European Annals of Otorhinolaryngology, Head and Neck diseases 136 (2019) 385–391

Available online at
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EM|consulte
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SFORL Guidelines

Guidelines (short version) of the French Society of Otorhinolaryngology (SFORL) on pediatric cochlear implant indications

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ARTICLE INFO

Keywords:
Child
Pediatric
Cochlear implant
Indications
Guidelines
France

ABSTRACT

Objectives: The authors present the guidelines of the French Society of Otorhinolaryngology – Head and Neck Surgery (Société française d'oto-rhino-laryngologie et de chirurgie de la face et du cou – SFORL) on the indications for cochlear implantation in children.
Methods: A multidisciplinary work group was entrusted with a review of the scientific literature on the above topic. Guidelines were drawn up, based on the articles retrieved and the group members' individual experience. They were then read over by an editorial group independent of the work group. The guidelines were graded as A, B, C or expert opinion, by decreasing level of evidence.
Results: The SFORL recommends that children with bilateral severe/profound hearing loss be offered bilateral cochlear implantation, with surgery before 12 months of age. In sequential bilateral cochlear implantation in children with severe/profound hearing loss, it is recommended to reduce the interval between the two implants, preferably to less than 18 months. The SFORL recommends encouraging children with unilateral cochlear implants to wear contralateral hearing aids when residual hearing is present, and recommends assessing perception with hearing-in-noise tests. It is recommended that the surgical technique should try to preserve the residual functional structures of the inner ear as much as possible.

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https://doi.org/10.1016/j.anorl.2019.05.018
1879-7296/

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1. Introduction

A first set of guidelines for cochlear implantation (CI) was drawn up by the French Health Authority (HAS) in 2012 [1]. Briefly, it was recommended that implantation be as early as possible in prelingual hearing-impaired children, to optimize language comprehension and production. In non-progressive congenital profound/total hearing loss, implantation was not recommended in over-5 year-olds unless oral communication was desired. Conversely, children acquiring oral communication benefit from CI at whatever age. Audiometric indications in children were mainly defined as profound hearing loss in which hearing aids do not enable language development, or severe hearing loss with $\leq 50\%$ discrimination on speech audiometry. Bilateral CI was recommended in bilateral hearing loss secondary to bacterial meningitis or temporal bone fracture to prevent bilateral cochlear ossification. CI efficacy in improving hearing, communication and language was reported to be major in the months following implantation. Surgical complications rates were low (< 5%), mainly consisting in bacterial meningitis.

Updating the guidelines for CI indications in children was confided to a French national multidisciplinary work group, using the French Health Authority's formalized expert consensus methodology for good practice guidelines (http://www.has-sante.fr/).

A pilot group organized the consensus conference logistics, choice of editorial group members and literature analysis by PubMed search. Articles were graded A, B, C or expert opinion according to decreasing level of evidence, following the literature analysis and guideline grading guide of the French National Agency for Evaluation and Accreditation in Health (ANAES). A rationale was drawn up as a basis for a first set of guidelines, assessed by the editorial group and modified according to feed-back.

2. Results

> Bilateral cochlear implantation is recommended for children with bilateral severe to profound hearing loss (grade B).

The aim of early bilateral CI in children is to restore binaural hearting, thereby improving hearing in silence and noise and achieving a certain degree of acoustic location. Children with bilateral CI were shown to have better speech perception in noise, auditory memory and verbal intelligence than with unilateral CI; they have better performance in all fields (level of evidence, 2) [2].

> In congenital bilateral profound hearing loss, CI should be proposed before 12 months of age (grade B).

Early CI optimizes results for auditory perception and oral language, especially when the first CI is performed before 12 months of age. A study (level of evidence, 2) found surgical risk to be comparable between under-12 month-old infants and over-12 month-old children [3]. A prospective study (level of evidence, 2) of 160 implanted children, 99 of whom had first CI before 30 months of age and 62 between 30 months and 5 years, found better language comprehension and expression in the former group. Another study (level of evidence, 2) found that children implanted before 12 months of age had better speech and language comprehension and production development, in a series of 28 hearing-impaired children all implanted before 24 months of age [4]. Finally, 2 studies by the same team (levels of evidence, 2) found that children implanted before 12 months of age had significantly better language comprehension and production than those implanted later, with no difference in scores compared to normal-hearing children [5,6]. Regarding CI before 6 months of age, there have been too few studies for any recommendations to be made.

