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Complications in Cochlear Implantation at the Clinical Center of Vojvodina

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SUMMARY

Introduction The first modern cochlear implantation in Serbia was performed on November 26, 2002 at the Center for Cochlear Implantation of the Clinic for Ear, Nose and Throat Diseases, Clinical Center of Vojvodina.

Objective The aim of the paper is the analysis of intraoperative and postoperative complications. 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.

Methods In the 2002–2013 period, 99 patients underwent surgical procedures and 100 cochlear implants were placed. Both intraoperative and postoperative complications were analyzed in the investigated patient population.

Results The analysis encompassed 99 patients, the youngest and the oldest ones being one year old and 61 years old, respectively. The complications were noticed 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 (4.04%) and transient facial nerve paralysis can be considered most frequent among our patients, whereas cochlear ossification (1.01%) and transient ataxia (2.02%) occurred rarely. Stimulation of the facial nerve (1.01%), intraoperative perilymph liquid gusher (1.01%), device failure and late infections (1.01%) were recorded extremely rarely.

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

Keyword: cochlear implantation; intraoperative complications; postoperative complications

INTRODUCTION

The first successful cochlear implantation in Serbia has been performed at the Center for Cochlear Implantation of the Clinic for Ear, Nose and Throat Diseases, Clinical Center of Vojvodina. The first modern cochlear implant, Nucleus 24, was placed on November 26 of 2002 in a 40-year-old female patient with postlingual hearing impairment. The surgery was performed by Prof. Dr. J. Jori and Prof. J. G. Kiss from the ENT Clinic, Szeged, Hungary, and Prof. Dr. Dragan Dankuc from the ENT Clinic, Novi Sad, Serbia.

Subsequently, for the first time in Serbia, Dragan Dankuc, under the assistance of Prof. Dr. J. Jori, has performed the first implantation of an artificial inner ear – a cochlear implant Nucleus 24 [1]. 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 Lemajić Komazec, specialized surdopedagogists Spomenka Nedeljkov, Ivana Sokolovac and Oliver Vajs, as well as engineers Tibor Mendrei and Vladimir Mrdjanov [2].

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OBJECTIVE

The paper's objective is to analyze possible intraoperative and postoperative complications. Major complications may result in the necessity for revision surgery, explantation, reimplantation, severe disease or even lethal outcomes. Minor complications, on the other hand, can resolve spontaneously and do not require any prolonged hospitalization of the patient.

METHODS

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

RESULTS

The analysis encompassed 99 patients, the youngest and the oldest ones being one year old and 61 years old, respectively. The patient population included 11 (11.1%) adults and 88 (88.9%) children as the majority of the patient population.

Both intraoperative and postoperative complications were analyzed in the investigated patient population. The complications were noticed in 11 patients, 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 patients (Figure 1A-B). 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 post surgery after appropriate therapeutic treatment. Transient ataxia was observed in two (2.02%) patients [3].

Some rare complications, such as facial nerve stimulation associated with electro-stimulation of the cochlea, late complication occurring one year post surgery, device failure identified at fitting session and late infection, were observed in one (1.01%) patient each. All complications were successfully managed by incision and drainage, while preserving the functionality of the device (Table 1).

DISCUSSION

The youngest patient was only one year old (i.e. 14.7 months) at the moment of surgery. In 27 (30.7%) children, the surgery was performed at the age below three, whereas 50 (56.8%) children underwent implantation procedure at the age under four years old. The aims of early implantation are to reduce the hearing deprivation period and to improve the development of auditory performance [4].

In adult patients with postlingual deafness, comprehensive evaluation of the ratio between potential benefit and risks associated with surgery itself and potential comorbidities should be performed. However, age is not the criterion for excluding a patient from implantation procedure unless other risk factors are present [5, 6].

Complications associated with cochlear implantation can be categorized as major and 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 [7, 8].

Cohen et al. [9] characterized implant-related complications as *major* if they required revision surgery, and *minor* if they resolved with minimal or no treatment. A survey reported 55 major (12%) and 32 minor (7%) complications.

Webb et al. [10] reporting their experience with 153 patients found 13.7% major and minor complications.

