Achieving early functional auditory access in paediatric cochlear implantation

Adattamento precoce dell'impianto cocleare in età pediatrica

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SUMMARY

Cochlear implantation (CI) is a viable option for providing access to auditory stimulation in severe-to-profound hearing loss/impairment of cochlear origin. It has been demonstrated that CI is safe and effective for deaf children. Younger age at activation after CI is linked with better outcomes. It is important to study variables and issues that can interfere with an early fitting and access to sound after CI. They range from patient characteristics, family compliance and support, to technical, medical or organisational problems. A SWOT analysis and a subsequent TOWS matrix was conducted to discuss issues and propose recommendations to be considered when operating an early switch on of the CI.

KEY WORDS: Cochlear implant children • Early intervention children • Cochlear implant fitting • Auditory stimulation children

RIASSUNTO

L'impianto cocleare costituisce una valida opportunità per fornire l'accesso alla stimolazione uditiva nei casi di ipoacusia severa o profonda di origine cocleare. E' stato ampiamente dimostrato che l'impianto cocleare è una soluzione sicura ed efficace e che la precocità nell'attivazione è associata a risultati migliori. E' importante studiare le variabili e gli aspetti che possono interferire con un adattamento precoce e un adeguato accesso al mondo sonoro: caratteristiche del bambino, alleanza terapeutica con la famiglia, aspetti tecnici, medici e organizzativi. Obiettivo di questo lavoro è quello di proporre raccomandazioni utili per gli aspetti organizzativi-pratici relativi alle attivazioni precoci di impianto cocleare, attraverso un particolare modello di analisi SWOT e TOWS.

PAROLE CHIAVE: Impianto cocleare pediatrico • Attivazione precoce • Adattamento dell'impianto cocleare

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Introduction

Cochlear implantation (CI) is a viable option for providing access to auditory stimulation in severe-to-profound hearing loss/impairment of cochlear origin. It has been demonstrated that CI is safe and effective for deaf children ¹. Several observational studies have shown that early auditory intervention with a CI and prompt enrollment in a (re)habilitation and education programme enable hearing impaired children to gain good quality access to auditory stimulation, achieve age-appropriate spoken language levels and eventually provide opportunities for normal social and academic development ²⁻⁹.

Younger age at activation after CI is linked with better overall outcome scores by about 0.5 SD, and significantly better developmental outcomes at 3 years of age ¹⁰, whilst delaying CI from 2 to 24 months of age in case of congenital hearing impairment is associated with a reduction of global outcomes ^{4-7 11}. This framework represents a driving force for hearing

screening programmes, early diagnosis and CI intervention. In addition, CI candidacy criteria have gradually expanded to include children with complex development disabilities ¹²⁻¹⁸. At present, although there is no consensus about how narrowly the critical window of time for optimal auditory development is defined, there is a growing body of evidence that supports implantation before 12 months of age ² and early activation after CI 19. Concerns are related to very early CI, because of the delayed maturation of auditory pathways, especially in preterm neonates, which could lead to an incorrect CI indication 20. Nevertheless, some of the evidence suggests that the sensitive period may extend to about 3 years of age. It must be considered that the younger children are, the more difficult it is to test their hearing and to determine benefit from wearing a hearing aid or from CI. A decision to implant may result in irreversible loss of whatever natural hearing is still present, but delaying that decision beyond the critical window of auditory development results in less than optimal abilchildren enables not only the development of the verbal communications, but also improves social skills, having broader consequences on the individual's life person ²¹. In order to achieve the most favourable access to sound with the CI, the sound processor parameters must be appropriately customised for the recipient after the switch on. This means that a number of parameters needs to be set to ensure that the electrical patterns generated by the device in response to sound offer optimal auditory speech discrimination, and thus a foundation for spoken language development. This procedure can be challenging in a typically uncooperative population such as infants and toddlers, and children with associated developmental disabilities. Families play an important role supporting and understanding the fitting procedure and subsequent specific auditory stimulation. It is important to study variables and issues that can interfere with early fitting and access to sound. They range from the characteristics of the child, family compliance and support, to technical and medical problems. The objective of this work is to discuss issues and propose recommendations to be considered when operating an early switch on of the CI using SWOT analysis. SWOT analysis was developed by the business community in early 1960s to facilitate planning strategies and nowadays is frequently used in healthcare care settings 22. The acronym SWOT stands for Strength (S), Weaknesses (W), Opportunities (O) and Threats (T), and corresponds to what the comments of the participants point out. The large amount of generated information is most frequently analysed and used to develop a strategic plan named TOWS matrix. In such way, the data obtained can be used to generate specific activities to accomplish better organization goals.

