

Complications of Cochlear Implant at Hawler Teaching Center (Rizgary Teaching Hospital)

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Abstract

Background and objectives: Cochlear implantation carries many morbidity, complications and even failure which may have an economic burden to candidates and medical administration. Several surgical techniques and implants had been suggested for optimum result and implant proper functioning. Our aim was to determine various complications types and rate encountered in cochlear implantation candidates of different age groups at Rizgary Teaching Hospital. Methods: Prospective case series review conducted on 110 cochlear implantation candidates who underwent cochlear implantation in Ear, Nose and Throat – Head & Neck Surgery department, at Rizgary Teaching hospital from January 2014 until January 2016. The cochlear implantation complications were identified as (minor) and (major). All complications were systematically studied and analyzed with maximum duration of follow-up of 24 months. All cochlear implantation candidates were received unilaterally multichannels cochlear implant. The same surgical team performed all surgical procedures. All patients provided written informed consent for the procedures.

Results: The overall rate of complications was 13.63% (15 out of 110). The minor complications were 12 cases (10.90%), including postoperative wound infections in 3 cases (2.72%), electrode issues in 3 cases (2.72%), acute otitis media in 2 cases and transient vertigo/dizziness in 2 cases (1.81%), transient facial palsy in 2 cases. The major complications were 3 cases (2.72%), including device failure in 2 cases (1.81%), cholesteatoma in 1 case; all major complications were required revision surgery, and other minor complications were managed medically. Conclusions: Cochlear implantation is a relatively safe and effective procedure with fewer complications rate when performed by experienced and skilled surgeons.

Keywords: Cochlear implantation; Minor complication; Major complication; Surgery.

Introduction

The development and improvement of cochlear auditory prostheses have radically improved the management of children and adults with profound hearing loss. Rapid evolution in the candidacy criteria and the technology itself has resulted in large numbers of individuals who have benefited from implantation¹.

No surgical procedure is without risk. Cochlear implantation is relatively free from complications².

Surgical complications were defined as an unexpected medical event related to the procedure itself causing additional morbidity or a need for additional surgery³.

There were various classification forms for cochlear implantation complications reported in literature.

The first and comprehensive report regarding surgical complications of cochlear implantation was conducted by Cohen et al⁴ on 1988 which classified surgical

complications into: Major Complications - when require additional surgery or revision surgery (explanation and re-implantation of the device) or hospitalization for those serious complications that are significant and require additional treatment, or Minor complications, when they settled spontaneously or that can be treated medically and conservatively in an outpatient ward⁴⁻⁶.

Kempf et al⁶. classified the complications On the base of their onset into early and late, complications have been defined as early postoperative (when occurred up to 3 months postoperatively) and late postoperative (more than 3 months postoperative, including electrode dislocation, device failure and cholesteatoma).

Patients and methods

Prospective review study involves (one hundred twenty-seven patients with severe to profound SNHL) infants,

young children, children, adolescents and adults who were candidates for CI and underwent cochlear implantation from January 2014 to January 2016. All surgical procedures (unilateral “monaural” cochlear implantation and revision surgery) performed at our Ear, Nose and Throat-Head and Neck Surgery department at Rizgary Teaching Hospital.

The same surgical team carried out all the procedures. We missed seventeen cases during follow up period only 110 patients remained.

Implantees have been followed up regularly every 3 months during the first year after implantation, then every 6 months during the second year, follow up done up to 24-months post implantation. We recorded major and minor complications rate that happened during this period. For this study, preoperatively proper general physical examination and otolaryngological examination done including: Audiologic hearing for evaluation the degree of hearing loss and imaging studies including computed tomography (CT) or magnetic resonance imaging (MRI) of the temporal bone to detect any abnormalities regarding cochlear and cochlear nerve, with other laboratory investigations that required accordingly.

All the patients were received multichannel cochlear implant including both Nucleus freedom implant with Contour Advance Electrode Freedom - CI24RE (CA) (Cochlear Limited, Lane Cove, Australia) for 100 patients and Advanced Bionics HR 90 KTM, and Advantage cochlear implant HF1J Electrode was used for the remaining 10 patients.

We select the better ear with normal anatomical configuration of inner ear depending on preoperative CT & MRI scanning we avoided implantation of an ear with marked auditory deprivation, selection of ear that least likely to benefit from hearing aid and also surgeon preference.

Surgical technique that had been used for the cochlear implantation for all patients: Mastoidectomy with posterior tympanotomy (MPTA) approach.

Inclusion criteria: All patients who diagnosed with severe/profound SNHL and older than 12 months.