In sequential bilateral cochlear implantation for severe to profound hearing loss, the interval between implantations should be short (grade B), preferably less than 18 months (expert opinion).

Bilateral CI is more effective in restoring binaural hearing when simultaneous or with a short interval. A 2013 review of the literature (level of evidence, 1) demonstrated an early critical period for dedicated brain area development [7]. A study (level of evidence, 1) comparing cortical potentials between 16 children with sequential bilateral CI, 10 with simultaneous bilateral CI, 8 with unilateral CI and 7 normal-hearing control subjects found that auditory cortex curves were not lateralized as in normal-hearing subjects if bilateral stimulation was introduced later than 18 months of age [8]. Demasking in noise and acoustic location vary with hearing history, inter-CI interval and age at second CI (level of evidence, 2) [9,10].

In sequential implantation, it is recommended to keep the interval as short as possible if a contralateral hearing aid fails to provide benefit (grade B).

In a 2017 study (level of evidence, 2) of 160 children with sequential CI, the longer the inter-CI interval the greater the risk of poor perceptual outcome and non-use of the second CI in the medium-term, unless a contralateral hearing aid provided benefit [11].

In case of residual hearing, tests in noise should be included in the pre-CI work-up as soon as feasible (grade C). In case of CI with contralateral hearing aid, perception should be assessed as early as possible, with speech-in-noise and acoustic location tests, and hearing aid efficacy should be regularly reassessed (grade B). In very young children with unilateral CI and useful residual hearing, caution is recommended in indicating a second CI, as binaural function is difficult to assess (expert opinion).

Perception of speech in noise indicates the efficacy of bimodal rehabilitation (CI + hearing aid) and guides indications for a second CI. A study (level of evidence, 2) showed that, while speech-in-silence perception in children with unilateral CI was comparable with or without contralateral hearing aid, the second group showed significantly poorer perception in noise [12]. A study (level of evidence, 1) showed that good post-implantation results did not correlate with residual hearing [13]. A 2015 study (level of evidence, 2) found that 1-syllable word perception in noise was better with bilateral CI than with bimodal rehabilitation [14]. Finally, another team reported that speech perception thresholds were comparable between bilateral CI and bimodal rehabilitation, while speech discrimination in nose and acoustic location were better in bilateral CI (level of evidence, 2) [15]. Speech discrimination with hearing aid and speech-therapy language-level work-up are the key examinations identifying candidates for CI. The objective contribution of a contralateral hearing aid, however, is more difficult to determine in children than in adults: in case of residual hearing or partial hearing loss, the audiometric threshold at which CI is preferable to a hearing aid is hard to define; several authors recommend systematic assessment of hearing in noise to this end (level of evidence, 3) [16] or else test of sentence recognition in noise (levels of evidence, 2 and 3) [17,18].

Vestibular assessment is recommended ahead of each CI (grade C).

Up to 50% of children with profound bilateral hearing loss show vestibular impairment (level of evidence, 4) [19,20]. CI surgery affects vestibular function in 0–71% of cases. A 2009 study (level of evidence, 3) of 71 CI children found a 71% rate of post-CI vestibular function modification, with 10% areflexia [21]. The risk of bilateral vestibular damage in bilateral CI needs to be taken into account, and surgery should be as atraumatic as possible, especially in children below walking age. Bilateral vestibular impairment should be avoided to prevent developmental disorder, notably cognitive. Sequential bilateral CI with a 3–6 month interval allows vestibular recovery to be checked, as impairment is often transient, ahead of second CI.

Pedopsychiatric assessment and brain MRI are recommended for children who are candidates for CI, or following CI in case of signs suggestive of autism spectrum disorder (grade B).

In a retrospective study of 785 children followed for hearing impairment, 17 were identified as having autism spectrum disorder (ASD): i.e., 2.2% in hearing-impaired children, twice the rate in the general population (level of evidence, 1) [22]. Incidence was especially high in hearing loss related to pregnancy pathology (13.8%) such as congenital cytomegalovirus infection. The children also showed higher incidence of associated pathologies such as mental (15.5%) or psychomotor retardation or visual deficit. ASD is hard to diagnose in hearing-impaired children, as specific tools are lacking; classical instruments such as the Autism Diagnostic Observation Schedule (ADOS) cannot be used in the standard manner (level of evidence, 2) [23]. In CI, results and progression are to be compared within the child rather than to children without behavioral disorder. Two studies (levels of evidence, 3) found improved perception and expression capacity (60% and 67%, respectively), better environmental awareness, and no increase in autistic hyperactivity following CI in ASD children [24,25]. Brain MRI is part of the work-up in suspected ASD (level of evidence, 3) [25].

