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Original Article

Worldwide Variation in Cochlear Implant Candidacy

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BACKGROUND: The aim of this study was to find out how candidacy criteria have evolved differently across the globe.

METHODS: Candidacy criteria and outcome measurements applied in 19 HEARRING clinics were analyzed.

RESULTS: Candidacy criteria vary between clinics. Overall, both bilateral implantation and cochlear implantation in patients with single-sided deafness are becoming more frequent.

CONCLUSION: Standardized outcome measurement instruments need to be applied to provide access to the hearing world to all patients with hearing loss who would benefit from cochlear implantation.

KEYWORDS: Cochlear implants, candidacy criteria, adults, children, guidelines

INTRODUCTION

The original cochlear implant (CI) candidate was a post-lingually deafened adult with a hearing loss (HL) greater than 100 dB and with no benefit from a hearing aid.[1] Over the years, candidacy criteria have considerably expanded, particularly with regard to pediatric implantation, bilateral implantation (BI), residual hearing, and single-sided deafness (SSD). The literature shows that early implantation under the age of 12 months is associated with speech and language development similar to their normal-hearing peers.[2-4] Bilateral cochlear implantation is used more often to help improve hearing in noise, spatial hearing, and sound localization both in adults and children.[5,6] Improvements in surgical techniques facilitate successful hearing preservation after cochlear implantation and thus allow successful combined electric-acoustic stimulation (EAS) in both adult and pediatric patients.[7-11] Patients with SSD benefit from cochlear implantation with regard to speech understanding, sound localization, hearing quality, quality of life, working performance, and associated tinnitus.[12-15]

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However, candidacy criteria have evolved differently across the globe, varying from country to country, and even from clinic to clinic. Existing regional and national regulations and guidelines, such as the Arbeit gemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. guidelines in Germany and the National Institute for Health and Care Excellence (NICE) guidelines in the United Kingdom, seem to be moving in the same direction but do not represent strict legal requirements. Reimbursement, socioeconomics, and medical concerns are constraints to the standardization of candidacy criteria. To encounter this, The HEARRING group created a series of standards covering all steps involved in the hearing implant solution process.[16]

The trends in CI candidacy still focus on audiological criteria and speech discrimination criteria. For speech discrimination assessment, mainly word tests are used; only a few clinics use sentence tests and some use a mixture of both.[17] The most frequently used speech tests in hearing assessment include the Bamford–Kowal–Bench or City University of New York sentence test, the North-Western University Children's Perception of Speech open-set sentence test, the Arthur Boothroyd word lists, and the Central Institute for Deaf (CID) everyday sentences for very young children or an equivalent test in the native language of the patient (Clinical Guidelines for Pediatric Cochlear Implantation, Australia).

More recently, experts have recommended attaching greater importance to hearing performance in *real-life* situations than to audiological criteria or speech discrimination, when discussing cochlear implantation with a patient with HL.[18,19]

Literature has shown that Australia, Germany, and Italy have the most liberal candidacy criteria and reimbursement models for both adults and children.[17] To get an overview of the clinical routine in hearing assessment in different countries and clinics, we launched a preliminary study on CI candidacy criteria.

MATERIALS AND METHODS

The study collected data via questionnaires from CI professionals, including surgeons, audiologists, and allied clinicians. We analyzed the minimal tests needed to determine candidacy for a CI or EAS device: audiometric criteria, aided speech criteria, age, BI, and implantation in patients with SSD. The data do not constitute approved indications but provide a sample of different candidacy criteria being used at different investigative clinics (HEARRING clinics, https://www.hearring.com) across the world.

Data Analysis

After data collection, the data were analyzed descriptively by summarizing and comparing the outcomes at the different clinics in a table.

Ethics

No individual or collective patient data were used. Therefore, no ethics committee approval was required.

All contributing authors got individual invitations to participate in the study.

RESULTS

Striking Differences in Candidacy Criteria

The HEARRING clinic in Australia has the most flexible criteria with no audiometric thresholds, no age limits, reimbursement for simultaneous and sequential BI in both adults and children, and SSD as an indication for a CI in adults. Overall, both BI and cochlear implantation in patients with SSD are becoming more frequent. Single-sided deafness is currently an indication for cochlear implantation in 6 out of the 19 HEARRING clinics presented in this study. Today, patients with residual hearing are also more frequently considered for cochlear implantation (Canada and Japan). From a global view, aided speech perception in quiet of up to 60% is taken as a criterion for cochlear implantation and up to 70% for EAS. At present, only 1 HEARRING clinic in Germany uses sentence scores in noise as a criterion ($\leq$60%) in addition to the monosyllabic score in quiet $\leq$50%. Table 1 provides a detailed overview with a list of all HEARRING clinic countries.

