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International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl



### **Review article**

## Diagnostic challenges and safety considerations in cochlear implantation under the age of 12 months

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#### ARTICLE INFO

Article history: Received 9 August 2009 Received in revised form 17 October 2009 Accepted 21 October 2009 Available online 24 November 2009

Keywords: Cochlear implants Infants Under 1 Deaf ASSR ABR OAE Risk Surgery Anesthesia

#### ABSTRACT

*Aim:* To review the current knowledge on cochlear implantation in infancy, regarding diagnostic, surgical and anesthetic challenges.

Study-design: Meta-analysis. EBM level: II.

*Materials/methods:* Literature-review from Medline and database sources. Related books were also included.

*Study selection:* Meta-analyses, prospective controlled studies, prospective/retrospective cohort studies, guidelines, review articles.

*Data synthesis:* The diagnosis of profound hearing loss in infancy, although challenging, can be confirmed with acceptable certainty when objective measures (ABR, ASSR, OAEs) and behavioural assessments are combined in experienced centres. Reliable assessment of the prelexical domains of infant development is also important and feasible using appropriate evaluation techniques. Overall, 125 implanted infants were identified in the present meta-analysis; no major anesthetic complication was reported. The rate of surgical complications was found to be 8.8% (3.2% major complications) quite similar to the respective percentages in older implanted children (major complications ranging from 2.3% to 4.1%).

*Conclusion:* Assessment of hearing in infancy is feasible with adequate reliability. If parental expectations are realistic and hearing aid trial unsuccessful, cochlear implantation can be performed in otherwise healthy infants, provided that the attending pediatric anesthesiologist is considerably experienced and appropriate facilities of pediatric perioperative care are readily available. A number of concerns, with regard to anatomic constraints, existing co-morbidities or additional disorders, tuning difficulties, and special phases of the developing child should be also taken into account. The present meta-analysis did not find an increased rate of anesthetic or surgical complications in infant implantees, although long-term follow-up and large numbers are lacking.

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<sup>0165-5876/\$ –</sup> see front matter @ 2009 Elsevier Ireland Ltd. All rights reserved. doi:10.1016/j.ijporl.2009.10.023

#### 1. Introduction

The introduction of universal neonatal hearing screening in some countries and the establishment of screening programs for high-risk infants in several others has facilitated early identification, referral, and diagnosis of children with hearing loss [1]. This in turn has led to early clinical interventions and a steadily decreasing age of cochlear implantation in profoundly deaf children [2].

Cochlear implantation in a young age ensures that the hearing impaired child will receive the maximum amount of auditory information during the critical periods for spoken language development, thus reducing the effects of auditory deprivation [3]. The potential of achieving age-appropriate spoken language skills has additionally led to a strong trend towards performing cochlear implantation in infancy [4]. The primary implication of the latter is that a sooner acquired spoken language competence may also enable an earlier and more successful transition to the mainstream educational system.

However, the uncertain means of assessing the exact auditory and developmental status in very young infants, hidden additional disabilities in this age group, and the surgical and anesthesiologic risks, which may be associated with performing an elective procedure so early in a child's life, should be taken into account, when considering cochlear implantation in infancy.

The aim of the present paper is to review the current knowledge on pediatric cochlear implantation before the age of 12 months, with regard to the diagnostic, surgical and anesthetic challenges associated with cochlear implantation in this age group. Specific concerns regarding device and user-related parameters will also be explored.

#### 2. Materials and methods

An extensive search of the literature was performed in Medline, Embase, Scopus, and Intute, from 1982 to December 2008, with two main objectives:

- (a) Evaluation of the methods for assessing an infant's hearing and their respective reliability.
- (b) Assessment of the surgical and anesthetic risks associated with an elective procedure (cochlear implantation) during the first year of life.

During the search, the keywords "cochlear implants", "age", "infants", "under 1", "ASSR", "ABR, "OAE", "risk", "surgery", and "anesthesia" were utilized. The keywords "cochlear implants", "infants", and "under 1" were considered primary and were either combined to each of the other keywords individually, or used in groups of 3.

#### 3. Results

Three meta-analyses, 4 prospective controlled studies, 25 prospective studies, 21 retrospective studies, 1 guideline, 8 review articles and 4 books met the defined criteria and were included in study selection.

#### 4. Discussion

#### 4.1. Hearing assessment in infants-evaluation of additional disorders

The widespread application of neonatal hearing screening programs in some countries has resulted in the assessment of the hearing acuity of approximately 85–99% of newborns within the first few days of their life [5]. As a consequence, very early referral, diagnosis and management of infants with hearing loss

are now feasible in the developed world. Thus, it is of great importance that the related methods accurately reflect the behavioural audiogram [6].

However, visual reinforcement audiometry (VRA) which may be used for behavioural testing in late infancy, is not applicable in young infants [7], due to their inability to make reliable direct head-turn responses towards sound sources [8]. In addition, children with additional disorders as well as prematurity may also not be able to complete VRA testing [9]. Objective audiometric tests (OAE, ABR, and ASSR) may be the only method of assessing candidacy for early cochlear implantation, not only in terms of identifying potential pediatric implantees, but also in order to exclude possibly inappropriate recipients (i.e. children lacking bilateral profound hearing loss).

Apart from scientific dilemmas, reliable diagnosis is very important to parents and family. Parents may indeed experience significant emotional stress during and following hearing assessment. Hence, both the diagnostic process and the certainty of the diagnosis are considered central for them to accept the problem and participate in future management [10]. In addition, parental and family bonding and behaviour towards the infant, along with their trust to physicians may be disturbed when the diagnosis is inaccurate or doubtful.

Even though clinical audiology has made significant progress during the last decades, none of the three objective tests typically performed in most specialist centres (otoacoustic emissions-OAEs, auditory brainstem responses-ABRs and auditory steady state responses—ASSRs) are perfect [9]. ABRs have been widely used for a long period of time, providing us with extensive data regarding their strengths and weaknesses. As they do not require any voluntary response from the examined infant, they are considered an objective technique for the assessment of hearing thresholds. However, the determination of the obtained waveforms and the estimated level of hearing can be subjective processes, which may, in large part, rely on the examiner's experience [11–13]. Even after applying the strictest diagnostic criteria and obtaining more than one waveforms in each stimulus, challenges with regard to the accuracy of the investigation, especially in difficult cases, may be encountered [14]. Moreover, ABRs assess a narrow frequency range; therefore cases with useful residual hearing (i.e. normal or near normal hearing in the lower frequencies) are usually missed, thus resulting to inappropriate amplification.

ASSRs are a relatively recent method which shows better specificity in various frequencies compared to ABRs [15]. They are also more objective, as they relate the prediction of an auditory response to statistical criteria, which are incorporated in their software, and not to the examiner's level of expertise. ASSR thresholds determined in infancy have been found to highly correlate to behavioural hearing levels obtained later in childhood, both for children with normal hearing and for sufferers of varying degrees of sensorineural hearing loss [16]. They seem, however, at least partially affected by the maturational development during the first weeks of life, thus demonstrating variable results across subjects during this period [17,18]. Hence, postponement of the examination, until after the immediate neonatal period may be required [19]. In addition, even though the detection of a positive response is objective, the measurement protocol has to be well considered and a critical approach is required during response interpretation. Indeed, when a variable recording length is allowed, the acceptance criterion of the statistical test needs adjustments in order to ensure a tolerable error rate [20]. Although more widespread use of this method is necessary to determine its full potentials and related weaknesses, ASSRs seem a very promising assessment method in identifying our target population for pediatric cochlear implant surgery [21].

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