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Research Article

EFFECTIVENESS AND TOLERABILITY OF BETAHISTINE IN IMPROVING QUALITY OF LIFE IN PATIENTS WITH PERIPHERAL VESTIBULAR VERTIGO

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ABSTRACT

A cohort study on 490 patients experiencing peripheral vestibular vertigo participated in an international postmarket surveillance study evaluating betahistine. Primary endpoints included the SF-36v2, the Hospital Anxiety and Depression Scale, and the Dizziness Handicap Index. The study revealed a significant 41-point improvement in the total Dizziness Handicap Index score, with statistically significant enhancements observed in each domain of the Dizziness Handicap Index scale. Betahistine therapy demonstrated notable improvements in anxiety and depression scores according to the Hospital Anxiety and Depression Scale, along with enhancements in both physical and mental components of SF-36v2. Within the safety population, only two suspected adverse drug reaction was reported. The study suggests that a daily dosage of 48 mg of betahistine is particularly effective in improving health-related quality of life measures among patients experiencing recurrent peripheral vestibular vertigo, and the drug was well-tolerated.

Key words:- Dizziness, vertigo, anxiety, depression, betahistine, and depression.

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INTRODUCTION

A study focusing on patients experiencing recurrent peripheral vestibular vertigo investigated the impact of betahistine 48 mg/day on both quality of life and dizziness symptoms [1,2]. The study, known as the OSVaLD study, involved participation, with hosting the largest group of patients. Within the scope of the study, a supplementary report specifically analyzed trends in health-related quality of life (HRQoL) among participants [3]. The findings indicated that betahistine therapy contributed to the improvement of HRQoL in individuals grappling with recurrent peripheral vestibular vertigo within this diverse, multinational population.

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METHODS AND MATERIALS

Previously detailed statistical methods and sample size calculations, as outlined in prior publications [4, 5], provide comprehensive information and can be referred to for further details. The study involved patients experiencing peripheral vestibular vertigo and was conducted openly with betahistine treatment over a span of three months. The prescribed daily dose of betahistine varied based on product information, specifying 48 mg twice or thrice daily. The study design aimed to assess the Dizziness Handicap Index (DHI) and SF-36v2® at regular intervals throughout the study, including the endpoint assessments. Inclusion criteria required patients to be prescribed betahistine, attend at least one subsequent clinic visit, and have scores recorded for at

least one of the endpoint measures. The statistical analysis of these endpoints has been reported separately. Safety reports were obtained from individuals receiving betahistine and those attending clinic visits. Adherence to international guidelines, including the Declaration of Helsinki, was a priority in the OSVaLD study. Regulatory compliance involved independent institutional review of the study protocol before initiation [6]. Each patient provided informed consent in accordance with local laws and regulations, with clear explanations given about their right to withdraw from the study at any time, without needing to provide a reason. Importantly, withdrawal from the study did not impact other ongoing treatments.

RESULT

The study recruited an estimated 490 patients across 84 centers. Supplementary material provides the names of participating practitioners. Table 1 outlines key demographic characteristics for each group.

Betahistine was predominantly introduced for new diagnoses or cases with ineffective existing treatments. Common diagnoses included peripheral vestibular vertigo, benign paroxysmal positional vertigo, and Meniere's disease, with similar proportions attributed to new diagnoses or ineffective treatment. Multiple diagnoses were recorded in 42 cases. Approximately 11% of participants in the efficacy group had ear infections, and 13.6% had psychosomatic or psychiatric disorders. The most prevalent diagnoses were cerebral vascular disease, cardiac disease, and metabolic disease.

The typical betahistine regimen remained twice daily throughout the study, with no changes in dosage distribution. The treatment duration was 90 days, with an additional 14.5 days. At baseline, 154 patients received combination antivertigo therapy, with Gingko biloba being the most commonly prescribed additional drug. Gingko biloba retained its status as the most frequently used agent by the end of the study. Combination therapy was associated with Menière's disease and PVVP or BPPV among single-diagnosis categories. Additionally, 54 patients taking psychotropic drugs and 94 taking cardiovascular drugs received combination therapy.

