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Cochlear implant complications in a low-income area of Brazil

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SUMMARY

OBJECTIVE: The primary objective was to analyze and report on the complications that occurred in the cochlear implant surgeries performed at a large philanthropic teaching hospital located in a low-income area of Brazil.

METHODS: A historical cohort study that analyzed surgical records of 432 patients of all age groups and both genders who received unilateral cochlear implant in a tertiary referral center that serves only Brazil's Public Health Care System patients, from February 2009 to December 2017.

RESULTS: A total of 67 (15.5%) complications occurred in the cochlear implant surgeries, with 21 (5.4%) major complications. Minor complications occurred in 50 (12%) cases. The most frequent major complication was receiver-stimulator displacement (four cases). There were three cases of hardware failure. Only one case of meningitis and one case of facial nerve paralysis (grade VI in House-Brackmann scale) were found. Six patients needed to be explanted due to a major complication. The relative risk of major complications in the population aged 60 years and older was 4.41 (1.53–12.72; 95% confidence interval [CI]).

CONCLUSIONS: Elderly patients suffered more complications than younger patients. receiver-stimulator displacement and dizziness were the most frequent complications (major and minor, respectively). The overall complication rates were comparable to those in the literature. Age as an isolated risk factor for complications in cochlear implant surgery is a path to be explored in future observations.

KEYWORDS: Otolaryngology. Cochlear implants. Postoperative complications.

INTRODUCTION

Hearing loss is a frequent public health problem worldwide, and approximately 350,000 Brazilians suffer from severe to profound hearing loss[1]. In such cases, rehabilitation may only be possible with the help of cochlear implant technology.

Cochlear implant surgery can be life-changing for patients, facilitating huge improvements in their social lives, as well as providing academic, professional, and economic gain[1]. However, the procedure is not always complication free and a constant self-assessment of outcome and any complications is necessary.

Complications in cochlear implant surgery are classified into "major" or "minor." Major complications include meningitis, magnet displacement, device failure, skin flap necrosis, implant extrusion, and others. In contrast, minor complications are wound infection that respond to local therapy, dizziness, late and transient facial paralysis, and facial nerve stimulation[2,3].

The overall complication rates in cochlear implant surgeries vary significantly (6–36%) in the literature[4]. The occurrence of surgery-related complications has reduced over the decades as technology and surgery techniques have improved[5]. Fixation techniques have been developed, alongside minimal incisions. The manufacture process of cochlear implant has also been improved to prevent device failure and biocompatibility of the devices has been enhanced. All these increments have promoted a decrease in the incidence rate of postoperative complications[3,5,6].

Brazil's Public Health Care System — also called SUS — guarantees access to a comprehensive audiological rehabilitation program to all citizens since 2005. Indeed, SUS also provides services in the audiological rehabilitation field. Diagnostic and therapeutic procedures, including newborn hearing screening, audiological tests, hearing aids, otolaryngologist appointments, stapes surgeries, and bone implant and cochlear implants, are all covered by Brazil's universal health care system[7].

This study was conducted in a large philanthropic teaching hospital located in a low-income area of Brazil that serves only SUS patients. The primary objective was to analyze and report on the complications that occurred in the cochlear implant surgeries performed at the institution.

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METHODS

A historical cohort study was conducted at the otolaryngology department of a tertiary referral center situated in the Northeast Brazil, where approximately 80 cochlear implant surgeries are performed each year. There are about 15 million inhabitants in the region served by the institution, and the average income of its population is approximately U$D157 per month (Dollar price against Real in October 2020)[8].

The medical records of all patients undergoing cochlear implant surgery were reviewed for any occurrences of complications. The study was approved by the Research Ethics Committee of the Institution (CAAE: 82817318.5.0000.0047) and included patients of all age groups and genders undergoing cochlear implant surgery from February 2009 to December 2017. As a retrospective study, no informed consent form was necessary.

The records of each postoperative review appointment were evaluated for complications, conducted treatments, and outcomes. Data were gathered via electronic form and exported to an Excel spreadsheet. Categorical variables were reported as means of absolute frequency and relative percentage and continuous or discrete variables were reported as median and interquartile range. Fisher's exact hypothesis tests, Pearson's chi-square (association between categorical variables), Shapiro-Wilk (adherence to normal distribution), and Mann-Whitney (differences between medians of continuous/discrete variables not adhering to normal distribution) tests were used. Gross relative risks and their respective 95% confidence intervals were estimated. The final level of significance adopted was 5%, and the software used for analysis was the R Core Team 2020.

