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Auditory brainstem implants: past, present and future prospects

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Summary

The purpose of the auditory brainstem implant (ABI) is to directly stimulate the cochlear nucleus complex and offer restoration of hearing in patients suffering from profound retrocochlear sensorineural hearing loss. Electrical stimulation of the auditory pathway via an ABI has been proven to be a safe and effective procedure. The function of current ABIs is similar to that of cochlear implants in terms of device hardware with the exception of the electrode array and the sound-signal processing mechanism. The main limitation of ABI is that electrical stimulation is performed on the surface of the cochlear nuclei, thereby making impractical the selective activation of deeper layers by corresponding optimal frequencies. In this article, we review the anatomical, and experimental basis of ABIs and the indications, and surgical technique for their implantation. To the best of our knowledge, we describe the first pathology images of the cochlear nucleus in a patient who had received an ABI.

Keywords: Neuromodulation; hearing loss; auditory pathway; treatment; ABI; rehabilitation.

Introduction

Since the initial applications in the early eighties, electrical stimulation of the auditory pathway at the cochlear nuclei, has proved to be an adequately safe procedure for rehabilitation of the hearing-impaired patients; the auditory brainstem implant (ABI) bypasses the affected structures and provides an adequate ascending stimulus. The majority of patients benefiting from ABIs suffer from neurofibromatosis type 2 (NF2), a severe and disabling disease which is associated with bilateral tumours in the cochleo-vestibular nerve, and consequently, bilateral retrocochlear sensorineural hearing loss (SNHL). The several disabilities induced by NF2 and associated to SNHL in these patients may affect the results of ABIs; the patient's audiological condition becomes an important selection criterion for this procedure. Patient education and rehabilitation, and a multidisciplinary approach to treatment, are of paramount importance in order to obtain the maximum benefit of this prosthetic auditory stimulation procedure [15].

Although currently about 500 patients around the world have received an ABI device, retrocochlear hearing impairment remains a challenging clinical problem. Given the clinical variety of retrocochlear SNHL, patients' performance with ABI cannot be predicted, and, hence, the results are generally poorer and more variable compared to those obtained with a cochlear implant (CI) [27]. In general, the auditory results with respect to word and sentence recognition in an open-set context are limited [16]. Nevertheless, recent reports show that ABIs are safe, have an acceptable ratio of surgical morbidity, and allow most patients to improve their communication abilities, especially lip-reading and awareness of environmental sounds [15]. This is particularly important in an emerging group of candidates who suffer from other causes of cochlear or retrocochlear SNHL namely cochlear ossification, and cochlear agenesis [4].

ABI design

The ABI device was designed initially to be fitted onto the cochlear nuclei, within the cerebellopontine area, simultaneously or after translabyrinthine or suboccipital tumour removal, in NF2 patients. Since the initial, single-channel, ball-type ABI electrode was developed in 1979, by Drs. House and Hitselberger at the House Ear Institute (Los Angeles, CA), ABIs have undergone substantial engineering modifications. Similarly to CIs, currents ABIs are made of an implantable part (electrodes and receiver-stimulator), and an external part, i.e. a speech processor worn by the patient and a transmission coil, placed over the skin, that transmits sound to the implant. These devices use surface electrodes for neural stimulation, built in platinum or platinum–iridium. The number of electrodes varies in the commercially available ABIs: 21 electrodes in the Nucleus 24 (Cochlear Ltd., Australia), 15 electrodes in the Digisonic (Laboratories MXM, France), and 12 in the Combi 40+ (MED-EL, Austria). Surface contact electrodes are disc-shaped, and are mounted on a silicone or Silastic plate that faces the cochlear nucleus complex (CNC). The other side of the plate is provided with a stripe of Dacron or polyester mesh that favours encapsulation, and helps prevent migration of the device.

