#### **Research Article**

## Cross-Sectional Analysis of Meniere's Disease: Comparing the American Academy of Otolaryngology-Head and Neck Surgery Diagnostic Criteria with Vestibular Staging

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Short running title: Cross-Sectional Analysis of Meniere's...

## Highlights:

- Comparing AAO-HNS criteria and vestibular staging showed a moderate correlation
- Definite Meniere's disease indicates stage C, while probable suggests stage B

# ABSTRACT

**Background and Aim:** This study compared the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) criteria for Meniere's Disease (MD) with vestibular staging methods that address inner ear progression, a consideration not found in the AAO-HNS criteria.

**Methods:** A cross-sectional study recruited patients with MD, aged 18 to 60, from June 8, 2022, to March 20, 2023; however, we excluded patients with problems such as difficulty rolling their eyes, difficulty turning their head, conductive or mixed hearing loss, cental nerves system disorders, retrocochlear lesions, pregnancy, and receiving psychotropic drugs. Furthermore, patients with a history of labyrinthitis, vestibular migraine, stroke, benign positional vertigo, or bilateral vestibulopathy within the past 6 months were excluded. All patients were tested with

audiometry, vestibular evoked myogenic potential, caloric test, and video head impulse test. Two neuro-otologists assessed and classified patients with MD according to the AAO-HNS (1990 and 2020) criteria.

**Results:** Forty-two patients were enrolled. The correlation between vestibular staging and both AAO-HNS (1990 and 2020) criteria was medium (p=0.02 and p<0.01, respectively). According to AAO-HNS 1995, 69% of definite MD cases were classified as stage C, whereas all probable MD cases and 30% of possible MD cases were categorized as stage B. Regarding AAO-HNS 2020, 70% of definite MD cases were classified as stage C, whereas 33.3% of probable MD cases were classified as stage B.

**Conclusion:** Definite MD could predict pathology in the cochleo-sacculo-utricular and lateral canals (stage C), whereas probable MD could suggest that the lesion involved the cochleo-sacculo-utricular canal (stage B).

**Trial registration:** This trial was registered at Thai Clinical Trials Registry on June 6, 2022 (TCTR20220606003) **Keywords:** Meniere's disease; vestibular test; vertigo; hearing loss; inner ear

#### Introduction

Meniere's Disease (MD) is a clinical syndrome that impacts an estimated 50–200 per 100000 adults [1-3]. The audiovestibular system is affected by endolymphatic hydrops that result in various clinical manifestations, including vertigo, unilateral fluctuating sensorineural hearing loss (SNHL), tinnitus, and aural fullness. These symptoms substantially disturb the overall Quality of Life (QoL) [4-6]. Therefore, the proper diagnosis and classification of MD are very important to facilitate its management, which ultimately enhances QoL.

The criteria for the diagnosis of MD were introduced by the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). In 1995, the AAO-HNS criteria [7] were based on clinical symptoms and audiometry information that classified MD into 4 categories: certain MD, definite MD, probable MD, and possible MD. However, in 2020, the AAO-HNS criteria [8] underwent a reclassification that was divided into 2 categories: definite MD and probable MD. This criterion gained renown for its application in clinical practice; nevertheless, there was no mention regarding the progression or spreading of disease.

Regarding the pathogenesis of MD, the initial changes in endolymphatic hydrops primarily affect the cochlear duct and the saccule. Afterwards, there is subsequent involvement of different inner ear structures, including the utricle and semicircular canal [9]. The prevalence of endolymphatic hydrops was reported to be 100% in the cochlea, 86.3% in the saccule, 50% in the utricle, and 36.4% in the semicircular canals (SCC) [10]; thus, this pathogenesis of MD should be considered to classify the staging of MD. Sobhy et al. [11] developed a new classification using a vestibular function test to establish a correlation between the clinical manifestation and pathological progression of disease from pars inferior to pars superior in the audiovestibular system. Patients who met the definite MD criteria according to the AAO-HNS (1995) underwent testing to determine their classification into 4 categories, including cochleosaccular (stage A), cochleo-sacculo-utricular (stage B), cochleo-sacculo-utricular and lateral canal (stage C), and entire labyrinthine involvement (stage D).

