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Review

Auditory Brainstem Implants in Children: Results Based on a Review of the Literature

Rafael da Costa Monsanto, Aline Gomes Bittencourt, Natal José Bobato Neto, Silvia Carolina Almeida Beilke, Nelson Fabricio Goetten de Lima, Fabio Tadeu Moura Lorenzetti, Raquel Salomone

Department of Otolaryngology, Sorocaba Eye Bank Hospital (BOS), Sorocaba, Brazil (RCM, NJBN, SCAB, NFGL, AGB, FTML, RS)
Department of Otolaryngology, University of Sao Paulo School of Medicine, Sao Paulo, Brazil (AGB, FTML, RS)

The objective of this study is to review the literature regarding Auditory Brainstem Implant (ABI) indications, surgical techniques, activation methods, and post-surgery follow-up in children. A search was performed in the LILACS, MEDLINE, SciELO, and PubMed databases in June 2014, and the key words used in the search were ((“auditory brain stem implant” OR “auditory brainstem implants”) OR (“auditory” AND “brainstem” AND (“implants” OR “implant”)). Forty-two studies that met the criteria described in “Study Selection” were read in full; 24 studies referred to the ABI fitting process in children, and were selected for appraisal. The studies showed 120 children (younger than 18 years old) fitted with ABIs. Evaluation after surgery showed that 112 (93.3%) of the patients improved in their ability to recognize environmental sounds and speech perception. Patients with tumors or those with cochlear or cochlear nerve malformations had good outcomes as well. Two of the children did not achieve any sound perception upon ABI activation. The results obtained in 120 children fitted with an ABI showed that the patients globally improved in their ability to detect sounds and communication skills. The phenomenon could be seen both in patients with tumoral diseases of the inner ear and those with malformations of the cochlea or cochlear nerve, although patients with non-tumoral issues achieved better results than patients with schwannomas. We propose that the Food and Drug Administration (FDA) ABI indications should be extended to patients younger than 12 years old with NT diseases of the cochlea and cochlear nerve.

KEY WORDS: Auditory brainstem implants, hearing aids, deafness, children, sensorineural hearing loss

INTRODUCTION

The auditory brainstem implant (ABI) is a semi-implantable prosthesis that allows the restoration of some degree of auditory perception in deaf people. Its indications are bilateral lesions in the auditory nerve and cochlear malformations or ossification that prevents the surgical placement of the arrays of the cochlear implant, as the ABI may be placed directly at the cochlear nucleus on the IV ventricle [1].

The U.S. Food and Drug Administration (FDA) has allowed, since December 2000, the Nucleus 24 Auditory Brainstem Implant System® (Cochlear Co., Lane Cove, Australia) for patients above 12 years old [2]. However, some authors, like Colletti et al. [1], have successfully fitted ABIs in patients younger than this age, with authorization of the research ethics committees. Only in January 2013 did the FDA give authorization to begin clinical trials for ABIs in children younger than 12 years old.

The objective of this paper is to review the literature about the results obtained by different authors regarding ABIs, as well as the indications, surgical techniques, activation of the device, long-term results, and factors that may influence the outcomes.

REVIEW of the LITERATURE

A search in the LILACS, MEDLINE, SciELO, and PubMed databases was performed in June 2014. The key words used on the search were ((“auditory brain stem implant” OR “auditory brainstem implants”) OR (“auditory” AND “brainstem” AND (“implants” OR “implant”)). Additional filters were used: Portuguese, English, or Spanish language; subjects younger than 18 years old; and the period of publication was set to 2000-2014. Duplicates were excluded at this point. The abstracts of all resulting studies were read, and after removing studies that did not comply with the inclusion/exclusion criteria, the remaining studies were read in full.

