Surgical complications and morbidity in cochlear implantation

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Introduction
Cochlear implantation (CI) has been established worldwide as the surgical treatment for individuals with bilateral severe-to-profound hearing loss. This is a safe and standard procedure in the hands of experienced implant surgeons. Complications due to surgery are minimal and are often encountered in cases of congenital anomalies of the temporal bone and inner ear.
Patients and methods
All patients receiving CI at our institution between 2014 and 2015 were included in the study.
Aim
The aim of this study was to report the frequency of surgical complications following 112 consecutive CIs in 102 children and 10 adults in the National Hearing and Speech Institute (HIS), Cairo, Egypt. The international consensus on the reporting of CI complications proposed by Hansen and colleagues was used and evaluated.
Results
In all, 112 implantations were performed in 102 pediatric and 10 adult patients. Overall, complications occurred in 21 (18.75%) patients, including minor complications in nine (8.03%) and major complications in 12 (10.71%) cases. Complications were delayed in nine (8.03%) cases. No death was attributed to device implantation. Major complications occurred in 12 cases, which included misplaced electrodes in two cases, cerebrospinal fluid leak (gusher) in four cases, labyrinthitis ossificans in one patient, magnet displacement in one case (chronic suppurative otitis media), central perforation in one case, seroma and hematoma (severe cutaneous infections) in one case, wound infection in one case, and persistent pain/discomfort (migration) in one case.
Conclusion
Complications of CI are more common in children than in adults with trauma as a major factor. Inner ear malformations should prompt specific preventive management. CI in young children did not appear to be a risk factor in this study.

Keywords:
cochlear implantation, complications, morbidity

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Introduction

Cochlear implantation (CI) is a relatively safe procedure [1–4]. However, complications occur associated with the surgical approach, the implantation of a foreign body, or with the failure of the implanted device.

As the number of CIs has increased dramatically during the last decade, it is important that both patients and practitioners be aware of the potential complications.

The rate of complications and/or reimplantation also has a direct economic impact.

Considerable data are available concerning surgical and medical complications [1–4], but many studies fail to provide long-term data as regards surgical complications, device failures, or specific medical complications such as facial palsy, tinnitus, or vertigo. Articles describing such complications in a large sample of patients with extensive follow-up data are rare, and equally sparse are those articles comparing results between adult and pediatric populations.

The present study addresses the first 112 consecutive CIs in the HIS, Cairo, Egypt.

Aim

The aim of this study was to report the frequency of surgical complications following 112 consecutive CIs in 102 children and 10 adults in the HIS, Cairo, Egypt. The international consensus on the reporting of CI

complications proposed by Hansen *et al.* [5] was used and evaluated.

Patients and methods

The medical records were examined for complications arising between April 2014 and December 2015.

Implantations performed after 31 December 2015 were not included in the study, as a time frame of 8 months after implantation was considered the minimum to allow for complications to arise.

As a rule, pediatric patients were defined as those under the age of 17 years.

Surgical complication

Surgical complication was defined as an unexpected medical event related to the procedure itself and causing additional morbidity (e.g. vertigo or infection) or a need for additional surgery (e.g. electrode migration) [5].

The surgical complications were characterized as major or minor.

A major complication was defined as follows:

(1) A significant medical problem (e.g. meningitis).
(2) An event leading to additional major surgery due to a patient-related problem (e.g. cholesteatoma or explantation of the device for any reason other than device-related failure).
(3) Any degree of permanent disability (e.g. permanent facial nerve paresis).

Any complication not falling into at least one of the above-mentioned categories was classified as minor (for further details on the classification of minor complications see Hansen *et al.* [5]).

The following were not classified as surgical complications:

(1) Medical complications (e.g. allergic reactions and drug adverse effects).
(2) Technical complications (e.g. facial stimulation and device failure).
(3) Conditions existing preoperatively (e.g. recurrent otitis media).
(4) Intraoperative and preoperative findings (e.g. abnormal anatomy and middle ear/cochlear fibrosis).

All registered complications were divided into three categories according to time of onset:

(1) Perioperative (occurring during or within 24 h after surgery).
(2) Early postoperative (occurring between 24 h and 1 week after surgery).
(3) Late postoperative (occurring later than 1 week after surgery).

