Poster No. 101

Developing international consensus on the use of unilateral cochlear implants for bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss in adults

Delphi Consensus Group on Cochlear Implantation in Adults

Background

- International guidelines on adult cochlear implant (CI) candidacy criteria are limited and country-specific guidelines are varied, leading to disparate levels of access across the world.[1–3]
- Further barriers to CI access include lack of awareness and understanding among potential candidates and their healthcare professionals, as well as a lack of defined referral pathways.
- We sought to address this lack of awareness and understanding of CI use in adults by carrying out a Delphi process – an established consensus-based technique which allows for the collection and aggregation of informed judgments from a group of experts in the field, using a systematic approach.[4]
- The objective of our Delphi consensus process was to develop a series of statements on the use of unilateral CIs in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss (SNHL), based on evidence from the literature and expert consensus from an international panel.

Methods

Systematic literature review

- A systematic literature review (SLR) was performed, by an independent third party, to identify studies relevant to at least one of the following areas: 1) awareness of CIs, 2) best practice for diagnosis, 3) best practice for surgery, 4) clinical effectiveness of CIs, including factors associated with postimplantation performance, 5) rehabilitation following cochlear implantation, 6) the relationship between hearing loss and depression, cognition and dementia, and 7) cost implications of CIs.
- Searches were conducted in July 2018 in MEDLINE, Embase and Cochrane Library.
- A quality assessment was carried out for all included studies using a modification of the method outlined in Eubank *et al.* 2016.[5]
- The SLR protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42018112099) and is fully compliant with the 2009 Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines.

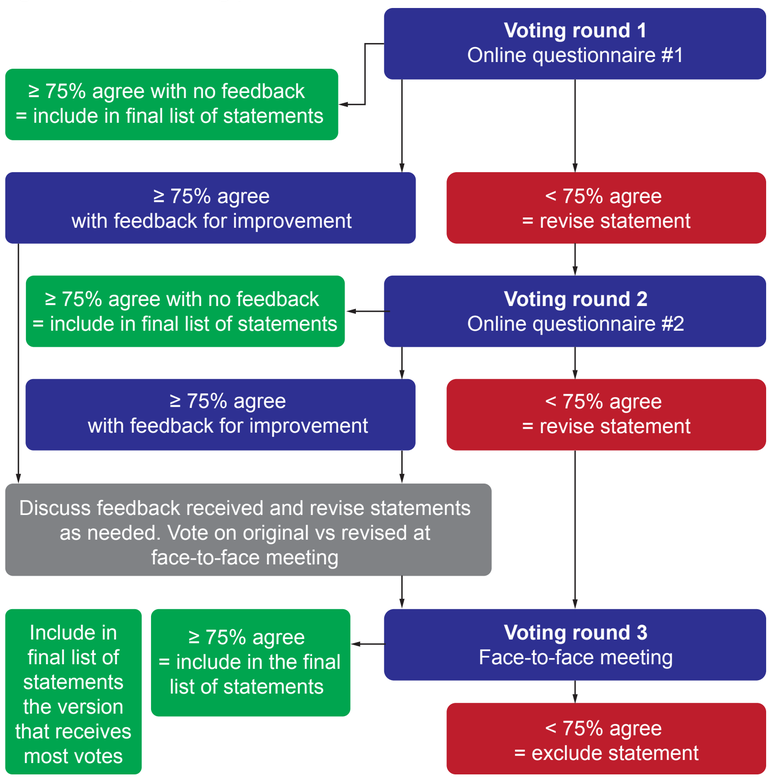
Development of consensus statements

- Evidence from the studies identified in the SLR was used to draft statements about CIs in each of the areas of interest.