However, the correlation between the new vestibular staging system and the criteria used to diagnose MD as defined by the AAO-HNS (1995) has not yet been investigated. Moreover, in recent times, the revised diagnostic criteria MD of AAO-HNS (2020) has been implemented globally, but the correlation with vestibular staging has not been explored. Therefore, analysis of the correlation between the new vestibular staging system and diagnostic criteria MD of AAO-HNS (1995 and 2020) was conducted to address this gap of knowledge and improve clinical follow-up assessment as well as management planning. The identification of specific pathological patterns associated with MD significantly enhances management strategies and prognosis by allowing healthcare providers to customize treatment plans tailored to individual patients. Recognizing distinct patterns enables clinicians to prioritize specific interventions, such as vestibular rehabilitation or targeted medications that address underlying dysfunction. Additionally, understanding these patterns aids in predicting disease progression, which allows for more proactive management practices by anticipating potential exacerbations. Regarding follow-up assessments, it will enable clinicians to focus on monitoring specific symptoms and conducting relevant tests, thereby facilitating timely adjustments to treatment. Furthermore, explaining the significance of these patterns to patients empowers them to engage actively in their management plans and comply with treatment regimens.

The objective of this research study was to investigate the correlation between the AAO-HNS criteria and vestibular staging in patients diagnosed with MD. Understanding this relationship aimed to enhance management strategies and

facilitate more individualized treatment approaches, ultimately improving patient outcomes and anticipating disease progression.

## Methods

This cross-sectional study was designed to investigate patients with MD in the otoneurologic clinic, ranging in age from 18 to 60 years. The recruitment period was extended from June 8, 2022, to March 20, 2023. Exclusion criteria were applied to omit patients who presented with various problems, including rolling the eyes, turning the head, conductive or mixed hearing loss, central nervous system disorders, retrocochlear lesions, pregnancy, and receiving psychotropic drugs. Furthermore, patients with a history of labyrinthitis, vestibular migraine, stroke, benign paroxysmal positional vertigo, or bilateral vestibulopathy within the past 6 months were excluded.

Regarding sample size, 42 patients with MD will ensure that a one-tailed test with  $\alpha$ -error of 5% has 90% power to effect size of disease of 0.5. Demographic data was presented in Table 1. All patients were evaluated for audiometry, Vestibular Evoked Myogenic Potential (VEMPs) test, caloric test, and video Head Impulse Test (vHIT).

The audiometric data was obtained by testing with interacoustic AC40 (Audiometer Allé 1, Middelfart, Denmark) within three months if patients had stable symptoms; however, retesting was performed if patients presented alterations in their clinical symptoms. The examination involved the assessment of pure tone frequencies ranging from 250 to 8000 Hz through the air conduction pathway as well as frequencies from 250 to 4000 Hz through the bone conduction pathway. The hearing level was classified as normal hearing, mild hearing loss, moderate hearing loss, severe hearing loss, profound hearing loss, and high-frequency hearing loss (at a frequency of 3–8 kHz).

The duet intelligent hearing system (Intelligent Hearing Systems Corp. Miami, Florida, USA) was used for the VEMP test. The parameters of the VEMP test included the sound stimulus via air conduction by ER3A insert earphones with tone burst 500 Hz at 105 dB nHL; the rate of stimulus was 5.1/s, 100–200 sweeps; the rarefaction polarity involved 50000x-100000 amplifier and filter 10–1000 Hz. The impedance of each electrode was less than 5 kOhm, and the differences of each electrode were less than 1 kOhm. All outcomes needed to be replicated at a minimum of two instances. Ocular VEMPs (oVEMPs) and cervical VEMPs (cVEMPs) were administered to all patients. For controlling muscle tone during the recording of cVEMPs, the patient was instructed to engage the sternocleidomastoid muscle by sitting upright, turning their head to the side opposite the test ear, and applying gentle resistance. Regarding the normal values for oVEMP and cVEMP tests, the difference in amplitude between p13 and n23 of both ears was indicated to be less than 35%.

