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Original Research Article

Pediatric otitis media post cochlear implant retrospective cohort study

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ABSTRACT

Background: A cochlear implant (CI) is a greatly effective therapy for severe to profound deafness. This study aims to examine the prevalence of otitis media (OM) in children after CI and its impact on the device's integrity with reporting the various management policies and results.
Methods: This retrospective cohort study included 307 children, aged one to five years, who had CIs performed by the surgical team between January 2016 and December 2019. A detailed pre, intra, and postoperative data collected from these patients' medical records was reviewed retrospectively by the same surgical team.
Results: There is a statistically significant difference in the distribution of OM in the operated ears; the p value was <0.001. There is a statistically significant association between post-implant OM and getting implantation, as the p value was <0.001. Multivariate analysis showed significant associations between post-implant OM and a history of receiving vaccination (no), a perioperative history of otitis media with effusion (yes), and a history of recurrent tonsillitis and enlarged adenoids (yes) (p value< 0.05).
Conclusions: In children, the prevalence of developing post-implant OM in the implanted ears does not rise, but rather falls, contradicting the theory that foreign bodies may aggravate the infection. Our findings supported the safety of CI in children with a history of post-implant OM, as all cases of post-implant OM were managed medically, with no additional surgical intervention required. Furthermore, no case had any significant complications, such as meningitis, or had a negative impact on the device's integrity.

Keywords: Pediatric, Otitis media, Cochlear implant

INTRODUCTION

Hearing loss (HL) is one of the most common health problems. Approximately 1-3 out of every 1000 babies are born with HL.[1] Although HL does not prevent people from knowing the outside world, it has a socioeconomic and emotional impact on them. Lack of acoustic stimuli to the auditory system arising from sensorineural hearing loss (SNHL) has usually been addressed with the inception of the cochlear implant (CI) in the 1980s. CI is a highly effective treatment for severe to profound deafness. CI can improve sound perception, auditory skills, speech, verbal language, and education, as well as suppress tinnitus in some patients.[2] It is a device that is surgically placed into the cochlea and converts sound into an electrical signal. This signal is carried to the spiral ganglion cells of the cochlea via electrodes.[3] CI is a worldwide and rather safe technique used for auditory rehabilitation.[4] The number of CIs has increased dramatically during the last decade.[5] On the other hand, the risks of complications associated with all major surgeries can occur in CI surgery.[6] A small but significant minority of CI users will experience some form of adverse event or complication, ranging from abnormal auditory or physical sensations to complete device failure.[7]

Adverse events are classified as hardware failures, medical or soft failures.[8] Hard failures are cases of implant device malfunction that can be definitively measured through device telemetry. Medical failures are those in which a specific medical cause, such as skin flap or middle ear infections, can be identified.[9] Otitis media (OM) is one of the most common infectious diseases in children. Acute otitis media (AOM) is characterized by an inflammation of the middle ear, in particular the tympanic cavity, with an acute beginning and a short duration of illness. Recurrent otitis media is defined by three episodes of AOM in six months or more than four attacks of AOM in twelve months with intermittent normalization of middle ear findings.[10] The age at which CI is performed in children generally corresponds to the age at which the prevalence of OM is highest. It thus seems reasonable to assume that in pediatric CI recipients, the risks of problematic middle ear infection and of potential spread of middle ear infection along the electrode array into the cochlea and the central nervous system with subsequent post-implantation meningitis are relatively high. Therefore, the usual practice of trying to limit OM management in the general pediatric population to conservative care may not be advisable in OM-prone CI candidates because the deferral might reduce the potential for maximal benefit from the implant.[11] Improvement in our understanding of CI adverse events is critical to preventing or, at the very least, minimizing the economic and emotional costs of these events.[8] This study aims to examine the prevalence of OM in children after CI and its impact on the device integrity with reporting the different management policies and results.

METHODS

This retrospective cohort study included 307 children, aged one to five years, who had CIs performed by the surgical team between January 2016 and December 2019. The data was collected by the same surgical team. The study was conducted at Al-Zahraa university hospitals, Cairo; Kafr-Elsheick university hospitals, Kafer-Elsheick; Al-Mabra insurance hospital, Tanta; one day surgery hospital, Cairo; and air defense hospital, Cairo, Egypt. The study was performed in accordance with the ethical principles of the Helsinki declaration and approved by the ethics committee of the faculty of medicine for girls at Al-Azhar University. A written, informed consent was obtained from the parents. Exclusion criteria were re-implantation cases, patients with a history of post-implant OM not proved by the surgical team, patients with congenital anomalies, and patients who experienced other postoperative complications rather than OM.