Exclusion criteria: Those who have syndromic or had congenital abnormalities or handicaps, absence of auditory nerve or lack of auditory nerve integrity bilaterally, patients

with cochlea or cochlear nerve agenesis, patients with mental diseases or retardation, medical risks of surgery that exceed the expected benefits of the procedure. The study was approved by the ethical committee of Kurdistan Board for Medical Specialties.

Results

One hundred twenty-seven patients were selected and diagnosed with profound to severe sensorineural hearing loss for CI device implantation. Seventeen patients failed to report for follow up were excluded from the study population. One hundred ten consecutive cases of various age groups were subjected to statistical analysis.

Age ranged from 1-54 years (mean age at implantation 28 years; median age 5 years);

56 (50.90%) and 54 (49.09%) were males and females, respectively.

(M/F ratio = 1.03).

Of these, ten cases were adults (9.09%; age range 21–45 years), while 100 cases were younger than 18 years (90.90%; age range 1 year and month – 16 years). Of the latter, 10 were infant (age range 1-23 months) and 44 young children (2-5 years), 30 were children (age range 6-10 years), 16 were adolescent (age range 11–17 years), Figure 1.

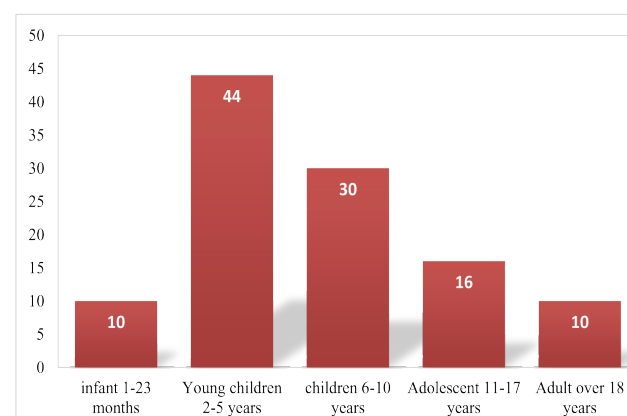


Figure (1): Distribution of study sample by age groups.

For the 101 (91.81%) of patients, the implantation was done in right ear according to surgeon preference and nine patients (8.18%) in the left. Of this number, 97 (88.18%) patients were with prelingual hearing loss, whereas only 13 (11.81%) patients were with postlingual hearing loss. We found that the overall rate of complications was 13.63 % (15 / 110). The minor complications were 12 cases (10.90%), including postoperative wound infection in

three cases (2.72%), electrode issues in 3 cases (2.72%), transient vertigo /dizziness in 2 cases (1.81%), acute otitis media in 2 cases (1.81%), and transient facial palsy in 2 cases (1.81%).

The major complications were 3 cases (2.72%), including device failure in 2 cases (1.81%), and cholesteatoma in 1 case; all major complications required revision surgery, while other minor complications (12 of 110) were managed conservatively by medication.

An intra-operative complication was seen in 3 patients (2.72%) including electrode array problems while the others were postoperatively.

10 of 15 (9.09%) complications happened in those age group younger than 18 years, and 5 of 15 (4.54%) in adults. The mean age of patients who had complications was 14 years, and the median age was 7 years.

Minor and major complications with their distributions are shown in Table 1 and Table 2, respectively.

Table (1): Minor complications after cochlear implantation in Rizgary Teaching Hospital (n=110).

Minor complications	No.	%
Wound infection (superficial skin infection)	3	2.72
Electrode issues	3	2.72
Transient vertigo/ dizziness	2	1.81
Acute otitis media	2	1.81
Transient facial palsy/ paresis	2	1.81
Total	12	10.90

Table (2): Major complications after cochlear implantation at Rizgary Teaching Hospital (n=110)

Major complications	No.	%
Device failure	2	1.81
Cholesteatoma	1	0.90
Total	3	2.72

Table (3): Complications rate in different age groups

Complications	Infant	Young children	Children	Adolescent	Adult
Minor					
Wound infection	1(0.90%)	1(0.90%)	1(0.90%)	-	-
Transient					2(1.81%)
Electrode issues	-	1(0.90%)	-	1(0.90%)	1(0.90%)
Transient facial paresis	-	-	1(0.90%)	-	1(0.90%)
Otitis media		1(0.90%)	1(0.90%)		
Major					
Device failure	1(0.90%)	-	1(0.90%)	-	-
Cholesteatoma					1(0.90%)
Total	2	3	4	1	5

