Cochlear implantation in Aksay University Clinic: A review of 135 cases

Operacje wszczepienia implantu ślimakowego w Klinice Uniwersytetu Aksay: przegląd 135 przypadków

Dina Galymkyzy Kussainova1ABCDE, Aigul Rakhmanalieva Medeulova1ABCDE, Rustem Moldir2E

1Department of Otorhinolaryngology, Asfendiyarov Kazakh National Medical University, Almaty, Kazakhstan
2Faculty of Medicine and Health, Al – Farabi Kazakh National University, Almaty, Kazakhstan

ABSTRACT:

Introduction: Around 430 million people today suffer from mild to profound hearing loss and require rehabilitation. One option offered to patients with sensorineural hearing loss is cochlear implantation.

Objective: The aim of this study was to determine the complication rate after cochlear implantation over an 8-month period. All complications were divided into 3 main groups: minor postoperative, major postoperative, and device-related failures. Additionally, the methods for prevention and management are discussed.

Study design: Retrospective analysis of surgical complications after cochlear implantation

Methods: Our study included a total of 135 children (65 boys and 70 girls) who underwent cochlear implantation in Aksay University Clinic from January 2022 to August 2022. The follow-up period ranged from 8 to 15 months. The mean age at the time of their respective procedures was 3.9 years (age range: 6 months – 17 years 8 months).

Results: A total of 21 complications (15.5%) were registered among the 135 patients. Of these, 9 (6.6%) were major complications and 12 (8.8%) were minor. The most prevalent cause of major complications was electrode misplacement (5 patients, 3.7%), while for minor complications it was hematoma (9 patients, 6.6%). In our study, there were more postoperative major complications and the number of complications was generally comparable to the world literature.

Conclusion: Cochlear implantation is a safe, modern surgical procedure for treating sensorineural hearing loss and it is associated with a low complication rate. However, patients have to be informed about all possible complications and surgeons have to know the means of optimal prevention.

STRESZCZENIE:

Wprowadzenie: Obecnie około 430 milionów ludzi cierpi z powodu upośledzenia słuchu o nasileniu od łagodnego do głębokiego i wymaga z tego powodu rehabilitacji. Jedną z opcji terapeutycznych dostępnych dla pacjentów z niedosłuchem czuciowo-nerwowym jest operacja wszczepienia implantu ślimakowego.

Cel: Celem niniejszego badania była ocena częstości występowania powikłań po operacji wszczepienia implantu ślimakowego w okresie 8 miesięcy. Wszystkie powikłania podzielono na 3 duże grupy: łagodne powikłania pooperacyjne, poważne powikłania pooperacyjne, a także powikłania związane z urządzeniem.

Projekt badania: Retrospektywna analiza powikłań chirurgicznych po operacji wszczepienia implantu ślimakowego.

Metody: Przeprowadzone przez nas badanie obejmowało łączny zespół 135 dzieci (65 płci męskiej, 70 płci żeńskiej) poddanych operacji wszczepienia implantu ślimakowego w Klinice Uniwersytetu Aksay w okresie od stycznia 2022 r. do sierpnia 2022 r. Okres obserwacji wahał się 8–15 miesięcy. Średni wiek w czasie wykonywania operacji wynosił 3,9 lat (przedział wiekowy: od 6 miesięcy do 17 lat i 8 miesięcy).

 Wyniki: Łącznie obserwowano wystąpienie 21 (15,5%) powikłań u 135 pacjentów. Spośród nich 9 (6,6%) było powikłaniami ważnymi, a 12 (8,8%) powikłaniami łagodnymi. Najczęstszym rodzajem poważnych powikłań była niewłaściwa lokalizacja elektrody (5 pacjentów; 3,7%), w przypadku powikłań łagodnych najczęściej występowały krwawienia (9 pacjentów; 6,6%). W naszym badaniu wykazana została większa liczba poważnych powikłań pooperacyjnych. Jednakże ogólnie częstość występowania powikłań jest porównywalna z danymi z literatury światowej.

Wnioski: Operacja wszczepienia implantu ślimakowego jest bezpiecznym i nowoczesnym zabiegiem chirurgicznym stosowanym w leczeniu niedosłuchu czuciowo-nerwowego i wiąże się z niskim odsetkiem powikłań. Jednakże pacjenci muszą być informowani o wszystkich możliwych powikłańach, aby chirurdzy mogli szybko i za pomocą optymalnej profilaktyki ich redukować.
INTRODUCTION

The World Health Organization (WHO) estimates that 430 million people worldwide suffer from hearing loss and require rehabilitation and that 34 million of them are children (congenital hearing loss affects 1–2 out of every 1,000 newborns) [1, 2]. The most striking consequence of profound hearing loss in children is the deterioration of speech development [3–5].