RESULTS

The study included 432 patients. All patients received unilateral cochlear implant. There was no statistical difference in complications with respect to gender. In total, 67 (15.5%) complications occurred in the cochlear implant surgeries, with 21 (5.4%) major complications. Minor complications occurred in 50 (12%) cases (Figure 1, Table 1).

The most frequent major complication was receiver-stimulator (RS) displacement (four cases). There were three cases of hardware failure. Only one case of meningitis and one of facial nerve paralysis (grade VI in House-Brackmann Scale) were found.

Six patients needed to be explanted due to major complication. Nine patients who had major complications underwent treatments that resolved the issue. In one case, the patient lost follow-up and four of the patients were still undergoing medical evaluation and their treatment was yet undefined and in progress (Table 2).

Complications were more frequent after 1 year from the procedure. The patients' age was statistically related to the occurrence of complications (Table 3). The relative risk of major

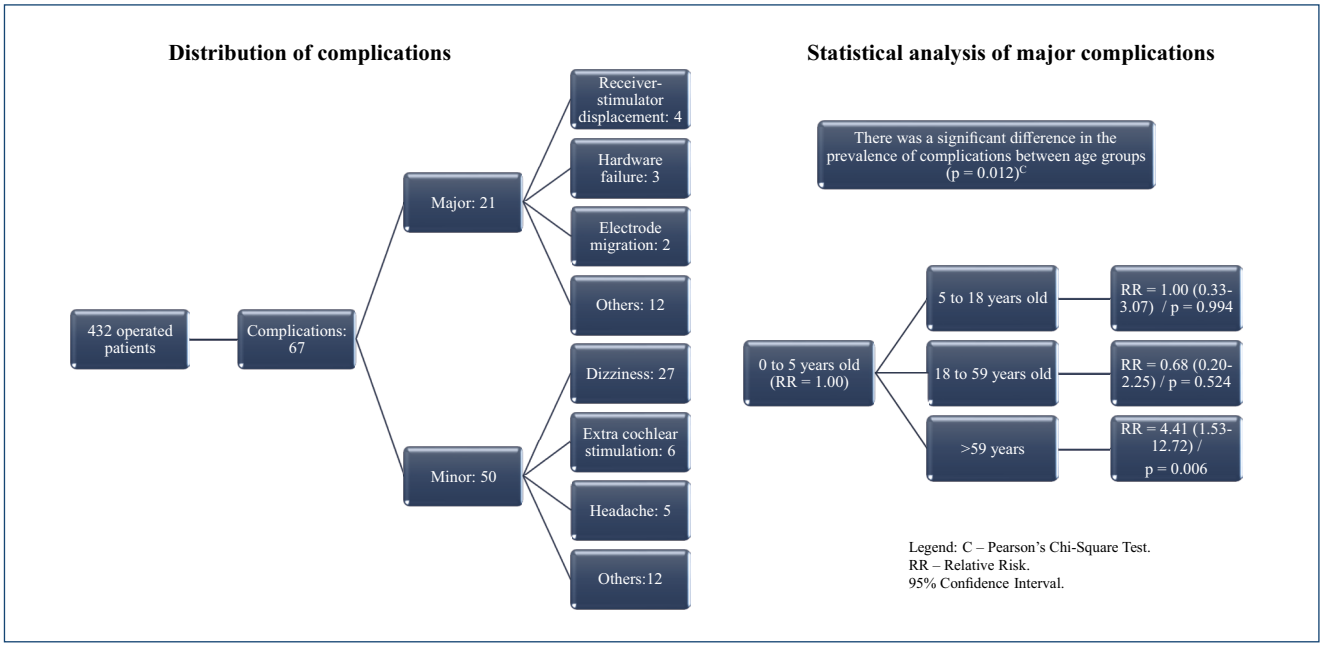

Figure 1. Cochlear implant complications and statistical analysis of major complications.

Table 1. Demographic data and occurrence of complications.

	n	%
Age		
Age group, year		
<2	20	4.6
2–5	132	30.6
5–18	109	25.2
18–59	145	33.6
>59	26	6.0
Gender		
Female	224	51.9
Male	208	48.1
Implant brand		
Advanced bionics (USA)	196	45.4
Med-el (Austria)	211	48.8
Cochlear (Australia)	18	4.2
Oticon (Denmark)	7	1.6
Complication		
Yes	67	15.5
No	365	84.5
MAJOR complication		
Yes	21	5.4
No	365	94.6
MINOR complication		
Yes	50	12.0
No	365	88.0
Time elapsed from surgery to complication		
<30 days	17	25.4
1–3 months	5	7.5
3–12 months	15	22.4
1–5 years	27	40.3
>5 years	3	4.5

n: absolute frequency. %: relative absolute frequency.

complications in the population aged 60 years and older was 4.41 (1.53–12.72; 95%CI), with p-value of 0.006.

