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RESEARCH ARTICLE

Clinical evaluation of a new electrocochleography recording electrode

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Abstract

Background and Aim: Electrocochleography is one of the most practically used tests in approaching Meniere's disease (MD). To record reliable response components, the type of applied electrode is of particular importance. The TIP-trode is an appropriate electrode due to its user-friendliness. Gutter electrode can be used in more than 100 subject. This study aimed to compare the results of the Electrocochleography (ECochG) test responses using TIP-trode and the Gutter electrode.

Methods: This cross-sectional study was performed on 20 normal subjects and 20 patients with MD, who referred to the Audiology Clinic of Iran University of Medical Sciences. The ECochG response components were randomly recorded with TIP-trode and Gutter-electrode consecutively, and then statistical analysis was accomplished.

Results: The mean impedance, action potential, and summation potential amplitudes were not significantly different between normal subjects and people with MD by using two types of electrodes. Moreover, the mean scores of summation potential/action potential (SP/AP) ratio of the Gutter electrode were higher than that of the TIP-trod. The mean SP/AP ratio between two types of electrodes was statistically significant differences in normal subjects ($p = 0.027$) and in MD group ($p = 0.009$).

Conclusion: We demonstrated that the utilization of the Gutter electrode in ECochG assessments was considerably effective and beneficial. It can significantly reduce expenses and be applied in clinical settings. It’s also recommended that 47.22% mean SP/AP amplitude ratio to be considered as upper limit of normality by using the Gutter electrode.

Keywords: Electrocochleography; Meniere's disease; Gutter electrode; TIP-trode; impedance

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Introduction

Nowadays, electrocochleography (ECochG) is a highly reliable test in assessment and diagnosis of inner ear diseases such as Meniere's disease (MD), auditory neuropathy, superior semicircular dehiscence, auditory sensitivity estimation, and intraoperative monitoring of cochlea and auditory nerve [1,2]. The earliest study of the ECochG was performed in 1930 and the recorded responses were attributed to the cochlea. A few years later, Davis confirmed the result of the

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previous study, however [3]. for the first time in 1970, recorded responses from the cochlea using the averaging technique were termed as ECochG by Aran [4].
To address the cochlear function, the ECochG can be the best auditory evoked response [1,5]. Cochlear microphonic (CM) potential is an alternating current that originates from the outer hair cells of the cochlea and is dependent on stimulus. Summation potential (SP) which appears as a result of presenting a continuous tone or transient signal, is a direct current that originates from the outer and inner hair cells of the cochlea and indicates active cochlear amplification. The action potential (AP) response is originated from the eighth cranial nerve and appears at about 1.5 ms after stimulus presentation [1,5]. ECochG is a proper tool for diagnosing and monitoring MD [1]. MD is an idiopathic disease involving the inner ear, characterized by vertigo, hearing loss, and tinnitus that causes an increase in the endolymphatic pressure of the inner ear [6]. The exact pathophysiology has not been established yet [7]. Researchers expressed the sensitivity of the SP amplitude in diagnosing MD by about 30%. In addition, the most commonly used indicator of ECochG recording parameters with a 60% sensitivity in diagnosing MD, is summation potential/action potential (SP/AP) ratio. This rate of sensitivity increases to more than 90% during symptoms recurrence [8-10].
Depends on the purpose of the ECochG recording, two approaches based on the positioning of electrodes are carried out: intratympanic (promontory and oval window) and extra tympanic (tympanic membrane and external auditory meatus). The electrodes can also be named based on their particular location, commonly known as the tympanic membrane/transtympanic (TM/TT) electrode and ear canal electrodes including butterfly, Tip-trode (and now, the Gutter electrode). The purpose of using ear canal electrodes is the facilitation of analysis of action potential components and summating potential. Generally, to record the low amplitude potentials such as when auditory sensitivity estimation and assessment of cochlear function in patients with auditory neuropathy is needed, more sensitive procedures required. Surgery is needed to place the electrodes in the tympanic space and these methods should be performed by a physician. However, when the test is performed at a supra threshold level, the placement of electrodes outside of the tympanic membrane is more convenient and reliable [5,11,12]. A silver metal spherical ball electrode placed on a promontory or round window was among the first electrodes administered. The type of used electrode varies due to several factors including diagnostic purposes, the health status of the hearing system, the patient's age, and the availability of medical services. Patient comfort is an important factor to be considered. Also, the material and appearance of the electrode should result in the least resistance along with the highest ion exchange [5,12].
There have been various electrodes introduced to record cochlear responses and all of them have their advantage and disadvantage. butterfly electrodes are the ear canal type. Due to the improper shape of these electrodes, they do not provide enough space for the attachment between the skin and its surface and sometimes damages the patient's ear canal [5,13]. TIP-trode is another type of the ear canal electrodes, which has an appropriate shape and appearance. It is proper for clinical applications; nonetheless main disadvantage of this electrode is its high cost and disposable identity. Its gold coating enhances the detection of action potential and N1 wave [5].The Gutter electrode is a new type of ear canal electrode that was first developed by Sameni and Anvarsamarein and introduced to the 16th Iranian Congress of Audiology (2017). Its design is in a way to minimize the weaknesses of the butterfly and TIP-trode electrode. The electrode is made of silver and silver-chloride coating. The physical structure of the Gutter electrode is adjustable relative to the size of the individual ear canal and increases the area of attachment to the skin of the ear canal wall. Insert earphone are coupled to the Gutter electrode by placing a probe tip, typically a foam plug into the electrode. The Gutter electrode is not disposable and it can be sterilized easily and reused.
In this study, we investigated the parameters of impedance, AP and SP amplitudes as well as