Adults

In the HEARRING clinics, the presentation level in speech tests ranges between 60 and 70 dB. Mostly, monosyllabic scores in quiet are taken as a candidacy criterion. The candidacy sentence scores ranged between 30% and 60% in the unaided condition in 12 clinics and between 60% and 100% in the aided condition in 6 clinics. Sentence scores are hardly taken as a candidacy criterion. Candidacy sentence scores in quiet ranged from 40% to 60% in the unaided condition in 4 clinics and were 50% in the unaided condition in 1 clinic. No data are available on whether clinics perform testing just in quiet or both in quiet and noise.

Fourteen clinics state that they perform BI in adults.

Eight clinics state that they perform cochlear implantation in adult SSD patients. In 4 of these 8 clinics, cochlear implantation in SSD is reimbursed but either based on individual criteria or as part of a clinical trial.

All clinics reported no limitation regarding maximum age at implantation.

Tinnitus is used as an indication for cochlear implantation in the Belgian center if tinnitus is a result of HL. In 1 HEARRING clinic in the United States, tinnitus patients must meet the standard criteria for

MAIN POINTS

- Cochlear implantation is globally the accepted way of rehabilitation for profound HL.
- Cochlear implant candidacy criteria are broadening worldwide although criteria vary widely.
- Bilateral implantation and cochlear implantation in patients with SSD are becoming more frequent across countries.
- The candidacy procedure involves a multi-disciplinary team consisting of a CI surgeon, an audiologist, a speech therapist, and other related experts.
- Standardized outcome measurement instruments need to be applied in order to generate evidence for universal cochlear implant candidacy criteria.

Table 1. Candidacy Criteria Applied in Different HEARRING Clinics Across the Globe

Country	Audiometric Thresholds (dB HL)	Aided Speech Perception Criteria	Presentation Level at Speech Test (dB SPL)	Minimum Age for Implantation	Maximum Age for Implantation	Bilateral Implantation	SSD
Argentina	70	Disyllabic score in quiet: <50% in adults and children	70	10 months	None	Sim. CI in children <5 years if HL caused by meningitis or auditory neuropathy; sequ. BI only in adults with specific additional needs	Indication for a CI in patients with up to 10 years of HL
Austria	70	Monosyllabic score in quiet: ≤50% in adults; ≤50% in children	65	6 months	None, provided the patient has the physical capacity to undergo surgery	Sim. BI in adults and children	Indication for a CI
Australia	None	Monosyllabic score in quiet: CNC words: ≤75% in non-implanted ear; ≤ 55% in implanted ear	65	None	None	Sim. BI and sequ. BI in adults and children	Indication for a CI
Belgium	70 dB mean of 3 frequencies out of 500-1K-2K-4K Hz in best hearing ear	<50% monosyllabic speech recognition unaided	70 dB SPL	None	None	Sim. BI and sequ. BI in children, no reimbursement in adults	In children for asymmetric HL worst ear 85d B, best ear 60 dB
Brazil	70 at 250-1250 Hz; 75 at 1250-1750 Hz; 85 at 1750-8000 Hz in adults and children	Sentence score in quiet: ≤50% in adults and children	70	9 months	86 years (however, no official age limit stipulated)	Only recently been approved.	No indication for a CI
Canada	None	Monosyllabic score in quiet: (CNC): ≤50% in adults sentence test score (HINT): ≤50% in adults	60	Not reported	Adult implantation in patients >18 years; no upper age limit, provided the patient has the physical capacity to undergo surgery	Sequ. BI accepted only research purposes in adults with profound HL affected by visual impairment, meningitis, or sudden bilateral sensorineural HL.	No indication for a CI
China	Average hearing threshold > 80 dBHL; aided threshold above 2 kHz > 50 dBHL; better hearing at low frequencies, but hearing threshold >80 dBHL at 2 kHz and above	Bisyllabic score: ≤70% in prelingual deafness; Sentence score: <70% in postlingual deafness	70	6 months	None; only physical capacity to undergo surgery required	Sim. BI and sequ. BI in adults and children	No indication for a CI
France	None	Bisyllabic score: ≤50% in children and adults	60	None; cognitive abilities to undergo rehab	None; cognitive abilities to undergo rehab	Sim. BI and sequ. BI in adults and children	Only in prospective studies
Germany	70	Monosyllabic score in quiet: ≤50%; Sentence score in noise: ≤60%	65	None but normally from 6 months on	Not reported	Sim. BI and sequ. BI in adults and children	Indication for a CI

(*Continued*)

Table 1. Candidacy Criteria Applied in Different HEARRING Clinics Across the Globe (*Continued*)