Corresponding Address:
Rafael Monsanto, Department of Otolaryngology, Sorocaba Eye Bank Hospital, Sorocaba, Brazil
Phone: 18031-060; E-mail: rafaelmonsanto@hotmail.com

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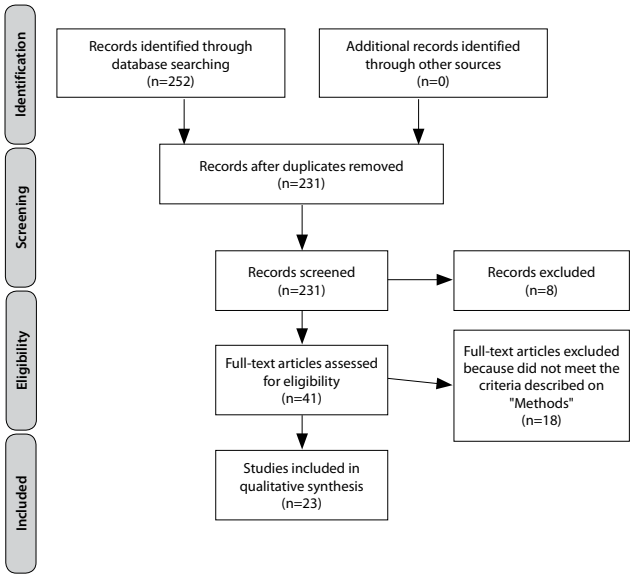

Figure 1. Flowchart of the decision process of the selection of the studies

The criteria for study selection were as follows:

a) Inclusion criteria:
   - Case reports, prospective and retrospective studies referring to ABI in children (subjects under 18 years old).

b) Exclusion criteria:
   - Meta-analysis and review studies
   - Studies that did not review the follow-up of patients after implantation of the device.

The results obtained in the different studies selected for appraisal were then gathered.

A flowchart of the decision process involved in the study selection can be viewed below (Figure 1):

Two hundred thirty-two studies were found, and after reading the abstract of those manuscripts, 42 studies were read in full. Finally, 24 studies were selected for appraisal. The studies show the results on 120 patients fitted with an ABI.

Most of the studies considered the indication of ABIs for patients with bilateral severe sensorineural hearing loss caused by issues in the cochlear nerve (aplasia or avulsion after a head trauma with bilateral temporal bone fracture, tumors, like sporadic schwannoma of the cochlear nerve, or bilateral tumors caused by neurofibromatosis type 2 [NF2]) [1, 3-7, 8], severe abnormalities of the cochlea (malformations or ossification)[9], or auditory neuropathy.[1] It is impossible to estimate the average age of the patients in the studies, since most of them showed results involving patients older than 18 years old. Twelve (10.0%) of the patients had associated anatomic deformities, and 15 (12.5%) had other associated deficiencies or disabilities, as presented in Tables 1 and 2 [7, 10-13].

Among the studies, 13 patients [10, 14] were fitted with the Pulsar CI100 ABI® (Med-El Co., Innsbruck, Austria), 5 patients were fitted with a Concerto ABI® (Med-El Co., Innsbruck, Austria) [10], 1 patient received a Nucleus 22 Auditory Brainstem Implant System® (Cochlear Co., Lane Cove, Australia) [15], and the other 48 [7, 13, 14, 16-19] were fitted with the Nucleus 24 Auditory Brainstem Implant System® (Cochlear Co., Lane Cove, Australia). The Nucleus 24 and 21 ABI® were activated using the spectral peak coding (SPEAK) strategy [7, 13, 14, 16-19], and the Pulsar CI100 ABI® was activated using the continuous interleaved sampling (CIS) technique [5].

Table 1. Auditory brainstem implant indications and associated malformations

Indication	No. of patients	Malformation
Cochlear nerve aplasia	34	2 (5.88%) - Internal/middle ear malformations
		2 (5.88%) - Unilateral absence of facial nerve
Cochlear malformations	19	1 (5.26%) - Crouzon's syndrome with Mondini cochlear dysplasia
		2 (10.52%) - Cleft lip
		1 (5.26%) - CHARGE syndrome*
		1 (5.26%) - CCGE**
		1 (5.26%) - Saethre-Chotzen syndrome
		1 (5.26%) - Muenke syndrome***
Reduced cochlear patency	4	
Type 2 neurofibromatosis	2	
Auditory neuropathy	1	
Deafness after head trauma	1	
Total	61	

