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Surgical timing for bilateral simultaneous cochlear implants: When is best?

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ABSTRACT

Introduction: Hearing loss is considered the most common congenital disease and the prevalence of neonatal deafness can be estimated between 1 and 2 cases per 1000 live births.

Infant deafness must be diagnosed as early as possible and an effective therapeutic intervention needs to be carried out in order to avoid the serious consequences of hearing deprivation during the evolutionary period: alterations in the development of central auditory pathways and lack of language acquisition.

The cochlear implant (CI) has proved to be the best instrument to solve the problem of auditory deprivation. In particular, the bilateral CI gives the patient access to binaural hearing which results in benefits in terms of sound localisation and discrimination.

The optimal age of application of the CI is a widely discussed topic in the scientific community and the current guidelines indicate a period between 12 and 24 months of age, even though the supporters of the application before 12 months of age are nowadays increasing.

Materials and methods: The study is observational, retrospective, monocentric. 49 paediatric patients (< 18 years) with simultaneous bilateral CIs were included. The audiometric threshold and speech tests were carried out during the follow-up 3, 6 and 12 months after the CIs activation and when the patient reached 2 years of age.

Results: The statistical analysis showed that undergoing bilateral implantation surgery before 2 years of age allows a satisfactory audiometric performance, while there are no particular benefits in performing the surgery before 1 year of age. As far as the speech outcome is concerned, the statistical analysis didn't show significant correlation between the earlier age of implantation and better speech performance if the operation is carried out before 2.5 years of age.

Conclusions: The results of the study indicate that the optimal age to perform the simultaneous bilateral CIs surgery is between 12 and 24 months, without demonstrating any particular benefit in carrying out the procedure before 1 year of age. This may be clinically relevant in terms of avoiding the risks of diagnostic mistakes and reducing the related surgical risk in children under 1 year of age.

1. Introduction

According to data released by the World Health Organisation in February 2017, 360 million people worldwide (about 5% of the population) are affected by a disabling hypoacusia and more than 32 million of them are children with a higher auditory threshold of up to 30 dB in the best ear [1]. Specifically, in Western countries the prevalence of neonatal deafness can be estimated between 1 and 2 cases per 1000 live births and represents the most common defect of a sense organ in infants [2].

Studies conducted on children have shown that the use of bilateral cochlear implants (CI) offers advantages over the unilateral CI. Having two CIs gives the patient access to binaural hearing with benefits in terms of sound localisation and discrimination in silence and noise [3] as well as in language discrimination [4], and prevents the negative consequences of the unilateral auditory deprivation on the central auditory pathways and the auditory cortex [5].

The two implants can be installed in one operation (simultaneous CI) or in two different operations separated by a period of time variable from months to years (sequential CI) [1].

A paper published in 2015 compared the clinical and speech outcome in children with simultaneous CI versus children with sequential CI. Despite the lack of statistical significance, all the analysed variables seemed to be in favour of the simultaneous over the sequential procedure [6]. The benefits of the bilateral hearing stimulation were described by Gordon et al. [7] showing that the immature human auditory

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cortex is led to reorganisation by the unilateral stimulation while, if the bilateral stimulation is restored within a limited delay of time, the brain can be protected from this reorganisation.

Most literature documents better results in relation to the earliness of the cochlear implant application, both in terms of audiometric performance (assessed with PTA – Pure Tone Average) and speech production and comprehension [1,8–10].

As far as the appropriate age of implantation is concerned, according to the literature, the age-limit within which the application of the cochlear implant ensures the correct development of language is 18 months [11–13]. In most countries the guidelines indicate a period of implantation between 12 and 24 months of age, while the application before 12 months of age is currently used as an emergency procedure, especially in case of post-meningitis cochlear ossification or fibrosis [1].

The scientific community is nowadays debating on the appropriateness of the CI application before 12 months of age in all children. Some studies showed that children implanted before 12 months of age developed better verbal perception and others pointed out a better receptive and expressive language development [14,15].

On the other hand, the main issue is the risk that operations pose in such young patients (e.g. anaesthetic risk, bleeding risk), especially related to recent discoveries on neurotoxicity associated with general anaesthesia and sedative drugs given in early life. Controlled studies in young animals suggest that the exposure of the mammalian brain to some anaesthetic drugs during a “critical period” can lead to brain damage such as neuronal apoptosis and neurodegeneration [16–18]. To date, however, this correlation in humans is still unclear but laboratory experiments on animals showed an increased risk of neurotoxicity in the case of long-lasting and repeated exposure to anaesthetics as well as multiple usage of anaesthetic drugs [19–21].

