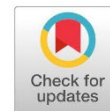


Research Article

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Cochlear Implant Complications in Children: Libyan Scenario and Experience

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Abstract:

A cochlear implant (CI) is considered a safe procedure. However, complications may happen either due to the presence of the implant itself, which acts as a foreign body, or congenital anomalies of the ear. One hundred eighty-two children implanted by the cochlear implant team in the Specialty Surgical Center (SSC)/Benghazi-Libya between May 2012 and December 2021, were recruited in this study. Demographic data: name, age and sex, vaccination history, audiological and radiological assessment in the form of a CT scan of the temporal bone and brain MRI, surgical procedures, and any difficulties encountered during the operation were recorded. Complications encountered were grouped as major and minor ones. One hundred eighty-two patients were studied; the age range was from seventeen months to twelve years. The major complications that need hospitalization or surgical interventions were seen at 3.29%, whereas minor complications that do not require hospitalization but resolve spontaneously or are treated in an outpatient department account for 13.7%. Accidental trauma was the major risk factor seen in both major and minor complications. Cochlear implantation in children continues to be reliable and safe in experienced hands, with a low percentage of severe complications as long as long-term medical follow-up is available. Major Complications of CI in children in SSC are related to trauma and hematoma formation as a major factor.

Keywords: Children, Cochlear Implantation, Cochlear Implant Complications, Complications.

INTRODUCTION:

Cochlear implantation (CI) is a relatively safe procedure (Arnoldner et al., 2005; Beadle et al., 2005; Black et al., 2007; Lassig et al., 2005). However, complications may occur. The rate of complications or re-implantation also has a direct economic impact (Sefein, 2018). Complications of cochlear implant surgery reflect the operation complexity, the skill of the surgical team, and the inherent risks of the procedure itself and risks inherent to the deep insertion of a large foreign body below the scalp (Cohen & Hoffman, 1993). Surgery has greatly changed, aiming at reducing the incidence of medical perioperative and postoperative complications, besides the efforts of the device manufacturing companies to correct system failures. Despite all of these, complications still happen, having an incidence of 12% in Cochlear Implant Centers in the USA (Cohen et al., 1991).



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Complications are classified into major if they require additional surgery or hospitalization and minor when they resolve in an outpatient clinic or even with no treatment, as advocated by (Cohen et al., 1988). Major complications involve meningitis, flap necrosis, device failure, electrode extrusion, facial nerve paralysis, and others, while minor complications involve facial nerve stimulation, electrode migration, vertigo, tinnitus, and others. The major complications that require surgery review, especially those associated with device insertion, are not common (Webb et al., 1991). American Cochlear Implant Centers reported an incidence of major and minor complications of 8% and 4.3%, respectively, in a sample of 2,751 implanted patients (Cohen & Hoffman, 1993).

The risk of bacterial meningitis, while low, is about thirty times as high compared to people who don't undergo CI procedures. Vaccination prior to the procedure is recommended. The surgical procedure most often used to implant the device is called mastoidectomy with a facial recess approach (Yawn et al., 2015).

MATERIALS AND METHODS

The present retrospective study was carried out at a specialty surgical center (SSC) for ENT & Urology in Benghazi/Libya, which is a governmental tertiary hospital. Children from 17 months to 12 years underwent cochlear implantation by the cochlear implant team in the SSC cochlear implant unit. Informed written consent was taken from the parents of the children in the specific informed consent form. The current study was approved by the Institute of Ethics Review Board.

This study highlighted the cochlear implant complications in one hundred eighty-two children ranging between seventeen months and twelve years of age. All the clinical data collected were studied for major and minor complications.

Surgeries were done between May 2012 and December 2021. The postoperative complications were classified into A) Minor when they resolved with minimal or no treatment and B) Major when they require additional surgery or hospitalization. Each child has a preoperative evaluation and a vaccination card that includes

HIB (Hemophilus influenza B), Meningococcal, and pneumococcal vaccines are obligatory to administer to children in Libya. Hearing aid trials (for 3-6 months) and speech rehabilitation were undertaken. The following assessments were made in the children who participated in the procedure: Clinical, audiological, and radiological assessment in the form of a CT Scan of the Temporal Bone and an MRI Brain scan.

There were three cases of renal tubular acidosis and one child with Alport syndrome on peritoneal dialysis. Systemic antibiotic ceftriaxone sodium (Augmentin) was given one day before surgery and one week post-operatively. A systemic steroid was given intraoperatively and for three to four days post-operatively.

A surgical approach is a post-auricular cortical mastoidectomy followed by a posterior tympanotomy, then a cochleostomy or round window approach. The round window approach is the main procedure in most of the cases. Drilling the device bed and tunnel for the electrode for the stability of the device was done in all cases. Device activation was done after four weeks post-surgery. Complications vary from one center to another because of different classification methods. Some reports consider device failure a major complication. However, others exclude it as it is not related to medical or surgical consequences but rather a manufacturer failure, as seen in Table 1.