*CHARGE (coloboma of the eye, heart defects, atresia of the nasal choanae, retardation of growth and/or development, genital and/or urinary abnormalities, and ear abnormalities and deafness); **CGE (cleft palate, heart defects, genetic anomalies, and ectrodactyly); ***Muenke syndrome: Craiosynostosis

Table 2. Additional disabilities found in children implanted with ABIs

Disability	Number of patients
Mild motor disability	10
Learning disability	8
Behavioural impairment	12
Language impairment	7
Visual impairment	2

The results of the imaging evaluation of 28 children fitted with ABIs [20] are shown in Table 3. Regarding the surgical procedure, 4 patients [13] were fitted with ABIs with the retrolabyrinthine approach, 8 with the suboccipital approach [14], 49 with the retrosigmoid approach, [10, 18, 21] and 2 with the translabyrinthine approach [1, 3, 6, 7, 9, 13-15, 22-24]. Both patients with bilateral schwannomas and tumors caused by NF2 received the retrosigmoid and transmeatal combined approaches for tumor removal. [14]

Intraoperative evaluation to observe the right position of the ABI array was performed with electrophysiological responses (EABRs), [1, 3, 6, 10, 22]

Table 3. Findings on imaging evaluation of 28 children fitted with Auditory brainstem implants

Deformity	Number of patients	Other
Internal auditory canal with normal size	11 (39.2%)	
Reduced internal auditory canal	17 (57.1%)	3 (10.7%): diameter of 1 mm or less
		7 (25%): diameter between 1.1–2 mm
		7 (25%): diameter of 2 mm or more
Labyrinthine malformations	16 (57.1%)	13 (46.4%): reduced internal auditory canal
		3 (10.7%): normal sized internal auditory canal

and if present, neural response telemetry (NRT) was used. The first test provides a near-source monitoring point for evoked potentials from the auditory brainstem and should help verify the correct positioning of the ABI in the lateral recess; the second defines the stimulus level to be used on ABI activation [1, 3]. It is also a routine to monitor the cranial nerves intraoperatively [1-30].

The time elapsed between the ABI surgery and initial stimulation of the cochlear nerve varied between 6 [6 ,22], 8 [5, 13], and 10 [6] weeks in the selected studies. The activation was performed in an intensive care unit, with cardiac monitoring. The patients were followed at 1 and 6 months, 1 year, and every year after that. The outcomes achieved by different authors are described in Table 4.

COMMENT

Hearing loss is recognized as one of the most common deficiencies in humans [24]. The number of Americans with hearing loss has evidentially doubled during the past 30 years [26, 27]. Blanchfield et al. [28] showed that in the United States, 5 per 10,000 children younger than 2 years old have profound hearing impairment.

Colletti et al. [1] proposed the following criteria to indicate ABIs in patients of all ages:

- Cochlear implant not indicated
- No contraindications
- The absence of neurological deficits capable of making rehabilitation difficult or even impossible
- Strong motivation in adults
- Motivated family and social environment for children
- Extensive experience in posterior fossa surgery of the surgical team
- Extensive experience in auditory rehabilitation of the rehabilitation team
- The possibility of prolonged, intensive rehabilitation

In patients with ossified cochlea fitted with ABIs, Tan et al. [17] considered that despite the better results of the ABI compared with the cochlear implant, there is a higher risk of complications, such as meningitis, hydrocephalus (transient or permanent), balance problems, cerebrospinal fluid leakage, wound seroma, minor infections, transient facial palsy, temporary dysphonia and dysphagia, and headache.

