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Research Paper

Pediatric Cochlear Implantation in Otitis Media with Effusion: Surgical Difficulties and Outcomes

Mohammed Raad Zaidan[1], Yaseen Adeeb Sakran[2]

ABSTRACT:

BACKGROUND:

Cochlear implantation is the surgical procedure of choice in patients with congenital profound hearing loss, which is a relatively not rare childhood disease, and this procedure may be associated with some surgical difficulties in the presence of such condition.

OBJECTIVE:

To evaluate the surgical difficulties and outcomes in pediatric cochlear implantation in the presence of otitis media with effusion.

PATIENTS AND METHODS:

A retrospective cohort study conducted at AL- Yarmouk teaching hospital /Baghdad/Iraq during 2022 on a sample of pediatric patients' candidates for cochlear implant who divided into 2 groups; normally aerated ear group (A) and persistent Otitis media with effusion group (B). Both groups had been followed-up for 6 months.

RESULTS:

The mean age of group A was (3.5± 1.3) years and for group B (3.4± 1.2) years. Normal tympanic membrane was found in 76 cases (90.5%) of group A, while abnormal tympanic membrane examination was found in 10 cases (83.3%) of group B. Intra-operatively, 5 cases (41.7%) of inflamed (congested) mucosa, excessive bleeding found in 6 (50.0%) of cases, and presence of fluid or glue in 7 (58.3%) of cases found in group B, with high significant differences between the studied groups ($p<0.001$) . Regarding post-operative complications, infection was found only in one case (1.2%) in group A, no meningitis was found in both groups, and only one case (1.2%) of mastoiditis was found in group A with no significant difference between the two groups regarding post-operative complications.

CONCLUSION:

Early and late post-operative complications were nearly the same for Cochlear implant in patient with Otitis media with effusion or without Otitis media with effusion.

KEY WORDS: Cochlear implant, Otitis media, Complications.

[1]M.B.Ch.B , F.I.B.M.S/ ENT , Al-Yarmouk Teaching Hospital. Baghdad, Iraq.
[2]M.B.Ch.B , F.I.B.M.S/ ENT , Consultant Otolaryngologist, Al-Yarmouk Teaching Hospital. Baghdad, Iraq.

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INTRODUCTION:

Cochlear implant is the best treatment option for those patients with substantial sensorineural hearing loss (SNHL) who are not helped by hearing aids [(1)]. Substantial sensorineural hearing loss (SNHL) is a broad term used to describe reduction of auditory threshold sensitivity. The pathology may be located in the cochlea (cochlear) and/or in the auditory nerve and central nervous system (retro-cochlear) [(2)]. Otitis media with effusion is one of the common indication for cochlear implant, which is an accumulation of mucus within the middle ear and/ or the mastoid air cell system. Chronic condition occurs when the fluid persist for 3 months or longer [(3,4)]. In children, otitis media with effusion (OME) may present with hearing loss, delayed speech and language development, poor social behavior and, in younger children, difficulties with balance. [(5)] It had been reported that otitis media with effusion is common in children, can even be diagnosed prior to one year of age, half of cases occur in infant patients under the age of 1year, and about 60% occur in infant patients under the age of two years [(6)]. The prevalence is particularly higher (60 and 85%) in pediatric patients with craniofacial malformations (trisomy 21, and cleft palate). Unfortunately, recurrent and persistent OME leads to severe complications such as hearing loss and permanent damage to the tympanic membrane (atrophy, cholesteatoma, and retraction pockets) which consequently may need hearing aid [(7,8)]. The age for implantation significantly decreased as a result of the

widespread use of neonatal hearing screening and the growing body of research on the advantages of early implantation. At the time of surgery, some candidates for cochlear implants may have OME, which could affect auditory assessments and cause challenges during the procedure [9]. In cases with OME, there could be a high incidence of bleeding and inflammatory mucosa in the mastoid bone and middle ear, which may make it difficult to see the anatomic structures clearly and increase the risk of complications during surgery[4]. Furthermore, this effusion may raise the risk of meningitis and other infectious problems. The insertion of a ventilation tube may relieve inflammatory mucosa and reduce the occurrence of complications, but it may also have certain drawbacks, such as disrupting the tympanic membrane, which increases the risk of infectious complications in infants. Many studies in Iraq investigate the possible challenges witnessed during and after operation [10], However, mastoidectomy and posterior tympanotomy are required for cochlear implantation surgery. Consequently, after cochlear implantations, middle ear care that is both healthy and poorly-ventilated can be administered and achieved with proper follow up [11].

