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Original Article

Adult Cochlear Implantation Under Local Anesthesia and Conscious Sedation with Dexmedetomidine: Efficacy and a Method to Interact with the Conscious and Cooperative Patient

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BACKGROUND: This study describes the efficacy of cochlear implantation under local anesthesia with conscious sedation with dexmedetomidine in adult patients and proposes a method to communicate with the conscious and cooperative patient intraoperatively. This less invasive anesthetic procedure is suitable for patients with comorbidities preventing general anesthesia.

METHODS: Unilateral cochlear implantation with Oticon Medical systems was performed in 10 adult patients with comorbidities preventing general anesthesia. Classical cochlear implantation was performed under local anesthesia and conscious sedation with dexmedetomidine. Cue cards were used to support intraoperative dialogue. Outcome measures were intraoperative adverse events, patient perceptions, as well as postoperative completions measured with a questionnaire.

RESULTS: The procedure was successful for all 10 patients. Dexmedetomidine lead to rapid and successful conscious sedation and no case of high blood pressure or aggravation of comorbidities was noted. Stapedial reflex measurements led to reliable thresholds. The usage of the cue cards was successful: patients were able to read the cue cards and thereby the medical team could inform the patients of surgical progress and ask the patients questions.

CONCLUSION: Cochlear implantation and intraoperative dialogue with the conscious and cooperative patient is possible. The main advantage of the anesthetic procedure is the reduction in intra- and postoperative complications. Further, expected benefits include a less invasive procedure, the conscious state of the patient which enables the recording of auditory perception, and the absence of nonauditory percepts such as facial nerve stimulation during implant stimulation, a shorter surgical duration, and lower-associated costs.

KEYWORDS: Cochlear implantation, local anesthesia, sedation, dexmedetomidine, rehabilitation

INTRODUCTION

Cochlear implantation is the most efficient treatment for severe-to-profound sensorineural hearing loss,[1] but comorbidities increase the risk of complications.[2-4] Cochlear implantation is most routinely performed under general anesthesia. When used, neuromuscular blockade[5] impacts intraoperative measurements that inform cochlear implant mapping and help identify complex cases, such as low sensitivity to electrical stimulation or facial nerve stimulation. For example, electrically evoked stapedial reflex thresholds are affected by the anesthesiologic agents and their dosage.[6-8] Sugammadex and neostigmine are used to reverse neuromuscular blockade, but their costs and side effects limit their usage.[9]

When making decisions about local versus general anesthesia, surgeons usually consider patient age, health condition, ability to follow instructions, procedure duration, and possible complications.[5] General anesthesia complications include bleeding and cardiac

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arrhythmia, and nausea and vomiting are common in the early postoperative period.[5] Contraindications include cardiovascular, nervous, or respiratory diseases, kidney or liver failure, and diabetes, as well as factors that compromise tracheal intubation.[5] Advantages of local anesthesia include the ability to interact with the patient and cost reduction. Furthermore, 89% of patients prefer undergoing middle-ear surgery under local anesthesia.[10]

The first 4 cases of cochlear implantations under local anesthesia were published in 1998.[11] Since then, several CI centers around the world, including Brazil, Finland, Germany, Hungary, India, Italy, Saudi Arabia, the United Kingdom, and the United States, have successfully carried out the surgery under local anesthesia with positive outcomes and high patient satisfaction.[12-29] These reports show that cochlear implantation under local anesthesia has the potential to widen indications to include patients at risk of developing complications from general anesthesia, especially older patients with comorbidities.

The patient under local anesthesia without sedation can display unintentional movements. The choice and dosage of sedatives are important to reduce movements and preserve hemodynamics and spontaneous breathing.[30] Agonists of α2-adrenoreceptors have been used for a long time.[31] Dexmedetomidine is a more recent highly selective agonist of α2-adrenoreceptors commonly used in emergency medicine.[32] It was first registered in the United States in 1999 under the trade name Precedex (Hospira Inc), and it is available in Europe under the trade name Dexdor (Orion Corporation Oyj).