Table 1. Complications of cochlear implants at the Center for Cochlear Implantation of the Clinic for Ear, Nose and Throat Diseases, Clinical Center of Vojvodina

Complications	Number
Without complications	94
Unsuccessful implantation	4
Transient paresis of n. VII	4
Cochlea ossification	3
Transient ataxia	2
Unwanted stimulation of n. VII	1
Perilymph gusher	1
Device failure	1
Late infection of incision site	1

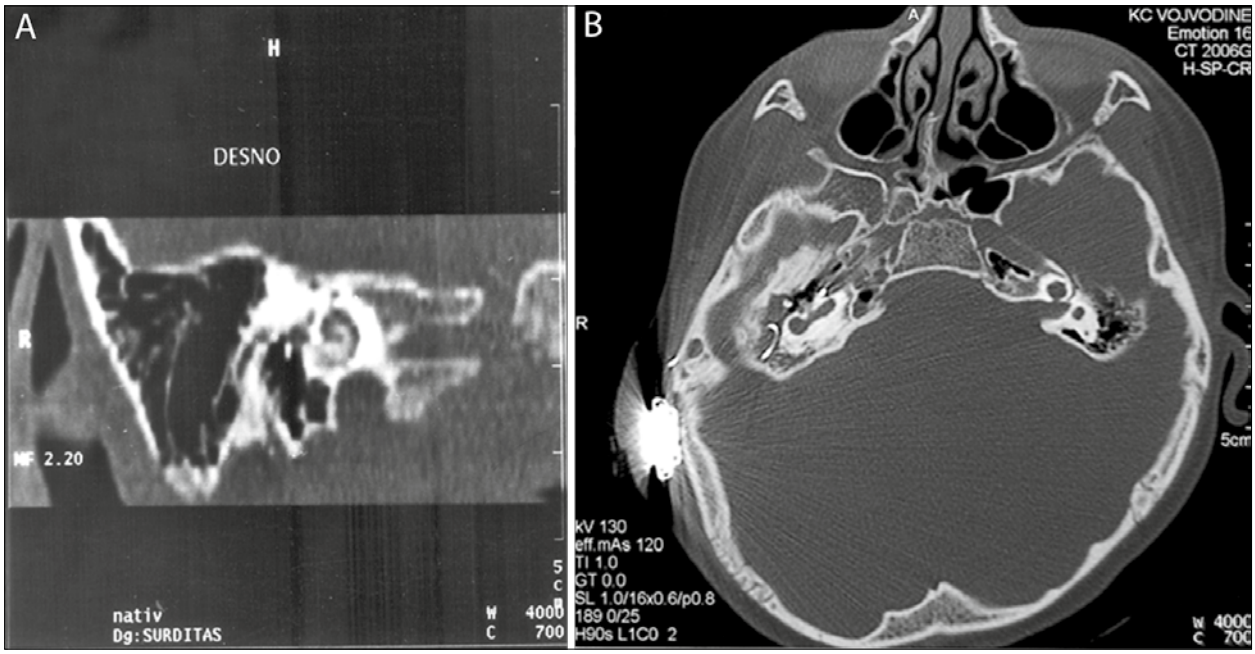

Figure 1. CT images: A) ossification of cochlea; B) congenital malformation

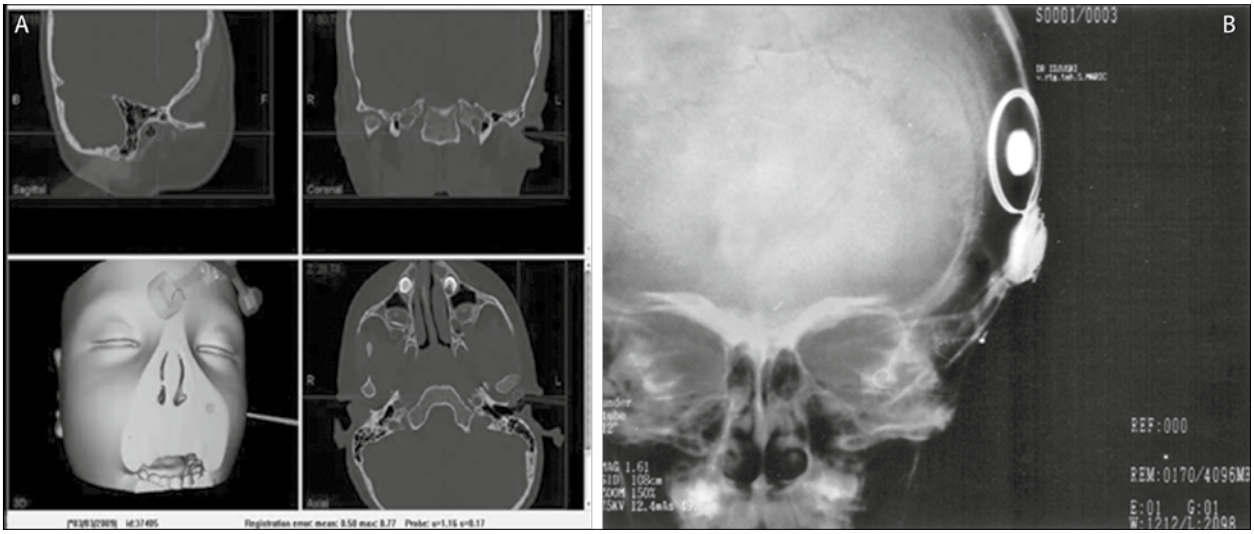

Figure 2. A) The surgical navigation system; B) Transorbital RTG – Hass

Hoffman and Cohen [11] noted that in later follow-up 220 (8%) major and 119 (4.3%) minor complications occurred among 2,751 implantations.

At 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 [12]. This incidence corresponds with the incidence rates reported from related centers worldwide, which is around 10%. In four (4.04%) patients treated at our Center, the single-stage surgery had not been 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 on the same side. In three other patients, the second-stage surgery was performed on the other side with favorable outcome.

In cases of congenital malformations of the inner ear in 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 (Figure 2A-B).

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 the facial nerve in the fallopian canal induced by the heating of its immediate surrounding structures during posterior tympanotomy. This impairment of nerve function was transient in all our patients. The symptoms resolved completely within the first month post surgery after conservative corticosteroid therapy without any need for subsequent surgical nerve decompression.

Major complications include facial nerve paralysis and implant exposure due to skin flap necrosis. Necrosis of the skin flap can lead to wound infection and device extrusion, necessitating scalp flap revision, and, when intractable infection is present, device removal with or without replacement.

