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Complications of paediatric cochlear implantation: experience in Izmir

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Abstract

Surgery for cochlear implantation (CI) bears the risks of complication associated with all major surgery, in addition to the particular risks associated with implanting a foreign body into the peripheral auditory system. Here we present a retrospective study involving 227 cochlear implant operations in 205 children to evaluate the rate of intra- and post-operative complications.

Complications were defined as major complications, requiring explantation of the device or further operation, causing a significant medical problem, or leading to any degree of facial paralysis or requiring additional hospitalization for treatment; or defined as minor complications, namely those that settled spontaneously, with conservative treatment, with local care and/or with medication alone.

In our study there were 15 (6.6 per cent) minor and 28 (12.33 per cent) major complications. The most frequent minor complication was dizziness and vomiting (3.08 per cent), followed by transient hemifacial oedema (1.76 per cent), head pain (1.32 per cent) and mild ataxia (0.4 per cent). The most frequent major complication was trauma to the device (9.69 per cent), followed by cerebrospinal fluid (CSF) gusher (2.2 per cent) and facial paresis (0.4 per cent). All of the device trauma cases were re-implanted. There were neither any life-threatening complications nor any facial nerve paralysis in our implanted children.

This study confirms that CI is relatively safe and that major complications are few and within acceptable limits.

Key words: Cochlear Implantation; Inner Ear; Surgical Procedures; Complications

Introduction

Cochlear implantation (CI) is a method of auditory rehabilitation for profoundly hearing-impaired patients. This provides a surgical means for ameliorating profound sensorineural deafness. The implants provide a direct stimulation of the spiral ganglion cells of the cochlear nerve by bypassing the destroyed hair cells.[1]

The currently accepted minimum age limit of two years for implantation was initially chosen for anatomical reasons. The cochlea is adult size at birth, and by the age of two years, the mastoid antrum and facial recess, which provide access to the middle ear for placement of the active electrode, are adequately developed. From a neuro-developmental view point, an even younger age limit may be desirable.[2] Today, reports have been published of children as young as 11 months of age, in whom CI has been successfully performed.[3]

Surgery for CI bears the risks of complications associated with all major surgery, in addition to the particular risks associated with implanting a foreign body into the peripheral auditory system.[4] Although the cochlea is adult size at birth, a potential for increased risk exists in children because of their thin scalps, relatively small skull size, incomplete mastoid development, a danger that their future skull growth will lead to movement of implant receiver stimulator or electrode array, and the high prevalence of otitis media in children and its subsequent related complications.[5–7]

Here we present a retrospective study involving 227 CI operations in 205 children to evaluate the rate of intra- and post-operative complications.

Material and method

Two hundred and five children were included in this study: 103 males and 102 females, aged between 22 months to 16 years. These patients had been operated on between 1998 and June 2004 and were chosen from a self-developed database (Microsoft® Access).

Complications were defined as major complications, requiring explantation of the device

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TABLE I

MINOR COMPLICATIONS IN THE PAEDIATRIC COCHLEAR IMPLANTATION STUDY GROUP

Dizzines and vomiting	7 (3.08%)
Transient hemifacial oedema	4 (1.76%)
Head pain	3 (1.32%)
Mild ataxia	1 (0.4%)

or further operation, causing a significant medical problem, or leading to any degree of facial paralysis or requiring additional hospitalization for treatment; or defined as minor complications, namely those that settled spontaneously, with conservative treatment, with local care and/or with medication alone.[6,8–10]

The distribution of deafness aetiologies in the paediatric CI population was also studied.

Results

There were 15 (6.6 per cent) minor complications, of which the distributions are shown in Table I. The most frequent minor complication was dizziness and vomiting (3.08 per cent), followed by transient hemifacial oedema (1.76 per cent), head pain (1.32 per cent) and mild ataxia (0.4 per cent). There were 28 (12.33 per cent) major complications, of which the distributions are shown in Table II. The most frequent major complication was trauma to the device (9.69 per cent), followed by CSF gusher (2.2 per cent) and facial paresis (0.4 per cent). All of the device trauma cases were re-implanted.

