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Treatment Results of Definite and Probable Meniere's Disease

Delgerzaya Enkhtaivan[1], Nayanjin Tergel[2], Chadraabal Sainbileg[2], Erdenechuluun Jargalkhuu[3], Avirmed Tovuudorj[3], Ja Won Koo[3]

[1]Department of Otorhinolaryngology, School of Medicine, Mongolian National University of Medical Sciences, Ulaanbaatar, Mongolia; [2]Department of Neurology, School of Medicine, Mongolian National University of Medical Sciences, Ulaanbaatar, Mongolia; [3]Department of Otorhinolaryngology–Head and Neck Surgery, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Republic of Korea

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Corresponding Author
Delgerzaya Enkhtaivan, MD
Department of Otorhinolaryngology, School of Medicine, Mongolian National University of Medical Sciences, Ulaanbaatar 15120, Mongolia
Tel: +976-9999-3119
E-mail: delgerzayaenkhtaivan@gmail.com

Objectives: To evaluate the treatment results of definite and probable Meniere's disease (MD). **Methods:** A total of 51 patients, who were diagnosed with Meniere's disease (MD) between January 2019 to January 2021 at EMJJ ENT hospital's vestibular laboratory in Mongolia, was included in our study. The diagnosis of Meniere's disease was according to the 2015 Diagnostic criteria of Menière's disease of the Classification Committee of the Bárány Society. The clinical dizziness handicap inventory (DHI) questionnaire was taken, and videonystagmography (VNG), caloric test, and PTA was done in all patients. **Results:** Of a total of 51 patients, 9 were diagnosed as probable MD, and 42 were diagnosed as definite MD. The mean age of the patients was 43.7, male to female ratio was 1:1.8, 37 (72.5%) patients were in treatment group I who all received medication only, and 14 (27.5%) patients were in treatment group II who were refractory to prior medical therapy underwent ITDI. Comparing the two treatment groups, there were significant differences in all test results ($p = 0.000$). After ITDI hearing improved ($p = 0.000$). **Conclusions:** VNG, caloric test, and DHI questionnaire results show that both medical treatment and ITDI are successful in improving vestibular function.

Keywords: Meniere's Disease, Videonystgamography, Caloric Test

Introduction

Meniere's disease (MD) is an inner ear pathology of unclear etiology which presents with vertigo, hearing loss, ear fullness and tinnitus. The main generally agreed underlying factor is endolymphatic hydrops. A 2010 study done in the USA showed that the prevalence was 190 per 100,000 population [1]. Worldwide 12 in 1000 people are diagnosed with MD [2].

An Italian study treating the acute symptomatic phase was based on diuretics in 83.5% of respondents, steroids in 66.7%, and vasodilators in 22% of cases [3]. Between 1962 and 2012, there were 439 studies on the medical treatment of Meniere's disease, including 19 studies at the Oxford Center for Evidence-Based Medicine published in full text online. Among them there were 5 studies using isosorbide, 6 studies using hydrochlorothiazide, 2 study using acetasolamide, 2 study using chlorthalidone, and 1 study using betahistine treatment in patients with MD. According to the study results, 42.1% had improved hearing, 79% had improved vestibular function, 52.7% had no side effects, 21.1% had gastrointestinal side effects, and no serious complications or deaths were reported [4]. One study done in Korea of patients with definite MD who underwent medical treatment with hydrochlorothiazide resulted in lower episodes of vertigo, improvement of hearing loss, and proved to be a relatively safe treatment with low incidence of side effects [5]. Although there are many studies on intratympanic steroid treatment in MD, the effect is questionable [6]. Intratympanic (IT) injections of aminoglycosides and corticosteroids can improve vertigo control. Hearing and vestibular loss however may result with IT aminoglycosides [7]. Also, in patients with MD refractory to medical treatment, intratympanic injection of gentamycin resulted in 83-91% reduction in vertigo episodes, but 5-15% loss in hearing threshold [2, 8].

There is no agreed consensus on treatment of MD until now. Therefore, additional studies are necessary to improve patient care and management of MD. The first and only vestibular laboratory in Mongolia was established in 2016, from then on, we have been diagnosing and treating peripheral vestibular disease. Until now there have not been any study on MD in Mongolia. Our study's primary objective was to diagnose definite and probable Meniere's disease. After that there is a comparison report of the treatment of two groups that used betahistine, hydrochlorothiazide, and intratympanic dexamethasone injection (ITDI). dy to enable further *Camelus bactrianus* nanobody research.