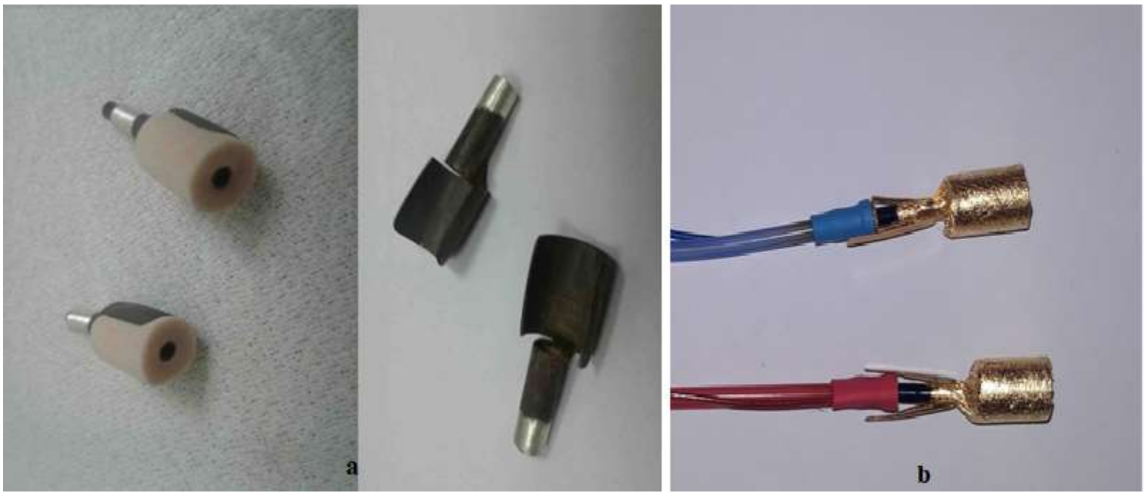

Fig. 1. The Gutter electrode with and without foam ear tips (a) and TIP-trode (b).

SP/AP ratio in the normal subjects and patients with MD using TIP-trode and the Gutter electrode.

