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ORIGINAL ARTICLE

Guideline on Cochlear Implants☆

Manuel Manrique,[a,*] Ángel Ramos,[a] Carlos de Paula Vernetta,[a] Elisa Gil-Carcedo,[a] Luis Lassaletta,[b,d] Isabel Sanchez-Cuadrado,[b] Juan Manuel Espinosa,[b] Ángel Batuecas,[b] Carlos Cenjor,[b] María José Lavilla,[c] Faustino Núñez,[c] Laura Cavalle,[c] Alicia Huarte[c]

[a] *Miembros de la Comisión de Otología de la Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello, Madrid, Spain*
[b] *Miembros de la Comisión de Otoneurología de la Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello, Madrid, Spain*
[c] *Miembros de la Comisión de Audiología de la Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello, Madrid, Spain*
[d] *Centro de Investigación Biomédica en Red de Enfermedades Raras (CIBERER-U761), Madrid, Spain*

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Abstract
Introduction: In the last decade numerous hospitals have started to work with patients who are candidates for a cochlear implant (CI) and there have been numerous and relevant advances in the treatment of sensorineural hearing loss that extended the indications for cochlear implants.
Objectives: To provide a guideline on cochlear implants to specialists in otorhinolaryngology, other medical specialities, health authorities and society in general.
Methods: The Scientific Committees of Otology, Otoneurology and Audiology from the Spanish Society of Otolaryngology and Head and Neck Surgery (SEORL-CCC), in a coordinated and agreed way, performed a review of the current state of CI based on the existing regulations and in the scientific publications referenced in the bibliography of the document drafted.
Results: The clinical guideline on cochlear implants provides information on: (a) definition and description of Cochlear Implant; (b) indications for cochlear implants; (c) organisational requirements for a cochlear implant programme.
Conclusions: A clinical guideline on cochlear implants has been developed by a Committee of Experts of the SEORL-CCC, to help and guide all the health professionals involved in this field of CI in decision-making to treathearing impairment.

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* Corresponding author.
E-mail address: mmanrique@unav.es (M. Manrique).

PALABRAS CLAVE
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Guía clínica sobre implantes cocleares

Resumen
Introducción: En la última década son numerosos los hospitales que han iniciado su actividad en pacientes candidatos a un implante coclear (IC), y se han producido numerosos y relevantes avances para el tratamiento de la hipoacusia neurosensorial que han desembocado en una ampliación de las indicaciones de los IC.
Objetivos: Ofrecer a los especialistas de otorrinolaringología, de otras especialidades médicas, autoridades sanitarias y a la sociedad en general una guía clínica sobre implantes cocleares.
Métodos: Las comisiones científicas de otología, otoneurología y audiología de la Sociedad Española de Otorrinolaringología y Cirugía de Cabeza y Cuello (SEORL-CCC), de manera coordinada y consensuada, han llevado a cabo una revisión del estado actual de los IC basándose en las reglamentaciones existentes y en las publicaciones científicas que se referencian en la bibliografía del documento elaborado.
Resultados: La guía clínica sobre implantes cocleares aporta información sobre: a) definición y descripción sobre IC; b) indicaciones de los IC; y c) requisitos organizativos para un programa de IC.
Conclusiones: Se ha elaborado por un comité de expertos de la SEORL-CCC una Guía clínica sobre implantes cocleares que aporta coordenadas de actuación para todos aquellos agentes de la sanidad en la toma de decisiones en el ámbito de los IC como forma de tratamiento de la discapacidad auditiva.

Definition and Description of Cochlear Implants

Definition of a Cochlear Implant

The principle of this methodology resides in the transformation of ambient sounds and noises into electrical energy that act on the afferent pathways of the cochlear nerve, thus determining an auditory sensation.