The Nucleus 24 ABI® was developed based on a 21-channel device (Nucleus 22 ABI®) and has been considered the 'gold standard' by Colletti et al. [1] since 1999. The Nucleus 24 ABI® differs from the Nucleus 22 ABI® in the stimulation strategies that can be used, with the possibility of performing intraoperative electrical monitoring of the neural interface, neural response telemetry (NRT), and the possibility of removing the magnet [1]. While the Nucleus 22 ABI® device uses only the SPEAK strategy, the Nucleus 24 ABI® has new speech processing strategies, such as CIS and an advanced combination encoder (ACE). The SPEAK strategy delivers the signal at a modest rate of stimulation (250 to 300 pulses/s) and selects the number and location of the electrodes to be stimulated, depending on the intensity and frequency of the incoming signal. The CIS strategy presents high fixed rates of stimulation (600 to 1800 pulses/s) to a small number of channels. The ACE strategy combines the advantages of both the SPEAK and CIS strategies by using a high rate of stimulation (600 to 1800 pulses/s) with dynamic electrode selection and a large number of available electrodes. Theoretically, this new strategy could improve the transmission of temporal and spectral speech information [3]. The Pulsar CI100 ABI® is capable of activation by the CIS technique [7, 22].

In order to activate the ABI, some authors [6, 22] state that the first step is to define the threshold (T) and the maximum comfort levels (C). There are no tonotopic relationships between the ABI array and the human cochlear nucleus; so, 'place-pitch scaling' and 'ranking' are performed to determine the pitch perception and define the tonotopic array order. The first is done as soon as the T and C levels are established. Then, the arrays are stimulated at the C levels, and the patient defines the sound on a scale from 1 (lower) to 100 (louder), and the software suggests the tonotopic order of the channels. The second is done in such a way that two arrays are successively stimulated, and the patient is asked to indicate which one has the higher pitch, helping the tonotopy of the electrodes. The programming process in children should follow the same steps as in adults; nevertheless, it requires different strategies, like behavioral observations to the stimulus given and responses with a pictured loudness scale. [17]
Colletti et al. [1] activated all of the ABIs with the SPEAK approach in the first 6 months; when the patient reached a 'plateau' phase (no improvements in auditory performance in 3 months), the strategy was changed to ACE. That was done based on experience with the technique in cochlear implants, where it allows improvement in open speech sound recognition [1, 3]. However, some studies showed that the change in strategy in ABIs leads to very little auditory gain [29, 30].
The hearing and speech evaluation of the implantees has been performed in different ways among authors. Colletti et al. [1, 6, 9, 22] and Kalamarides et al. [15] tested hearing using the following tests: (1) recognition of environmental sound or sound detection test; (2) closed-set vowel confusion test; (3) closed-set consonant confusion test; (4) closed-set word recognition in the vision-only mode (lip-reading), sound-only mode, and "sound plus- vision mode"; (5) open-set sentence recognition in the vision-only mode, sound-only mode, and sound-plus-vision mode; and (6) speech-tracking test [9, 18]. Goffi-Gomez et al. [13] and Eisenberg et al. [24] used the "Infant Toddler Meaningful Auditory Integration Scale" (IT-MAIS) to evaluate hearing capacity and the "Meaningful Use of Speech Scale" (MUSS) to evaluate speech performance. Other authors [10, 21] used the "Categories of Auditory Performance" (CAP) scale, using a graduation from 0-7 to

