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Outcome of Cochlear Implantation in Deaf Children with Co-Existing Otitis Media with Effusion

A comparative study

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Abstract

***Objective*:** Cochlear implantation (CI) is the definitive treatment for profound hearing loss in children and adults. Operating on an infected ear is considered a challenge; the institution of cochlear implant the presence of otitis media with effusion (OME) prior to CI surgery has created a debate among neuro-otologists: treat the OME first or go ahead with surgical intervention. This study was conducted to determine whether cochlear implantation in patients with OME at the time of surgery has any influence on the procedure, post-operative complications and surgical outcome. ***Methods*:** Retrospective descriptive analysis of data collected from records of patients who underwent CI in a tertiary care hospital from 2000-2018 was done. The age targeted was 6 months to 14 years old, excluding all adults, and those who had their operations outside the chosen institution. ***Results*:** Out of 369 children, 175 had OME preceding surgery compared to 194 who did not have OME. Intra-operative oedematous hypertrophied middle ear mucosa was observed only in OME patients (n=18, *P* <0.050). Moreover, among the OME patients, six cases developed mild intra-operative bleeding compared to only one case from non-OME group (*P* <0.050). Overall, there was no significant difference in post-operative surgical complications between the two groups (P >0.050). ***Conclusion*:** The presence of OME is associated with intra-operative technical difficulties, such as impaired visualization and bleeding.

However, OME is not determinative on performing cochlear implantation in terms of post operative complications and outcome. Therefore, there is no need to delay the implantation until the OME resolves.

Keywords: Cochlear implantation, otitis media with effusion, children, and sensorineural hearing loss

Advances in Knowledge

- The study highlight that CI shouldn't be delayed due to the existing OME as it is not statistically influence the treatment of deaf children with CI. This information is vital as early institution of CI is decisive in successful rehabilitation of deaf children and the presence of OME should not delay implantation which might affect the outcome.

Applications to Patient Care

- This study shows that the delay is not justified, so CI could be done as soon as the patient is diagnosed with profound SNHL regardless the finding of OME

Introduction

Otitis media with effusion (OME) is a common problem encountered in pediatric age group. It is defined as presence of fluid (effusion) in the middle ear cavity without infection.[1] The nature of the fluid is either mucoid or serous. It is managed either by watchful waiting, medical therapy or surgery. Cochlear implantation (CI) is the standard of care in management of children with profound sensorineural hearing loss (SNHL).[2-15] In our health care system, children with a confirmed diagnosis of profound SNHL will be evaluated for potential CI. The indications of CI in our study group were congenital, infection (e.g. meningitis) and or syndromic. The incidence of complications among patients with OME who undergo CI ranges from 1.7 to 4.1%.[3,16]

Management of OME in children who are the candidates for the CI is the subject of debate on whether the OME should be treated prior to CI or not. The presence of OME has been reported to increase the risk of post-operative surgical site infection, meningitis and device extrusion[4-11] as well as impaired visualization and bleeding in the presence of inflamed middle ear mucosa, leading to a high risk of complications in the post-operative period.[5,6,7] Some surgeons insert a ventilation tube (VT),[7] while

others treat it medically, with some operating regardless.[4-6,8-11] This study describes our experience of CI in patients with OME prior to and at the time of surgery. The effect of OME on the procedure, post-operative complications and surgical outcome were evaluated and presented.

Methods

This was a single-center retrospective case control study of consecutive pediatric patients presenting with profound hearing loss and underwent cochlear implantation from 2000 to 2018 in Al Nahdha hospital, Muscat, Oman. All data was collected from electronic medical records.

We collected patient characteristics including age, gender, and demographic profiles. The data related to assessment included clinical examination findings, complete otological, head and neck examination in an outpatient setting. Audiological test results such as Tympanometry, Brainstem auditory evoked response audiometry (BAERA) and the details of Imaging (High resolution temporal bone computed tomography (CT), magnetic resonance imaging (MRI)) were also collected. The study included all pediatric patients aged 6 months to 14 years. Those who were above 14 years, those who presented after the first surgery done elsewhere then re-implanted in our center and those with incomplete data were excluded. The surgery was performed by our otology team in the department of ENT including 3 senior otologists.