It is recommended to assess the resources, difficulties and needs of the family environment of hearing-impaired children and to encourage the child to be involved in the management of hearing loss and rehabilitation and to accompany him or her in this (grade B).

Poor family investment is a factor for poor perceptual and linguistic outcome in CI (level of evidence, 2) [26,27]. Accompaniment should consist in dialogue, support, guidance and supervision from diagnosis through rehabilitation (level of evidence, 4) [28].

Parents of children with pathologies associated with hearing loss (multi-disability) should be informed that CI results may be limited; they should consider their expectations in dialogue with a multidisciplinary team (grade B).

Hearing loss is sometimes part of a complex clinical presentation including other psychological, psychiatric and physical aspects. A study (level of evidence, 2) found poorer speech intelligibility ratings (SIR) 5 years post-CI in case of associated abnormality compared to isolated hearing loss (70% vs. 96%); SIR was inversely proportional to the number of associated abnormalities [29]. Low IQ does not in itself contraindicate CI, but should be included in the multidisciplinary assessment. Audiophonologic rehabilitation does not significantly improve IQ, but improved hearing can facilitate schooling and learning (level of evidence, 2) [30].

It is recommended that CI surgery should so far as possible spare external, middle and inner ear structures that remain functional (with or without preoperatively preserved low-frequency air-conduction thresholds) (grade C).

Electroacoustic stimulation is now applicable in certain pediatric CI candidates with low-frequency residual hearing, using cautious surgery and last-generation implants. It is important to avoid intraoperative perilymph aspiration and blood or debris penetration in the cochlea (level of evidence, 4) [31]. Patients with postoperative residual hearing show better speech performance on pure electrical stimulation (level of evidence, 2) [32].

It is recommended that the parents be informed of the risk of immediate postoperative and long-term loss of residual hearing following CI (grade C).

A lateral electrode through the cochlear window optimally preserves residual hearing (level of evidence, 3) [33,34], although no reported surgical techniques guarantee complete short- or long-term preservation.

Rehabilitation should combine acoustic and electrical stimulation in case of low-frequency residual hearing (grade B).

Combined electrical and acoustic stimulation enables better speech discrimination in noise and tune recognition than electrical stimulation alone (level of evidence, 2) [35,36].

Perioperative corticosteroids are recommended if residual hearing is intended to be preserved (expert opinion).

Low-level studies (level of evidence, 4) showed moderate benefit of perioperative corticotherapy [37]. The literature does not support any particular mode of administration.

Children with unilateral CI should be encouraged to use a contralateral hearing aid in case of residual hearing (grade B).

CI + hearing aid compared to unilateral CI alone improves recognition of 2-syllable words, sentences in silence and noise and everyday communication (level of evidence, 3) [38] and acoustic location (Level of evidence, 1) [39].

It is recommended that studies should assess the benefit of CI in children with acquired or congenital severe to profound unilateral sensorineural hearing loss (expert opinion).

In France, CI has no formal or consensual indications in unilateral childhood hearing loss. The first small-scale studies reported a certain efficacy for speech perception in noise, but results were variable and sometimes disappointing (level of evidence, 4) [40,41]. The medium-term risk in patients with generally effective hearing is that the CI will be abandoned (by up to 3 in 5 patients) (level of evidence, 4) [42].

It is recommended to assess pre- and post-CI quality of life alongside audiometry (grade A).

Quality of life assessment gives the patient and family an active role in the care pathway, and is especially relevant to patients with chronic disease and/or disability without hope of cure. Taking real-life needs and feelings into account via quality of life questionnaires places the patient at the center of care. Correlations between perceptual and quality of life results are limited, which only reinforces the interest of exploring this subjective dimension in complement to audiometric assessment (level of evidence, 1) [43].

Several versions of a given quality of life instrument should be available, adapted to age (expert opinion).

Generic questionnaires are based on those used in the general population, enabling comparison between populations or disease groups. They have the advantage of having validation and normal values for interpretation, and are more meaningful for public health decision-makers; however, they fail to give detailed account of the specificities of each pathology. Specific questionnaires tend to be

Table 1
Generic quality of life instruments used in pediatric cochlear implantation.

