Original Research Article

Cochlear implant complications in Misrata Central Hospital

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ABSTRACT

Background: Cochlear implantation is a safe and reliable method for auditory restoration in patients with severe to profound hearing loss.

Methods: Unilateral surgical procedures cochlear implants were performed in Misrata Central Hospital, Libya, between November 2012 to November 2016, involving 140 patients, retrospective data analysis was performed.

Results: Of 140 cochlear implantations analyzed; 130 were pre-lingual, and 10 were post-lingual. The ratio of M:F were 3:2, the total complications were seen in 24 cases (17.14%), major complications rate was (2.86%) 4 cases and minor complications rate was (14.28%) 20 cases.

Conclusions: There was a low rate of complications, most of them been successfully managed, these results confirm that the cochlear implant is a safe procedure can be done for the profoundly deaf patient.

Keywords: Cochlear implant, Complications, Operative complication in cochlear implantation

INTRODUCTION

Cochlear implantation is a well-established, safe and effective method of rehabilitation for many cases with bilateral severe to a profound hearing loss in patients who do not benefit from using an individual sound amplification device (ISAD).1

The complications of cochlear implantation are associated with either the surgical technique or implantation of a foreign body or device failure. The majority of publications on this subject classify complications as minor complications (requiring conservative management) and major complications (requiring surgical interventions or hospitalization for medical treatment).2,4 This classification is according to the criteria from Cohen and Hoffman.3

Major complications as electrode failure, permanent facial nerve palsy, profuse hemorrhage, post-operative acute otitis media (AOM) with perforated tympanic membrane (TM), explantation (removal of implanted device). Minor complications as wound infection, hematoma, tinnitus, vertigo, otitis media (OM), nonauditory stimulation, transient facial nerve (FN) palsy.6

Since the article published by Cohn in 1991 (one of the first extensive series evaluating the complications after cochlear implantation), the global complications rate after cochlear implantation has regularly decreased as a result of improvement of surgical techniques with smaller incisions and the use of increasingly miniaturized and biocompatible implant.7,8
Aim and objectives

This study aimed to analyze the prevalence of complications associated with cochlear implantation in Misrata central hospital, Libya.

METHODS

unilateral surgical procedures cochlear implants (CI) were performed in Misrata central hospital (MCH), Libya, between November 2012 to November 2016, involving 140 patients, retrospective data analysis was performed.

Materials

140 patients with different age complaining of sever to profound sensory neural hearing loss were operated in Misrata central hospital and the follow-up time was of at least one year for all patients.

All patients or their relatives were informed about the study protocol before surgery, and a written, informed statement consent were obtained.

All ethical approvals were obtained from Misurata Medical Center’s (MMC) ethical committee.

Device type

The type of devices used were the nucleus implant, from Cochlear company, contour advance electrode type in 139 patients and straight type electrode used in one patient (due to cochlear deformity, Mondini malformation).

Operative technique

All operations done under general anesthesia by post auricular Lazy S incision with subperiosteal temporal pocket then cortical mastoidectomy and posterior tympanotomy were done in all patients and the electrodes then inserted through round window (most of cases through round window, rare through cochleostomy). Wound closed in layers, intravenous ceftriaxone intra operative and during the first two days is routinely given.

Post-operative

Oral antibiotics and analgesia for seven days, with a wound dressing each other day for first 7-10 days until the wound healed.

Statistical analysis

Statistical analysis is performed using statistical package for social science (SPSS) software version 22 for windows. Chi square test was used for the significance of association between variables. The level of significance considered a p>0.05.

RESULTS

140 patients were included in our study, the number of males was 84 (60%); 81 children and 3 adults and the number of females was 56 (40%); 54 children, 2 adults. Total number of children was 135, with mean age 5.33 years, whereas the total number of adult 5 patients with mean age 28.64 years (Table 1).

