# Findings of Cochlear Hydrops Analysis Masking Procedure (CHAMP) in Subjects with Suspected and Confirmed Meniere's Disease

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## Abstract

*The present study was carried out to develop norms for Cochlear Hydrops Analysis Masking Procedure (CHAMP) in normal hearing subjects and to compare CHAMP results in subjects with suspected Meniere's disease with that found in normal hearing subjects in order to validate Don et al.'s (2005) study. Two groups of participants were considered. The subjects in the control group included 30 normal hearing ears. The experimental group included 30 ears with Meniere's disease. These subjects were further classified into two groups, i.e., those with definite Meniere's disease and those with possible/probable Meniere's disease basing on the AAO-HNS guidelines. CHAMP recording was done for click alone and, click with ipsilateral pink high pass masking noise at frequencies 8,4,2,1, and 0.5 kHz. Both stimulus intensity and intensity of noise were at 60 dB nHL. The results of the present study revealed that the absolute latency of wave V (ms) increased from 8 kHz to 0.5 kHz HPM condition and this increase was more for normals, less for definite Meniere's disease and least for possible/probable Meniere's disease. Definite and possible/probable Meniere's differed significantly from each other for latency shift for high frequencies (8, 4, & 2 kHz) but not for low frequencies (1 kHz & 0.5 kHz). Duration of the disease did not have any correlation with that of latency shift of wave V. The present study yields an overall specificity of CHAMP to be 76.6% and sensitivity of 73.3%.*

***Key words:*** *CHAMP, Meniere's disease, latency shift.*

Meniere's disease (MD) is characterized by the following symptoms: episodic vertigo, tinnitus, fluctuating hearing loss, and sensation of fullness or pressure. However, all of these symptoms are not always present, especially at the onset of the disease. There are a number of other diseases like perilymphatic fistula, vestibular neuritis, lyme disease that can mimic early stages of Meniere's disease, leading to misdiagnosis. Thus, early detection and diagnosis of Meniere's disease is important but difficult. Audiological tests play an important role in the diagnosis of Meniere's disease.

Don, Kwong, and Tanaka (2005) conducted a study wherein they compared two groups of subjects: 38 non-Meniere's normal hearing subjects and 23 patients with symptoms of Meniere's disease. Auditory brainstem responses to clicks presented ipsilaterally with masking noise that was high pass filtered at the following frequencies: 8, 4, 2, 1 and 0.5 kHz were recorded. The results showed that in Meniere's patients the latency of wave V in the presence of masking noise is similar to the latency of wave V in response to clicks alone as the masking noise is insufficient. In non-Meniere normal hearing subjects the undermasked component was either absent or delayed because of the masking noise. Hence, the differences in delays between both the populations lead to separating the two groups with 100% sensitivity and 100% specificity.

On the other hand, De Valck, Claes, Wuyts, and Heyning (2007) used Cochlear Hydrops Analysis Masking Procedure (CHAMP), which is a new ABR technique developed by Bio-logic Systems Corporation in collaboration with Don et al, (2005) (House Ear Institute), to evaluate the applicability and diagnostic value of CHAMP in a clinical setting. They analyzed a consecutive series of patients with inner ear disorders and compared the CHAMP results between the different diagnostic categories of Meniere's disease according to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). The results of the study showed that CHAMP yielded a sensitivity of 31% and a specificity of 28%.

Ordonez-Ordonez et al, (2009) found a sensitivity of 31.3% and specificity of 100% in subjects with definite MD. Hence they conclude saying that if definite MD is suspected then an abnormal result would confirm the diagnosis however a normal result would not rule out the Meniere's disease diagnosis.

It is essential to differentially diagnose a subject with suspected Meniere's disease from that with non-Meniere's, as more prolonged the hydrops condition, the poorer the likelihood of a cure and the higher the chance of permanent cochlear damage. The CHAMP procedure proposed and illustrated by Don et al. in 2005 is a promising non-invasive technique to confirm Meniere's disease. However De Valck et al. (2007) have refuted the findings of Don et al. (2005) saying that the sensitivity and specificity are not as high as that stated by them. Hence the CHAMP

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technique is yet to be validated and the present study attempts to duplicate Don et al.'s (2005) study to verify the specificity and sensitivity of CHAMP.

Aim of the present study is to develop norms for Cochlear Hydrops Analysis masking Procedure (CHAMP) in normal hearing subjects, to compare CHAMP results in subjects with definite and possible/probable Meniere's disease with that found in normal hearing subjects in order to validate Don et al.'s (2005) study.

## Method

The present study was carried out with the aim of developing norms for Cochlear Hydrops Analysis Masking Procedure (CHAMP) in normal hearing subjects and also to compare its results with definite Meniere's and possible/probable Meniere's disease.