This study included 112 cases, 102 (91.07%) children younger than 17 years of age and 10 (8.93%) adults who underwent CI from April 2014 to December 2015, in the Ear, Nose, and Throat Department, Hearing and Speech Institute Imbaba, Giza, Egypt, of whom 13 (11.60%) patients were congenital prelingual deaf children.

All of the patients were followed up at least every 1 month in our department.

The mean follow-up was 10.5 months (range: 1–20 months). Cases that were lost to follow-up were not included in this study.

The complications were categorized as early or late and as major or minor.

Early complications occurred within 7 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

Intraoperative protocol

The surgical procedures were performed by four senior surgeons (I.S., A.G., A.M., and N.F.) who specialize in this area with mastoidectomy and posterior tympanotomy allowing access to the promontory. The round window (RW) membrane was exposed using transmastoid facial recess approach. Instead, we accessed the scala tympani directly through the RW. To completely visualize the circumference of the RW membrane, we used the 1.2 mm microdrill to remove the superior lip of the RW niche.

Antibiotic prophylaxis was carried out (i.e. ceftriaxone sodium therapy for 3 days). The first fitting was programmed 3 weeks postoperatively.

The following devices were implanted in 112 patients (Fig. 1 and Table 1).

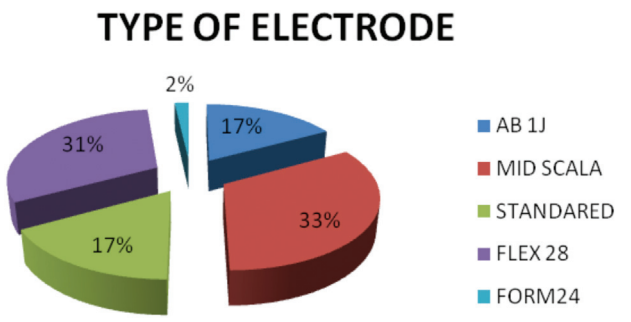
Hifocus 1J electrode (19 cases, 17%), HiFocus mid-scala electrode (37 cases, 33%), (Anheuser-Busch Inc., Sylmar, California, USA), Sonata TI100^{+} titanium implant footprint with standard electrode (19 cases, 17%), Sonata TI100^{+} titanium implant footprint with Flex 28 electrode (35 cases, 31%), and Sonata TI100^{+} titanium implant footprint with Form 24 electrode (two cases, 2%) (Med-El, Innsbruck, Austria). Cochleostomy was performed in 38 (34%) cases and RW approach was used in 74 (66%) cases (Fig. 2).

The mean age of patients was 6.4525 years (range: 2–42 years). There were 55 (49%) male and 57 (51%) female patients. There were 102 (91.07%) pediatric patients, 51 boys and 51 girls, and 10 adults (8.928%), four male and six female (Figs 3–5).

Table 1 Type of electrode used in this study

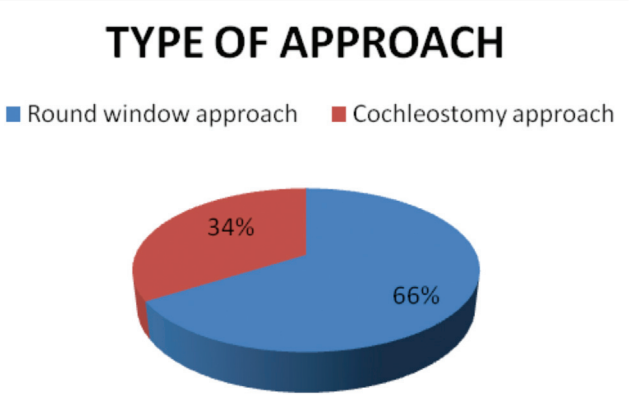
Type of electrode	*n* (%)
AB 1 J	19 (17)
Mid scala	37 (33)
Standard	19 (17)
Flex 28	35 (31)
Form 24	2 (2)

Figure 1



Type of electrode used in this study.

Figure 2



Type of approach in this study.

The patient's right ear was operated as the patient was right-handed and had similar inner ear anatomy on both sides. Only three cases were operated on the left ear due to ossification of the cochlea on the right side.

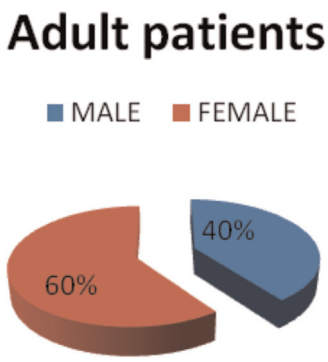
The study was approved by the Ethics Review Committee of the HIS and the parents or legal guardians of each child provided written informed consent before entry into the study.