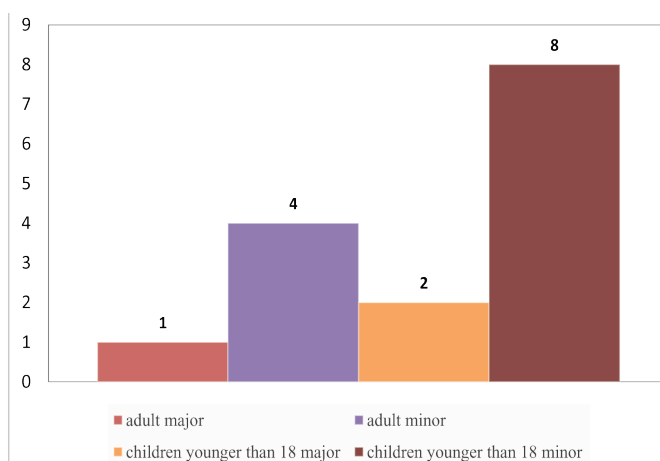


Figure (2): Total number of complication both minor and major in both adult and younger children groups.

Discussion

Cochlear implantation (CI) surgery has been performed recently at our Ear, Nose and Throat – Head & Neck Surgery department, at Rizgary Teaching hospital, Current study represent our new experience with cochlear implantation surgery, it was crucial for our center to review and report various postoperative complications types and rate that encountered in different age groups and genders after cochlear implantation in order to analyze the factors contributing the complications, and then comparing the result with the other global rates. We are beginner in performing such types of surgery. Our efforts done for minimizing or eliminating the complications and also for future program.

The postoperative complications of the surgery represent some of the most frustrating and difficult to deal by surgeons, and involve different variables intrinsically associated with the patient and the surgical team. Such complications reflect the procedure's complexity, surgeon's skill and risks inherent to the deep insertion of a large foreign body under the scalp⁷.

Over the past years, the surgical procedure for implantation has undergone modifications, with changes directed at preventing surgical and medical complications⁸⁻¹⁰. Manufacturers for Cochlear implant made every effort to prevent malfunctions and device failures.

The overall rate of complications in current study was 13.63 % (15 out of 110 patients), our study is in accordance to result of study reported by Júnior L, Penna LR et.al showed that complications in 33 cases was (13.2%)¹¹.

In current study, we found most of the complications 9.09% (10 of 15) happened in those age group younger than 18 years, this was due to predominantly younger population in our study (n = 100/110), and 4.54% (5 of 15) in adults. Our result is similar to result of another article conducted by Ciorba A. et al. showed that 4.3% (19 of 438) and 4.8% (21 of 438) occurred in children, adolescents, and in adults, respectively¹². Generally, our study revealed that minor complications are not uncommon it happened in 10.90% (12 cases), rates compare very well with other reported incidence rates between 7% and 37% that conducted by Webb et al⁵ and Cohen et al¹³.

Current study demonstrated that major complications rate

2.72% (3 out of 110) was every low, compared with the rate that reported by other literature, the incidence of their major complications was reported between 3% and 13%¹⁴⁻¹⁶.

Comparing our study regarding postoperative complications both minor and major rates with a study conducted by Tolga kandoğan et al¹⁷. is nearly similar to results reported in both minor and major complications rate 13.33 % (14 of 103) and 3.8 % (4 of 103), respectively. In our study wound infection, electrode issues and device failure had the highest relevant.

The most common complications encountered was wound infection, the overall infections (superficial wound) rate was 2.72% (3 cases) occurred after 3 days, 2 weeks and 2 months postoperatively, all cases were treated by local disinfectants and standard prophylactic antibiotic. We routinely used a single dose of Ceftriaxone 1gm intravenously intraoperatively, and postoperatively as well. We reported that all infections were occurred in younger age group, the reason for that may be related to type of incisions "C shape incision" done in this age group and this is in accordance to Gerard et al.¹⁸ reported that large incision in pediatric age group (standard C-shaped, U-shaped inverted) significantly increases the risk of necrosis and wound complications compared with a minimal classical retroauricular incision because of the large dead space that occur. In contrast to Black et al¹⁹, reported that they had no major complication with using small C incision. Our result is similar to global rate that demonstrated by other literature ranges from 1.7 to 16.6%^{8,10,11}.

Another complications encountered in current study was electrode issues which reported in three patients (2.72%), two case with difficulty during insertion of electrode array and a case with partially inserted array into RWN, this incidence is similar to those reported in other studies of the same nature fortunately, no one required further explanation and reimplantation as postoperatively was functioning well.

Older studies showed a higher incidence of electrode problems of 4.3% in 4969 patients and an incidence of 6.5% in 153 patients who underwent cochlear implantation¹⁴.