**Participants:** Two groups of participants were selected for the study, namely control group and experimental group. The subjects in the control group had hearing thresholds not more than 15 dB HL at octave frequencies between 250Hz to 8000 Hz. 20 ears (both ears) of 10 females and 4 ears (one ear each) of 4 females in the age range of 18-25 years with a mean age of 20.92 years (SD= 2.733) and 6 ears of 3 males in the age range of 18-23 years with a mean age of 21.33 years (SD= 2.582) were included in the control group. All the subjects had normal middle ear functioning and no other neurological problems. Experimental group included 30 ears of 20 subjects. The subjects had no history of any neurological problems. Auditory brainstem responses were done to rule out retro cochlear pathology in these subjects.

The subjects were classified into two groups, that is, those with definite Meniere's disease and those with possible/probable Meniere's disease based on AAO-HNS (American Academy of Otolaryngology-Head and Neck Surgery, 1995) criteria and by an ENT specialist based on the symptoms and history.

In the definite Meniere's disease group, there were 6 females (9 ears) in the age range of 35-57 years with a mean age of 49.16 years (SD = 7.88) and 5 males (6 ears) in the age range of 25-65 years with a mean age of 50 years (SD = 15.81). In the possible/probable Meniere's disease group 5 females (7 ears) in the age range of 34-43 years with a mean age of 38.20 years (SD = 3.49) and 4 males (8 ears) in the age range of 31-65 years with a mean age of 44.25 years (SD = 14.68) participated in the study.

Hearing loss for these participants was less than 55 dBHL and air-bone gap was less than 10 dBHL at the octave frequencies from 250 Hz to 8000 Hz.

**Instrumentation:** Madsen OB922 with TDH-39 headphones were used for pure tone audiometry, speech audiometry and for finding the uncomfortable level for the subjects whereas bone conduction thresholds were estimated using the Radio ear B-71 bone vibrator. GSI-TYMPSTAR was used to assess the middle ear functioning of the subjects. ABR and CHAMP recordings were done using Bio-logic Navigator Pro. Biologic Insert 580-SINSER-012 was used for ABR recording and Broadband Insert 580-BINSER-012 for CHAMP recording. The entire testing was carried out in a sound treated air-conditioned room with ambient noise levels within permissible limits as recommended by ANSI (S3.1.1991).

**Procedure:** A detailed case history was taken to ensure that the subjects fulfilled the inclusion and exclusion criteria. For each participant, the air conduction thresholds were estimated at the frequencies 250 Hz, 500 Hz, 1 kHz, 2 kHz, 4 kHz, and 8 kHz. The bone conduction thresholds were estimated at frequencies 250 Hz, 500 Hz, 1 kHz, 2 kHz, and 4 kHz. Speech Recognition Threshold (SRT) and Speech Identification Scores (SIS) were established. The uncomfortable loudness level was also obtained. Immittance audiometry was carried out with a probe tone frequency of 226 Hz. Ipsilateral and contralateral acoustic reflexes thresholds were measured for 500 Hz, 1000 Hz, 2000Hz, and 4000Hz.

For recording ABR, subjects were made to relax on a reclining chair. ABR was recorded from one channel using the conventional vertical electrode montage. ABR was recorded using the protocol given in Table-1.

*Table 1. Protocol for ABR testing for ruling out retro cochlear pathology*

| | |
|---|---|
| Electrode placement | Non-inverting: Cz (vertex)<br>Inverting: Mastoid of the test ear.<br>Ground: contralateral mastoid |
| Transducer | Biologic Insert 580-SINSER-012 |
| Stimulus | Clicks (100μs) |
| Stimulus polarity | Rarefaction |
| Stimulus intensity | 90 dBnHL |
| Repetition rate | 11.1/s and 90.1/s |
| Number of sweeps | 2000 |
| Filter settings | 100 Hz-3000 Hz |
| Time window | 10 ms |
| Gain | 1 lakh |

CHAMP was recorded using the test protocol in the Table-2. CHAMP recording was done at least two times to check the reliability of the response in each condition. Only when the responses were repeatable, they were considered for analysis.