Table 4. Auditory and speaking results obtained by different authors

Author	Year	Patients	Indication	Approach	ABI	Activation	Auditory results	Speaking skills
Bayazit et al. [10]	2014	12	9 cochlear malformation 1 cochlear nerve aplasia 1 cochlear nerve hipoplasia 1 cochlear ossificatio	Retrosigmoid	7 Pulsar CI100 ABI® 5 CONCERTO ABI®	-	1 (8.33%): Understand common phrases, no lip-reading 2 (16.66%): Discrimination of speech sounds 2 (16.66%): awareness of environmental sounds 6 (50%): no response 1 (8.33%): not yet evaluated	3 (25%): Imitates words 1 (8.33%): Slightly increased vocalizations 2 (16.66%): Uses some words
Colletti et. al. [21]	2013	21	-	Retrosigmoid	-	-	3 (14.2%): Able to talk on the telephone	3 (14.2%): Understand, conversation no lip-reading 3 (14.2%): Understand common phrases, no lip-reading 4 (19%): Discrimination of speech sounds 5 (24.2%): Identification of environmental sounds 3 (14.2%): Response to speech sounds.
Bento et al [19]	2012	3	1 Cochlear malformation 2 Cochlear ossification	Retrolabyrinthine	Nucleus 24 ABI®	-	-	-
Goffi-Gomez et al. [13]	2012	4	1 Cochlear ossification 3 Cochlear/cochlear nerve malformation	Retrolabyrinthine	Nucleus 24 ABI®	SPEAK	1 (25%) improved sound awareness 1 (25%) poor auditory skills 2 (50%) no auditory responses at activation	1 (25%) good and 2 (75%) poor speaking skills; 1 (25%) no oral or sign language
Tan et al. [17]	2012	1	1 Cochlear ossification	-	-	-	1 (100%): improved hearing outcomes; speech discrimination of 15% (audition only) and 60% (audition with lip reading).	-
Colletti et al. [6]	2011	3	3 Cochlear nerve aplasia	Retrosigmoid	Nucleus 24 ABI®	SPEAK	3 (100%) good environmental sound awareness and moderate speech detection (65% of 7 fundamental phonetic sounds, a, e, i, o, u, s, sh, listed in 10 items; 40% of onomatopoeic sounds)	3 (100%) rudimentary speaking ability
Choi et al. [5]	2011	6	6 Non-tumoural diseases of cochlear nerve and cochlea	Suboccipital	Pulsar CI100 ABI®	-	6 (100%) clear responses on initial stimulation; awareness of pure tones at a threshold of 30 to 50 dB HL	-
Sennaroglu et al. [7]	2011	11	11 Cochlear or cochlear nerve malformations	Retrosigmoid	Nucleus 24 ABI®	SPEAK	11 (100%): improvements on basic auditory skills; 2 (18.2%): excellent results, able to talk on the phone; 2 (18.2%): inconsistent results, improving with continuous training	2 (18.2%) obtained excellent speaking skills, are able to talk on the phone; 7 (72%) improved; 2 (18.2%): inconsistent speech.
Eisenberg et al. [24]	2008	1	1 Auditory nerve aplasia	-	-	-	Increased attention to sounds; discrimination between continuous and interrupted speech	Draw the attention of family by vocalising and pointing
Colletti et al. [10]	2007	24	18 Cochlear nerve aplasia 1 Auditory neuropathy 1 Cochlear ossification 4 Cochlear malformation	Retrosigmoid	Nucleus 24 ABI®	SPEAK	19 (79.1%): environmental sound awareness, detection of instrumental sounds and lip-reading enhancement; disyllabic word recognition, understanding of commands. 5 (20.9%): no results until the end of the study	-
Sanna et. al. [9]	2006	1	1 Cochlear ossification	Translabyrinthine	Nucleus 24 ABI®	SPEAK	Scores: 100% sound identification, 90% recognition of bisyllable words, and 100% sentences recognition,	

Table 4. Continued

							with 31 words per minute at speech tracking. Patient able to talk on the phone	
Colletti et al. [1]	2005	8	6 Cochlear nerve aplasia 1 Auditory neuropathy 1 Cochlear ossification	Retrosigmoid	Nucleus 24 ABI®	SPEAK	8 (100%) showed improvement in auditory skills; 4 (50%): achieved 10% to 30% in the closed-set word recognition test in the auditory mode alone, and 1 (12.5%) achieved 10% of correct responses in the open-set sentence recognition test.	8 (100%) improved speech production progressively from the utterance of vowel sounds with attempts to imitate the voice to the use of verbal language with the production of simple sentences.
Colletti et. al. [18]	2004	1	1 Deafness after head trauma	Retrosigmoid	Nucleus 24 ABI®	SPEAK	Scores: 80% in the auditory-alone-mode closed-set word recognition test and 10% in the auditory-alone-mode open-set sentence recognition test	-
Otto et. al. [8]	2004	21	21 Bilateral schwannomas	-	-	-	19 (95%): Auditory sensations. 1 (2.5%): No responses 1 (2.5%): Disconnected because of non-auditory sensations.	-
Colletti et al. [3]	2004	2	1 Bilateral cochlear nerve aplasia 1 Auditory	Retrosigmoid	Nucleus 24 ABI®	SPEAK	Patient 1: 95% of detection of instrumental sounds. 60% of discrimination neuropathy of instrumental sounds and 50% of onomatopoeic sounds; 40% of identification of instrumental sounds and 30% of onomatopoeic sounds.	
							Patient 2: 100% of detection of instrumental sounds. 100% of discrimination of instrumental sounds and 100% of onomatopoeic sounds; 95% of identification of instrumental sounds and 90% of onomatopoeic sounds.	-
Kalamarides et. al. [15]	2001	1	1 Bilateral schwannomas	Translabyrinthine	Nucleus 21 ABI®	SPEAK	Scores: Open disyllabic words identification: 40%; Open set recognition: 80%.	-