The patients had received vaccinations for *Pneumococcus* spp. and *Haemophilus influenza*.

Study design

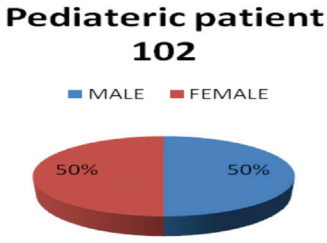
All young children underwent a thorough otorhino-laryngological examination and audiometric tests using behavioral audiometry, aided free-field audiometry,

Figure 3



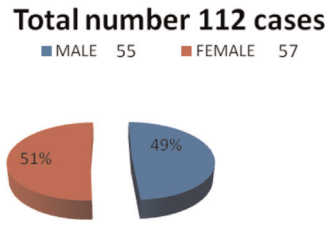
Sex distribution in adult patients in this study.

Figure 4



Sex distribution pediatric patients in this study.

Figure 5



Sex distribution in this study.

tympanometry, and electrophysiological tests including auditory brainstem response and otoacoustic emission.

Preoperative radiological evaluation

Each child with a diagnosis of prelingual severe-to-profound hearing loss underwent high-resolution computed tomography (HRCT) examination and inner ear and brain magnet resonance imaging (MRI). All studies were performed using a standard temporal bone protocol with contiguous 0.5 mm scans of the temporal bone acquired in the axial and coronal planes.

Results

In all, 112 implantations were performed in 102 pediatric and 10 adult patients.

Overall, complications occurred in 21 (18.75%) patients, (Table 2), including minor complications in nine (8.03%) and major complications in 12 (10.71%) cases (Table 1). Complications were delayed in nine (8.03%) cases. No death was attributed to device implantation. Major complications occurred in 12 cases, which included misplaced electrodes in two cases, cerebrospinal fluid (CSF) leak (gusher) in four cases, labyrinthitis ossificans in one patient, magnet displacement in one case, [chronic suppurative otitis media (CSOM)] central perforation in one case, seroma and hematoma (severe cutaneous infections) in one case, wound infection in one case, and persistent pain/discomfort (migration) in one case.

The overall major complication rate was 10.71% (12/112), and there were nine minor complications that occurred in nine cases (8.03%, 9/112), which were resolved with conservative treatment or minor intervention. Minor complications included transient facial nerve paresis in three cases, injured chorda tympani during the drilling in two cases, and delayed otitis media in four patients.

Major early postoperative complications

Seven (6.25%) patients had major early postoperative complications.

Electrode misplacement in two (1.79%) patients

Lateral semicircular canal misplacement occurred in a 4-year-old boy who presented with a right congenital meatal atresia and was operated upon this ear.

Table 2 Complications encountered in the study population

Complications	Adult (*n*=10) [*n* (%)]	Children (*n*=102) [*n* (%)]	Total (*n*=112) [*n* (%)]	Management
Minor complications	3 (30)	6	9 (8.035)	
Early				
Transient facial nerve paresis	2 (20%)	1 (0.89)	3 (2.678)	Conservative management – steroids/physiotherapy
The chorda tympani had been injured during the drilling	1 (10)	1 (0.98)	2 (1.785)	
Late				
Delayed otitis media	0	4 (3.921)	4 (3.571)	Medical management
Major complications	2 (20)	10 (9.80)	12 (10.71)	
Early				
Electrode misplacement	1 (10)	1 (0.89)	2 (1.785)	Reimplantaion of the same electrode 2 days postoperatively
A cerebrospinal fluid leak (gusher)	0	4 (3.921)	4 (3.571)	I/V mannitol and cochleostomy or RW seal
Labyrinthitis ossificans	1 (10)	0	1 (0.89)	Fibrous tissue removed with picks from the lumen of the basal turn with successfully full insertion of the electrode through cochleostomy approach
Late				
(CSOM) central perforation	0	1 (0.89)	1 (0.89)	Explanation and staged revision CI
Seroma and hematoma (severe cutaneous infections)	0	1 (0.89)	1 (0.89)	Aspiration, pressure dressings, C&S (pseudomonas) –antibioticsReimplantation
Implant magnet migration	0	1 (0.89)	1 (0.89)	Repositioning of new magnet into receiver–stimulator coil
Wound infection	0	1 (0.89)	1 (0.89)	Successfully treated with appropriate flap designs and intravenous antibiotics
Persistent pain/discomfort (migration)	0	1 (0.89)	1 (0.89)	Drilling a sharp edge of the cavity at its inferior aspect and sutures are used to fix it

CI, cochlear implantation; CSOM, chronic suppurative otitis media; RW, round window.