*Table 2. Protocol for Cochlear Hydrops Analysis masking Procedure (CHAMP)*

| | |
|---|---|
| Electrode placement | Non-inverting: Cz (vertex)<br>Inverting: Mastoid of the test ear.<br>Ground: Contralateral mastoid. |
| Transducer | Broadband Insert 580-BINSER-012 |
| Stimulus | Clicks (100 μs) alone, and clicks presented with ipsilateral pink noise high-pass filtered at 8 kHz, 4 kHz, 2 kHz, 1 kHz and 0.5 kHz. |
| Stimulus polarity | Rarefaction |
| Stimulus intensity | 60 dB nHL |
| Intensity of the noise | 60 dB nHL |
| Repetition rate | 45.5/sec |
| Number of sweeps | 2048 |
| Filter settings | 100 Hz-3 kHz |
| Time Window | 13 msec |
| Gain | 1 lakh |

## Results and Discussion

The present study was carried out with two aims, that is, firstly to develop norms for Cochlear Hydrops Analysis Masking Procedure (CHAMP) in individuals with normal hearing and secondly to compare CHAMP results in subjects with definite and possible/probable Meniere's disease with that found in normal hearing subjects in order to validate Don et. al.'s (2005) study. The data analysis was done using SPSS software version 16.0.

**Qualitative analysis of the two groups, that is, definite Meniere's disease and possible/probable disease with respect to symptoms and duration of the disease**

*Qualitative analysis of definite Meniere's and possible/probable Meniere's disease ears with respect to symptoms:* Presence of the four hallmark symptoms, that is, tinnitus, vertigo, aural fullness and fluctuating hearing loss was variable among individuals with Meniere's disease. Normal hearing individuals did not have any of these symptoms and hence not considered for analysis.

The qualitative analysis of the two groups with respect to the four hallmark symptoms are shown in Table-3.

*Qualitative analysis of definite Meniere's and possible/probable Meniere's disease ears with respect to duration of the disease:* The duration for which the disease lasted was classified into five categories: Category 1= <6 months, Category 2= 6 months- 1 year , Category 3= >1- 2 years, Category 4= >2- 5 years, Category 5= >5 years.

*Table 3. Qualitative analysis of ears with definite Meniere's and possible/probable Meniere's disease with respect to presence of the four hallmark symptoms (tinnitus, vertigo, aural fullness and fluctuating hearing loss)*

| Groups | Symptoms | | | |
|---|---|---|---|---|
| | Tinnitus | Vertigo | Aural fullness | Fluctuating hearing loss |
| Definite Meniere's disease | n = 15 (100%) | n = 15 (100%) | n = 10 (66.66%) | n = 14 (93.33%) |
| Possible/ Probable Meniere's disease | n = 15 (100%) | n = 15 (100%) | n = 7 (46.66%) | n = 6 (40%) |

Table-4 illustrates the qualitative analysis of the two groups with respect to the duration of the disease.

*Table 4. Qualitative analysis of ears with definite Meniere's and possible/probable Meniere's disease with respect to duration of the disease (n= no. of ears)*

| Groups | Duration | | | | |
|---|---|---|---|---|---|
| | < 6 months | 6 months- 1 year | >1- 2 years | >2-5 years | >5 years |
| Definite Meniere's disease | n = 2 (13.33 %) | n = 1 (0.06%) | n = 3 (20% ) | n = 5 (33.33 %) | n = 4 (26.66% ) |
| Possible/ Probable Meniere's disease | n = 9 (60%) | n = 2 (13.33 %) | – | n = 2 (13.33 %) | n = 2 (13.33% ) |

**Absolute latency of wave V (ms) in different high pass masking noise conditions across the three groups:** The mean and standard deviation were obtained using descriptive statistics for the absolute latency of wave V in different conditions for ears with normal hearing, definite Meniere's disease, and possible/probable Meniere's disease. Table-5 gives the mean and standard deviation of absolute latency of wave V across three groups in different conditions.

As it is evident from table-5 that the mean of absolute latency of wave V increased successively by 2.55 ms from click alone to click + 8 kHz HPM noise to click + 0.5 kHz HPM noise in normal hearing ear.

*Table 5. Mean of absolute wave V latencies (ms) for click alone and clicks with different high pass masking noise in individuals with normal hearing, definite Meniere's disease, and possible/probable Meniere's disease (clk = click)*

| Conditions | Normals | | Definite Meniere's disease | | Possible/Probable Meniere's disease | |
|---|---|---|---|---|---|---|
| | N (ears) | Mean (SD) (ms) | N (ears) | Mean (SD) (ms) | N (ears) | Mean (SD) (ms) |
| Click alone | 30 | 5.70 (0.21) | 15 | 6.25 (0.55) | 10 | 5.93 (0.30) |
| Click + 8 kHz HPM | 30 | 6.15 (0.32) | 13 | 6.33 (0.55) | 9 | 6.07 (0.36) |
| Click + 4 kHz HPM | 30 | 6.67 (0.39) | 12 | 6.40 (0.36) | 5 | 6.28 (0.55) |
| Click + 2 kHz HPM | 29 | 7.27 (0.52) | 11 | 6.52 (0.46) | 4 | 6.37 (0.34) |
| Click + 1 kHz HPM | 26 | 8.00 (0.89) | 8 | 6.51 (0.42) | 4 | 6.27 (0.45) |
| Click + 0.5 kHz HPM | 23 | 8.70 (1.15) | 7 | 6.75 (0.54) | 3 | 6.16 (0.03) |

In the ears with definite Meniere's disease the mean of absolute latency of wave V (ms) increased only by 0.42 ms from click + 8 kHz HPM noise to click + 0.5 kHz HPM.