ABI: auditory brainstem implant; SPEAK: spectral peak coding

demonstrate the level of hearing capacity of children. The possible scores of the CAP are listed below:

(7): Patient is able to talk on the phone
(6): Understand conversation, no lip-reading
(5): Understand common phrases, no lip-reading
(4): Discrimination of speech sounds
(3): Identification of environmental sounds
(2): Response to speech sounds (e.g. "go")
(1): Awareness of environmental sounds
(0): No awareness of environmental sounds

Colletti et al. [1] consider the retrosigmoid surgical technique as the preferred technique. The translabyrinthine approach is the only one allowed by the FDA, [15, 22] as it is considered by some authors as the most straightforward way to the foramen of Luschka, but experimental evidence suggests the necessity for more manipulation in order to observe the lateral recess, increasing the risks [22]. Bento et al. [19] showed the feasibility of exposing of the jugular bulb without complications when using the retrolabyrinthine approach. The authors [19] also state that the distance to the bulbar nerves, in their series of patients, was short, allowing good manipulation of the cerebellar flocculus and choroid plexus, as well as excellent visualization of the foramen of Luschka.

About the auditory results of the ABI in patients with tumors of the cochlear nerve versus patients with non-tumoral diseases (NT), Colletti et al. [1] observed that NT patients scored much better than patients with sporadic acoustic neuroma and with NF2. The factors that may have influenced the results are:

- The tumor itself could cause distortion of the cochlear mechanism
- Tumor removal could cause brainstem distress due to traction and compression
- The anatomy of the cochlear nuclei may undergo modification due to expansion of the area compressed by the tumor

Tan et al. [17] described in a case report a patient that had an ABI fitted in an ear and a contralateral cochlear implant in the other simultaneously. This led to auditory confusion, increased numbness of the

body, and twitching on the lower arm on the ABI side in the patient. Hence, the use of the cochlear implant was discontinued, which led to the resolution of these side effects. This case suggests that the combination with a cochlear implant significantly aggravates the non-auditory side effects of the ABI and compromises its potential for optimal hearing results.

Colletti et al. [11] considered the global performance of children fitted with ABIs to be very satisfactory. The children had increased communication skills, and improvement in lip reading and environmental sound perception was observed as soon as the ABI was activated.

There are only a few studies that have referred to ABIs in children younger than 18 years old. This fact may have occurred because of the age limitations imposed by the FDA in past years. Since the FDA has given authorization for clinical trials to be performed, the number of papers in this specific area might bring more valuable information in this subject in the next years.

In conclusion, Even though untill recentlty FDA only approved the auditory brainstem implant for children older than 12 years old, the results obtained in 120 children fitted with an ABI showed that the patients globally improved in their ability to detect sounds and communication skills. The phenomenon could be seen both in patients with tumoural diseases of the inner ear and those with malformations of the cochlea or cochlear nerve, although patients with NT issues achieved better results than patients with schwannomas. The FDA only recently approved clinical trials for patients younger than 12 years old. So, we propose that the FDA auditory brainstem implant indications should be extended to patients with non-tumoral diseases of the cochlea and cochlear nerve and younger than 12 years old.

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