Methods

Participants

This cross-sectional (descriptive-analytical) study was randomly performed on 20 normal subjects (8 women and 12 men) with a mean age of 28 ± 4.32 years old and 20 individuals suspected to MD (13 women and 7 men) with a mean age of 30.7 ± 4.71 years old. Inclusion criteria for normal subjects were included air conduction (AC) audiometry thresholds of less than or equal to 25 dB HL at all frequencies (250−8000 Hz), no gap between AC and bone conduction (BC) audiometry results, normal speech audiometry, type An tympanogram, presence of ipsilateral acoustic reflex, having no family history of MD, and absence of tinnitus and vertigo in addition to balance dysfunction in the past two years.

Patients with MD were entered into the study with symptoms at least six months ago, including sensory-neural hearing loss (in low frequencies), ear fullness, roaring tinnitus, and episodic vertigo with a duration of more than a few minutes to several hours. Likewise, the disease was diagnosed by an expert otologist. The patient group covered the symptoms both unilaterally or bilaterally. Those with conductive hearing loss, other pathology of the vestibular system, moderate (50−60 dB HL) or greater sensory-neural hearing loss at 2−4 kHz, person's unwillingness to continue the study, or not experiencing vertigo attack in the recent years were excluded.

Procedure

At first, the ear canal was cleaned by a swab dipped in Nuprep gel. Then, a TIP-trode (b) and a Gutter electrode (a) (Fig. 1), were randomly inserted into each patient's ear canal. The patient's ear canal was carefully observed by an otoscope, since it was necessary to accurately estimate the size of the canal to determine the size of the Gutter electrode. The patient was also referred to an otologist if high amount of cerumen in the canal was observed.

The size of the electrode and consequently its placement in the ear canal should not cause any pain and it was required to be fully in contact with the wall. To resize the electrode, first, ear-tips foam was needed to be attached to the insert device and then connected into the cylindrical space of the Gutter electrode. Afterwards, the foam was pressed to open and close the electrode to prevent fracture or cracking the electrode surface. Before conducting the test, the impedance of the electrodes was measured and recorded. Impedance below 1 kΩ was considered a requirement of the test. Then, ECochG test was