A cochlear implant (CI) essentially consists of one or 2 microphones located in the processor, which is either a retroauricular, corporal or ''button'' type. The signals heard are transmitted to a processor. There is also a compartment in the processor where batteries providing energy to the system are stored. The processor's mission is to encode the signals and send them to a transmitter or spool which is attached to the surface of the skin in the parietal-temporal region and that they stay in this position due to magnetic pull between 2 magnets, one located on the transmitter and the other in the receiver-stimulator. The transmitter emits modulated radio frequency signals through the skin that travel to an antenna and a receiver-stimulator, which have been surgically implanted on the surface of the cranial bone underneath the skin in the retroauricular region. This receiver-stimulator encodes the message, sending it to each of the electrodes generally stationed inside the cochlear, thereby stimulating the cochlear nerve. This nerve structure is usually composed of 35 000 bipolar type neurons, with a dendritic portion that fire synapse at the base of the hair cells in the inner ear, a soma which forms part of the spiral ganglion and axons extending along the cochlea modiolus, the inner auditory canal and the cerebellopontine angle, to fire a synapse in the complexity of the cochlear nuclei, at brainstem level. Any of the elements composing the cochlear nerve neurons may be stimulated by implant electrodes. An efficient way of stimulating the fibres of the auditory nerve, with good selectivity, consist of applying bipolar stimulation. In this modality the electric current runs from the active electrodes to the reference electrodes which are both located inside the cochlea. In monopolar stimulation the current flows from the active electrodes situated inside the cochlea to a reference electrode situated outside the cochlea.

Classification of Cochlear Implants

There are different types of cochlear implants which may be classified according to 3 criteria: (1) types of intracochlear electrode arrays (straight, perimodiolar); (2) number of stimulation channels (single or multichannel) and (3) treatment of sound signal (encoding strategies).

Types of Electrode Arrays in a Cochlear Implant

The intracochlear position of the carrier array of CI electrodes with regard to the modiolus of the cochlea is the argument which supports this classification criteria. CI may be classified into perimodiolar or straight, depending on whether the electrodes stay within the modiolar region of the cochlea or in a more lateral position. In either of the 2 modalities their diameter, length and flexibility have been improved to provide minimally traumatic properties during implantation.

The existence of hearing impairments associated with the presence of cochlear malformations or the appearance of obliterating phenomenon of the cochle has led to the design and development of special models of CI arrays which may be adapted to the anatomical peculiarities of the cochlea in each individual case. Modifications have thus been introduced to their length with variations in location and distance between electrodes. Carrier arrays of biforked electrodes have also been designed for use in ossified cochleas.

Sound Signal Treatment

Encoding strategies used in the treatment of sound signals have recently undergone major advances with generally more satisfactory clinical outcomes. Cochlear implants have also been introduced where it is possible to select, from several types, the most appropriate encoding for each patient, thus providing these systems with versatility that contributes to improving outcomes. There are 2 major families of encoding. The first is based on the human voice formant extraction (for example F0−F2, F0−F1−F2, MPEAK, SPEAK, etc.), which selects the most relevant information for recognition of the spoken word. The other sends all the sound information within a wide range of frequencies to the electrodes (for example CA, CIS, SAS, FSP, HiRes, etc.), without enhancing the spectral information of the human voice. Mixed strategies also exist (for example ACE) which functions by combining principles from both families.

Indications for Cochlear Implants

Introduction

Most authors are of the opinion that CIs are suitable for patients who present with profound bilateral sensorineural hearing loss where little benefit from hearing aids may be obtained. This condition corresponds to a wide range of congenital or acquired causes that may occur in the pre- peri- or post-lingual stages of language development. However, in recent years major modifications in CI indication criteria have taken place and this has supported the need for the creation of this clinical guide on CI. CI indications will now be analysed separately in different population groups, in accordance with age, hearing loss characteristics and aetiology.

Indication for Cochlear Implants in Accordance With Age

Children

Taking as a reference the Health technology assessment report AIAQS 2010/03 and the Clinical guideline for the recommendation of cochlear implants in the Autonomous Community of Navarre[1] and the NICE Guidance[2] the following circumstances are considered suitable for CI recommendation in the population group aged 0−18 years:

1. Bilateral sensorineural hearing loss which is severe (hearing loss of 71−90 dB HL) to profound (hearing loss over 90 dB HL) in conversational frequency range (from 500 to 4000 Hz) in children from 6 months of age. In the case of children, apart from audiometry criterion, consideration must be made to what extent language has been developed and listening abilities correlated with chronological age and cognitive development. In children under 1 year of age, trained hospital staff with adequate resources are required, so that under these conditions any anaesthetic and surgical risks of a child under one year would be comparable to that of older children and adults.[3] As a result, these centres must have teams and professionals who are capable of carrying out a reliable audiometric diagnosis so that the lower age limit is marked by diagnostic safety to determine the degree of hearing loss.[4−6]
2. With no or minimum benefit from a hearing aid after a trial period of 3−6 months (unless contraindicated).
3. Pre-lingual, peri-lingual or post-lingual hearing loss.
4. Imaging studies (MNR or the combination of CT+MNR) confirming the viability of insertion of electrodes into the cochlea and the presence of the cochlear nerve, in the absence of central alterations compromising the auditory pathway. Of note is that the appearance of a bilateral PHL in the context of meningitis must be considered an emergency situation for implantation of a single or bilateral CI due to the risk of ossifying labyrinthitis.
5. Positive psychological, paediatric and neurological assessment which confirms the benefit of an implant. Indication for CI must be made by a multidisciplinary team.