Fujita et al reported that full insertion of electrode array inside the cochlea is not always possible due to variety of reasons such as the angle in which the round window (RW) opening is present, anatomical variations or intra-cochlear obliteration²¹.

An overall complication rate during electrode array insertion in most literature was 3.9%.

We also reported vestibular complication (vertigo and dizziness) in two adult patients (1.81%). Symptoms observed immediately after the recovery time post implantation.

Our result is favorably in accordance to results of study conducted by Tolga kandoğan et al¹⁶ their result were 2.85% occurred in three cases. In current study, both cases were transient and rapidly resolved with proper medical treatment for associated nausea and vomiting (ondansetron hydrochloride 4 mg IV daily)

We are reported two case (1.81%) of transient facial paresis on second and third days after operation in a child female and an adult male patient respectively, despite using electromyographic facial nerve monitoring during the procedure. This regard as early onset complication, most probable cause were abnormality or edema of the nerve or may be due to thermal injury during the posterior tympanotomy by drill or could be due to extensive manipulation during surgery. Both of them were treated with steroid 1mg /kg/dose and facial nerve were return to grade I House-Brackmann.

Our results are in accordance to results of study conducted by Tolga kandoğan et al¹⁶ that occurred also in two patients (1.9%). Several authors reported facial paresis in their series. Its incidence vary between 0.55-3%^{14,16}.

There were two (1.81%) patients with postoperative acute otitis media (AOM), at 4 years and 6 years of age, at 2 weeks and 4 weeks postoperatively, respectively.

The first patient had previous history of AOM. Both patients required hospitalization and treated medically with intravenous antibiotic - Ceftriaxone 50mg/kg/day for seven consecutive days no one required further surgical intervention.

Previous study by Yakirevitch et al²² reported that children with history of otitis media before implantation had higher risk of AOM post implantation than healthy children

because of smaller mastoid pneumatization and also round window niche surrounded by inflamed mucosa.

Device failure after CI surgery is one of the more common problems, some studies not considered as a surgical complication, the cause rarely being due to surgical mismanagement.

The overall rates of major complications requiring surgical intervention range from 2% to 5% in large series. We reported 2 cases (1.81%) with spontaneous device (hard ware) failure as major complications, both devices failed after sixteen and eighteen months post implantation respectively (explanation and re-implantation of 2 new device done. Our result is similar to study conducted by Lassig et al²³. Noted a device failure rate of 3.7% in a series of more than 900 implants from 1985 to 2003.

In a series conducted by Wang JT et.al²³ reported that the most common indication for revision surgery was device failure (57.8%), in which hard failures comprised 0.6%^{3,4}. The occurrence of cholesteatoma with cochlear implant is rare, but whenever occurs regards as late complications of cochlear implantation. Patients with persistant otorrhea after surgery should arouse suspicion for cholesteatoma²⁵. In current study, we reported a case (0.9%) with cholesteatoma in adult patient that had previous history of surgery for cholesteatoma, presented after 17 months post implantation. The case required revision surgery and reimplantation.

In the presence history of surgery for cholesteatoma, recurrence of disease is always possible with potentially serious consequences after cochlear implantation. Our study rate were similar to rate of a study conducted by C. Arnoldner et.al²⁶ who also reported cholesteatoma in one adult (0.54%).

Conclusions

In general, cochlear implantation regards as relatively safe and effective procedure with fewer complications rate when performed by experienced and skilled surgeons.

Current study provided evidence regarding surgery-related complications that benefits greatly outweigh the risks as no death reported from the procedure, there were no difference regarding implanted device complications, happened in both types equally, minor complications

reported commonly in younger age group while major complications nearly equally recorded among various age groups.