Transient ataxia was observed in two (2.02%) patients, who presented with symptoms of postoperative instability and nausea. The patients responded well to symptomatic therapy and recovered rapidly without any consequences. This complication might be explained by perilymph and endolymph leakage during the formation of the cochleostoma. After the surgery, upon reestablishment of the homeostasis of the semicircular canals, ataxia resolves spontaneously without need for any specific therapy.

Postoperative facial nerve stimulation was observed in one (1.01%) female patient. According to the available literature, this major complication of cochlear implantation occurs in some 0.31–14% of cases. Switching off the electrodes that directly stimulate the nerve might be the potential solution in such cases; however, this can result in reduced sound perception, which was the case in our patient. Thus, implantation of the second ear was performed to accomplish satisfactory overall hearing performance through bilateral stimulation at sub-maximal level. Instead of electrode remapping, facial nerve stimulation can be managed by botulinum toxin injections; however, this therapeutic option requires repeated administration at three- to six-month intervals [13, 14].

Extensive intraoperative perilymph gusher was observed in one (1.01%) patient. This is considered a minor complication, and was successfully managed during surgical procedure without affecting the outcome.

Function of external sound processor may be lost due to direct trauma, exposure to water and most frequently normal wear and tear of connecting lead-wires linking the sound processing unit with the magnetically retained antenna that relays information and power to the internal device. An internal device failure typically presents as either an immediate cessation of function or intermittency associated with reduced quality of sound and a period of diminishing function over days to weeks. Reports of painful stimulation have been noted, bat are rare. Device failure is the most common indication for revision surgery and cochlear reimplantation.

Device failure at mapping session occurred in one (1.01%) patient. Such failures are considered major complications, as they inevitably require second surgery, which was successfully performed in our patient.