Moreover, a study carried out in 2015 by our group of researchers documented the consistent risk of diagnostic errors in the first year of life with described cases of children who improved their hearing performance (from severe to mild) during the first year of life [22].

2. Aim of the study

The aim of the study is to evaluate audiometric and speech performance at 3, 6, 12 and 24 months after the application of the simultaneous bilateral cochlear implant and at 3 years of age in a group of 49 paediatric patients.

The final aim is to evaluate the outcome in order to define the most appropriate age of surgery in simultaneous bilateral cochlear implants.

3. Materials and methods

3.1. Type of study

The study is observational, retrospective, single-centre.

3.2. Population analysed

We have analysed the clinical documentation of our patients who underwent simultaneous bilateral cochlear implantation surgery from January 2010 to March 2016 at the ENT Clinic of the University Hospital of Padua (Italy).

We included the paediatric patients who underwent cochlear implant surgery < 7 years of age, with profound sensorineural pre-verbal hearing loss.

In all cases, the CI surgery was performed by the same surgeon following the same procedure (mastoidectomy with posterior tympanotomy and parafenestral cochleostomy).

With the collected data we created a database with the following information:

- personal data: date of birth and sex;
- pathological history: etiology of deafness, age at onset of deafness, presence or absence of psychomotor delay;
- cochlear implant information: surgical technique, duration of surgery, days of hospitalisation, date of implant activation, age at implant activation, brand and cochlear implant model;
- results: behavioural tonal audiometry and speech therapy tests at 3,6,12 and 24 months after surgical intervention and at 3 years of age.

Data was examined in agreement with the Italian privacy and sensible data laws (D. Lgs 196/03) and the ENT Clinic of the University Hospital of Padua internal rules.

3.3. Audiometric evaluation

The patients were tested with one implant at a time or alternatively in free field wearing both the cochlear implants for poorly collaborating patients. The hearing threshold was expressed in terms of PTA (Pure Tone Average: average of tonal threshold found at the frequencies of 500-1000-2000 Hz).

PTA inferior or equal to 35 dB at the 12 months follow-up was considered as a “positive audiometric outcome”.

3.4. Speech evaluation

The speech perception evaluation was conducted employing live voice at the sound intensity of 60 dB.

During every follow-up we evaluated the children by means of three different speech perception levels: detection, identification and comprehension.

This auditory skills hierarchy is often used as a framework for the organisation of auditory training curricula [23–26]. In our study the score criteria are the same used in a previous study by Ghiselli et al. [27].

Detection (or sound awareness): the first level is the most basic auditory skill and simply refers to being able to detect the absence or presence of a sound. In our study Ling 6 sound was used and detection corresponds to Ling 6 sound score > 80% and identification of disyllabic words score < 50%.

Identification [28]: the second level of auditory skills is the ability to correctly label or name a sound or word that is heard. In a closed-set format, a restricted choice of alternative responses is provided in picture format. For example, individuals may be provided visually with the following closed-set of words: “cat, dog, frog”. Words were selected based on the children's linguistic skills. In our study disyllabic Italian words were used (animals or other simple words) in a set of 4 possibilities and identification corresponds to identification of disyllabic words score > 50% and comprehension of disyllabic words < 50%.

Comprehension: the last level is the ability to interpret the sounds that have been identified and to understand the meaning of spoken messages. Facilitating the generalisation of improved auditory skills to a variety of speech materials, talkers, and acoustic environments, is an important aspect of auditory training. In this task a verbal production skill is necessary. Words were selected based on the children's linguistic skills. In our study we used a list of 10 simple words that the child is able to pronounce (e.g. mum, dad, cat, dog, sea) and this level corresponds to the comprehension of disyllabic words > 50%.

In our study we considered the children's performance at two fundamental steps, 24 and 36 months of age, to verify the appropriate linguistic development.

For the statistical analysis we considered comprehension in speech tests at 36 months of age as a “positive speech outcome”.

3.5. Statistical analysis

For normally distributed variables we used the Student's T test, for