Nowadays, cochlear implantation (CI) is the safest and most effective procedure offered for patients with severe and profound sensorineural hearing loss. This surgery has a history of more than 30 years. The aim of CI is to improve the quality of life of patients with severe or profound hearing loss by developing the ability to hear and reproduce sounds, which contributes to understanding others, communicating effectively, and safely moving around their environment [6].

CI has been performed in Kazakhstan since 2007 [6]. The guaranteed amount of free medical care covers one-sided CI with the right to install a cochlear implant on the contralateral ear the following year. This procedure was introduced at Aksay University Clinic (Almaty, Kazakhstan) in 2007 and almost 5,000 children have since gained the ability to hear. There is an audiology center which is fully equipped to provide high-quality specialized medical and diagnostic care for children with sensorineural or conductive hearing loss.

The purpose of this paper is to retrospectively analyze the clinical outcomes after cochlear implantation performed in our clinic between January and August 2022. The rates of intraoperative and postoperative complications were evaluated.

MATERIAL AND METHODS

A total of 135 children were included in this study (65 boys and 70 girls; age range: 6 months – 17 years 8 months; mean age: 3.9 years). Their diagnoses were confirmed by audiological examination in our center and CT imaging of the temporal bone pyramids was performed. All children underwent cochlear implantation consecutively between January 2022 and August 2022 at the Department of Otorhinolaryngology, Aksay University Clinic; they all underwent a follow-up period of at least 8 months. All parents signed their informed consent for the procedure which included information about the possible outcomes. All surgeries were performed by one experienced surgeon.

The standard surgical procedure was performed in all children: retroauricular skin incision, posterior tympanotomy, and routine mastoidectomy. Round window or promontorium cochleostomy was performed to insert an electrode into the cochlea. Auditory nerve response telemetry was performed afterward. As there is no opportunity to perform intraoperative X-ray imaging of the temporal bone to verify the correct positioning of the electrode, we do imaging right after the patient regains consciousness in the intensive care unit.

In the majority of cases, a Med-EL device (MedEl, Austria) was used (n = 115; 85%). Ten patients (7.5%) received a Cochlear device (Cochlear Corporation, Australia) and 10 patients (7.5%) received an Advanced Bionics device (Advanced Bionics Corporation, CA) (Tab. I.).

Negative outcomes were classified according to Cohen and Hoffman [7]:

1. Medical/surgical complications:
   • major (those which required further surgery and/or hospitalization for treatment);
   • minor (those which healed by themselves and/or with medication).

2. Device-related problems (mechanical failure of the implanted device).

RESULTS

A total of 135 children underwent CI and were included in our study. Of them, 112 were implanted unilaterally for the first time (83%); 22 patients were hospitalized for the second CI on the contralateral ear (16.3%); and 1 patient (0.7%) underwent bilateral cochlear implantation.

A total of 21 (15.5%) complications were observed in 136 cochlear implants placed in 135 patients (Tab. II.). Nine (6.6%) of these were major and 12 (8.8%) were minor complications.

MAJOR COMPLICATIONS

Nine major complications were observed in the follow-up period (Tab. II.). A total of 5 patients (3.7%) required reimplantation in the next 3–24 postoperative hours due to electrode misplacement.

ABBREVIATIONS

CH-IV – cochlea with hypoplastic middle and apical turns
CI – cochlear implantation
CSF – cerebrospinal fluid
CT – computed tomography
EABR – electrically evoked auditory brainstem response
ECAP – electrically evoked compound action potential
ECoG – electrocochleography
HADS – Hospital Anxiety and Depression Scale
IP-II – Mondini deformity
MRI – magnet resonance imaging
NRT – neural response telemetry
OAEs – intraoperative otoacoustic emissions
WHO – World Health Organization
Two patients (1.9%) underwent reimplantation due to the coil of the implant being displaced, as confirmed by X-ray imaging at least one month after the operation due to no answer during device setup. Successful reimplantation was performed in all of these patients.

One patient suffered from tympanic membrane perforation perioperatively. The child was discharged home with recommendations and presented with a fully recovered tympanic membrane at the 3-month follow-up visit.