The pharmacokinetics of dexmedetomidine include fast action ($t1/2\alpha = 6$ minutes) and a short biological half-life of approximately 2 hours.[32] Its hemodynamic effects are biphasic: a therapeutic dose reduces arterial pressure but does not affect central venous pressure nor systemic vascular resistance (i.e., no clinically significant bradycardia). A high dose reduces arterial pressure, as the agent influences the adrenergic receptors of peripheral, rather than central, vessels. Dexmedetomidine stabilizes hemodynamics and suppresses the activity of the sympathetic nervous system. Most anesthetic agents cause a dose-dependent suppression of breathing, but, due to their different sedation mechanisms, this is not the case for dexmedetomidine.[33] In ENT patients, dexmedetomidine promotes hemodynamic stabilization, decreases intraoperative bleeding, and eases the postoperative period.[32]

Given the benefits of dexmedetomidine, it has been used successfully in cases of cochlear implantation.[12,17,20,22,24-29] These reports confirm the advantages of dexmedetomidine, including its cost-effectiveness over general anesthesia.[22] However, these reports do not specify how to best interact with the conscious patients. The objectives of this study were to describe the efficacy of this less invasive anesthetic procedure for cochlear implantation in adult patients and to propose a method to communicate with the conscious patients intraoperatively.

MAIN POINTS

- Cochlear implantation under local anesthesia with conscious sedation with dexmedetomidine in adult patients leads to few intra- and postoperative complications.
- A method for successful intraoperative dialogue with the conscious and cooperative patient during cochlear implantation is presented.
- Further expected benefits include a less invasive procedure, the conscious state of the patient which enables the recording of auditory perception, and the absence of nonauditory percepts during implant stimulation, a shorter surgical duration, and lower-associated costs.

MATERIALS AND METHODS

Ethics

The procedures followed were in accordance with the ethical standards of the Helsinki Declaration. Ethical committee approval was received from Ethics Committee of The National Medical Research Center for Otorhinolaryngology of the Federal Medico-Biological Agency of Russia (02 march 2020, Approval no: 01/2020). Written informed consent was obtained from all participants who participated in this study.

Patients

Ten patients aged 30-58 years with bilateral postlingual hearing loss underwent unilateral cochlear implantation under local anesthesia and conscious sedation with dexmedetomidine at the Scientific-Clinical Center of Otorhinolaryngology in Moscow, Russia, in the period January to September 2019 (Table 1). All patients had an American Society of Anesthesiologists Physical Status classification of II or III (i.e., mild or severe systemic disease). Patients with cochlea-vestibular pathology (e.g., malformation or ossification) were excluded.

Preoperative Workup and Anesthesia Procedure

The medical team informed patients preoperatively of the steps of cochlear implantation and potential complications. Preoperative preparation was performed in accordance with comorbidities. Sterile surgical drapes covered patients while allowing them to read the cue cards shown by the medical team.

Dexmedetomidine was infiltrated 15 minutes prior to the start of the surgical procedure (0.6-0.7 mg/kg/h) as well as intraoperatively (0.9-1.0 mg/kg/h). No neuromuscular blocking agents were used. Lidocaine 2% and epinephrine 1 : 100 000 were infiltrated in the retro-auricular and external auditory meatus areas. An anesthesiologist was always present in the operating room.

Surgical Procedure

Surgery was performed under a microscope and using a standard approach with retro-auricular C-shaped incision, mastoidectomy, posterior tympanotomy, and electrode array insertion through the round window membrane. All patients received one Oticon Medical cochlear implant system (Digisonic SP implant and Saphyr Neo behind-the-ear sound processor) with the 20-channel Classic straight electrode array. The Oticon Medical system has a small and thin receiver that is fixated with titanium screws, requiring minimal elevation of the soft tissues and no bonebed drilling. The implant design reduces the surgery duration, minimizes intraoperative discomfort and pain, provides a reliable fixation of the implant, and prevents implant migration postoperatively.

Intra- and Postoperative Procedures

Routine intraoperative monitoring was performed with an electrocardiogram, noninvasive blood pressure cuff, and pulse oximeter to

Table 1. Patient Demographics (n = 10)

