Expert opinion: Time to ban formal CI selection criteria?

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This contribution addresses cochlear implantation (CI) selection criteria as a discussion topic. It expresses a personal viewpoint that challenges the usefulness and necessity of formal selection criteria. Scientifically, it is argued that CI selection must be highly individual, whereas the current criteria are general, not valid, not based on a wide consensus, and not up-to-date. Morally, it is argued that it is not legitimate to presume equality between patients and CI centers, that the current selection criteria create an ethical dilemma, and that an unresolvable contradiction exists between quality of life and measurability. Finally, liberalizing the criteria would probably have only a minimal impact on current practice and budget.

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Introduction

When asked to make a contribution on the European perspective around the indication for cochlear implants (CI), the need dawned upon me to call the formal aspect of these into question. Although this may come across as challenging, it is especially meant to be an exercise in critical thinking that is motivated by scientific concern and social responsibility. This debate transcends our CI domain. It addresses an inherent conflict between two opposing, albeit closely intertwined relationships, namely the highly individual relationship between the patient and his/her clinical team on the one hand, and the societal relationship between healthcare purchasers and consumers on the other. Whereas the first relationship should be driven by uniqueness and excellence, the second is driven by uniformity and the average. Although this exercise is my personal one, it is my belief that it is shared by many.

The rationale

The justification for selection criteria is obvious, especially from a historical perspective. Some 30 years ago, CIs were novel devices. Every aspect of them was adventurous: the technology, the surgery, the fitting process, and the results. As these things go, a few pioneers started implanting CIs with caution and hesitation in a first few patients (Worthing, 2015). The pioneers were surrounded by strong scientific teams who meticulously analyzed and reported on the first experiences. Based on growing insights, the pioneers decided which of the next patients they thought would benefit from CI. Gradually, that evolved into recommendations and selection criteria, initially for their own internal use, and later for new colleagues as well. CIs being extremely expensive, governments and other purchasers took on these criteria once asked to consider reimbursement.

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The scientific criticism

Real criteria are highly individual

From a scientific and clinical standpoint, selection criteria must only rely on the comparison between the current patient's performance and the performance that can be reasonably expected with CI. This comparison is highly individual. The balance depends on factors that are specific to the individual patient and the individual CI team. Most of the factors are barely even known or discussed. For the patient, it is a matter of the cause and duration of hearing loss, age, the surviving neural population, central auditory factors, cognition, motivation, socio-economic factors, etc. (Blamey *et al.*, 2012). For the CI team, it is a matter of surgical experience, the implant used, counseling, the quality of the fitting, rehab, etc. (Vaerenberg *et al.*, 2014). Thus, the balance between the current patient's performance and the expected performance with CI is not universal, but highly individual to each center and each patient. It is scientifically not correct to predict this balance by means of general parameters, thereby discarding the complex individual condition of the CI candidate, much of which is known to the CI team.

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The current criteria are invalid

All the criteria currently used are based on two measures: (1) sound field audiometry and (2) speech audiometry. Neither is valid in evaluating the cochlear function. The cochlea is a receptor whose electrophysiological function is well known. In general, a receptor is responsible for the coding of its particular signal, which in this case is sound. Before anything else, the receptor must detect the sound and convert it to an electrical signal, but what is most important is that two different sounds give rise to two different electrical patterns. The composition of sound is determined by three physical parameters: intensity, spectral content, and temporal properties. Thus, the cochlea is responsible for encoding these three parameters such that even the smallest differences are discernible. Speech recognition is not the responsibility of the cochlea. Good speech-intelligibility of course requires good functioning of the cochlea, but that is merely a precondition. There are numerous additional factors that determine the quality of speech understanding. It is quite remarkable that after 30 years, we still only use a test of detection (audiometry) and a speech-intelligibility test (speech audiometry) to consider whether CI is appropriate in an individual patient or to evaluate the outcome of CI. And this while ample other psychophysical tests exist to evaluate the cochlea's capacity for encoding loudness, spectral and temporal content, but these are almost never used in the context of CI selection or CI outcome assessments.

The current criteria are not based on wide consensus

Whereas sound field audiometry comes with universal standards, this is not at all the case for speech audiometry. The results of speech audiometry not only depend on multiple patient-related factors, but also on the type of speech material and the test methods used. In the Anglo-Saxon world, monosyllabic CVC words are the standard. There are many languages however where very few such words exist, in which case disyllabic or multisyllabic words are used. Moreover, the speech lists used are never checked for their phonetic or phonological representativeness for the language, nor for their lexical representativeness, nor for their morphosyntactic complexity, etc. Even the presentation levels are not universal, because there are regions where the lists are distributed on CD with proper calibration, and there are more centers where the lists are simply recited live by the audiologist. Also, there are countries where presentation levels are expressed in dBSPL, whereas that is done in dBHL elsewhere, and even the definition of dBHL is subject to regional differences. In short, a speech audiometric score of 40% at 65 dB on a French FOURNIER list does not correspond at all to 40% on an English ARTHUR BOOTHROYD list. As a result, preoperative audiometry and speech audiometry are very poor predictors of CI outcome (Lazard *et al*., 2012).

The current criteria are not up-to-date

As with any medical technique, CI is subject to continuous evolution and improvements in all aspects. The technology of the implants changes constantly, the electrodes change, and there is constant evolution of the front-end processing, surgical techniques, fitting and rehabilitation, etc. Moreover, all the centers follow a learning curve and, thus, get better over time. For this reason, the average results now are systematically better than 5 or 10 years ago (Fig. 1). Current criteria, however, are based on statistical analyses from many years ago, and it is not feasible to keep updating these all the time. By adhering to outdated criteria, we are systematically denying access to better hearing to a significant number of patients.

