

ORIGINAL ARTICLE

Postoperative Infection in Cochlear Implantation

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Objectives: The aim of this study is to evaluate the different infectious origin complications in a population of 350 implanted patients, with a minimum follow up of one year.

Methods: We present a retrospective study which includes children and adults implanted in a period of 5 years. General exploration was performed, obtaining samples for microbiology study from the infection. A detailed history was obtained, related to cochlear implant surgery (cochlear implant device, surgical trauma...). Clinical specimens were placed and inoculated to several growth media. The detection and identification of bacteria was done by common systems. Patterns of resistance and susceptibility of bacteria were tested.

Results: Different infections related complications were found: otitis media, mastoiditis, retroauricular abscess, wound infection and delayed infection. In five cases a surgical procedure was performed and in three of them a reimplantation was carried out. There were no cases of meningitis in our study group.

Discussion: In our opinion, cochlear implantation is a relatively safe otosurgical procedure with a low complications rate. The most important pathogens in our study were gram positive bacteria *Staphylococcus aureus* and *Staphylococcus epidermidis*. *Streptococcus pneumoniae* was the most common isolated bacterium in otitis media cases. The majority of infections can be managed without removing the implant device.

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Introduction

The overall incidence of postoperative infections in cochlear implantation has been established between 4 to 9 % of the cases.^[1,2] Major infectious complications take place in 3,0 % of cases and most of them need surgical intervention. These complications frequently involve surgical wound problems such as skin flap necrosis and wound dehiscence which may result in persistent infection and device extrusion.

A history of chronic ear disease may increase the risk of infectious complications.^[1]

An increase in the number of implant-related meningitis, mainly secondary to otitis media, in both adults and children, took place during 2000 and 2002. There were intensive efforts by governmental agencies, cochlear implant (CI) manufacturers and CI surgeons to analyze this phenomenon and to propose mechanisms of control.^[3]

A postoperative infection in a cochlear implanted patient may place the patient at increased risk for intracranial complications due to the potential spread along the electrode through the inner ear. This is the reason why infections after cochlear implantation may

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involve an aggressive medical therapy and/or surgical revision that can require the removal of the implant. Current recommendations include active immunization against *Streptococcus pneumoniae* and *Haemophilus influenzae* type B in all prospective implant candidates as well as patients with an implant already in place. In addition, the use of perioperative antibiotic prophylaxis should be taken into account.

The objective of this paper is to present the complications of infectious origin, in a consecutive series of 350 patients, submitted to surgery by the same surgical team with the subsequent control and follow-up for a minimum period of one year. We show the description and handling of the complications.

Methods

We present the different infections related complications that we found in a series of 350 cochlear implantations, consecutively implanted in a 5-year period (January 2004 to January 2009), with a minimum follow up of 1 year after surgery and a maximum of 6 years.

Devices from all three major CI manufacturers (Cochlear Corporation, Sydney, Australia; Advanced Bionics, Sylmar, California, USA; and Med-El Corporation, Innsbruck, Austria) were reviewed.

Clinic charts were reviewed to identify patients with evidence of a postoperative infection or infectious complication involving the implanted ear. Selected data from these patients was obtained from clinic charts and hospital records and entered onto a data collection sheet designed for this study. Variables including device type, surgical time, perioperative antibiotics, surgical complications, time course to infection, infection organism and history of previous ear disease were analyzed.

The isolated bacteria antibiogram was studied in the Microbiology Department.^[4] In those cases in which the explantation was needed, we made the microbiology and pathology analysis of the surrounding tissue of the cochlear implant and the device analysis. We also analyzed the different specific strains involved in this kind of infections as well as the biofilm production of these bacteria through the use of a scanning electron microscope.

Infections were classified as being a surgical wound infection, acute suppurative otitis media, mastoiditis, retroauricular abscess, delayed infection of the cochlear implant and meningitis. Cases of acute suppurative otitis media were infections resulting in adverse sequelae such as tympanic membrane perforation. Complications from infection were classified as major if they resulted in device explantation, surgical revision, hospitalization and intravenous (IV) antibiotics, or meningitis. Minor complications were identified as those requiring local wound care and/or oral antibiotics.