			Hearing Loss					
ID	**Gender**	**Age**	**Etiology**	**Duration**	**Degree (PTA)**	**Implanted Side**	**Comorbidity**	**ASA**
01	Male	58	Chronic otitis	40 years	R: >90 dB HL; L: 85 dB HL	R	CD, CKF, CVO, HTN	Severe (III)
02	Male	47	Temporal bone fracture	7 years	R: >90 dB HL; L: 75 dB HL	R	CCI	Mild (II)
03	Male	42	Temporal bone fracture	2 years	R: 80 dB HL; L: 85 dB HL	L	CCI	Mild (II)
04	Female	56	Progressive hearing loss	30 years	R: 85 dB HL; L: 90 dB HL	L	HTN, SPD	Severe (III)
05	Male	30	Sudden deafness	2 years	R: 75 dB HL; L: 85 dB HL	R	CCI, HTN	Severe (III)
06	Female	45	Progressive hearing loss	15 years	R: 85 dB HL; L: 80 dB HL	L	DM, HTN	Mild (II)
07	Female	52	Progressive hearing loss	5 years	R: 85 dB HL; L: >90 dB HL	L	CKF, DM	Severe (III)
08	Female	48	Temporal bone fracture	5 years	R: 80 dB HL; L: 85 dB HL	L	CCI, CD, CKF	Mild (II)
09	Female	57	Temporal bone fracture	3 years	R: 85 dB HL; L: 85 dB HL	L	CCI, CD, CVO, HTN	Mild (II)
10	Female	51	Chronic otitis	18 years	R: 75 dB HL; L: 80 dB HL	L	HTN, SPD	Severe (III)

ASA, 2014 American Society of Anesthesiologists physical status classification system; CCI, condition after closed craniocerebral injury; CD, cardiac decompensation; CKF, chronic kidney failure; CVO, cervical vertebral osteochondrosis; DM, diabetes mellitus; HTN, hypertension; PTA, pure-tone average of hearing thresholds at frequencies 500, 1000, and 2000 Hz; SPD, severe pulmonary disease.

quickly identify and address any unforeseen incident. Intraoperative facial nerve monitoring was not used. The patient's head was turned in a typical position for ear surgeries. For more comfort, sterile surgical drapes were used to limit the visual field of the patient while allowing the patient to read the cue cards presented by the medical team. Given preoperative information, sedation with dexmedetomidine, and interoperative communication, no head fixation/immobilization system was required.

To ensure successful exchange with the patients during the surgery and to inform them about the stages of the procedure, intraoperative cue cards presenting surgical steps, instructions, and questions were prepared (Table 2). The cue cards were presented for the patients to read as needed. When a question was presented,

Table 2. Examples of Intraoperative Cue Cards

Questions	**Procedural Updates**	**Instructions**
Do you feel sleepy?	We will inject the local anesthesia now. It may sting behind your ear. Half of your face will feel numb. You will not be able to close your eye or move that part of your face.	Please remain calm.
Do you feel any pain?	You may feel a drilling sensation now.	Please do not move.
Do you feel any vibrations?	The implant will go in now. You may feel dizzy. Please stay calm.	Please be patient.
Do you feel dizzy?	Now we will test the implant. You may feel as though your ear tingles. You may hear beeps.	If you feel pain, let us know immediately.
Do you hear a sound?	We are almost finished. We are now stitching the skin.	
Do you feel discomfort in your ear?		
Do you feel your face contracting?		

Figure 1. Positioning of the patients and medical team to allow for the successful usage of the cue cards.

patients were instructed to respond verbally. Figure 1 shows how the patients and medical team were positioned to allow for the successful usage of the cue cards. The member of the medical team showed the instruction cards monitored visually the patient's face. Telemetry of the implant (impedance for every electrode and electrical stapedial reflex thresholds for electrodes #1, 5, 10, 15, and 20) was performed.

Patients reported any complications or sequelae in the first 5 postoperative days through a questionnaire. All patients were assigned nonsteroidal anti-inflammatory drugs post-surgery.

RESULTS

The sedative effects of dexmedetomidine were achieved shortly after infiltration. For no patient did blood pressure increase significantly nor an aggravation of comorbidities was observed. No patient-reported pain during the incision and subsequent stages of the surgical procedure (Table 3). Some patients reported light dizziness during the opening of the round window membrane and the insertion of the electrode array in the scala tympani. All patients reported auditory perception during the implant's testing. Impedance and stapedial reflex thresholds were successfully measured in all patients.