There was 1 patient (0.7%) with late postoperative inflammation of the mastoid process. Postauricular dressings and intramuscular antibiotics were prescribed to the patient. There were no symptoms of intracranial involvement associated with implantation; therefore, surgery was not required.

No other listed major complications were observed during the follow-up period (Tab. II.).

**MINOR COMPLICATIONS**

Twelve minor complications were observed and required outpatient medical care or prolongation of the hospital stay. Two children (1.4%) suffered from transient vestibular syndrome lasting up to 1.5 months after the operation. All patients were consulted additionally by a neurologist and were prescribed an anti-vertigo medication (Betaser® 8 mg/16 mg, approved in Kazakhstan to treat nausea, vomiting, tinnitus, and vertigo) and saline solutions.

Minor hematomas developed in 9 cases (6.6%). These were found during daily wound dressing 24–72 hours postoperatively and cured with needle aspiration and/or pressure dressings with hypertonic saline solution. No additional surgery was performed. The patients were discharged from the hospital on the 7th–12th day after operation.

One child (0.7%) developed a keloid scar retroauricularly 1 month after the operation. She was recommended a topical keloid scar cream.

There were no reported cases of acute otitis media in our study. As the average age of our patients was 3.9 years, it is difficult to analyze the dysfunction of chorda tympani (taste disorders). None of the cochlear implant devices showed technical damage during the follow-up period.

**INTRAOPERATIVE FINDINGS**

Of the 135 patients, 6 children (4.4%) had malformations of the middle and/or inner ear (Tab. III.). Four children (2.9%) had a middle ear and/or inner ear anomaly. Inner ear anomalies were classified according to Sennaroglu and Bajin (2017) [8]. Two children had hypoplasia of the tympanic cavity with normal cochlea, while 1 child presented with rotated cochlea (not classified) and 1 had a cochlea with hypoplastic middle and apical turns (CH-IV). Two children (1.4%) had a severe inner ear malformation, such as a Mondini deformity (IP-II).

Cochlear ossification was found in 5 patients (3.7%): 4 cases were identified before CI (confirmed by CT scan of the temporal bones), while the remaining case was found in the operating room (the CT scans of this patient showed no anomaly of the cochlea preoperatively). Anamnesis morbi of some of these patients represents a previously transferred neuroinfection.

A cerebrospinal fluid (CSF) gusher was found in 2 cases (1.4%). Round window sealing with a temporalis muscle flap was performed in all cases. One patient underwent a reimplantation on the following day because the electrode was displaced by the increased flow of CSF. No cases of meningitis occurred.

Mucosal hyperplasia and edema of the tympanic cavity was observed in 9 children (6.6%), which hindered identification of anatomical landmarks and prolonged the operation time.

One patient presented a bare geniculum of facial nerves. There was no transient or permanent facial nerve palsy in the follow-up period.

All of the patients underwent successful CI procedures despite the intraoperative findings.

**DISCUSSION**

Increased audiologic screening of newborns in Kazakhstan led to early detection of children with sensorineural hearing loss. They could thus receive the most modern and advanced medical care as early as possible. Nowadays, with the improved surgical techniques and implant models, cochlear implantation has become a routine procedure. Because of the increased patient flow, it is important to raise awareness about all potential negative outcomes.

The complication rate during cochlear implantation is a well-studied area. Cohen and Hoffman (1991) were the first authors to...
describe the negative outcomes and divide them into major and minor ones [6]. They reported rates of 4.8% and 7% for minor and major complications, respectively. Since that time, numerous studies have been published with complication rates following cochlear implantation. A recent study by Dagkiran et al. (2020) revealed rates of 4.75% for major complications and 5.44% for minor ones in 1,452 patients [9]. On the other hand, a retrospective analysis of 148 cases by Garrada et al. (2021) showed 11.5% and 7.4% (minor and major outcomes, respectively) with an overall rate of 18.9% [10].

In our study, the total rate was 15.5%, with 8.8% for minor complications and 6.6% for major complications.

This procedure culminates in the positioning of the electrode array inside the cochlea. Misplacement of the implant's electrode was identified as the most prevalent major complication in our research. X-ray imaging in Schuller's view confirmed that the electrode arrays were implanted mostly in the internal auditory meatus, hypotympanic air cells, and vestibule. In 5 patients (3.7%), reimplantation was done 3–24 hours postoperatively. The correct location of a misplaced electrode array was confirmed postoperatively using X-ray imaging of the temporal bone. All patients underwent successful device setup after 1 month.