ity to develop speech and language skills 2. Early CI in

Materials and methods

A group of rehabilitation professionals involved in CI programmes was asked to complete a survey focused on improving CI early fitting. To examine issues related to achieving early access to sound after CI, the survey asked participants to report at least 2 strengths, weaknesses, opportunities, and threats for use in strategic planning. This phase was conducted with the principles of SWOT analysis. The responses obtained were reviewed by the specialists responsible for this working area. To generate recommendations from the SWOT analysis, a TOWS matrix was used to match the external threats and opportunities with internal weaknesses and strengths of the organization or program ²². An exhaustive explanation of the study design was provided. The detailed description of the SWOT and TOWS matrix analysis procedure can be found elsewhere in this issue. The study and the survey was focused on this specific aim: achieving a hearing threshold within 35 dB HL within 3-6 months from CI activation for children who received a CI between two to three years of age.

Table I. Roles of rehabilitation professionals (n = 20) involved in the survey.

Professional role	n
Otolaryngologist/Physician in Audiology	8
Audiologist/Hearing Acoustician	2
Physician in Neonatology	1
Speech and language therapist	1
Psychologist	1
Cochlear implant technical specialist	4
Parent/Association	2
Primary Care Paediatrician	1

Results

The rehabilitation professionals study group was composed of 20 participants with expertise in paediatric CI (Table I). All participants completed the SWOT questionnaire. The 288 open-ended answers (S=85, W=75, O=60, T=68) were reviewed by the authors and grouped in main key points (Table II).

Table II. Main key points extrapolated from the questionnaires. **Table IIa.** *Strengths.*

Strength key points	n (%)
Multidisciplinary collaboration and staff expertise	31 (37%)
Good organisation	29 (34%)
Family involvement and support	18 (21%)
Surgical technology and fitting	7 (8%)
	85

Table IIb. Weaknesses.

Weakness key points	n (%)
Staff inefficiency	36 (48%)
Recipient/family issues	24 (32%)
Excessive workload and unsuitable infrastructures	15 (20%)
	75

Table IIc. Opportunities.

Opportunity key points	n (%)
Cooperation and guidelines	30 (50%)
Instrumental and methodological developments	22 (37%)
Family support	8 (13%)
	60

Table IId. Threats.

Threats key points	n (%)
Management problems/efforts for staff	28 (41%)
Training and guideline insufficiency	16 (23%)
Concerns linked to CI companies	12 (18%)
Family issues	12 (18%)
	68

Strengths key points analysis

The four most frequently cited strengths were family involvement and support (41%), team work and staff expertise (23%), issues linked to CI companies (18%) and family issues (18%) (Table IIa). These themes are analysed in detail as follows:

Family involvement and support

This theme includes family counselling pre- and post-CI surgery, which is technical (CI operating principles, surgery steps, CI accessories), informative (i.e. regarding all aspects of the hearing problems, different possible communication modes, normal and abnormal child development) or linked with the support needs of the family (n = 8). This theme includes also issues regarding family-clinic alliance or sustain offered to the family by support groups and associations (n = 5). A family centred intervention is required to achieve better outcomes in CI recipients. The first month following CI is crucial to be helpful to the family, and given support can be boosted by the collaboration with regional associations of families of deaf children (n = 5).

Teamwork and staff expertise

This theme includes the multidisciplinary team collaboration with companies'CI clinical specialists (n = 17), whose support should be directed to enable clinicians to be independent in CI fitting (n = 4). Other issues concern continuing education and shared training opportunities for all professionals involved (n = 10).

Good organisation

This theme includes answers related to a good organisation regarding logistics and timeline (suitable and comfortable place, determined time for fitting, telephone line reserved for this purposes) (n = 7). Good organisation of pre-surgical work-up allows accurate audiologic, logopedical, cognitive evaluations before CI (n = 10), facilitates early activations (n = 6) and allows to start specific rehabilitation together with the fitting of CI (n = 6).

Surgical technology and fitting

This theme includes the answers related to the best possible surgical equipment (n = 7), which should be regularly updated and verified; the introduction of innovative materials is advisable.