Table 3. Patients' Reactions to Different Stages of Cochlear Implantation Procedure (n = 10)

Stages of Procedure	Reported Reaction (n = 10)	
	Pain	Others
Before incision	Not applicable	**Feeling of sleepiness** Yes = 10 No = 0
Incision of soft tissue	Yes = 0 No = 10	**Feeling of sleepiness** Yes = 8 No = 2
Mastoidectomy	Yes = 0 No = 10	**Feeling of sleepiness** Yes = 6 No = 4 **Feeling of vibration** Yes = 7 No = 3
Opening of round window membrane	Yes = 0 No = 10	**Feeling of dizziness** Yes = 5 No = 5
Electrode array insertion	Yes = 0 No = 10	**Feeling of dizziness** Yes = 4 No = 6
Implant testing	Yes = 0 No = 10	**Auditory perception** Yes = 10 No = 0 **Discomfort** Yes = 3 No = 7 **Facial nerve stimulation** Yes = 0 No = 10
Tissue suturing	Yes = 0 No = 10	Not applicable

Table 4. Number of Patients Who Reported Complications or Sequelae in the First 5 Postoperative Days (n = 10)

	Day 1	Day 2	Day 3	Day 4	Day 5
Pain in wound area	10	5	2	0	0
Inflammation in wound area	0	0	0	0	0
Hematoma	1	0	0	0	0
Dizziness	2	2	1	0	0
Nausea	2	2	1	0	0
Vomiting	0	0	0	0	0
Facial nerve paralysis	0	0	0	0	0
Implant migration	0	0	0	0	0

Measurement results were similar to those recorded in similar patients under general anesthesia.

The cue cards were successful for dialogue and information transfer between the surgical team and the patients. Patients were able to answer all questions presented on the intraoperative cue cards. The average surgical duration ("skin-to-skin") in the 10 patients was approximately 25-35 minutes.

Table 4 summarizes the postoperative complications and or sequelae patients reported in the first 5 postoperative days. All patients reported moderate pain in the wound area the day after surgery, which was initially resolved with oral analgesics and which disappeared for all patients by postoperative day 4. Only 2 patients reported slight nausea and dizziness which stopped by postoperative day 4. No facial nerve paralysis or implant migration was observed. Also, no complication of somatic origin was reported.

DISCUSSION

This case series showed how local anesthesia and conscious sedation with dexmedetomidine is a suitable option for adult cochlear implant candidates with comorbidities. The Oticon Medical cochlear implant system is particularly well suited for local anesthesia. Its small receiver requires minimal elevation of the soft tissues and its unique screw fixation system does not require a bone bed preparation with drilling, therefore reducing the duration of the surgery and minimizing patient discomfort during this surgical step while reliably fixating the implant, therefore preventing implant migration postoperatively. The absence of complications observed is in line with previous reports of cochlear implantation that used dexmedetomidine.[12,17,20,22,24-29] While no adverse events of dexmedetomidine were observed during surgery in the 10 cases presented, the analgesic has been most frequently associated with hypo-/hypertension, nausea, and dry mouth, and less frequent adverse events include fever, rigors, cyanosis, and muscle weakness.[34]

This study showed how cue cards are a simple and efficient tool for the patient and the surgical team to interact intraoperatively.

Advantages of cochlear implantation under local anesthesia and conscious sedation with dexmedetomidine include a less invasive procedure without intubation. Implant testing intraoperatively is

simplified and the ability to interact intraoperatively with the conscious patient allows to evaluate hearing sensation during implant stimulation and identify any stimulation of the facial nerve.

The quicker surgical procedure and ensuing postoperative recovery, including the reduced side effects during the early postoperative period suggest cost-effectiveness. The fourfold decrease in dexmedetomidine costs over the past years has made this anesthetic option increasingly cost-effective.[22] However, wound healing and cochlear implant aftercare and outcomes are similar regardless of the anesthetic method. All anesthetic methods have their advantages and disadvantages,[5] and these should inform clinical decisions.

Further research should address the limitations of this case series by recording surgical duration, adverse events, stability of telemetry results measured intraversus postoperatively, audiological outcomes, and patient satisfaction in an experimental as well as a control group of adult patients. Whether cochlear implantation under local anesthesia can be suitable for other patient groups such as children, teenagers, or adults with developmental/cognitive disability remains to be determined.

CONCLUSION

In summary, local anesthesia and conscious sedation with dexmedetomidine are safe and effective anesthetic options for cochlear implantation. This increases the number of patients with severe-to-profound hearing loss suitable for cochlear implantation.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of The National Medical Research Center for Otorhinolaryngology of the Federal Medico-Biological Agency of Russia (02 march 2020, Approval no: 01/2020).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

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