Materials and Methods

A Total of 51 patients, who were diagnosed with MD between January 2019 to January 2021 at EMJJ ENT hospital's vestibular laboratory, was included in our study.

Inclusion criteria: Diagnosed as MD (adult), agreed to participate in the study, and had follow up evaluation. The diagnosis of MD was made according to the 2015 diagnostic criteria of Meniere's disease according to the Classification committee of the Barany Society [9]. Clinical questionnaire, dizziness handicap inventory questionnaire, videonystgamography, caloric test, and PTA was done in all patients.

Exclusion criteria: Diagnosed with central vestibular disorder, diagnosed with other peripheral vestibular disorder, having dizziness related to cardiovascular disorders, having dizziness related to psychogenic disorders, diagnosed with other systemic disorders, and pregnant or lactating women.

Clinical questionnaire

The questionnaire consisted of three parts: the first part contained general information of the patient (name, age, sex, and address), the second part contained the information regarding the history of current illness (start of the symptom, last episode, frequency and duration of the episodes, risk factors), and the third part contained 6 questions containing MD major signs and symptoms according to AAO-HNS Meniere disease guideline [10].

Dizziness handicap inventory

We used AAO-HNS's 1990 dizziness handicap inventory to evaluate the severity of the patient's perception of the handicap caused by dizziness. DHI was taken before and after the treatment [11].

Videonystagmography (VNG) and caloric test

We used SLMED "Easy-eyes" videonystagmography, and SLAIR-0512 caloric test to evaluate the nystagmus and objectively diagnose and evaluate the treatment results. The Caloric test was done using two-channel VNG equipment. Each ear was irrigated with air at different temperatures (24±0.4C, 50±0.4C). The induced nystagmus was characterized by its

slow-phase velocity along with the test duration recording or until it faded away. We used a modified Jongkee's formula to quantitatively measure the response. A normal caloric test was defined when canal paresis (CP) was ≤25%.

Diagnostic criteria for Meniere's disease

The diagnostic criteria for MD include two categories: definite MD and probable MD. The diagnosis of definite MD is based on clinical criteria and requires the observation of an episodic vertigo syndrome associated with low to medium frequency sensorineural hearing loss and fluctuating aural symptoms (hearing, tinnitus and/or fullness) in the affected ear. Duration of vertigo episodes is limited to a period between 20 minutes and 12 hours. Probable MD is a broader concept defined by episodic vestibular symptoms (vertigo or dizziness) associated with fluctuating aural symptoms occurring alongside vertigo for a period from 20 minutes to 24 hours [9].

Treatment groups of Meniere's disease

I group: Medical treatment

Betahistine 16 mg twice a day and hydrochlorothiazide 25 mg once in the morning for 1 month.

Indication: Diagnosed as either definite or probable MD, no prior history of medical treatment.

II group: Intratympanic dexamethasone injection (ITDI)

Dexamethasone injection: 0.5 ml (4mg/ml) of dexamethasone solution was injected into the middle ear cavity once every 3 days for a total of 5 times.

Indication: Diagnosed with definite MD, refractory to 3-6 months of medical treatment, at least 12-month history of imbalance and hearing loss, and at least 6-months passed since the first vertigo episode. Mild SNHL (20-40 dB) in frequencies 0.5, 1, 2, and 3 Hz. We evaluated the treatment results after 1, 3, and 12 months with a clinical questionnaire.

Procedure of intratympanic injection (ICD-9-CM Procedure Codes 20.94)

Patients were lying down in a supine position with the head elevated up to 30 degrees and turned to the other side at 45 degrees. The ear canal and tympanic membrane were anesthetized by a cotton ball permeated with 2% lidocaine. Then, 0.5 ml of dexamethasone or gentamycin solution was injected into the middle ear cavity with a 25-G spinal needle at the anterior-superior area of the tympanic membrane. After the injection patients were advised to remain in that position for at least 20 minutes and to avoid swallowing or yawning.