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>N</th>
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<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
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<tr>
<td>Child</td>
<td>81</td>
</tr>
<tr>
<td>Adult</td>
<td>3</td>
</tr>
<tr>
<td>Female</td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td>54</td>
</tr>
<tr>
<td>Adult</td>
<td>2</td>
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<tr>
<td>Age (in years)</td>
<td></td>
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<tr>
<td>Child up to 18</td>
<td>135</td>
</tr>
<tr>
<td>Adult up to 60</td>
<td>5</td>
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<tr>
<td>Time of hearing loss</td>
<td></td>
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<tr>
<td>Pre lingual</td>
<td></td>
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<tr>
<td>Child</td>
<td>130</td>
</tr>
<tr>
<td>Adult</td>
<td>0</td>
</tr>
<tr>
<td>Post lingual</td>
<td></td>
</tr>
<tr>
<td>Child</td>
<td>5</td>
</tr>
<tr>
<td>Adult</td>
<td>5</td>
</tr>
</tbody>
</table>

Surgical complications

Complications occurred in 24 (17.14%) patients out of 140 cases, 4 of them were major complication (2.86%), and 20 were minor (14.28%). An intraoperative complication was seen in 4 patients while other 20 were postoperative (Table 2).

<table>
<thead>
<tr>
<th>Age (in years)</th>
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<tbody>
<tr>
<td>Children</td>
<td>21</td>
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<tr>
<td>Adult</td>
<td>3</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
</tr>
<tr>
<td>Type of complication</td>
<td></td>
</tr>
<tr>
<td>Minor</td>
<td>20</td>
</tr>
<tr>
<td>Major</td>
<td>4</td>
</tr>
<tr>
<td>Time of complication</td>
<td></td>
</tr>
<tr>
<td>Intra op.</td>
<td>4</td>
</tr>
<tr>
<td>Post op.</td>
<td>20</td>
</tr>
</tbody>
</table>

Types of major and minor complications

Major complications: The most important major complications seen in our study were incomplete insertion, explantation and wound superinfection (Table 3).
Minor complications: The most important minor complication seen in our study were infection of scalp at magnetic site (area at which internal and external parts of cochlear device met together), wound infection, intraoperative bleeding, AOM, hematoma, transient FN palsy, dizziness and vertigo (Table 4).

<table>
<thead>
<tr>
<th>Major complications</th>
<th>Incomplete insertion</th>
<th>Explantation</th>
<th>Wound superinfection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Adult</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3: Major complications.

<table>
<thead>
<tr>
<th>Minor complications</th>
<th>Magnetic site infection</th>
<th>Wound infection</th>
<th>Intra op. bleeding</th>
<th>Post op. bleeding</th>
<th>AOM</th>
<th>Hematoma</th>
<th>Posterior canal wall perforation</th>
<th>FN palsy</th>
<th>Dizziness</th>
<th>Vertigo</th>
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<tbody>
<tr>
<td>Children</td>
<td>8</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
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<td>0</td>
</tr>
<tr>
<td>Adults</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4: Minor complications

The most important and significant major complication is incomplete electrode insertion problem seen in 2 (1.42%) cases.

20 minor complications were observed in 17 children and 3 adults, (p=0.014) and managed by outpatient medical treatment (Table 4). The magnetic site inflammation was the main minor complication and seen in 8 patients (5.7%) and noticed in children only.

DISCUSSION

In this study, out of 140 cochlear implant operations, we find that the global complication is 17.14% (24 patients), major complications 2.86% (4 cases) and the minor complications for 14.28% (20 cases). This prevalence of complications in this study is little higher compared with the study done by Hoffman in which he reports global complication rate 12.2% with 7.4% of major complications in a series of 4969 implants. This is because cochlear implantation surgery in our hospital is newly started with low experience of our surgeons participate actively in cochlear implant programe and also due to short duration of the study (4 year).

The 4 major complications (2.86%) were all seen in children, (p=0.014) (Table 2). Incomplete electrode insertion seen in 2 cases (1.42%), one case due to ossification of the cochlea secondary to chronic otitis media and another case had Mondini malformation, therefore the patients with hearing loss matching etiology with potential risk for ossifying labyrinthitis must be adequately evaluated in the preoperative period about the increased risk of device insertion failure. Arnold et al and other studies show different rates of incomplete electrode insertion, some is lower and other is higher.