In the ears with possible/probable Meniere's disease, the mean value of absolute latency of wave V (msec) increased by only 0.09 msec from click + 8 kHz HPM to click + 0.5 kHz HPM. The same findings of mean of absolute latency of wave V in different high pass masking noise conditions in normal hearing, definite Meniere's disease and possible/probable Meniere's disease.

The increase in absolute latency of wave V (msec) from click + 8 kHz HPM condition to click + 0.5 kHz HPM condition is more for normal hearing individuals, less for definite Meniere's disease and least in possible/probable Meniere's disease.

**Comparison of CHAMP findings (absolute wave V latency) between normal hearing, definite Meniere's and possible/probable Meniere's disease:** The absolute latency of wave V (msec) for click alone and click with different HPM noise was compared between normal hearing, definite Meniere's disease, and possible/probable Meniere's disease using Kruskal-Wallis test of group comparison. The result of this comparison is given in Table-6.

As it is evident from the table-6 that the absolute latency of wave V in normal hearing, definite Meniere's and possible/probable Meniere's disease ears significantly differ from each other for click alone condition and click + 2 kHz HPM, click + 1 kHz HPM and click + 0.5 kHz HPM at significance level of $p < 0.05$. But these three groups do not differ from each other for click + 8 kHz HPM and click + 4 kHz HPM noise condition as $p > 0.05$.

*Table 6. Comparison of absolute latency of wave V (ms) for click alone and clicks with different HPM noise conditions between normal hearing, definite Meniere's and possible/probable Meniere's disease*

| Conditions | p |
|---|---|
| Click alone | *0.001 |
| Click + 8 kHz HPM | 0.511 |
| Click + 4 kHz HPM | 0.088 |
| Click + 2 kHz HPM | *0.000 |
| Click + 1 kHz HPM | *0.000 |
| Click + 0.5 kHz HPM | *0.000 |

*significantly different.

In normals as the cochlea is successively masked from 8 kHz down to 0.5 kHz there is an increase in wave V latency. The reason being that the pink high pass masking noise goes on decreasing the response region on the basilar membrane and restricts the response to come from the regions which respond to lower frequencies.

Don and Eggermont (1978), on analyzing click-evoked brainstem potentials in man using high-pass noise masking, showed that by using derived band technique, narrow band contributions to ABR from specific portions of basilar membrane are obtained and there is a gradual increase in latency as the central frequency becomes lower, that is, when centre frequencies are from apical parts of the cochlea.

In the present study, in individuals with definite Meniere's disease the whole of basilar membrane would have become stiff and hence there is not a great increase in wave V latency as the frequency of high pass masking noise is lowered. Moreover in

only 7 ears out of 15 ears with definite Meniere's disease a wave V was detected at 0.5 kHz HPM condition.The findings of the present study are similar to the results obtained by Don et al. (2005), De Valck et al. (2007) and Ordonez-Ordonez et al. (2009).

In ears with possible/probable Meniere's disease also there was an increase in the absolute latency of wave V (ms) as the high pass masking noise was reduced from 8 kHz down to 0.5 kHz, in the present study. However, there was only a marginal increase in wave V latency and was less as compared to that seen in ears with definite Meniere's disease. Furthermore only 3 ears out of 15 ears had a detectable wave V for click + 0.5 kHz HPM. It could be reasoned out that in individuals with possible/probable Meniere's disease, the disease is in the early stages, hence affecting the apical portions of the cochlea. Initially the basal portions are not affected and hence the masking effects of the noise is evident with the greater increase in absolute latency of wave from 8 kHz HPM to 1kHz HPM condition, but the increase in latency from 8kHz HPM condition to 0.5 kHz HPM masking condition is less compared to that till 1 kHz HPM.

This finding can be supported by findings in early cases of endolymphatic hydrops by Tonndorf (1957) where the author showed that in such cases of early hydrops when the endolymphatic fluid volume was increased the maximum distension was that on the apical end of the basilar membrane and this caused a loss in sensitivity of basilar membrane displacement at low frequencies. Similar finding that the apical end of basilar membrane is affected in cases of early Meniere's disease was also reported by Schuknecht (1963) and Nageris, Adams, and Merchant (1996). Sperling, Paparella, Yoon, and Zelterman (1993) who reported that as the hydrops condition advances further, other regions other than apical regions are also affected.

