Medical and Surgical Complications in Pediatric Cochlear Implantation

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Objectives: To report complications of cochlear implantation (CI) in children and to analyze risk factors.

Design: Retrospective study from January 1, 1990, through April 30, 2008, with a mean follow-up of 5.5 years (range, 1 month to 17 years).

Setting: Tertiary academic center.

Patients: Four hundred thirty-four patients younger than 16 years. Mean age at CI was 4.7 (range, 0.6-16.0) years. Forty-one children (9.4%) underwent CI when younger than 24 months. Forty-three (9.9%) had inner ear malformations.

Main Outcome Measures: Complications after CI, classified into early (0-8 days) or delayed (>8 days) and major or minor. Spontaneous failures of internal devices were excluded. Correlation to age at CI, local trauma, and inner ear malformations were analyzed using the χ² test.

Results: Forty-three patients (9.9%) experienced complications. Delayed complications occurred in 28 patients (65.1%), with a mean delay of 2.2 (range, 0.1-8.4) years. Twenty-four patients (5.5%) had major complications, consisting of severe cutaneous infections (15 patients), magnet displacement (3), meningitis (2), cholesteatoma (2), cerebrospinal fluid leak (1), and electrode misplacement (1). Nineteen (4.4%) had minor complications, consisting of vertigo (9 patients), soft-tissue infection (5), persistent otitis media (4), and facial palsy (1). Complications led to reimplantation in 13 of the 43 patients (30.2%). Trauma to the mastoid area (14 patients) and inner ear malformations (51) were highly correlated with major delayed complications (P < .001) and early minor complications (P < .001), respectively. Young age at CI was not correlated with any type of complication.

Conclusions: Complications of CI in children are common, with trauma as a major factor. Inner ear malformations should prompt specific preventive management. Cochlear implantation in young children did not appear to be a risk factor in this study.


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HE SUCCESS OF COCHLEAR implantation (CI) as an auditory rehabilitative tool requires a thorough knowledge of indications, limitations, and potential risks. Since 1990, the number of pediatric CIs has increased significantly, and more specific pediatric evaluation of the medical and surgical risks can be collected. This study reports on the complications occurring in a pediatric population and analyzes the predisposing risk factors.


METHODS

PATIENTS

This study included 434 children younger than 16 years who underwent CI from January 1, 1990, through April 30, 2008, in the Ear, Nose, and Throat Department, Hôpital d’Enfants Armand-Trousseau. All of the patients were followed up at least annually, either in our department or through a standardized medical questionnaire administered by a local otorhinolaryngologist. Mean age at CI was 4.7 (range, 0.6-16.0) years. Forty-one children (9.4%) underwent CI when they were younger than 24 months. Forty-three (9.9%) had inner ear malformations (eg, dilation of the vestibular aqueduct, cochlear dysplasia, and various malformations of the semicircular canals). Mean follow-up was 5.5 years (range, 1 month to 17.0 years). Nine patients (2.1%) were lost to follow-up. The complications were categorized as early or late and as major or minor. Early complications occurred within 8 days after CI. A major complication was defined by the need for surgery or the occurrence of any ear-related medical condition requiring a new admission and/or an extended hospital stay.

SURGICAL TECHNIQUE

The surgical procedures were performed by senior surgeons (N.L., G.R., F.D., and E.N.G.) who specialize in this area. Surgical techniques underwent few changes during the study period, with mastoidectomy and posterior tympanotomy...
panotomy allowing access to the promontory. All cochleostomies were accomplished anteriorly and superiorly to the round window. The following aspects of the procedure have been modified, mostly since 2000: a smaller retrosigmoid incision, without the collection of bone dust; systematic monitoring of the facial nerve; and antibiotic prophylaxis (ie, ceftriaxone sodium therapy for 3 days). The first fitting was programmed postoperatively. The following devices were implanted: Nucleus (Cochlear Limited, Lane Cove, Australia) in 88.7% of patients, Clarion (Advanced Bionics Corporation, Valencia, California) in 5.0% of patients, and Digisonic (Neurelec, Val-lauris, France) in 2.7% of patients. Statistical correlation to age at CI, local trauma, and inner ear malformation were studied using the χ² test.

**RESULTS**

Overall, complications occurred in 43 patients (9.9%), including major complications in 24 (5.5%) and minor complications in 19 (4.4%). Complications were delayed in 28 of these cases (65.1%). The mean time after surgery before delayed complications was 2.2 (range, 0.1-8.4) years.

