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Cochlear Implantation: Patients, Problems and Surgical Complications

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Koklear İmplantasyon: Olgular, Problemler ve Cerrahi Komplikasyonlar

Koklear implantasyon (Kİ), geleneksel amplifikasyon yöntemlerinden yararlanamayan ve derin işitme kaybı olan hastaların rehabilitasyonunda kullanılabilecek güvenilir ve etkili bir yöntemdir. Bu çalışmanın amacı intrakoklear multikanal cihaz kullanım deneyimimizin paylaşılması, Kİ programında karşılaştığımız problem ve komplikasyonların bildirilmesi ve görüşlerimizin tartısılmasıdır. Kasım 1995 ve Ağustos 2000 tarihleri arasında implantasyon uygulanan, yaşları 1.5 ile 67 arasında değişen (yaş ortalaması 21.8) 40 bayan (%60) ve 27 erkek (%40) olmak üzere toplam 67 olgu incelendi. Olgularımız 30 çocuk (yaş ortalaması 6.7; yaş aralığı 1.5-14; 20 kız ve 10 erkek olgu) ve 37 erişkinden (yaş ortalaması 34; yaş aralığı 15-67; 20 bayan ve 17 erkek olgu) oluşmaktadır. Beş koklear ossifikasyonlu ve 4 koklear otosklerozlu olgu ile karşılaşıldı. Wegener granülamotozisi, Usher sendromu, kronik renal yetmezlik, kronik otitis media ve Mondini deformitesi gibi yüksek komplikasyon riski olan olgularda da Kİ uygulandı. Takip süresi boyunca çoğunluğu kendiliğinden veya medikal tedavi ile düzelen minör komplikasyonlardan oluşan çeşitli komplikasyonlar tespit edildi. Koklear implant, hastanın hayat kalitesinde önemli düzelmeler sağlamaktadır. Cerrahi teknik, kritik durumlarda Kİ ve cihaz donanımı ile ilgili araştırma ve gelişmeler ilerledikçe işitme engelliler için daha dinamik bir rehabilitasyon yöntemi elde edilecektir.

Anahtar Sözcükler: Koklear implantasyon, işitme kaybı, rehabilitasyon, cerrahi komplikasyon.

Abstract

Cochlear implantation (CI) has been established as a safe and effective method of rehabilitation of the profoundly hearingimpaired patients, who derive insufficient benefit from traditional amplification. The purpose of this report is to share our experience with intracochlear multichannel devices, describe the rationale of our surgical approach, report on the problems and complications encountered in establishing CI program and discuss our viewpoint with suggestions. Sixty-seven patients (40 women [60%] and 27 men [40%]) with an average age of 21.8 years (range, 1.5 to 67 years) have been implanted between November 1995 and August 2000. The patients consisted of 30 infants (average age 6.7 years, range 1.5 to 14 years; 20 female and 10 male patients) and 37 adults (average age 34 years, range 15 to 67 years; 20 female and 17 male patients). We performed CI in patients with cochlear ossification (n=5) and cochlear otosclerosis (n=4). We experienced the implantation in patients with high risk of complications (Wegener's granulomatosis, Usher's syndrome, chronic renal failure, chronic otitis media and Mondini's deformity). Complications were detected during the follow-up period, the majority of which were minor and self-limiting, or amenable to medical therapy. Cochlear implant makes a very perceptible improvement in patient's quality of life. Further research and development in surgery and hardware is a dynamic form of rehabilitation for the deaf.

Key Words: Cochlear implantation, hearing loss, rehabilitation, surgical complication.

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Introduction

Cochlear implantation (CI) has been established world-wide as a safe and effective method of reha-

bilitation of the profoundly hearing-impaired adult or infant, who derives insufficient benefit from amplification. In the past, lip reading and signing had been the only options for the profoundly deaf patient. As cochlear implant technology becomes more refined, the likelihood of success to return deaf patients to a world of sound increases.

Experiences, results and complications have appeared in the world literature over the last decade.¹⁻⁶ Such publications have confirmed the overall low incidence of major complications, those encountered do tend to occur in the patients implanted early in the program, and how other centres might prevent them.

In this review, we examine in detail the data from this particular centre and report on the problems and complications encountered in establishing CI programme. The purpose of this report is to share our experience in intracochlear multichannel devices, describe the rationale of our surgical approach, and discuss our viewpoint with considerations and suggestions.

Materials and Methods

Information was gathered prospectively on the database and reviewed. All the case notes were examined for further details if a complication had occurred, and also to verify details on the database to ensure that no information has been overlooked.

Guidelines for the implant candidates prescribe a stable bilateral profound sensorineural hearing impairment with a pure-tone average of 500, 1000, 2000 Hz worse than 90 dB hearing level, speech discrimination score below 30%, no evidence of benefit from conventional amplification, high motivation and appropriate expectations and no other physical or mental contraindications.