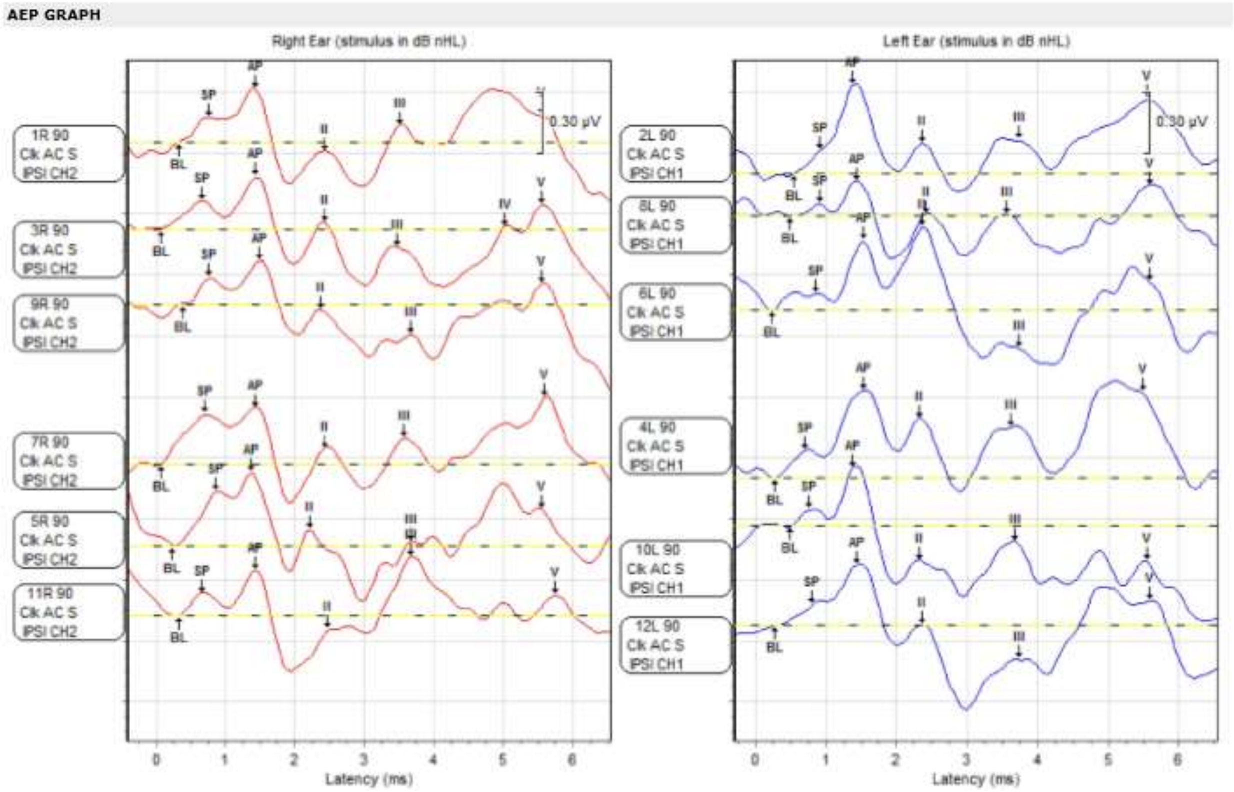

Fig. 2. Sample recordings of electrocochleography using Gutter electrode (the top three waves in both panels) and TIP-trode (the down three waves in both panels) in a normal ear (left panel) and a patient with Meniere's disease (right panel).

performed using the Vivosonic Integrity system version 8.3 (Toronto, ON, Canada). The stimulus parameters included a presentation rate of 11.1 per second, 200 microsecond click stimulus, alternative polarity, constant 90 dB nHL intensity level, 2000 sweeps, and 7 ms time window. 30 Hz high pass and 2400 Hz low pass with 12−24 dB/octave filter was used to record the response. Electrode placement was in horizontal array: inverting electrode in the test-ear canal, non-inverting electrode in the non-test ear canal, and ground electrode at Fpz. Three acceptable waves with a residual noise of less than 100 nV were recorded utilizing each electrode in each ear (Fig. 2). There was also 30-minute interval time considered for re-preparation and switching electrodes. After performing the test, the impedance and amplitude data of two main parameters of SP and AP were collected. To obtain the SP/AP amplitude ratio, the baseline was considered in the pre-SP wave depths.

In the descriptive statistics section, the mean and standard deviation of the variables were analyzed. Then Kolmogorov-Smirnov statistical test was used to investigate the normal distribution of data, finally, for the variables, paired t-test was used according to SP and AP amplitude normal distribution and for the variables, the Wilcoxon test was used according to impedance and SP/AP amplitude ratio non-normal distribution. Data were analyzed by SPSS software version 20.

Results

In the healthy control group, the results of ECochG components using the TIP-trode were mean impedance of 0.77 ± 0.21 KΩ, mean AP amplitude of 0.29 ± 0.12 µV, mean SP amplitude of 0.06 ± 0.04 µV, and mean SP/AP amplitude ratio of 22.61 ± 7.69%. In the same group by using the Gutter electrode, the results of

Table 1. Mean (standard deviation) of electrocochleography measures and electrode impedance recorded by Gutter and TIP-trode electrodes in normal participants and patients with Meniere's disease.