The moral criticism

It is unjust to presume equality

Adhering to strict criteria, especially when they represent cochlear performance in a simplified and invalid way, does no justice to the diversity inherent in medical practice. No two patients are the same, and neither are two surgeons nor two fitting centers, etc. It is both the art and the duty of the medical profession to care for the most individual needs of the patient. It must take into account the complex and holistic individuality of the patient along with the respective capacities of the doctor and his/her team. Selection criteria can be useful, e.g. for training, guidance, and also when introducing new techniques. However, they have no right to exist if they are used to deny the rich diversity of people while serving mostly administrative or financial interests.

Selection criteria create a moral dilemma

Selection criteria determine which patients may or may not get access to CI. Every CI center regularly sees hearing-impaired patients for whom they are deeply and honestly convinced that a CI would improve hearing substantially. It would allow them to hold conversations easier, be socially stronger, and have better opportunities in their academic career or on the job market. When these people fail to meet the current CI selection criteria based on averages, the treating physician is faced with the impossible dilemma between his moral obligation to provide all possible care to the patient seeking help, and the bureaucratic restrictions arising from the criteria. In the past, access to CI has all too often and unjustifiably been denied to a proportion of hearing impaired

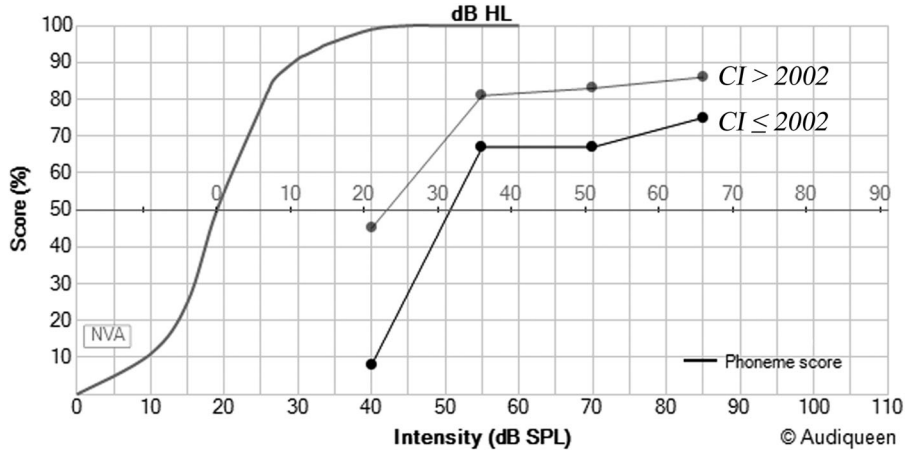

Figure 1 The median phoneme scores on speech audiometry (Flemish NVA lists) in 56 otherwise unselected deaf-born children who received an implant before the age of 3 years. Half of the children were implanted in 2002 or before, the other half after 2002. In all children the test was performed at the age of 10 years (range 8–12 years). The figure shows a marked difference between the early and the more recently implanted group of children.

people. Among the many examples, perhaps the most poignant is the baby with congenital deafness. While the body of evidence was present for years and constantly growing, there are entire cohorts of babies who did not receive a CI at the necessary early age because of the administrative criteria of many countries. For the rest of their lives these children are doomed to a disability that is much greater than what should have been.

The philosophical perversion of Quality of Life

The term 'Quality of Life' made its way into the financial context of medical assessments several years ago. Although everyone involved in this domain is obviously concerned about quality of life, there is an absolute contradiction in the measurability of that quality. In the ancient Socratic philosophy, the terms quality and quantity were consistently used to distinguish between what is measurable and what is not. Quality is precisely what is not measurable, this lies in the definition of that word. That certainly does not preclude the fact that quality can vary greatly in scale, or that we can get a sense of magnitude associated with quality; but it does mean that it is wrong to express that magnitude in measurable figures. In doing so, well-meaning people can create scientific artifacts that give the illusion of measurability and size. A clinician is more than just an academic. He is certainly a scientist who measures and weighs, analyzes and seeks out evidence. But he is also a caregiver who observes and feels, who has a sense of appreciation and seeks quality.

What if we banned formal criteria?

As much of a blasphemy as it seems, what would the CI domain look like if, after 30 years of strictness, we quit using formal selection criteria? In these 30 years, we have evolved from curious adventurers to mature, experienced experts. We know the subtleties of our patients, of technology, and our own capabilities, and we have the insight to realize that excellence lies in the unique and not in the average. Our expectations of CI have become realistic and if we continue to explore its boundaries out of curiosity and a healthy drive to make progress, then we do so cautiously, in open conversation with our peers and in consultation with our non-naive patients who critically and deliberately entrust their fate to our care. I think that we are now able to handle that level of freedom and that we must begin to demand that freedom from a scientific and moral standpoint. We can do this in respect of the financial constraints that are imposed on healthcare purchasers, because it is unlikely that the proposed liberalization of criteria will lead to an explosion of the indications. For instance, in Belgium, the number of CIs being implanted annually has been stable for many years, despite the fact that the criteria have been relaxed in a stepwise fashion (unpublished Belgium National Health Care figures). However, even if the numbers of implantations would increase, this would be scientifically and morally justified; and it is not us, but rather the healthcare purchaser and society who must decide whether that is also financially justified.

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