The absolute latency of wave V among the three groups differed significantly due to the physiological changes that increase the stiffness of the basilar membrane in individuals with Meniere's disease and hence the difference between normals and individuals with Meniere's disease.

As it is evident from Table-5 that the mean of absolute latency of wave V increased successively by 2.55 msec from click alone to click + 8 kHz HPM noise to click + 0.5 kHz HPM noise in normal hearing ear. In the ears with definite Meniere's disease the mean of absolute latency of wave V (ms) increaed only by 0.42 ms from click + 8 kHz HPM noise to click + 0.5 kHz HPM. In the ears with possible/probable Meniere's disease, the mean value of absolute latency of wave V (ms) increased by only 0.09 ms from click + 8 kHz HPM to click + 0.5 kHz HPM.

**Comparison of CHAMP findings (absolute wave V latency) between definite Meniere's and possible/probable Meniere's disease:** The results showed that absolute latencies of wave V for click alone and click with 8 kHz, 4 kHz, 2 kHz, 1 kHz and 0.5 kHz HPM noise conditions did not differ significantly between definite Meniere's and possible/probable Meniere's ears as $p > 0.05$ for all conditions.

Therefore, it can be concluded that the normal ears differed from the other two groups with respect to the absolute latency of wave V for click alone and different HPM conditions but ears with definite Meniere's disease did not differ from ears with possible/probable Meniere's disease for absolute latency of wave V across all conditions. Therefore, the hypothesis, that findings of CHAMP in the different conditions are different in definite Meniere's and possible/probable Meniere's disease, is rejected.

**Latency shift of wave V in different conditions across ears with normal hearing, definite Meniere's and possible/probable Meniere's disease:** It is evident from figure-2. that the shift in latency increases with successive decrease in high pass masking noise from 8 kHz to 0.5 kHz in normal hearing ears. The shift in latency of wave V is very minimal in subjects with definite Meniere's disease with successive decrease in high pass masking noise from 8 kHz to 0.5 kHz.

For ears with possible/probable Meniere's disease the shift in latency with decrease in frequency of high pass masking noise is not as much as that seen in normals but is more compared to that seen in definite Meniere's disease.

**Comparison of CHAMP findings (latency shift of wave V in different high pass masking noise conditions with respect to wave V latency for click alone) between ears with normal hearing, definite Meniere's and possible/probable Meniere's disease:** The shift in latency of wave V (msec) in different high pass masking noise conditions with respect to click alone was compared across the three groups, that is, normal hearing, definite Meniere's and possible/probable Meniere's disease using Kruskal-Wallis test of group comparison. The results of this comparison are shown in Table-7.

According to Table-7, it can be concluded that the normal hearing, definite Meniere's and possible/probable Meniere's disease ears differ significantly from each other based on the shift in latency of wave V for 8 kHz, 4 kHz, 2 kHz, 1 kHz

