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A Study of Electrically Evoked Stapedius Reflex Threshold and Comfort Level in Cochlear Implant Patients

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ABSTRACT

In cochlear implants, mapping devices for stimulating the spiral ganglia must be used. In mapping, it is important to decide both the behavioral threshold levels (T level) and comfort levels (C level). Decisions about C levels are often difficult because they depend on the response of each subject, especially in prelingual hearing-loss children who have never experienced any sense of sound. Measurement of the electrically evoked stapedius reflex (ESR) and ESR threshold (ESRT) has the potential for deciding the C level because of its involuntary nature, and hence could be of assistance to such children. Thus, intraoperative and postoperative electrically evoked stapedius reflex thresholds (IOESRTs and POESRTs) and initial behavioral comfortable levels (C level) were investigated. Twenty-one subjects who had undergone cochlear implantation under general anesthesia in our institute, were entered into the study. Nucleus®22 (N22), Nucleus ®24 (N24), and Clarion™16 (CLN) systems were implanted in six, eight, and seven cases respectively. The selected volatile agents were sevoflurane (in 16 cases), and isoflurane in the remaining cases. In eleven of the subjects (52.4%), intraoperative ESR was recognized. In the N24 group six cases (75%) of the intraoperative ESR was determined however ESR rarely appeared in any of the CLN group (14.3%). There were higher IOESRTs than POESRTs. IOESRTs were mostly higher than POESRTs and this might have been caused by the volatile agent. The relationship between IOESRTs and POESRTs and initial C levels was shown to be an almost linear function in each individual. This tendency was remarkable in that electrodes were placed in median sides, whereas POESRTs and C levels did not differ obviously in its apical side. We suggest that estimated C levels in median sides obtained from IOESRTs and POESRTs in apical sides might be valuable as a mapping reference. In the case of N24, the relationship between the concentration of sevoflurane and ESRTs appeared to be linear. Furthermore, POESRTs were in accordance with the estimated ESRTs at 0% sevoflurane. Further study concerning ESRTs is needed for better cochlear implant use. *Ryukyu Med. J., 21(3,4) 133~141, 2002*

Key words: intraoperative electrically evoked stapedius reflex, postoperative electrically evoked stapedius reflex, volatile agent, estimated C level

INTRODACTION

The fact that an electrical stimulation to the ear could produce a sense of hearing has been well known since it was first reported by Volta in 1800[1]. This suggested the possibility of recovering from hearing loss. In the 1970's House *et al* also reported clinical uses of single channel cochlear implants[2]. Since then cochlear implants have been found to be useful for patients who have lost their hearing due to various causes. Technological progress has contributed to the number of channels, the mode of stimulation and the method of speech processing. However cochlear implants have not yet been perfected and patients who have received cochlear implants need continuous rehabilitation or mapping for adequate use.

Mapping of each patient is carried out by their response to electric stimulation from a behavioral minimal threshold level (T level) to a comfortable level (C level) with all active channels. In some cases, initial construction of the mapping is difficult especially with prelingual deaf children. Thus numerous investigators have explored the relationship between objective methods and the levels so that mapping may progress smoothly and speedily without discomfort to the patients. Because both the auditory brain stem response (ABR) and the acoustic stapedius reflex (ASR) are frequently used as objective hearing measurements owing to their steady, simple and non-invasive nature, electrically evoked auditory brain stem response (EABR) or electrically elicited stapedius reflex (ESR) have been discussed in relation to T or C levels.

Since the ABR waveform is recognized around the hearing threshold, the EABR probably reflects the T level. On the other hand, the ASR is a protective function of the delicate inner ear against loud sounds greater than 75 dB, so its threshold is therefore somewhat lower than the uncomfortable sound level. Thus it is generally believed that the electrically elicited stapedius reflex threshold (ESRT) is generally closely related to the C level. We have tried to measure the intraoperative and postoperative levels of the ESRT in cochlear implantation. The ESRT is not always identical to the initial behavioral C level, hence we have tried to slightly lower the value (e.g. minus 3% of the net value) of the ESRT and referred to as initial C levels.

