Summary

Introduction. The first cochlear implant surgery was performed at the Center for Cochlear Implantation of the Department of Ear, Nose and Throat Diseases, Clinical Center of Vojvodina in 2002 after long preparations and that was the first successful cochlear implantation in Serbia. Material and Methods. Over the period from November 2002 to November 2013, 99 patients underwent surgical procedures and 100 cochlear implants were placed. Results. The analysis encompassed 99 patients, the youngest and the oldest one being 1 year and 61 years old, respectively. Prelingual and postlingual deafness developed in 84 (84.9%) and in 15 (15.1%), respectively. Postlingual deafness was observed in all 11 adult patients. The prelingual deafness was diagnosed in 84 (95.4%) children, whereas in four (4.6%) children it occurred after the development of speech between 6 and 8 years of age. Progressive hearing loss was observed in 11 patients - seven adults and four children. The majority of our patients, i.e. 74 (74.75%) manifested idiopathic deafness of unknown cause. A range of usually reported hearing loss etiologies included ototoxic medications in seven (7.07%), hereditary factor in some (7.07%) and bacterial meningitis in four (4.04%) patients. Some other less common causes were perinatal hypoxia in three (3.03%), premature birth in three (3.03%), Down syndrome in one (1.01%), and chronic otitis media in one (1.01%) patient. Conclusion. Both intraoperative and postoperative complications were analyzed in the investigated patient population. The complications developed in 11 patients, i.e. in 10.5% of 105 surgical procedures. The majority of procedures (89.5%) were not accompanied by any post-surgical complications. Unsuccessful implantation in a single-step procedure and transient facial nerve paralysis can be considered most frequent complications. Unsuccessful implantation in a single-step procedure (89.5%) were not accompanied by any post-surgical complications. Unsuccessful implantation in a single-step procedure (89.5%) were not accompanied by any post-surgical complications.

Key words: Cochlear Implants; Cochlear Implantation; Risk Factors; Hearing Loss; Deafness; Intraoperative Complications; Postoperative Complications; Infant; Child; Adolescent; Adult; Middle Aged

COCHLEAR IMPLANT SURGERY AT THE CLINICAL CENTER OF VOJVODINA – TEN-YEAR EXPERIENCE

KOHLEARNI IMPLANTACIJA U KLINIČKOM CENTRU VOJVODINE – DESETOGODIŠNJE ISKUSTVO

Dragan DANKUC, Darja ŠEGAN, Zoran KOMAZEC, Ljiljana VLAŠKI, Slobodanka LEMAJIĆ KOMAZEC and Ivana SOKOLOVAC