One hundred and eighty-eight of our paediatric patients received a Med-El® (Medical Electronics, Innsbruck Austria) and 39 of them received Clarion® (Advanced Bionics Corporation, California USA) CI.

One hundred and twenty-six (61.46 per cent) of our children were congenitally deaf (five of them with Waardenburg syndrome, seven of them with Mondini deformity and six were common cavity cases), 32 (15.6 per cent) children became hearing impaired after a meningitis infection, eight (3.9 per cent) children became progressively deaf, one of them an Osteogenesis Imperfecta case, 26 (12.68 per cent) children were deaf after a hyperthermic viral infection, and 13 (6.34 per cent) children were idiopathically deaf (Table III).

Discussion

The first detailed report of surgical complications of CI was that of Cohen *et al.* in 1988.[11] The complications of CI surgery are a reflection of the complexity of the surgical procedure, the skill of the operating surgeon, the surgeon's level of experience with the operation being performed, and the risks inherent in the insertion of a large foreign body immediately deep to the scalp.[6,12]

TABLE II

MAJOR COMPLICATIONS IN THE PAEDIATRIC COCHLEAR IMPLANTATION STUDY GROUP

Facial nerve paresis	1 (0.4%)
CSF gusher	5 (2.2%)
Trauma to the device	22 (9.69%)

TABLE III

DEAFNESS AETIOLOGIES OF THE PAEDIATRIC STUDY GROUP

Aetiology	Number of children
Congenital	126 (61%)
Meningitis	32 (15.5%)
Progressive	8 (3.8%)
Viral infections	26 (12.6%)
Idiopathic	13 (6.3%)

Minor complications

Though it has been stated that a significant number of patients experience vertigo and vomiting after CI surgery, this percentage was low in our series.[13] 3.08 per cent of the children had early post-operative dizziness and vomiting, but all of these cases subsided without medication within 24 hrs. This mild complication may result from anaesthesia medications or irritation of the vestibular system. Our policy for vertigo and vomit management in paediatric CI surgery is to wait at least 24 hrs without any medication post-operatively. In a serious case lasting more than 24 hrs, the case will be re-examined if it is also resistant to vestibular stabilizing agents, since it may be a sign of a perilymph fistula.

There were also four children with transient hemifacial oedema caused by dressing, that totally subsided after undressing, three children with chronic head pain that began after the implantation and continued intermittently without explanation, and one child who suffered from mild ataxia but further neurological examination revealed no pathology and this did not necessitate any further treatment.

Major complications

Facial nerve paresis is a serious complication. The facial recess approach to the mesotympanum places the facial nerve at risk. Particularly in children with congenital malformations, an anomalous facial nerve may be injured even by an experienced surgeon. Facial nerve injury may be minimized by using a facial nerve monitor, but even this is not a guarantee of avoidance of injury.[12] By carefully identifying the short process of incus in the fossa incudis and the corda tympani nerve, the boundaries of the facial recess can be defined without exposing the facial nerve.[7] The corda tympani nerve can usually be preserved, but occasionally a narrow facial recess necessitates sacrifice of this structure.[14] A thin shelf of bone covering the facial nerve also provides a measure of protection from any required instrumentation performed through the facial recess and may be very helpful should the need for revision surgery arise. Continuous irrigation should be employed while opening the facial recess since considerable thermal energy is generated by diamond burrs and burr shafts.[7]

Facial nerve injury would seem to be more likely in children because of the relatively high incidence of facial nerve anomaly with the Mondini deformity of the cochlea.[11] In our series, seven facial nerve anomalies were found during implantation, one of them (0.4 per cent) had transient facial paresis post-

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operatively, which resolved within 48 hrs. This was attributed to heat generated by the burr shaft during the cochlear drill-out, and it was treated with corticosteroid therapy.