The total sample size was 369 patients who were divided into 2 groups: those with OME and those without. Patients who were suspected to have OME during the clinical examination were subjected to acoustic immittance tympanometry. Radiological evidence of middle ear opacification on the CT scan was also considered for further workup. B type flat curve on were considered positive of OME. The treatment and follow up of these children were collected and analyzed. All children who had OME prior to surgery underwent a period of watchful waiting or symptomatic treatment in terms of nasal spray or antihistamine syrup. There was no treatment given intra-operatively or post-operatively for these children. Surgical steps included post-auricular incision, followed by cortical mastoidectomy. Surgeons performed a posterior tympanotomy followed by a round window or cochleostomy approach, based on the anatomical variations. Device function was tested intra-

operatively using neural response telemetry (NRT) and stapedial reflex in most of the patients. Intra-operative findings and post-operative surgical outcomes were observed in both groups. Intra- or post-operative portable X-ray was used to confirm the correct placement of the electrode in all patients. The Statistical Package for Social Sciences (SPSS), version 20 (IBM Corp., Armonk, NY) was used in data analyses. A *P* value of <0.05 was considered statistically significant. Ethical approval was obtained from the research and ethical committee at the hospital.

Results

The study included 369 patients. 195 (52.8%) were male and 174 (47.2%) female. The OME group consisted of 175 (47.4%) children with 92 males (24.9%) and 83 females (22.5%). In the non-OME group, there were 194 (52.6%) patients in total, 103 (27.9%) were male and 91 (24.7%) were female. There was no statistically significant difference between the two groups ($P = 0.5$). In the OME group, 42 (24%) of patients were less than 2 years old at the time of evaluation and surgery whereas 133 (76%) children were 2 years old and older at the time of presentation. All the children in both the age groups with OME had received treatment (medical or surgical) prior to cochlear implantation, however, all of them scheduled for CI regardless of treatments received.

The mean age at implantation was 3.2 years with no statistical significant difference between the two groups. Intra-operative findings and post-operative complications with surgical outcomes were analyzed. The average operative time was 2.5 to 3 hrs. In the OME group, middle ear inflammation was encountered in only 2 (1.1%) cases compared to 1 (0.5%) case in the non-OME group ($P = 0.46$). Granulation tissues were seen in only 1 case (0.6%) in OME group compared to 2 (1%) cases in non-OME group, with no statistically significant difference. Hypertrophied mucosa was observed in 18 cases (10.3%) in the OME group compared to no cases in the non-OME group. This was statistically significant ($P <0.001$). Intra-operative minimal bleeding was encountered in 6 (3.4%) cases and 1 (0.5%) patient in the OME and non-OME groups, respectively, with a significant *P* value of 0.046. Perilymph leak was observed in 5 cases from each group, intra-operatively, without statistical significance. Intra-/post-operative portable x-rays confirmed the correct placement of the electrode in all patients. (Table 1 summarizes the intra-operative findings in the

cases included in this study). Post-operative complications were also analyzed for both groups. Immediate or early post-operative complications were recorded in 4 patients in both groups. Early wound bleeding was observed in 1 (0.6%) patient in the OME group and 2 (1%) in the non-OME group (*P* value = 0.53). Only 1 patient was taken to the operating room again on the same day for re-exploration from the non-OME group due to a misplaced electrode. All other complications were delayed in nature. One patient (0.5%) in the non-OME group developed a temporary facial nerve palsy on the fifth post-operative day, compared to none of the patients in the OME group (*P* value = 0.52). Conservative management was successful in this child, with full recovery. With regards to swelling at the wound site, 12 (6.9%) patients in the OME group developed swelling compared to 22 (6%) in the non-OME group. Diagnosis ranged from simple induration at the wound site to seroma or hematoma. These patients were managed accordingly using local antibiotic cream, needle aspiration and pressure bandage or incision and drainage under general anesthesia. Device trauma was considered if there was a history of direct hit to the device with external force either due to a fall, hit by an object or sport trauma; 8 patients (4.6%) in the OME group had a trauma to the device, compared to only 6 (3.6%) in the non-OME group. Wound infection was reported in 3 (1.7%) patients in the OME group and 7 (3.6%) in the non-OME group. Wound dehiscence was only noted in one patient in the OME group. Ear discharge occurred in 5 patients from each group. Six patients were re-implanted in the OME group compared to 2 in the non-OME group. In the OME group, the patients were re-implanted due to device failure. The reason of this failure was not known in 4 of the cases. In one case, the reason was a kinked electrode. The sixth patient had cracked the device after direct trauma. One patient in the non-OME group was re-implanted due to device failure, while the other patient had a misplaced electrode in the internal auditory meatus (IAM). This child was re-explored during the same admission and re-implanted. The difference in post-operative complications between the two groups was not statistically significant. (Table 2 which illustrates the post-operative complications of the study groups).

