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Evaluation of Nimodipine as an Alternative Treatment for Ménière's Disease and Endolymphatic Hydrops in a Specialized Outpatient Clinic

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Abstract

Introduction: *Ménière's Disease (MD), first described by Prosper Ménière in 1861, is an inner ear condition associated with Endolymphatic Hydrops (EH). MD is characterized by episodic vertigo, fluctuating hearing loss, tinnitus, and aural fullness. Currently, the treatment for MD focuses on symptom management, but there is no definitive cure.*

Objective: *This study aims to evaluate the use of Nimodipine as an alternative treatment for MD and EH, analyzing its efficacy in reducing vertigo episodes and improving patients' quality of life.*

Methods: *A retrospective study was conducted with 30 patients diagnosed with MD and EH. These patients were treated with Nimodipine over a period of 6 months. The study evaluated the frequency of vertigo episodes, hearing improvement, and the presence of tinnitus before and after treatment. Patients were followed in a specialized clinic in southern brazil from 2003 to 2019.*

Results: *The results demonstrated a significant reduction in the frequency of vertigo episodes in patients treated with Nimodipine. Additionally, there was an improvement in hearing levels and a reduction in tinnitus intensity. Conclusion: Nimodipine presents as a promising alternative treatment for MD and EH, contributing to the reduction of vertigo episodes and improving patients' quality of life. However, further studies with larger sample sizes and longer follow-up periods are needed to confirm these findings.*

Keywords: Meniere' s Disease, Hydrops, Endolymphatic, Vertigos, Nimodipine, Neuroprotectant

1. Introduction

Ménière's Disease (MD) is characterized as a clinical syndrome that includes spontaneous vertigo, usually accompanied by unilateral fluctuating sensorineural hearing loss, aural fullness, and tinnitus. In some cases, cochlear symptoms may occur between episodes of vertigo [1,2]. The epidemiology of MD is relatively unknown due to the lack of widely accepted diagnostic criteria, but it is estimated to affect 33 to 190 people per 100,000 individuals [3,4]. MD is more common in adults and typically appears between 30 and 70 years of age, with a slight predominance among women. It is frequently associated with acquired otological diseases. The likelihood of developing MD is higher in elderly, Caucasian, and severely obese patients [5-7].

The evolution of MD is variable. In some patients, the disease may manifest with progressive hearing loss and low-frequency vestibular symptoms. Others experience recurrent and intense vertigo with mild auditory complaints, while some experience vestibular and auditory symptoms to similar degrees. Most patients have periods of active symptoms interspersed with long remissions. Initially, hearing loss is usually fluctuating and affects only low frequencies [8-10]. Over time, this hearing loss tends to progress over eight to ten years, resulting in permanent hearing loss of all frequencies in the affected ear [11-13].

The diagnostic criteria for MD consider several factors, including dizziness, sensorineural hearing damage, fluctuating auditory manifestations – tinnitus, fullness, or hearing loss-and symptoms that are not explained by another vestibular diagnosis [14-16]. Hydrops can be divided into two categories: Endolymphatic Hydrops (EH) and Perilymphatic Hydrops (PH). EH is associated with MD; however, the differences between this and MD, which also involves excess fluid in the inner ear, are the recurring nature of vertigo episodes and hearing loss [17]. Although there is some overlap in symptoms between the two conditions, MD

is considered a more specific and severe form of EH [18]. Therefore, the main objective of our study is to evaluate the efficacy and treatment duration of Nimodipine as monotherapy in the treatment of Ménière's Disease and Endolymphatic Hydrops, considering the dosage, duration, and applicability of its use in a predefined group of patients being monitored at a private Reference Clinic in southern Brazil. Additionally, there will be a basic epidemiological assessment of both diseases.

2. Methods

2.1. Study Design

This is an epidemiological, observational, cross-sectional, retrospective study, using indirect documentation (electronic medical records), in a non-probabilistic intentional sample. The aim is to provide a descriptive analysis of the profile of patients with Ménière's Disease and Endolymphatic Hydrops treated at the Vertigo Outpatient Clinic of the Paraná Institute of Otolaryngology (IPO) from 2003 to 2019. A direct search was conducted in the records of the Vertigo Outpatient Clinic of the Paranaense Hospital of Otolaryngology to identify cases diagnosed with Ménière's Disease and Endolymphatic Hydrops that were followed in this service. Medical records were reviewed retrospectively to determine the main clinical and demographic characteristics of each case. Data collection began only after the approval of this research project by the Ethics Committee from the Hospital Paranaense de Otorrinolaringologia (CAAE 69568823.0.0000.5529), starting from August 2023 to December of the same year. The collected data from the records included sex, the date of the first appointment, the follow-up period, the date of Nimodipine use initiation, medication dosage, duration of Nimodipine use, and clinical outcomes 90 days after the start of treatment.