Regarding minor complications, 27 patients complained of postoperative dizziness, and 4 patients showed signs of surgical site infection that were resolved with clinical treatment. Adults had more minor complications than children, with a relative risk of 2.43 (18–59 years old) and 3.32 for the group aged 59 years and older (p-value of 0.009 for both groups).

DISCUSSION

All surgeries were performed or supervised by three different attending otologists, using the same surgical technique (mastoidectomy). Despite all particularities, the complication rates were comparable to those reported in the literature, including other teaching hospitals[4,9-11].

Receiver-stimulator displacement occurred in four cases and patients needed procedures to reposition the implant. No head trauma or magnetic resonance imaging (MRI)-induced movement was reported in those cases, which are common in cases of RS displacement[12,13]. It is possible that the migration occurred due to frequently repeated small forces applied to the implanted device[14]. In our surgical technique, a well is drilled into the bone to house the RS, combined with a tight periosteal pocket. No sutures are usually made[15,16].

One patient had three episodes of meningitis and had to be explanted (0.23%). Our patients are routinely vaccinated against *Pneumococci*, *Haemophilus influenzae*, *Neisseria meningitidis,* and *influenza virus*[17]. After 2002, the relation between meningitis and cochlear implants was widely studied by cochlear implant companies and U.S. regulation agencies. It was found that one kind of cochlear implant positioner commonly used was related to a higher risk of meningitis, and, furthermore, that deaf children had also a higher risk than normal hearing individuals[18].

Only a single case of facial paralysis occurred: the first patient operated in our program. No other case of permanent facial paralysis occurred. A facial nerve monitor is routinely used in the surgeries[17].

Six patients needed to be explanted. The number of contralateral implants performed in those cases was not gathered. The occurrence rate of major complications remained under 9% each year during the analyzed period. The highest complication per year rate was seen in 2012 (8.6%), whereas the lowest occurred in 2011 (2.1%). The occurrence rate of minor complications fluctuated from 2.4% in 2015 to 23.3% in 2017. The overall rate for major complications was 5.2%.

Elderly adults suffered significantly more from major complications when compared to other age groups in our study. However, it is not clear whether this occurred due to the presence of comorbidities or if age is a significant risk factor by itself. It is a path to be explored in future observations. Wilkerson et al. reported that no specific comorbidity significantly contributed to the general complication rates in either the older or younger patient population[19].

Surgical site infection was reported in 4 (0.9%) cases and none of them needed surgical treatment. Infection rates range

Table 2. Major complications by patient, their treatment, and outcome.

Age (year)	Major complication	Time from surgery to complication	Treatment	Outcome
3	Cholesteatoma	Over 5 years	Mastoidectomy	Complication resolved
57	Cholesteatoma	Over 5 years	On schedule for re-operation	In progress
12	Electrode array extrusion	9 months	Re-operation	Complication resolved
73	Electrode migration	26 months	Patient lost follow up	Patient lost follow-up
7	Electrode migration	7 months	Re-operation	Complication resolved
80	Electrode misplacement	4 months	Re-operation	Complication resolved
3	Electrode misplacement	15 months	Re-operation	Complication resolved
60	External ear canal erosion and tympanic membrane perforation	11 months	Tympanoplasty	Complication resolved
67	Facial paralysis	Immediate	Re-operation	Facial paralysis HB VI
6	Hardware failure	36 months	Internal component replacement	Complication resolved
4	Hardware failure after head injury	6 months	Internal component replacement	Complication resolved
3	Hardware failure after head injury and poor adaptation	30 months	Explant	Explant
16	Headache	<30 days	Explant	Explant
2	Receiver-stimulator extrusion	16 months	Explant and contralateral implant	Explant
65	Receiver-stimulator displacement	48 months	On schedule for re-operation	In progress
42	Receiver-stimulator displacement	22 months	On schedule for re-operation	In progress
3	Receiver-stimulator displacement	24 months	On schedule for re-operation	In progress
33	Receiver-stimulator displacement	27 months	Re-operation	Complication resolved
5	Meningitis	51 months	Explant	Explant
30	Poor outcome	25 months	Explant	Explant
3	Skin infection after insect sting	27 months	Explant and contralateral implant	Explant

Table 3. Statistical analysis of major complications.