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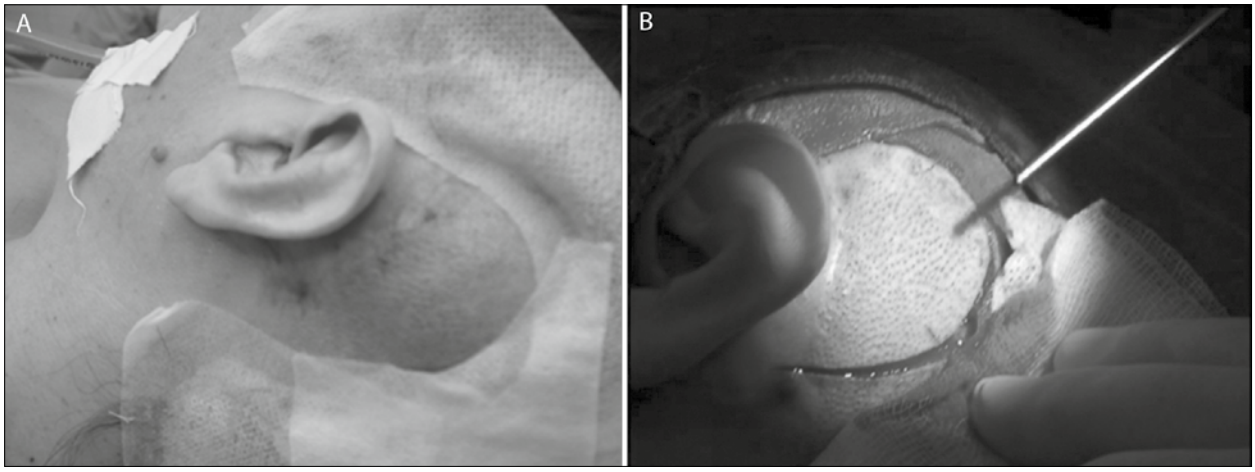

Figure 3. Implant region: A) skin infection; B) skin incision

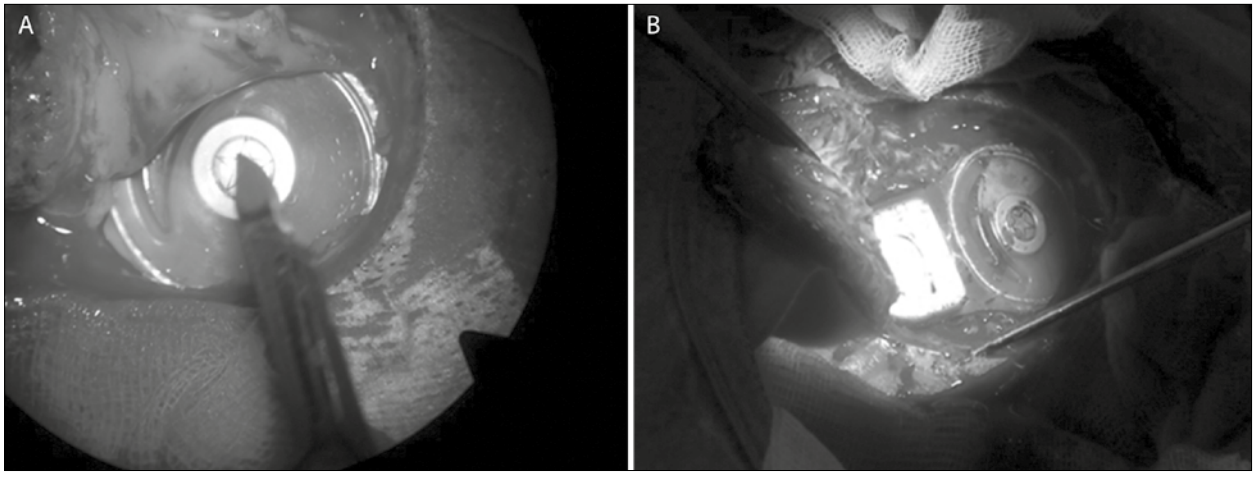

Figure 4. A) Infection with biofilm formation; B) Exposed implant with biofilm

Infection and flap breakdown require reimplantation less frequently [15]. Luetje and Jackson [16] reported a 9% rate of device failure in a review of 55 children.

Cochlear implants are rarely complicated by microbial infections. When such infections do occur, they can be difficult to treat with conventional antibiotic therapy, and may consequently require surgical removal of the implant [17, 18, 19]. Several studies have demonstrated that infections of cochlear implants are due to biofilm formation [20, 21]. A biofilm-related infection is difficult to treat, as biofilm formation results in increased bacterial resistance both to the body's immune response and to antibiotic therapy [22, 23]. Numerous studies have demonstrated that antimicrobial resistance is considerably increased when bacteria grow in biofilm mode [24, 25].