STUDY OBJECTIVES:

To assess the surgical complications and outcomes in pediatric cochlear implantation in the presence of otitis media with effusion.

PATIENTS AND METHODS:

Study design: Retrospective cohort study.

Study Setting and duration: The patients enrolled in the current study were children consulting department of Otolaryngology at Al-Yarmouk teaching hospital in 2 years duration (2020-2022) and prepared for cochlear implantation.

Sample size and sampling method: Ninety-six children aged between (12 months to 7 years) were enrolled in the current study who underwent cochlear implantation and follow up for a period of 6 months and met the inclusion criteria were divided into two groups;

A. Children candidate for cochlear implantation with normally aerated middle ear(n=84).
B. Children candidate for cochlear implantation with persistent OME despite medical treatment (antibiotics, nasal topical steroids, mucolytics) for at least 1-month duration (n=12).

Inclusion criteria: pre-lingual deaf children, patients with persistent Otitis Media with effusion despite medical treatment for at least 1-month duration.

Exclusion criteria: Children with: recurrent discharging ear, tympanic membrane perforation, Craniofacial anomalies as cleft palate, previous adenoidectomy and myringtomy± grommet operations, OME and big size adenoid requiring adenoidectomy, and any abnormalities of the cochlea as diagnosed by C.T scan.

Data collection and Assessment of patients: A team work of cochlear implantation is formed for assessment of patients; this team is composed of (otolaryngologist, audiologist, paediatrician, neuro-medicine specialist and psychiatrist). **A structured questionnaire was filled by the researcher for each candidate consisted of:**

1/ A Full history is taken from the family include the age of onset of hearing lost, progression of hearing loss, bilaterality, history of ear disease or surgery, risk factors, history of using hearing aid.

2/ Examination include both general and otolaryngology examinations were done for each patient seeking for sign of ear disease whether acute or chronic. Nasal examination, oral cavity, nasopharynx, oropharynx, neck and cranial nerve examination were done routinely

3/Neurological assessment: -Done by a neurologist to exclude mental retardation, neurological abnormality.

4/Psychiatric assessment: - Done by a psychiatrist for major psychological or psychiatric disorder.

5/Paediatric assessment: - Done by paediatrician for delay in growth or in (mile stone) and any other associated diseases.

6/Audiological test: Otoacoustic emission (O.A.E), Tympanometry, Auditory brainstem response (A.B.R) done for hearing assessment.

7/Radiological tests: CT scan, MRI (if indicated) for temporal bones.

A 3-6months trial period by using appropriate amplification, with intensive speech and auditory training was performed as an integral and vital component of the candidacy assessment in those children.

Preoperative Management:

All patients were reassessed for identification and treatment of any problems in the nose, throat and chest and ear (in case of paediatric patient who candidate for cochlear implant and presented with OME kept him on medical treatment (Antibiotic, topical nasal steroids, mucolytic) for 1month duration before undergoing cochlear implantation

- Blood tests done for all patients include C.B.P., blood sugar, blood urea and serum creatinine and virology and P.C.R for covid-19 infection.

The type of cochlear implant: All the implants used in this study from (Med-El company)

Statistical analysis: The data had been analyzed using (SPSS) version 26. Data was presented in terms of mean, standard deviation, and ranges. Categorical data presented by frequency, and percentages. Chi square test is used to assess the association between certain variables. A significant association was considered when the level of P value less than 0.05.

Ethical consideration: Discussion of consent to surgery with the family had been done, include type of the surgery, the risk of anesthesia and surgery in addition to postoperative follow up.