Data analysis began in November 2023 and ended in July 2024. Consequently, the report began to be written in November 2023 and was finalized in February 2024. The study faced difficulties in including patients who were exclusively on Nimodipine monotherapy or who remained on monotherapy for a minimum period of 90 days. Consequently, the initial number of 80 patients was reduced to 30, decreasing the sample size to be analyzed. Therefore, a new patient recruitment was conducted through medical records, but no additional patients were included in the study, and there was no impact on the time allocated for this recruitment.

Furthermore, in the analysis of clinical improvement, characterizing patient improvement presented significant challenges due to the subjective nature of evaluations and the lack of standardized record-keeping in medical records. The improvement reported by patients largely depends on their individual perception and knowledge of the disease affecting them, which can be influenced by psychological factors, personal expectations, and variability in symptom interpretation. This subjectivity imposes a methodological limitation, as the absence of objective and quantifiable metrics makes the analysis of treatment efficacy more complex.

The adopted methodology included a detailed analysis of specific symptoms to evaluate the clinical response to Nimodipine treatment. The monitored symptoms included tinnitus, vertigo, aural fullness, hearing loss, and combinations thereof, as reported by patients. Improvement was classified into the following categories:

- **Tinnitus:** Evaluation of the reduction in tinnitus intensity or frequency.
- **Vertigo:** Analysis of the decrease in vertiginous episodes and severity of crises.
- **Aural Fullness:** Observation of the reduction in the sensation of pressure or fullness in the ear.
- **Hearing Loss:** Assessment of improvement in hearing perception through patient reports, ideally complemented by audiometry.
- **Combination of Symptoms:** Cases where patients reported simultaneous improvement in multiple symptoms, such as tinnitus and vertigo.
- **Unspecified Improvement:** General reports of improved quality of life without detailed symptom specification.

Following the advisor's guidelines, an anamnesis protocol and complementary exams were conducted to be included in the research form, allowing for a more targeted search. This protocol is evidenced in Table 1.

INITIAL LETTERS OF THE NAME	
AGE	GENDER
MALE	YES
FEMALE	NO
DATE OF THE FIRST VISIT	
FOLLOW-UP TIME	
BEGINNING OF USE OF NIMODIPINE	
CLINICAL IMPROVEMENT AFTER 90 DAYS OF NIMODIPINE USE	
ASSOCIATED COMORBIDITIES	

Table 1: Anamnesis Protocol

2.2. Sample Selection

All patients with Ménière's Disease and Endolymphatic Hydrops who were followed up at the Vertigo Outpatient Clinic of the Instituto Paranaense de Otorrinolaringologia (IPO) hospital from 2003 to 2019 were selected. Patients who did not undergo treatment with Nimodipine, or who did not use this medication as monotherapy for these comorbidities, were excluded from the study. Those who were lost to follow-up or were outside the stipulated research period were also not included in this project's analysis.

2.3. Data Collection

A direct search was conducted in the records of the Vertigo Outpatient Clinic of the IPO hospital to identify cases diagnosed with Ménière's Disease and Endolymphatic Hydrops that were followed in this service. Medical records were reviewed retrospectively to determine the main clinical and demographic characteristics of each case. Data collection began only after the approval of this research project by the Ethics Committee, starting from August 2023 to December of the same year. The collected data from the records included sex, the date of the first appointment, the follow-up period, the date of Nimodipine use initiation, medication dosage, duration of Nimodipine use, and clinical outcomes 90 days after the start of treatment.

2.4. Statistical Analysis

The results of quantitative variables were described by mean, standard deviation, median, minimum, and maximum values. Categorical variables were presented as frequency and percentage. The association between two dichotomous variables was analyzed using Fisher's exact test. Quantitative variables were compared between the two groups using the student's t-test for independent samples when they showed a normal distribution. When the normality assumption was not met, the non-parametric Mann-Whitney test was used. Values of $p<0.05$ indicated statistical significance. Data were analyzed using IBM SPSS Statistics v.29.0. Armonk, NY: IBM Corp. No imputation was made for missing data correction.

3. Results

Between 2003 and 2019, 30 patients were followed in a specialized outpatient clinic and used Nimodipine 30 mg for at least 90 days. We collected demographic and clinical data from the patients, with 15 males (50%) and 15 females (50%). The average age of the sample was 58 years (Table 2). Improvement in vertiginous, auditory, and balance symptoms of patients was evaluated over a three-month period. Of the total sample, 21 patients showed clinical improvement in 90 days with the use of Nimodipine (70%). Clinical improvement was established based on subjective patient reports. A detailed analysis of the specific symptoms that improved showed that out of the 21 patients who reported improvement, 6 (28.6%) indicated a significant reduction in tinnitus, a symptom characterized by ringing or noises in the ear. Another 6 patients (28.6%) reported a notable decrease in episodes of dizziness. There were no reports of isolated tinnitus improvement from the sample. Two patients (9.5%) mentioned clinical improvement without clearly specifying which symptoms were relieved, suggesting a general perception of well-being or a reduction in multiple symptoms. Two patients (9.5%) experienced simultaneous improvement in both tinnitus and dizziness. Additionally, five patients (23.8%) became asymptomatic after treatment (Table 2).