The purpose of the present study was to investigate an estimation of C level with respect to intraoperative ESRT (IOESRT) and postoperative ESRT (POESRT).

MATERIAL AND METHODS

Twenty-one patients with profound hearing loss who underwent cochlear implantation under general anesthesia in our department were entered into the study. Informed consent for the operation was obtained from individual patients themselves and close relatives like parents, husband or wife, or siblings. In the case of legal minors, parents gave informed consent. We then attempted to examine the intraoperative and postoperative ESR, and initial behavioral C levels. Details of the subjects are shown in Table 1. The applied volatile agents were sevoflurane (in 16 cases) and isoflurane (in five cases). The selected cochlear implant devices were eight Nucleus®24 Systems (N24), six Nucleus®22 Systems (N22), and seven Clarion™ 16 Systems (CLN).

The stimulation mode was depend on the type of device; monopolar +1 mode (MP1+2) for N24, common ground mode (CG) for N22, and monopolar stimulation mode for CLN. Stimulation levels of ESRTs and C levels were recorded as either current level (CL) for N24, N22 or clinical unit (CU) for CLN. The relationship between these parameters and the stimulating electric current values (μA) is generally logarithmic. The spectrum peak coding method (SPEAK) was employed for most of the N22 and N24 users, while continuous interleaved sampler (CIS) was used for the Clarion users as the encoder strategy. The pulse width of each stimulus was 25 μs (N22,N24), 75μs (CLN). For CLN, 150μs was used if needed.

During evaluation of the thresholds, the concentration of the volatile agent was maintained and no muscle relaxants were administrated for at least half an hour prior to the measurement. The method of determining each ESRT and C level was as follows: starting from the lower level (180～200CL for N24, N22, 150～160 CU for CLN), the stimulation levels were elevated through 5～10 levels step by step. On confirmation of a response to a stimulus, the value was reduced 3～5 levels, then when a response was again given, this level was defined as the threshold.

IOESRTs were indicated by careful observation through a microscope of the construction of the stapedius muscle. POESRTs were determined with an impedance audiometer (Zodiac901) at the contralateral ear. Except for undesirable facial nerve spasm with a few electrode stimuli in two cases, no apparent clinical complication occurred.

Since it was not easy to measure the ESR in all twenty-two electrodes of both the N22 and N24 systems during the operation, five electrodes were sampled from Electrode (EL) 3 of the apical side to EL 22 of the basal side every three to five electrode intervals. However for the Clarion device, odd numbered electrodes were used.

Values of IOESRTs, POESRTs and C levels were analyzed in N24 users because the same electrode stimulation conditions with respect to encoder strategy or pulse width were maintained through all phases from IOESRT to C level measurement. Each ESRT was plotted on graphs of IOESRT against POESRT, POESRT against C levels, and IOESRT against C levels. The various relationships were evaluated. A method for estimating the C level derived from IOESRT and POESRT was investigated. For statistical analysis, the Wilcoxon signed rank test was used.

In one case of N24, due to concentration changes of the volatile agent sevoflurane, the ESRT of the opposite ear was investigated with an impedance audiometer. The concentration started at 2.25%, and was reduced by 0.25～0.5% steps, with at least five-minute intervals between. After a stable concentration of sevoflurane was confirmed for at least five minutes, each IOESRT was measured.

RESULTS

Identification of the rate of intra and postoperative ESR

Out of the 21 cases, eleven (52.4%) were identified as intraoperative ESR. There was a difference in the rate among devices. Sixty-seven percent (four out of six) of N22 users, 75% (six out of eight) N24 users and 14.3% (one out of seven) Clarion users were detected with ESR.

Postoperative ESR appeared in most of the cases. Furthermore there was no case of intraoperative ESR without a postoperative one. This tendency was common in the CLN.