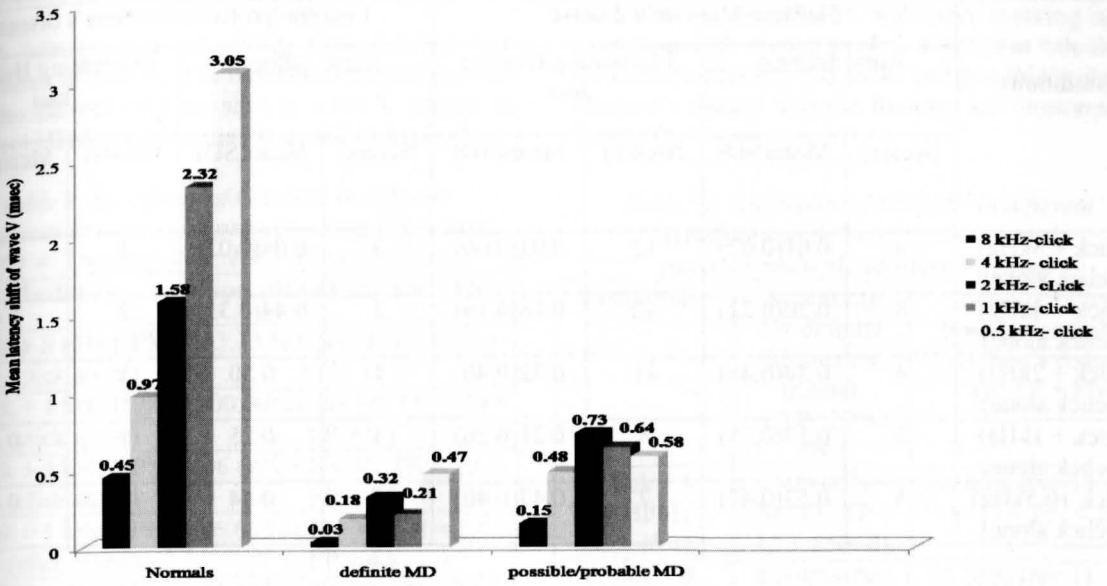


*Figure 1. Mean of latency shift of wave V (ms) in different high pass masking noise conditions with respect to latency of wave V for click alone in individuals with normal hearing, definite Meniere's disease and possible/probable Meniere's disease.*

and 0.5 kHz HPM noise condition with respect to click alone at a significance level of $p < 0.05$.

Hence, the results indicate that the hypothesis that CHAMP findings in different conditions are different in normals, definite Meniere's disease and possible/probable Meniere's disease, is accepted.

**Comparison of CHAMP findings (latency shift of wave V (ms) in different high pass masking noise conditions with respect to wave V latency for click alone) between ears with normal hearing and definite Meniere's disease and between normal hearing and possible/probable Meniere's disease:** It was found that shift in wave V latencies for 8 kHz, 4 kHz, 2 kHz, 1 kHz and 0.5 kHz HPM noise condition with respect to latency of wave V for click alone between normal hearing and definite Meniere's disease ears and normal hearing and possible/probable Meniere's disease ears are significantly different from each other at a significance level of $p < 0.05$.

**Comparison of CHAMP findings (latency shift of wave V (ms) in different high pass masking noise conditions with respect to latency of wave V for click alone) between ears with definite Meniere's and possible/probable Meniere's disease:** It was found that definite and possible/probable Meniere's differ significantly from each other for latency shift for click + 8 kHz, click + 4 kHz, click + 2 kHz HPM noise with respect to latency of wave V for click alone as ($p < 0.05$).

*Table 7. Comparison of shift in wave V latencies (ms) for 8 kHz, 4 kHz, 2 kHz, 1 kHz and 0.5 kHz HPM noise condition with respect to wave V latency for click alone across ears with normal hearing, definite Meniere's and possible/probable Meniere's disease*

| Conditions | p |
|---|---|
| (Click + 8 kHz HPM) – (click alone) | *0.000 |
| (Click + 4 kHz HPM) – (click alone) | *0.000 |
| (Click + 2 kHz HPM) – (click alone) | *0.000 |
| (Click + 1 kHz HPM) – (click alone) | *0.000 |
| (Click + 0.5 kHz HPM) – (click alone) | *0.000 |

*significantly different.

However, the shift in latencies for click + 1 kHz and click + 0.5 kHz HPM noise does not differ significantly between the two groups as $p > 0.05$. It could be reasoned that in possible/probable cases of Meniere's the apical portion of the basilar membrane, that is, the low frequencies region alone may be stiff compared to the stiffness in the entire basilar membrane in ears with definite Meniere's disease. Hence, for higher frequencies there was shift

*Table 8. Mean and standard deviation of shift in latency of wave V in different conditions with respect to aural fullness and fluctuating hearing loss in definite Meniere's and possible/probable Meniere's disease*

| Conditions | Definite Meniere's disease | | | | Possible/probable Meniere's disease | | | |
|---|---|---|---|---|---|---|---|---|
| | Aural fullness | | Fluctuating Hearing loss | | Aural fullness | | Fluctuating Hearing loss | |
| | N(ears) | Mean(SD) | N(ears) | Mean(SD) | N(ears) | Mean(SD) | N(ears) | Mean (SD) |
| (Click + 8kHz) – (click alone) | 8 | 0.01(0.07) | 12 | 0.01(0.06) | 3 | 0.04(0.03) | 3 | 0.14 (0.14) |
| (Click + 4kHz) – (click alone) | 8 | 0.20(0.22) | 12 | 0.18(0.19) | 2 | 0.44(0.35) | 2 | 0.44 (0.35) |
| (Click + 2kHz) – (click alone) | 8 | 0.34(0.46) | 11 | 0.32(0.40) | 1 | 0.50 | 1 | 0.50 |
| (Click + 1kHz) – (click alone) | 5 | 0.17(0.21) | 8 | 0.21(0.26) | 1 | 0.25 | 1 | 0.25 |
| (Click +0.5kHz) – (click alone) | 5 | 0.53(0.47) | 7 | 0.47(0.40) | 1 | 0.44 | 1 | 0.44 |

in latency of wave V in ears with possible/probable Meniere's but not in ears with definite Meniere's. Moreover at lower frequencies, that is, the apical portion of basilar membrane, would be stiff in both the groups as early hydrops affects apical portion (Tonndorf, 1957), hence no difference is observed for the lower frequencies, that is, 1 kHz and 0.5 kHz for both the groups.