All patients were diagnosed with bilateral severe to profound SNHL by the standard preoperative assessment of candidates for CI surgery, which included a medical history, a clinical examination, a full audiological evaluation, a linguistic and psychometric evaluation, and a complete radiological evaluation (HRCT and MRI), and met the criteria established by the general authority for health insurance (age between 2 and 6 years, no benefit from hearing aids, and a normal radiological evaluation). On the induction of anesthesia, all patients received a single dose of a prophylactic antibiotic injection. All of the CIs were performed on one side. All operative procedures were performed by one of the CI surgeons, who are well trained to perform such procedures using the standard, classic surgical technique (mastoidectomy and posterior tympanotomy). All medical records were reviewed, irrespective of the type of CI device. After surgery, all patients were kept in the hospital for 48 hours. During the hospital stay, a prophylactic broad-spectrum antibiotic was given intravenously, and the patient was discharged home with oral antibiotics. On the seventh post-operative day, the wound was examined for any potential complications, and the sutures were removed. Fitting of the external part was done in the third week after surgery. The post-implant follow-up period was calculated as the time elapsing from the time of the implantation to the end of the study period. The time interval between implantation and the development of post-implant OM in the implanted ears and the age of the patients at the time of the development of post-implant OM in the implanted ears were calculated. Regular follow-up examinations at the department of Otorhinolaryngology were not scheduled. Whereas, regular follow-up examinations performed by a doctor at the department of Audiology were typically scheduled 1, 6, and 12 months later. Subsequently, patients were offered further follow-up examinations on request. Patients' parents were instructed to contact the department in case of complications following discharge from the hospital (e.g., signs of infection, severe vertigo, etc.).

Approximately one month after surgery, all the patients had the external part of the CI attached at the department of Audiology. A surgical complication was defined as an unexpected medical event related to the procedure itself that resulted in additional morbidity (e.g., vertigo or infection) or a need for additional surgery (e.g., electrode migration). The primary outcomes were to investigate the prevalence of OM in children following CI and to report on management policies and their outcomes. Secondary outcomes included post-implant OM complications such as meningitis and the impact of post-implant OM on device integrity.

Statistical analysis

Data collected and outcome measures were coded, entered, and analyzed using the IBM statistical package for social science (SPSS) version 25 (Armonk, NY: IBM Corp.). The qualitative data group was represented by number and percentage, whereas the quantitative data group was represented by mean±standard deviation (SD) and compared by an independent "t" test. The Student's t-test was used to test for statistical significance of variance between the means of the two samples. The Chi-square test ($\chi 2$) was used to study the comparison and association between two qualitative variables When 25% of the cells have expected count less than 5 Fisher exact test was used. Binary regression analysis was used to study the relationship between post-implant OM and the history of peri-post-operative associated co-morbidities in the patients. The confidence interval was set to 95%, and the margin of error accepted was set to 5%. A p value (level of significance) of <0.05 was considered statistically significant, and 0.001 was considered highly significant for two-tailed tests. The smaller the p value obtained, the more significant the results.

RESULTS

The distribution of the studied patients according to gender, age at the time of the implantation, the post-implant follow-up period, a history of recurrent attacks of tonsillitis and large adenoids, a history of perioperative OME, the history of receiving a routine vaccination schedule for pediatric CI recipients, the history of receiving the seasonal influenza vaccine, and the history of receiving double vaccination is depicted in (Table 1).

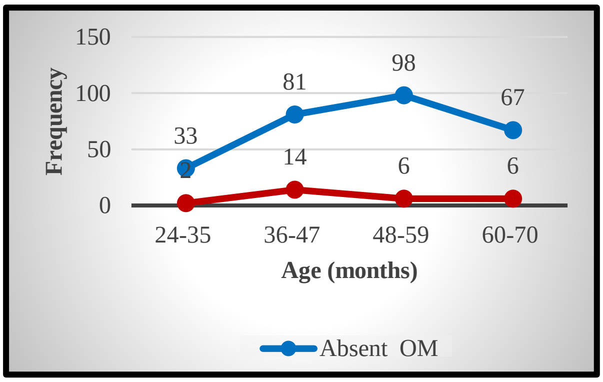

Figure 1: A multiple line chart showing correlation between the risk of developing post-implant OM and the age of the studied patients at the time of implantation.