Sažetak

Uvod. Centar za kohlearnu implantaciju Klinike za bolesti uva, grla i nosa Kliničkog centra Vojvodine započeo je rad nakon višegodišnjih priprema 2002. godine kada je i urađena prva prva implantacija. U ovom centru, dakle, izvedena je prva uspešna kohlearni implantacija u Srbiji. Materijal i metode. U periodu od novembra 2002. do novembra 2013. godine operisano je 99 pacijenata, a pritom je ugrađeno 100 kohlearnih implantata. Rezultati. Analizom je obuhvaćeno 99 pacijenata, od kojih je najmlađi pacijent bio star jednu godinu a najstariji 61 godinu. Kod većine pacijenata, njih 94 (84,9%), gluvoća se razvila prelingvalno a kod 15 (15,1%) postlingvalno. Svih 11 odraslih pacijenata imali su gluvoću razvijenu postlingvalno, dok je u grupi dece 94 (95,4%) ogleđno pre nego na ovog govor, a četvoro (4,6%) nakon razvoja govoa, u uzrastu između 6 i 8 godine. Ukupno 11 pacijenata imalo je progresivni tip razvoja nagluovo sti, 7 odraslih i 4 dece. Kod najvećeg broja pacijenata gluvoća je idiopatska, odnosno nepoznatog uzroka, i to kod 74 pacijenata (74,75%); među ostalim uzrocom najčešće se navode otokotinski lekovi, kod 7 pacijenata (7,07%), nasledni faktor kod 6 pacijenata (6,06%) i bakterijski meningitis kod 4 pacijent (4,04%). Od ostalih, manje zastupljena uzroci uključuju se navode perinatalna hipoksija kod 3 pacijenta (3,03%), prevremena rođenost kod 3 pacijenta (3,03%), Danon sindrom kod jednog (1,01%) i kronična upala srednjeg uvu kod jednog pacijenta (1,01%). Zaključak. Intraoperativne i postoperativne komplikacije analizirane su u ispitivanoj grupi pacijenata. Komplikacije su se javile kod 11 pacijenata od 105 (10,5%) izvršene operaciji, njih 89,9%, prošlo je bez komplikacija. Od češćih komplikacija bilo je uspešna implantacija u prvom aktu i prolazna oduzetost falajca. Od redih komplikacija javile su se oštećenja kohleare i prolazna ataksija. Naije reči su bile stimulacija falajca, intraoperativno pojačano isticanje perilimfe, kvar aparata i kasna infekcija. Ključne reči: Kohlearmi implant; Kohlearni implantaaci; Faktori rizika; Publikat slohu; Gluvoća; Intraoperativne komplikacije; Postoperativne komplikacije; Odojč; Dete; Adolescent; Odrasli; Odrasli, srednjih godina.
The first modern cochlear implant, Nucleus R 24, was placed on November 20th, 2002 in a female patient with postlingual hearing impairment (patient I. J., aged 40). The surgery was performed by Prof. J. Jori, MD, PhD, Prof. J. G. Kiss from the Ear, Nose and Throat (ENT) Clinic Szeged, Hungary and Prof. Dragan Dankuc, MD, PhD from the Department of Ear, Nose and Throat Diseases in Novi Sad.

Subsequently, for the first time in Serbia, Prof. Dragan Dankuc, MD, PhD, assisted by Prof. J. Jori, MD, PhD, performed the first implantation of an artificial inner ear – a cochlear implant Nucleus R 24. Ever since, the cochlear implant surgery in Novi Sad has been exclusively performed by an experienced team led by eminent professors Zoran Komazec, Dragan Dankuc, Ljiljana Vlaški, Slobodanka Lemajic Komazec, surdology specialists Spoimenka Nedeljkov, Ivana Sokolovac and Oliver Vajs as well as engineers Tibor Mendrei and Vladimir Mrdanov [1, 2].

Material and Methods

Over the period from November 2002 to November 2013, 99 patients underwent surgical procedures and 100 cochlear implants were placed. In four patients, a single-stage surgery was not applicable because of intraoperative complications, thus successful implantation was accomplished in the second procedure. Late postoperative complications required the revision surgery (reimplantation) in one patient, whereas one female patient underwent bilateral cochlear implantation.

Results

The analysis encompassed 99 patients, the youngest and the oldest one being 1 year and 61 years old, respectively. The patient population included 11 (11.1%) adults and 88 (88.9%) children as the major population. The gender ratio was 56 (56.6%) females to 43 (43.4%) males (Graph 1a).

Prelingual and postlingual deafness developed in 84 (84.9%) and in 15 (15.1%), respectively. Postlingual deafness was observed in all 11 adult patients. Prelingual deafness was diagnosed in 84 (95.4%) children, whereas in four (4.6%) children it occurred after the development of speech, between 6 and 8 years of age (Graph 1b). Progressive hearing loss was observed in 11 patients - seven adults and four children.

The distribution of patients by the year when implant surgery was performed and their age is presented in (Graph 2).

The average number of surgeries performed per year is 8.4, with the largest number of procedures [20] recorded in 2006.

The majority of our patients, i.e. 74 (74.75%) manifested idiopathic deafness of unknown cause. A range of usually reported hearing loss etiologies included ototoxic medications in seven (7.07%), hereditary factor in six (6.06%), and bacterial meningitis in four (4.04%) patients. Somewhat less common causes were perinatal hypoxia in three (3.03%), premature birth in three (3.03%), Down syndrome in one (1.01%), and chronic otitis media in one (1.01%) patient (Graph 3).