Caloric examination was performed with an interacoustic device produced by Micromedical (Audiometer Allé 1, Middelfart, Denmark). The test commenced with the application of warm air at a temperature of 50°C, which was then followed by the application of cool air at a temperature of 24°C. Each stimulation lasted for a duration of 60 seconds, with a volume of 8 litres being utilized. The examination was carried out in a dark room, with the participants keeping their eyes closed and wearing goggles throughout the entirety of the test. Bilateral weakness was indicated when the sum of the Slow-Phase Velocities (SPVs) from all four irrigations was less than 25 degrees per second, or when the total response for either the left or right ear was less than 12 degrees per second. In contrast, unilateral weakness was determined by calculating the difference between the sum of peak SPVs of the warm and cool responses of the right ear and those of the left ear, divided by the total of all four peak SPV responses. A difference of 25% or more suggested significant unilateral weakness in the ear with the lesser responses.

An Interacoustic EyeseeCam vHIT device (Audiometer Allé 1, Middelfart, Denmark) was utilized in this study. The velocity of the device ranged from 150 to 250 degree per second, while the acceleration spanned from 2000 to 6000 degree per second squared. Normal gain values for vHIT were considered to be around 0.8 to 1.2. The outcomes of vestibular function tests were categorized according to the degree of hearing, as shown in Table 2.

Two neuro-otologists, who were masked to the outcomes of all vestibular tests, performed an independent assessment of the patient's conditions and classified their clinical characteristics according to the AAO-HNS criteria (1995 and 2020). If the interpretation outcome varied among patients, a consensus was reached to achieve a conclusion. In the context of vestibular staging, an audiologist classified patients based on audiometric and vestibular function test results into four progressive stages. Stage A showed abnormality in the audiogram and cVEMPs. Stage B added abnormal oVEMPs. Stage C included caloric test abnormalities. Stage D further included vHIT deficits.

The correlation of staging between the AAO-HNS criteria (1995 and 2020) and vestibular staging was analysed by Kendall's tau statistic, as revealed in Table 3. A value of p<0.05 was considered statistically significant.

## Results

The forty-two patients included 12 males and 30 females (mean age  $49.3\pm8.6$  years). The most common symptoms were vertigo (92.9%), SNHL (85.7%) and tinnitus (71.4%) (Table 1). Regarding the diagnostic criteria of MD in accordance with AAO-HNS, a total of 42 patients fulfilled the 1995 diagnostic criteria, whereas only 41 patients met the requirements in the revised criteria of 2020. This difference can be attributed to one patient who had vertigo but no aural symptoms. As a result, this patient met the possible MD according to the 1995 criteria but did not meet the criteria for probable MD in accordance with the 2020 criteria.

The results of vestibular function tests were classified based on the level of hearing that was shown in Table 2. Most of our patients who presented with abnormal vestibular function test results also complained of mild hearing loss, which was subsequently followed by moderate hearing loss. The correlation between vestibular test staging and diagnostic criteria according to AAO-HNS (1995) and AAO-HNS (2020) was assessed by Kendall's tau coefficient, which allowed values of 0.52 (p=0.02) and 0.49 (p<0.001), respectively (Table 3).

