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Randomized Controlled Trial and Analysis of ABR and EcochG Tests in Meniere's Disease

*Narendra BS**

VAV Care Clinic and Sarvoday Hospital, India

Abstract

Purpose: 1. To determine and compare the wave III latency values on ABR test and SP/AP ratios on EcochG test in affected ears of Meniere's disease with control group of healthy ears.

2. To bear the hypothesis of deviation of III wave latency values on ABR test in definite active Meniere's disease as abnormal feature and compare with Electrocochleographic electro potential ratios in the same diseased subject group.

Study Design: A prospective observational control study is done in clinically definite of active Meniere's Disease (MD) between 2016-2020. There are 38 consecutive patients of unilateral MD (Group A) as per criteria laid upon by Barany's society (1995) and 31 normal subjects (Group B). All the subjects undergo thorough clinical ear examination, PTA and ABR in both ears in group A and group B ears. EcochG is conducted for affected ears in group A and randomly selected ears in group B. The valued results of ABR and EcochG in group A are considered for comparison with each other's for the possibility of cochlear hydrops; as well with group B with normative data. The relevant biostatistical tests are applied for further interpretations.

Results: All 36 subjects of unilateral MD displayed abnormal findings for at least one test than the controlled 32 subjects. The cut off value on ABR for latency of wave III suggesting cochlear hydrops is 3.645 ms; while SP/AP ratio in EcochG is 0.5 suggesting the cochlear hydrops in MD. there was mutual agreement between the ABR and EcochG tests in 21/36 as affected ears and mutual agreement for as non-affected ears in 7/36 and neither agreement/disagreement in 8/36 ears.

Conclusion: In affected ears of MD ABR test evaluation for wave III latency and SP/AP ratio on EcochG displayed significant valued differences from normative data obtained for. The sensitivity and specificity of EcochG is 71% and 81% while that of ABR test is 80% and 67% respectively and are found to be useful to diagnose MD.

Level of evidence: IB

Keywords: ABR: Acoustic brainstem response; EcochG: Electrocochleogram; MD: Meniere's Disease

Correspondence:
Narendra B Suratwala, VAV Care Clinic and Sarvoday Hospital, 4/138, Haripura, Surat-395003, India,
E-mail: nandu.ns290@gmail.com

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Introduction

Since the introduction Meniere's disease by Sir Prosper Meniere, it has ever remained as a mysterious entity and yet to be fully understood. In clinical practice it is not uncommon to miss its diagnosis on initial visit made by the patient visiting a vertigo clinic. This is because of lack of classical presentation as (aural fullness, fluctuant or low frequency hearing deficit, tinnitus and vertigo) in a considerable group of patients [1,2]. Over last few decades only the EcochG test is considered as a gold standard to diagnose MD. The recent imaging technique with gadolinium contrast either by systemic or intratympanic route to view vestibular system needs standardization which could be universally acceptable. The presented study is bearing the hypothesis of deviation of latent wave pattern on ABR in MD patients from the normative data obtained in normal ear subjects (group B). The outcome of ABR and EcochG tests in diseased and control groups are put under comparison.

Materials and Methods

The data sample drawn of 36 clinically certain patients of unilateral Meniere's disease bases on Barany Society's criteria as well comparable to clinical stage II and stage III of Shea's classification for Meniere's disease) [1] who are otherwise healthy and 32 group of normal subjects serving as a control were categorized as group "A" and "B" respectively. Group A was subjected to PTA, bilateral

Table 1: Wave III latency readings in BERA and EcochG values in Diseased (N=36) *vs.* Control group (32-random unilateral ear subjected) and accord/discord between L-III and SP/AP readings for cochlear hydrops.