A literature review on CI complications reported that the prevalence of incorrect electrode positioning ranged from 0.2% to 5.8%, with an average of 1.02%. Auditory tube, internal acoustic meatus, internal carotid artery, vestibule of the inner ear, and superior semicircular canal were noted as the most typical areas of misplacement [11].

The following general advice can be given to avoid misplacement:

1. **Preoperative** – proper evaluation of CT scans of the temporal bones and detailed examination of the round window region (to exclude inner ear anomaly, hyperplasia, and edema of the mucous membrane of the middle ear); thorough collection of disease anamnesis should be done as a routine procedure in every case prior to CI; additional MRI imaging is valuable in cases of inner ear deformities, as it provides the opportunity to analyze the anatomical structures, create a preoperative surgical strategy, make a postoperative prognosis (for example, early fibrosis of the cochlea which will not be visualized in CT imaging), and visualize a cochlear nerve directly.

2. **Intraoperative** – good visualization of the anatomical structures (round window, stapedial tendon, and pyramidal recess) before implantation of the electrode, as well as electrophysiological tests to confirm the correct positioning of a cochlear electrode during cochlear implant surgery.

- Electrically evoked compound action potential (ECAP) – measures the neural response to electrical stimulation of the cochlea, assesses the viability of the auditory nerve, and confirms the proximity of the electrode to the target neural tissue [12];
- Neural response telemetry (NRT) – evaluates the response of the auditory nerve to electrical stimulation, providing information about stimulation thresholds and the interaction between the electrode and the auditory nerve, and aids in determining the electrode's location and verifying a functional connection between the electrode and the auditory nerve; although neural response telemetry cannot confirm whether the active electrode is implanted inside the scala tympani or in the inner ear vestibule (as vestibular and cochlear action potentials may be the same), it is nonetheless a useful tool [11];
- Electrically evoked auditory brainstem response (EABR) – evaluates the neural responses along the auditory pathway, including the brainstem, measures the electrical activity generated in response to cochlear stimulation, and provides information about the cochlear implant’s functionality [12];

**Tab. II. Distribution of cochlear implantation complications among patients.**

<table>
<thead>
<tr>
<th>MAJOR COMPLICATIONS</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misplacement</td>
<td>5</td>
<td>3.7%</td>
</tr>
<tr>
<td>Displacement</td>
<td>2</td>
<td>1.9%</td>
</tr>
<tr>
<td>Facial nerve damage</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Flap necrosis</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Wound infection required surgery</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Major hematoma required surgery</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Cholesteatoma</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Tympanic membrane perforation</td>
<td>1</td>
<td>0.7%</td>
</tr>
<tr>
<td>Meningitis</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Mastoiditis</td>
<td>1</td>
<td>0.7%</td>
</tr>
<tr>
<td>Seizures</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Subtotal</td>
<td>9</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MINOR COMPLICATIONS</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vestibular syndrome (vertigo, nausea, vomiting)</td>
<td>2</td>
<td>1.4%</td>
</tr>
<tr>
<td>Minor hematoma</td>
<td>9</td>
<td>6.6%</td>
</tr>
<tr>
<td>Long healing of skin incision</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Cosmetic defect (formation of keloid scar)</td>
<td>1</td>
<td>0.7%</td>
</tr>
<tr>
<td>Chorda tympani dysfunction</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Acute otitis media</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Subtotal</td>
<td>12</td>
<td>8.8%</td>
</tr>
<tr>
<td>Device-related failure</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

**pathology** can lead to improper positioning of an implant electrode. The most prevalent cause is accidental positioning of an electrode into hypotympanic air cells, especially if the location of the round window is in doubt. In cases of fibrous or bony obliteration of the round window, such a situation may happen even in the hands of a surgeon with extensive experience. Therefore, reliance on anatomical landmarks such as oval window, stapes position is vital after opening the facial recess. The exact location of the round window and promontory must be identified by a surgeon and must not be mistaken with hypotympanic air cells [11].
Electrocochleography (ECoG) – records the electrical potentials generated within the cochlea in response to sound or electrical stimulation and can be used to assess the cochlear microphonic response and the compound action potential in order to verify the electrode placement [11, 12];

Intraoperative otoacoustic emissions (OAEs) – measure the sounds produced by the cochlea in response to external stimuli, can help assess the integrity of the cochlear mechanics, and can indirectly confirm the appropriate position of the electrode [12];

Impedance – measures the electrical resistance and reactance of the cochlear implant electrode within the cochlea; monitoring impedance values can provide information about the electrode’s position and the integrity of the electrode–tissue interface [12].