References

1. P. Ashley Wackym, MD , Christina L. Runge-Samuelson, PhD:James B.Snow JR.,MD,FACS ,editors Ballenger's otorhinolaryngology 17 head and neck surgery. 17 edition:McGraw-Hill Medical Publisher. 2009: 363
2. Richard T. Ramsden : Huw R. Cooper and Louise C. Craddock, editors Cochlear implant; A practical guide. Second Edition .England : Whurr Publishers Limited; 2006:238.
3. Hansen S, Anthonsen K, Stangerup S, Jensen J, Thomsen J, Cayé-Thomasen P. Unexpected findings and surgical complications in 505 consecutive cochlear implantations: a proposal for reporting consensus. *Acta oto-laryngologica*. 2010; 130(5):540-9.
4. Cohen N, Hoffman R. Complications of cochlear implant surgery in adults and children. *Annals of Otolology, Rhinology & Laryngology*. 1991;100(9):708-11.
5. Webb R, Laszig R, Lehnhardt E, Pyman B, Clark G, Franz B. Surgical complications with the cochlear multiple-channel intracochlear implant: experience at Hannover and Melbourne. *Annals of Otolology, Rhinology & Laryngology*. 1991;100(2):131-136.
6. Kempf H, Johann K, Lenarz T. Complications in pediatric cochlear implant surgery. *European archives of oto-rhino-laryngology*. 1999;256(3):128-32.
7. Cohen N, Hoffman R. Surgical complications of multichannel cochlear implants in North America. In *Cochlear implants: New perspectives* 1993; 48:70-4.
8. Venail F, Sicard M, Piron J et al Reliability and complications of 500 consecutive cochlear implantations. *Archives of Otolaryngology–Head & Neck Surgery*. 2008;134(12):1276-81.
9. Bhatia K, Gibbin K, Nikolopoulos T, O'donoghue G. Surgical complications and their management in a series of 300 consecutive pediatric cochlear implantations. *Otology & neurotology*. 2004; 25(5):730-9.
10. Roland J. Complication of cochlear implant surgery. In:Waltzman SB, Cohen NL (eds) *Cochlear implants*. 1997. Thieme, New York: 171–5
11. Júnior L, Penna L, Rodrigues Júnior F et al. Postoperative complications in implanted patients in the Cochlear Implant Program of Rio Grande do Norte-Brazil. *Brazilian journal of otorhinolaryngology*. 2010;76(4):517-21.
12. Ciorba A, Bovo R, Trevisi P, et al,. Postoperative complications in cochlear implants: a retrospective analysis of 438 consecutive cases. *European Archives of Oto-rhino-laryngology*. 2012; 269(6):1599-603.
13. Cohen N, Hoffman R, Stroschein M. Medical or surgical complications related to the Nucleus multichannel cochlear implant. *Annals of Otolology, Rhinology & Laryngology*. 1988; 97(5_suppl2):8-13.
14. Hoffman RA. Complications of cochlear implant surgery. *Ann Otol Rhinol Laryngol*. 1995;104(166):420-2.
15. Aschendorff A, Marangos N, Laszig R. Complications and reimplantation. In *Cochlear Implant and Related Sciences Update 1997* (Vol. 52, p. 167-70). Karger Publishers.
16. Proops D, Stoddart R, Donaldson I. Medical, surgical and audiological complications of the first 100 adult cochlear implant patients in Birmingham. *The Journal of Laryngology & Otolology*. 1999;113(24):14-7.
17. Kandogant T, Olgun L, Gultekin G. Complications of cochlear implantation in adults. *hypertensionHypertension*. 2006; 1:0-9.
18. Gérard J, Monnoye V, Deggouj N, Gersdorff M. A classical retro-auricular incision in cochlear implantation. *Mediterr J Otol*. 2005;1(3):105-9.
19. Black B, Black J, Wallwork B. Early paediatric implantation: Cochlear implant surgery at the crossroads. *Mediterr J Otol*. 2005;1 (2):94-103.
20. Tambyraja R, Gutman M, Megerian C. Cochlear implant complications: utility of federal database in systematic analysis. *Archives of Otolaryngology–Head & Neck Surgery*. 2005 ;131(3):245-50.
21. Fujita T, Shin J, Cunnane M et al. Surgical Anatomy of the Human Round Window Region: Implication for Cochlear Endoscopy Through the External Auditory Canal. *Otology & Neurotology*. 2016;37(8):1189-94.
22. Migirov L, Yakirevitch A, Henkin Y et al., Kaplan-Neeman R, Kronenberg J. Acute otitis media and mastoiditis following cochlear implantation. *International journal of pediatric otorhinolaryngology*. 2006;70(5):899-903.
23. Lassig A, Zwolan T, Telian S. Cochlear implant failures and revision. *Otology & Neurotology*. 2005;26(4):624-34.
24. Wang J, Wang A, Psarros C, Cruz M. Rates of revision and device failure in cochlear implant surgery: A 30 year experience. *The Laryngoscope*. 2014;124(10):2393-9.
25. Kaila R, Evans RA. Cochlear implant infection due to cholesteatoma. *Cochlear implants international*. 2005;6(3):141-6.
26. Arnoldner C, Baumgartner W, Gstöttner W, Hamzavi J. Surgical considerations in cochlear implantation in children and adults: a review of 342 cases in Vienna. *Acta oto-laryngologica*. 2005;125(3):228-34.