Adults

Taking as a reference the Health technology assessment report AIAQS 2010/03 and the Clinical guideline for the recommendation of cochlear implants in the Autonomous Community of Navarre[1] and the NICE Guidance[2] CI indication is considered in adults (>18 years of age) under the following circumstances:

1. Bilateral sensorineural hearing loss which is severe (hearing loss of 71−90 dB HL) to profound (hearing loss over 90 dB HL) in conversational frequency range (from 500 to 4000 Hz).
2. Post-lingual or pre-lingual hearing loss.[7]
3. With no or minimum benefit with hearing aid on both a tonal and functional level (under 40% in voice test to 65 dB SPL) after a trial period of 3−6 months.
4. Patient's conviction that the auditory improvement of an implant would personally and socially enhance them. Prior evaluations on a personal, work-related and psychological level are recommended.
5. Imaging studies (MNR or the combination of CT+MNR) confirming that the cochlea could house the electrode, and the presence of the cochlear nerve. Of note is that the appearance of a bilateral PHL in the context of meningitis must be considered an emergency situation for implantation of a single or bilateral CI, due to the risk of ossifying labyrinthitis.

Indication for Cochlear Implants in Accordance With Hearing Loss Characteristics in Both Ears

Table 1 represents the different hearing loss characteristics in both ears which may lead to an CI indication, the

Table 1 Indications for Cochlear Implants.

Ear 1	Ear 2	Hearing aid	Adults	Children
PHL	PHL	CI in ear 1 or ear 2	Established indication	Established indication
PHL	PHL	CI ear 1+CI ear 2	Special indication	Established indication
PHL	M-SHL	CI ear 1+hear aid in ear 2	Emerging indication	Emerging indication
PHL	Normal hearing or MHL	CI in ear 1	Special indication	Special indication
M-PHL	M-PHL	(CI+hear.aid)+hear.aid	Established indication	Emerging indication

Hear.aid: hearing aid; MHL: mild sensorineural hearing loss; M-PHL: mild to profound sensorineural hearing loss M-SHL: moderate to severe sensorineural hearing loss; PHL: profound sensorineural hearing loss CI: cochlear implant.

necessary hearing aids and their state of application in adults and children.

An established indication is understood to be that with an extended period of implementation and which has been demonstrated to be effective with an acceptable cost benefit. An emerging indication is understood to be one of recent introduction, the initial results of which are positive and which are engaged in the cost-benefit study phase. Special indication is understood to be that which is applicable to specific cases, such as the case of bilateral CI in adults with problems associated with severe vision or meningitis with signs of obliteration in both labyrinths. CI would also be used in adults with unilateral hearing loss and incapacitating tinnitus.

Severe-profound Bilateral Hearing Loss: Bilateral Cochlear Implants

The main benefits of binaural hearing is greater understanding of noise and the ability to locate the sound.[8] In addition to the before-mentioned benefits, implantation of bilateral CI, implanting bilateral CI in pre-lingual children aids optimum development of the auditory pathways and centres.[9] Bilateral implantation may be undertaken sequentially or simultaneously. Studies prove that whenever possible it is better to indicate a simultaneous bilateral implantation and if not, that the time elapsing between implantation in both ears be as short as possible.[9,10] Taking as reference that expressed by NICE[2] and Marcia Yuri Tsumura Kimura[11] we would recommend considering the following premises for bilateral cochlear implantation in children and adults:

Children:

- All the children with severe-profound pre or post-lingual bilateral sensorineural hearing loss should receive, health permitting, a simultaneous bilateral implantation.
- In the case of sequential implantation in children the second implant must be undertaken if possible, within an interval of under one year.
- Children bilaterally implanted simultaneously or sequentially, before they are 4 years of age will obtain great benefit, with the performance of the bilateral implants gradually lessening between the ages of 4 and 7 years.
- In children over 7 years of age with pre-lingual deafness the sequential bilateral implant will be indicated in accordance with pronounced audiometric criteria, with a good development of the oral language, with early implantation of the first (recommended before 2 years of age) and with an interval between the 2 implants of no more than 5 years, provided that there is no major cognitive impairment or a severe degree of autism. However, the result of the second implant will always be variable, with the acoustic stimulation received prior to implantation being essential.
- Adults:
- In post-lingual deafness the sequential bilateral implant is indicated in adults with severe-profound sensorineural hearing loss who have used the first cochlear implant for at least one year and in accordance with the set criteria.
- In people with sensorineural hearing loss associated with a severe visual impairment or a disease involving phenomena of bilateral labyrinth obliteration.

