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Identification and Evaluation of Cochlear Implant Candidates with Asymmetrical Hearing Loss

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Asymmetrical hearing loss · Bimodal stimulation · Cochlear implant · Tinnitus

Abstract
Objective: Recommendation for cochlear implant (CI) treatment for individuals with severe to profound single-sided deafness (SSD) and asymmetrical hearing loss (AHL) is on the rise. This raises the need for greater consistency in the definition of CI candidacy for these cases and in the assessment methods of patient-related benefits to permit effective comparison and interpretation of the outcomes with both conventional and implantable options across studies. ***Method:*** During a dedicated seminar on implant treatment in AHL patients, the panellists of the closing round table reviewed the clinical experience presented with the aim to define clear audiometric characteristics for both AHL and SSD cases, as well as a common data set enabling consistent evaluation of hearing benefits in this population. ***Conclusions:*** The panellists agreed on a clear differentiation between AHL and SSD CI candidates, defining average pure-tone thresholds up to 4 kHz for better and poorer ears. Agreement was reached on a minimum set of assessment procedures, and included the necessity of trials with conventional CROS/BICROS hearing aids and bone conduction devices before considering CI treatment. Objective assessment of sound localisation abilities was identified as the most relevant criterion to quantify performance before and after treatment. In parallel, subjective assessment of overall hearing ability was recommended via the Speech, Spatial and Qualities of hearing questionnaire. Longitudinal follow-up of these parameters and the hours of daily use were considered essential to reflect the potential treatment benefits for this population. The consistency in the data collection and its report will further support health authorities in their decision on acceptable gains from available hearing loss treatment options.

Introduction

Cochlear implants (CI) were first made available for the treatment of bilateral, permanent, sensorineural hearing impairment decades ago, providing electrical stimulation directly to the cochlea to help restore hearing function in one or both deafened ears. Individuals who have an asymmetrical hearing loss (AHL) have either normal hearing or a mild-to-moderate hearing loss in one ear and a more significant permanent sensorineural hearing loss in the other ear. As a result of the severity of deafness in one ear, in the absence of adequate bilateral auditory input through conventional acoustic treatments, these patients experience a substantial hearing handicap in their daily lives. Recent application of CI as a treatment for the poorer ear, in some of these cases, is providing a growing body of evidence for the effectiveness of combined acoustic and electrical stimulation for bilateral auditory inputs as the foundation for restoring binaural hearing in daily life. The outcomes for this extended indication for CI needs to be compared to outcomes with existing alternative treatments such as conventional CROS hearing aids and CROS bone conduction devices.

Round Table Discussion

The impetus for the round table discussion was to identify common evaluation methods, the main criteria of judgement being supported by audiological evaluations and quality-of-life questionnaires in AHL in order to satisfy the variety of competent authorities and health reimbursement agencies across Europe. The final goal of this round table was to identify the potential candidates for a CI in the paediatric and adult AHL populations. One such concept encourages the option of pooling comparable medical evidence to balance the benefits of CI treatment against the risks and costs involved. Underlying this concept is the commitment to agree on common patient selection and assessment paradigms. These matters were considered and discussed by a group of experts specialised in CI treatment invited as panellists to the round table based on their involvement in AHL treatment in the clinical or research setting.

The panellists addressed four main questions related to the target population of AHL patients, pre- and postsurgical evaluations, measures of treatment effectiveness and the minimum criteria for evidence to support reimbursement decisions.

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Table 1. Definition of SSD and AHL based on pure-tone average hearing thresholds for each ear

SSD	Poorer ear	Severe to profound hearing loss
	Better ear	≤30 dB HL to 4,000 Hz inclusively
AHL	Poorer ear	Severe to profound hearing loss
	Better ear	>30 dB HL to 4,000 Hz inclusively ≤60 dB HL to 4,000 Hz inclusively
Interaural asymmetry		≥30 dB (poorer ear PTA_4 – better ear PTA_4)

PTA_4 = Four-frequency pure-tone average threshold.

Target Population. AHL is a very broad term used to describe any degree of interaural asymmetry for hearing acuity; the extreme case being where the poorer ear presents with total deafness while the contralateral is a normal-hearing ear or has a mild degree of hearing loss. Typically, this extreme case is called unilateral hearing loss (UHL) or single-sided deafness (SSD). In this target population, the factors that predict who can benefit from a CI should be identified to support the rationale for reimbursement from the various agencies throughout Europe.

The Definition of AHL. The next step was to further define AHL. The panel defined interaural asymmetry as a difference of 30 dB HL or more between the four-frequency (i.e. 0.5, 1, 2 and 4 kHz) pure-tone average thresholds in each ear, with the poorer ear meeting traditional CI criteria. Furthermore, the panel suggested and agreed upon the additional criterion that the average threshold in the better-hearing ear should be better than 60 dB HL (i.e. including normal-hearing thresholds for SSD cases), which is thus not suitable for implantation in that ear. The proposed definitions are summarised in table 1.

The Incidence of AHL. Estimates of the size of the AHL population amongst children vary but may range from 1 to 3% in children according to universal newborn hearing screening data. Even after inclusion of children with acquired unilateral deafness, the number of qualifying CI candidates is expected to remain small due to the high incidence of auditory nerve stenoses (approx. 50%) which preclude consideration of CI surgery. At this time, there is also a tendency for parents to be reluctant to decide for implantation for their child with a close to normal contralateral hearing ear even when acoustic amplification in the poorer ear provides marginal benefit, particularly in young children with congenital disease. This is somewhat different when hearing loss starts later in childhood and the loss of binaural function is more evident.