**Statistical analysis of symptoms versus latency shift of wave V**

Table-8 illustrates the mean and standard deviation of shift in latency of wave V in different conditions with respect to aural fullness and fluctuating hearing loss in definite Meniere's and possible/probable Meniere's disease.

Hence, it can be concluded from table 8 that presence of fluctuating hearing loss, tinnitus and vertigo as hallmark symptoms in ears with definite Meniere's resulted in very less shift in latency of wave V in different high pass masking noise conditions with respect to click alone and could serve as a good indicator to diagnose ears with definite Meniere's disease. But these cannot be generalized to ears with possible/probable Meniere's disease.

**Statistical analysis of duration of the disease versus latency shift of wave V:** Spearman's rank correlation was done to correlate the effect of duration on definite and possible/probable Meniere's disease. In ears with definite Meniere's disease there was no correlation for [(8 kHz – click)-click alone] ($r=0.006$, $p>0.05$); [(4 kHz – click)- click alone] ($r=0.323$, $p>0.05$); [(2kHz – click)-click alone] ($r=0.035$, $p>0.05$); [(1 kHz – click)-click alone] ($r=0.735$, $p> 0.05$); [(0.5 kHz – click)-click alone] ($r=0.585$, $p>0.05$) with duration of the disease. Even in ears with possible/probable Meniere's disease there was no correlation for [(8 kHz – click)-click alone] ($r= 0.214$, $p>0.05$); [(4 kHz – click)-click alone] ($r=0.667$, $p>0.05$); [(2 kHz – click)-click alone] ($r=1.00$, $p>0.05$); [(1 kHz click)-click alone] ($r=0.949$, $p>0.05$); [(0.5 kHz – click)-click alone] ($r=0.866$, $p>0.05$) with duration of the disease.

Hence, the present study shows that the duration of the disease is not correlated with the latency shift of wave V in different high pass masking conditions with respect to click alone.

The findings of the present study is supported by Mateijsen et al. (2001), that classification of Meniere's disease based on hearing loss is possible but relating it to the duration of the disease is not correct. This conclusion was based on the fact that no relation exists between the duration of the disease and the classification of hearing loss over three months before hospital admission, as given by patients in a questionnaire.

**Specificity and sensitivity and of CHAMP findings in normal hearing, definite Meniere's and possible/probable Meniere's disease**

Specificity of a test refers to the ability of the test to identify normal individuals as normals. Specificity of the CHAMP findings in terms of latency shift of wave V in different high pass masking noise conditions with respect to click alone was calculated. Don et al. (2005) reported that a shift in latency of greater than 0.3 msec with respect to click alone will be considered as the absence of Meniere's disease. Whenever there was no response it was considered as having a very minimal shift and considered as having Meniere's disease. Therefore,

the specificity and sensitivity of CHAMP was calculated based on these criteria.

A latency shift of greater than 0.3 ms was considered as normal. The number of normal ears (in %) who showed >0.3 ms shift in wave V latency in different HPM conditions is illustrated in Table-9.

*Table 9. Specificity of CHAMP in different conditions in ears with normal hearing ( N = ears; TN = True Negative; FP = False Positive)*

| Conditions | Specificity ( TN/TN + FP ) |
|---|---|
| (Click + 8 kHz HPM) – (click alone) | 63.33 % ( N=30: TN = 19 + FP = 11 ) |
| (Click + 4 kHz HPM) – (click alone) | 100.00% ( N= 30: TN = 30 + FP = 0 ) |
| (Click + 2 kHz HPM) – (click alone) | 96.66% ( N= 30: TN = 29 + FP = 1 ) |
| (Click + 1 kHz HPM) – (click alone) | 86.66 % ( N= 30: TN = 26 + FP = 4 ) |
| (Click + 0.5 kHz HPM) – (click alone) | 76.66% ( N= 30: TN = 23 + FP = 7 ) |

It is evident from Table-9 that the shift in latency of wave V was >0.3 ms in 63.33% of normal ears for 8 kHz HPM; 100.00% for 4 kHz HPM; 96.66% for 2 kHz HPM; 86.66% for 1 kHz HPM, and 76.66% for 0.5 kHz HPM. It can be noted that only for 4 kHz HPM 100% of the ears had shift of >0.3 ms. Don et al. (2005) reported 100% specificity for CHAMP findings when using 0.5 kHz to calculate the shift in latency of wave V with respect to click alone. However, the findings of the present study suggest that specificity is 76.66% when using 0.5 kHz HPM to calculate the latency shift. The reduction in the percentage could be because in 7 ears out of 30 ears with normal hearing wave V was not detected at all in 0.5 kHz HPM condition. On the other hand, it was the 4 kHz HPM condition which showed 100% criteria. It is possible, considering the cut off shift criteria for the 4 kHz HPM condition rather than for the 0.5 kHz HPM condition may be more useful to rule out both the definite Meniere's disease and possible/probable Meniere's disease. This will be shown only with a larger data base.