Clinical experience demonstrated the safety and biotolerance of ABIs. It is important that when stimulation is performed, according to existing recommendations, the response of neural tissue to chronic electrical stimuli shows that no substantial damage occurs and that ascending auditory activation is clinically safe [27]. Sound-coding strategies used by the speech processor are similar to those currently used in CIs. The selection of speech processing strategies is dependent on the following variables: a) correct surgical placement, b) degree of functionality of the auditory pathway, c) number of active electrodes with different pitch perception, d) type of speech processor, and e) type of internally implanted device [15]. During programming sessions, electrodes producing non-auditory sensations are disconnected.

Neuroanatomical basis for ABIs

The target area for electrical stimulation of the ascending auditory pathway with ABIs is the cochlear nucleus complex (CNC). The CNC has an intricate structure and is divided into 3 regions based on the cell-morphology, and the structures with which they connect. These subdivisions are the Anterior Ventral Cochlear Nucleus (AVCN), the Posterior Ventral Cochlear Nucleus (PVCN), and the Dorsal Cochlear Nucleus (DCN). The CNC receives its ascending afferent input from the auditory nerve, and is the first station in the auditory pathway where neural processing occurs. The CNC contains a variety of cell types encoding different auditory functions, and consequently, for any given sound, there are multiple neural representations of that sound in the outputs of the CNC [2].

The CNC has a tonotopic organisation, which is strictly projected by cochlear ascending frequency-related fibers. Thus, apical cochlear fibers (transmitting low-frequency sounds) project mainly to the ventral portion of the AVCN, PVCN, and DCN, in contrast to basal cochlear fibers (transmitting high-frequency sounds) that project mainly to the dorsal portions of each subdivision of the CNC [18]. This organisation is best defined in the DCN, the most superficial and exposed part of the CNC at the brainstem, where the axis of the tonotopic gradient is oriented parallel to the brainstem surface [14]. Although this issue might be a theoretical advantage for electrical stimulation, most important ascending information is processed in the deepest part of the AVCN, which is almost unexposed within the lateral recess area. This relative inaccessibility of the tonotopic axis of the CNC prompted some investigators to evaluate the feasibility of intranuclear stimulation [19, 25]. Moreover, surface ABI electrical stimulation may be distorted because of tumour-induced anatomo-physiological changes of the area [4]. The above limitations can contribute to the patient's impaired perception of sound frequency, intensity, and temporal cues, and may explain in part why ABI-patients have limited auditory results with the use of their devices [27]. Recent reports show that in NF2 patients, either the tumor or the process of its removal could cause irreversible CN damage, and reduce speech understanding significantly [4]. Conversely, this is not the case in non-tumour patients, whose auditory performance is comparable to the most successful CI users. Currently available ABIs are not inserted inside the CNC. Instead, ABIs are placed onto the surface of the CNC within the lateral recess of the fourth

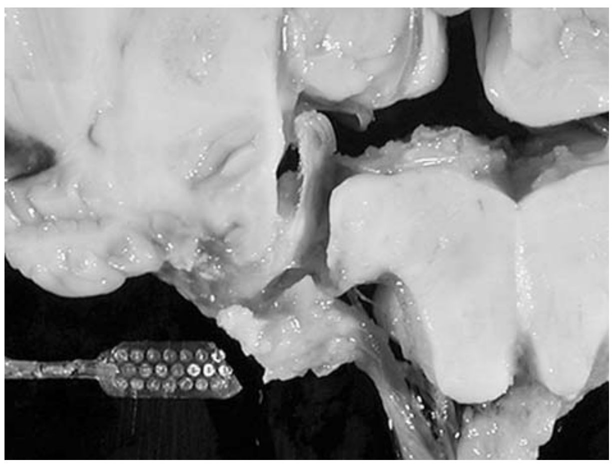

Fig. 1. Macroscopic preparation of autopsy. Coronal section of the brain from a successful patient of our ABI program, who died from pneumonia 2 years after implantation. The ABI has been removed from the implantation site, making visible the Dacron mesh integrated in to the scar tissue. The brain and brainstem appear shrunken because of the formalin fixation

