NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of auditory brain stem implants

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared by Bazian Ltd in December 2002.

Procedure name

- Auditory brain stem implants.

Specialty societies

- British Association of Otorhinolaryngologists, Head and Neck Surgeons
- Society of British Neurological Surgeons

Description

Indications

Deafness caused by damage to the vestibulocochlear nerve resulting from tumours or surgery.

Tumours of the vestibulocochlear nerve (acoustic neuromas) are rare and generally benign. The most common cause is a rare genetic condition called neurofibromatosis.

In people with vestibulocochlear nerve damage, hearing is not improved by hearing aids or cochlear implants.

What the procedure involves

Auditory brain stem implants are electrodes placed in a part of the brain (the cochlear nucleus) responsible for processing sound signals carried from the ear through the

vestibulocochlear nerve. This nucleus lies in the lower part of the brain, called the brain stem.

Removal of vestibulocochlear nerve tumours and placement of auditory brain stem implants is often done at the same time. The surgeon makes an incision in the skin of the side of the head, and removes some of the bone behind the ear. This exposes the tumour so that it can be removed and also allows access to the brain stem beneath it. Sometimes the surgeon approaches the brain stem through the back of the head.

People with auditory brain stem implants wear an external receiver and speech processor. This device converts sounds into electrical signals, which are then sent to the implant.

Literature reviews

Appraisal criteria

Studies of auditory brain stem implants were included if they examined clinical outcomes.

List of studies found

No systematic reviews, randomised controlled trials or non-randomised controlled studies were found.

Twelve publications were found describing case series.[1-4] The four largest are described in the table.

References to smaller studies are given in the Appendix

Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Ebinger[1] Case series USA 1994 to 2000 92 people, age range 13 to 68 years 88 people with follow up data Most followed up at 6 months; some only 3-month data available	Received auditory sensations: 75/88 Used device daily: 97% (denominator not clear) Reported having benefit from it: 83% (denominator not clear)	Tingling in various parts of the body 'not uncommon'	Uncontrolled case series. Short follow up.
Otto[2] Case series Los Angeles, USA 1992 to 2000 61 people, age range 12 to 71 years Follow up to 7 years	Mean improvement in communication over lip-reading alone: 26% (range 0-66%) Improvements continued up to 7 years after implantation	Cerebrospinal fluid leak: 2 people Meningitis: 1 person 'Severe or serious non-auditory sensations': none	Uncontrolled case series.. Same centre as in Ebinger[1]; likely to be overlap of patients.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Hitselberger [3] Case series Los Angeles, USA 1979-2000 More than 100 people	Restoration of limited hearing: 80%		Uncontrolled case series. Data extracted from abstract only. Same centre as in Ebinger[1]; likely to be overlap of patients.
Sollman[4] Case series 1 Asian and 9 European countries (main author Germany) 1992-2000 54 people, mean age 33 years Follow up: up to 7 years	Some hearing: 94% Daily use: 89%	Pulmonary embolism: 1 person	Uncontrolled case series.

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
Schwartz M (2003) [5] Case Series 86 consecutive patients – 60 were evaluable	Patients had significant improvement in scoreces on several audiologic tests compared to baseline. Improvement was also seen when used to augment lip reading.	Authors did not report on complications	**This study was identified during the consultation process in June 2004.** Same centre as in Ebinger[1]; likely to be overlap of patients. Number of patients (n=-16) were excluded from analysis. Limited outcomes (no absolute numbers were given in the paper)

Validity and generalisability of the studies

All the studies found are case series.

All are small, so do not provide precise estimates of risk of complications.

Bazian comments

It appears that there are two main centres publishing work on auditory brain stem implants, one in the USA and one in Germany.

Specialist Advisor's opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

The best results allow conversation using the device, and lip reading. At worst, the device at least gives contact with environmental noise.

They listed the potential adverse effects of the procedure as death, damage to lower cranial nerves, intracranial haematoma/brainstem stroke, meningitis, and infection of device.