Variable	Classification	n	Results*
Age (years)		30	58 ± 17,5; 58,5 (31 - 92)
Gender	Female	30	15 (50%)
	Male		15 (50%)
Follow-up time (months)		30	85,4 ± 66,8; 52,7 (3,7 - 206)
Follow-up time (months) until begining of Nimodipine		30	30,5 ± 32,7; 17,5 (0,8 - 127,3)
Source: The Author (2024)			

Table 2: Characterization of the Sample

*The categorical variables were described by frequency (percentage) and the quantitative ones by mean standard deviation; median (minimum value - maximum value)

Among the patients who showed clinical improvement, the average age was 54.7 years (± 17.7 years), with an average follow-up time until the start of Nimodipine of 31.5 (± 36.2) months. No significant differences were found between the groups regarding age, sex, or the time between the start of follow-up and medication initiation (Tables 3 & 4).

Variable	Classification	n	Results*
CLINICAL IMPROVEMENT IN 90 DAYS OF USE OF NIMODIPINE	No	30	9 (30%)
	Yes		21 (70%)
SYMPTOM THAT IMPROVED	Improvement of Tinnitus	21	6 (28,6%)
	Improvement of Dizziness		6 (28,6%)

	Improvement not specified		2 (9,5%)
	Improvement of Tinnitus and Dizziness		2 (9,5%)
	Asymptomatic		5 (23,8%)
Source: The Author (2024)			

Table 3: Evaluation of Clinical Improvement with The Use of Nimodipine

*The categorical variables were described by frequency (percentage) and the quantitative ones by mean standard deviation; median (minimum value - maximum value)

Variable	No improvement after 90 days of beginning of administration of Nimodipine (n=9)	Improvement after 90 days of beginning of administration of Nimodipine (n=21)	p
Age	65,9 ± 15,1; 66 (37 - 92)	54,7 ± 17,7; 48 (31 - 85)	0,108£
Gender			0,427¬
Female	3 (33,3%)	12 (57,1%)	
Male	6 (66,7%)	9 (42,9%)	
Time (months) of follow-up until the beginning of Nimodipino	28,3 ± 24,7; 24 (2,8 - 72,9)	31,5 ± 36,2; 16,8 (0,8 - 127,3)	0,790
Source: The Author (2024)			

Table 4: Comparison of Age, Sex and Follow-Up Time Until the Beginning of Nimodipino Among those who Presented or not Clinical Improvement

£ Significance of the studant t test for independent samples.
¬ Significance of the exact Fisher test.
§ Significance of the non-parametric Mann-Whitney test.

4. Discussion

Ménière's Disease and Endolymphatic Hydrops are debilitating conditions that affect the inner ear, resulting in symptoms such as vertigo, tinnitus, hearing loss, and a sensation of aural fullness. This study investigates the efficacy of Nimodipine 30mg as monotherapy in treating these disorders. The data indicate that 70% of patients reported clinical improvement after 90 days of using Nimodipine. Although the statistical analysis did not show significance, there is a clear positive trend in the association between the use of the medication and symptom improvement, particularly in the reduction of tinnitus and dizziness. Previous studies support these results, indicating that Nimodipine may benefit neurological disorders, suggesting some clinical benefit [19].

The observed improvement in specific symptoms such as tinnitus and dizziness reinforce the specificity of Nimodipine's effects. The 90-day period was adequate to observe therapeutic effects, and the fixed dose of 30mg proved appropriate. The mechanism of action of Nimodipine, which includes improving cerebral blood flow and neuroprotective effects, supports the biological plausibility of treating Ménière's Disease [20]. Factors such as age and sex may influence treatment efficacy21. The use of Nimodipine in Ménière's Disease highlights the need for additional studies to better understand these variables and optimize therapeutic strategies for different patient subgroups [20].

The reduction of debilitating symptoms suggests that Nimodipine may be a viable therapeutic option. The sample was well-balanced in terms of age and sex, representing a diverse population with Ménière's Disease [21]. Despite its limitations, this study offers interesting results. The absence of a control group limits the ability to directly attribute causality to Nimodipine. The variability in treatment response and the lack of detail on adverse reactions indicate the need for better investigations to understand this intervention's effects on MD. Additionally, better characterization of individuals who respond positively to treatment is necessary. Prolonged evaluations, larger samples, and multicentric studies are needed to assess Nimodipine's continuous efficacy and safety. This study aims to fill the existing gap in the medical literature on the use of Nimodipine alone in managing these diseases, offering a new therapeutic perspective that could improve the quality of life for affected patients.

5. Conclusion

This study aimed to evaluate the efficacy of Nimodipine as monotherapy in the treatment of Ménière's Disease (MD) and Endolymphatic Hydrops (EH), as well as to investigate the detailed epidemiological characteristics of patients, including age, sex, disease duration, and clinical response over 90 days of follow-up. The analysis revealed that 70% of patients treated with Nimodipine reported clinical improvement. However, despite this high positive response rate, the statistical analysis of the data did not show statistical significance in vertiginous, auditory, and tinnitus symptoms.

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