			Mean (SD)			
Group	**n**	**Electrode type**	**SP (mV)**	**AP (mV)**	**SP/AP**	**Electrode impedance (kΩ)**
Normal	**20**	**Gutter electrode**	0.09 (0.05)	0.33 (0.12)	28.34 (9.44)	0.85 (0.28)
		TIP-trode electrode	0.06 (0.04)	0.29 (0.12)	22.61 (7.69)	0.77 (0.21)
Meniere's disease	**20**	**Gutter electrode**	0.16 (0.07)	0.26 (0.11)	64.36 (13.75)	0.92 (0.23)
		TIP-trode electrode	0.13 (0.05)	0.26 (0.12)	53.87 (14.46)	0.82 (0.20)

SP; summating potential, AP; action potential

average ECochG parameters revealed mean impedance of 0.85 ± 0.28 KΩ, mean AP amplitude of 0.33 ± 0.12 µV, mean SP amplitude of 0.09 ± 0.05 µV, and mean SP/AP amplitude ratio of 28.34 ± 9.44%.

The findings of subjects with MD using the TIP-trode illustrated mean impedance of 0.82 ± 0.20 KΩ, mean AP amplitude of 0.26 ± 012 µV, mean SP amplitude of 0.13 ± 0.05 µV, and mean SP/AP amplitude ratio of 53.87 ± 14.46%. In the patients group using the Gutter electrode, the average ECochG parameters including mean impedance of 0.92 ± 0.23 KΩ, mean AP amplitude of 0.26 ± 0.11 µV, mean SP amplitude of 0.16 ± 0.07 µV, and mean SP/AP amplitude ratio of 64.36 ± 13.75% were obtained.

The mean amplitudes of AP ($p = 0.278$) and SP ($p = 0.058$) in the normal group showed no significant differences between the two types of electrodes. As well, the mean amplitudes of AP ($p = 0.913$) and SP ($p = 0.125$) in the group of patients with MD exhibited no statistically significant differences between the two types of electrodes.

The mean impedance between the two electrodes was not significantly different in any of the studied groups ($p = 0.188$ and $p = 0.09$). Nevertheless, the results of the SP/AP amplitude ratio analysis depicted significant differences between the two electrodes ($p = 0.027$ and $p = 0.009$) (Table 1).

Comparison the results of SP/AP amplitude ratio with the Gutter electrode and TIP-trode between the two groups of normal subjects and MD, showed a significant difference in the mean SP/AP ratio between normal and MD by both electrodes ($p < 0.001$). Also, the 95% confidence interval indicated a significant difference between the SP amplitude in the two groups of the normal subjects and MD using both electrodes ($p = 0.002$ and $p = 0.011$). Although there was no significant difference between the results of the impedance parameters and amplitude of AP and SP, as shown in Table 1, the overall mean of these parameters by application of the Gutter electrode was greater than the TIP-trode.

Discussion

In the current study, we investigated the clinical applicability of the Gutter electrode as a cost-effective and reliable alternative to the TIP-trode, which is an expensive and disposable product. There was special attention to compare the recorded impedance using both electrodes. The results demonstrated no significant differences between them. It can be explained in part, because of the silver-chloride material coating the Gutter electrode structure. In other words, the rapid ionization of silver chloride material due to the existence of chlorine ion can be considered as a reason for the appropriate impedance of the Gutter electrode [14,15].

One of the findings of the present study was the increase of SP amplitude in patients with MD. The increase in amplitude was well observed using both Gutter electrode and TIP-trode.

