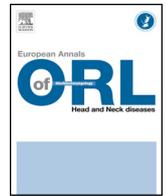




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SFORL Guidelines

French Society of ENT (SFORL) guidelines. Indications for cochlear implantation in adults

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ABSTRACT

The authors present the guidelines of the French Society of ENT and Head and Neck Surgery (SFORL) regarding indications for cochlear implantation in adults. After a literature review by a multidisciplinary workgroup, guidelines were drawn up based on retrieved articles and group-members' experience, then read over by an independent reading group to edit the final version. Guidelines were graded A, B, C or "expert opinion" according to decreasing level of evidence. There is no upper age limit to cochlear implantation in the absence of proven dementia and if autonomy is at least partial. Bilateral implantation may be proposed if unilateral implantation fails to provide sufficiently good spatial localization, speech perception in noise and quality of life, and should be preceded by binaural hearing assessment. Rehabilitation by acoustic and electrical stimulation may be proposed when low-frequency hearing persists. Quality of life should be assessed before and after implantation.

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1. Introduction

Cochlear implants are indispensable for the treatment of severe to profound bilateral sensorineural hearing loss. In 2013, the French Health Authority revised its 2007 guidelines [1]; in adults, the main criterion is $\leq 50\%$ discrimination at 60dB on speech audiometry using Fournier lists or the equivalent in silence with two hearing aids. The French Society of ENT (SFORL) has drawn up the present further clinical practice guidelines for cochlear implantation in the

elderly, bilateral implantation, electro-acoustic stimulation, contralateral hearing aids, implantation in unilateral hearing loss and quality of life assessment after implantation.

2. Materials and methods

Drawing up the guidelines was entrusted to a multidisciplinary work-group from various regions of France. The French Health Authority's formalized expert consensus methodology for good practice guidelines was used (<http://www.has-sante.fr>). A pilot group organized the logistics of the consensus conference, choice of reading group members, and literature analysis on the PubMed data-base. Articles were graded 1, 2, 3 or 4 by decreasing level of

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evidence, and guidelines were graded A, B, C or “expert opinion” in line with the literature analysis and guidelines grading guide of the French national health accreditation and evaluation agency (ANAES). A rationale was drawn up for a first series of guidelines, assessed by the reading group and revised according to their comments.

3. Results

3.1. Elderly persons and adult cognitive assessment

Several reports have focused on the association between hearing loss, cognitive disorder and dementia [2] (level of evidence: 2). According to the Alzheimer’s Association International Conference, hearing loss is the main treatable risk factor for dementia; preserving hearing between the ages of 45 and 65 years could reduce subsequent onset of dementia by 9% [3] (expert opinion). There are at present no randomized studies with sufficient power demonstrating benefit for cognitive function with aural rehabilitation by cochlear implantation, but several longitudinal observational studies reported that hearing-impaired subjects showed better cognitive prognosis in case of hearing rehabilitation [4,5] (level of evidence: 2). Patients with profound hearing loss also seem to show a particular, reversible form of cognitive decline [6], and cochlear implantation was reported to improve cognition in elderly patients 1 year after implantation [7] (level of evidence: 2).

- There is no upper age limit for cochlear implantation in adults, if neuropsychological assessment has been made and there is no proven dementia (Grade A).
- Cognitive disorder is not a contraindication to cochlear implantation (Grade B).
- Candidates for cochlear implantation should be totally or partially autonomous or have the requisite help to look after the equipment (Expert opinion).

3.2. Bilateral cochlear implantation in adults

In the 2007 French Health Authority report [8], updated in 2011, cochlear implantation is indicated in case of loss of benefit contralateral to the first implanted side, impacting socio-occupational life or inducing loss of autonomy in an elderly subject. In certain particular clinical situations, such as acute bacterial meningitis or bilateral temporal bone fracture at high risk of cochlear ossification, simultaneous bilateral implantation may be indicated. The advantages of bilateral over unilateral implantation have been widely studied, focusing on both auditory benefit and improved quality of life. The choice between bimodal stimulation and bilateral cochlear implantation can be difficult, and is mainly founded on assessment of the usefulness of the residual hearing contralateral to the implant [9] (level of evidence: 2).