Several authors reported facial paralysis or paresis in their series. Its incidence varies between 0.27 per cent[10,15] and 1 per cent.[7] In general, its rate has fallen from 1.74 per cent in 1988 to 0.2 per cent in 1995.[16]

Facial nerve stimulation could be another problem, which may be seen on stimulation of particular electrodes. These can be programmed out in the process of creating a map.[14] Facial nerve stimulation was encountered mostly in the post-meningitis patients. One explanation for this phenomenon is the demineralization of bone due to intra-labyrinthine infection.[10] The problem was solved by changing the mode of the stimulation pattern of the implant used.

CSF gusher is another possible serious complication in CI surgery because it has been associated with subsequent cases of meningitis.[4] In children with sensorineural hearing loss (SNHL), the presence of a congenital syndrome increases the likelihood of a cochlear or vestibular abnormality.[17] There were eight children with cochlear anomaly in our series, and seven with Mondini deformity, all of them of incomplete partition type and with a large vestibular aqueduct syndrome, respectively. During implantation there were five cases of CSF gusher in children with Mondini deformity. Minor perilymph leakage was also encountered in six children during the CI operation (5.5 per cent) in our study. All of them settled spontaneously. There was no special policy for perilymph leakage in our centre. In all cases, after the electrode insertion the cochleostomy is sealed with fat and fibrin glue. The use of fat and fibrin glue together not only prevents perilymph leakage but also reduces the chance of possible infection. CSF gusher reported in the literature varies between 0.53 and 1 per cent.[7,12] A perilymph gusher should be anticipated when operating on a dysplastic cochlea or a patient with a wide and/or short internal auditory canal, but there are no contraindications for implantation.[7,10,12,18] By allowing the CSF reservoir to drain off or by carefully sealing the cochleostomy with connective tissue or small pieces of muscle the problem can be solved. In cases of profuse CSF flow, a total obliteration of the middle ear should be carried out. Adjunct lumbar CSF drainage may be helpful.[7,10,12]

There were 22 (9.69 per cent) cases of device failure due to trauma in our study group, all of which were re-implanted. After analysis, we observed that all of these implantation surgeries were carried out in 1998–2000. During this period, the processors were implanted in the postero-superior location of the auricle, far from the protection provided by it. The malfunction of the device ceased at once after we started implanting it behind the auricle, and the device manufacturing company changed the firm that does the ceramic plating of the processor.

Several authors reported device failures in their series. Its incidence varies between 1.81 per cent[11,12] and 14.9 per cent.[19] There are concerns about the potential damage or trauma caused by re-implantation. Results of earlier animal studies suggested that re-implantation may induce significant damage to stria, spiral ligament, and organ of corti, as well as degeneration of spiral ganglion cells in the apex of the cochlea. But more recent animal and human studies have indicated that re-implantation may be accomplished without damage to the cochlea.[20] The presence of ossification within the scala tympani following initial implantation often makes re-implantation technically challenging. Balkany *et al.* also stated that following re-implantation, the mean length of the insertion, the number of channels actively programmed, and the speech recognition scores were at least as good as findings before initial implant failure, and they stated that re-implantation is safe and effective.[21] But, Henson *et al.* reported that speech recognition ability with a replacement CI may significantly increase or decrease from that with the original implant.[22] Experienced CI patients facing re-implantation must be counselled regarding the possibility of differences in sound quality and speech recognition performance with their replacement device.

There were also other complications in CI surgery, which we did not have in our series. These are mainly wound infection, otitis media, improper electrode insertion, meningitis and flap breakdown.

Wound infection is a minor complication that may result after CI surgery. In our centre, 24 hrs before the operation, ceftriaxone 50 mg/kg is started intravenously for infection prophylaxis, which is also continued during hospitalization. Children are treated as in-patients at the centre for about 5–7 days with daily wound treatment using regular antiseptics. Since it is difficult to remove sutures in children after the operation, 5/0 absorbable sutures are used for skin closure. After discharge, cefixime 8 mg/kg is prescribed for seven days. There are no special considerations for CI children with regard to in-patient treatments, as they are hospitalized in three-patient wards with other patients.