Asymmetrical Hearing Loss: Bimodal Stimulation

The audiometric hearing criteria for CI indication would be as follows: severe-profound sensorineural hearing loss in one ear and moderate to severe (between 41 dB HL and 90 dB HL) in the contralateral ear. The implantation of the CI would be performed in the ear with the worst hearing loss.[12]

These patients simultaneously use a CI in the ear most affected by severe-profound hearing loss and a hearing aid in the contralateral ear. This stimulation is called bimodal strategy. It has been confirmed that with this strategy patients reach sterophonia and better levels of discrimination of language, both in silence and when there is noise, compared to that obtained using hearing devicess or just one CI.[13,14] In cases where it is difficult to establish an implantation in one ear with long-term severe-profound hearing loss the realisation of function hearing tests (cortical auditory evoked potentials or auditory BEP) is justified to obtain information on the level of functionality-plasticity of the auditory cortical areas.[15]

Unilateral Deafness: Unilateral Cochlear Implant

These are patients with severe-profound hearing loss in one ear and normal hearing or mild hearing loss in the contralateral ear. A CI is one of the options which may be offered to these patients (CROS hearing aid, bone conduction implants).[16] This indicates that central integration of the electric and acoustic stimulation is possible, even in those cases in which there is normal contralateral hearing.

Adults. A unilateral hearing loss may occur in isolation without other accompanying symptoms. However, the association of hearing loss and tinnitus in adults in the ear with unilateral hearing loss is not infrequent. As a result the following criteria must be considered for the implantation of a CI in this patient group:

1. Adults over 18 years of age.
2. In the ear subject to CI:
   - Severe-profound sensorineural hearing loss.
   - Speech performance tests with silent two syllables at 65 dB SPL in optimum conditions without lip reading assistance <50%.
   - Score of >58 in the Tinnitus Handicap Inventory
   - Tinnitus causing disability related with or caused by hearing loss and not by other causes.
   - Duration of tinnitus >1 year.
3. In the contralateral ear of the CI:
   - Normal hearing or mild hearing loss.
4. Should tinnitus exist the failure of conventional treatments of this symptom, including tinnitus retraining therapy, for at least 6 months. Patients with tinnitus of central origin will be excluded (for example tumour or stroke), pulsatile tinnitus connected to blood flow, paroxistic tinnitus, somatosensory tinnitus, tinnitus related with headaches and post-traumatic tinnitus. Lastly, those patients with unrealistic expectations regarding the possible benefits, risks and limitations of the procedure and the prosthetic device will be excluded.

Results shown in the literature demonstrate that benefits may be obtained in restoring hearing input and clinical improvements are observed with regard to perception and tolerance of tinnitus.[17–19]

Children. The impact of unilateral profound hearing loss in a child's communication, family and social life may be relevant. There is a high rate of unilateral deafness and its direct implication in auditory development may affect the academic performance and self-esteem of these children.[20]

In this population group of children with unilateral deafness, indication for CI may be classified as an emerging indication. The results obtained with it are still considered preliminary. Studies report positive results both at auditory integration level and from the benefits derived from binaural hearing.[21–23] In addition to the before-mentioned clinical benefits, one of the main reasons for promoting cochlear implantation in children with unilateral deafness is to support a complete development of the central auditory system within the critical period or that of greater sensitivity which corresponds to the first years of life. This indication is of particular interest in certain groups of children whose unilateral deafness is associated with visual impairments or who present with situations of fragility in the normal hearing ear (labyrinth malformations [dilation of the vestibular aqueduct, incomplete partitions of the cochlear, etc.], osteodystrophias of the temporal bone, middle ear disease [congenital cholestreatoma]).

The inclusion criteria for children with unilateral deafness are as follows:

1. Children aged between 0 and 12 years.
2. Unilateral hearing loss which involves the following characteristics:
   - Ear to be treated with CI: severe-profound hearing loss, with a duration of hearing loss under 12 years.
   - Contralateral ear: normal hearing or mild hearing loss.