Weakness key points analysis

The three most frequently cited weaknesses were staff inefficiency (48%), recipient/family issues (32%) and excessive workload and unsuitable infrastructures (20%) (Table IIb). These themes are analysed in detail as follows:

Staff inefficiency

Some answers were related to ineffective interdisciplinary collaboration between clinics and cochlear implant companies (i.e. poor support in case of failure or damage of the CI, challenging fitting) (n = 20), to the lack of education and training for all professional profiles (physicians, audiometrists, speech-language therapists, paediatricians) (n = 7), to the lack of guidelines and insufficient tools for fitting of the CI (i.e. modality of masking of good ear in CI for single sided deafness, new electrophysiological instruments capabilities) (n = 6), or to inadequate family counselling (n = 3).

Recipient/family issues

This theme includes difficulties related to the management of families whose place of residence is distant from the audiology referral centre (n=16). The answers focused on the difficulties to build a systematic communication network with health services from the patient's hometown, and on the management and organisation of controls necessitating more than one day stay. The interaction with users belonging to different cultures is even more difficult, where cultural and linguistic barriers are a serious obstacle for accepting diagnosis and receiving CI or hearing aids. Other issues concerned the difficulties related to early age management and/or presence of associated disabilities (n=8).

Excessive workload and unsuitable infrastructures

In this category the answers regarding excessive workload of small groups and unsuitable infrastructures (scattered locations, organisation of the working places, facilities for children and families) (n = 15).

Opportunities key points analysis

The three most frequently cited opportunities were cooperation and guidelines (50%), instrumental and methodological developments (37%) and family support (13%) (Table IIc). These themes are analysed in detail as follows:

Cooperation and guidelines

This theme includes the answers concerning the opportunity to increase guidelines, training and new interdisciplinary models (n = 23), i.e. training and education for clinicians and territorial rehabilitation professionals, regional guidelines for early rehabilitation.

Other issues concerned the cooperation between clinical and technical groups (CI companies, hearing aids specialists) (n = 7), i.e. shared education and training, regulation of in-hospital activity of company hearing aids.

Instrumental and methodological developments

This theme includes the answers concerning new methods, tools and techniques for rehabilitation, monitoring and fitting (n = 22). The answers focused on improving technological systems as data logging, fitting techniques, tools to optimise communication between the CI centre and the family, databases and tools for rehabilitation.

Family support

This theme includes opportunities to strengthen the counselling that is systemised and well inserted in the diagnostic path, CI selection and rehabilitative process, either for information or support (n = 8).

Threats key points analysis

The four most frequently cited threats were training and guideline insufficiency (41%), family issues (23%), concerns linked to CI companies (18%), management problems/efforts for staff (18%) (Table IId). These themes are analysed in detail as follows:

Training and guideline insufficiency

This theme includes the answers concerning poor or expensive professional education/training and poor scientific evidence-based research (guidelines) (n = 12) as well as scarce knowledge of bimodal and bilateral fitting management (n = 4).

Family issues

This category includes the answers concerning family efforts when dealing with extraterritorial recipients and linguistic/cultural diversity (n = 12). The answers focused on the difficulties in building a systematic communication network with health services from the patient's hometown, and on the management and organisation of controls necessitating more than one day stay. The interaction with users from different cultures is even more difficult, where cultural and linguistic barriers are a serious obstacle for understanding/accepting clinical information and CI or hearing aids.

Concerns linked to CI companies

This theme includes the answers concerning commercial aspects related to CI companies and conflicts of interest (n = 10), i.e. different fitting strategies between CI centres and CI companies, commercial constrains. Other answers were related to specific technical issues (n = 2).

Management problems/staff efforts

This theme includes the answers concerning insufficient funding aimed at audiologic clinics with subsequent reduced staff, long waiting lists and scarcity of funds for research projects (n = 16). Other issues were related to complex and prolonged family management for clinicians and linguistic/cultural barriers (n = 6), and to medical assessment of complications (n = 6)

Discussion

Starting from the SWOT analysis data, a TOWS matrix was created, which compares Strengths-Opportunities, Weaknesses-Threats and Weaknesses-Opportunities on the basis of the multidisciplinary discussion. These recommendations can represent food for thought for tertiary care audiology centres, to optimise resources and generate positive changes. Analysing and discussing the data obtained from this research, 9 recommendations were obtained (Table III). The 9 recommendations have been

Table III. TOWS matrix (see text for explanation).

