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CLINICAL & BASIC RESEARCH

Cochlear Implantation in Deaf Children with Coexisting Otitis Media with Effusion

A comparative study

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abstract: ***Objectives:*** Cochlear implantation (CI) is a definitive treatment for profound hearing loss in children and adults. Operating on an infected ear is considered a challenge. Hence, CI in the presence of otitis media with effusion (OME) prior to CI surgery has sparked a debate among neurotologists: treat the OME first or go ahead with surgical intervention. This study was conducted to determine whether CI in patients with OME at the time of the surgery has any influence on the surgery procedure, post-operative complications and surgical outcome. ***Methods:*** A retrospective descriptive analysis of data collected from records of patients who underwent CI surgery in Al Nahdha Hospital, Muscat, Oman, from 2000 to 2018 was conducted. The targeted age group was six months to 14 years old, excluding all adults and patients whose operations were done outside the chosen institution. ***Results:*** Out of 369 children, 175 had OME preceding surgery compared to 194 who did not have OME. Intraoperative oedematous hypertrophied middle ear mucosa was observed only in patients with OME (n = 18; *P* <0.050). Moreover, among the patients with OME, mild intraoperative bleeding occurred in six cases compared to only one case in the non-OME group (*P* <0.050). Overall, no significant difference was observed in postoperative surgical complications between the two groups (*P* >0.050). ***Conclusion:*** The presence of OME is associated with intraoperative technical difficulties, such as impaired visualisation and bleeding. However, OME is not determinative in performing CI in terms of postoperative complications and outcome. Therefore, there is no need to delay CI until the OME resolves.

Keywords: Children; Cochlear Implantation; Otitis Media with Effusion; Sensorineural Hearing Loss, Oman.

Advances in Knowledge

- *This study highlights that cochlear implantation (CI) should not be delayed due to existing otitis media with effusion (OME) as OME does not statistically affect the treatment of deaf children with CI.*

Applications to Patient Care

- *This study shows that the delay is not justified, so CI should be done regardless of OME as soon as the patient is diagnosed with profound sensorineural hearing loss.*
- *This information is vital as early CI is decisive in the successful rehabilitation of deaf children and a delay in the implementation due to the presence of OME might negatively affect the outcome.*

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

Management of OME in children who are candidates for CI surgery has been the subject of debate—whether the OME should be treated prior to CI or not. OME has been reported to increase the risk of postoperative surgical site infection, meningitis and device extrusion, as well as impaired visualisation and bleeding in the presence of inflamed middle ear mucosa, leading to a high risk of complications in the postoperative period.[4–11] Some surgeons insert a ventilation tube to treat OME, while others treat it medically, with some operating regardless.[4–11] This study describes the experience of CI surgery in patients with OME prior to and at the time of surgery. The effects of OME on the surgery procedure, postoperative complications and the surgical outcome have also been evaluated in this study.

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Methods

This was a single-centre retrospective case-control study of consecutive paediatric patients presenting with profound hearing loss and who had undergone CI surgery from 2000 to 2018 in Al Nahdha Hospital, Muscat, Oman. All the data were collected from electronic medical records.

The patient characteristics, including age, gender and demographic profiles, were collected. The data related to the assessment included clinical examination findings and a complete otological and head and neck examination in an outpatient setting. Audiological test results such as tympanometry and brainstem auditory evoked response audiometry and the details of imaging (high-resolution temporal bone computed tomography [CT] and magnetic resonance imaging) were also collected. The study included all paediatric patients aged six months to 14 years. Patients who were above 14 years of age, who had presented at the authors' centre after the first surgery was done elsewhere and then re-implanted at the authors' centre and those who had incomplete data were excluded. The surgery was performed by the otology team in the Department of ENT, which included three senior otologists.

The total sample size was 369 patients, who were divided into two groups: those with OME and those without. The patients suspected to have OME during the clinical examination were subjected to acoustic immittance tympanometry. Radiological evidence of middle ear opacification on CT scans was also considered for further workup. B-type flat curves were considered a positive indication of OME. The treatment and follow-up data of these patients were also collected and analysed. All the patients who had OME prior to surgery underwent a period of watchful waiting or symptomatic treatment in terms of nasal spray or antihistamine syrup. No treatment was given to these children intraoperatively or postoperatively. The surgical steps included post-auricular incision, followed by cortical mastoidectomy. The surgeons performed a posterior tympanotomy, then adopted a round window or cochleostomy approach, based on the anatomical variations. The device function was tested intraoperatively using neural response telemetry (NRT) and stapedial reflex in most of the patients. Intraoperative findings and postoperative surgical outcomes were observed in both groups. Intra- or postoperative portable X-rays were used to confirm the correct placement of the electrode in all patients. The Statistical Package for Social Sciences (SPSS), Version 20 (IBM Corp., Armonk, New York, USA), 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 Al Nahdha Hospital.