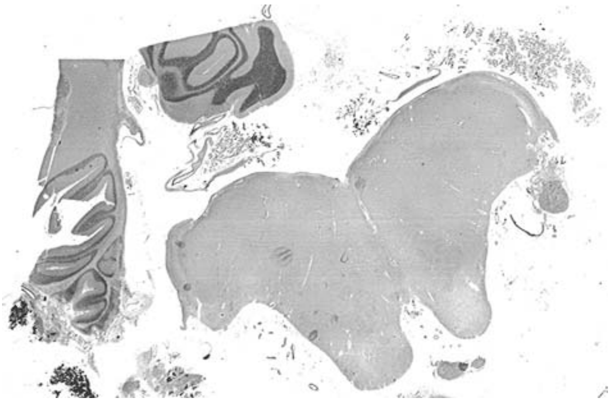

Fig. 2. Scan of a microscopic slide of the brainstem (hematoxilin and eosin stain). The section corresponds to the patient in Fig. 1. At both sides of the brain stem, the fat tissue used in subsequent surgical procedures is visible. On the left side of the section, the CNC is visible; the ABI was placed on top of it. Between the cerebellum and the CNC, a refringent material is present. This corresponds to Dacron fibers of the mesh used for device stabilisation. The architecture of the CNC is fairly well preserved, as both ventral and dorsal nuclei are recognisable, with typical cytology of the cochlear nuclei preserved. There was no evidence of intranuclear damage due to either intolerance of ABI materials, or to the electrical stimulation

ventricle (Figs. 1, 2). Such placement increases the likelihood of electrical stimulation of other surrounding cranial nerves or other neural structures. These unwanted non-auditory side-effects can be programmed-out at mapping sessions [31].

Experimental basis for ABIs

Similarly to what happened in other medical advances, the clinical rationale for ABI had been already set up [10, 17] before any integrated experimental evidence was available. This prompted us to start, in 1995, an experimental research study using non-human primates that completed the existing knowledge on electrical stimulation of CNC in the lower species [20, 28, 29, 35]. The research aimed at knowing the macaques normal neuroanatomy, the effects of surgical auditory translabyrinthine deafferentation [3, 11, 12], and the changes after ABI implantation [21, 22]. In a group of primates, we used a dummy ABI to mimic the surgical-related changes, and an active ABI. The ABI was similar, in terms of materials and types of stimulation, to that we used clinically on the CNC surface. A total of fourteen non-human primates underwent a translabyrinthine bilateral auditory deafferentation, and simultaneous unilateral active ABI ($n = 8$) or dummy ABI ($n = 6$) implantation. The ABI was connected via a cable to an external stimulator in the 8 animals undergoing chronic electrical stimulation.

In addition to the pathological examination, the volume and number of neurons of the CNC were estimated in both groups of animals. No mortality or major complications occurred. Brainstem neuropathological lesions or changes were observed in relation to the surgical trauma, and were mainly located at the cerebellar flocculus. The CNCs of the operated animals maintained their gross structure and preserved their neuron types but were reduced in size and showed changes associated with degeneration of the cochlear nerve fibers. In all implanted animals, we found a local superficial reaction around the ABI. In one stimulated animal, an asymptomatic brainstem abscess occurred. The electrical stimulation protocol could not be completed in two animals because of cable breaks or ABI extrusion. Nevertheless, neuropathological and stereological studies did not reveal significant changes in the CNC morphology, its volume or in the number of neurons. The most important factor contributing to tissue damage seems to be the intensity of the current. The duration of stimulation does not seem to have an influence on the damage, and hence, a prolonged period of stimulation does not seem to cause further damage.

Surgical anatomy and procedures

In NF2 patients, most surgical teams encourage ABI implantation at the time of first tumour removal. This may allow them to gain experience with the device while hearing is still present in the contralateral ear [15]. The choice on the surgical approach to the CNC-translabyrinthine or retrolabyrinthine-depends on the surgical team's preference and on the individual case, as the approach itself is not a major factor influencing surgical success [27]. A *translabyrinthine* approach is more common among otologists as it permits a complete control of the facial nerve, does not require cerebellar retraction, and provides a better access to the lateral recess, facilitating the ABI insertion. A disadvantage of this approach is a limited exposure and control of lower cranial nerves and vessels of the posterior fossa. In our opinion, this procedure is the first choice for patients with a tumour near the fundus and normal anatomy of the temporal bone. The *suboccipital approach* is traditionally preferred by most neurosurgeons, as it is performed more quickly and enables an optimal exposure of the posterior fossa, including cranial nerves and vessels. Disadvantages of this approach are the limited control of the lateral recess and fundus of the internal auditory canal, the retraction trauma of the cerebellum, and the higher risk of injury to the facial nerve. Nevertheless, it might be the choice for ABI candidates who have normal anatomical landmarks and no tumours.