**MAJOR EARLY POSTOPERATIVE COMPLICATIONS**

Three patients had major early postoperative complications. Vestibular misplacement occurred in a 14-year-old girl who presented with a Mondini deformity (Pendred syndrome); a gusher was observed at cochleostomy. Computed tomography revealed the vestibular electrode misplacement, and the patient underwent reimplantation a few days later.

Varicella-zoster virus meningitis occurred 4 days after surgery in a 3-year-old boy with Mondini dysplasia. The varicella-zoster virus was thought to be responsible for the meningitis because the chickenpox skin eruption occurred a few days later. The child recovered completely after medical treatment. No other complication occurred during 4 years of follow-up.

A persistent cerebrospinal fluid leak occurred in a 10-year-old girl with a common cavity malformation; a gusher was observed at cochleostomy. Treatment with intravenous hyperosmolar solution (acetazolamide sodium [Diadox]) achieved resolution in 3 days. No other complication occurred during 10 years of follow-up.

**MINOR EARLY POSTOPERATIVE COMPLICATIONS**

Minor early postoperative complications occurred in 12 patients. Partial facial nerve palsy was observed in a child aged 14 months, which resolved itself in a few days. The chorda tympani had been injured during the drilling.

When unbalanced walking, nystagmus, or dizziness was observed, vertigo was reported; this occurred in 9 patients. Vestibular function tests were not systematically planned preoperatively and postoperatively until recently. All 9 patients presented with signs of vertigo within the first postoperative days. Three of these had inner ear malformations, representing 3 of 43 (7.0%) in that group.

Vertigo rapidly resolved in all cases with medical treatment (ondansetron hydrochloride and acetylcysteine).

Two children had hematoma of the scalp that resolved spontaneously within 15 days. In both cases, a large skin flap had been obtained during surgery.

**MAJOR LATE POSTOPERATIVE COMPLICATIONS**

Major late postoperative complications occurred in 21 patients. Two of these had severe middle ear disease. Both patients developed cholesteatoma and a retraction pocket ipsilateral to the ear undergoing implantation 5 years after surgery (age at CI, 6 and 11 years). The contralateral ear was healthy. In both cases, bone dust had been used to fill in the mastoid cavity. Both patients had received cartilage grafts to reinforce the eardrum. The patient with the cholesteatoma had undergone reimplantation at the same time because of traumatic extrusion of the electrodes.

Severe cutaneous infections or hematoma developed in 15 patients. Cutaneous lesions occurred in 20 patients, and surgery was needed for 15 of these (75%), with reimplantation in 11 patients because of recurrent infectious problems or device failure. Mean delay to initial CI was 28 months (range, 1.5 months to 7 years). Mean age at CI in this group was 4.0 (1.3-9.9) years. One patient had undergone CI before the age of 2 years.

Meningitis occurred in 1 patient (4 years after surgery) during ipsilateral acute middle ear infection at 6 years of age. Culture of the purulent paracentesis and cerebrospinal fluids yielded *Streptococcus pneumoniae* with intermediate sensitivity to penicillin. The patient's vaccine status was up to date, and there were no identifiable risk factors. Successful outcome was achieved with intravenous combined antibiotic therapy. No further complications were observed during 3 years of follow-up.

Implant magnet migration occurred in 3 patients. The migration was secondary to local trauma in 2 patients and to cerebral magnetic resonance imaging in 1. In the latter case, the implant magnet (Nucleus device) moved despite tight dressing, following the recommendation of the manufacturer. One of the 3 children had undergone CI before 2 years of age.

Fifteen children experienced local trauma. For 12 of them (80.0%), this was important trauma to the mastoid area and resulted in a major complication.

**MINOR LATE POSTOPERATIVE COMPLICATIONS**

Minor late postoperative complications occurred in 7 patients. Four of these consisted of middle ear abnormalities. Two patients had persistent otitis media requiring postoperative grommets after unsuccessful medical treatment. These children had undergone CI at 2.5 and 3.2 years of age and needed the grommets 6 and 12 months later, respectively. The other 2 patients underwent CI at 21 months and 7 years of age and had acute otitis media at 2 and 6 weeks postoperatively, respectively. Medical treatment was successful, with no further complications during follow-up.