Preoperatively the patients underwent standard preimplant evaluation including ENT examination, audiological testing, and evaluation of psychological and social background. In the beginning of our implant program, a promontorium test was performed to find out whether electrical stimulation led to acoustic sensations.

High resolution computed tomography (HRCT) images of the temporal bones were obtained from all patients and compared to the intraoperative fin-

dings. The HRCT scans were accomplished on a GE HiSpeed CT (General Electrics, USA). Infraorbitomeatal base line was used and axial and coronal 1.5 mm slices were taken of the temporal bones and petrous apex. The magnetic resonance (MRI) scans were obtained from GE Signa 1.5 Tesla superconductive MRI apparatus (General Electrics, USA). The operative findings were then compared with the HRCT description of the cochlea. In selected cases, MRI was obtained to determine if a fluid-filled scala was present in patients with apparent cochlear obliteration.

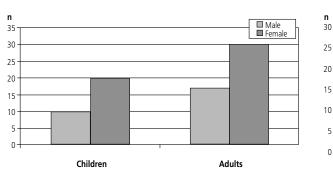
CI surgery consisted of a mastoidectomy and posterior tympanotomy (facial recess) approach performed in all cases. The scala tympani was opened by anteroinferior promontory cochleostomy without touching the round window membrane. By drilling of the promontory bone, the cochlear endosteum was visualized and opened with a needle to a diameter of 1 mm. Healon (sodium hyalurinate, Pharmacia & Upjohn AB, Uppsala, Sweden) was applied through the cochleostomy as a lubricant before insertion. Insertion of the electrode array of the Nucleus implant was started by manually reversing counter-clockwise to the right ear after an insertion of approximately 5-10 mm. Inserting 15 mm, the electrode was controlled depressed anteriorly by a claw to make the electrode slide along the laterocaudal wall. A claw was used to support the electrode posteriorly for further electrode advancement with the aim of deep-insertion. The electrode was never moved further against resistance.

After the insertion of the electrode array, stapedial reflex was controlled and neural response telemetry (NRT) was applied.

A major complication was defined as one leading to explantation or re-implantation, death of a patient, or excess hospitalization of one week. A minor complication was defined as a self-limiting, or settling with medical treatment and causing little distress to the patient.

Results

67 patients (40 women [60%] and 27 men [40%]), with an average age of 21.8 years (range, 1.5 to 67 years) were implanted between November 1995 and August 2000. The patients consisted of 30 in-



15 10 5 0 0 to 10 11 to 20 21 to 30 31 to 40 41 to 50 51 to 60 Age range

No. of patients

61 to 70

Figure 1. Sex ratio of patients.

Figure 2. Age groups.

fants (average age 6.7 years; range 1.5 to 14 years; 20 females and 10 males) and 37 adults (average age 34 years; range 15 to 67 years; 20 females and 17 males) and they were implanted with the slight preponderance of females in both groups (Figures 1, 2).

The commonest etiology of deafness was congenital progressive sensorineural hearing loss, followed by post-meningitis and other infective causes (Figure 3). Twenty-nine patients (43%) were prelinguistic and 38 patients (57%) were postlinguistic.

The patients had an extended endaural (Hannover) incision and received Nucleus 22 (n=7, 10.5%), Nucleus 20+2 (n=2, 3%) and Nucleus 24 (n=58, 86.5%) implants.

For adults, the average duration of the followup was 34 months, with a range of 4 to 49 months. For children, the average duration of follow-up was 31.3 months, with a range of 11 to 41 months. All patients are still under regular controls.

Of the 67 cases reviewed, the HRCT scans were used to predict the patency of cochlear lumen, presence of cochlear ossification and cochlear otosclerosis.

Five patients (7.5%) with the etiologies of hearing loss due to meningitis (n=3), viral encephalitis (n=1) and congenital sensorineural deafness with an agenetic stapes (n=1) were detected for cochlear ossification on HRCT scans and/or intraoperatively and, a full insertion was achieved only in one case. Two patients had scala vestibuli and 1 patient had middle turn insertions. The remaining 2 patients had scala tympani insertions. The HRCT scans were successful in detecting cochlear patency in 3

patients while cochlear lumen was seen patent on HRCT in 2 patients, while the intraoperative findings revealed some degree of ossification and partial insertion of the cochlear array was managed during surgery.

Four patients (6%) were detected to have cochlear otosclerosis on HRCT, and the findings were supported by MRI scans to evalute if a fluid-filled scala was present in patients with apparent cochlear obliteration. Two of these patients had scala vestibuli insertion. The remaining patients in our series received scala tympani insertion.