## Discussion

MD is related to endolymphatic hydrops in cochleovestibular structures that are potentially caused by a complicated pathophysiological mechanism than obstructive structures. The dysregulation of ionic composition in endolymphs [12, 13] has led to clinical presentations that include hearing and balance disorders. The prevalence of abnormal audiovestibular tests was mentioned by Sobhy et al. [11]. They reported abnormal findings, including Pure Tone Average (PTA) (85%), cVEMP (72.5%), oVEMP (67.5%), caloric test (32.5%), vHIT lateral (20%), anterior (7.5%) and posterior (5%) SCC abnormalities. These prevalence patterns of abnormality tests, similar to our study, included PTA (85.7%), oVEMPs (78.6%), and cVEMPs (76.2%). However, our caloric test abnormality (64.29%) and vHIT (9.53%) SCC abnormality showed higher abnormal caloric and lower abnormal vHIT findings than Sobhy's study [11]. It may be affected by the difficulty controlling confounding factors, including patient alertness and head position. Nevertheless, the overall disease progression pattern was the same as that in a previous study by Sobhy et al. [11] and Huang et al. [14] in which early MD started with the cochlea, otoliths and SCCs in the late stage. However, vestibular staging is a new and fascinating concept that should be developed by integrating complementary diagnostic tests, such as advanced imaging, or by incorporating patient-reported outcome measures that reflect the subjective experience of symptoms related to the depth of involvement, which could complement objective staging. This development would improve the ability to classify MD patients.

Regarding the correlation staging with vestibular function tests and diagnostic criteria (AAO-HNS), we found a resulting value of 0.52, which indicated a moderate positive correlation (p=0.02) for AAO-HNS 1995, whereas the correlation value was 0.49 (p<0.001) for AAO-HNS 2020, which also allowed a moderate correlation. Although the diagnostic MD criteria of AAO-HNS were revised, MD staging with vestibular function tests had a stable moderate correlation that provided potentially discriminative power.

According to the diagnostic criteria of AAO-HNS, there were 29 definite MD cases with version 1995 and 20 definite MD cases with version 2020. Sixty-nine percent of definite MDs (1995) and 70% of definite MDs (2020) were classified into vestibular test stage C, which predicted lesion involvement in the cochleo-sacculo-utricular and lateral canals. Moreover, there were few patients with definite MD that were classified into other vestibular stages (Table 2). These findings showed that definite MD can involve any subunits of the inner ear; however, the most common site of definite MD involvement was the cochleo-sacculo-utricular and lateral canal (stage C).

Regarding patients with probable MD, three patients were categorized into the probable MD according to AAO-HNS 1995. After recategorization as AAO-HNS 2020, there were 21 patients with probable MD. All three probable MDs (1995) were classified into vestibular test stage B (cochleo-sacculo-utricular involvement), whereas 21 probable MDs (2020) were classified into various vestibular test stages (4.8% stage A; 33.3% stage B; 28.6% stage C; 4.8% stage D). The probable MD could involve cochleo-sacculum to all audiovestibular structures, but the most common site involvement was cochleo-sacculo-utricular (stage B). Moreover, the possible MD in the AAO-HNS 1995 criteria were evaluated, which classified all three patients into vestibular test stage B; however, the possible MD was not

classified in AAO-HNS 2020. Thus, two of three possible MDs (1995) were reclassified that met the criteria of the probable MD (2020).

Furthermore, there were seven possible MDs (1995) and six probable MDs (2020) that could not be classified into vestibular test staging because the results of the patients' vestibular tests did not meet the criteria of Shoby et al.'s vestibular staging [11]. These results could suggest that the progression of MD in some patients varies from the classical pattern, where it typically begins with cochlear involvement and then proceeds sequentially to involve the saccule, utricle, and semicircular canals.

Our findings showed a moderate correlation between vestibular test staging and the diagnostic criteria of AAO-HNS. Most patients had definite MD related to vestibular test stage C, whereas most patients had probable MD related to vestibular test stage B. Therefore, definite MD could predict pathology in the cochleo-sacculo-utricular and lateral canals, whereas probable MD could suggest that lesions involved the cochleo-sacculo-utricular. These pathological patterns aided in the follow-up assessment and management of MD by providing clearer insights into the correlation between vestibular staging and the AAO-HNS criteria, thereby facilitating more accurate patient classification and diagnosis. The findings improved understanding, enabling clinicians to modify treatment plans based on the specific pathological patterns identified in patients, focusing on specific therapies that addressed underlying inner ear involvement. Furthermore, recognizing this relationship enabled active surveillance, specifically in cases of probable MD, utilizing caloric testing during exacerbations to assess and monitor disease progression for possible worsening episodes. This proactive approach led to timely interventions and improved patient education on these correlations, consequently promoting adherence to treatment regimens.