De Valck et al. (2007) reported very low specificity of around 28%. But according to Don et al. (2008) there were some errors, made in their calculation of specificity and when corrected, the specificity increased to 80% which is almost similar to the findings obtained in the present study. Hence, CHAMP findings have higher specificity and can be used clinically to separate out normal hearing individuals from that of Meniere's disease.

Sensitivity of CHAMP test refers to its ability to identify individuals having Meniere's disease having Meniere's disease. Sensitivity of the CHAMP findings in terms of latency shift of wave V, which was <0.3 ms in different high pass masking noise conditions with respect to click alone, was calculated for definite Meniere's disease and possible/probable Meniere's disease and the findings are illustrated in Table-10.

*Table 10. Sensitivity of CHAMP in different conditions in definite Meniere's and possible/probable Meniere's disease*

| Conditions | Sensitivity for definite Meniere's disease ( TP/ TP + FN ) | Sensitivity for possible/probable Meniere's disease ( TP/ TP + FN ) |
|---|---|---|
| (Click + 8 kHz HPM) – (click alone) | 100.00% (N= 15: TP = 15 + FN= 0) | 86.66% (N= 13: TP = 13 + FN = 2) |
| (Click + 4 kHz HPM) – (click alone) | 86.66% (N= 13: TP = 13 + FN = 2) | 73.33% (N= 11: TP = 11 + FN = 4) |
| (Click + 2 kHz HPM) – (click alone) | 60.00% (N= 9: TP = 9 + FN = 6) | 73.33% (N= 11: TP = 11 + FN = 4) |
| (Click + 1 kHz HPM) – (click alone) | 86.66% (N= 13: TP = 13 + FN = 2) | 80.00% (N= 12: TP = 12 + FN = 3) |
| (Click + 0.5 kHz HPM) – (click alone) | 73.33% (N= 11: TP = 11 + FN = 4) | 80.00% (N= 12: TP = 12 + FN = 3) |

(N = ears; TP = True Positive; FN = False Negative)

The sensitivity of CHAMP findings was calculated in the present study applying the criteria as reported by Don et al. (2005), which is less than or equal to 0.30 ms latency shift for 0.5 kHz HPM noise condition with respect to the latency for click alone. A fairly high sensitivity of 73.33% was obtained in the present study indicating that this criterion can be used for diagnosing cases with definite Meniere's disease. The results of the present study also show that that the other HPM noise conditions also contribute for the sensitivity of CHAMP.

Don et al. (2005) reported 100% sensitivity of CHAMP findings to diagnose individuals with definite Meniere's disease but this was refuted by De Valck et al. (2007) who obtained a sensitivity of 31% for diagnosing definite Meniere's disease. But as stated earlier that there were some errors in their calculation which when corrected by Don et al. (2008) yielded a sensitivity of 100%. Hence, CHAMP can be used as a test to diagnose individuals with definite Meniere's disease, as the sensitivity of the test is high and according to the present study it is 73.3%, which though not high, is still good.

Moreover Ordonez-Ordonez et al. (2009) have reported that CHAMP yielded a specificity of 100% but its sensitivity was 31.3% in individuals with definite Meniere's disease. However, the present study yielded a sensitivity of 73.3% and specificity of 76.6%, which is not very low and validates Don et al.'s (2005) findings to use this test in order to differentially diagnose individuals with definite Meniere's disease from non-Meniere's subjects.

The results of the present study validate the findings of Don et al. (2005) in terms of diagnostic significance of CHAMP in ears with Meniere's disease. Further, the results of the present study have shown a large scope to study the significance of wave V latency shift in the various HPM conditions and not necessarily the 0.5 kHz HPM condition.

## Conclusions

The present study validates the findings of Don et al. (2005) in terms of diagnostic significance of CHAMP in ears with Meniere's disease. Further, the results of the present study have shown a large scope to study the significance of wave V latency shift in the various HPM conditions and not necessarily the 0.5 kHz HPM condition. The present study yields an overall specificity of CHAMP to be 76.6% and sensitivity of 73.3%.

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