Statistical analysis

Fisher's exact test was used to compare demographic characteristics for probable MD and definite MD groups. The ages of the patients in both groups were compared using independent t-tests. The main effects of time, treatment type, and their interaction were determined using a mixed two-way ANOVA with a Greenhouse-Geiser adjustment for lack of sphericity. A critical p-value of < 0.05 was used. The repeated measurements within subjects were then compared to the previous time interval using paired t-tests. The treatment I and treatment II groups' differences at each time interval were tested using the independent t-tests. A Bonferroni-type correction was applied to all t-test results resulting in a significance level set at $p < 0.017$ (= 0.05/3). SPSS version 24 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

Ethical statement

Ethical approval for this study was obtained from the Mongolian National University of Medical Sciences Research Ethics Committee on December 21, 2018. /№2018/3-18/ Informed consent was obtained from all the participants.

Results

A total of 51 patients, who were diagnosed with MD between January 2019 to January 2021 at EMJJ ENT hospital's vestibular laboratory, were included in our study. Nine were diagnosed as probable MD and 42 were diagnosed as definite MD. The mean age of the patients was 43.7±11.3, (min 24, max 68), and the male to female ratio was 1:1.8. A total duration of MD was 2.13±2.61 years and was 22.08±22.12 days (min 2, max 10 days), and a total number of vertigo episodes was 5.25±5.15 (min 1, max 24). When asking duration since the last vertigo episode to hospital visit as to the possible cause of the vertigo episodes, 30 (58.8%) people answered fatigue or tiredness and 10 (19.6%) people answered stress. From a total of 46 patients who were referred from other hospitals, only 5 (9.8%) were diagnosed as MD. According to the clinical questionnaire, all patients had 6 main signs and symptoms of MD diagnostic

criteria. Spontaneous nystagmus decreased from 33% to 2% (p = 0.000) and head shake nystagmus decreased from 82.4% to 31.6% after treatment (p = 0.008). Before treatment average, the main indication of dysfunction of labyrinth in caloric test canal paresis decreased from 37.32±22.64% to normal 17.8 ± 8% (p = 0.032).

Table 1. Comparison between definite and probale MD.

Characteristics	Probable MD (n=9)	Definite MD (n=42)	p-value
	Mean ± SD	Mean ± SD	
Age	40.33 ± 11.3	44.45 ± 11.4	0.000
Duration (days)	0.84 ± 0.73	2.41 ± 2.79	0.407
Number of total episodes	5.41 ± 3	5.57 ± 5.6	0.000
DHI before treatment	59.4 ± 9.3	58.5 ± 10.7	0.047
DHI after treatment	20.0 ± 4.8	18.14 ± 7.4	0.056
Gender	N(%)	N(%)	
Male	3 (33.3)	15 (35.7)	*0.785
Female	6 (66.6)	27 (64.3)	
Affected side			
Right	4 (44.4)	20 (47.6)	*0.823
Left	5 (55.6)	22 (52.4)	
Visit hospital			
Previous visit other hospital	8 (88.8)	38 (90.5)	*0.962
First visit	1 (11.1)	4 (9.5)	
Pre-diagnosis			
Verify diagnosis	7 (87.5)	29 (90.6)	*0.841
Meniere's disease	1 (12.5)	4 (9.4)	
Presumed cause			
Stress	-	10 (27.8)	-
Fatique, tiredness	7 (77.7)	23 (63.9)	
Other	1 (11.1)	3 (8.4)	

*Fisher's exact test

Table 2. Comparison CP between two treatment groups.

Investigations and follow-up visit	Treatment I (n=37)	Treatment II[a,b,c,d,e] (n=14)	*p-value
Caloric test/CP	Mean ± SD	Mean ± SD	
First	31.9 ± 19.4	51.7 ± 25.1	0.000
After 1 month	24.2 ± 13.5	41.1 ± 20.9	0.000
After 3 months	23.2 ± 13.0	23.9 ± 10.6	0.000
After 12 months	17.3 ± 8.9	21.6 ± 6.7	0.000

Two-way mixed ANOVA results: Interaction of time and treatment F(1.818, 337.59) = 24.185, p < 0.002; Main effect of time F (1.917, 327.59) = 334.31, p < 0.051; Main effect of treatment F(1,176) = 0.667, p = 0.426; *Independent t-test between treatment I and treatment II; Paired t-test: [a]first vs. 1mth, p = 0.041; [b]first vs. 3^{mths}, p = 0.001; [c]first vs. 12^{mths}, p = 0.031; [d]1^{mth} vs. 12^{mths}, p = 0.043; [e]3^{mths} vs. 12^{mths}, p = 0.011; [f]first vs. 3^{mths}, p = 0.042.