Results

22 out of 350 patients were identified with postoperative infections with an overall incidence of 6,2 %.

Postoperative infections were classified as acute suppurative otitis media (n = 8), surgical wound infection (n = 7), mastoiditis (n = 3), delayed infection of the device (n = 3) and retroauricular abscess (n = 1). No cases of meningitis or other major infections were found (Table 1).

There were 12 pediatric and 10 adult patients (figure 1).

The most important pathogens in our study were gram positive bacteria: *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Streptococcus pneumoniae*.

The pathogens we found in otitis media group were: *Streptococcus pneumoniae* (5), *Haemophilus influenzae* (2) and *Streptococcus pyogenes* (1). In the surgical wound infection group the bacteria isolated were *Staphylococcus aureus* (4), *Staphylococcus epidermidis* (methicilin resistant) (2) and *Staphylococcus epidermidis* (methicillin susceptible) (1). The bacteria isolated in mastoiditis cases were: *Streptococcus pneumoniae* (2)

Table 1. Types and number of infectious complications during a 5-year period in a 350 consecutive implanted patients.

Infections in CI patients (n: 22) (6,2%)	
Meningitis	n:0
Mastoiditis	n:3
Acute Suppurative Otitis Media	n:8
Surgical Wound Infection	n:7
Retroauricular abscess	n:1
Delayed Infection of the CI	n:3

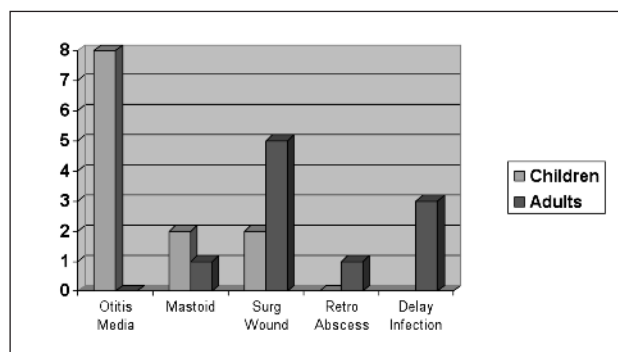


Figure 1. Categories of postoperative infections (n = 22). There were 12 paediatric and 10 adult patients.

and *Achromobacter xylosoxidans* (1). In the delayed infection group: *Staphylococcus aureus* (1), *Staphylococcus epidermidis* (methicillin resistant) (1) and *Pseudomona aeruginosa* (1). The bacterium related to the retroauricular abscess was *Staphylococcus aureus*. (Table 2)

In Table 3 we present the different complications and treatment provided. 12 cases out of the 22 postoperative infections identified were successfully managed with oral antibiotic therapy or local wound care. The remaining 10 cases required more aggressive treatment consisting of IV antibiotics (n = 6), device explantation and reimplantation (n = 3) and surgical and medical treatment (n = 2).

The treatment for these pathogens is analyzed in the table (Table 4).

In the otitis media group (n = 8), 3 cases needed hospitalization with intravenous Cefotaxime. The others 5 cases, whose antibiograms were *Streptococcus pneumoniae* penicillin susceptible

(MIC-0.01), *Streptococcus pyogenes* penicillin susceptible (MIC-0.01) and erythromycin susceptible (MIC-0.05) and *Haemophilus influenzae* penicillin susceptible (MIC-0.01) were treated with oral Amoxicillin + Clavulanic acid and local wound cares.

In mastoiditis group, only one child needed surgical drainage of pus, having used a retroauricular approach for it. In this case, scar tissue and thickened mastoid mucosa was removed. The antrum was reopened and a small drainage tube was inserted and kept in place for up to 5 days. Hospitalization and IV antibiotics were required in one adult patient with Piperacillin + Tazobactam (resistant to Ciprofloxacin) with *Achromobacter xylosoxidans* and intravenous Ceftriaxone for two children with *Streptococcus pneumoniae* penicillin susceptible (MIC-0.01).