The CNC is located superficially bulging in the dorsolateral aspect of the brain stem, and forming the ‘‘acoustic tubercle’’. The ventral portion of the CNC lies over the cerebellar peduncle, while the DCN is in contact with the lateral recess of the IV ventricle. Anatomic landmarks for intraoperative localisation of the CNC include the stump of cranial nerve VIII, cranial nerves VII and IX entering the brainstem, choroid plexus, and tenia, which is a layer over the foramen of Luschka [1, 26]. Probably, the single best landmark – when present – is the stump of the cranial nerve VIII as it can be followed right into the medial surface of the foramen [15], and the IX cranial nerve.

Continuous electrophysiological monitoring during ABI surgery has become an established procedure [7]. Intraoperative monitoring should include at least facial and glossopharyngeal nerves, and acoustic function if present. Once the anatomical landmarks and far-field electrical auditory brainstem responses (EABR) target the site for implantation, the ABI is inserted with the electrodes facing the CNC. The implant is to be stimulated *in situ* to confirm correct placement over the CNC, the integrity of the system, and also to determine the necessary levels of stimulation for the auditory activation. These fine adjustments are achieved through recording the EABR.

Indications for ABI

Currently, the main limitation of ABI-implantation is that electrical stimulation is performed on the surface of the cochlear nuclei, lacking the possibility of selectively providing an optimum frequency activation of the cochlear nuclei. ABIs have limited access to the tonotopic axis of the cochlear nuclei because ascending projections follow a strict frequency-related pattern affecting both VCN and DCN. To improve the access to pitch information, new developments the penetrating ABIs (PABIs) are currently under investigation and in some cases have been clinically tested. Similarly to cochlear implants, selection criteria for brainstem implants continue to evolve, as experience is gained. Initial criteria for clinical trials were quite strict [27], but they have been broadened. Currently, the most commonly accepted inclusion criteria are: NF2 or a traumatic lesion of both auditory nerves, and age over 12 years [30]. A profound bilateral SNHL is only required for patients with traumatic cochlear nerve avulsion, but is not a pre-requisite for patients with NF2 [5]. These may have serviceable hearing in one or both sides when implanted, depending upon the natural history of the disease, and the surgical approach for tumour removal.

Surgical implantation of the ABI in NF2 patients may be done in the first or the second tumour-removal procedure, or in a separate one. Patients should be willing to enrol in the ABI program, and should be in adequately good medical condition so that they can follow a regular program of rehabilitation sessions. Previous conventional otoneurosurgical or stereotactic radiosurgery (*gamma-knife*) treatments of cerebello-pontine angle tumours were initially exclusion criteria for ABI, due to the concerns of some investigators about the degenerative effect these could have on the structure of the cochlear nucleus and the reduced likelihood of electrically induced auditory sensation [27]. Nevertheless, increasing experience shows that such patients can also be offered an ABI, and have similar auditory performance to patients who have not been treated previously by either surgical or radiotherapeutic methods [13, 34]. In addition, there is a patient population who suffer from bilateral SNHL due to severe lesions of the cochlear nerve (aplasia, nerve avulsion, neuropathy), or severe cochlear abnormalities (malformations, acquired ossification), in whom CI may be either impossible or very demanding, or even useless [4]. In non-tumour patients, the absence of distortion in the anatomy of the auditory pathway allows an effective and fairly well organised activation of the auditory pathway [5].