Potential risk factors for deafness recorded in our patients included positive family history of hearing loss in 13 (13.1%), premature birth in 11 (11.1%) patients as well as administration of ototoxic medications from the group of aminoglycosides to the mother during pregnancy or to the child in 10 (10.1%) cases. Significant perinatal hypoxia and postpartum incubation period were recorded in eight (8.08%) patients. History of bacterial meningitis was reported in five (5.05%) patients. Prolonged neonatal jaundice was observed in five (5.05%) children. Examination by a pediatric psychologist revealed symptomatic delay in development in four (4.04%) children. Birth weight under 1500 g was recorded in four (4.04%) newborns. Three (3.03%) patients had history of chronic otitis media, whereas sepsis and neonatal intracranial hemorrhage were recorded in three (3.03%) patients each. Falling-associated head injuries, febrile convulsions and presence of cytomegalovirus (CMV) anti-
bodies were recorded in one (1.01%) patient each (Graph 4).

The analysis of the age at which the hearing impairment had been observed was performed according to heteroamnnesia based on parents’ reports. The average age at which the parents reported the suspect hearing impairment or underdevelopment of speech is 13.12 months, ranging from 0 months (parents reported the hearing loss from the very birth) to maximum 36 months, when hearing loss was diagnosed in three (3.4%) children by audiology screening.

The analysis encompassed patients’ age at the moment of establishing the diagnosis and at implant surgery, as well as the total time between the confirmation of diagnosis and implantation procedure [3–5].

Both intraoperative and postoperative complications were analyzed in the investigated patient population. The complications developed in 11 patients (Graph 3).

Graph 4. Incidence of risk factors for sensorineural hearing impairment

Graph 5. Patients’ age at the moment of diagnosing and of implant surgery

shortening the period between the confirmation of diagnosis and implantation procedure [3–5].
ents, i.e. in 10.5% of 105 surgical procedures. Implant placement in a single-stage procedure was not possible in four cases because of acute otitis media in one patient (diagnosed during surgery) and the ossification of the cochlea that prevented electrode array placement in the remaining three cases. The second surgery was successfully performed in all four patients, without any subsequent complications. Transient facial nerve paresis was recorded in four (4.04%) patients, which completely subsided two months after surgery and administration of antibiotic treatment. Transient ataxia was observed in two (2.02%) patients [6].

Some rare complications such as facial nerve stimulation associated with electro stimulation of the cochlea (late complication occurring one year after surgery), device failure identified at tuning the cochlea (late complication occurring one year after surgery and administration of antibiotic treatment) were observed in one (1.01%) patient each. All complications were successfully managed by incision and drainage, while preserving the functionality of the device (Graph 6).

Graph 6. Cochlear implant complications

Grafikon 6. Komplikacije kohlearne implantacije

Discussion

The youngest patient was only 1 year old (i.e. 14.7 months) at the moment of surgery. In 27 (30.7%) children, the surgery was performed before the age of 3 years, whereas 50 (56.8%) children underwent implantation procedure before the age of 4 years. According to the research of Valencia et al. from the ENT Clinic of Minnesota Medical Center, U.S.A., a completely safe procedure of implant placement can be accomplished even in infants under 12 months of age (their youngest patients was 6.6 months old) provided that there are no medical risks associated with anesthesia at this age. The aims of early implantation are to reduce the hearing deprivation period and to improve the development of auditory performance [7].

In adult patients with postlingual deafness, comprehensive evaluation of the ratio between potential benefits and risks associated with surgery itself and potential comorbidities should be performed. However, the age itself is not the criterion for excluding the patient from implantation procedure unless other risk factors are present [8, 9].

Habilitiation process in children who were completely deaf until the moment of implant switch-on implicates the appropriate auditory training aimed at establishing acoustic memory and then, as a second stage, the development of speech [10].

A wide range of etiological factors may be responsible for sensorineural hearing impairment, including intraterine, perinatal and postnatal ones. More than 60% of all prelingual hearing impairments are attributed to genetic factors (Vivero et al.) and genetic deafness is either nonsyndromic or syndromic. Nonsyndromic hereditary deafness is mostly attributed to the defect of connexin 26 (Cx26), a structural protein located on the long arm of human chromosome 13. The absence and dysfunction of this protein cause the disturbance of intracellular junctions resulting in the dysfunction of receptor cells of the inner ear and their irreversible loss. Some more rare genetic conditions are usually inherited in a mitochondrial deoxyribonucleic acid (DNA) pattern or are syndrome-related [11–13].

