gaps were identified, including factors that change cochlear implantation outcomes. Although various factors have been recognized, the magnitude of association of these factors is unclear given different study designs and confounding factors. Other factors associated with the technical aspects of cochlear implants[92] and several factors in combination may also alter outcomes.[93,94] Additional large, longitudinal studies using consistent and comparable methods are needed to validate these findings and identify additional factors that can change outcomes. Additional prospective studies would also be beneficial to demonstrate the cost-effectiveness of cochlear implantation and the long-term benefits on a societal and economic level for individuals with hearing loss.

Another evidence gap identified in this study is our understanding of the association between hearing loss and cognition and dementia. The Lancet Commission on the topic of dementia reported that hearing loss is the single largest modifiable risk factor for dementia in midlife (45-65 years).[95] Our consensus study highlights the need for longitudinal studies to better understand the precise nature and causality of this factor, the association of hearing loss with the rate of cognitive decline, and the potential for treatment of hearing loss with cochlear implantation to reduce the risk of cognitive impairment and dementia.

Strengths and Limitations

A strength of this study is that the consensus statements were developed based on both the evidence identified in a robust SR and the expert opinion of a multidisciplinary Delphi consensus panel with experience in cochlear implantation. This dual approach is in line with the American Academy of Otolaryngology–Head and Neck Surgery Foundation methods for the development of clinical consensus statements,[96] resulting in evidence-based consensus statements that are in line with clinical experience.

A limitation of the study is the minimal representation of the Middle East and Africa on the Delphi consensus panel. Specific expert experience in these regions was thus not considered in the development of the consensus statements, and further research in this area would be beneficial.

Conclusions

The scope of this study was to develop consensus statements associated with the use of unilateral cochlear implantation for the treatment of severe, profound, or moderate sloping to profound bilateral SNHL in adults. Further research to develop consensus statements for unilateral cochlear implants in children, bilateral cochlear implantation, combined electric-acoustic stimulation, unilateral implantation for single-sided deafness, and asymmetrical hearing loss in children and adults will be beneficial for optimizing hearing and QOL for these patients.

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