Children with the following characteristics will be excluded:

1. Ossification or other cochlear malformation which impedes the complete insertion of the implant's active electrodes.
2. Signs of retro-cochlear or central hearing loss.
3. Unrealistic expectations by parents regarding the possible benefits, risks and limitations of the procedure.

Mild to Profound Hearing Loss: Electro-acoustic or Hybrid Stimulation

Inclusion criteria of these candidates are as follows:

1. Six years of age or older.
2. Severe to profound sensorineural post-lingual hearing loss in frequencies of >1.500 Hz and mild to moderate sensorineural post-lingual hearing loss in frequencies of >500 Hz, without audiometric restrictions for the contralateral ear.
3. Hearing loss duration <30 years.
4. Recognition of two syllable words with help (correctly adjusted prosthesis) in the implantation ear between 10% and 50%, in silence and up to 65 dB SPL.

In this patient group with the example of special electrode arrays and a refined surgical technique, which has become known as minimally traumatic, it is possible to preserve the remnants of hearing in the implanted ear. This has resulted in the possibility of the same ear simultaneously receiving electrical stimulation with the CI and acoustic stimulation with the hearing aid (hybrid or electro-acoustic stimulation). Reported results indicate notable advantages in listening in noisy environments and possessing musical perception.[24,25]

Indication for Cochlear Implants in Accordance With Aetiology

There is a large number of ''traditional candidates'' who fulfil the previously described audiometric criteria. However, for several of them an indication for implantation requires particular detail due to concurring factors of great prognostic importance regarding the aetiology of hearing loss. Such is the case of patients with genetic or acquired alterations which lead to congenital malformations of the inner ear,[26] which may or may not be associated with other disabilities.[27]

Entities such as bacterial meningitis, temporal bone fractures, osteodystrophies, autoimmune diseases, otogenic labyrinthitis and other aetiologies may give rise to different degrees of fibrosis and cochlear ossification.[28]

The experience published by the Sydney Cochlear Implant Centre shows that, in the majority of auditory neuropathies good outcomes were obtained following implantation,[29] suggesting that 75% of neuropathies are due to a presynaptic alteration of the internal hair cell function. Neuropathies of postsynaptic origin have a poor prognosis after CI. During patient selection clinical history, genetic assessment,[30] MNR and intracochlear and cortical electric potentials may help us to determine which patients with auditory neuropathy will obtain better outcomes with the CI.[31,32]

All of these conditions require extremely meticulous preoperative study, as they may condition the outcome after CI implantation or in some cases clearly present a contraindication for it.

Contraindications

Contraindications of the cochlear implant are: congenital malformations with bilateral agenesis of the cochlea, absence of auditory canal function, the presence of diseases leading to central type hearing loss, severe psychiatric diseases, diseases that would contraindicate surgery using general anaesthesia, the absence of motivation towards implantation or noncompliance of audiological criteria. Some patients with these contraindications (colchlear malformations and malformations of the cochlear nerve, total cochlear ossifications of meningitis origin) could be candidates for treatment with auditory brainstem implants. The indication of these devices which stimulate the auditory pathway at cochlear nuclei level in the brainstem require an exhaustive study prior to taking a final decision.

Organisational Requirements for a Cochlear Implant Programme

Objectives of a Cochlear Implant Programme

The CI technique does not merely consist of a surgical intervention. Implantation requires the organisation of a programme which ensures the following: correct candidate selection; effective execution of surgery and its programming; appropriate, sufficient rehabilitation; close coordination between the specialists involved in the programme and appropriate implanted patient follow-up and device maintenance.

Structure of a Cochlear Implant Centre

In order to comply with all these issues a multidisciplinary, coordinated team must be available and be able to cover each of the steps of the CI programme: selection, surgery, programming, rehabilitation and follow-up.

Structure of a Cochlear Implant Programme in Adults
Taking as reference the requisites specified by the Agency for Evaluation of Healthcare Technology of the Carlos III institute[33,34] and the Royal Board on Disability,[2] the professionals to be involved in a CI centre are:

- Otorhinolaryngology specialists. They are involved in diagnosis, surgery and follow-up of patients.
- Audiologist or otolaryngology specialist. They are in charge of diagnosis, programming and follow-up.
- Audiology and vestibular examination technicians: involved in diagnosis, programming and follow-up.
- Audio technician. Involved in diagnosis and programming tasks.
- Speech therapist. Involved in diagnosis and rehabilitation tasks.
- Specialists in neurophysiology. Involved in diagnostic tasks.
- Psychiatric-psychologist specialists. Involved in diagnostic tasks.
- Specialists in radiology. Involved in diagnostic tasks.
- Other professionals such as neurologists, geneticists, social workers, neurophysiologists, anaesthetists, ophthalmologists, specialists in nuclear medicine, etc. May offer great support in certain situations, and it is therefore recommendable to work in an environment which encourages their collaboration.

