



PRE-ASSESSMENT *Auditory Brain Stem Implants*

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Before CCOHTA decides to undertake a health technology assessment, a pre-assessment of the literature is performed. Pre-assessments are based on a limited literature search; they are not extensive, systematic reviews of the literature. They are provided here as a quick guide to important, current assessment information on this topic. Readers are cautioned that the pre-assessments have not been externally peer reviewed.

Introduction

Neurofibromatosis type 2 is a rare genetic condition in which benign tumours (bilateral acoustic neuromas or vestibular schwannomas) develop on both sides of the auditory nerves.¹ Depending on the size and location of the auditory nerve tumours that are surgically removed, the auditory nerves may also be cut during surgery, causing total hearing loss. Devices such as cochlear implants or hearing aids cannot restore hearing when these nerves are damaged.

An auditory brain stem implant (ABI) consists of a receiver-stimulator (electrode array), an external speech processor that transmits sounds to the receiver and a clinical software program. The receiver is surgically implanted in the part of the brainstem that picks up electrical signals from the ear (the cochlear nuclei).² An ABI can allow users to sense some sound, but does not restore normal hearing.

Research Questions

In October 2002, a provincial medical director asked the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) for assessment information on auditory brain stem implantation. The information that was provided at that time has been updated in this pre-assessment, as this technology may be of interest to other jurisdictions.

Assessment Process

The initial (October 2002) and updated (February 2004) literature searches included PubMed, The Cochrane Library (Issue 1, 2004), the UK Centre for Reviews and Dissemination databases (DARE, HTA and NHS EED) and the EuroScan database of new and emerging health technologies. Additional references were obtained through an Internet search using Google.com, from the web sites of the US Food and Drug Administration (FDA), Health Canada and health technology assessment (HTA) agencies (as indicated in CCOHTA's checklist).

Summary of Findings

The Nucleus[®] 24 ABI (Cochlear Corporation) has been licensed by Health Canada for sale in Canada.³ The device received pre-marketing approval from the FDA in October 2000.² The US approval states that the Nucleus 24 ABI is indicated for use in teenagers and adults who have been diagnosed with neurofibromatosis type 2. The device may be implanted in individuals who have had auditory nerve tumours removed; or during the first- or second-side tumour removal surgery.⁴



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The other options for neurofibromatosis type 2 patients with total deafness are sign language, lip reading training, and externally worn tactile devices, which convert sound waves into vibrations or electrical currents that are felt on the skin.⁴

The FDA approval of the Nucleus 24 ABI was based on a study of 90 people who had been implanted with the device. Six-month follow-up data were available for 60 trial participants. The FDA Talk Paper on this device stated: “Results varied: 82% of the 60 patients were able to detect certain familiar sounds, such as honking horns and ringing doorbells; 85% were able to hear and understand conversation with the aid of lip reading; and 12% were able to hear well enough to use the phone. Of the 90 patients who received this implant, 18% were not able to hear any sound. This was due either to migration of the implant after surgery or misplacement of the device during surgery.”² The safety and effectiveness summary prepared for the FDA approval explains that, in neurofibromatosis type 2 patients with large tumours, the anatomy of the brainstem may be distorted, making it impossible for the surgeon to correctly place the device. The ABI device may not be of benefit to these patients.⁴

The Alberta Heritage Foundation for Medical Research, Health Technology Assessment Unit (AHFMR) identified this technology in a 2000 emerging technology alert.⁵ The Comité d’Evaluation et de Diffusion des Innovations Technologiques (CEDIT), in France, is the only health technology assessment agency that has prepared an assessment of cochlear brainstem implants and ABIs.⁶ The assessment is available in French from CEDIT. An English summary is posted on the CEDIT web site (<http://cedit.ap-hop-paris.fr>). The CEDIT summary concludes that: “Cochlear and auditory brainstem implants must be managed by a multidisciplinary team. The surgical side of ABIs requires the presence of ENT [ear, nose and throat] surgeons and neurosurgeons and such a team...must satisfy international criteria...These criteria require that surgeons have cumulative experience of over 100 acoustic neuroma operations, and a cumulative experience of at least 50 cochlear implants, or no less than 10 cochlear implants in the previous year. Also, international specialists recommend providing recognition to cochlear implant teams conducting at least 20 cochlear implant procedures per year. The quality of the final result, however, depends on the availability of multidisciplinary teams...a condition for optimal management before and after implantation....”⁶

Several US health insurance agencies have published coverage policies on ABIs.^{7,8} There are many published case reports and reviews of the use of ABIs; and ongoing trials of the technology.^{9-13 14,15}

Conclusion

The assessment done in response to the original request for information on ABIs was completed in October 2002. As this technology may be of interest to others, the search has been updated and the findings summarized in this pre-assessment. There is no need for CCOHTA to undertake a full assessment of this technology at this time.

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