Comparison of intraoperative and postoperative ESRT and C level

Six N24 users were entered into the analysis. Sevoflurane and isoflurane were used as the volatile agents for general anesthesia, the former was used in five cases whereas the latter was used in one case. With regard to their concentration during examina-

Table 1 Profile of subjects

No.	sex	age	cause of deafness	term of deaf (year)	operated ear	device	volatile agent*/ concentration at ESRT measurement (%)	intra-operative ESR*
1	F	39	Usher syndrome	24	R	N22	ISO/1.5	Det.
2	M	5	congenital	5	R	N22	SEV/1.5	Det.
3	F	5	unknown	4	L	N22	SEV/2.2	Det.
4	M	44	Usher syndrome	0.6	R	N22	ISO/1.5	Det.
5	M	56	meningitis	1	R	N22	ISO/1.5	N.D.
6	F	4	congenital	4	R	N22	SEV/1.7	Det.
7	F	8	congenital	8	L	N24	SEV/1.8	Det.
8	F	6	congenital	6	R	N24	SEV/2.0	Det.
9	F	3	Leopard syndrome	3	L	N24	SEV/2.0	Det.
10	M	11	congenital	11	R	N24	SEV/2.0	Det.
11	M	4	congenital	4	R	CLN	SEV/1.5	N.D.
12	M	6	congenital	6	R	CLN	SEV/2.0	N.D.
13	M	8	Waardenburg syndrome	7	L	CLN	SEV/1.5	N.D.
14	M	6	Waardenburg syndrome	5	R	CLN	SEV/1.4	N.D.
15	F	3	congenital	3	R	CLN	SEV/2.0	N.D.
16	F	2	Mondini malformation	2	R	N24	SEV/2.0	N.D.
17	M	61	unknown	14	R	CLN	SEV/2.0	N.D.
18	M	41	unknown	0.5	L	N24	ISO/1.2	Det.
19	F	42	Mithocondria disease	0.4	L	N24	ISO/0.8	N.D.
20	F	2	congenital	2	R	N24	SEV/2	Det.
21	M	3	congenital	3	R	CLN	SEV/2.0	N.D.