Discussion

Our study showed that delaying the surgery in children with profound sensorineural hearing loss to treat OME will not add any benefit during surgery. As literature showed, management of OME in preparation for CI surgery is still an area of a

debate.[4,11,17] Does delaying the implant lead to easier middle ear access and electrode insertion? Additionally, the consequences of postponing the intervention on the development of speech and language can be a major concern.[8,14,17] The fear of post-operative complications due to OME is justified.[3] However, attributing complications solely to OME has no solid ground. Luntz et al. stated that CI surgery will not increase the incidence or severity of otitis media, in fact, it does quite the opposite.[12,13] Antihistamines and intra-nasal corticosteroids were noted to be the treatment of OME.[9] Furthermore, VT insertion was recommended in patients with OME who failed medical treatment.[4,6,8,11] One study recommended VT insertion around 6 weeks before CI.[7] Notably, VT-related problems, such as otorrhea and residual tympanic membrane perforations do exist.[18,19,20] We analyzed the 369 cases included in this study, looking into the children who had OME before CI and compared the findings intraoperatively with post-operative surgical outcome. Acute otitis media (AOM) in these children was not included as a parameter in this analysis. As AOM is managed in primary care facilities, it is unusual to see patients with AOM in our institute, therefore we did not include these patients in this study, and it was not noted if patients had AOM previously.

Inflammation, granulations and hypertrophied mucosa were some of the intra-operative findings noted during CI, not during the clinical assessment. Alzhrani et al. considered children who were found to have granulations or effusion intra-operatively with no findings pre-operatively to be AOM patients.[15] In this study, OME was a pre-operative diagnosis. Pre-operative diagnosis was not changed based on intra-operative findings. The diagnosis of OME was based on clinical examination and audiological evaluation by tympanometry. Radiological investigations, such as CT scans, may provide insight into OME as well. If the tympanic membrane cannot be visualized due to wax impaction or a small/narrow canal, the canal will be cleaned and the diagnosis of OME will be based on tympanometry flat curve. A B-curve without OME due to small canals can be noted especially in children who are less than a year old. To overcome this, this study only included those clearly diagnosed with OME clinically and by tympanometry with direct visualization and flat B curve. Dubious cases were excluded. Middle ear inflammation was noted in 2 cases in the OME group, compared to one patient in the non-OME group. Apart from minimal bleeding, no difficulties were noted during CI surgery, either during drilling or in electrode insertion, and

finding the round window was not an issue as well. The method of checking electrode placement changed over the period of study. Previously, x-rays were used after surgery to evaluate the position. One case of electrode misplacement led to a change in practice. The current practice is to check the device function intra-operatively via NRT and stapedial reflex test, with x-rays being obtained as well. One study, by Alzoubi et al., reported one case of excessive bleeding and middle ear inflammation during CI in a patient with OME. Despite this, they encouraged medical treatment before CI surgery. This study also concluded that the decision for CI and the timing of surgery should not be delayed to avoid the consequences of delaying the intervention. A follow up did not show any long-term complications.[10] The findings from this study support this observation, that CI should not be delayed in fear of serious complications. The patients in this study who had VTs were delayed for at least 7 months. Multiple factors played a role in this delay. Firstly, the belief that operating on a patient with OME has increased risk of intra- and post-operative problems. Secondly, surgeons indicated that they wanted to wait until the VT was extruded to avoid the risk of exposing the electrode to the exterior. Furthermore, a limited operating time created a long waiting list for surgery. All of these factors contributed to surgery delay in the patients in this study, but particularly in patients with VTs. None of the VT patients developed any kind of VT-related complications. All of these patients had an intact tympanic membrane before surgery. Notably, we have observed that some patients with OME on the operating table with no previous findings, potentially indicating that spending time on a middle ear effusion issue could be a waste of time. Granulation tissues were encountered during the surgeries with or without inflamed mucosa. Sun et al. reported dealing with pathological granulation tissues due to OME with bleeding in the surgical field, and this was managed using a diamond burr.[5] No post-operative complications were reported, even though the patients in that study were below 2 years of age.[5] In another study, published by Cevizci et al., 105 of a total of 890 had OME, with only 5 undergoing VT insertion. All of the patients with OME were found to have granulation tissues, edematous middle ear and mastoid mucosa.[6] Analysis revealed longer than average operating times, but they did not report any complications attributed to OME after the surgery, concluding that OME diagnosis should not delay the surgery.[6] The findings from the current study reflect the findings noted in other studies, such as those by Alzoubi et al. and Cevizci et al. In this study, hypertrophied mucosa and minimal bleeding were