It’s important to note that the specific tests used during cochlear implantation may vary depending on the surgeon’s preference and the available equipment. In our study, we used neural response telemetry to identify the location of the electrode.

3. Postoperative – in case of any doubts, immediate X-ray imaging in Schuller’s view should be used to confirm the proper placement of electrodes right after implantation. If the surgery went well and neurophysiological measures are good, many centers today do not perform routine X-ray imaging.

In our study, 2 children underwent cochlear reimplantation due to device displacement which was found spontaneously at 1 and 2 months postoperatively, although intraoperative electrophysiological tests were positive and postoperative radiological imaging confirmed proper positioning of the implant. No direct causes such as head injury or retroauricular edema were observed according to the parents. In both cases, migration was found during the first implant connection. The body of the implants were found at a lower position than usual in both patients.

Though device migration is extremely rare and there are few studies related to this problem, the surgeon must place and fix the body of the implant adequately by creating a perichondrial bed using a device sample where particular device will ideally fit.

There was 1 patient (0.7%) with late postoperative mastoiditis. He complained of swelling of the mastoid area and mild pain during palpation 3 months after cochlear implantation. There were no symptoms of intoxication or intracranial problems associated with the implant. Retroauricular dressing and intravenous antibiotics were administered to the patient. The symptoms regressed 3 days later and the patient was discharged with further recommendations.

Our patients had no cases of flap necrosis or infection in the early postoperative period. A longer follow-up period is needed to investigate the late postoperative period. In the literature, the prevalence of flap necrosis is reported as 0.24–3.8% and the rate of flap infection was 2.04% [13–16]. Thus, it is crucial to follow the vascular feeding of the flap when performing the flap incision, to appoint adequate antibiotic therapy intraoperatively, and to change the wound dressings daily [9].

Seizures are typically the most frightening complication after CI for most parents. Out of 816 children who were implanted in a study by Shinghal et al. (2012), 10 of them were reported to have seizures based on examinations by a pediatric neurologist and brain electrical activity tests. Three of these 10 children reported seizures for the first time after cochlear implantation. However, no direct cause was found between cochlear implantation and seizures [17].

Temporary or permanent facial nerve paralysis is another unpleasant outcome which may appear after cochlear implantation. As facial nerve monitoring is routinely used in our institution, we did not experience this complication during the study period. Dagkiran et al. (2020) reported a rate of facial nerve paralysis of 0.34%, compared to 0.7% reported in other studies. Most of the cases improved spontaneously over time or with steroid therapy [9].

Hematomas ranging from large to small are also an issue in the postoperative period. In our study, we had no cases of major hematomas requiring drainage in the operating room, while the rate of minor hematomas was 6.6%. Needle aspiration and pressure dressing with 3% NaCl solution were enough to control hematomas in these patients. In the literature, the rate varies from 0.4–5.8% after CI [18–20]. The type and depth of incision, the coagulation profile, the tightness of the postoperative dressing, and trauma are predisposing factors for hematoma [9].

In our study, 2 children (1.4%) suffered from vestibular syndrome, which included symptoms of vertigo, dizziness, nausea, and vomiting more than 4 times (they were not those children who were reoperated). The prevalence of vertigo after CI has been reported as 2–35%, and 20–80% for vestibular dysfunction [21, 22]. Although CI is a routine surgery which is done on an everyday basis, the chance of damaging the semicircular canals or other structures is never totally eliminated.

The following mechanisms of vestibular damage during or after cochlear implantation were presented by Ibrahim et al. (2017) [23]:

- electrode array implantation trauma;
- labyrinthitis provoked by the formation of cochleostomy;
- immune reaction to foreign body;
- increased hydraulic pressure within the inner ear endolymphatic system;
- implant evoked electrical stimulation.

Although the surgical approaches of cochlear implantation have improved over time and become “soft” (soft electrode arrays,
CONCLUSION

Cochlear implantation is a modern surgery for the treatment of severe to profound sensorineural hearing loss. More than 50 years of experience have demonstrated its safety and efficacy. More children are being diagnosed with sensorineural hearing loss since audioligic screening was increased among newborns in Kazakhstan. This fact has made cochlear implantation a routine procedure in our clinic. The major and minor complication rates in this study are similar to those reported in the literature, proving that it is a safe and effective procedure in terms of hearing rehabilitation. Additionally, ways to avoid future complications are discussed.
The authors declare that they have no competing interests.

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