Although no significant difference in SP amplitude was reported between them, the mean SP amplitude was greater by using the Gutter electrode. The results of our study are in accordance with those of Odenthal and Eggermont [13] and several other studies [1,2,16].
The increased endolymphatic fluid accumulation in scala media, increased pressure on the Reissner's membrane, changes in the velocity of traveling wave, and ultimately a change in the electrical response of the hair cells [17]. The ear canal electrode was used in this study. As mentioned before, the sensitivity of the SP amplitude in the diagnosis of MD is expressed at about 30%. Considering 1 standard deviation interval as a criterion of SP amplitude abnormality, 14 patients with MD were identified, which is equivalent to 17% of the patient population. This criterion covered about 50% of the normal population, therefore it can be concluded that there is no proper estimation of the specificity with the SP amplitude. Extensive Coats [18] Mori et al. [19] studies also confirm the inadequacy of the SP domain criterion in the diagnosis of MD, suggesting the use of the SP/AP domain ratio.
There was no difference in the AP amplitude for both electrodes. The distance of the ear canal electrodes from the AP response generators might be responsible. The ear canal electrode is more effective in decreasing AP amplitude due to long distance from the response generator although the small difference between them was not observed in small amplitudes.
Another important finding was the significant increase in the SP/AP amplitude ratio in the group of patients with MD. Goin et al. were the first group of researchers that reported an increase in the SP/AP amplitude ratio by presenting click stimuli and recording from the external auditory canal in the Meniere patients [20]. Ferraro published initial reports on using ECochG as a predictor of MD [16]. Moving away from the source of response generation has a greater impact on the AP response and this may be one of the reasons for to increase the SP/AP ratio. However, other studies using transtympanic (TT) electrodes have also reported ratio increment. Therefore, increased SP/AP ratio in patients with MD strongly supports the cochlear mechanism changes. Many studies have reported increased SP/AP amplitude ratios in patients with MD over the past years [21]. Among the most important studies is the one by Hornibrook et al.[17]. Oh et al. did not report any differences in ECochG response parameters between Meniere patients and normal subjects [22]. The participants in their study were in the early phase of MD. Interestingly, early stages of MD are not necessarily associated with endolymphatic hydrops, so ECochG may not be a prequalified tool to diagnose this stage. Nevertheless, our study included people with definitive MD with a period of at least six months.
Another aspect of our results was higher levels of the standard deviation of mean SP/AP amplitude ratio in patients with MD. It may be because of the high variability of the SP/AP amplitude ratio range in patients with Meniere's disease, that maybe caused by different phase of MD occurrence in each patient. One of the similar studies is the Gibson [1] and Ferraro [16], which reported greater variability in the SP/AP amplitude ratio using ear canal electrode.
Among the solutions to reduce the SP/AP ratio variability include replacement of TT electrodes, using tone burst stimuli, and applying a 95% confidence interval as a baseline to assess the probability of MD [23].
There was a significant increase in the SP/AP amplitude ratio when using the Gutter electrode. Lake and Stuart, in a study comparing TIP-trode and Tymp-trode reported the enhanced amplitude ratio for the tympanic membrane electrode [24]. Nevertheless, in our study, both electrodes were ear canal electrodes. The normal values in the present study were less than 40% for the Gutter and less than 25.07% for the TIP-trode electrodes. Ferraro et al. reported normal values for the ear canal electrode around 40% [9]. In another study, Stypulkowski and Staller reported normal values for two types of ear canal electrodes, 21 and 27 percent, respectively [25].
Since the type of the electrode affects the SP/AP amplitude ratio, it is recommended to use the standard values of the present study for clinical practice of the Gutter electrode [23]. The level of

background noise is one of the most important factors in improving the amplitude of recording [26]. For some reason, noise interference by using Gutter electrode is less than other ear canal electrodes. First, because of the usage of silver chloride material, it absorbs less inductive electromagnetic noise than electrodes made of gold. As we know, the transducer utilized in ECochG test is one of the sources of electromagnetic noise [26].

Second, the higher diameter of this electrode leads to an increase in the number of conductor ions, improving the electrical current exchange performance in comparison with thin gold plates. It can be concluded that applying the Gutter electrode improves the amplitude of the main signal through reducing noise.

Conclusion

Considering the easy and cost-effective use of the Gutter electrode, it seems rational and safe to utilize the Gutter electrode more in clinical trials with respect to the normal values upper limit of normality, 47.22% mean obtained.

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Conflict of interest

No potential conflict of interest relevant to this article was reported.

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