Seven cases of wound infection within the first month after surgery without device exposure were identified in two children and five adults. Successful treatment with oral antibiotics/ local wound care was done with Amoxicillin-Clavulanic acid in two children and two adults with *Staphylococcus aureus* (methicillin susceptible) and two adults *Staphylococcus epidermidis* methicillin susceptible. The patient with *Staphylococcus epidermidis* methicillin resistant needed oral treatment with Levofloxacin.

In the retroauricular abscess case the adult patient developed a *Staphylococcus aureus* subperiosteal abscess 3 months after the cochlear implant surgery, needing hospitalization, surgical drainage and IV antibiotics with vancomycin. Four months later a recurrence took place and the option we chose was to remove the implant and make a new implantation in the other side.

Table 2. Pathogens isolated from the different cultures. The most important pathogens in our study were gram positive bacteria: *Staphylococcus aureus* and *Staphylococcus epidermidis* for surgical wound infection (cinnamon colour) (n = 7). In otitis media (n = 8) *Streptococcus pneumoniae* was the most common isolated bacteria (turquoise colour). MR = Methicillin resistant; MS = Methicillin susceptible.

	S. pneumoniae	S. pyogenes	H. influenzae	A. xylosoxidans	S. aureus	S. epidermidis		P. aeruginosa
						MR	MS	
Otitis Media (n:8)	5	1	2					
Mastoiditis (n:3)	2			1				
Surgical Wound (n:7)					4	2	1	
Retroauricular (n:1)					1			
Delay Infection (n:3)					1	1		1
TOTAL	7	1	2	1	6	3	1	1
22 cases	31,8%	4,5 %	9 %	4,5 %	27,3 %	13,6 %	4,5 %	4,5 %

Table 3. Complications and treatment provided. Complications from infection were classified as major if they resulted in device explantation, surgical wound revision, or hospitalization and intravenous (IV) antibiotics. Minor complications were identified as those requiring local wound care and/or oral antibiotics.

	MINOR COMPLICATIONS		MAJOR COMPLICATIONS	
	Medical Treatment (Ambulatory)	Medical Treatment (Hospital)	Surgical and Medical Treatment	Reimplantation
Otitis Media (N:8)	5	3		
Surgical Wound Infection (N:7)	7			
Mastoiditis (N:3)		2	1	
Retroauricular abscess (N:1)			1	
Delay Infection of CI (N:3)		1		2
Total	12	6	2	3
22 cases	(54,5 %)	(27,3 %)	(9 %)	(13,6 %)

Table 4. Antibigram of the different pathogens isolated. The most common oral antibiotic therapy in ambulatory regimen was amoxicillin-clavulanic acid. 3 cases needed reimplantation, 2 adults surgical and medical treatment, and 6 patients IV antibiotics.

	MINOR COMPLICATIONS		MAJOR COMPLICATIONS		
	Bacterial	Ambulatory Treatment	Hospital Treatment	Surgical drainage	Reimplant
Otitis Media (n = 8)	S. pneumoniae		Cefotaxime		
	S. pyogenes	Amoxi-clav			
	H. influenzae	Amoxi-clav			
Mastoiditis (n = 3)	S. pneumoniae		Ceftriaxone		
	A. xylosoxidans			√	
Surgical Wound (n = 7)	S. aureus	Amoxi-clav	Piperacillin + Tazobactam		
	S. epidermidis MR	Levofloxacin			
	S. epidermidis MS	Amoxi-clav			
Retroauricular (n = 1)	S. aureus		Vancomycin	√	√
Delay Infection (n = 3)	S. aureus		Vancomycin		√
	S. epidermidis MS		Vancomycin + Ciprofloxacin		
	P aeruginosa		Ceftazidime + Tobramycin		√

The other two cases which were removed after delayed infections were caused by *Staphylococcus aureus* and *Pseudomonas aeruginosa* (radical cavity). In both cases the reimplantation was made in the same ear six months later with a successful result.

