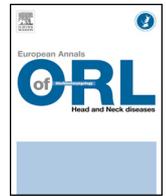




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Original article

Multi-electrode sequential versus single electrode stimulation to elicit the stapedial reflex during cochlear implantation: Correlation with maximum comfort level



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ABSTRACT

Objectives: To assess whether electrical stimulation sequentially delivered through 4 electrodes located in different cochlear areas may elicit the stapedial reflex at lower levels compared to single electrode stimulation and to correlate the sequentially obtained values with the maximum comfort level (C-level).

Patients and methods: A retrospective study was performed on 35 post-verbal adult patients (age 19–80 years) consecutively implanted in 2 cochlear implant centers, evaluating the level of stimulation (pulse width) necessary to electrically evoke the stapedial reflex with two different stimulation modalities: single electrode versus sequential 4 electrode stimulation. Threshold values were compared with C-level obtained at activation.

Results: The average differences of pulse width and C-level were significantly smaller ($P < 0.0001$) when the stapedial reflex was obtained with the sequential stimulation modality and reached statistical significance for every single electrode ($P < 0.0001$).

Conclusions: Stapedial reflex thresholds obtained with sequential stimulation through 4 different electrodes significantly correlate to the C-level obtained at the first setting and may be helpful in defining the upper limit of the dynamic field during initial CI mapping.

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The stapedial reflex (SR) protects the ear from the effects of loud noise. The possibility to elicit this reflex via electrical stimuli transmitted by a cochlear implant (CI) is an easy and reliable way to intraoperatively confirm the integrity of the auditory pathways [1]. In addition, assessment of electrically elicited stapedius reflex threshold (ESRT) provides useful details in defining the dynamic field during initial fitting of the CI. The dynamic field is the area comprised between the T-level (minimal amount of electrical stimulation required to perceive auditory sensation) and the C-level (upper limit of electrical stimulation tolerated without discomfort) as measured for each electrode of the CI. The amount of electrical current necessary to elicit an auditory sensation varies for each electrode and in each individual.

In young children and uncooperative patients, definition of the dynamic field of electrical stimulation may be challenging and the use of non behavioral measures like neural response telemetry (NRT), electrically evoked brainstem auditory potentials (eBAP) and

ESRT do provide objective parameters to be used as an initial point for mapping in order to avoid over-stimulation and safely define the C-level [2]; in particular, several investigators reported a significant association between the ESRT and the C-level in CI users [1,3–6].

Intraoperative ESRT elicitation protocols include stimulation transmitted through single electrodes [7–10] or simultaneous multi-electrode activation in the same area of the cochlear region or in different cochlear locations [2].

The aims of this paper were to assess whether electrical stimulation, sequentially delivered through 4 electrodes located in different cochlear areas, may elicit the ESRT at lower levels compared to single electrode stimulation and to correlate the sequentially obtained ESRT values with the C-level obtained during activation.

1. Materials and methods

After institutional review board approval, 35 post-verbal adult patients consecutively implanted in 2 different otological centers between January 2010 and December 2012 with the Digisonic

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SP cochlear implant system (Neurelec, Vallauris, France) were included in the study group.

The mean age of the subjects was 47 years (range 19–80 years); 17 males and 18 females composed the study group. Causes of deafness included progressive/idiopathic etiology (21 patients), autoimmune deafness (4 cases), ototoxicity (3 cases), Meniere’s disease (3 cases), large vestibular aqueduct (4 cases). Mean duration of deafness was 18.6 months (range 8–48 months).

The implanted patients received their audioprocessors four weeks postoperatively. Patients with medical conditions that could interfere with elicitation or observation of the stapedial reflex (i.e. otosclerosis, previous radical cavity) or revision cases were excluded. Informed consent was obtained by all patients; the study was carried out in accordance with the Declaration of Helsinki. Stapedial muscle contraction was assessed by direct intraoperative visual observation by the surgeon (through the microscope) and the audiologist (through the monitor).

Stimuli were generated using the electrode positioned at the apical end of the array (electrode n. 20), 2 mid-array electrodes (electrodes n. 15 and n. 10) and an electrode at the basal end of the array (electrode n. 5). The Digistim system (Neurelec, Vallauris, France) was used for intra-operative stimulation and recording.

A monopolar stimulation modality was used in all patients. Electrical parameters for the stimulation were: intermittent stimulus, burst number: 10, stimulus duration: 400 ms, stimulus delay: 1000 ms, stimulus intensity: 70 current units and pulse rate: 600 Hz [11]. Variation in the stimulation charge level was obtained through changes in the pulse width, while the stimulus amplitude was maintained stable. The pulse width was 20 μs at first stimulation, followed by stepwise increments of 2 μs until a reflex was elicited.