Table (1) shows the results of major & minor complications at different centers in comparison with SSC.

No.	Author/year	Major complications	Minor complications	Total
1.	(Cohen et al., 1988)	12%	7%	19%
2.	(Loundon et al., 2010)	5.5%	4.4%	9%
4.	(Sefein, 2018)	10.7%	8.03%	18.73%
5.	(de Jong et al., 1998)	3.8%		3.8%
6.	(Webb et al., 1991)	13%	0.7%	13.7%
7.	(Kempf et al., 1999)	3		3%
8.	SSC (Benghazi/Libya)	3.29%	13.7%	16.99%

This variation in the incidence of complications is because some centers include adults and children in the same study, and others do not. Device failure is not a surgical or medical complication. Some authors include it in major complications, while others exclude it.

A study (Cohen & Hoffman, 1993) characterized implant-related complications as major if they required revision surgery and minor if they resolved conservatively. In this study, fifty-five major (12%) and thirty-two minor (7%) complications were reported. Another published report by (Webb et al., 1991) reported their experience of one hundred fifty-three patients. They report 13% major and 0.3% minor complications. In a third study at the Clinical Center of Vojvodina, a center for CI, complications were observed in 10.05% of performed surgical procedures (Dankuc et al., 2014).

A study in Egypt in 2018 by (Sefein, 2018), reported major complications in twelve cases (10.7%), of which two (1.79%) patients required re-implantation, and the number of minor complications was nine (8.03%). Trauma to the mastoid area was shown to correlate with major delayed complications.

The inner ear malformations are another causative factor of major complications. Natalie Loundon et al. and their co-workers (Loundon et al., 2010) in Brazil reported a complication of 9.9% (major 5.5%, minor 4.4%). The major complication rate was one of two hundred sixty-two patients (0.4%) in Iran (Ajallouyeen et al., 2011). In a multicenter analysis of implantation in the United States, (Cohen et al., 1991) reported a major complication rate of 3.9% for three hundred nine children, though it seems that device failure was included in their criteria as a major complication. (Kempf et al., 1999) reported a major complication rate of 3% among one hundred cases (Kempf et al., 1999).

(Ray et al., 2004) reported a major complication rate of 6% in the first one hundred adults who underwent implantation in Sydney, but they include an obliterated cochlea that could not be implanted, as a surgical complication. (de Jong et al., 1998) reported major complications in two out of fifty-two (3.8%) children who underwent implantation in Toronto, one of which was a device failure. In a large single-center pediatric series, (de Jong et al., 1998) reported 8.9% and 7.8% of major and minor complications.

RESULTS

In this current study, one hundred eighty-two (182) children were included, with equal male and female distribution and age ranges from 17 months to 12 years. 91.2% of the cases are at the age of 6 years and below (166 patients), as seen in Figure 1. Complications are seen in 16.99% of cases, as seen in Figure 2. Minor complications are seen in 25 cases (13.7%), as shown in Table 2, whereas major complications are seen in 6 cases (3.29%), as shown in Table 3.

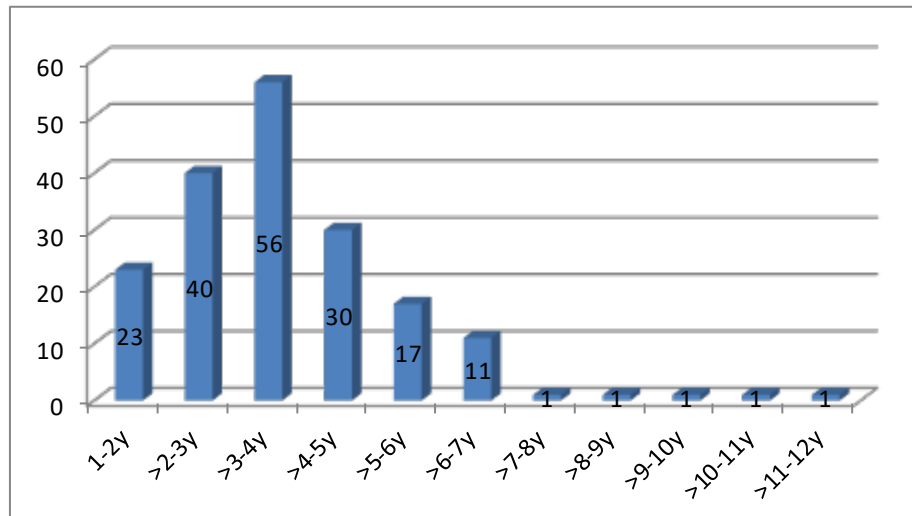


Figure (1). Distribution of cases according to age in years:

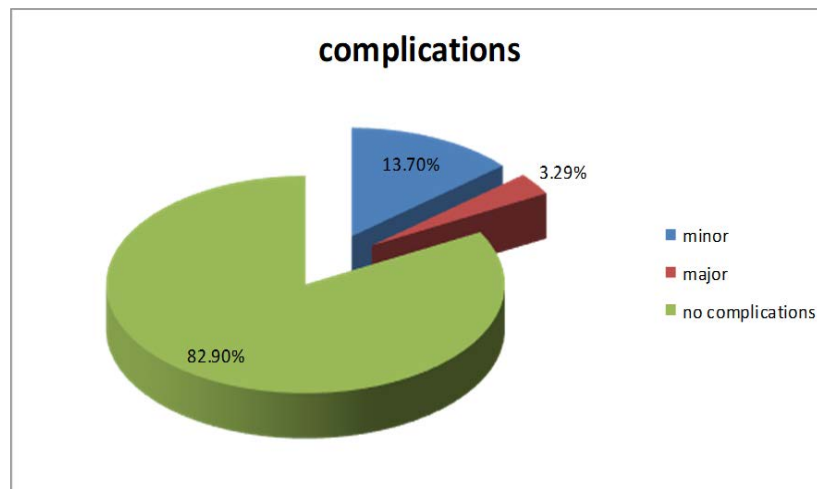


Figure (2): Percentage of major and minor complications:

Table (2): Minor complications and their management & outcome

No	Complications	Number of cases	Outcome
1.	Minimal swelling at the operation site	3	resolved by bandage dressing
2.	Corneal abrasion and keratitis	4	antibiotic ointment & drops
3.	Incomplete insertion of the electrode	2	Did well post-operative
4.	Minimal epistaxis	2	Stop spontaneously
5.	Do not use an external device.	1	Family education and reassurance
6.	Vomiting	5	Antiemetic
7.	Transient facial nerve paresis	1	Resolved spontaneously
8.	Accidental injury of the external auditory canal and dura	5	Passed without any harmful effect
9.	Eye twitches in two cases	2	Reprogramming
10	Total No. of complications	25	

Table (3). Major complications and their management

No.	Complications	Number of cases	Management
1.	Wound gap (clean wound).	2	Re-stitched in the operation room
2.	Haematoma formation. First week post-operative	2	Aspiration or incision and drainage then re-stitched in the operation room
3.	Late Haematoma formation (after 9 yrs.)	2	*Incision and drainage and repositioning of CI in one case *Re-implantation on the other side in the other case
Total No. of complications		6	

Wound gap and hematoma healed well when recognized early. Late hematoma after accidental head trauma may occur at any time as children play and move without caution. In one case, drainage was done. The area was cleaned, and the wound edges were re-stitched. It did well for some time, but then the wound dehiscence recurred again. The wound was cleaned under anesthesia and the site of the implant was changed on the same ear. The wound was stitched and the patient did well. Another case comes with an infected hematoma after a fall. Dressing and cleaning of the wound were tried many times, but biofilm formed and was removed from the implant, cleaning of the wound was done, and re-implantation on the other ear was performed. Cases of corneal abrasions on the same side of an operated ear were treated by an ophthalmologist using local antibiotics and eye closure for a few days without any subsequent harmful effects.

DISCUSSION:

The success of cochlear implantation (CI) as an auditory rehabilitative tool requires a thorough knowledge of indications, limitations, and potential risks (Dankuc et al., 2014). Although CI is a safe procedure, complications still happen.

The youngest implanted child in this series was at the age of 17 months. More than 77% of the cases were below the age of 4. Early diagnosis of hearing loss leads to early intervention and less hearing deprivation of neural cells. This improves post-operative results in terms of language and speech development and early school integration.

With regard to hematoma formation or swelling around the device, bandage dressing should be kept for the first week postoperatively to avoid swelling at the operation site and to avoid the risk of post-operative wound infection. Corneal abrasions were noticed in four cases; a head drape during surgery is thought to be the reason for that. Careful eye closure with plaster should be done before the operation to avoid accidental corneal abrasion by dressing during surgery.

No case of meningitis has been recorded in this series. Completion of the vaccination program was insisted on before the operation.

Two cases of hematoma developed after nine years of implantation, which highlights that long-term close follow-up is needed to pick up and treat hematoma before infection and biofilm development. Results of SSC/Benghazi/Libya in major complications are favorable. We selected straightforward cases for surgery. We didn't face gusher or post-operative meningitis in this series of cases. Minor complications were greater (13.7%) because post-operative anesthesia complications, such as vomiting in minor complications, were included. No cases of device failure have been reported in this

series. However, one patient did not use his external device. We include this as a minor complication.