Otitis media in CI children have been reported and discussed by many authors.[5,6,10] In our study group there were no otitis media cases of both ears for at least 4–6 weeks following the operation, e.g. during the time the children were under our supervision until the first fitting. Here it is important to note that about 75 per cent of the CI child patients are residents of other cities, thus follow-up observations after the fitting were limited, e.g. monthly or in some cases even less frequently. Though this is not reported here, otitis media can be misinterpreted by patients' parents or by family practitioners. Fortunately, there was no increased occurrence of otitis media in the ears of the CI children and no complications when otitis media occurred in the presence of this large foreign body.[12,23]

Improper electrode insertion can be another problem in CI surgery. To manage this problem, pre-operative computed tomography (CT) and magnetic resonance imaging (MRI) of the cochlea and

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temporal bone are necessary. They alert the surgeon to possible anatomic limitations. CT and MRI are now standard examinations prior to the insertion of a cochlear implant. Both methods have advantages and disadvantages in terms of discovering potentially pathological structures in the inner ear.[24] There were no cases of improper electrode insertion in our study group, but seven cases had partial electrode insertion, two of which were meningitis cases with partial ossification of the cochlea. If the electrode seems to meet an obstruction within the scala tympani, it should be withdrawn slightly, rotated 180º to bring the tip away from the basilar membrane and then inserted further.[8] The electrode should remain in the cochlea, thus keeping open the intra-cochlear space.[10] Following CI, post-operative imaging of the electrode is very important in order to measure the depth of insertion and the position of the electrode, so that kinking and incorrect electrode placement can be clearly identified.[25] Problems related to misplaced electrodes have fallen from 1.74 per cent of cases in 1988 to 1.18 per cent in 1995.[16]

Meningitis is a life-threatening complication after CI surgery. The infection can be fatal in some instances. A recent increase in the incidence of otogenic meningitis among CI wearers is of concern. Not all cases have been subsequent to otitis media, and symptoms have developed from less than 24 hrs up to a few years after implantation.[26] The Food and Drug Administration (FDA) has reported 87 cases of meningitis, of whom 17 have died. According to the FDA, the majority of the Cochlear Corporation and MED-EL cases had predisposing factors for meningitis unrelated to the implant (e.g. Mondini inner-ear deformity, or a pre-implantation history of meningitis).[26] Although vaccination is usually protective against both pneumococcus and *Haemophilus influenzae*, two cases of pneumococcal meningitis and two cases of *H. influenzae* meningitis developed after the patient had received the appropriate vaccine. As discussed earlier, sealing the cochleostomy with fat and fibrin glue reduces the risk of possible infection, hence the lack of any meningitis in our data.

Another major complication of CI surgery is flap breakdown, which may require explantation of the device. The most important factor in managing this problem is the location and type of the incision in the flap design.[10] The design should preserve a good vascular supply and optimum venous and lymphatic return. It is also important that the incision does not intersect the implant bed at any point. An excessively thin flap is more likely to break down, especially when subjected to pressure from opposing magnets. Delayed flap healing and necrosis may be related to improper handling of the flap during surgery. Problems related to flaps have fallen from 5.44 per cent in 1988 to 2.79 per cent in 1995.[16] Securing the implant is another important concern in CI surgery. In our centre, it is secured to bone with 2/0 absorbable sutures. Since 1998, we have not seen any problems related to implant securing, such as emergence of the sutures from the wound months or years after surgery.

In light of the strong trend toward performing CI in infants, it is necessary to consider anaesthetic issues. Just as anaesthetic risk may play an important role in surgical candidacy in the elderly population, anaesthesia is also of special consideration in infants. Even healthy infants are known to be at increased risk of anaesthetic complications; for this reason, most elective surgical procedures are not routinely done within the first year of life. Therefore, it is necessary to consider anaesthetic issues when contemplating the use of cochlear implants in infants of less than 12 months of age.[27]

- **This study reports the complications in 227 cochlear implant operations in 205 children**
- **Minor complications (6.6 per cent) included post-operative vertigo, hemifacial oedema and headache**
- **Major complications (12.3 per cent) included trauma to the device, CSF fistula and facial paralysis**

Conclusion

This study confirms that cochlear implantation is relatively safe in children and that major complications are within acceptable limits. There should be no reason for parents to reject cochlear implantation for their children because of major operative risks.

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