In the cases we removed the implants an analysis of the tissue located around the device was done. The three explanted cases had developed a fibrous tissue around the implant with inflammatory reaction, calcium deposit areas and a vascular component (Figure 2) Figure 3). In the delayed infections caused by gram positive bacteria (*S aureus* and *S epidermidis*) a pattern of infection with rounded colonies of bacteria with great capacity of adhesion to the implant surface was found (Figure 4).

To conclude we can affirm that the incidence of infections in patients with profound hearing loss that

have received a cochlear implant is low if compared with other surgical procedures in the same area.^[2,5]

Although antibiotic therapy was required in all cases of postoperative infection, surgical intervention was required in 18,2 % of cases.

Latent colonization of bacteria as a result of local surgical trauma or infections from middle ear structures are common causes for delayed infections of the implant.

Biofilm production and high rates of antibiotic resistances derives in removal of the devices in many cases.

It is important to evaluate the antimicrobial activity by determining the susceptibility of a particular bacterial strain against a specific antibiotic in all cases.



Figure 2. Fibrous tissue surrounding the cochlear implant.

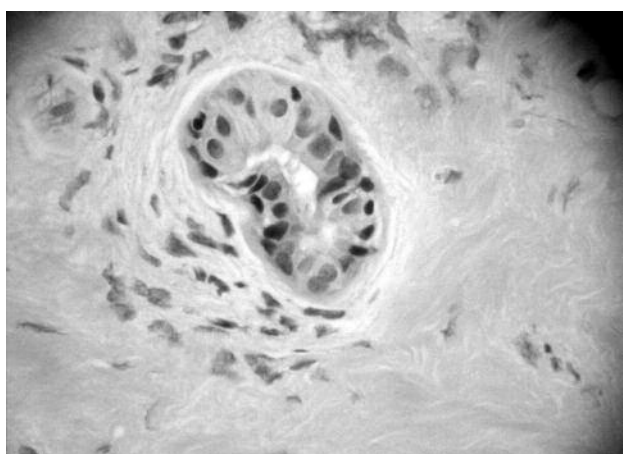


Figure 3. Magnified image of the fibrous tissue around the cochlear implant.

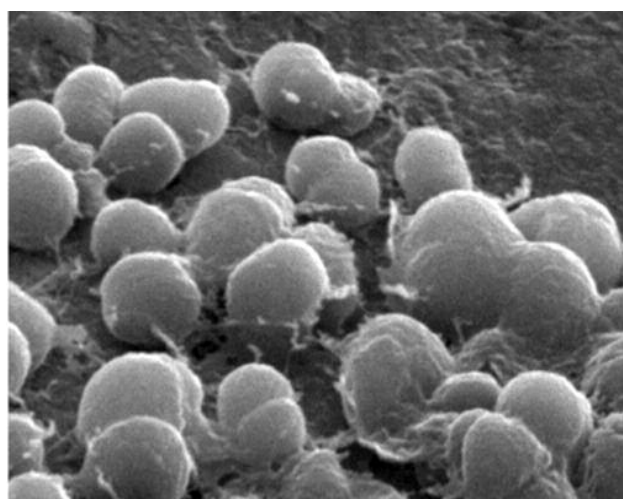


Figure 4. Pattern of infection for *Staphylococcus aureus* through a scanning electron microscope.

Discussion

Complications associated with cochlear implants are relatively rare and usually involve flap problems such as skin necrosis and wound dehiscence.^[6,7] The overall incidence of postoperative infections in cochlear implantation has been established between 4 to 9% of the cases. Major infectious complications occurred in 3,0 % of cases, and most of the infections required surgical intervention.^[1,2] Our review of 350 cochlear implant procedures revealed an overall incidence of infection of 6,2 %. Excluding minor complications treated with local wound care and/or antibiotics, the incidence of major infectious complications was 3,14 %. These results are consistent with the previously published literature.