We experienced the implantation in the patients with high risk of complications. Two patients with a history of renal transplantation after chronic renal failure were deafened after ototoxic drug usage and had their CI during dialysis programme. One of these patients had a mild and transient facial paralysis postoperatively. We applied CI to the patients with Wegener's granulamatosis (n=1) and Usher's syndrome (n=1). Four previously operated chronic otitis media patients having radical or modified radical mastoidectomy cavities also received implantation. A 5 year old patient was diagnosed as Mondini's deformity and had a successful CI.

Major and minor complications were detected during the follow-up period. Three patients had transient facial nerve paresis and one patient had transient imbalance. One patient had arytenoid luxation linking to entubation of anesthesia. After detection of displacement, the cartilage was successfuly manipulated into position. Perilymph fistula from the cochlear aquaductus was detected in one patient and was sealed off successfuly. One patient had partial slippage of electrode tie into the radical mastoidectomy cavity after 19 months and

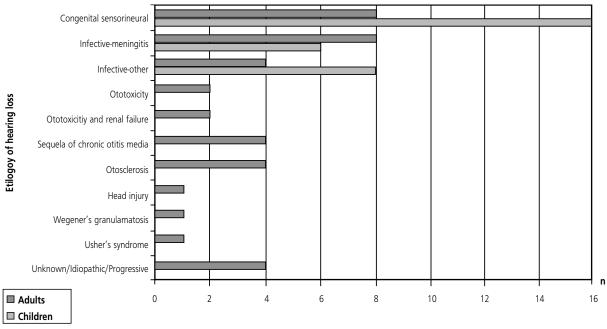


Figure 3. The etiologies of hearing loos.

required a revision operation to insert the array back to its original position. Tragal cartilage was used to support the array in the place. We did not encounter any flap-related complications.

Discussion

The cochlear implants are still in a developmental stage and our knowledge of hearing mechanisms and of the pathogenesis of hearing disorders remains limited. Therefore, input from all specialists with different backgrounds and viewpoints is needed. The aim in CI is to place an electrode in a position that will maximize the chances of differentially or selectively stimulating the remaining neural elements within the cochlea.⁷ For surgical purposes, the anatomical structures to be surgically considered are the skull, mastoid, middle ear (promontory, round window), and inner ear (cochlea, in particular the scala tympani).² The main surgical approach is the posterior tympanotomy-facial recess approach.

Postoperative success in cochlear implanted patients has been shown to depend on the anatomical structures and different variables.⁸ Surviving ganglion cells and auditory nerve fibers are not evenly distributed through the cochlea and changing the strategy of stimulating electrodes may yield better results. More nerve fibers and ganglion cells must be stimulated and optimal responses of NRT can be obtained.

Regarding the question of minimum age of implantation, the answer is as soon as there is a reliable diagnosis of bilateral profound hearing loss.³ In some cases of expected cochlear obliteration or ossification such as after meningitis, very early successful implantation in children younger than 2 years of age has been reported.^{3,9} A shorter duration of deafness means a greater potential for successful adaptation to the CI. In our series, we have applied CI to a patient of 1.5 years of age, 5 months after meningitis. However, the maximum age at implantation is not easy to settle. The selection of especially prelinguistic adults requires a special program within a CI program.^{3,10} The selection criteria of these candidates should be strictly defined.

CI in Wegener's granulamatosis (WG) is undetermined. El Hmd *et al*, reported CI in a patient with bilateral profound sensorineural hearing loss due to WG.¹¹ We could not find any other reported case of CI in WG in the literature. No surgical problem was encountered in our patient with WG during CI. Usher's syndrome (US) is an autosomal recessive disorder characterized by congenital sensorineural hearing loss and progressive visual loss secondary to retinitis pigmentosa.¹² The most widely recognized clinical type of US is type 1 with profound sensorineural hearing loss, absent vestibular function and retinitis pigmentosa. Children with US type I are profoundly deaf and typically receive little benefit from traditional amplification. For this reason it is likely that the majority of patients with US are cochlear implant candidates with early implantation facilitating maximum auditory skill growth.¹² Our US patient with progressive visual loss and bilateral profound sensorineural hearing loss had a successful CI without any surgical complications.

There have been a number of clinical reports about CI in anomalous cochlea.¹³⁻¹⁵ It has been stated that a cochlear implant might represent the final resource to help a patient with Mondini's dysplasia.^{13,14} One of our patients had Mondini's dysplasia and bilateral profound sensorineural hearing loss. She was considered to be a suitable candidate for CI. Increased risk of perilymph or cerebrospinal fluid leak should be taken seriously during the surgery.¹⁵

Before 1988 imaging evidence of cochlear ossification was widely considered to be a contraindication to CI.¹⁶ Among the factors considered in determining ossification to be contraindication are the questions about the ability to insert the electrode, resistance to spread of electrical stimuli, and survival of stimulable neural elements.^{17,18} Since 1988, safety and efficacy of implanting ossified cochleas have been demonstrated. Balkany *et al*, reported the prevalence of intrascalar ossification to be 9%.¹⁶ The prevalence of cochlear ossification in our series is 7.5% (n=5).