When unbalanced walking, nystagmus, or dizziness was observed, vertigo was reported.

Patients presented with signs of vertigo within the first postoperative day.

CT revealed the lateral semicircular canal electrode misplacement, and the patient underwent reimplantation of the same electrode 3 days later. Vertigo rapidly resolved after reimplantation.

Middle ear misplacement occurred in a 25-year-old male adult patient.

CT revealed the middle ear and mastoid cavity electrode misplacement, and the patient underwent reimplantation of the same electrode a few days later.

Perioperative complications

CSF leak (gusher) occurred in four (3.571%) pediatric cases, two female and two male, intraoperatively. On making an incision on the RW membrane, pulsatile CSF gushers were started [two cases with large vestibular aqueduct syndrome and two common cavity malformation (Mondini type II)]. Thereafter, the head end of the table was raised and intravenous 20% mannitol drip (1.5 g/kg body weight over 20 min) was started. The gusher was significantly reduced within 10 min and the electrode array of the implant inserted through the RW. None of these cases required lumbar drainage.

Preoperative diagnosis of one (0.89%) case of labyrinthitis ossificans was made. Axial high-resolution CT was abnormal (grade 1 sclerosis without narrowing of the basal turn in the left ear, grade 2 sclerosis with narrowing of the basal turn in the right ear – cochlear fibrosis and decreased fluid signal in the basal turn), attenuation of intracochlear fluid signal in T2-weighted MRI is a more sensitive method of assessing blockage. Contrast-enhanced T1-weighted MRI can detect early fibrosis.

An 18-year-old postmeningitic man was implanted in the left ear. Fibrous tissue was removed with picks from the lumen of the basal turn with successful full insertion of the electrode through cochleostomy approach.

Major late postoperative complications

Major late postoperative complications occurred in five (4.46%) patients.

One of the pediatric female patients (0.89%) had severe middle ear disease CSOM. The patient developed central perforation of the drum with persistent otorrhea despite medical treatment ipsilateral to the ear undergoing implantation 2 months after surgery (female patient age at CI, 3 years and 11 months). The patient had received cartilage grafts to reinforce the eardrum and had undergone reimplantation in the same ear 6 months later.

Seroma (severe cutaneous infections) occurred in a pediatric female patient (0.89%) and surgery was needed with reimplantation after subsidence of infection because of recurrent infectious problem.

Implant magnet migration occurred 1 year after implantation in one (0.89%) pediatric male patient who was 6 years and 3 months of age. The migration was secondary to local trauma. This was important trauma to the mastoid area and resulted in a major complication. We replaced the old magnet with a new sterilized one. We drew a half circle (180°) incision line around the posterior edge of the device/headpiece ~1 cm away. An incision was created along this half circle. One must ensure that the blood supply to the skin flap is not compromised. The flap was raised carefully dissecting the fibrous tissue to locate the silicone portion of the coil (antenna) and we removed the old magnet, which was out of its silicone bed. We used a sterilized magnet to replace the original one, and lifted the silicone retainer edge using an elevator and pressed the new magnet into position.

As regards wound infection, one (0.89%) pediatric female case presented with major infections that supervened 6 months after implantation and considered abscesses with erosion of the skin (resolution occurred following revision surgery using gel foam impregnated with garamycin and intravenous ceftriaxone). None of the patients experienced new infections.

Persistent pain/discomfort occurred in one (0.89%) pediatric male patient who presented with CI migration from its osseous bed. The symptoms were obvious at 6 months postoperatively with the patient having local pain due to skin compression between the sound processor and the implanted device. She was discouraged from using the CI consequently. Sutures are used to fix the device to bone.

The palpation of the retroauricular region provided enough data for diagnosis. The surgical review of the implant bed and drilling a sharp edge of the cavity at its

inferior aspect suture used to fix it without electrode array mobilization resulted in symptom relief.