Second major complication was wound superinfection seen in one patient (0.7%), it is little different from literature where this is a most frequent complication. Care during making the flap is an essential factor to decrease complication. Factors that have been cited as underline causes including type of incision used, the amount of tissue handling during surgery, excessive use of diathermy are now thought to be responsible for many infective complications. Flap failure is the most common major complication has been reported as 1.55-3.3%. Surgical technique is an ultimate factor in the prevention of local flap failure. A large skin incision disturbing blood supply to the flap, over the use of diathermy may also cause the late flap necrosis. Black et al used small C shapes incision and had no major complication, whereas Gerald et al reported that classical S shaped retro-auricular incision had fewer major wound complication than C shaped incision. Kim et al reported fewer flap necrosis 3 (0.41%) out of 720 patients. In our study S-shaped incision was used. The wound infection can be reduced with prophylactic antibiotic, routinely a single dose of ceftriaxone I.V. intraoperative and postoperatively as well. Explanation occurs in one case (0.7%) due to A.O.M. bilateral with perforated tympanic membrane without reimplantation. Explanation has been reported in the literature, and postoperative complication of infection is associated with high risk of explantation.

The 20 minor complications were observed (14.28%), (p=0.0001) are required outpatient medical treatment (Table 4). In literature, the rate of minor complications has been reported as 4.4%-16%. All minor complications reported in this study were managed with conservative measures.

Magnetic site inflammation observed in 8 cases (5.7%), which less high than that reported in the literature. All were managed by local antibiotics and decrease the magnetic pressure. 3 cases (2.1%) developed wound infection within one week and treated with oral antibiotics and daily dressing, which is less than that reported in the literature. Intraoperative bleeding has also been reported in the literature. Notably, in some cases, the mastoid emissary vein is larger than usual. Therefore, it should be examined radiologically before the operation.
However, if bleeding occurs from mastoid emissary vein, it can be controlled with pressure, bone wax, or crushed muscle. In our study, there were 2 cases (1.42%) had severe bleeding from the emissary vein, controlled by pressure.

In this study, one case (0.7%) had postoperative bleeding that stopped on the 3rd postoperative day. Acute otitis media was noticed in one case (0.7%), treated with I.V. antibiotics. 1 case (0.7%) had a hematoma on the 3rd day, successfully managed with aspiration, and dressing, and antibiotics. Injury to the posterior canal wall during surgery occurred in one case (0.7%) which corrected with chips from cortical bone.

Facial nerve palsy was observed during the immediate postoperative period in one case (0.7%), comparable to the rates reported by Mosnier et al, which is (0.7%), or by the Cochlear company (0.4%) based on a larger series. Many authors have reported facial nerve paralysis or paresis in their series with different incidence from 0.53% to 3%. It happened may be due to the possibility of intraoperative heating of the facial nerve during cochleostomy or following posterior tympanostomy. The facial nerve is at risk as a surgical approach through the facial recess to mesotympanum for cochleostomy, this is can be avoided by using facial nerve monitor but this is not guaranteed of avoidance of injury. This complication can be further limited by accurate preoperative assessment of the course of the facial nerve by CT scan of the petrous temporal bones.

In this study, the facial nerve palsy treated by corticosteroid and physiotherapy. It happened might be due to of thermal injury of the facial nerve during cochleostomy or posterior tympanostomy. Continuous irrigation should be used while opening the facial recess since considerable thermal energy is produced by diamond burrs and burr shaft.

Vestibular complications, dizziness, and vertigo were reported in two patients, occurred immediately postoperatively and rapidly resolved in response to medical treatment.

In literature, the rate of minor complications has been reported as 4.4% to 16%. In this study 20 (14.2%). All minor complications reported in this study were managed with conservative measures.

**CONCLUSION**

Surgical complications is very low, and most of them successfully treated conservatively or by minor intervention. These complications should be kept in mind during cochlear implant surgery and can be avoided or decreased with careful preoperative evaluation, delicate surgical technique and appropriate postoperative care and follow up. However further researches on other population are recommended.

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**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

**REFERENCES**