3.2.1. Usefulness of residual hearing contralateral to the implant

The residual hearing contralateral to the implant can be useful for loudness perception of symmetrical sounds [10] (level of evidence: 3), speech perception in noise in dichotic listening [11] (level of evidence: 3) and perception of para- or extra-linguistic information [12] (level of evidence: 4). The threshold of useful residual hearing is hard to determine, but can help decide between bimodal stimulation and bilateral implantation in patients with severe to profound hearing loss. Assessment of the contribution of the residual hearing contralateral to the implant is essential.

3.2.2. Assessment of binaural hearing

Binaural hearing can be assessed by testing:

- acoustic localization: this is usually assessed by a system comprising several loudspeakers arranged in a horizontal arc at the subject’s ear height. Although there are no official guidelines on the subject, at least 9 speakers covering 180° are required. Stimuli usually consist in wide or narrow band noise of less than 500 ms duration [13] (level of evidence: 3). The mean angle of error can be completed by the general localization index, which identifies specific directional problems to the left or the right and assesses a global localization deficit [14] (expert opinion).
- speech perception in noise: although there are no official guidelines on the subject, the Hirsh [15], Hearing In Noise [16] or Matrix [17] tests may be used.

- When implant bilateralization is considered, at least one of the standardized hearing-in-noise and localization tests should be used to assess binaural hearing in hearing-impaired patients (Expert opinion).

Localization is significantly improved by bilateral implantation [9] (level of evidence: 2), which moreover seems to improve signal-to-noise discrimination [18] (level of evidence: 2), although differences in protocol limit the reproducibility of these findings [9] (level of evidence: 2).

- If a hearing aid contralateral to the implant fails to improve horizontal localization, implant bilateralization should be proposed (Grade C).
- If a hearing aid contralateral to the implant fails to improve speech perception in noise, implant bilateralization should be proposed, as results are better than with a unilateral cochlear implant (Grade C).

Benefit of bilateral cochlear implantation for quality of life.

Restoring bilateral hearing and, to a certain extent, binaural hearing is regularly reported to improve quality of life by patients with bilateral cochlear implants. Improvement is usually assessed on specific quality-of-life questionnaires such as the Speech, Spatial and Qualities of Hearing Scale [19] or Nijmegen Cochlear Implant Questionnaire [20] or generic questionnaires such as the Health Utility Index 3 [21] or EuroQoL-5D [22].

- If a hearing aid contralateral to the implant fails to improve quality of life, implant bilateralization should be proposed (Grade B).

3.3. Electroacoustic stimulation

Electroacoustic stimulation is now permissible in certain candidates for cochlear implantation with residual low-frequency hearing, thanks to careful surgery and latest-generation implants. Implantation should take care not to damage the ossicular chain or block it with tissue intended to staunch perilymphatic leakage, or

to damage the organ of Corti, so as to conserve functional structures [23] (level of evidence: 4). Likewise, it is important to avoid aspirating perilymph or letting blood or bone debris penetrate the cochlea [24] (level of evidence: 4). Patients with residual postoperative hearing show better speech perception performance with pure electrical stimulation [25] (level of evidence: 2).

- The surgical technique should optimally conserve outer, middle and inner ear structures that remain functional, in cochlear implantation in all patients, with or without residual low-frequency air-conduction hearing thresholds at preoperative levels (Grade C).

No surgical techniques are reported to guarantee complete preservation of residual hearing over the short or the long term. However, a laterally positioned electrode inserted via the round window helps preserve residual hearing as well as possible [26] (level of evidence: 4).

- The patient should be informed of the risk of immediate and long-term postoperative loss of residual hearing after cochlear implantation (Grade C).

Combined electric and acoustic stimulation improves speech perception in noise and tune recognition better than isolated electric stimulation [27,28] (level of evidence: 2). Combined electric and acoustic stimulation improves speech perception better than isolated electric stimulation, even in the absence of speech perception with acoustic stimulation alone [29] (level of evidence: 4).

- Rehabilitation should combine acoustic and electrical stimulation when residual low-frequency hearing has been preserved (Grade B).

Studies of small series reported moderate benefit for perioperative corticotherapy [30,31] (level of evidence: 4). No particular molecule, means of administration or duration of treatment can be recommended based on the literature data.

- Perioperative corticotherapy is recommended with a view to preserving residual hearing (Expert opinion).

3.4. Cochlear implant and contralateral hearing aid

A hearing aid contralateral to the implant is worth keeping if it helps localization or speech perception in noise. If not, contralateral implantation can legitimately be suggested.

- If there is residual hearing in the ear contralateral to the implant, adults should be encouraged to wear a hearing aid (Grade B).
- The benefit provided by a contralateral hearing aid should be assessed on perceptual tests and suitable questionnaires before suggesting implant bilateralization (Grade C).