CONCLUSION

To conclude, our current study reported that precautions should be taken to minimize complications in CI surgery. In this study, accidental trauma and hematoma formation act as a precursor for infection and wound breakdown with possible device extrusion. It should be taken into consideration from the immediate post-operative day and for life. If these complications are recognized early, aspiration alone is sufficient. Delayed recognition and intervention lead to infection, biofilm formation, wound breakdown down, and even extrusion of the implant. Long-term close follow-up is necessary for early recognition of complications. Major complications of CI in children in SSC are related to trauma and hematoma formation as a major factor.

Cochlear implantation in children continues to be reliable and safe in specialized centers of CI and experienced hands, with a low percentage of severe complications as long as long-term regular medical follow-up is available.

Our recommendations are family education and taking preventive measures to avoid trauma, especially in the head as much as possible.

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Author contributions: Contribution is equal between authors.

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REFERENCES:

- Ajallouyeen, M., Amirsalari, S., Yousefi, J., Raeesi, M.-A., Radfar, S., & Hassanlifard, M. J. I. J. o. P. (2011). A report of surgical complications in a series of 262 consecutive pediatric cochlear implantations in Iran. *21*(4), 455.
- Arnoldner, C., Baumgartner, W. D., Gstoettner, W., & Hamzavi, J. J. A. o.-l. (2005). Surgical considerations in cochlear implantation in children and adults: a review of 342 cases in Vienna. *125*(3), 228-234.
- Beadle, E. A., McKinley, D. J., Nikolopoulos, T. P., Brough, J., O'Donoghue, G. M., Archbold, S. M. J. O., & Neurology. (2005). Long-term functional outcomes and academic-occupational status in implanted children after 10 to 14 years of cochlear implant use. *26*(6), 1152-1160.
- Black, I., Bailey, C., Albert, D., Leighton, S., Hartley, B., Chatrath, P., & Patel, N. J. C. I. I. (2007). The Great Ormond Street Hospital paediatric cochlear implant programme 1992–2004 a review of surgical complications. *8*(2), 53-67.
- Cohen, N. L., Hoffman, R. A., Stroschein, M. J. A. o. O., Rhinology, & Laryngology. (1988). Medical or surgical complications related to the Nucleus multichannel cochlear implant. *97*(5_suppl2), 8-13.

- Cohen, N. L., & Hoffman, R. A. J. A. i. O.-r.-l. (1993). Surgical complications of multichannel cochlear implants in North America. *48*, 70-74.
- Cohen, N. L., Hoffman, R. A. J. A. o. O., Rhinology, & Laryngology. (1991). Complications of cochlear implant surgery in adults and children. *100*(9), 708-711.
- Dankuc, D., Šegan, D., Komazec, Z., Vlaški, L., Lemajić-Komazec, S., & Sokolovac, I. J. M. p. (2014). Cochlear implant surgery at the Clinical Center of Vojvodina-ten-year experience. *67*(suppl. 1), 25-31.
- de Jong, A. L., Nedzelski, J., Papsin, B. C. J. J. o. O.-H., & Surgery, N. (1998). Surgical outcomes of paediatric cochlear implantation: the Hospital for Sick Children's experience. *27*(1), 26.
- Kempf, H.-G., Johann, K., & Lenarz, T. J. E. a. o. o.-r.-l. (1999). Complications in pediatric cochlear implant surgery. *256*, 128-132.
- Lassig, A.-A. D., Zwolan, T. A., Telian, S. A. J. O., & Neurotology. (2005). Cochlear implant failures and revision. *26*(4), 624-634.
- Loundon, N., Blanchard, M., Roger, G., Denoyelle, F., Garabedian, E. N. J. A. o. O. H., & Surgery, N. (2010). Medical and surgical complications in pediatric cochlear implantation. *136*(1), 12-15.
- Ray, J., Gibson, W., & Sanli, H. J. C. i. i. (2004). Surgical complications of 844 consecutive cochlear implantations and observations on large versus small incisions. *5*(3), 87-95.
- Sefein, I. K. J. T. E. J. o. O. (2018). Surgical complications and morbidity in cochlear implantation. *34*, 33-41.
- Webb, R. L., Laszig, R., Lehnhardt, E., Pyman, B. C., Clark, G. M., Franz, B. K.-H. J. A. o. O., Rhinology, & Laryngology. (1991). Surgical complications with the cochlear multiple-channel intracochlear implant: experience at Hannover and Melbourne. *100*(2), 131-136.
- Yawn, R., Hunter, J. B., Sweeney, A. D., & Bennett, M. L. J. F. R. (2015). Cochlear implantation: a biomechanical prosthesis for hearing loss. *7*.