M: Male　F: Female
R: Right　L: Left
* SEV : Sevoflurane　ISO : Isoflurane

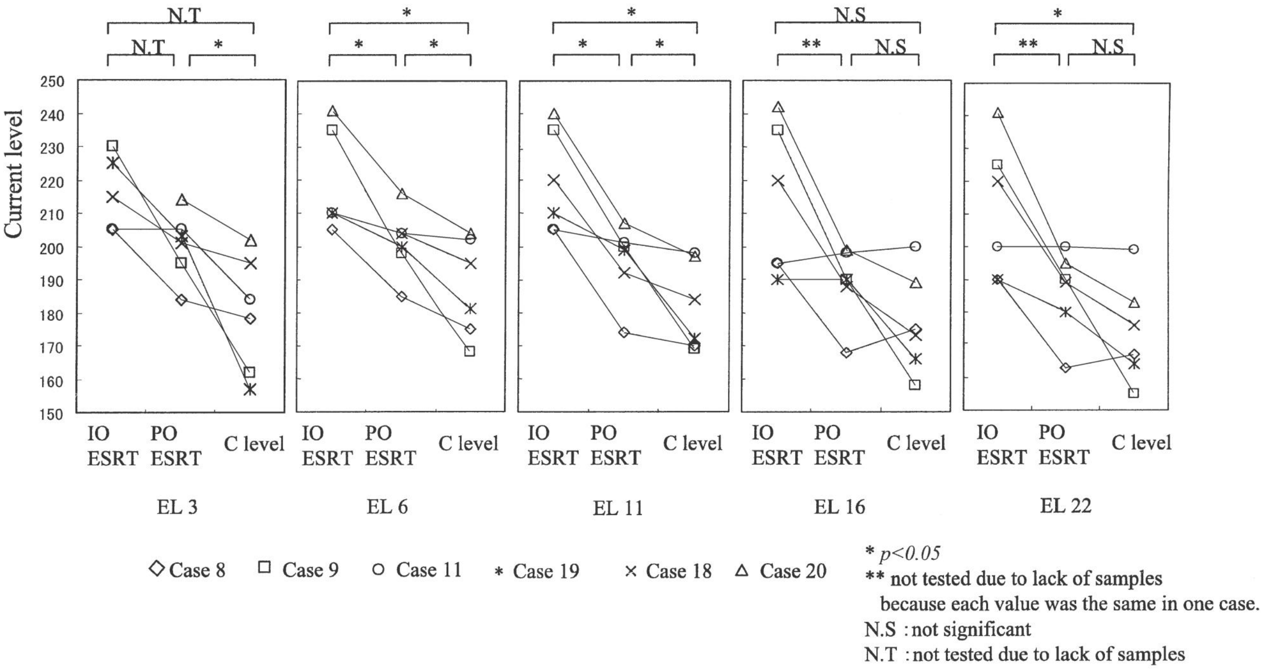

Fig. 1 Relationship between intraoperative ESRT (IOESRT), postoperatve ESRT (POESRT), and initial C level of N24. Significant differences in the values of intraoperative and postoperative ESRTs were identified in electrodes 6 and 11($p<0.05$). Significant differences concerned with postoperative ESRTs and C levels tended to appear with the electrodes placed in the basal to median sites (electrode 6 and 11, $p<0.05$).

Table 2 Estimated C levels of each electrodes. The estimated C levels were obtained by multiplying the postoperative ESRTs and the ratio of postoperative ESRTs / intraoperative ESRTs

		Case 8	Case 9	Case 11	Case 18	Case 19	Case 20
	IOESRT	205	230	205	215	225	-
EL 3	POESRT	184	195	205	201	203	214
	C level	178	162	184	195	157	202
	Estimated C level	165	165	205	188	183	N/A
	IOESRT	205	235	210	210	210	241
EL 6	POESRT	185	198	204	204	200	216
	C level	175	168	202	195	181	204
	Estimated C level	167	167	198	198	190	194
	IOESRT	205	235	205	220	210	240
EL 11	POESRT	174	200	201	192	199	207
	C level	170	169	198	184	172	197
	Estimated C level	148	170	197	168	189	179
	IOESRT	195	235	195	220	190	242
EL 16	POESRT	168	190	198	188	190	199
	C level	175	158	200	173	166	189
	Estimated C level	145	154	201	161	190	164
	IOESRT	190	225	200	220	190	241
EL 22	POESRT	163	190	200	189	180	195
	C level	167	155	199	176	164	183
	Estimated C level	140	160	200	162	171	158