3.5. Cochlear implantation in severe to profound unilateral hearing loss in adults

Single-side deafness (SSD) with normal to subnormal contralateral hearing impairs auditory performance: mainly for hearing in noise, but also in silence, especially when the speaker is on the hearing-impaired side, and for acoustic localization. This may sometimes be aggravated by disabling tinnitus in the hearing-impaired ear. Cochlear implantation can help control tinnitus in patients with profound hearing loss treated by bilateral cochlear implantation [32] and also in unilateral severe to profound hearing loss [33] (level of evidence: 2). Cochlear implantation in SSD seems to significantly improve not only localization and speech perception [34] (level of evidence: 2) but also any associated tinnitus [35] (level of evidence: 3).

- Adults with single-side deafness (SSD) and disabling tinnitus should be informed that cochlear implantation on the SSD side controls the tinnitus in a large number of cases, although this indication does not as yet have French Health Authority approval (Grade B).
- Patients with SSD and impaired speech perception and/or acoustic localization should be informed that in some cases cochlear implantation is more effective than air- or bone-conduction CROS (contralateral routing of signal) systems, although this indication does not as yet have French Health Authority approval (Grade B).

3.6. Quality-of-life and perceptual questionnaires: update and validation

Quality-of-life (QoL) assessment gives the patient and family an active role to play in the health-care pathway. It is defined by the World Health Organization (WHO) as “individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns” [36] (expert opinion). It is a multidimensional concept, with physical aspects (autonomy and physical capacities), psychological aspects (emotion, anxiety, depression) and social aspects (family, relational and occupational environment). Correlations between results on perceptual tests and QoL instruments are limited, which makes it all the more important to explore this subjective dimension as a complement to audiometry [37,38] (level of evidence: 1). Also, subjective QoL assessment is an integral part of medico-economic studies assessing the cost-effectiveness of therapeutic interventions [39] (expert opinion).

Table 1
Generic and specific quality of life questionnaires used in the literature to assess cochlear implantation. All exist in validated French-language versions.

Type of Questionnaire	Instruments	Domains explored	Studies	
Generic Questionnaires	EQ-5D (EuroQoL-5D)	Quality of life	Perneger, 2010 [41]	
	HUI 3 (Health Utility Index 3)	Quality of life	Horsman, 2003 [42]	
	WHOQOL (World Health Organization Quality Of Life)	Quality of life and financial dimension	The WHOQOL [36] Bauman, 2010 [43]	
	SF 36 (Short Form 36)	Quality of life	McHorney, 1993 [44] Leplège, 1998 [45]	
	GHSI (Glasgow Health Status Inventory)	Quality of life	Gatehouse, 1998 [46]	
	GBI (Glasgow Benefit Inventory)	Quality of life	Robinson, 1996 [47]	
	Specific Questionnaires	HHIA (Hearing Handicap Inventory for Adults)	Emotional and psychosocial	Newman, 1990 [48]
		HHIE (Hearing Handicap Inventory for Elderly)	Emotional and psychosocial	Ventry, 1982 [49]
		NCIQ (Nijmegen Cochlear Implantation Questionnaire)	Physical, psychological and social	Hinderink, 2000 [20]
		ERSA (Évaluation du Retentissement de la Surdit� chez l'Adulte: Assessment of hearing-loss impact in adults)	Personal, social and occupational quality of life	Ambert-Dahan, 2017 [50]

• Patients' quality of life should be assessed before and after cochlear implantation, as a complement to audiometry (Grade A).

The QoL impact of a disability is classically assessed on standardized questionnaires. Generic questionnaires have the advantage of being validated, with established normal values for interpretation purposes, and are easier for public health deciders to deal with. On the other hand, they do not display the specificities of a given pathology and thus lack sensitivity in assessing slight changes in health status. Disease-specific questionnaires tend to be more sensitive to clinical variations, especially related to treatment, and thus to functional change [40] (level of evidence: 1). Ad-hoc questionnaires constructed specifically for a given study provide rich and detailed information, but can be difficult to interpret due to the lack of validated measurement and normal values. Table 1 presents the various generic and specific QoL questionnaires used in the literature to assess cochlear implantation.

• It is recommended to use several age-adapted versions of a given QoL assessment instrument (Expert opinion).

Disclosure of interest

The authors declare that they have no competing interest.

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