There is a statistically significant difference in the distribution of OM in the operated ears; the p value was <0.001. There is a statistically significant association between post-implant OM and getting implantation, as the p value was <0.001. There is a statistically non-significant relationship between the development of post-implant OM in the implanted ears and either the gender or age of the patients with post-implant OM in the implanted ears and the age of the studied patients at the time of implantation. There is a statistically non-significant association between the developing post-implant OM and the length of the post-implant follow-up period (Table 2). The patients aged 36 to 47 months, 48 to 59 months, and ≥60 months had an increased risk of OM in implanted ears by 2.85, 1.01, and 1.48 folds, respectively (Figure 1).

Table 1: Distribution of the studied patients according to gender, age at the time of the implantation, the post-implant follow-up period, a history of recurrent attacks of tonsillitis and large adenoids, a history of perioperative OME, the history of receiving routine vaccination schedule for pediatric CI recipients, the history of receiving the seasonal influenza vaccine and the history of receiving double vaccination (n=307).

Parameters		N (%)
Gender	**Male**	159 (51.8)
	Female	148 (48.2)
Age (months)		49.31±11.44
24-35		35 (11.4)
36-47		95 (30.9)
48-59		104 (33.9)
60-70		73 (23.8)
Post-implant follow-up period (months)		48.2±14.09
1-35		72 (23.5)
36-47		75 (24.4)
48-59		77 (25.1)
60-72		83 (27)
Recurrent tonsillitis and enlarged adenoids		30 (9.5)
History of perioperative OME		28 (9.1)
History of receiving influenza vaccine		17 (5.5)
History of double vaccination		15 (4.9)
History of receiving routine vaccination schedule		281 (91.5)

Data are presented as mean±SD or frequency (%)

Table 2: Distribution of the studied patients according to the prevalence of OM in implanted ears, the prevalence of OM in implanted ears and non-implanted ears (control group), correlation between the risk of developing post-implant OM and gender and the age of the studied patients at the time of implantation, and correlation between the risk of developing post-implant OM in the implanted ears and the post-implant follow-up period (n=307).

Parameters	Observation, frequency (%)		P value
OM among implanted ears	28 (9.1)		<0.001*
OM in the studied population	**Present (N=84)**	**Absent (N=530)**	
Implanted ear	28 (33.3)	279 (52.6)	<0.001*
Non-implanted ear	56 (66.7)	251 (47.4)	
Gender	**Present (N=28)**	**Absent (N=279)**	
Female	13 (46.4)	135 (48.4)	0.843
Male	15 (53.6)	144 (51.6)	
Age at the time of implantation (months) (mean±SD)	46.46±11.22	49.6±11.44	0.167
Post-implant follow-up period (mean±SD)	50.79±15.13	47.94±13.98	0.305

*p≤0.001 is statistically significant, Data are presented as mean±SD or frequency (%)

Table 3: Relation between follow-up period and gender of patients with post-implant OM in implanted ears, correlation between patients according to a history of recurrent tonsillitis and enlarged adenoids as regards OM attacks in the implanted ears, correlation between patients according to a history of perioperative OME as regards OM in the implanted ears, correlation between the risk of developing post-implant OM and a history of receiving vaccinations among implanted ears.

Parameters		Present OM frequency (%)	Absent OM frequency (%)	P value
Post-implant follow-up period (months) (mean±SD)		47.46±15.76	53.67±14.48	0.288
1-35		4 (30.8)	3 (20)	0.25
36-47		2 (15.4)	0 (0)	
48-59		2 (15.4)	6 (40)	
60-72		5 (38.5)	6 (40)	
Recurrent tonsillitis and enlarged adenoids		**Present (N=28)**	**Absent (N=279)**	
Positive history		24 (85.7)	36 (12.9)	<0.001*
Negative history		4 (14.3)	243 (87.1)	
Perioperative history of OME		18 (64.3)	10 (3.6)	<0.001*
History of receiving routine vaccination	**Positive history**	17 (60.1)	263 (94.3)	<0.001*
	Negative history	11 (39.9)	16 (5.7)	
History of receiving the seasonal influenza vaccine	**Positive history**	2 (11.8%)		<0.001
	Negative history	15 (88.2%)		
History of receiving double vaccination	**Positive history**	1 (6.7%)		<0.001
	Negative history	14 (93.3%)		

Data are presented as mean ± SD or frequency (%), *p≤0.001 is statistically significant

Table 4: Correlation between the risk of developing post-implant OM, the developing further major complications, and integrity of the device. Correlation between the different management protocols of the developed post-implant OM in the implanted ears.