Results

A total of 369 patients were included, 195 (52.8%) were males and 174 (47.2%) were females. The OME group consisted of 175 (47.4%) children with 92 (24.9%) males and 83 (22.5%) females. The non-OME group included 194 (52.6%) patients with 103 (27.9%) being male. No statistically significant difference was observed between the two groups (P = 0.50). In the OME group, 42 (24%) patients were less than two years old at the time of evaluation and surgery, whereas 133 (76%) patients were two or more than two years old at the time of presentation. All the children in both age groups with OME had received treatment (medical or surgical) prior to CI; however, all of them were scheduled for CI regardless of those treatments.

The mean age at implantation was 3.2 years, with no statistically significant difference between the two groups. The intraoperative findings and postoperative complications with surgical outcomes were analysed. The average operative time was 2.5–3 hours. In the OME group, middle ear inflammation was encountered in only two cases (1.1%) compared with one case (0.5%) in the non-OME group (P = 0.46). Granulation tissues were seen in only one case (0.6%) in the OME group and two cases (1%) in the non-OME group, with no statistically significant difference between the two groups. Hypertrophied mucosa was observed in 18 cases (10.3%) in the OME group compared with no cases in the non-OME group. This was statistically significant (P <0.001). Intraoperative minimal bleeding was encountered in six cases (3.4%) and one case (0.5%) in the OME and non-OME groups, respectively (P = 0.046). Perilymph leak was observed in five cases in each group, intraoperatively, without statistical significance. Intra- or postoperative portable X-rays confirmed the correct placement of the electrode in all patients. Postoperative complications were also analysed for both groups. Immediate or early postoperative complications were recorded in four patients in both groups. Early wound bleeding was observed in one patient (0.6%) in the OME group and two patients (1%) in the non-OME group (P = 0.53).

Only one patient from the non-OME group was taken to the operating room again on the same day for re-exploration 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 postoperative

Table 1: Comparison of the intraoperative findings among the study groups (N = 369)

Intraoperative finding	n (%)*				*P* value
	OME (n = 175)		Non-OME (n = 194)		
	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 (1.0)	192 (98)	0.534
Hypertrophied mucosa	18 (10.3)	157 (89.7)	0 (0.0)	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

OME = otitis media with effusion.
**Percentage is calculated within OME/non-OME groups.*

Table 2: Comparison of the postoperative complications among the study groups (N = 369)

Postoperative complication	Early versus delayed	n (%)*				*P* value
		OME (n = 175)		Non-OME (n = 194)		
		Present	Absent	Present	Absent	
Facial nerve palsy	Delayed	0 (0.0)	175 (100.0)	1 (0.5)	193 (99.5)	0.52
Swelling at wound	Delayed	12 (6.9)	163 (93.1)	22 (6.0)	172 (94.0)	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 (1.0)	192 (99.0)	0.53
Wound dehiscence	Delayed	1 (0.6)	174 (99.4)	0 (0.0)	194 (100.0)	0.47
Ear discharge	Delayed	5 (2.9)	170 (97.1)	5 (2.6)	189 (97.4)	0.55
Re-exploration	Early	0 (0.0)	175 (100.0)	1 (0.5)	193 (99.5)	0.52
Re-implantation	Delayed	6 (3.4)	169 (96.6)	2 (1.0)	192 (99.0)	0.111

OME = otitis media with effusion.
**Percentage is calculated within OME/non-OME groups.*

day, compared with no patients in the OME group (*P* = 0.52). Conservative management was successful in this patient, leading to full recovery.

With regard to swelling at the wound site, 12 patients (6.9%) in the OME group developed swelling compared with 22 patients (6%) in the non-OME group. The diagnoses ranged from simple induration at the wound site to seroma or haematoma. These patients were managed accordingly using local antibiotic cream, needle aspiration and pressure bandage or incision and drainage under general anaesthesia. Device trauma was considered if there was a history of a direct hit to the device by external force due to a fall, being hit by an object or due to sports trauma; eight patients (4.6%) in the OME group had experienced trauma to the device, compared with only six patients (3.6%) in the non-OME group. Wound infection was reported in three patients (1.7%) in the OME group and seven patients (3.6%) in the non-OME group. Wound dehiscence was noted in only one patient in the OME group. Ear discharge occurred in five patients in each group. A total of six patients were re-implanted in the OME group compared to two patients in the non-OME group. In the OME group, the patients were re-implanted due to device failure. The reason for this failure was not known in four of the cases. In one case, the reason was a kinked electrode, and in the other, the 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. This patient was re-explored during the same admission and re-implanted. The difference in postoperative complications between the two groups was not statistically significant. Table 1 summarises the intraoperative findings in the cases included in this study, and Table 2 illustrates the postoperative complications of the study groups.

Discussion

The current study showed that delaying the surgery in children with profound SNHL for treating OME would not add any benefit to the surgery. As the literature showed, the management of OME in preparation for CI surgery is still an area of debate.[4,11,17] The question if delaying CI would lead to easier middle ear access and electrode insertion still remains. 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 postoperative complications due to OME is justified.[3] However, attributing complications solely to OME has no solid ground. Luntz *et al*. stated that CI surgery does not increase the incidence or severity of otitis media; in fact, it does the opposite.[12,13] Antihistamines and intranasal corticosteroids have been noted as the treatment of OME.[9] Furthermore, studies recommend ventilation tube (VT) insertion in patients with OME who had failed medical treatment.[4,6,8,11] One study recommends VT insertion approximately six weeks before CI.[7] However, VT insertion poses issues as well, such as otorrhea and residual tympanic membrane perforations.[18–20] The authors of the current study analysed 369 cases, looking into the children who had OME before CI and compared the findings intraoperatively with postoperative surgical outcomes. Acute otitis media (AOM) in these children was not included as a parameter in this analysis. AOM is managed in primary care facilities, so patients with AOM are not usually encountered in the authors' institute. Therefore, these patients were not included in this study nor was it noted whether the patients had AOM previously or not.