The increased antibiotic resistance of bacteria growing in a biofilm has been attributed to a number of factors, including decreased antibiotic penetration, altered metabolism of bacteria growing in biofilm and expression of biofilm-specific antibiotic resistance genes.

Skin infection in implant region was noticed as a late complication in one (1.01%) adult patient several months post surgery (Figure 3A-B). Prophylactic perioperative application of antibiotics can greatly reduce such infections, but other authors also reported the occurrence of this complication at the incidence of some 1%. In our patient, the infection was successfully managed by drainage and antibiotic therapy while preserving the functionality and position of the implant. In our case, the patient will have the infected implant temporarily removed and bathed in 3% hydrogen peroxide solution for approximately 30 minutes, in an attempt to eradicate the bacterial biofilm (Figure 4A-B). After this period of disinfection, the implant is replaced as before and the patient is discharged on a high-dose course of appropriate antibiotics (Figures 5A-B and 6A-B).

The risk of bacterial infection of an implanted device producing labyrinthitis or meningitis and associated reactive fibrosis and destruction of neural elements appears to be low. Reefhuis et al. [26] conducted a study of 4,264 children implanted between 1997 and 2002 and found 29 cases of bacterial meningitis of all implanted children. This rate of meningitis caused by *Streptococcus pneumoniae* was 30 times the incidence in the general population.

Complications reported in the literature, such as electrode extrusion, skin necrosis over the implant, or meningitis, which is considered the most severe postoperative complication, have not been recorded at our Center since

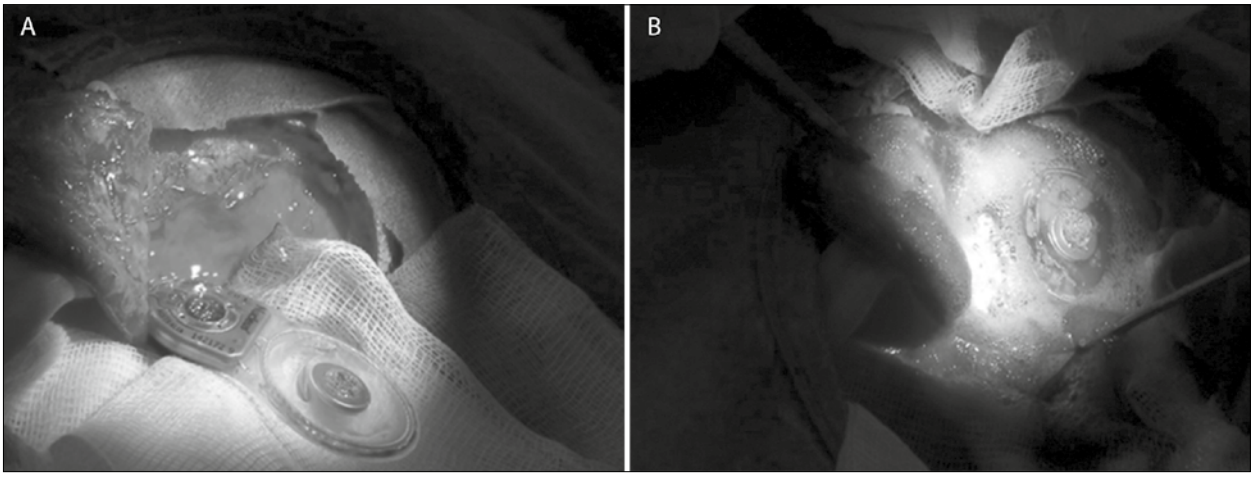

Figure 5. A) Infected implant removed; B) Implant bathed in a 3% hydrogen peroxide solution