Efficacy outcomes

DHI score

Consequently, there were significant changes in all the indices from their baseline values. Similar Dizziness Handicap Index (DHI) scores were observed for BPPV, PVVP, and Ménière's disease. Both genders exhibited comparable responses in terms of DHI. Patients receiving betahistine monotherapy (n = 336) showed slightly higher DHI responses compared to those on combination therapy (n = 154), although these differences did not reach statistical significance. Nevertheless, DHI scores in both categories exhibited a significant decrease from baseline.

HADS score

The Hospital Anxiety and Depression Scale (HADS) scores at baseline, end of study, and throughout the study are presented below. A noteworthy disparity was identified between the initial and concluding HADS scores, indicating a significant improvement in anxiety and depression levels among vertigo patients.

SF-36v2 score

At the commencement of the study, the physical component summary score was 39.1 ± 8.8, while the mental component summary score was 34 ± 10. Individuals within this cohort exhibited diminished Health-Related Quality of Life (HRQoL) scores. Over the course of the treatment period, significant improvements were noted in both scores. While there were numerical distinctions between men and women in certain domains, these variances did not attain statistical significance.

Table: 1 Demographics characteristic

	Efficacy population (490)	**Safety Population (518)**
Gender		
Men	174	186
Women	316	342
Age in class		
18-30	22	26
31-40	60	66
41-50	84	88
51-60	122	136
61-70	92	98
71-80	56	60
81-90	18	18
More than 90	4	4
Height	165±7	166±7
Weight	71.1±11.3	71±11.5
Body mass index	25±3.1	24.8±3.1

Table: 2 HADS-anxiety and HADS-depression scores.

	Baseline	Final visit	Change (final-baseline)
HADS-anxiety score	10±3.3	5.1±2.3	-2.8±3.7
HADS-anxiety level (%) Severe Moderate	 24.2 27.5	 0.8 7.2	
HADS-depression	7±3.5	3.1±2.2	-2.4±3.8
HADS-depression level (%) Severe Moderate	 8.7 15.6	 3.2 0	

Table: 3 Trends in the PCS and MCS subscales of the SF-36v2.

	Baseline	Final visit	Change (final-baseline)
PCS	39.1±6.8	48.3±6.3	8±6.3
PVVP	38.7±6.7	48±7.3	7.2±7.1
BPPV	40.4±5.7	48.5±5.2	6.8±5.1
Ménière's disease	41±7.2	50.2±5.2	8.4±6.1
MCs	34±10	46.5±7	11.5±9.4
PVVP	33.7±10.3	47.6±5.8	12.1±9.2
BPPV	32.5±9.7	46.6±6.5	12.3±11
Ménière's disease	35±10.1	47.1±8.1	11.4±9.5

Weight of the body

Within the efficacy population, there was a weight change of 0.3 ± 2.6 kg observed between the baseline and the final visit, with both men and women undergoing similar changes. Notably, patients with PVVP exhibited a lower average weight gain compared to patients with BPPV or Meniere's disease.

Efficacy evaluation on a subjective basis

Irrespective of their diagnosis, all patients receiving betahistine rated the treatment as either "excellent" or "good." Assessment levels did not show significant differences between men and women. Impressions of treatment by both patients and physicians were closely aligned, with a correlation coefficient of 0.65 (P=0.0001).

Tolerability and safety

Within the cohort study, the lone suspected adverse drug reaction (ADR) was dyspepsia in a 46-year-old male patient. No serious or severe events were associated with the study medication. A total of 152 adverse events were reported by 96 patients in the study. The data suggested that two doses of 24 mg were more effective than three doses of 16 mg, correlating with a higher incidence of suspected ADRs. Among 54 patients, 66 suspected ADRs were reported, including abdominal pain, nausea, dyspepsia, and 28 cases of neurological disorders (headaches). In 66 patients, there were 94 suspected adverse events, with 56 events classified as moderate in 38 patients. Importantly, the study did not result in any deaths.