Indications for AHL and CI. Indications for CI treatment differ between children and adults with AHL, and they may need to be considerably more stringent in children. The aim of the indications should be to keep the interval of auditory deprivation in only one ear as short as possible to avoid potential deleterious central reorganisation. The time interval from the onset of hearing loss to implantation must therefore be kept to a minimum in AHL children. Amongst the panellists, the timing for considering cochlear implantation in children with congenital or early-onset deafness was debated, and caution was suggested after 4 years of auditory deprivation. Careful recommendation of earlier rather than later CI treatment in both older children and adults was suggested as appropriate following a diagnosis of AHL, particularly if the individual is at risk of developing a significant hearing loss in their contralateral, better-hearing ear.

Implications for AHL with Tinnitus. A large subgroup of adult AHL candidates present with incapacitating tinnitus, which affects their daily activities. The incidence of sudden SSD is estimated at 1/10,000, with 40% of this group presenting with severe tinnitus, yielding a potential 20–25 new candidates/million inhabitants per year. The panellists concluded that hearing evaluation should remain the main criterion for CI treatment to support the rationale for reimbursement as it is equally applicable to those with and without tinnitus. However, it was pointed out that CI candidates presenting with debilitating tinnitus and AHL tend to be very motivated to use their implant, which has a positive influence on their exposure to binaural acoustic cues and their ability to use them.

Evaluation Tools. There was agreement that an attempt to provide access to CI alternatives (i.e. conventional and bone conduction CROS and BICROS devices) should be included in the assessment protocol unless contraindicated. Two main measurement outcomes were recommended to assess and compare pre- and post-CI performance in AHL patients consistently. Specifically, these were measures of sound localisation and disease-specific quality-of-life questionnaires, such as the Speech, Spatial and Qualities of Hearing Scale (SSQ). Localisation is needed in daily life and reflects one of the greatest performance deficits experienced by these AHL individuals before CI treatment with the potential to demonstrate large gains after CI treatment. While it is particularly challenging to assess localisation in very young children, especially below the age of 4–6 years, being a time-consuming task and requiring higher cognitive development, the assessment of the head shadow effect (i.e. a robust physical effect) may be an alternative and relevant method to demonstrate the benefits of sound stimulation to both ears. While an optimal disease-specific quality-of-life measure for use does not yet exist, the hearing disease-specific questionnaire, the SSQ, was proposed as a suitable measure to reflect daily hearing abilities and difficulties broadly for AHL patients. Finally, speech in noise is a deficit area for those without binaural hearing and should be considered for evaluation of treatment options.

Risk/Benefit Ratio. Adverse effects should be recorded systematically in a dedicated register. Where a randomised controlled trial is not used in conducting research, other methodological alternatives such as propensity scores, which are useful when trying to draw causal conclusions from observational studies, should be considered. While assessment of the quality-adjusted life years is possible through select generic quality-of-life assessment tools, such as the Health Utilities Index Mark 3 questionnaire (HUI3), there was no agreement amongst the panellists on the choice or appropriateness of such a measure to assess the benefits of hearing implant treatment for AHL individuals. Nevertheless, panellists agreed that, ideally, an alternative generic quality-of-life measure needs be developed that is sensitive to communication problems, in order to be able to compare the treatment effects with other medical interventions. In the meantime, the HUI3 could be used. The added value of measuring success of implant treatment for these individuals through the record and report of daily use (e.g. h/day) was also considered as it may in turn reflect the perceived overall benefits to hearing and quality of life.

Acceptable Minimum Gain/Benefit. The decision and discussion on what constitutes an acceptable level of positive benefit from CI treatment, or the type of measure and subsequent evidence needed, are all influenced by the interested party viewing the evidence and how they wish to use it. Medical evidence needed to satisfy an organisation such as insurers or public health authorities, hearing field professionals such as surgeons and audiologists or the end user, including the parents or patients themselves, will vary. Ultimately, the panellists agreed on four recommended longitudinal repeated measures to establish medical evidence to demonstrate the benefits of CI treatment for AHL patients:

(1) audiological assessment of localisation measures (i.e. following a standard protocol for the evaluation methodology that will need to be defined collaboratively);
(2) subjective assessment of hearing benefits via the SSQ;
(3) subjective assessment of global quality-of-life benefits using a validated questionnaire, e.g. HUI3, and
(4) the 'daily use criterion' reflecting the hours of consistent implant use and the environments encountered (e.g. making use of state-of-the-art technical options such as data logging functions in CI systems).

Whatever the measure or 'number' used to indicate that CI treatment is effective for the individual patient, the outcomes must be validated on sufficiently large AHL populations to support and permit consensus amongst the clinicians using them and to convince the authorities of their value in reaching conclusions for health service provision.

Future Directions

Ultimately, through collaborative cooperation amongst hearing professionals to gather comparable data sets for the AHL population at large in a consistent manner, more efficient use of outcomes reported independently through research and clinical experience should be made available. This would permit a meta-analysis and summary in a unified manner, which in turn may 'accelerate' access to 'innovative applications' of implantable hearing devices. This, along with consistent, long-term follow-up, will help to clarify the benefit of CI and alternative treatment options (e.g. CROS devices) and their respective indications further, and identify needs for technological advances. As indications evolve, it is indeed a difficult challenge and remains of paramount importance to provide sufficient evidence that the treatment benefits significantly outweigh any risks involved. With reference to CI treatment for AHL patients, for example, it is desirable that hearing implant manufacturers further strive to improve technologies to optimise outcome for users of bimodal stimulation potentially through enhanced synchronisation. As part of the cycle in developing therapies and broadening their application, the international community, working as a coherent group of expert professionals, can help guide and drive the never-ending process involving continual assessment, review of outcomes, follow-up and evolving indications.

Disclosure Statement

The authors declare that they have no conflicts of interest.

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