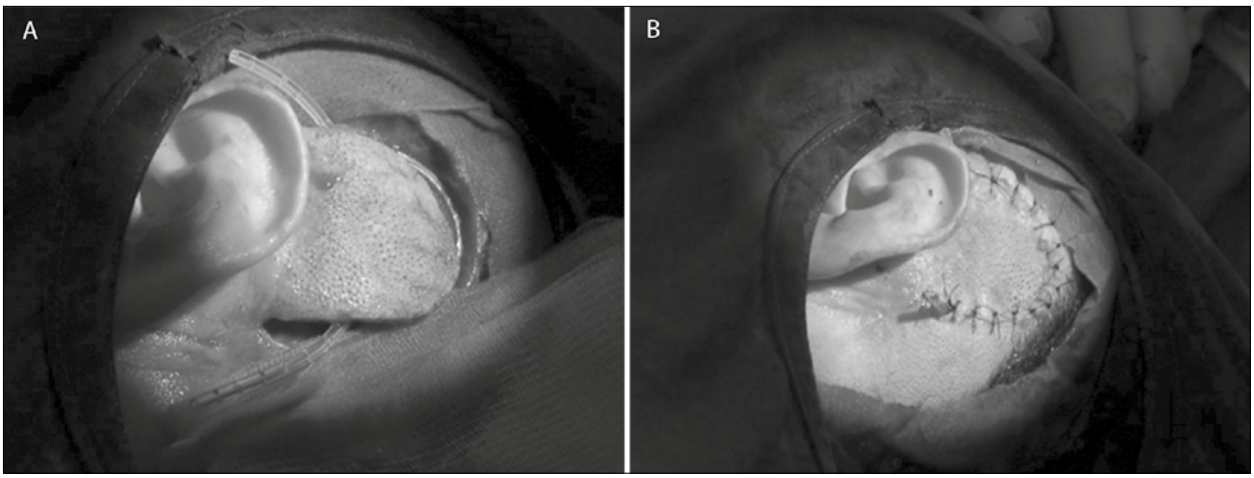

Figure 6. A) The implant is replaced; B) Drainage with local antibiotics

the very beginning. Absence of postoperative meningitis in patients treated at the Center can be attributed to timely pneumococcal vaccination of children.

CONCLUSION

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

At our Center for Cochlear Implantation of the Clinical Center of Vojvodina, the majority of procedures (89.5%) were not accompanied by any post-surgical complications. The complications were observed in 11 patients, which is 10.5% of performed surgical procedures. Unsuccessful implantation in a single-step procedure and transient facial nerve paralysis can be considered to be the most frequent complications among our patients, whereas cochlear ossification and transient ataxia occurred rarely. Stimulation of the facial nerve, intraoperative perilymph gusher, device failure and late infections were recorded extremely rarely.

Complications such as electrode extrusion, skin necrosis over the implant, or meningitis, considered to be the most severe postoperative complication, have not been recorded at our Center, which can be attributed to timely pneumococcal vaccination of children.

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Компликације кохлеарне имплантације у Клиничком центру Војводине

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КРАТАК САДРЖАЈ

Увод Прва савремена кохлеарна имплантација у Србији урађена је 26. новембра 2002. године у Центру за кохлеарну имплантацију Клинике за болести ува, грла и носа Клиничког центра Војводине у Новом Саду.

Циљ рада Сврха овог рада је анализа интраоперационих и постоперационих компликација. Велике компликације су све оне које доводе до потребе за поновном операцијом, експлантацијом и реимплантацијом или доводе до тешког обољења, односно смрти болесника. Мале су све остале компликације које се могу санирати спонтано или конзервативним лечењем и не захтевају продужену хоспитализацију болесника.

Методе рада У периоду 2002–2013. године оперисано је 99 болесника и при том уграђено 100 кохлеарних имплантата. Интраоперационе и постоперационе компликације анализиране су у испитиваној групи болесника.

Резултати Анализом је обухваћено 99 болесника, од којих је најмлађи имао једну, а најстарији 61 годину. Компликације су се јавиле код 11 испитаника од 105 (10,5%) извршених операција. Већина операција (89,5%) прошла је без компликација. Од чешћих компликација забележене су неуспешна имплантација у првом акту (4,04%) и пролазна одузетост фацијалног живца. Од ређих компликација јавиле су се осификација кохлеје (1,01%) и пролазна атаксија (2,02%). Врло ретке су биле стимулација фацијалног живца (1,01%), интраоперационо појачано истицање перилимфе (1,01%), квар апарата и касна инфекција (1,01%).

Закључак Компликације попут екструзије електроде, некрозе коже изнад имплантата и менингитис, који се сматра најтежом постоперационом компликацијом у Центру за кохлеарну имплантацију од почетка његовог рада, нису забележене. Чињеница да се менингитис није јављао код болесника оперисаних у нашем центру може се објаснити увођењем правовремене вакцинације деце применом пнеумококне вакцине.

Кључне речи: кохлеарна имплантација; интраоперационе компликације; постоперационе компликације

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