Major complications	Yes	No	p-value	RR (95%CI)	p-value
Age, *Median (IQR)*	12.2 (3.9–58.7)	7 (3.8–32.3)	0.166 [W]		
Age group, year, ***n (%)***					
<2	0 (0) [a,b]	18 (100)	0.012 [C]		
2–5	7 (5.6) [b]	117 (94.4)		1	
5–18	5 (5) [a,b]	96 (95)		1.00 (0.33–3.07)	0.994
18–59	4 (3.3) [b]	116 (96.7)		0.68 (0.20–2.25)	0.524
>59	5 (21.7) [a]	18 (78.3)		4.41 (1.53–12.72)	0.006
Gender, *n (%)*					
Female	12 (6)	187 (94)	0.658 [F]		
Male	9 (4.8)	178 (95.2)			

n: absolute frequency. %: relative absolute frequency. IQR: interquartile range. W: Mann-Whitney test. C: Pearson's chi-square test. F: Fisher's exact test. [a,b]Different subgroups at the 5% level for the Z-test for proportions with Bonferroni correction. RR: relative risk. 95%CI:95% confidence interval.

between 1% and 13% in the literature[20]. Surgical infection rates were significantly higher in the past. This recent reduction is partly due to the evolution in surgical techniques (smaller incisions, for example) and the development of more biocompatible materials used for prostheses[21]. In our surgeries, the surgical wound is closed with absorbable sutures. Ceftriaxone is

used just before the beginning of the surgery and kept for 24 h. Patients are usually discharged on the second day with a sterile dressing and with pain/nausea drugs prescription. The first postoperative appointment is typically 5 days after discharge, when the dressing is removed.

Many patients complained about dizziness (6.25%) and, indeed, Hänsel et al. showed in a meta-analysis that 9.3% of the patients on average suffer from postoperative vertigo after cochlear implant surgery[22].

Cochlear implants are a costly (although cost-effective) rehabilitation tool. Maintaining a publicly funded cochlear implant program in a teaching hospital of a developing country is challenging. Despite all of its qualities, SUS is not a perfect system. Brazil is a huge country with the fifth largest population in the world and profound socioeconomic disparities. Our patients frequently find it difficult to afford transportation and speech therapy, and medical appointments were often missed. A universal health care system is very expensive and, although SUS resources are theoretically guaranteed by the Brazilian Constitution, an imbalance is often seen between the provided funding and the need for resources. In some places, there are extremely long waiting times for treatment and poor housing, for example. Insufficient inputs and low and delayed wages are not uncommon as well.

CONCLUSIONS

Elderly patients suffered significantly more from major complications when compared to other age groups. RS displacement and dizziness were the most frequent complications (major and minor, respectively). The overall complication rates were comparable to those in the literature. Age as an isolated risk factor for complications in cochlear implant surgery is a path to be explored in future observations.

Limitations and strengths

A limitation of the study is that a comparative assessment was not performed between other variables, such as the presence of comorbidities. In the study, specific populations (e.g., patients with Ménière's syndrome, otosclerosis, and chronic otitis media) were part of the whole sample. The impact of those conditions in the occurrence of complications in our analysis could not be assessed.

A strength of the study is its sample size. The total number of patients included allowed the authors to perform a solid statistical analysis, which lead to elaboration of hypothesis to be explored in the future, as stated in the "Conclusion" section.

Also, the study pictured the cochlear implant complications rates in a regional reference center located in a low-income area, which can serve as a parameter for other surveys with similar settings in the future.

AUTHORS' CONTRIBUTIONS

GC: Conceptualization, Data curation, Formal Analysis, Investigation, Methodology, Project administration, Writing –original draft, and Writing –review & editing. **HS**: Conceptualization, Data curation, Formal Analysis, Methodology, and Writing – review & editing. **RA**: Conceptualization, Data curation, Formal Analysis, Methodology, and Writing – review & editing. **ABGA**: Data curation, Formal Analysis, Investigation, Writing – original draft, and Writing – review & editing. **LSRO**: Data curation, Formal Analysis, Investigation, Writing – original draft, and Writing – review & editing. **RG**: Data curation, Formal Analysis, Supervision, and Writing – review & editing.

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