Instruments	Original language	Validation in French	Target age (years)	Respondents	Versions	Domains explored	Studies
EuroQoL-5D (EQ-5D)	English	Yes	Not stated	C and P	C: EQ-5D-Youth P: EQ-5D-5L/3L	QoL	The EuroQOL Group, 1990 Sach, 2007
Health Utility Index 3 (HUI 3)	English	Yes	> 5	P	P	Utility scores QALY	Cheng, 2000 Horsman, 2003 Lovett, 2010 Spareboom, 2012
Child Health and Illness Profile (CHIP)	English	Yes (version AC and PRF)	6–17	C and P	C: CRF (6–11) and AE (11–17) P: PRF (6–11)	QoL	Starfield, 1993 Clark, 2010 Riley, 2004
Child Health Questionnaire (CHQ)	English	Yes	5 mo–18	C and P	C: PF-28 (5–18) P: PF-50 (5 mo–15 yrs)	QoL	Landgraf, 1998 Ravens-Sieberer, 2001 Wake, 2004
Pediatric Quality of Life 4 (PedsQL 4.0)	English	Yes	2–18	C and P	C: (5–18) P: (2–18)	QoL	Borton, 2010 Lovett, 2010 Sparreboom, 2012 [50] Varni, 2011, 2007 Beijen, 2007 Rajendran, 2010
Kinder Lebensqualitäts-frabebogen (KINDL)	German	Yes	4–16	C and P	Kiddy (4–7) Kid (8–11) Kiddo (12–16)	QoL	Huber, 2005 Warner-Czyz, 2009 Bullinger, 2008 [44] Warner-Czyz, 2011 Loy, 2010
Youth Quality of Life Instrument (YQOL)	English	No	11–18	C	C	QoL	Edwards, 2002 Patrick, 2002 Kushalnagar, 2011 Schick, 2013
KIDSCREEN-27	English	Yes	8–18	C and P	27 items	QoL	Ravens-Sieberer, 2005 Robitail, 2007 Razafimahefa-Raoelina, 2016
Glasgow Children's Benefit Inventory (GCBI)	English	No	1–15	C and P	C P	QoL after H&N surgery	Kubba, 2004 Lovett, 2010

C: child; P: parent; QALY: quality-adjusted life years; QoL: quality of life.

Table 2
Specific quality of life instruments used in pediatric cochlear implantation.

Instruments	Original language	Validation in French	Target age (years)	Respondents	Versions	Domains explored	Studies
Paediatric Audiology Quality of Life Questionnaire (PAQL)	English	No	3–18	P	P	QoL with associated comorbidity	Edwards, 2012 [45]
Parent's Views and Experiences with pediatric Cochlear Implant Questionnaire (PVECIQ)	English	No	5–16	P	P	Parental perception of CI-associated benefit/limitations and child's QoL	Archbold, 2002 O'Neill, 2004 Nunes, 2005 [48] Incesulu, 2003 Nicholas, 2003 [47]
Kinder Lebensqualitäts-frabebogen – Cochlear Implant module (KINDL-CI module)	German	Yes	4–16	C and P	Version 4–7 Version 8–16	QoL	Bullinger, 2008 [44] Warner-Czyz, 2011
Youth Quality of Life – Deaf and Hard of Hearing (YQOL-DHH)	English	No	11–18	C and P	C: YQOL-DHH P: YQOL-DHH-PROBE	QoL	Kushalnagar, 2011 Schick, 2013 Patrick, 2011 [49] Hintermair, 2011 [46]

C: child; P: parent; QoL: quality of life.

more sensitive to clinical variations, notably related to treatment, and thus to functional change. Generic and specific questionnaires used in the literature for assessment of pediatric CI are presented in Tables 1 and 2 [43–50].

3. Conclusions

Management of hearing-impaired children should be multidisciplinary, and parents should be accompanied to optimize outcome. It should be adapted to age, severity and comorbidity. In case of CI, implementation should be early (before 12 months of age) to optimize outcome, with a short interval (less than 18 months) between sequential bilateral implantations. Hearing-in-noise tests are important to assess residual hearing or efficacy of bimodal rehabilitation. Surgery should be sparing, to preserve residual cochlear and vestibular function.

Disclosure of interest

The authors declare that they have no competing interest.

Acknowledgments

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