Parameters	Frequency (%)
Complete resolution	307 (100)
Spread of infection	0 (0)
Chronicity	0 (0)
Device failure	0 (0)
Medical management	307 (100)
Surgical management	0 (0)

*p≤0.001 is statistically significant.

Table 5: Binary regression analysis of the relationship between post-implant OM and history peri-post-operative associated co-morbidities of patients.

Parameters	Post-implant OM				
	P value	Exp (B)	AOR	95% CI for Exp (B)	
				Lower	Upper
History of receiving vaccination (no)	0.017*	1.685	5.394	1.353	21.511
Perioperative history of OME (yes)	0.001*	3.319	27.631	7.429	102.763
Recurrent tonsillitis and enlarged adenoids (yes)	0.001*	3.295	26.969	7.219	100.745

P value, AOR adjusted odds ratio, COR crude odds ratio CI confidence interval, *p<0.05 is statistically significant

There is a statistically significant association between the developing post-implanted OM in the implanted ears and a history of recurrent tonsillitis and large adenoids, as the p value <0.001. There is a statistically significant association between the developing post-implant OM in the implanted ears and a history of perioperative OME, as the p value was <0.001. There is a statistically significant association between the developed post-implant OM in the implanted ears and the history of receiving the routine vaccination schedule for pediatric CI recipients, as the p value <0.001 (Table 3). One patient received both vaccines and developed post-implant OM with a significant change in distribution (p<0.001) (Table 4). Multivariate analysis showed significant associations between post-implant OM and a history of receiving vaccination (no), a perioperative history of OME (yes), and a history of recurrent tonsillitis and enlarged adenoids (yes) (p<0.05) (Table 5).

DISCUSSION

CI, a surgically implanted electronic device placed in the cochlea that converts sound to an electrical signal that is then transmitted via electrodes to the spiral ganglion cells in the cochlea, improving sound perception, auditory skills, speech, verbal language, and education, is the worldwide safest current treatment for patients with severe to profound SNHL.[12]

There is a statistically significant link between post-implant OM and getting implantation, as the p value was <0.001 and the COR (95% CI) was 2.22 (1.37-3.61). Non-operated ears had an increased risk of developing OM by about twofold, with 28 (9.1%) of operated-ear patients developing post-implant OM. However, among non-operated ears, 56 (18.2%) patients developed OM, indicating a decrease in the prevalence of post-implant OM development as a result of implantation.

This dramatic decrease in the prevalence of post-implant OM in the implanted ears coincides with Migirov et al and may be due to a natural tendency to decline in the OM incidence with age, the potential impact of mastoidectomy and post-tympanotomy being performed during CI surgery, the use of preoperative prophylactic antibiotics intravenously by Luntz et al and the probable added benefit of immunization (discussed later).[13,14] In our study, 15 boys (53.6%) had OM in the implanted ears, while 13 girls (46.4%) had OM. Gender has no statistically significant relationship with post-implant OM in the implanted ears, as the p value was 0.843. Boys had a 1.08 times higher risk of developing OM in their implanted ears, with a COR (95% CI) of 1.08 (0.5-2.36). This is consistent with the findings of Kaur et al and Van Dyke et al who discovered that OM is slightly more common in boys than in girls due to a higher incidence of infectious disease in boys.[15,16]

The time interval between implantation and the onset of the developed post-implant OM in the implanted ears ranged from 8 to 60 months, with a mean of 33.04 months and a median of 33 months. The data collected from studies reported that the median interval from the time of implantation to the first episode of post-implant OM was 6 months, with a range of 1 week to 65 months, the time from implant insertion to mastoiditis ranged from months to approximately five years.[17,18] In our study, there was no statistically significant relationship between post-implant OM and either the length of the post-implant follow-up period, as the p value was 0.305, or the time interval between implantation and the onset of the developed post-implant OM in the implanted ears, as the p value was 0.134. In our study, there was a statistically significant link between post-implant OM in the implanted ears and a history of recurrent tonsillitis and large adenoids, as the p value was ≤0.001.