Minor early postoperative complications

Minor early postoperative complications occurred in five (4.46%) patients.

Transient facial nerve paresis was observed in three cases (2.678%).

They were treated with prednisolone, in combination with antibiotics. The facial nerve was not abnormally located or exposed in any of the three patients, nor did any of them show signs of infection. Complete resolution was seen in all patients in a few months.

Minor late postoperative complications

Minor late postoperative complications occurred in four (3.571%) children.

The patients had delayed otitis media and were treated only with antibiotics.

The patients underwent CI at 3, 4, 4.1, and 7 years of age and had acute otitis media at 12, 16, 18, and 24 weeks postoperatively, respectively. Medical treatment was successful, with no further complications during follow-up.

Discussion

CI is a surgical procedure performed routinely in numerous centers around the world. Expanding the criteria for CI leads to a significant increase in the number of patients using such devices.

This study uses the consensus on CI complications proposed by Hansen *et al.* [5] besides the authors. Complications following CI at the HIS were not frequent.

Mechanical failures of the device are included as complications in several studies. We exclude device failure as a complication from our study. Similarly, in a few studies, perilymph/CSF leaks amounting to 'gushers' were not reported as complications but as intraoperative findings. We have included only CSF gushers, which required immediate intervention into the study, as surgical complications. Moreover, in our study we reported intraoperative finding of a case with labyrinthitis ossificans with fibrous band in the basal turn of the cochlea, which was diagnosed radiologically preoperatively and required removal of fibrous band with hook before insertion of the electrode.

On analyzing the association of the syndromic deafness and complication rates, our study shows that there is no correlation between the syndromic deafness with complication rate except for the intraoperative perilymph gusher, which is associated with common cavity deformity, Mondini's deformity, and enlarged vestibular aqueduct syndrome (EVAS).

It is now important to evaluate the efficiency and the safety of such procedures to improve them and to reduce the incidence of complications. Various classifications have been proposed: early versus late complications (with early meaning 1 week or 3 months [5,6]), and major versus minor with or without spontaneous implant failure in the complication rate [7–9].

For early complications, we preferred to consider these as occurring during the week after surgery. These criteria were previously proposed by Bhatia *et al.* [10] 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 [10].

In our series, the overall rate of complication was 18.75% during a maximum follow-up period of 20 months.

The number of major complications was 12 (10.7%), of which two (1.79%) patients required reimplantation, and the number of minor complications was nine (8.03%).

Venail *et al.* [11] reported in their series that the overall rate of complication was 16% during a maximum follow-up period of 18 years and the rate of major complications (5.6%) was lower than that found in previous studies (18.3%) [10] and 11.8% excluding device failures [12].

However, if they include device failure as a major complication, this rate becomes comparable (13.8%) to that described elsewhere [10,12,13]. Moreover, the rate of reimplantation in Venail *et al.* [11] series is similar (7.2%; 36/500) to that observed in other studies [10].

Thus, our study shows comparable rate of complications reported in other studies. However, we should take into consideration that the number of patients in our study is lower, with a shorter period of follow-up.

Inner ear malformations are known to aggravate technical difficulties during surgery, such as persistent CSF leak, misplacement of the electrode, meningitis, and facial nerve injury [14,15].

In our study, inner ear malformations were frequent, representing about 13 (12.745%) pediatric cases of the overall pediatric patients.

CSF leak (gusher) occurred in four (3.921%) pediatric cases with inner ear malformations in our study, two female and two male, intraoperatively. On making an incision on the RW membrane, pulsatile CSF gushers were started [two cases of large vestibular aqueduct syndrome and two cases of common cavity malformation (Mondini type II)]. Thereafter, the head end of the table was raised and intravenous 20% mannitol drip (1.5 g/kg body weight over 20 min) was started. The gusher was significantly reduced within 10 min and the electrode array of the implant inserted through the RW. None of these cases required lumbar drainage.

The ossification of the cochlea is mentioned in the literature as a known major difficulty in patients having meningitis in their medical record. Nevertheless, one would expect to discover the process to a certain degree from imagistics. Our case proved that it is not always possible to ascertain these abnormalities in detail. Operations on such patients should always be performed with caution and with different types of electrode arrays at hand. Moreover, certain rules should be discussed with the manufacturers of CIs as regards a proper decision to implant these cases.