Two different stimulation protocols have been adopted; in both protocols the pulse width was progressively increased until the reflex was observed and then decreased to the threshold limit (i.e. disappearance of the reflex). In the first protocol, each of the 4 electrodes was separately activated, progressively increasing the pulse width till the appearance of the reflex. In the second protocol, all 4 preselected electrodes were stimulated in a sequential manner starting from the basal turn of the cochlea (i.e. from electrode n.5 to electrode n.20); the pulse width was progressively increased starting from the central electrodes (i.e. electrode 10 and 15) and subsequently in the apical and basal electrodes, till the appearance of the SR. After observing the SR, the pulse width of the apical and

basal electrodes was decreased by one unit step (2 μs) and subsequently the central electrodes were decreased too, in order to find the minimal threshold for SR and simulate a stimulating “bell-like” configuration similar to the one created during implant activation (due to the larger dynamic field for central electrodes).

Intraoperative ESRT data were compared with the values of the C-level obtained in the same patient during activation.

The C-level was obtained for each electrode during activation and mapping, starting from 20 μs pulse width and progressively increasing it in 2 μs steps in each of the 20 electrodes.

Data were analyzed with a statistical software program (SPSS Statistics for Windows version 20, Chicago, IL). Continuous data were summarized as mean and range. Categorical data were presented as frequencies and percentages. Data were tested for normality with the Shapiro-Wilk test. The differences between the values obtained with both modalities of intraoperative stimulation and the value of the C-levels obtained at activation were compared with the Wilcoxon test. P values <0.05 were considered significant. For multiple comparisons, the P value was adjusted using the Bonferroni correction.

2. Results

Cochlear implant surgery was performed using a standard trans-mastoid approach with posterior tympanotomy. Array insertion was performed through the round window membrane; the membrane was opened only when completely exposed and after careful cleaning of blood and bone dust residues from the operating field.

Complete electrode insertion (n: 20) through the round window was achieved in all cases. Stapedial muscle contraction following electrical stimulation was identified in all patients.

Mean values of pulse width necessary to elicit a reflex with the two modalities of intraoperative stimulation (single electrode or sequential electrode activation) and to obtain the C-level at activation are summarized in Table 1 and represented in Fig. 1. Mean pulse width values needed to electrically evoke the SR were lower for every single electrode when adopting the sequential stimulation if compared to those required to elicit the reflex when the stimulus was transmitted through a single electrode (P<0.0001) (Table 1). For electrodes n. 5 and 10, there was no significant statistical difference between the value of the pulse width necessary

Table 1
Average values of the pulse width (μs) for electrodes 5, 10, 15 and 20 required to intraoperatively elicit the stapedial reflex with the single electrode stimulation and sequential stimulation modalities and values of C-level at activation.

Stimulation modality	Mean (μs)	SD	Median (μs)	IC	Difference Seq vs 1-el P value	Difference 1-el vs C(a) P value	Difference Seq vs C(a) P value
Electrode 5							
Sequential	30.12	6.07	30	27.92–32.27	0.0001*	0.0001*	0.138
Single electrode	38.36	6.19	36	36.16–40.56			
C-level activation	31.03	5.12	31	29.21–32.85			
Electrode 10							
Sequential	37.42	6.30	39	35.19–39.67	0.0001	0.0001*	0.813
Single electrode	47.21	6.72	47	44.82–49.59			
C-level activation	37.57	6.04	38	35.43–39.71			
Electrode 15							
Sequential	37.06	6.54	38	34.73–39.38	0.0001*	0.0001*	0.009*
Single electrode	46.69	7.27	48	44.11–49.27			
C-level activation	34.42	6.09	35	32.26–36.58			
Electrode 20							
Sequential	37.06	6.54	38	34.73–39.38	0.0001*	0.0001*	0.011*
Single electrode	46.69	7.27	48	44.11–49.27			
C-level activation	34.42	6.09	35	32.26–36.58			

1-el: single electrode modality; C(a): Comfort level at activation; IC: Interval of confidence; SD: standard deviation; Seq: sequential modality.

* Asterisks indicate statistically significant differences (P<0.05).