Internal Strength (S) Weakness (W) W0 strategy S0 strategy Fast achievement of technological and methodological advances Fast implementation of the technological improvements that that encourage, facilitate and accelerate organised teamwork enable distant follow-up reduce the workload for the CI centre and family alliance in the rehabilitation process (as remote (tele-sharing of data between the professionals using, tele-Opportunities (0) control for NRT, data logging, material for parents/ling six sounds Entire team shared education by means of new interdisciplinary test). Strengthen the family counselling by outlining the surgical models, which should include most technical aspects of CI fitting procedure and the following steps immediately after selecting even for speech therapists, and early intervention modalities for the implant, by establishing a "therapeutic agreement" and using CI technicians, and should be organised written and illustrated material/video. Review the guidelines and evidence-based results that, as part of a good organisation, can speed up the first phases of CI fitting (e.g. early activation of the speech processor, validity of the electrophysiological tests, neural adaptation course). ST strategy WT strategy Multidisciplinary team, constantly updated and shared education Difficult cases should not be managed by incompetent centres (e.g. for achieving clear collaboration with the companies, (e.g. complex syndromes, severe disabilities, logistic issues). Threats (T) effectiveness in short term and mild impact decisions, e.g. Reduce contradictory, not coherent, or obscure indications to managing technical assistance for failures, administrative issues the families and communications among territory, hospital, unexpected reactions of the child) companies. Family involvement with effective connections to the territorial audiology services, in order to minimize cultural and extraterritoriality issues

summarised into 3 main fields of action to speed up the first phases of CI fitting and achieving and early and effective auditory stimulation:

- to strengthen family counselling, achieving high levels of alliance and therapeutic agreement along the preand post-surgical rehabilitation process;
- to implement technological and methodological advances directed at improving outcomes and teamwork, while reducing the workload;
- to establish a multidisciplinary approach and a cooperation platform among professionals, regulated by up-to-date guidelines, latest evidence-based principles and shared information.

CI is not yet a standardised procedure ²³. Moreover, indications to paediatric CI and technological advancements are constantly updated, causing potential differences of care and misunderstandings among professionals and families involved in the CI programme ²³. Several pre-operative variables have been identified in association with successful activation and early achievement of an effective auditory stimulation. Even if traditional candidacy to paediatric CI is actually based on a few basic parameters, i.e. severe-to-profound deafness with poor aided performance, outcomes are largely affected by patient-related factors and possibly by surgical factors. Moreover, some candidacy criteria are sometimes bypassed, such as in skipping the hearing aid trial case of progressive hearing loss, or in the case of delayed diagnosis auditory deprivation. Presurgical patient-related factors are previous effective auditory experience, previous trial with hearing aids, proactive family involvement and support, absence of concurrent disabilities, and conclusive audiologic evaluation. Surgery may possibly be involved in improving early outcomes by using minimally invasive approaches that are associated with a smaller surgical injury/wound and allow less inflammation/tissue swelling, better telemetry results and very early activation (up to 24 hours after surgery). In our opinion, the therapeutic alliance with the parents of the deaf child can lead to early achievement of best fitting. Considering that the introduction of some new technologies is aimed at increasing the collaboration between families and CI centres, e.g. in the case of remote control telemetry, data logging capabilities, information sheets for parents, tele-fitting, distance learning, distance mentoring, education about these advancements and their implementation in the daily clinical practice is encouraged as both a strength and opportunity to achieve the specific goal of early optimal auditory stimulation. The development, review and constant update and sharing of guidelines covering all the aspects of early rehabilitation after CI is needed. There are new and controversial aspects related to early CI in congenital deafness, early activation after CI in children 19, reliability of electrophysiological tests in view of the auditory maturation process, especially in children affected by severe adjunctive disabilities 12 20. There is a lack of international consensus also on how to apply bilateral, bimodal or electroacoustic strategies and on how to select patients for those indications. It may be difficult to interpret with the authority the actual impact of the different technologies that are available on the market. Caution is deemed in proposing new technologies to be applied on children before extensive research has been carried out 12 18 23. Good and clear connections among patients, patient associations, territorial audiology services, private hearing aid centres, technical specialists of cochlear implants and tertiary referral centres are of utmost importance ²⁴. Moral and ethical issues are still associated with biomedical engineering technologies, and may be modulated by personal background and cultural heritage. Rehabilitation methodologies of the deaf children may also raise discussion with parents. The therapeutic alliance with the family requires moral and ethical issues to be made plain ²⁵.

Conclusions

To achieve early access to functional auditory stimulation after paediatric CI, recommendations have been developed directed to professionals involved in the (re)habilitation process. Establishing a cooperative platform among professionals, overcoming organisational issues, strengthening family counselling and sharing continuing education of high quality are mandatory. New interdisciplinary models are needed shared within all surgery and rehabilitation professionals. Interdisciplinary training should include updated technical and methodological aspects of CI fitting and early auditory stimulation.