Among the patients included in our study, genetic analysis revealed the mutation in the gene encoding connexin 26 in one patient only. The prevalence of such mutations is believed to be higher; however, genetic analysis aimed at identifying the etiology of hearing impairments are not a part of routine practices in our country. Moreover, the majority of such mutations are inherited through autosomal recessive inheritance pattern that corresponds with the negative family history of hearing disorder, even though more than half of hearing impairments are considered genetically related.

Otoxic medications were reported as the cause of hearing loss in seven (7.07%) of our patients. In these cases, hearing loss was directly associated with the administration of ototoxic medications, whereas application of drugs from the category of aminoglycosides (predominantly Gentamycin) during the intrauterine or postnatal period was identified as a risk factor in 10 (10.10%) patients. Histopathological studies have demonstrated that outer receptor cells are most susceptible to aminoglycosides ototoxicity, that is, a symmetrical, irreversible, high frequency sensorineural hearing loss occurs as the first stage. Exposure of the child to increased cumulative drug doses rapidly compromises the hearing ability in speech relevant frequencies.

According to numerous authors, timely prevention of adverse effects of aminoglycosides, even in cases when their application is justified and inevitable, could be accomplished through routine application of relevant diagnostic methods, especially Transient-Evoked Otoacoustic Emission (TEOAE), which is a highly sensitive, non-invasive and objective technique. Such monitoring throughout the period of aminoglycoside therapy would enable timely detection of hearing loss in children hospitalized for severe Gram-negative bacterial infections and consequent reduction of drug dosage or further adjustment of treatment regimen [14].

According to the data from the literature, bacterial meningitis has been reported as a risk factor in
6.10% of children (Bielecki et al.). In these patients, the changes of the inner ear are highly progressive involving fibrosis or ossification of the cochlea. In case of prolonged delay of surgical procedure, the insertion of electrode could be compromised due to complete obliteration of membranous labyrinth. Thus, an early implantation procedure is highly advisable within maximum 6 months after meningitis [15–17].

In our study, perinatal hypoxia of newborns was identified as a cause of hearing impairment in three (3.03%) and as a positive risk factor in eight (8.08%) patients. Premature birth was believed to be a cause of hearing loss in three (3.03%) patients. Prematurity, that is, delivery before the 37th gestation week was identified as a positive risk factor in as many as 11 (11.1%) patients from our study sample. According to international reports, prematurity is confirmed as a risk factor for acquired sensorineural hearing disorder; however, it is quite difficult to estimate its incidence since prematurity is commonly associated with a range of comorbidities and risk factors. Premature birth with subsequent period in incubator was observed in eight (8.08%) children, which corresponds to the number of prematurely born children in our case study [18–20].

Down syndrome was identified as a cause of deafness in one (1.01%) patient. According to some authors, some 4–20% of children with Down syndrome manifest sensorineural hearing loss. Since Down syndrome is the most common genetic disorder with an incidence of 1:800 live-born children, the aforementioned percentage is not negligible. In the past, children with Down syndrome were not considered candidates for cochlear implantation and subsequent habilitation because of apparent morphological problems and learning disorders. However, such an approach has recently been abandoned thanks to novel information and positive experiences. Regrettably, the postoperative outcomes of cochlear implantation in a child with Down syndrome were not satisfactory in our case. A number of authors reported very good postoperative outcomes in such children, especially when implanted at an early age [21, 22].

Chronic cholesteatomic otitis media has been identified as a cause of deafness in one (1.01%) adult female patient. This is not a very common situation since cholesteatomic inflammations rarely result in complete bilateral deafness.

Besides the aforementioned risk factors, a range of other conditions associated with perinatal period was recorded in our patients: prolonged neonatal jaundice in five (5.05%), extremely low birth weight (below 1500 g) in four (4.04%), perinatal sepsis in three (3.03%), and intracranial hemorrhage in three (3.03%) children. All these factors are regarded as risk factors for hearing loss in the reports of other authors.