The average age of patients diagnosed as definite MD was 44.45, which is older than patients diagnosed as probable MD (p = 0.000). Also, the number of vertigo episodes was higher in the definite MD patients (p = 0.000). There were no different other characteristics between patients who were diagnosed as definite MD compared to patients who were diagnosed as probable MD (Table 1). Thirty seven (72.5%) patients were in treatment group I who all received medication only and 14 (27.5%) patients who were refractory to prior medical therapy underwent ITDI.

Table 3. Comparison DP between two treatment groups.

Investigations and follow-up visit	Treatment I (n=37)	Treatment II[a,b,c,d] (n=14)	*p-value
DP			
First	15.2 ± 15.5	17.9 ± 24.0	0.000
After 1 month	5.4 ± 7.6	9.1 ± 7.4	0.000
After 3 months	5.7 ± 5.4	8.1 ± 7.5	0.000
After 12 months	6.2 ± 3.3	10.5 ± 10.2	0.000

Two-way mixed ANOVA results: Interaction of time and treatment F(1.928, 347.56) = 23.195, p < 0.003; Main effect of time F (1.917, 347.59) = 345.31, p < 0.002; Main effect of treatment F(1,176) = 0.678, p = 0.416; *Independent t-test between treatment I and treatment II; [a]first vs. 1[mth], p = 0.023; [b]first vs. 3[mths], p = 0.033; [c]first vs. 12[mths], p = 0.001; [d]1[mth] vs. 3[mths], p = 0.053.

Table 4. Comparison audiometry between two treatment groups.

Investigations and follow-up visit	Treatment I (n=37)	Treatment II[a] (n=14)	*p-value
Audiometry			
First	37.9 ± 29.3	63.4 ± 22.4	0.000
After 3 months	35.7 ± 25.8	57.1 ± 21.5	0.000
After 12 months	39.8 ± 27.9	58.9 ± 21.7	0.000

Two-way mixed ANOVA results: Interaction of time and treatment F(1.918, 337.59) = 23.195, p < 0.001; Main effect of time F (1.918, 337.59) = 335.31, p < 0.001; Main effect of treatment F(1,176) = 0.666, p = 0.416; *Independent t-test between treatment I and treatment II; Paired t-test: [a]first vs. 12[mths], p = 0.014.

Comparing the two treatment groups, there were significant differences in all test results. Treatment group I used betahistine 16 mg twice a day and hydrochlorothiazide 25 mg once in the morning for 1 month. Treatment group II used dexamethasone 0.5 ml (4 mg/ml) solution that was injected into the middle ear cavity. To compare the two treatment groups caloric test canal paresis, directional preponderance, head shake nystagmus, and audiometry were used. All of treatment group II's indicators were higher than treatment group I (p = 0.000) (Table 2,3,5). Also one different result is to compare the first audiometry test to after 12 months. Treatment group II's hearing improved (p = 0.000), but treatment group I's had no improvement in hearing (Table 4).

Table 5. Comparison HSN between two treatment groups.

Investigations and follow-up visit	Treatment I (n=37)	Treatment II[a,b] (n=14)	*p-value
VNG (Head shaking nystagmus)			
First	1.3 ± 0.8	0.93 ± 0.6	0.444
After 1 month	0.92 ± 0.9	0.5 ± 0.7[b]	0.006
After 3 months	0.35 ± 0.7	0.21 ± 0.6	0.000
After 12 months	0.35 ± 0.8	-	

TTwo-way mixed ANOVA results: Interaction of time and treatment F(1.927, 347.59) = 23.295, p < 0.050; Main effect of time F (1.928, 337.59) = 345.31, p < 0.001; Main effect of treatment F(1,276) = 0.654, p = 0.416; *Independent t-test between treatment I and treatment II; Paired t-test: [a]first vs. 3[mths], p = 0.043; [b]1[mnth] vs. 3[mnths], p = 0.002.