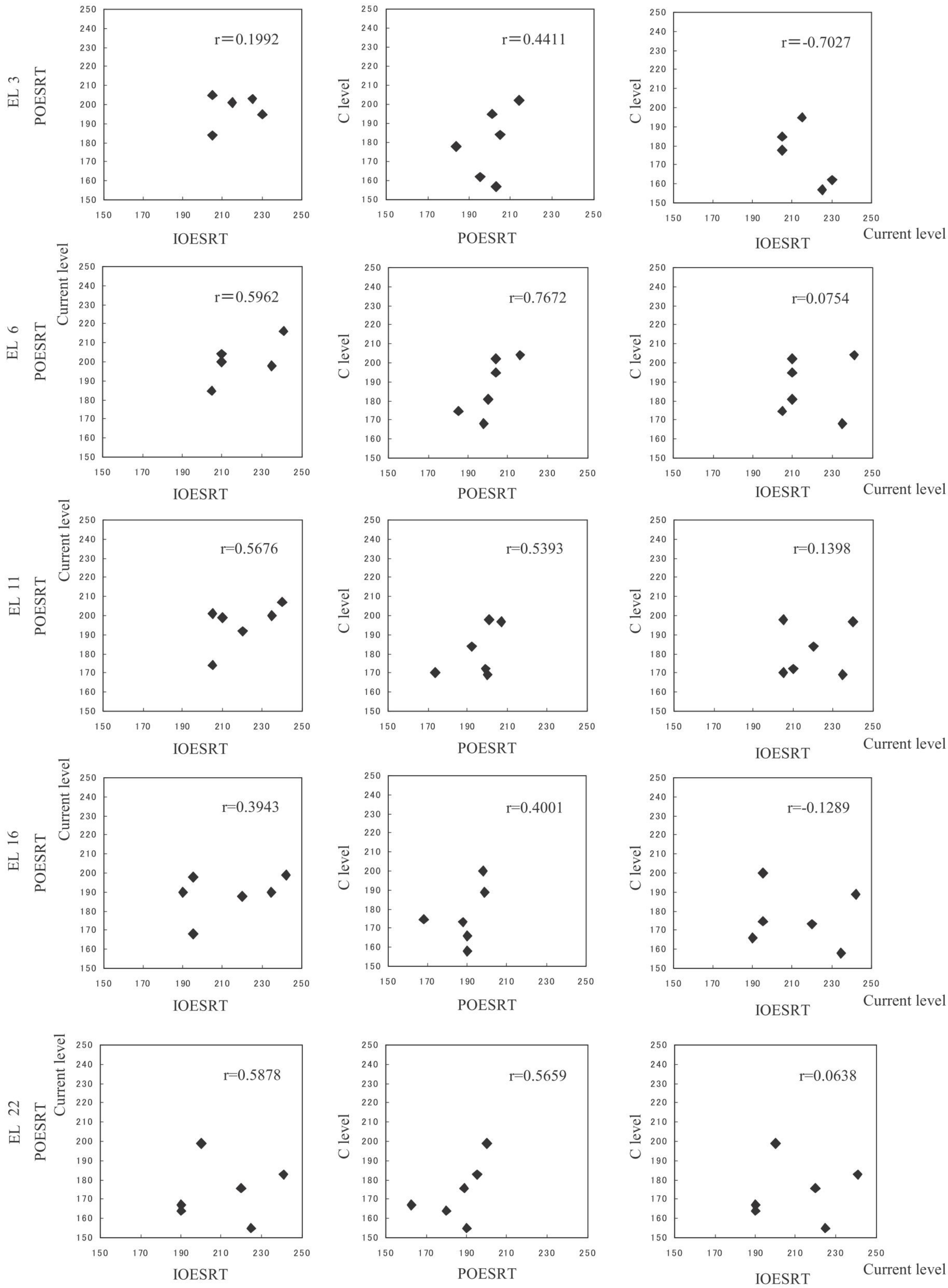

Fig. 2 Correlation between intraoperative and postoperative ESRTs, postoperative ESRTs and C levels, intraoperative ESRTs and C levels. POESRT and C level of EL6, IOESRT and C level coefficient were fairly high.

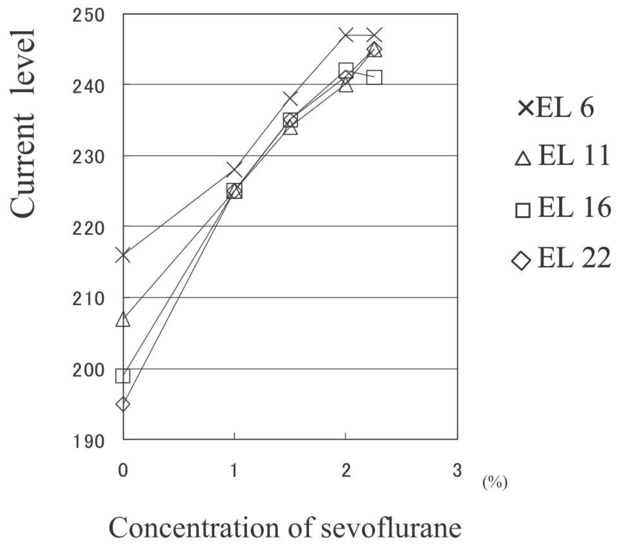

Fig. 3 Relationships between concentration of sevoflurane and ESRT in each electrode of case 20. Obvious linear relationships were recognized in all four studied electrodes. Values at 0% were postoperative ESRTs.

tion of ESR, the sevoflurane cases ranged from 1.7% to 2.2% (Table 1).

The sampled electrodes (EL) were EL3, EL6, EL11, EL16, and EL22 from the apical side of the array to the basal side. In one case, IOESRT of EL3 was not tested. The values of the IOESRT, POESRT, and C levels are noted in Fig 1. Significant differences in the values of IOESRTs and POESRTs were identified in EL6 and EL11. The other electrodes could not be analyzed due to lack of samples for the Wilcoxon signed rank test. Significant differences in the POESRTs and C levels were observed in the electrodes from the basal to the median sides (EL3, EL6, and EL11).