Another emerging indication for ABI is the fortunately uncommon condition of bilateral cochlear agenesis. Besides the promising auditory results in these children, one of the most important things that Colletti’s group demonstrated was the presence of consistent intraoperative electrophysiologic central auditory activity during ABI surgery for cochlear nerve aplasia [6], making the classical axiom ‘‘function follows anatomy’’ invalid for the auditory pathway. Patients with extensive bilateral ossifying labyrinthitis have poor and inconsistent results after CI due to partial insertions and the associated severe degeneration of peripheral sensorineural elements [9]. In cases of cochlear hypoplasia, in severely ossified cochleae only a restricted number of electrodes can be positioned within the cochlea or aside the modiolus, thus providing a limited effective stimulation. ABI can be an efficient mean of auditory rehabilitation in cases of bilateral SNHL with totally ossified cochleae [8].

Future prospects

Currently, the main limitation of ABI implantation is that electrical stimulation is performed on the surface of the cochlear nuclei, without the possibility of selectively providing an optimum frequency activation of the cochlear nuclei. ABIs have a limited access to the tonotopic axis of the CNC. To improve the access to pitch information, new developments like PABIs are currently under experimental investigation. The group of McCreery *et al*. [25] at the Huntington Medical Research Institute (Pasadena, CA, USA) have successfully implanted a PABI device in cats. They demonstrated the ability of the electrode arrays to evoke tonotopically localised neural activation in the next auditory relay station of the brainstem, the inferior colliculus; in some cases, these devices have been already clinically tested. The House Ear Institute (Los Angeles, CA, USA) and the Huntington Medical Research Institute have started a clinical trial approved by the FDA and have started to report their results [33]. PABI may offer the following additional advantages: a decrease of non-auditory side effects given to more direct stimulation; an increase in the number of electrode contacts providing more numerous channels for stimulation, a reduction in power consumption and the possibility to use faster speech strategies. Since 2000, our group in the University of Navarra has been working on experimental PABI using the same macaque model we have used for ABIs; this is done in collaboration with the Huntington Medical Research Institute which provided the insertion tools needed in surgery. In the first group of primates, we have used a dummy PABIs, and our preliminary results are very promising [23, 24]; the surgical procedure is quite similar to ABI implantation and is well tolerated by the animals (Figs. 3, 4). Currently we are working on a second group of primates to study PABI electrical stimulation.

Fig. 3. Macroscopic autopsy preparation. Lateral view of the brain after a successful PABI implantation in a macaque. The cable of the PABI has been cut before the device was removed. The stump of the VIII cranial nerve is recognized and the PABI is seen with the plate *in situ*, over the CNC area, and the pins inserted within the CNC (not visible)

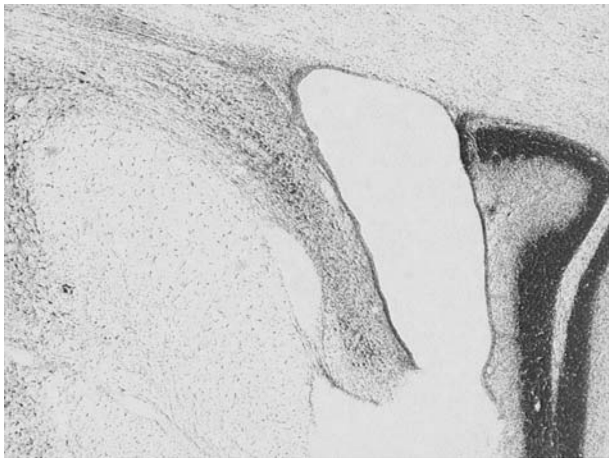

Fig. 4. Microscopic view of the brain stem (Nissl stain). The section corresponds to the animal in Fig. 3. On the left side, the pontobulbar part of the brain stem, and on the right, the flocculus of the cerebellum are seen. The photograph is centred on the CNC and shows the dorsal nucleus on the upper part, and the ventral nucleus on the distal part. The pseudocapsule which surrounded the ABI is visible

Conclusions

The indications for ABI continue to evolve in parallel with the growing experience of implant centres and the improvements in technology. Amazing clinical advances by reputed clinicians lead to emerging indications and open new frontiers for physiological or anatomical research and provide insights into auditory signal processing in the nervous system [32].

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