SUBJECTS Group A Group B Diseased Control		Group A L-III SP/AP (Log)		Group B Normative data (Control) L-III SP/AP (Log)		Remarks on ABR test of L-III	Accord between (Based on Critical values) of L-III and SP/AP in affected ear of MD
1.KGN M/28	LMD M/22	3.088	0.51	3.75	0.47	Shift to left.	Y
2.JJL M/33	LKD M/45	3.42	0.57	3.95	0.45	Shift to left.	Y
3. PLO M/62	MNF F/49	3.64	0.48	3.71	0.45	No shift.	y
4. FRS M/55	WEM/45	3.3	0.49	3.38	0.46	Shift to left.	Y
5. GTU F/22	HMN F/36	3.41	0.47	3.754	0.43	Shift to left,	N
6. HJP M/ 42	WRV M/32	3.38	0.55	3.908	0.49	Shift to left.	Y
7.PPT F/36	POP M/37	3.41	0.61	3.854	0.49	Shift to left.	Y
8. NND M/56	JDB M/52	3.5	0.44	3.52	0.46	No shift.	Y
9. YNP M/49	KLS M/44	3.456	0.49	3.5	0.49	Insignificant shift.	N
10.ROP M/42	LLM M/34	3.38	0.47	4.12	0.44	Shift to left.	N
11. BDS F/72	HAS M/37	3.42	0.59	3.87	0.48	Shift to left,	Y
12.TMS F/52	DOA	4.106	0.46	3.88	0.44	No Shift	Y
13.YKD M/56	MNJ M/64	3.95	0.47	3.72	0.42	No shift	Y
14.PMO M/5	JJN M/44	3.336	0.55	3.92	0.45	Shift to left	Y
15.PLK M/51	JKM M/45	3.276	0.52	3.76	0.45	Shift to left	Y
16. RJD F/65	KLMM/34	3.45	0.46	3.826	0.44	Shift to left	N
17. HHP M/46	LMM/39	3.424	0.51	4.124	0.46	Shift to left	Y
18. BBT F/37	KGM/36	3.56	0.54	3.888	0.47	N0 shift l	N
19.MDB F/4	ERT M/44	3.424	0.54	3.92	0.47	Shift to left	Y
20. FRS F/7	JGL M/51	3.33	0.52	3.98	0.45	Shift to left	Y
21. GTR M/45	GMR M/23	3.46	0.49	3.82	0.41	Shift to left	N
22. KLP M/61	LKM M/32	3.5	0.52	3.78	0.45	No shift	N
23. JKL F/3	MMV M/27	3.34	0.56	3.8	0.46	Shift to left	Y
24. POL M/ 42	MNV M/37	3.58	0.51	3.95	0.44	No shift	N
25. HUL M/67	DKM M/45	3.33	0.54	3.41	0.48	Shift to left	Y
26. BBD M/45	SRT M/28`	3.36	0.52	3.95	0.44	Shift to left	Y
27. ERT M/44	SRC M/34	3.41	0.52	3.78	0.42	Shift to left	Y
28. NBS M/65	DNS F/36	3.28	0.58	3.95	0.48	Shift to left	Y
29. KDJ M/26	JJJ M/43	3.3	0.56	3.8	0.45	Shift to left	Y
30. NKN F/43	PDP M/45	3.42	0.51	3.98	0.45	Shift to left	Y
31. GYT M/55	GHR M/34	3.33	0.58	3.95	0.44	Shift to left	Y
32. WRI F/70	No	3.56	0.53	3.78	0.41	No shift	N
33. MND F/46	No	3.46	0.56	N.A.		Shift to left	Y
34. LLP M/61	No	3.28	0.53	N.A.		Shift to left	Y
35. MKL M/42	No	3.44	0.44	N.A.		Shift to left	N
36. PPD F/67		3.46	0.54	N.A.		Shift to left	Y Accord 24/36
Mean ± S.D.		3.438 ± 0.178	0.52 ± 0.042	3.82 ± 0.175	0.45 ± 0.021	Cut off (low) for L-III 3.645 ms and cut off (high) for SP/AP 0.50 Suggesting hydrops. *(after log correction)*	

Interpretations: Using independent T test to compare the parameters as L-III and SP/AP ratio between group A and group B the significant difference in values are noted p ≥ 0.05 (p=0.000) and p<0.05 (p=0.000) respectively. Upper CI value (95%) for L-III in group B is -Mean + 0.06=3.82+0.06=3.88, Lower CI value (95%) for L-III in group B is-Mean -0.06=3.82-0.06=3.78; while for SP/AP ratio it is -Mean=0.0078=0.45+0.0078=0.457 and -Mean-0.0078=0.45-0.0078=0.442 respectively.
Abbreviations: For Group A diseased ear: Y= Both tests suggest accord for presence of hydrops. N= Suggest disagreed values (cut off) for individual test for presence of hydrops; NA: Not Available

ABR and EcochG tests in affected ear only in their full conscious state while group B was subjected to PTA, bilateral ABR and randomly selected ear for EcochG tests. It was ensued upon that all the participants had stopped all the medication 48 h before these tests. Inclusion and exclusion criteria for selection of subjects are drawn on Table 1.

Table 2: Showing resulted agreement vs disagreement in between conducted ABR and EcochG testing in MD subjects.

Positive ABR and EcochG (Y)	Negative ABR and EcochG (Y)	Positive ABR and negative EcochG (N)	Negative ABR and Positive EcochG (N)
21	3	8	4

(Positive findings on ABR=Below cut off value of L-III (lesser to 3.645 ms), Negative findings = At par with normatives. Positive EcochG findings = Above cut off value (more than 0.5) ratio of SP/AP) Negative for both test =Values above or below the respective cut off values.