In our study, an 18-year-old (0.892%) male post-meningitic patient was implanted in the left ear; fibrous tissue was removed with picks from the lumen of the basal turn with successful full insertion of the electrode through cochleostomy approach. The right ear showed total obliteration of the basal turn of the cochlea.

Surgical complications

We found no cases of excessive/sustained bleeding, electrode kinking, dural tear, meningitis, or death related to implantation in our series.

All of our patients who received their implants were vaccinated against *H. influenzae* and *Streptococcus pneumonia*.

Infection is a major concern in CI surgery.

The overall rate of infections reported in the literature ranges from 1.7 to 16.6% [16,17].

In our survey, infection occurred in seven (6.25%) cases in our study.

Four (3.921%) cases had late minor complication with delayed otitis media. The infection was a complication of acute otitis media; medical treatments were successful.

One (0.89%) pediatric female patient had severe middle ear disease CSOM. The patient developed central perforation of the drum with persistent otorrhea despite medical treatment ipsilateral to the ear undergoing implantation 2 months after surgery (female patient age at CI, 3 years and 11 months). The patient had received cartilage grafts to reinforce the eardrum and had undergone reimplantation in the same ear 6 months later.

Severe cutaneous infections (seroma) occurred in one (0.89%) pediatric female patient 6 months after surgery and surgery was needed with reimplantation after subsidence of infection because of recurrent infectious problem.

There was one (0.89%) case of skin flap infection in our study. Intensive medical treatment was given followed by surgical intervention in the form of using a skin flap to adequately cover the device and was good in follow-up.

Displacement (migration) of the receiver with persistent pain and discomfort occurred in one of 112 (0.89%) cases compared with one of 500 (0.6%) cases in the study by Venail *et al.* [11]. As reported elsewhere, displacement was a consequence of minor head traumas [16,18]; repositioning the receiver firmly in its seat is usually sufficient to prevent further displacement.

Migration of the CI from its bed is possible when no sutures are used to fix it. Drilling a sharp edge of the cavity at its inferior aspect is one way to prevent such a problem. What is worth noting is that, in small children, the cranial bone is very thin, making the use of transfixion/fixing sutures difficult.

One additional complication, also following minor head trauma (also as described elsewhere [19]), was a case of magnet displacement observed in one case, a young boy (0.89%). Repositioning of new magnet into receiver–stimulator coil was carried out.

Misdirected implantation occurred in two (1.79%) cases in our study with early correction 2 days after first surgery and reimplantation using the same electrode; even if uncommon, this potential misrouting highlights the usefulness of postoperative and preoperative radiography to provide early correction [20].

Other surgical complications related to CI occurred.

Facial palsy remains a rare and transient complication of CI. Transient facial nerve paresis occurred in three cases (2.678%) in our series immediately postoperatively due to overheating during drilling compared with one of 500 cases (0.002%) in the study by Venail *et al.* [11] and 0.33 and 2.22% [21] in other studies. As demonstrated elsewhere, facial palsy is usually of late onset and moderate, implying that the underlying cause is an inflammatory and edematous mechanism rather than direct trauma during drilling [10].

These cases was managed with conservative treatment – steroids/physiotherapy with complete resolution in 4 weeks in cases of partial facial paralysis and in 3 months in the case of complete facial paralysis.

Medical complications in the pediatric versus adult population

Interestingly, the rate of complications as a whole was not significantly different between the adult and pediatric populations in this survey. Some authors have reported higher rates of complications in children [1]. However, we observed a different distribution of complication rates between the pediatric and adult groups. Specifically, the rates of magnet displacement and postoperative otitis media tended to be greater in the pediatric group.

Conclusion

CI is an effective and reliable procedure to restore auditory sensation in profoundly deafened patients. The results of this survey spanning confirm the improved device reliability of more recent generations of CIs.

Despite this improvement, however, revision surgery may eventually be required to solve certain technological, mechanical, and infection problems.

On analyzing the association of the syndromic deafness and complication rates, our study shows that there is no correlation between the syndromic deafness with complication rate except for the intraoperative perilymph gush, which is associated with common cavity deformity and Mondini's deformity and EVAS.

Final comments

CI continues to be a reliable and safe procedure, with a low percentage of severe complications when performed by experienced surgeons. The patients should receive lifetime follow-up. These patients need lifetime follow-up to monitor for potential complications and to facilitate their care if complications occur.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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