However, there was a limitation in our study. The sample size in each category of MD in the diagnostic criteria of AAO-HNS was not equal and was small; therefore, it is difficult to perform subgroup analysis. Additional research should be carried out to resolve this limitation.

#### Conclusion

The correlation between vestibular test staging and diagnostic criteria Meniere's Disease (MD) (American Academy of Otolaryngology-Head and Neck Surgery) was moderate. Definite MD could predict pathology at the cochleo-sacculo-utricular and lateral canal (stage C), whereas probable MD could suggest that the lesion involved the cochleo-sacculo-utricular (stage B). However, this correlation was concerning due to the small sample size; therefore, further studies needed to be conducted to address this issue.

## **Ethical Considerations**

## **Compliance with ethical guidelines**

The study was approved by the Local Ethics Committee (HE651110). Additionally, this study was registered with the Clinical Trial Registry (TCTR20220606003). Written informed consent was obtained from all participants after they received a detailed description of the study. The clinical data of this study was conducted in accordance with the principles of the declaration of Helsinki.

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#### Authors' contributions

LS: Conceptualization, design, data collection, original draft, read and approved the manuscript; PK: Conceptualization, design, data collection, original draft, critical editing, study supervision, read and approved the manuscript; NC: Conceptualization, design, critical editing, study supervision, read and approved the manuscript; PT: Conceptualization, design, critical editing, study supervision, read and approved the manuscript; KY: Conceptualization, design, critical editing, study supervision, read and approved the manuscript; KY:

#### **Conflict of interest**

All authors have no personal financial or institutional interest in any of the materials and devices described in this article. The authors have no conflicts of interest to declare.

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Table 1. Demographic data

Characteristic		Number	Percentage			
Gender						
Male		12	28.6			
Female		30	71.4			
Age (mean±SD)		49.3±8.6				
Clinical symptoms						
Vertigo		39	92.9			
Hearing loss		36	85.7			
Tinnitus		30	71.4			
Type of hearing			2			
Normal hearing		6	14.3			
Hooring loss	Unilateral hearing loss	22	52.4			
ricar nig 1088	Bilateral hearing loss	14	33.3			
Hearing level						
Normal hearing		6	14.3			
Mild hearing loss		13	31.0			
Moderate hearing loss		10	23.8			
Moderate to severe hearing loss		5	11.9			
Severe hearing loss		2	4.8			
Profound hearing loss		1	2.4			
High frequency hearing loss (3–8 kHz)		5	11.9			
Diagnostic criteria MD of AAO-HNS						
	Possible	10	23.8			
Version 1995	Probable	3	7.1			
	Definite	29	69.0			
Version	Probable	21	51.2			
2020	Definite	20	48.7			

MD; Meniere's disease, AAO-HNS; Academy of Otolaryngology-Head and Neck Surgery



Table 2. The outcomes of vestibular function tests categorized according to the degree of hearing