ABR low rate at 120 dB PeSPL, multiple clicks stimuli, sweep time 12 m, stimulation rate 11/sec., duration of 100uS, filter band 250 Hz to 2500 Hz with sensitivity of 2.5 amp. for 2,000 numbers of stimuli at impedance <0.50 Ohm [1,3]. EcochG is performed with TT electrodes at 105 PeSPL tone bursts for 1000 under standard instrumental setting (100 sum at 11/sec. stimulus, duration 100us at 2000Hz and 2.5amp. sensitivity) at impedance < 1 Ohm [1,4-7].

For both tests to be performed in group A and B following criteria was applied.

Criteria for Inclusion include as; 1. Unilateral disease, 2. Clinical suspected Stage II/III (Shea's grading), 3. Normal external auditory canal, 4. Normal tympanic membrane thickness, 5. ACT-lower than 70 dB &/BCT lower than 60 dB for speech frequencies.

Criteria for exclusion include as; 1. Bilateral disease, 2. Clinically suspected Early or late stages I/IV, V (Shea's grading), 3. External canal abnormality, 4. Scarred/thinned/atrophic tympanic membrane, 5. ACT-above 70 dB &/BCT more than 60 dB for speech frequencies, 6. Presence of active ear infection, 7. Subject on antivertigo medicines acting on peripheral/central organs for last 48 h.

Complete data of both groups are collected, tabulated and processed for biostatical analysis and inferences. Table 1, 2 with log correction applied for SP/AP ratio after EcochG test [8].

Results

All 36 subjects of definite unilateral MD display abnormal findings for at least one test than the controlled 32 subjects. For wave L-III statistical analysis provided 3.645 ms as a lower cut off value on ABR and 0.50 for SP/AP ratio on EcochG. In the presented observations the sensitivity and specificity of EcochG is 71% and 81% while that of ABR test is 80% and 67% respectively (Table 1, 2).

Discussion

In diagnosing the Meniere's disease various modalities have been used like ENG, EcochG, various caloric tests and imaging with contrast media. Nevertheless, history and PTA showing low frequency hearing loss pattern provides useful clue to suspect hydrops pathology; yet one needs to attest the firm diagnosis of MD.

Abundant literature provides the useful information regarding various audio vestibular tests practiced worldwide in various institutes and universities. The common inference drawn on from such practices are variability of outcomes intra-tests as well inter-tests in respect to sensitivity and specificity.

Most commonly practiced audio vestibular tests are PTA, Epoch and VNG with or without varied caloric tests. However, Dobie RA [3] reported no correlation between ENG findings and hearing loss in Unilateral MD cases. BERA (Low rate ABR) is considered time consuming with lack of standardization and hence underused.

In an attempt to standardize usage of ABR test and to understand variations of parametric measures of evoked potential after auditory stimuli, authors hypothesize the latency values are deviated from the normative data figures especially and more consistently of wave III.

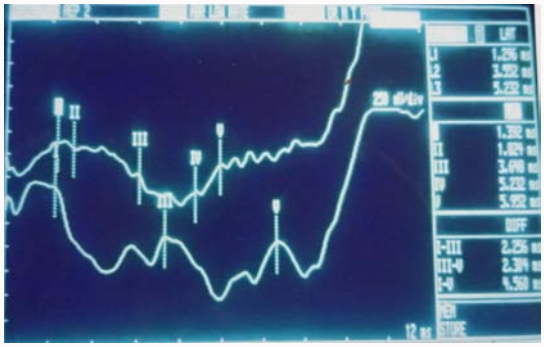

Figure 1: Displaying tracing from responses in ABR test on both sides in a case of Unilateral Meniere's disease. Upper tracing > Right ear, lower tracing > Left ear

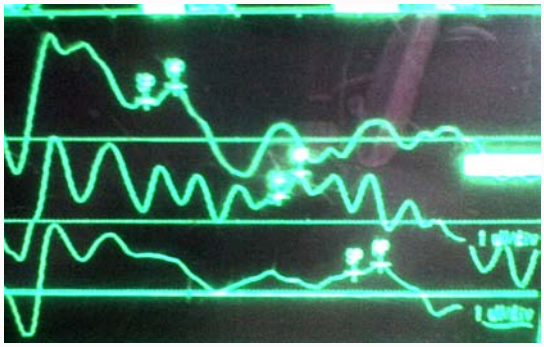

Figure 2: Displays response on EcochG test in same case of Meniere's disease in an affected Right ear.