There seemed to be a linear relationship between the values of IOESRTs to initial behavioral C levels existed in individual cases, but the slopes of the lines were scattered among the individuals. This tendency was more obvious in basal and median sides.

The estimated C levels obtained by multiplication of the POESRTs and the ratio of POESRTs / IOESRTs are shown in Table 2.

The correlation among IOESRTs and POESRTs, POESRTs and C levels, IOESRTs and C levels were investigated (Fig 2). In all cases, there were no significant correlations except for the relationship between POESRT and C level of EL6, IOESRT and C level of EL3. These results suggest that IOESRT or POESRT did not always reflect whether the C level was higher or lower.

Concentration changes of sevoflurane and contralateral ESRT

Obvious linear relationships between the concentration of sevoflurane and ESRT were recognized in all four electrodes studied (Fig. 3). When the concentration of the volatile agent reached its peak, ESRT saturation occurred in two electrodes (EL6 and EL16). This led to the obvious assumption that there was a very little difference between POESRTs and IOESRTs at 0 % of sevoflurane.

DISCUSSION

The first report of electrical stimulation to the ear to cause the sense of hearing was made by Volta [1]. The fact was generally accepted and on this basis, cochlear implantation has become a useful method for treating profoundly deaf patients. The use of these devices has gradually widened because of the good results and low risk of adverse effects.

Compared with earlier cochlear implant systems, recent devices can offer better performance owing to improved technology. However, even with the latest cochlear implants, hearing function is a long way from that of the original auditory system. One reason for the less-than-optimum performance of cochlear implants, is that adjustments according to the response from individual users to the stimulation, are essential for the appropriate use of these implants. Particularly in cases of prelingual deafness, objective evaluation methods are obviously required for adjusting the device[3].

The stapedius reflex, which is induced by certain loud sounds, has been widely applied as a useful method for assessing hearing levels[4]. An essential feature of the method is the independence of an answer from the patient with respect to sounds in contrast to measurement using pure-tone audiometry. Therefore, it is beyond doubt that measurement of stapedius reflex thresholds with an impedance audiometer is extremely effective with little children who cannot accurately respond to sounds.

The fact that not only sound pressure but also electrical stimulation induces contraction of the stapedius muscle in monkeys was first reported by Burnett *et al*[5]. As for humans, Jerger *et al.*[6] gave the first report of a cochlear implant operation.

They reported the precise characteristics of the acoustic stapedius reflex (ASR) and the electrically elicited stapedius reflex (ESR). Essential aspects of ASR and ESR were extremely similar to latencies or duration of impedance changes, except for subtle differences on the duration of the plateau phase. Therefore, ESR seems to be a valuable method for hearing evaluation elicited by electrical stimulation, especially for cochlear implant patients.

Similarly, one of the objective hearing measurement methods that is commonly available, the auditory brain stem response (ABR), which is evoked by electrical stimulation as well as sound pressure, with little difference in wave forms or latencies[7]. It is suggested that electrically evoked ABR (EABR) may offer useful information concerning device fitting[8], especially behavioral T levels[9, 10].

In contrast, some investigators reported that ESR might become a preferable behavioral C level predictor[8, 11-15], even though there is a contradictory report[16]. Both T levels and C levels are important values for device mapping, especially the latter which may result in an uncomfortable sensation if the level is too loud. If the user is an infant, the mapping process will be difficult due to the lack of ability to communicate. In view of this, the potential of ESRT for C level estimation should be investigated.

The results of our study suggested the possibility of initial C level estimation from IOESRT and POESRT. High-dose barbiturates, frequently used for intravenous anesthesia or for the induction of general anesthesia, suppress the acoustic reflex[17], but the effect on the ESRT of our patients who were administered these agents seemed uneffected because evaluation of ESRT started two hours or more after the start of the operation. Of course, the stapedius muscle is the smallest skeletal muscle, so we took care to avoid the effect of muscle relaxants by keeping to intervals of at least half an hour after administration. As for volatile agents, Bissinger *et al.* reported halothane, enflurane and isoflurane caused suppression of ASR independent of the application of N_2O, and might be similar to ESR[18]. Our results showed a similar tendency with respect to ESRT.