Patients with a positive history of recurrent tonsillitis and large adenoids had a significantly increased risk of post-implant OM by approximately 41 folds, with 24 (85.7%) of the studied patients having a positive history of recurrent tonsillitis and large adenoids and 4 (14.3%) not, as the COR (95% CI) was 40.5 (13.28-123.49). A number of studies have discovered a link between acute tonsillitis and adenoid enlargement and the development of OM.

Danishyar and Ashurst discovered that OM begins as an inflammatory process following an upper respiratory tract infection.[19] As during respiratory illness, colonization of the nasopharynx by potential respiratory pathogens such as S. pneumoniae, H. influenza, and M. catarrhalis increases significantly in OM-prone children. In our study, 9.1% of patients had a history of perioperative OME. This corresponds to the normal incidence of OME in young children, which ranges from 1.3% to 31.3% depending on research methodology, race, and environmental factors.[20] There is a statistically significant link between post-implant AOM in the implanted ear and a history of perioperative OME, as the p value was ≤0.001. We discovered that 18 (64.3%) of the patients with post-implant AOM had a positive history of perioperative OME, while only 10 (35.7%) had a negative history of perioperative OME. Patients with a history of perioperative OME had a 48-fold increase in the risk of post-implant AOM in the implanted ear, as the COR (95% CI) was 48.4 (17.85-131.4). These findings corroborate previous findings that children with OME are five times more likely than controls to develop AOM.[21] In our study, 281 (91.5%) of the patients were vaccinated with the routine vaccination schedule for pediatric CI recipients, while 26 (8.5%) were not. Vaccination rates vary greatly around the world. Annie et al reported a baseline vaccination rate of 53.45% (95% CI, 37.02%-69.51%) in a July 2020 systematic review and meta-analysis. while Canada has a rate of 98% and Poland has a rate of 49.39%.[22-24] Our findings regarding the uncertain effect of vaccination on preventing AOM in children are consistent with those of a multi-center study conducted in the United States, which discovered that PCV7 serotypes were responsible for only 65% of pneumococcal AOM.[25]

Furthermore, the Hib vaccine does not prevent colonization or infection with non-serotype b strains of H. influenzae, which account for the majority of AOM strains (45% of tympanocentesis isolates).[15] In our study, 17 (5.5%) of the patients were vaccinated with the annual influenza vaccine, while 290 (94.5%) were not. Out of 17, only 2 (11.8%) of the patients develop post-implant OM in the implanted ears. There is a statistically significant association between post-implant OM in the implanted ear and a history of receiving the annual influenza vaccination (p value <0.001), but the small size of the study group makes it insufficient to conclude its potential. However, it is advised for patients with CI to decrease the frequency of AOM episodes, and it is strongly considered for their household contacts.[26] In our study, we found that 15 patients had a history of receiving both vaccines, but only one (6.7%) patient developed post-implant OM with a significant change in distribution (p value <0.001). In our study, post-implant OM in the implanted ears was treated medically without the need for additional surgical intervention, and this was closely related to the same results reported by Vila et al. [17] Our treatment protocols include prompt treatment of OM with antibiotic therapy (which is considered critical), local and systemic nasal decongestants, and pain relievers, and should not be managed with observation due to the possibility of progression to meningitis (although the risk is relatively low). Our antibiotic selection protocol is similar to an American Academy of Pediatrics policy statement on the treatment of OM in children with CI published in 2010 by starting with ceftriaxone in a dose of 50 to 75 mg/kg/day in one or two divided doses or cefotaxime (as a reasonable alternative agent for patients with cefotraixione hypersensitivity) in a dose of 150 mg/kg/day in three divided doses for three days, followed by amoxicillin-clavulanate for targeted treatment of nontypeable H. influenzae in a dose of 80 to 90 mg/kg per day orally divided every 12 hours or cefdinir (as a reasonable alternative agent for patients with beta-lactam hypersensitivity) in a dose of 30 mg/kg per day in one or two divided doses for seven days.[17] In our study, post-implant OM in the implanted ears had no effect on the device's integrity. This was related to the same findings reported by Luntz et al, Migirov et al.[12-14]

CONCLUSION

In children, the prevalence of developing post-implant OM in the implanted ears does not rise, but rather falls, contradicting the theory that foreign bodies may aggravate the infection. Our findings supported the safety of CI in children with a history of post-implant OM, as all cases of post-implant OM were managed medically, with no additional surgical intervention required. Furthermore, no case had any significant complications, such as meningitis, or had a negative impact on the device's integrity.

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