This hypothesis may be supported by understanding the dependence of "I" (Current-amps. A) on "v" (drift velocity-m/s) and "A" (cross sectional area of conductor/nerve); arriving at formula as; I=vAnq [9].

Further, power voltage and current are interdependent which is explained by;

I = (P/V). when Power equals Current time voltage (P=VxI) and Voltage equals Power divided by Current (V=P/I).

Thence as the diameter of conductor (nerve) is constant.

In cochlear hydrops the cochlear electric potential when tested for auditory stimuli between 250 Hz to 2500 Hz during EcodhG test, the electrodes placed on/near the promontory will pick up more electric energy as compared to the electrodes placed on tympanic membrane [10,11]; thence the variations in recording the action potentials are bigger (4-6 times) with Trans Tympanic Electrode (TTE) than Trans Membranous Electrode (TME) [7]. This variation with use TTE may be corrected by applying the log ratio.

During ABR testing in subjects with clinical sages of II and III one may consider; latencies of major waves will depend on velocity of electric current travelling through auditory neural pathway. Provided neural architecture is intact the velocity is dependent on power and

current time (Equation-vide supra). This implicates the cochlear electric generator when produces more power (electric potential) the velocity of current will be more and hence the shortened latency of waves. In clinical stage I with mild symptoms of MD the hydrops is minimal. So, the cochlear potential/power generation is less as compared to stages II and III. These subjects may show lesser sensitivity to deviation of latencies of wave and can be compared to normative/controlled data. Clinical stage IV, V have lost most of its cochlear electric generation power function, hence the deviation in latencies of waves may show delayed pattern.

Charlotte, Hero. Reported in 20 subjects, latency delays could be measured in both ears. The mean latency delay for the affected ears (0.55 ms; standard error, 0.12 ms) differs significantly from that for the unaffected ears (3.36 ms; standard error, 0.43 ms). With the standard criterion to separate ears with an abnormally short delay (<0.3 ms) from ears with a normal delay, in only 7 of 20 affected ears, an abnormally short delay was measured. All 33 other ears produced a normal delay. With the less than 0.3 ms criterion and including the ears in which no delay could be measured, the sensitivity of the CHAMP is 32%. A. Further the CHAMP test is used in the affected ear with SNHL up to 60 dB for useful frequencies. (Low and Mid) and las low utility [12,13].

The presented method differs from CHAMP test described above as: 1) Can be applied for SNHL above 60 dB. 2) Only solitary intensity is used. 3) Time saving.

In the presented study the sensitivity and specificity of ABR test (considering EcochG as gold standard) is 80% and 67% respectively which appears to produce higher yield than the CHAMP test.

However, in clinical stage II and III which is considered severely symptomatic due to immense hydropic pressure resulting in to tense Reissner's membrane, it may be assumed that the cochlear generator is on its peak for power production; thus, resulting into greater variations in latencies as compared to normative figures. Most of the literatures suggest wider range of latencies for wave I and V than wave III; thus, these waves in MD subjects will show lesser sensitivity than wave III in previous study reported by authors [1] with effect of dehydration the wave III latencies are seen restoring to normal range in significant proportion of cases with no change in values for wave V latencies; may imply the auditory nerve conduction at and beyond is independent of cochlear electrolyte composition.

Most of the researchers in their published study agree that EcochG test is a very specific analytic method to diagnose in MD; however few reports are not in favor of performing EcochG in early and late stages of MD because of its low sensitivity met with even after in dehydrated state.

The present study of 36 subjects of definite unilateral MD displayed abnormal findings for at least test than the controlled 32 subjects. For wave L-III statistical analysis provided 3.645 ms as a lower cut off value on ABR and 0.50 for SP/AP ratio on EcochG. In the presented observations the sensitivity and specificity of EcochG is 71% and 81% while that of ABR test is 80% and 67% respectively which appears to produce higher sensitivity yield than the CHAMP test (32%).

While comparing outcomes of ABR and EcochG tests in a subject it is perceived that one is estimating the outputs of charged electric battery (cochlear generator) by two different methods; say ABR measuring effective wattage *vs.* EcochG measuring voltage reading from the battery terminals these two tests measure the same event in different terms at different stations from power generation plant. (Cochlea).

Conclusion

Low rate ABR test may be safely included in a test battery to test audio vestibular function in definite MD. Considering most hydropic state of inner ear in clinical stages II and III, this test along with EcochG appears to yield higher sensitivity in diagnosing the hydrops of MD. How ever errors in interpreting specificity of both tests can be minimized by adhering to the criteria mentioned in materials and methods.

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