RESULTS:

The total number of patients was 96 cases, the sample was categorized in to two groups; group A (n =84) contain the normally aerated ears and group B (n=12) contain persistent OME patients. The most common age group was 3-4 years (27 cases in group A, and 4 cases in patients of group B), The mean age of patients in group A was (3.5±1.3) years while those in group B was (3.4±1.2) years with no significant difference between two groups (P=0.8). Males were 51 cases (43 cases in group A, and 8 cases in group B), while females were 45 cases, (41 in group A, and 4 in group B).

Table 1: Age and sex distribution of the studied sample.

Variables		Patients group		P-value
		Group A (n=84), %	Group B (n=12), %	
Age	**Mean ±SD**	3.5±1.3	3.4±1.2	0.8 Ns
Gender	**Male**	43 (51.2%)	8 (66.7%)	0.3 Ns
	Female	41 (48.8%)	4 (33.3%)	0.3 Ns

Hs: highly significant, S: significant, Ns: not significant, NA: not applicable

Pre-operative finding: Normal Tympanic membrane was found in 78 cases (76 in group A, and only 2 in group B. Tympanometry finding shows that 84 (100.0%) of patients in group A presented with normal finding (type A). (table 2

Table 2: Tympanic membrane examination findings.

Variables		Patients group	
		Group A (n=84), %	Group B (n=12), %
Tympanic membrane examination finding	**Normal (n=78)**	76 (90.5%)	2 (16.7%)
	Abnormal (retracted, dull, congested) (n=18)	8 (9.5%)	10(83.3%)
Tympanometry findings	**Normal (type A)**	84 (100.0%)	0 (0.0%)
	Abnormal	0 (0.0%)	12(100%)

Intraoperatively, five cases (41.7%) of inflamed (congested) mucosa in group B. Excessive bleeding found in 6 (50.0%) of cases in group B, and presence of fluid or glue in 7 (58.3%) of cases found in group B. Highly significant differences found regarding inflamed (congested) mucosa and excessive bleeding between the studied groups (p<0.001) (table 3).

Table 3: Intra operative findings in the studies sample.

Intra operative findings	Patients group		P-value
	Group A (n=84), %	Group B (n=12), %	
Inflamed (congested) mucosa	2 (2.38%)	5 (41.7%)	<0.001 Hs
Excessive bleeding	4 (4.7%)	6 (50.0%)	<0.001 Hs
Presence of fluid or glue	0 (0.0%)	7 (58.3.0%)	NA

X^2 test Hs: highly significant, NA: not applicable

In table 4, obscure middle ear anatomy was found in 8 (66.7%) cases in group B with high significant difference (P value <0.001). Difficulty in electrode insertion was found in 4 (33.3%) cases in group B with high significant difference (P value <0.001). the time duration of surgery is highly increased significantly in group B (130±30.8) minutes (table 4).

Table 4: Intra-operative difficulties during cochlear implantation in the studies sample.

Intra-operative difficulties	Patients group		P-value
	Group A (n=84), %	Group B (n=12), %	
Obscure middle ear anatomy	1 (1.2%)	8 (66.7%)	<0.001 HS
Difficulty in electrode insertion	1 (1.2%)	4 (33.3%)	<0.001 HS
Duration of surgery (minutes)	105±11.2	130±30.8	<0.001 Hs

X^2 test Hs: highly significant

Wound infection found as one case (1.2%) in group A, 2 cases (2.38%) of seroma in group A, and impaired balance found as 5 cases (5.9%) in group A with one case (8.3%) in group B with high significant difference among the studied groups (P<0.001). Regarding to the late post-operative complications in the current study, infection was found only in one case (1.2%) in group A, no cases of meningitis were found in both groups, and only one case (1.2%) of mastoiditis found in group A. table 5

Table 5: Early and late post-operative complications in the studies sample.

Post-operative Complications		Patients group		P value
		Group A (n=84), %	Group B (n=12), %	
Early complications	**Wound infection**	1 (1.2%)	0 (0.0%)	NS
	Seroma	2 (2.38%)	1 (8.3%)	<0.001 HS
	Impaired balance	5 (5.9%)	1 (8.3%)	<0.001 HS
Late complications	**Infection (skin or CI)**	1 (1.2%)	0 (0.0%)	NA
	Meningitis	0 (0.0%)	0 (0.0%)	NA
	Mastoiditis	1 (1.2%)	0 (0.0%)	NA

X^2 test , highly significant p value <0.001

Persistent OME not found in group A, while one (8.3%) case in group B, no cases of Tympanic membrane perforation in both groups, and recurrent AOM found as one case in group A (1.2%), and one case (8.3%) in group B (table 6).