Country	Audiometric Thresholds (dB HL)	Aided Speech Perception Criteria	Presentation Level at Speech Test (dB SPL)	Minimum Age for Implantation	Maximum Age for Implantation	Bilateral Implantation	SSD
India	Not reported	Monosyllabic score in quiet: ≤40% in children and adults	50	10 months	Not reported	Sim. BI and sequ. BI in adults and children, no reimbursement	Indication for a CI only in children
Japan	90 in adults and children	No conventional speech tests; only for EAS: Monosyllabic score in quiet only: ≤60%; children who do not exceed a hearing level of 45 dB or sound recognition of 50% using an appropriate hearing aid after 6 months are considered candidates	65 (EAS)	Approximately 12 months; younger children may be considered if their body weight is >8 kg	None	Sim. BI and sequ. BI in adults and children	No indication for a CI yet; trial going on
Russia	Not reported	Not reported	Not reported	6-9 months	None	Sim. BI and sequ. BI in adults and children	No indication for a CI
Saudi Arabia	Adults: 80 at 250-2000 Hz; 70 at 2000-8000 Hz; children: 70 at 250-1500 Hz; 80 at 1500-8000 Hz	Monosyllabic and/or disyllabic (bisyllabic) score in quiet: ≤60% in adults and children	MCL	None	None	Only sequ. BI in adults; Sim. BI in children only up to 5 years; BI in children > 5 years only permitted if the child is prelingually deafened and has been wearing a hearing aid	Indication for a CI only in adults
Spain	Adults: 70 at 500-4000 Hz; Children: 90 at 500-4000 Hz	Adults: disyllabic (Bisyllabic) score in quiet: ≤50%; children: disyllabic (bisyllabic) score in quiet: ≤40%	65 (adults); 50 (children)	Approved for children < 2 years with stricter criteria than for children > 2 years	Adults must have a life expectancy of at least 3-5 years	Children: Sim. BI in children with bilaterally profound congenital HL. If there is no hearing aid benefit in the not implanted ear after CI, then sequ. implantation is considered. Adults: Sim. BI in special cases, e.g., meningitis; majority have sequ. BI	Requires individual evaluation for a CI in adults; no indication for a CI in children
Switzerland	None	Monosyllabic score in quiet: ≤40%	65	None; approximately 9-12 months	None; approximately 85 years	Sim. BI & sequ. BI in adults & children regardless of age; sequ. interval: 3-12 months, in special cases longer	No indication for a CI
United Kingdom	90 at 2000-4000 Hz (NICE guidelines); clinics, however, may apply for funding outside the NICE criteria	BKB Sentence score in quiet: ≤50% (NICE guidelines)	70	None; only physical capacity to undergo surgery required	None; only physical capacity to undergo surgery required	Mainly sim. BI performed in patients up to 18 years; BI in adults if registered as blind or if they have an additional disability for spatial awareness	No indication for a CI
United States	Adults: 70 at 500-2000 Hz; children: 90 at 1000-8000 Hz	Adults: Sentence score: ≤40% (Medicare insurance); ≤60% depending on other insurance; Children: Sentence score in quiet: ≤30% regardless of insurance; limited	60 (adults and children)	12 months for children; 18 years for adults	Not reported	BI accepted in adults and children depending on the insurance but not with the government insurance (Medicare)	No indication for a CI

SSD, single-sided deafness; CI, cochlear implant; BI, bilateral implantation; CNC words, consonant-nucleus-consonant words;EAS, electric-acoustic stimulation; MCL, most comfortable loudness; Sequ., sequential; Sim., simultaneous.

cochlear implantation to be candidates for cochlear implantation. In the second HEARRING clinic in the United States, patients with severe tinnitus will be implanted if the aim is also to improve speech perception in the ipsilateral ear. In Austria, cochlear implantation is not a standard treatment for HL-induced tinnitus. In Austria, cochlear implantation is only performed in tinnitus patients if additional benefits are expected; detailed counseling is considered important. The majority of the clinics implanting patients with SSD report improvement of concomitant tinnitus secondary to the HL, even if the patient experiences the tinnitus as worse than the SSD.

Children

Eighteen clinics state that they perform BI in children. In 17 of these 18 clinics, simultaneous bilateral cochlear implantation is reimbursed.

Nine clinics state that they perform cochlear implantation in pediatric SSD patients; 9 do not. It is variable if cochlear implantation is reimbursed in pediatric SSD patients as a routine or only as part of a clinical trial.

Minimum age at implantation is between 4 and 12 months.

DISCUSSION

While the candidacy criteria for cochlear implantation vary significantly, both nationally and internationally, there exists the very real risk of excluding patients who would benefit from implantation. Key candidates may be missed because of governmental decisions that are mainly based on economic considerations.