Three patients had soft-tissue problems, including hematoma and flap infections. All of these cases resolved with local dressings and antibiotics. These complica-
Literature documenting the surgical outcomes after CI gives complication rates for pediatric and adult populations. Some studies focus on particular complications or specific populations, such as very young children. Various classifications have been proposed: early vs late complications (with early meaning 1 week or 3 months) and major vs minor with or without spontaneous implant failure in the complication rate. For early complications, we preferred to consider these as occurring during the week after surgery. These criteria were previously proposed by Bhatia et al and enabled us to make a distinction in survey and management. The definition of a major complication after this surgical procedure is based on the following medical and surgical criteria: the need for further surgery or reimplantation (excluding a spontaneous implant failure) and the need for hospitalization. We decided not to include spontaneous device failures because they did not depend on surgery or medical treatment.

The overall complication rate in our series was almost the lowest reported among children, at 2.3% to 8% for major complications and 3.8% to 16% for minor complications. The long duration of follow-up and the low rate of loss to follow-up are important for assessing rates as precisely as possible. However, we did not have a large series of very young children, which could have modified the rates of some complications such as middle ear abnormalities. Rate variation can be mostly attributed to follow-up duration, methodological differences, and the type of population (eg, very young children). Kang et al reported a major complication rate of 12.3%, which included spontaneous implant failure and perioperative leakage. In our series, inner ear malformations were frequent, representing about 10% of the overall population. The complication rate was significantly higher than that found in the rest of the population (P = .01) and correlated with major (P = .001) and minor (vertigo) (P < .001) early complications. Inner ear malformations are known to aggravate technical difficulties during surgery, such as persistent cerebrospinal fluid leak, misplacement of the electrode, meningitis, and facial nerve injury. Hyperosmolar solution has been used systematically for some years, and no major complications have been seen in that time in our population.

Vertigo, although representing two-thirds of minor complications in our population, still remained infrequent. In children, vestibular dysfunction is clinically underestimated, in particular in our series. In the study by Jacot et al, ipsilateral postoperative areflexia was observed in 10% of cases, with only 3% reporting clinical signs. Systematic vestibular examination before and after CI would provide a more precise rate, especially in young children.

Middle ear abnormalities, although frequent in young children, did not constitute a significant cause of complications in this series. All of the patients had been treated for ear, nose, and throat infections, and, if needed, grommets were inserted before surgery. Some studies have noted a low rate of middle ear abnormalities after CI, when aggressive preoperative treatment was organized. Also, the percentage of children younger than 2 years was limited in this series, contributing to a lower observed rate. However, chronic middle ear abnormalities can develop over time, as seen in our study, with retraction and cholesteatoma a few years after surgery, highlighting the need for long-term medical follow-up.

Soft-tissue complications were the most frequent problem, contributing to nearly 40% of cases and requiring surgical intervention for more than 70% of cases. Such lesions are theoretically more likely to occur in children, with an increased risk at a younger age. The thinness of the skin and bone sometimes does not allow sufficient impaction and protection of the device, and direct trauma and a tight magnet can lead to injury of the scalp. Despite several surgical procedures (muscle flap or impacted bony site), recurrent infections lead to ipsilateral reimplantation in most cases, without complications. Infectious recurrences were probably related to the biofilm covering of the device.

Local trauma is of major concern in young children. The major complication rate of the study shows a significant difference from that found in the general population of those with implants (P < .001). The late meningitis case highlights the need for reiterated, precise information concerning the infectious risks, even in children undergoing CI who have no particular risk factors and have been correctly vaccinated. More widely, we believe that pediatric teams should plan for the transition from adolescence to adulthood and reiterate information even a few years after surgery so that adults who undergo CI are aware of the required minimal medical follow-up to ensure their safety.

Complications of CI in children are not rare and may be largely delayed. Trauma to the mastoid area was shown to correlate with major delayed complications and inner ear malformations. The finding of complications several years after surgery highlights the need for long-term medical follow-up in this population and the importance of repeatedly providing information to the patients and their family. The specific features of pediatric CI warrant a specialized, experienced care center.

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Author Contributions: Drs Loundon and Blanchard had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Loundon and Denoyelle. Acquisition of data: Loundon and Garabedian. Analysis and interpretation of data: Loundon, Blanchard, and Roger. Drafting of the manuscript: Loundon, Blanchard, Denoyelle, and Garabedian. Critical revision of the manuscript for important intellectual content: Loun-
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