References

Ebinger K, Otto S, Arcaroli J, Staller Set al. Multichannel auditory brainstem implant: US clinical trial results. *Journal of Laryngology & Otology* 2000, 114: 50-3.

Otto SR, Brackmann DE, Hitselberger WE, Shannon RV, et al. Multichannel auditory brainstem implant: update on performance in 61 patients. *Journal of Neurosurgery* 2002, 96: 1063-71.

Hitselberger WE, Brackmann DE, Day JD, Shannon R, et al. Auditory brain stem implants. *Operative Techniques in Neurosurgery* 2001, 4: 47-52.

Sollmann W-P, Laszig R, Marangos N. Surgical experiences in 58 cases using the nucleus 22 multichannel auditory brainstem implant. *Journal of Laryngology & Otology* 2000, 114: 23-6.

Schwartz, M.S., Otto, S.R., Brackman, D.E., Hitselberger, W.E., Shannon, R.V. Use of a multichannel auditory brainstem implant for neurofibromatosis Type 2. Stereotactic and Functional Neurosurgery 2003, 81 (1-4) 110-114.

Appendix: References to studies not described in the table

Note: these studies are carried out by a small number of authors (the Otto [USA] group and the Sollman [Germany] group in particular). It is possible that some of the people included in the series are reported on more than once.

Reference	Number of study participants
The Sollmann group	
Nevison B, Laszig R, Sollmann W P, Lenarz T, et al. Results from a European clinical investigation of the Nucleus multichannel auditory brainstem implant. *Ear & Hearing* 2002; 23: 170-183.	27
Marangos N, Stecker M, Sollmann W-P, Laszig R. Stimulation of the cochlear nucleus with multichannel auditory brainstem implants and long-term results: Freiburg patients. *Journal of Laryngology & Otology* 2000; 114: 27-31.	18
Laszig R, Marangos N, Sollmann W-P, Ramsden R T. Central electrical stimulation of the auditory pathway in neurofibromatosis type 2. *Ear, Nose, & Throat Journal* 1999; 78: 110-117.	14
Marangos N, Laszig R, Sollmann W P. [Long-term results of multi-channel stimulation of the cochlear nucleus with auditory brain stem prostheses] [German]. *Wiener Medizinische Wochenschrift* 1997; 147: 259-263.	11
The Otto group	
Otto SR, Shannon RV, Brackmann DE, Hitselberger WE, et al. The multichannel auditory brain stem implant: performance in twenty patients. *Otolaryngology - Head & Neck Surgery* 1998; 118: 291-303.	20
Otto SR, Brackmann DE, Staller S, Menapace CM. The multichannel auditory brainstem implant: 6-month coinvestigator results. *Advances in Oto-Rhino-Laryngology* 1997; 52: 1-7.	15
Otto, S. Staller, S. Multichannel auditory brain stem implant: case studies comparing fitting strategies and results. *Annals of Otology, Rhinology, & Laryngology* - Supplement 1995; 166: 36-39.	12
Soussi T, Otto SR. Effects of electrical brainstem stimulation on tinnitus. *Acta Oto-Laryngologica* 1994; 114: 135-140.	18
Otto SR, House WF, Brackmann DE, Hitselberger WE, et al. Auditory brain stem implant: effect of tumor size and preoperative hearing level on function. *Annals of Otology, Rhinology & Laryngology* 1990; 99: 789-790.	15
Other groups	
Vincent C, Zini C, Gandolfi A, Triglia JM, et al. Results of the MXM Digisonic auditory brainstem implant clinical trials in Europe. *Otology & Neurotology* 2002; 23: 56-60.	14
Lenarz M, Matthies C, Lesinski-Schiedat A, Frohne C, et al. Auditory brainstem implant part II: Subjective assessment of functional outcome. *Otology and Neurotology* 2002; 23(5); 694-7.	11
Lenarz T, Moshrefi M, Matthies C, Frohne C, et al. Auditory brainstem implant: part I. Auditory performance and its evolution over time. *Otology & Neurotology* 2001; 22: 823-33.	14