Structure of a Cochlear Implant Programme in Children
A child's lack of collaboration, the selection procedure and the surgical idiosyncrasies for the youngest children, together with the long period of time needed to begin objectifying outcomes encumber the programming and follow-up of children with a CI. As a result, when a CI programme is aimed at children, the different specialists and units, referred to in the previous section, should have extensive professional experience in caring for children with hearing disabilities. Paediatricians and neuropaediatricians should also work together with them. Specially trained professionals are essential for the programming of the implant and for coordinating rehabilitation tasks which are to be carried out in the family, school, hospital or speech therapy unit environments. The desired outcome may only be achieved by everyone working together. It is also important to have at least 5 years of experience in post-lingual adults in order to address a CI programme for children. Exchange of information between professionals with the post-lingual implanted adults complements the learning and training of professionals using these techniques.

Coordinator in Cochlear Implant Programmes
At least one member of this team will take on the functions of the coordinator. This person will not only coordinate the work of all the specialists, but will also ensure that the candidates receive an extensive and appropriate information on the CI programme, looking out for the appropriate follow-up of the patient once they have been implanted.

Equipment of a Cochlear Implant Centre

The appropriate means must be made available to the CI programme and therefore the specialists involved in it, to complete its mission. They must therefore have at their deposal each of the explorations described by the Commission of experts of the Royal Board on Disability.[12] In particular, the following must be made available:

- ENT consultation: with the necessary means to carry out an ENT examination and particularly otoscopy.
- Imaging equipment: high resolution CAT and MNR.
- Audiometric examination equipment: soundproof booth for free field examination, liminal pure tone audiometry equipment and vocal audiometry equipment, behavioural audiometry, otoacoustic emissions, middle ear analyser.
- Equipment for neurophysiological exploration of the auditory pathway: electrocochleography equipment, auditory brainstem evoked potentials, auditory stable state evoked

potentials. It is optional but recommended to also have a cortical auditory evoked potentials equipment.
- Vestibular examination equipment: videonystagmography, VEMPS, VHIT.
- Equipment for the adaptation and assessment of hearing instruments: analyser and interface for connection between the hearing instrument and the computer system.
- Access to the necessary materials for undertaking the following tests, scales and questionnaires which provide information on the following areas (as an example some of the materials are quoted in brackets): intelligence (Weschler Intelligence Test, WAIS for adults), level of development of compressive and expressive language (Manchester scale, Lip reading, Induced Phonological Register; Peabody or Carrow vocabulary test, Illinois test of psycholinguistic aptitudes, oral language test of Navarre, Reynell scales, CAP, MAIS, MUSS, Little Ears tests), personality (Minessota multifactorial personality inventory MMPI) and tinnitus (Tinnitus Handicap Inventory).
- Rooms for CI programming with programming IT teams.
- A room for auditory rehabilitation.

Number of Implantations

There has to be a sufficient and coordinated number of implantations practised by a team. It is therefore not recommended that a cochlear implant programme be initiated to treat a small number of patients per year (fewer than an average 30 patients), nor is it recommended to implant a large number of patients within a short space of time when it would be difficult to subsequently offer them personalised attention. Furthermore, it should also be considered that cochlear implantation is for life, and as time passes and the number of implanted patients increase, the resources dedicated to their follow-up must also increase to the same proportion.

We also believe that abundant material and human resources are required for such a complex process as the selection, surgery, programming and follow-up of cochlear implantation. As a result rationalisation of resources must be made in function with needs. The corresponding healthcare administration could initially be responsible for ensuring the establishment of programmes which are sufficiently staffed and adapted to the demands of the population so as to ensure homogenous and appropriate patient treatment. It could be of interest to create a national network of cochlear implantation centres, with periodic audits, formed by centres which are experienced and highly qualified in the subject, so that they become benchmark units for candidates or users of a CI.

Conflict of Interests

The authors have no conflict of interests to declare.

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