Modified Delphi process

- A modified three-step Delphi consensus method was used to finalize the statements, by seeking consensus from an international group of CI experts: the Delphi panel.
- The Delphi panel consisted of 26 participants – representing the USA, Europe and Asia–Pacific regions – selected by a steering committee of five members, including one chair. All members of the panel and steering committee, except the chair, took part in the voting rounds of the Delphi process. Two clinical experts had a shared role on the Delphi panel, resulting in a total of 29 voting members.
- The Delphi process consisted of three voting rounds (**Figure 1**), which took place over a 9-month period (July 2018 to March 2019).
- At each voting round, the Delphi panel members marked their level of agreement or disagreement with each of the drafted statements, according to a 6-point Likert response scale. Panel members were also invited to provide further comments on each statement. During this process, all members had access to a report of the SLR evidence, including the results of the quality assessment of included studies.
- In the situation of conflicting comments on the statements, the chair provided the casting vote on what to include and what not to include at each voting round.
- Consensus was defined *a priori* as agreement by at least 75% of respondents.
- The first two voting rounds were conducted via online questionnaires and the third voting round was conducted at a 1-day face-to-face meeting held in Los Angeles, CA, USA on March 30, 2019.

Figure 1. Delphi voting process.



Results

Evidence from the literature

- The SLR identified 6492 papers. After removal of duplicates, 74 articles fulfilled all inclusion criteria (**Figure 2**).
- A total of 21 statements on unilateral cochlear implantation were developed based on findings from the included studies.

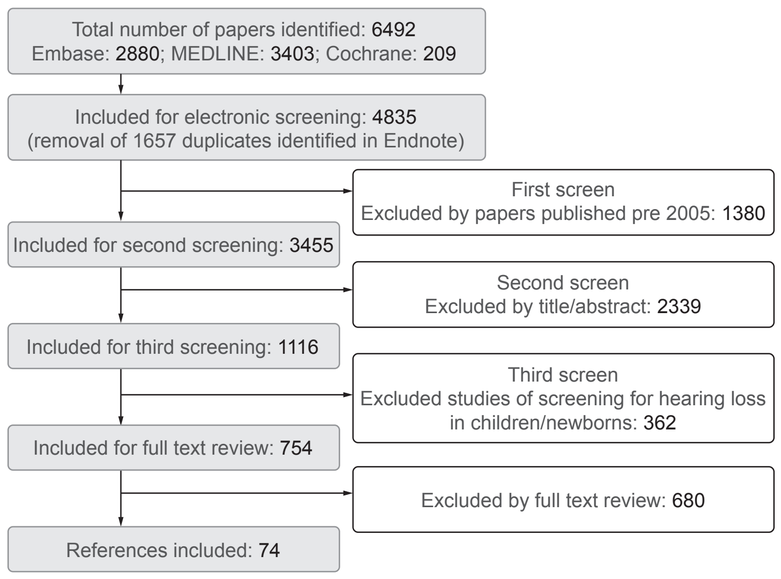
Summary of voting results

- Of the 29 voting members, 22 (75.9%) participated in voting round 1, 27 (93.1%) participated in voting round 2 and 24 (82.8%) participated in voting round 3. All members participated in at least one round of voting.
- Of the 21 statements that entered voting round 1, only two statements did not meet the consensus threshold of 75%, and one of these failed to meet consensus again at rounds 2 and 3. By the end of the final round, 20 consensus statements had been agreed and endorsed by the Delphi panel (**Figure 3**).