References

- ¹ Forli F, Arslan E, Bellelli S, et al. *Systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in paediatric patients*. Acta Otorhinolaryngol Ital 2011;31:281-98.
- ² Russell JL, Pine HS, Young DL. *Pediatric cochlear implantation*. *Expanding applications and outcomes*. Pediatric Clin 2013;60:841-63.
- ³ Kral A. Auditory critical periods: a review from system's perspective. Neuroscience 2013;247:117-33.
- 4 Kral A, Sharma A. Developmental neuroplasticity after coclea implantation. Trends Neurosci 2012;35:111-222.
- Kral A, O'Donoghue GM. Profound deafness in childhood. N Engl J Med 2010;363:1438-50.
- Moeller MP. Early intervention and language development in children who are deaf and hard of hearing. Pediatrics 2000;106:E43.
- Nicholas JG, Geers AE. Spoken language benefits of extending cochlear implant candidacy below 12 months of age. Otol Neurotol 2013;34:532-8.
- 8 American Academy of Pediatrics, Joint Committee on Infant Hearing. Year 2007 Position statement principles and guide-

- *lines for early hearing detection and intervention programs.* Pediatrics 2007;120:898-921.
- ⁹ Joint Committee on Infant Hearing of the American Academy of Pediatrics, Muse C, Harrison J, Yoshinaga-Itano C, et al. Supplement to the JCIH 2007 position statement: principles and guidelines for early intervention after confirmation that a child is deaf or hard of hearing. Pediatrics 2013;131:e1324-49.
- Ching TY, Dillon H. Major findings of the LOCHI study on children at 3 years of age and implications for audiological management. Int J Audiol 2013;52:S65-8.
- Geers AE, Nicholas JG. Enduring advantages of early cochlear implantation for spoken language development. J Speech Lang Hear Res 2013;56:643-55.
- Waltzman S, Scalchunes V, Cohen N. Performance of multiply handicapped children using cochlear implants. Otol Neurotol 2000;21:329-35.
- Daneshi A, Hassanadeh S. Cochlear implantation in prelingually deaf persons with additional disability. J Laryngol Otol 2007;121:635-8.
- Soman UG, Kan D, Tharpe AM. Rehabilitation and educational considerations for children with cochlear implants. Otolaryngol Clin N Am 2012;45:141-53.
- Van Naarden K1, Decouflé P. Relative and attributable risks for moderate to profound bilateral sensorineural hearing impairment associated with lower birth weight in children 3 to 10 years old. Pediatrics 1999;104:905-10.
- Wakil N, Fitzpatrick EM, Olds J, et al. Long-term outcome after cochlear implantation in children with additional developmental disabilities. Int J Audiol 2014;14:1-8.

- ¹⁷ Wiley S, Jahnke M, Meinzen-Derr J, et al. *Perceived qualitative benefits of cochlear implants in children with multi-handicaps*. Int J Pediatr Otorhinolaryngol 2005;69:791-8.
- Palmieri M, Berrettini S, Forli F, et al. Evaluating benefits of cochlear implantation in deaf children with additional disabilities. Ear Hear 2012;33:721-30.
- ¹⁹ Marsella P, Scorpecci A, Pacifico C, et al. Safety and functional results of early cochlear implant switch-on in children. Otol Neurotol 2014;35:277-82.
- ²⁰ Hof JR, Stokroos RJ, Wix E, et al. *Auditory maturation in premature infants: a potential pitfall for early cochlear implantation*. Laryngoscope 2013;123:2013-8.
- ²¹ Chang YS, Moon IJ, Kim EY, et al. Social skills and developmental delay: importance in predicting the auditory and speech outcomes after cochlear implantation in children. Acta Otolaryngol 2015;135:154-61.
- ²² White K, Blaiser K. *Strategic planning to improve early hearing detection and intervention programs*. The Volta Review 2011;111:83-108.
- ²³ Trabalzini F, Muzzi E, Orzan E. Current standards in cochlear implantation. Preliminary results of a survey among Politzer Society. J Int Adv Otol 2012;8:379-84.
- 24 Moeller MP, Carr G, Seaver L, et al. Best practice in family-centered early intervention for children who are deaf or hard of hearing: an international consensus statement. J Deaf Stud Deaf Educ 2013;18:429-45.
- ²⁵ Lee J. Cochlear implantation, enjancements, transhumanism and posthumanism: some human question. Sci Eng Ethics 2015; in press.

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