A range of further risk factors observed in our patients includes symptomatically retarded psychomotor development in four (4.04%) patients, chronic otitis media in three (3.03%), head injury in one (1.01%), febrile convulsions in one (1.01%), and positive diagnosis to cytomegalovirus associated with progressive hearing loss in one female patient (1.01%).

The average age of children at which the parents suspected hearing disorder was 13.12 months. In 15 children (17.04%), the parents noticed the hearing impairment and reported it to the physician to be diagnosed when their child was two or more years old, which strongly suggests the denial of parents to face the expected diagnosis. In view of the well-established fact that early diagnosis and amplification is crucial for proper development of a child, such a delay represents highly harmful time loss for the child on a long-term basis.

Another possibility of time-loss pertains to the period between the moment of establishing final diagnosis and implantation procedure. As shown in Graph 6, the average period is one year showing decreasing tendency, thus greatly reducing the time-loss and increasing probability of successful outcomes of the procedure [23, 24].

Complications associated with cochlear implantation can be categorized as major or minor ones. Major complications include those resulting in the necessity for revision surgery, explantation, reimplantation, severe disease or even lethal outcomes. Minor complications resolve spontaneously or can be managed by conservative therapy and do not require any prolonged hospitalization of the patient [25, 26].

In our Center for Cochlear Implantation of the Clinical Center of Vojvodina, complications were observed in 11 patients, that is, 10.05% of performed surgical procedures. This incidence corresponds to the incidence rates reported from related centers worldwide, being around 10%. In four (4.04%) patients treated at our Center, the single-stage surgery was not initially possible, thus implantation was postponed and successfully accomplished in the second stage. In one patient, successful implantation using another type of electrode was performed at the same side. In other three patients, the second-stage surgery was performed at the other side with a favorable outcome.

In cases of congenital malformations of the inner ear (two of our pediatric patients), the placement of the electrode into the altered cochlea could not be accomplished in spite of the surgical navigation system. Transient postoperative peripheral facial nerve paresis was observed in four (4.04%) patients. This condition is considered a minor complication and is explained by transient edema of facial nerve in the fallopian canal induced by the heating of its immediate surrounding structures during lateral tympanotomy. This impairment of nerve function was transient in all our patients. The symptoms resolved completely within the first month after surgery and administration of conservative
Cochlear implant surgery

Dankuc D, et al.

Complications reported in the literature, such as electrode extrusion, skin necrosis over the implant or meningitis, which is considered to be the most severe postoperative complication, have not been recorded in our Center since the very beginning. Absence of postoperative meningitis in patients treated at our Center can be attributed to timely pneumococcal vaccination of children.

Conclusions

The majority of our patients, i.e. 84 (84.9%) manifested prelingual hearing loss, whereas postlingual disease type was observed in 15 (15.1%) cases.

Deafness of unknown etiology was recorded in 74 (74.75%) patients. Among known causes of hearing loss, administration of ototoxic drugs was the most prevalent one followed by hereditary factors and somewhat fewer cases of meningitis, perinatal hypoxia and premature birth. Down syndrome and chronic otitis media were recorded in only one patient, each.

Positive family history of sensorineural hearing disorder was identified as the most common risk factor. Premature birth, administration of ototoxic drugs, postpartum incubation and perinatal hypoxia were observed more rarely. Other risk factors identified within our patient population included meningitis, prolonged postpartum jaundice, low birth weight, symptomatic developmental disorder, chronic otitis media, sepsis, intracranial hemorrhage, head injury, febrile convulsions, and cytomegalovirus infection.

In all children, the deafness was diagnosed before the 4th year of age, and the implantation was performed before the 5th year of age.

The majority of procedures (89.5%) were not accompanied by any post-surgical complications. Unsuccessful implantation in a single-step procedure and transient facial nerve paralysis can be considered most frequent among our patients, whereas cochlear ossification and transient ataxia occurred more rarely. Stimulation of facial nerve, intraoperative perilymph liquid gusher, device failure and late infections were recorded extremely rarely.

References