Final consensus statements

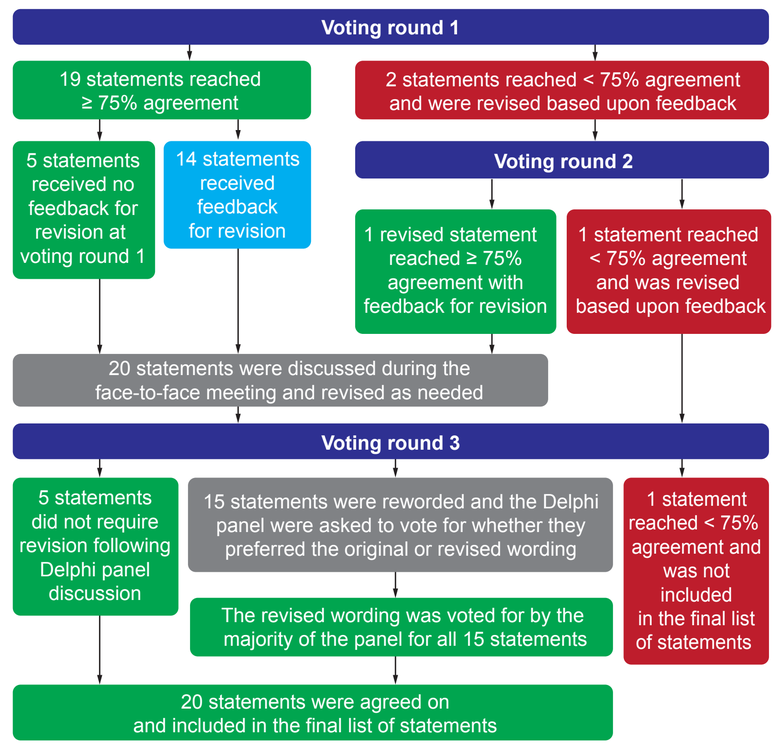
- The consensus statements provide recommendations on: CI awareness (n = 1); diagnosis (n = 3); surgical implications (n = 2); clinical effectiveness and factors associated with postimplantation performance (n = 7); rehabilitation (n = 1); association of hearing loss with depression, cognition and dementia (n = 5); and cost-effectiveness (n = 1).
- The list of final statements is provided in **Table 1**.

Figure 2. PRISMA diagram for systematic literature review on cochlear implant use, July 18, 2018.



References were excluded at full text review stage owing to no relevant data. References were excluded owing to 1) outcomes not of interest, 2) animal/*in vitro* studies, 3) population not of interest, 4) genetic study, 5) editorial/commentary/narrative review/letter, 6) case series and case studies, 7) not in English and 8) pediatric studies.
Further exclusion criteria applied at full text review stage included: 9) single-sided hearing impairment, 10) unspecified if bilateral or unilateral CI, 11) bilateral CI, hybrid/EAS and/or CI-CROS, 12) countries not including Australia, Canada, China, Europe, India, Japan and the USA, 13) studies with data from children and adults combined, 14) studies with data relating to unilateral and bilateral CIs, hybrid/EAS and/or CI-CROS combined, 15) study population N < 20 and 16) self-reported hearing loss and non-SNHL.
CI, cochlear implant; CI-CROS, cochlear implant with contralateral routing of signal; EAS, electric-acoustic stimulation; PRISMA, Preferred Reporting Items for Systematic reviews and Meta-Analyses; SNHL, sensorineural hearing loss.

Figure 3. Results of Delphi voting at rounds 1, 2 and 3.



Discussion and conclusions

- We used a systematic approach to develop statements on CI use in adults based upon both evidence identified in an SLR as well as the expert opinion and clinical experience of an international panel.
- Our consensus process is among the first of its kind to consolidate evidence and expertise in the area of cochlear implantation for bilateral SNHL.
- The final set of consensus statements provides recommendations on the use of CIs in adults and could eventually be developed into clinical practice guidelines. Such guidelines could increase access to CIs worldwide, mitigate disparities in CI care and lead to improved hearing and quality of life in adults with bilateral SNHL who are eligible for a CI.
- Limitations of our Delphi consensus process include:
  - the limited representation on the Delphi panel from the Middle East and African regions
  - several evidence gaps in the literature, including the level of awareness of CIs among primary and hearing healthcare providers, the magnitude of effect of various factors on CI outcomes, the best practice for rehabilitation following implantation, and the impact of CIs on well-being, cognitive impairment and risk of dementia. Increasing knowledge in these areas would be valuable in the future development of clinical practice guidelines for CIs.
- In conclusion, these 20 consensus statements represent the initial step in the development of a set of international guidelines on best practice for CI in adults with bilateral SNHL.