Discussion

Treatment result was evaluated by VNG, caloric, audiometric test results, and DHI questionnaire. VNG and caloric test results after the treatment showed statistically significant improvement. Before treatment average, the main indication of dysfunction of labyrinth in caloric test canal paresis decreased. From the same study the prevalence of hyporeflexia in the caloric test was higher in symptomatic (56.4%) and asymptomatic (36%) ears of patients with Meniere's disease compared to the ears of control subjects (7.5%), p < 0.001 and p = 0.004, respectively [12-15]. However, audiometric results were the same before and after the treatment which is similar to other studies of medical treatment effect on hearing. A 2018 study by Andres Rosenbaum et al.

showed that diuretic treatment in patients with MD did not improve hearing [16-18].

In one multicenter study on the treatment of MD in Kore after hydrochlorothiazide treatment, DHI scores of patients who were diagnosed with definite MD decreased from 52.0 to 18.27 [5]. And in one other study, DHI scores ranged from 2 to 100 (average: 47.08, SD 24.45) in Meniere's disease [19]. And long-term outcomes of intratympanic dexamethasone in an intractable unilateral Meniere's disease study showed the mean dizziness handicap inventory score was reduced from 91.58 (range 80-100) to 31.00 ($p = 0.00$) at 3 months of treatment. With successive follow-up periods, the mean DHI scores were reduced to 51.50, 46.6, and 50.90 at the end of 6, 12, and 24 months ($p = 0.04$, 0.35, and 0.49 respectively) [20]. In our study, the average DHI score of all treatment groups before the treatment was 58.5 which decreased to 18.14 after the treatment. Comparing the two treatment groups, there were significant differences in all test result ($p = 0.000$). Patients diagnosed as definite Meniere's disease refractory to 3-6 months of medical treatment with significant hearing loss (> 40 dB hearing loss by PTA of 0.5, 1, 2, and 3k Hz) documented by audiometry, can undergo ITGI [21]. During our study period, no patient fulfilled the indication for ITGI. A minimum 2-year follow-up is required for enough assessment of treatment efficacy according to the AAO-HNS 1995 guidelines in MD [10]. A Systematic Review showed in 2020, a total of eight articles were included for data extraction and analysis. For subjective outcomes, ITG was slightly favored compared to intratympanic corticosteroids. This was significant only in three studies ($p < 0.05$). For objective outcomes and complications, no significant differences were seen [22]. The study found that vertigo control required 3 dexamethasone infiltrations in 10 patients (90.9%), and 6 infiltrations were required in only one patient (9.09%) in the follow-up period. All patients improved significantly. Similar to the published literature, the use of intratympanic dexamethasone may be useful to control vertigo due to MD, and to avoid or to be a prior step to other more invasive treatments [23]. In a prospective, randomized, double-blind study with 2-year follow-up, dexamethasone (4 mg/mL) inner ear perfusion in a group of patients with unilateral Meniere's disease showed 82% complete control of vertigo over placebo (57%). There was also a subjective improvement in hearing (35%) [24]. Also, our study showed intratympanic dexamethasone is successful in improving vestibular function with an improvement in hearing (8%) $p = 0.000$. Our study demonstrated an improvement in vestibular function through investigation indicators. And, both medical treatment and ITDI are successful in improving vestibular function. There are a few limitations to our study. First, the disease is a rare disorder. Secondly, the population of our country is small and scattered. Third, there is only one balance laboratory in our country. Therefore, the number of participants in our two-year study is relatively small. In the future, this study needs to be conducted over a longer time, involving more people. It is also possible to compare many different treatments.

Conclusions

VNG, caloric test, and DHI questionnaire results show that both medical treatment and ITDI are successful in improving vestibular function. ITDI improved hearing. There was no difference in treatment results between patients who were diagnosed as definite MD compared to patients who were diagnosed as probable MD. Comparing the two treatment groups, there were significant differences in all test result. All ITDI group's indicators were higher than the medical treatment group. People who had a longer duration of symptoms had higher DHI scores and feel more handicapped due to their vertigo episodes.

Conflict of Interest

The authors state no conflict of interest.

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