What might be the reasons for this outstanding variation? There seem to be 3 major reasons for the great variety in candidacy criteria and, hence, for the fact that only a small percentage of potential CI candidates become CI recipients. First, there is a severe lack of referral guidelines, which results in inconsistent and often inadequate referral of potential candidates by general practitioners or ENT doctors.[20] Second, there seems to be a lack of awareness both among medical professionals and the general population.[21] Third, the great variation in candidacy criteria also owes to a lack of consensus regarding CI criteria as demonstrated by our survey. Only when clear referral guidelines for potential CI candidates exist, only when we have become aware of the global impact of HL, and only when a consensus has been achieved can standardized criteria be established. And only with standardized criteria, we can ensure effective treatment of disabling HL worldwide. Such criteria will also help promote BI in children, early implantation, and implantation in postlingually deafened with SSD.

With these considerations in mind, quality standards for minimal outcomes measures in both adults and children were established by the HEARRING group[22] based on a collection of outcome measures reported in the literature since the early 2000s and based on a questionnaire survey among experts in the field. Further, quality standards for the different steps of the entire hearing treatment journey—ranging from referral to follow-up care—were established for both adults and children and adolescents.[23,24] These standards are mostly upheld by the clinics of the HEARRING group. However, no standardization has been achieved so far with regard to audiological and speech perception outcomes. This is why we conducted a survey among all HEARRING members as the first step toward consensus and standardization.

In general, different reimbursement conditions, governmental decisions, and national guidelines do impact the creation and practicability of standardized candidacy criteria. For example, the guidelines of the NICE in the United Kingdom used to be quite stringent in the early phase but were finally alleviated in 2019[25] (https://www.nice.org.uk/guidance/ta566/resources/cochlear-implants-for-children-and-adults-with-severe-to-profound-deafness-pdf-82607085698245) after a consensus of the British Cochlear Implant Group in 2017: children with a hearing threshold of 80 dB HL and no benefit from hearing aids are eligible for bilateral cochlear implantation in the United Kingdom since 2019. In the United States, for example, children with sensorineural HL under the age of 9 months have only been considered for cochlear implantation since 2020.

High-income countries seem to be stricter with regulations and bound by the government, whereas low-mid income countries are more bound by reimbursement and private paying systems; less means imply less control. Criteria are becoming more adapted to the expected outcomes; reimbursement agencies often want to see the clear benefit of a CI over a hearing aid, especially in patients with residual hearing or SSD.

Another factor for the huge variety in candidacy criteria might be the fact who is actively involved in the decision-making process. The HEARRING guideline that was established on the different steps of the hearing treatment journey[23,24] suggests the involvement of a multi-disciplinary team consisting of a CI surgeon, an audiologist, a speech therapist, a teacher of the deaf, and a psychologist. In some countries, the multidisciplinary approach has already been established as a clinical routine, for example, in Belgium, the United Kingdom, and Germany. However, in some countries, such as China and Austria, the final decision on CI provision tends to be highly surgeon-influenced. Nevertheless, in none of the cases presented in our study, surgeons make a decision without obtaining the other experts' opinions beforehand.

In view of all the considerations mentioned above, the major goal of the HEARRING group is to elaborate a unified statement of guidelines that will benefit as many patients as possible. This can only be achieved by providing substantial scientific evidence to national health care politicians for the widening of the criteria to encompass all subjects who may benefit from a CI. Access to a CI, however, will always inevitably be restricted in some health care systems for financial reasons; higher governmental investment in CIs might be detrimental to other treatments. One solution to this would be a reduction in price in the case of BI, for example.

Study Limitations

This study reports on the compulsory criteria applied in the HEARRING centers in 2019. As health criteria are often issued by regional health authorities, the table is not always representative of the whole country. It is also possible that some of the criteria have changed by now. Nevertheless, this paper provides a good picture of the worldwide trend of candidacy criteria. However, this trend is not applicable to low-income countries where a dedicated approach is required.

CONCLUSION

Regardless of financial constraints, criteria for uniform and broadened access need to be endorsed by high-quality evidence generated from sufficient high numbers of patients. Likewise, the current degree of variability can offer an opportunity for well-designed and appraised studies leading to the early adoption of new evidence by some centers. It is important that collaborative work is undertaken to increase the evidence base for cochlear implantation and that centers report agreed core sets of outcome domains using outcome measurement instruments that are standardized to age and/or not language-specific.[26] Only then it will be possible to compare and combine meta-analysis studies in a clinically meaningful and methodologically robust manner and to develop the much-needed large data sets for children, young people, and adults following cochlear implantation. This is a preliminary study from the HEARRING clinics which will serve as the basis for a larger study on global CI candidacy criteria.

Ethics Committee Approval: N/A

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

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