Table 1. Final consensus statements on unilateral cochlear implantation in adults with severe, profound, or moderate sloping to profound bilateral sensorineural hearing loss.

Category	Number	Statement
Awareness of cochlear implants	1	Awareness of cochlear implants among primary and hearing healthcare providers is inadequate, leading to under-identification of eligible candidates. Clearer referral and candidacy pathways would help increase access to cochlear implants
Best practice for diagnosis	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 sensorineural hearing loss
	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
	4	Age alone should not be a limiting factor to cochlear implant candidacy, as positive speech recognition and quality of life outcomes are experienced by older adults as well as younger adults
Best practice for surgery	5	Both curved (perimodiolar) and straight electrodes are clinically effective for cochlear implantation, with a low rate of complications
	6	When possible, hearing preservation surgery can be beneficial in individuals with substantial residual hearing
Clinical effectiveness of cochlear implants	7	Cochlear implants significantly improve speech recognition in both quiet and moderate noise in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss; these gains in speech recognition are likely to remain stable over time
	8	Both word and sentence recognition tests should be used to evaluate speech recognition performance following cochlear implantation
	9	Cochlear implants significantly improve overall and hearing-specific quality of life in adults with bilateral severe, profound, or moderate sloping to profound sensorineural hearing loss
	10	Adults who are eligible for cochlear implants should receive the implant as soon as possible to maximize postimplantation speech recognition
Factors associated with postimplantation outcomes	11	Where appropriate, individuals should use hearing aids with their cochlear implant in order to achieve bilateral benefits and the best possible speech recognition and quality of life outcomes
	12	Many factors impact cochlear implant outcomes; further research is needed to understand the magnitude of the effects
	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
Rehabilitation following cochlear implantation	14	Adults who have undergone cochlear implantation should receive programming sessions as needed to optimize outcomes
The relationship between hearing loss and depression, cognition and dementia	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
	16	There is an association between age-related hearing loss and cognitive/memory impairment
	17	Further research is required to confirm the nature of cognitive impairment in individuals with hearing loss, and its potential reversibility with treatment
	18	The use of cochlear implants may improve cognition in older adults with bilateral severe to profound sensorineural hearing loss
	19	Hearing loss is not a symptom of dementia; however, treatment of hearing loss may reduce the risk of dementia
Cost implications of cochlear implants	20	Unilateral cochlear implantation in adults is cost-effective when compared with no implant or no intervention at all and is associated with increased employment and income

References

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Disclosures

CB has equity interest in Advanced Cochlear Diagnostics, LLC, and is a consultant for Advanced Bionics, Envoy Medical and IotaMotion; AB is a consultant for Cochlear and the Institute for Cochlear Implant Training (ICIT); RB is a consultant for Cochlear; CD is a consultant for Advanced Bionics, Cochlear and Envoy Medical; HF is a member of the surgical advisory boards of Advanced Bionics and Med-El and has received grant funding from Advanced Bionics; BG is a consultant for Cochlear; R Gifford is a consultant for Advanced Bionics, Cochlear and Frequency Therapeutics; R Gurgel is on the surgical advisory board of, and has received institutional research support from, Cochlear and Advanced Bionics; M Holcomb is a consultant for the audiology advisory councils of Advanced Bionics and the American Speech Language Hearing Association, is on the board of directors for the American Cochlear Implant Alliance (ACI Alliance) and is a consultant for ICIT; JL is on the board of the ACI Alliance; EM is employed by the Radboud University Medical Center, which has received grants from Cochlear, Advanced Bionics and Oticon Medical; JTR is a consultant for and advisory board member of Cochlear Americas and has received research support from Advanced Bionics, Cochlear and Med-El; PVdH is employed by Antwerp University Hospital, which has received research grants from Cochlear and Med-El; TZ is a member of the advisory boards of Cochlear Americas and Envoy Medical. Remaining authors have no disclosures to declare.

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