Cochlear ossification is most commonly the result of meningitis with labyrinthine ossificans restricting the depth of insertion of the electrode array into the cochlea.^{9,16,19} Sensorineural hearing loss is common complication of bacterial meningitis, affecting between 5 to 35% of survivors.²⁰ The surgeon must be prepared to encounter cochlear ossification when performing cochlear implantation especially when the hearing loss was caused by meningitis.⁹ Because ossification is thought to be progressive, the earlier one can implant a postmeningitic child, the better the chance of finding a patent cochlear lumen.²¹ Twelve postmeningitic patients have undergone CI in our series (17.9%). Cochlear ossification was encountered in 3 postmeningitic patients (4.4%). If ossification is suspected, the facial recess is widely opened and the round window is identified. If the round window is obliterated, it may be identified by drilling 1.5 mm inferior to the pyramidal process until abnormal bone is identified. The bone is then followed anteriorly into the basal turn. Through the facial recess, cochleostomy is performed with a diamond drill, identifying abnormal bone and following it forward for a distance of approximately 8 mm. By extending the drilling with the circum-modiolar trough, all electrodes may be inserted, providing the possibility of improved function.

Because of the high incidence of bilateral otosclerosis, profound deafness develops in some patients with otosclerosis regardless of whether successful surgery has been performed or not. In these patients, CI is the last therapeutic possibility.²² CI is sometimes a bit complicated, since ossification may take place. But in almost all cases successful implantation, at least a number of electrodes, is achieved.²³ We have performed full-insertion CI in four otosclerosis patient with varying degrees of cochlear obliteration

Conclusion

Radiographic imaging of the temporal bone is invaluable to the otologic surgeon contemplating cochlear implantation. HRCT scanning technology has increased the ability to assess the structures within the petrous pyramid. An HRCT scan of the temporal bone reveals four major features: inner ear malformations, the patency of cochlear coils, the position of the jugular bulb (which if high enough may reach up to the level of the round window), and the presence of the retrocochlear and infracochlear air cells which may be mistaken for the round window niche.²⁴

MRI techniques have been used to image the cochlea. By using the T2-weighted sequences, the fluid of the cochlea, the semicircular canals, and the cerebellopontine angle can be visualized.²⁴ All these spaces have the same signal in the normal state. Absence of the signal seems to indicate ossi-

fication. This anomaly can be partial, localized on the first basal turn, sometimes only on one side. However ossification can be partial or one-sided, and MRI images must be carefully analysed in a comperative way. Using the T2-weighted images, the absence of cochlear fluids has been detected after meningitis and in the malformed inner ear.²⁴ The MRI appears to be more sensitive in imaging the inner ear fluid spaces and obstruction of the cochlear lumen.^{24,25} MRI also adds information not gathered from CT imaging, such as the presence and size of the cochlear nerve.²⁶

CI is rehabilitative surgical procedure and ill effects should be minimized. Proper patient selection and care with anesthetic and surgical techniques are both very important. In various series, there have been a variety of problems occurring at the implant site. Most have been transient or have responded to local measures. Other complications have required prolonged treatment, revision, or even explantation.

The most significant complications are due to wound breakdown and flap-related complications.^{4,27} We have solved the problem by using extended endaural flap design of Hannover. The importance of flap design and size is emphasized. The flap incision must be well away from the implant and properly sutured in layers and without tension. The care of the flap is also very important. It should not be crushed by instruments and should be kept warm and moist during the procedure.

Electrode misplacements and compressions are also reported.⁴ In one of our patients, there was partial slippage of electrode tie into radical mastoidectomy cavity after 19 months which required a revision operation to push the array back to the original position. The cavity was returned to a cul-desac and the array was supported with a tragal cartilage after the obliteration of the cavity with omental fat.

Problems with perilymph or cerebrospinal fluid leaks occur typically in cases of congenital abnormalities.^{4,13,15} In these cases, the entry point into the scala tympani should be carefully sealed with fibrous tissue. If necessary the whole middle ear and mastoid must be packed.

Care must be taken not to injure the facial nerve when carrying out the posterior tympanotomy.⁴ Our 3 patients had mild transient facial parasis in our series, recovered in 72 hours with tapering prednisolone 1 mg/kg/day treatment.

Failure in implantation or stimulating the auditory nerve are problems related to the preoperative evaluation, in particular radiography and electrical stimulation of promontory.⁴ Even with abnormal findings, it has been shown that in partially ossified cochleas it is possible to insert electrode arrays for 25 to 26 mm along the scala tympani when the bone, which is situated in the basal turn near the round window is removed.¹⁸ With more complete fibrosis or ossification of the scala tympani it is possible to enter the scala vestibuli and make the insertion.

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