The majority of wound cultures obtained in our series revealed *Staphylococcus aureus*, which is the most common pathogen found in surgical implant infections and may represent a skin contaminant at the time of surgery.^[8]

Although we had no cases of meningitis, and it is a rare complication, lots of reports of meningitis associated with cochlear implants had further increased awareness of the potential complications of implant infections,^[8] specially since 2002, due to an increase in the number of cases of cochlear implant-related meningitis reported to the US Food and Drug Administration. The most common organism identified as the origin of meningitis in implanted patients was *Streptococcus pneumoniae*. The incidence of pneumococcal meningitis was found to be greater than of an age matched cohort in the general population. Risk factors identified from the clinical records of patients with cochlear implants included an implant with a positioner, inner-ear malformations with and without cerebral spinal fluid leak, presence of a CSF leak after cochlear implantation and a history of otitis media.

Early postoperative complications are usually a result of flap technique or contamination at the time of implantation. Once foreign material becomes contaminated with microorganisms, there is a risk for subsequent infection. The most serious way of infection is extension along the electrode into the cochlea because connection between perilymph and

cerebrospinal fluid potentiates the risk of meningitis. The perioperative administration of systemic antibiotics are provided to minimize the risk of bacterial contamination at the time of surgery. However, the type and length of this antibiotic administration continues unclear. Frequency of dosing can vary from administration of a single dose to a course of antibiotics extended for 2 weeks. Hirsch⁹ published that the administration of a single dose of antibiotics (they used cefazolin in 83 % of patients) administered 30 minutes before the skin is incised was enough and did not need to be repeated unless the operating time extends beyond 6 hours. Basavaraj¹⁰ addressed the question of short-term versus long-term antibiotic prophylaxis in cochlear implant surgery and proposed that the rate of infection was higher in patients who had long-term antibiotics (5 to 7 days) than those with 1 day of medication. Since January 2003 we started using perioperative antibiotics in all cases. Nowadays we use vancomycin plus clindamycin intravenous before starting the surgery and during the 48 hours patients usually stay hospitalized, in both children and adults, because this antibiotic provides adequate central nervous system penetration and protection against the gram positive bacteria (staphylococcus and streptococcus) origin of most of the postoperative infections. Once the patients go home we recommend them to take oral amoxicillin-clavulanic three times per day during one week. We need a new study to determine the results in the incidence of infections before and after this period.

Few reports exist in the literature regarding management of postoperative infections following cochlear implantation. Rubinstein^[11] presented four patients who had revision surgery for delayed cochlear implant infections. They demonstrated that surgical dogma regarding infected foreign bodies does not always apply to cochlear implants: if there were evidence of systemic infection, an infected implant must be removed. Although previous studies have recommended removal of the infected implant to allow healing of the wound, current recommendations call for conservative options. Postoperative infections must be assessed for the severity of infection to determine how aggressive treatment should be. Treatment may involve oral antibiotics and local wound care,

intravenous antibiotics, and/or surgery. Oral antibiotics and local wound care was enough in 54,5 % of our cases. However, 22,8 % of our patients required surgical intervention, being the rate of device explantation 13,6 %.

When device removal is necessary, we recommend leaving the electrode in the cochlea. The electrode is cut at the facial recess and the intracochlear portion is left in place to act as a stent. Failure to leave the electrode stent will most likely finish in cochlear ossification in the setting of an infection and may compromise future attempts at re-implanting the same ear.

Infectious complications related to acute otitis media and mastoiditis occur more frequently in children.^[12] During the preimplantation study in children it is important to examine the nasopharynx and the presence of otitis media with effusion because in that cases we can carry out an adenoidectomy and/or insertion of grommets before implantation in order to reduce the incidence of acute otitis media in children after implantation. Another way for trying to avoid the otitis media post-implantation is executing a careful subtotal mastoidectomy during cochlear implant surgery.

Advances in surgical technique and flap design have decreased the occurrence of wound-related complications. However, identification of risk factors for infection and optimization of treatment regimens will further reduce the complications associated with postoperative infection.

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