	Vestibular function test (N=42)							
	cVEMPs		oVEMPs		Caloric test		vHIT	
Hearing level	Normal N(%)	Abnormal N(%)	Normal N(%)	Abnormal N(%)	Normal N(%)	Abnormal N(%)	Normal N(%)	Abnormal N(%)
Normal	2(4.7) (95%CI: 1.3– 15.8)	4(9.5) (95%CI: 3.7–22.1)	2(4.7) (95%CI: 1.3– 15.8)	4(9.5) (95%CI: 3.7–22.1)	3(7.1) (95%CI: 2.4– 19.0)	3(7.1) (95%CI: 2.4–19.0)	5(11.9) (95%CI: 5.2–25.0)	1(2.4) (95%CI: 0.4– 12.3)
Mild HL	4(9.5) (95%CI: 3.7– 22.1)	9(21.4) (95%CI: 11.7– 35.9)	2(4.7) (95%CI: 1.3– 15.8)	11(26.2) (95%CI: 15.3– 41.1)	4(9.5) (95%CI: 3.7– 22.1)	9(21.4) (95%CI: 11.7– 35.9)	13(31) (95%CI: 19.1– 46.0)	0
Mod. HL	1(2.4) (95%CI: 0.4– 12.3)	9(21.4) (95%CI: 11.7– 35.9)	1(2.4) (95%CI: 0.4– 12.3)	9(21.4) (95%CI: 11.7– 35.9)	4(9.5) (95%CI: 3.7– 22.1)	6(14.3) (95%CI: 6.7–27.8)	9(21.4) (95%CI: 11.7– 35.9)	1(2.4) (95%CI: 0.4– 12.3)
Mod. to severe HL	1(2.4) (95%CI: 0.4– 12.3)	4(9.5) (95%CI: 3.7–22.1)	2(4.7) (95%CI: 1.3– 15.8)	3(7.1) (95%CI: 2.4–19.0)	1(2.4) (95%CI: 0.4– 12.3)	4(9.5) (95%CI: 3.7–22.1)	5(11.9) (95%CI: 5.2–25.0)	0
Severe HL	1(2.4) (95%CI: 0.4– 12.3)	1(2.4) (95%CI: 0.4–12.3)	1(2.4) (95%CI: 0.4– 12.3)	1(2.4) (95%CI: 0.4–12.3)	1(2.4) (95%CI: 0.4– 12.3)	1(2.4) (95%CI: 0.4–12.3)	1(2.4) (95%CI: 0.4–12.3)	1(2.4) (95%CI: 0.4– 12.3)
Profound HL	0	1(2.4) (95%CI: 0.4–12.3)	0	1(2.4) (95%CI: 0.4–12.3)	0	1(2.4) (95%CI: 0.4–12.3)	0	1(2.4) (95%CI: 0.4– 12.3)
HF HL	1(2.4) (95%CI: 0.4– 12.3)	4(9.5) (95%CI: 3.7–22.1)	1(2.4) (95%CI: 0.4– 12.3)	4(9.5) (95%CI: 3.7–22.1)	2(4.7) (95%CI: 1.3– 15.8)	3(7.1) (95%CI: 2.4–19.0)	5(11.9) (95%CI: 5.2–25.0)	0

cVEMPs; vestibular evoked myogenic potential, oVEMPs; Ocular vestibular evoked myogenic potential, vHIT; video head impulse test, HL; hearing loss, Mod.; moderate, HF HL: high frequency hearing loss

Table 3. The correlation between the diagnostic criteria of Academy of Otolaryngology-Head and Neck Surgery and vestibular test staging

	Diagnostic criteria accordance to AAO-HNS 1995 (n=42)				Diagnostic criteria accordance to AAO-HNS 2020 (n=41*)		
Vestibular test staging	Possible MD N(%)	Probable MD N(%)	Definite MD N(%)	Kendall's tau coefficient	Probable MD N(%)	Definite MD N(%)	Kendall's tau coefficient
Stage A	0	0	1(3.5) (95%CI: 0.6-17.2)	0.52 (p=0.02)	1(4.8) (95%CI: 0.8–22.7)	0	0.49 (p<0.001)
Stage B	3(10.0) (95%CI: 10.7–60.3)	3(100) (95%CI: 2.4–19.0)	5(17.2) (95%CI: 7.6–34.5)		7(33.3) (95%CI: 17.2–54.6)	4(20.0) (95%CI: 8.1–41.6)	
Stage C	0	0	20(69.0) (95%CI: 50.8–82.7)		6(28.6) (95%CI: 13.8–49.9)	14(70.0) (95%CI: 48.1–85.5)	
Stage D	0	0	3(10.3) (95%CI: 3.6–26.4)		1(4.8) (95%CI: 0.8–22.7)	2(10.0) (95%CI: 2.8–30.1)	
Out of staging	7(70.0)	0	0		6(28.6)	0	

(95%CI: 39.7–89.2)	(95%CI: 13.8–49.9)	
AO-HNS; Academy of Otolaryngology-Head and Neck Surgery; MD; Meniere's disease.		