Inflammation, granulations and hypertrophied mucosa were some of the intraoperative findings noted during CI and not during the clinical assessment. Alzhrani *et al*. considered children who were found to have granulations or effusion intraoperatively with no findings to indicate they were AOM patients before the operation.[15] In this study, OME was a preoperative diagnosis and the preoperative diagnosis was not changed based on intraoperative findings. The diagnosis of OME was based on clinical examination and audiological evaluation by tympanometry. Radiological investigations, such as CT scans, can provide insight into OME as well. If the tympanic membrane cannot be visualised due to wax impaction or a small or narrow canal, the canal should be cleaned and the diagnosis of OME should be based on the tympanometry flat curve. A B-curve due to small canals can be noted in children without OME, especially in children less than a year old. To overcome this, this study included only patients diagnosed with OME clinically and through tympanometry with direct visualisation and a flat B-curve; dubious cases were excluded. Middle ear inflammation was noted in two cases in the OME group, compared with one case in the non-OME group. Apart from minimal bleeding, no difficulties were noted during CI surgery, either during drilling or during electrode insertion; finding the round window was not an issue as well. The method of checking electrode placement has changed over the years. Previously, X-rays were used after surgery to evaluate the position. But one case of electrode misplacement led to a change in practice. The current practice is to check the device function intraoperatively via NRT and stapedial reflex test, with X-rays being obtained as well. 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. Their study also concluded that the decision for CI and the timing of surgery should not be delayed to avoid its consequences. A follow-up did not show any long-term complications.[10] The findings of this study support the 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 seven months. Multiple factors played a role in this delay. First, it was believed that operating on a patient with OME increases the risk of intra- and postoperative problems. Second, the surgeons indicated that they preferred 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 these factors contributed to the surgery delay for the patients in this study, particularly in patients with VTs. None of the VT patients developed any VT-related complications. All of them had an intact tympanic membrane before surgery. Notably, some patients were encountered to have OME on the operating table but had no previous findings in the pre-operative evaluation (such as dull tymbanic membrane, B curve on tympanogram, etc), 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*. explored dealing with pathological granulation tissues due to OME along with bleeding in the surgical field, which was managed using a diamond burr.[5] No postoperative complications were reported, even though the patients in that study were below two years of age.[5] In another study, published by Cevizci *et al*., 105 out of a total of 890 patients had OME, with only five undergoing VT insertion. All of the patients with OME were found to

have granulation tissues, edematous middle ear and mastoid mucosa.[6] The analysis revealed longer than average operating times, but the authors 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*.[6,10] In the current study, hypertrophied mucosa and minimal bleeding were observed in 18 and six patients in the OME and non-OME groups, respectively. No significant differences were observed in the postoperative complication rates between the two groups. A total of five patients from each group developed a perilymph leak during CI, due to inner ear anatomical malformations, similar to those noted by Mondini.[21] In the current study, three patients with perilymph gusher developed complications postoperatively. Two of these patients were from the non-OME group and one was from the OME group. The patient from the OME group had dysplastic cochlea with perilymph gusher intraoperatively. This patient presented a few years later with device failure and was re-implanted successfully. One of the patients from the non-OME group presented with a haematoma after a fall that led to direct trauma to the device. The second patient presented a few months after the surgery with a mild wound infection and was treated conservatively with local wound care. The presence of OME did not contribute to either gusher or postoperative complications.

With regard to the limitations, first, this was a retrospective study, which limited the planning and design. Second, the decision regarding the preoperative OME management was left to the surgeon's preference, leading to variations in the standardisation of the treatment approach. It should be noted, however, that all the surgeons agreed on the same treatment duration. Another limitation was 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 the cases was determined to be 2.5–3 hours. Also, the hearing and speech outcome specifically after the surgery was not analysed as it was not an objective of this study.

Conclusion

OME is a common paediatric problem encountered in patients with profound SNHL undergoing CI surgery. Difficulties during CI surgery, such as bleeding and impaired visualisation, should not prevent early intervention. The postoperative compilations are not detrimental in patients with OME regardless of prior treatment, as revealed in this study. Therefore, the presence of OME at the time of surgery should not lead to a delay in CI surgery. This study concluded that postponement or vigorous treatment of OME prior to CI surgery is no longer needed since OME does not affect the surgical outcome afterwards.

AUTHORS' CONTRIBUTION

AAL conceptualised and designed the study. SAH collected the data and performed the literature review. SAH and KAZ analysed the data. KAZ drafted the manuscript. AAL and KAZ supervised the work. All authors approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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