Table 6: Post-operative middle ear status.

Post-operative middle ear status	Patients group		P-value
	Group A (n=84), %	Group B (n=12), %	
Persistent OME	0 (0.0%)	1 (8.3%)	NA
Tympanic membrane perforation	0 (0.0%)	0 (0.0%)	NA
Recurrent AOM	1 (1.2%)	1 (8.3%)	NA

NA: not applicable

DISCUSSION:

The importance of proper hearing at an early age is critical for development of speech and language; thus, cochlear implant for congenitally deaf patients and children with otitis media with effusion who failed to respond to medical treatment is typically pursued at an early age. Several studies advocate that there is minimum benefit of treating effusion before the cochlear implantation, and cochlear implant pediatric patients with OME can be safely implanted with close monitoring and follow up [12,13], which was the corner stone principle in this study.

Mean age of participants was around 3 years and male predominance was obvious in the current study which is in agreement with previous Iraqi study carried by Al-Salami PH and the results of Kennedy R [14,15] who stated that the mean age of cochlear implant is around 3 years with male predominance.

Tympanic membrane examination and tympanometry findings were found to be normal in the first group, whereas abnormal findings were noted in the second group, while intra operatively, different findings were detected mainly in OME patients like congestion, presence of fluid or glue and excessive bleeding which were significantly different between the two groups. These findings had been mentioned in Alzoubi F et al. study [16] as they found that congested edematous mucosa was present significantly in patients with middle-ear effusion, in addition to the presence of glue in some of the cases which was aspirated using posterior tympanotomy.

On the other side, some challenges had been witnessed during surgery like obscured middle ear anatomy, difficulty in electrode insertion which found mainly in patients with otitis media with effusion with highly significant difference than the normal aerated ear patients. This is in agreement with Alzoubi F et al study [16] who mentioned that certain difficulties and challenges were present intra operatively full but were almost identical in both groups. This can be explained as the presence of effusion before implantation surgery is usually associated with the need to remove obscuring granulation tissues and mucosal inflammation, in addition to the bleeding in the surgical field. Therefore, consequences of OME found to increase the risk of difficulties associated with cochlear implant surgery in addition to determining timing of cochlear implantation in the presence of otitis media with effusion which is one of the major challenges confronting surgeons [17].

Post-operatively, wound infection, seroma and impaired balance found mainly in otitis media patients. This is in disagreement with Sokolov M et al. study[13] which found no significant difference between the two groups of patients regarding this difference, that may be attributed to the difference in sample size between the two studies, while infection and mastoiditis were the only late post-operative complications encountered in those patients with effusion accompanied otitis media.

Recurrent otitis media after cochlear implantation surgery carries some risk of infection spread of the middle ear along the electrode array reaching the cochlea and to the central nervous system [18]. The rate of recurrence after implantation in our study was low and less than the rate reported by one of the earliest studies regarding otitis media following implant, by House WF et al. in 1985, [19] who revealed that otitis media was recurred postoperatively and diagnosed as early as 3 weeks following implantation in 26 % of patients, while in our study otitis media recurred in 1.2% in group A and 8.3% in group B.

This decline in otitis media post-operatively in the current study could be resulted from rigorous and continuous pre-operative otitis media control in addition to the decline of the overall incidence of otitis media with age, and with the probable added benefit of doing mastoidectomy which being usually performed during the cochlear implantation surgery.

CONCLUSION:

Early and late post-operative complications were nearly the same for cochlear implant in patient with OME or without OME, nevertheless, intra-operative surgical difficulties such as inflamed edematous middle ear mucosa, obscured middle ear anatomy, and excessive bleeding, difficulty in electrode insertion where the major challenges faced in the operation room, and its recommended to be anticipated by the surgeon before deciding for doing operation to the otitis media with effusion children.

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