observed in 18 and 6 patients in the OME and non-OME groups, respectively. There were no significant differences noted in the post-operative complication rates between the two groups. Five patients from each group developed a perilymph leak during CI, due to inner ear anatomical malformations, similar to those noted by Mondini. In the current study, 3 patients with perilymph gusher had complications post-operatively. Two of these patients were from the non-OME group and one patient was from the OME group. The patient from OME group had dysplastic cochlea with perilymph gusher intra-operatively. This patient presented a few years later with device failure and was re-implanted successfully. One child from the non-OME group presented with a hematoma after a fall with direct trauma to the device. The second patient presented a few months after the surgery with mild wound infection, treated conservatively with local wound care. The presence of OME had no contribution to either gusher or post-operative complications.

Firstly, this was a retrospective study, limiting the planning and design. Secondly, the decision regarding the OME management pre-operatively was left up to the surgeon's preference, leading to variations in the standardization of treatment approach. It should be noted, however, that all surgeons agreed on the same treatment duration. Another limitation is the duration of the surgery. As this was a retrospective study retrieving the duration of surgery from old records was a challenge, however, the average recorded surgical time of all cases was 2.5 to 3 hours. Also, we did not analyse the hearing and speech outcome specifically after the surgery as it was not an objective of this paper.

Conclusion

OME is a common pediatric problem that can be found in patients with profound SNHL undergoing CI surgery. Difficulties during CI surgery, such as bleeding and impaired visualization, should not prevent early intervention. The post-operative compilations are not detrimental in patients with OME regardless of prior treatment as revealed in our study and therefore, the presence of OME at the time of surgery should not lead to its delay. We concluded that postponement or vigorous treatment of OME prior to CI is no longer needed since OME does not affect the surgical outcome afterwards.

Conflicts of interest

The authors declare that they have no conflict of interest

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Authors Contribution:

Al Habsi S contributed via data collection, literature review and data analysis. Al Zaabi K contributed to the work by supervising the first author, review of the data, final literature review and write up of the manuscript. Al Lawati A is the senior author who created the study question, designed and supervised the whole work scheme.

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Table 1: Comparison of intra-operative findings among the study groups (N=369)

Intra-operative finding	OME (n = 175)		Non-OME (n = 194)		Statistical significance (*P* value)
	Present	Absent	Present	Absent	
Middle ear inflammation	2 (1.1%)	173 (98.9%)	1 (0.5%)	193 (99.5%)	0.601
Glue ear	32 (18.3%)	143 (81.7%)	8 (4.1%)	186 (95.9)	<0.001
Granulation tissues	1 (0.6%)	174 (99.4%)	2 (1%)	192 (98%)	0.534
Hypertrophied mucosa	18 (10.3%)	157 (89.7%)	0	194 (100%)	<0.001
Bleeding	6 (3.4%)	169 (96.6%)	1 (0.5%)	193 (99.5%)	<0.046
Perilymph leak	5 (2.9%)	170 (97.1%)	5 (2.6%)	189 (97.4%)	0.551

**% is within OME/non-OME, OME = otitis media with effusion*

Table 2: Comparison of post-operative complications among the study groups (N = 369)

Post-operative complications	Early vs delayed	OME (n = 175) (%)		Non-OME (n = 194) (%)		Statistical significance (*P* value)
		Present	Absent	Present	Absent	
Facial nerve palsy	Delayed	0	175 (100%)	1 (0.5%)	193 (99.5%)	0.52
Swelling at wound	Delayed	12 (6.9%)	163 (93.1%)	22 (6%)	172 (94%)	0.31
Device trauma	Delayed	8 (4.6%)	167 (95.4%)	6 (3.1%)	188 (96.9%)	0.32
Wound infection	Delayed	3 (1.7%)	172 (98.3%)	7 (3.6%)	187 (96.4%)	0.21
Bleeding from wound	Early	1 (0.6%)	174 (99.4%)	2 (1%)	192 (99%)	0.53
Wound dehiscence	Delayed	1 (0.6%)	174 (99.4%)	0	194 (100%)	0.47
Ear discharge	Delayed	5 (2.9%)	170 (97.1%)	5 (2.6%)	189 (97.4%)	0.55
Re-exploration	Early	0	175 (100%)	1 (0.5%)	193 (99.5%)	0.52
Re-implantation	Delayed	6 (3.4%)	169 (96.6%)	2 (2.2%)	192 (99%)	0.111

**% is within OME/non-OME, OME = otitis media with effusion*