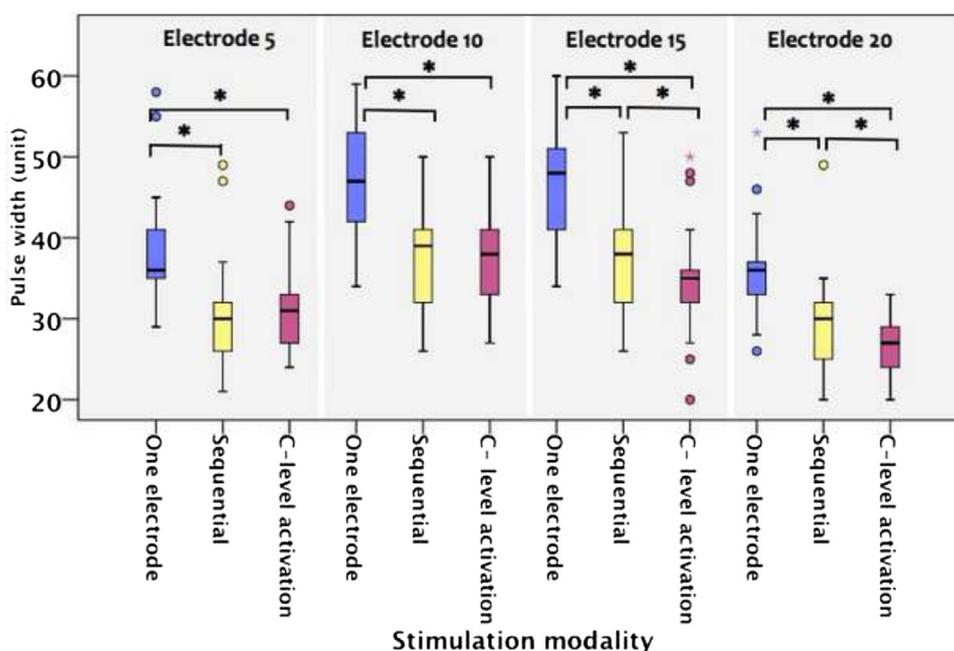


Fig. 1. Box-plots showing median pulse width (μs) for electrodes 5, 10, 15 and 20 necessary to elicit the stapedial reflex in the two modalities of stimulation tested (single electrode stimulation and sequential stimulation) and the pulse width of the C-level at activation of the cochlear implant. Asterisks indicate statistically significant differences ($P < 0.05$).

to evoke the SR with the sequential stimulation and the value of the C-level identified at activation. For electrodes 15 and 20, the differences between these two values were statistically significant, but still pulse width values of the sequential modality were closer to the value of the C-level at activation than the pulse width value of single electrode stimulation (Fig. 1).

The average difference of pulse width between the single electrode stimulation and the value of the C-level at activation was 7.3, 9.6, 12.27 and 8.93 μs for stimulation on electrodes 5, 10, 15 and 20 respectively. These differences were significantly smaller ($P < 0.0001$) when the SR was obtained with the sequential stimulation modality (values 0.19, 0.15, 2.63, 2.24 μs for electrodes 5, 10, 15 and 20, respectively) and reached statistical significance for every single electrode ($P < 0.0001$). These findings were confirmed at the 3 months follow-up evaluation.

3. Discussion

Initial fitting of a CI is often a challenging task, particularly in very young children or uncooperative patients. Intraoperative electrophysiological tests such as neural response telemetry, eBAP and ESRT give useful figures in defining the dynamic field when behavioral responses are not considered sufficiently reliable.

Electrically evoked stapedial reflex threshold values demonstrated a consistent correlation to the C-level obtained when programming a CI [2,7]. Some technical issues should be taken into account when considering ESRT. Stapedial reflex threshold may be recorded in different ways: by direct visual observation, tympanometry and electromyographic (EMG) measurement [1,8]. Direct visualization of the movement of the stapes produced by stapedial muscle contraction is the simplest method but some middle ear diseases (i.e. otosclerosis) may alter the effect of the muscle contraction; visually detected threshold value may moreover be higher than actual EMG thresholds. When compared to direct visualization, intraoperative tympanometry is a more objective way to record the reflex, but it is time consuming and does not overcome the problem of stapes fixation [1]. In presence of stapedial

fixation, the SR can be recorded placing a needle electrode in the muscle itself [7]. EMG measurement could also be useful in gusher patients; cerebrospinal fluid leakage as in case of modiolar defects in cochlear malformation patients, may in fact hinder correct visual evaluation of stapedial tendon contractions.

Anesthesia may interfere with SR elicitation; in particular, volatile anesthetics suppress the SR in a dose-dependent manner suggesting that ESRT measurements acquired during volatile anesthesia will over-estimate the C-level [12–15]. For the same reasons, long lasting curare should be avoided when SR recording is planned during CI surgery because of its paralyzing effect [16]. Evaluation of the stapedial reflex cannot be performed when the stapes-tendon-stapedial muscle unit is absent (i.e. complex revision cases or cochlear implantation in some cases of destructive chronic otitis) or in case of brainstem anomalies or cochlear nerve aplasia/hypoplasia. In the latter cases, moreover, there are no validated objective measurements that can reliably predict functionality and functional performances of the cochlear implant [17].

This study confirmed the correlation between the ESRT and the maximum comfort level at activation in a group of adult patients: the values of ESRT achieved through a sequential multi-electrode stimulation protocol were close to postoperative C-level values for the same electrodes. Values obtained with sequential stimulation were significantly lower if compared to values obtained with single electrode stimulation.

The lower thresholds and the proximity to the C-level when adopting a sequential stimulation modality may be explained by its similarity to the stimulation method adopted in the speech processor, with a larger dynamic field in the central electrodes.

On the basis of the results obtained from this study, ESRT values gathered through a sequential multi-electrode stimulation significantly correlate to the maximum comfort level at activation in post-verbal adult implantees.

Even if specific studies involving paediatric patients are needed, electrically evoked stapedial reflex threshold elicited through a sequential stimulation modality may be helpful in defining the upper limit of the dynamic field during initial CI mapping and

reduce the risk of excessive stimulation at activation in uncooperative patients and very young children.

Disclosure of interest

The authors declare that they have no competing interest.

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