Standardization of ECochG Recording and Measurement Protocols

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Abstract

Purpose and Outcome Objectives

Electrocochleography (ECochG) has been an effective tool in the diagnosis, assessment and monitoring of Meniere's disease (MD)/endolymphatic hydrops (ELH) for over two decades, and more recently, superior semicircular canal dehiscence (SCCD). However, the various protocols used to perform and measure ECochG continue to vary considerably among clinicians who include this procedure in their diagnostic test battery for MD/ELH/SCCD. This lack of standardization makes it difficult to compare/share results across clinics/clinicians and most certainly has affected the outcomes of several studies related to the effectiveness of ECochG as a clinical tool. Thus, the objectives of this study are to:

- **Present a set of standardized patient preparation, recording and measurement protocols for performing ECochG for the purpose of helping to diagnose MD/ELH/SCCD, and**
- **Facilitate/improve the use of an important clinical tool for patients suspected of having MD/ELH/SCCD**

Methods

Standardization guidelines for ECochG recording and measurement protocols were determined via the consensus of three clinicians/clinical scientists who have used this diagnostic tool in the clinic and have conducted research in this area for several years. All three individuals perform non-invasive ECochG, using the lateral surface of the tympanic membrane (TM) as the primary recording site. Standards for recording TM ECochG are recommended to include: TM electrode selection and placement procedures, and ECochG recording parameters. Guidelines to identify and measure the cochlear summating potential (SP) and cochlear nerve action potential (AP) and interpreting the electrocochleogram also are presented.

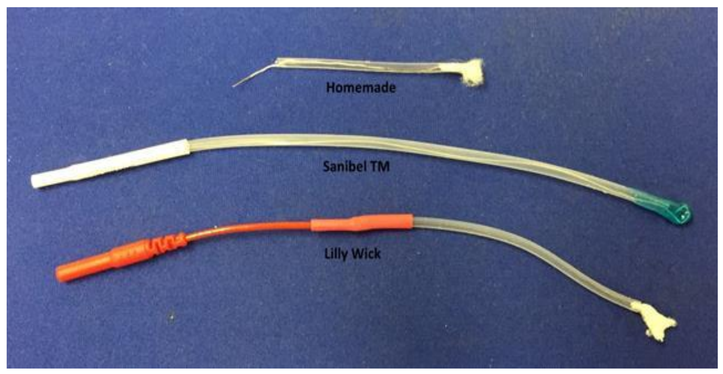
Results and Conclusions

Development of a set of standardized guidelines for performing and interpreting TM ECochG in the diagnosis of MD/ELH/SCCD.

TM Electrodes

As shown in Figure 1, TM electrodes can be fabricated by the examiner (i.e., "homemade") (Stypulkowski and Staller, 1987; Ferraro, 1997) or purchased commercially. Currently, there are two commercial versions, one distributed by Sanibel, and the other designed by Lilly (Lilly and Black, 1989) and distributed by Intelligent Hearing Systems. The cotton tip of the homemade device must be infused with electrode gel prior to placement, while both commercial electrodes need to be dipped in saline for a few minutes and then coated with electrode gel before placement on the TM. It should be noted that the commercial devices are manufactured according to industry-accepted clean standards, while the homemade one is not. The Sanibel and Lilly electrodes also have warnings on the package regarding who is eligible to purchase them. Thus, in deference to liability concerns, the authors recommend the use of the commercial electrodes (which include special cables that interface to the input of most AEP systems) over the homemade one.

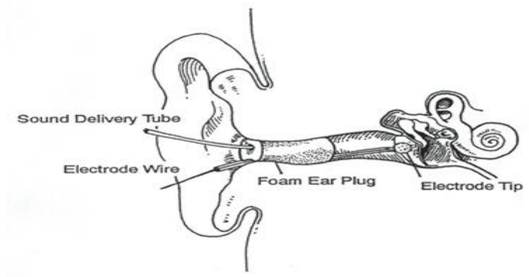
Figure 1. TM Electrodes



Patient Preparation and Electrode Placement

Patients are either lying comfortably in a supine position with some head support (i.e., a pillow), or reclined in an exam chair. Cerumen may need to be removed to allow a clear path to the TM. Some clinicians apply a saline/Lidocaine wash just prior to placement. Caution is advised with the use of Lidocaine, however, which could cause significant vertigo if the eardrum is not intact. The TM electrode is placed under direct otoscopic/oto-microscopic visualization to ascertain that the tip rests against the tympanic membrane. Contact with the membrane is further verified by examining the electrode impedance, which typically is high, and ranges between 10 and 100 kΩ. It is important to note that the impedance measurement alone does not confirm or ascertain contact with the tympanic membrane since these values also are seen when the tip is against the ear canal. Additional verification steps involve visually monitoring the electrical noise floor, which should drop dramatically and stabilize when contact with the TM is achieved, and asking the patient to acknowledge when it feels like the electrode is touching the eardrum. As illustrated in Figure 2, the electrode is held in place using the standard foam tip of the tubal insert stimulus transducer (supra- or cirum-aural headphones are not recommended/appropriate for TM ECochG). This procedure stabilizes the electrode in the ear canal and no further fixation is necessary. If done correctly, placing the TM electrode should be painless and well-tolerated by most patients.