In the N24 group, IOESRTs, POESRTs and initial behavioral C levels showed an almost linear correlations at electrodes placed in basal to median sides, and also the ratios of each value in individuals were diverse. Makhdoum *et al.* reported that a relationship exists between IOESRT and the concentration of the volatile agents, isoflurane and halothane[19]. They suggested a different action existed for each of the volatile agent to ESRTs. The former seemed linear, the latter was shown as logarithmic and the results of individual patients varied widely. The present study suggests that IOESRTs, POESRTs and initial behavioral C levels should be discussed not by using average values from a group of patients but by using serial values of individual cases. This is because the slope of the lines drawn for IOESRTs and POESRTs and initial behavioral C levels are different in each case as shown in Fig.1. This result may indicate a hypothesis in which the level of impact of volatile agents on ESRTs reflects differences between POESRTs and initial C levels. Furthermore, it seems that estimated C levels might be obtained from the POESRTs and the ratios of IOESRTs and POESRTs according to their linear correlation. The estimated C levels scarcely exceeded and were almost similar the corresponding initial C levels, especially in median sides. Because stimuli exceeding the behavioral C level may cause discomfort, this point is possibly an advantage of the proposal. This suggestion might be considered in median sides because the tendency is inconspicuously seen in apical sides.

Additionally, no significant differences between POESRTs and C levels were seen in EL16 and EL22. Thus, estimated C levels in median sides and POESRTs in apical sides might be somewhat suitable as a reference for the C level decision.

In the case of N24, we evaluated the relationship between the concentration of the volatile agent and IOESRTs. The estimated values of 0% volatile agent were considered suitable as an approximation of POESRTs. If this tendency is confirmed, several values of concentrations of volatile agents obtained during operations may substitute for POESRTs.

As for electrode positions for ESRTs, there was a tendency to show that differences between POESRTs and behavioral C levels seemed to be present at a more basal sides. Stephan *et al.* reported that attitude to the acoustic reflex may not be affected by frequency of the sound stimulation[20]. According to the place theory, higher pitched sounds act more on the basal sides, while lower pitched sounds act on the more apical sides[21]). The positions of the stimulating electrodes should decide the frequency of the evoked sound sensation. As far as electrical stimulation is concerned, Makhdoum *et al.* explained the discrepancy among the stimulated electrodes as the difference in relative position in each stimulating electrode, the modiolus, and the reference electrode placed on the temporal skull bone[19]. Because patients were subjected to a monopolar mode in the present study, this opinion appears to agree with our results.

One of the weak features of impedance audiometry, the basis of stapedius reflex measurement, is produced by middle ear disorders, for example, otitis media, and especially in the pediatric population, ossicle abnormalities[22]. Direct observation of stupedius muscle contraction is preferable, because this is scarcely affected by middle ear conditions. Consequently, we chose ipsilateral ESRT during the operation. After the operation, stagnant effusion or a clot will affect middle ear compliance and reinforcement around an electrode array for the protection of perilymph leakage and dislocation have the risk that ESRT may not be detected despite contraction of the stapedius muscle. Therefore, we selected contralateral ESRT as the postoperation.

The other weak point is that intraoperative ESR was not elicited in several cases. The fact was more remarkable in CLN users. This phenomenon might be caused by different modes of stimulation between devices. Since the CIS mode of the CLN features higher frequency stimulation per electrode, responses by spiral ganglia were possibly easily affected by the volatile agent. Another reason for the phenomenon was perhaps the different sensitivity of individuals. Further studies concerning various ESRTs will be needed for the development of cochlear implant use.

In conclusion, the present study shows that the initial C level may be established by POESRT and the ratio of POESRT / IOESRT in basal to median sides, while POESRT is applicable to C level in apical sides with regard to N24 users. Since CLN users indicated no useful relationship between ESRT and behavioral comfortable level, further study is needed using variant stimulating condition, e.g. pulse width or stimulating rate.

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