Figure 2. TM Electrode in place and stabilized by foam earplug of tubal insert transducer (modified from Ferraro, 1992)



Signal Averaging and Stimulus Parameters

Tables 1 and 2 below display the recommended signal averaging and stimulus parameters when ECochG is used to help diagnose/monitor MD/ELH/SCCD. In cases where ranges/multiple options are presented, the authors have found that using settings within these limits have little/no effect on the resultant recordings.

Table 1. Recommended Signal Averaging Parameters

Number of Recording Channels	1
Electrode Configuration*	Primary (+, non-inverting) – TM Secondary (-, inverting) – opposite mastoid/earlobe/FPz Common/Ground – low forehead/ipsilateral mastoid
Amplifier Gain	50,000 – 150,000X
High-/Low-Pass Filter Settings	5-20 Hz/1,500 - 3,000 Hz
Timebase	5 – 10 milliseconds (10 ms allows identifying wave V as well)
Repetitions	1,000

*Electrode configuration will display the AP as a downward/negative deflection. Some clinicians prefer to view it as a positive/upward peak (as is customary for ABR recordings). Simply reversing the primary and secondary inputs to the preamplifier will accomplish this change.

Table 2. Recommended Stimulus Parameters

Transducer	Tubal Insert
Stimulus Type	Broad Band Click
Polarity	Alternating
Duration of Electrical Pulse	100 microseconds
Beginning Level	90 dB nHL*
Repetition Rate	8.7 - 11.3/second

*0 dB nHL = the average threshold of a young group of adults to the BBC stimulus.

Summating Potential and Action Potential

Using the protocols described above, Figure 3 illustrates a resultant electrocochleogram and how the amplitudes of cochlear **SP** and auditory nerve **AP** (N_1 and N_2) are measured. These measurements are then used to derive the **SP/AP amplitude ratio**, which is a primary feature of the response when ECochG is used to help diagnose/assess MD/ELH/SCCD. Figure 4 illustrates how the SP and AP areas are determined to form the **SP/AP area ratio**. This latter measurement was originally described by Ferraro and Tibbils (1999) and has been shown to improve the sensitivity of ECochG to MD/ELH when combined with the SP/AP amplitude ratio (e.g., Ikino and Almeida, 2006; Almomani, Ferraro et al., 2009,). The software for measuring SP ad AP areas is now available on various commercial AEP units (e.g., Natus, Interacoustics)

Figure 3. SP/AP Amplitude Ratio

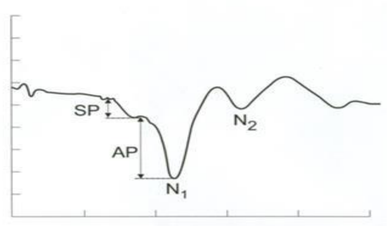
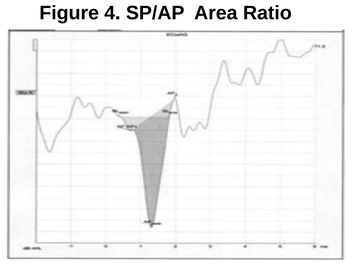


Figure 4. SP/AP Area Ratio

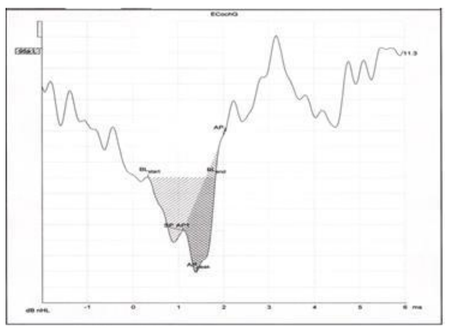


Normative Data

Normative data are based on a recent study by Grasel and her colleagues in South America who recorded TM ECochG using the parameters described above from 100 subjects (N=200 ears), 59 females, aged between 19 and 71 years from September 2010, to April 2014. Inclusion criteria: normal otomicroscopy, hearing thresholds ≤25 dB HL from 250 to 4000 Hz, normal tympanogram, no symptoms of MD according to the AAO-HNS 1995 criteria and Gibson's score <7. Subjects with dizziness, aural fullness or other symptoms of endolymphatic hydrops were excluded.

There was no significant difference between right and left ears (Intraclass correlation coefficient < 0.6). Normal **SP/AP amplitude ratios varied between 0.084 and 0.356** and normal **SP/AP area ratios between 0.837 and 1.671** (percentiles 5 and 95). The AP latency difference to rarefaction and condensation clicks was between 0.0 and 0.333ms. **Thus, SP/AP amplitude and area ratios > 0.37, and >1.70, respectively, are considered to be positive findings for endolymphatic hydrops.** Figure 5 displays an example of an electrocochleogram where the amplitude and area values exceed these limits .

Figure 5. Electrocochleogram that is positive for endolymphatic hydrops (SP/AP amplitude ratio = 1.3, SP/AP area ratio = 2.0). Stimulus onset is at 0 ms.



Conclusions

The above guidelines are designed to help standardize the protocol for performing and interpreting ECochG recordings from the TM (the preferred site for non-invasive measurements). Important principles underlying all forms of "objective" electrophysiological testing include:

- the background/training (i.e., competence) of the examiner are crucial to achieving good recordings, and
- the utility of the response is only as good as the quality of the waveform.

These principles are especially true for ECochG, where considerable knowledge of and background in auditory electrophysiology is vital for performing this procedure, and substantial attention must be paid to the technical aspects of recording (as described above) to achieve valid results.

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