DISCUSSION

Patients with peripheral vestibular system diseases may experience a considerable impact on their quality of life, as indicated by elevated baseline HADS scores and diminished HRQoL according to baseline SF-36v2 data in the OSVaLD study [7,8]. The analysis of baseline and final DHI scores revealed statistically significant improvements in the physical, emotional, and functional domains, surpassing a minimally important threshold for total DHI score improvement. The positive impact of betahistine on HRQoL observed in patients with BPPV aligns with findings from other trials exploring the beneficial effects of betahistine, particularly in Ménière's disease and vestibular vertigo [9]. The study suggests that betahistine may be beneficial for some BPPV patients [10], especially in cases where physicians may lack confidence in performing repositioning maneuvers. While OSVaLD examined betahistine at a dose of 48 mg/day, the potential effectiveness of higher doses remains unexplored, particularly in severe cases of Ménière's disease [11]. The open-label nature of the study and its format were considered appropriate for a multinational trial conducted

within routine care [12]. Betahistine demonstrated good tolerability in OSVaLD, with only 2.5% of participants experiencing adverse events, and these findings contribute to the understanding of betahistine's safety profile in routine clinical practice.

CONCLUSION

In an analysis of 490 patients over a three-month period, Betahistine at a dosage of 48 mg/day significantly improved Health-Related Quality of Life (HRQoL). As a result of these positive outcomes, Betahistine effectively improved the individual's well-being and quality of life. As a result of this, Betahistine's safety profile was favorable, with only one suspected adverse reaction reported throughout the entire cohort. Based on the low incidence of adverse events in this study, Betahistine at the prescribed dosage appears safe and tolerable. Combined with a reassuringly low incidence of adverse reactions, the study provides encouraging evidence that Betahistine improves HRQoL among patients, suggesting that it can be an effective therapeutic option for peripheral vestibular system patients

REFERENCES:

1. Bennecke H, Pérez-Garrigues H, Bin Sidek D. (2010). Effects of beta- histine on patient-reported outcomes in routine practice in patients with vestibular vertigo and appraisal of tolerability: experience in the OSVaLD study. Int Tinnitus J. 16, 14–24.
2. Pérez-Garrigues H, Kuessner D, Benecke H. (2007). Patient baseline charac- teristics in a multinational study of betahistine in recurrent peripheral vestibular vertigo: the OSVaLD study. Curr Med Res Opin. 23, 2753–2761.
3. Jacobson GP, Newman CW. (1990). The development of the Dizziness Handicap Inventory. Arch Otolaryngol Head Neck Surg. 116, 424–427.
4. Enloe LJ, Shields RK. (1997). Evaluation of health-related quality of life in individuals with vestibular disease using disease-specific and general outcome measures. Phys Ther. 77, 890–903.
5. Jarlsäter S, Mattson E. (2003). Test of reliability of the dizziness handicap inventory and the activities-specific balance confidence scale for use in Sweden. Adv Physiother. 5, 137–144.
6. Kammerlind AS, Ledin TE, Skargren EI, Odkvist LM. (2005). Reliability of clinical balance tests and subjective ratings in dizziness and disequilibrium. Adv Physiother. 7, 96–107.
7. Ware JE Jr, Sherbourne CD. (1992). The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. Med Care. 30, 473–483.
8. Horney CA, Ware JE Jr, Raczek AE. (1993). The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care. 31, 247–263.
9. McHorney CA, Ware JE Jr, Lu JF, Sherbourne CD. (1994). The MOS 36-item Short-Form Health Survey (SF-36): III. Tests of data quality, scaling assumptions, and reliability across diverse patient groups. Med Care. 32, 40–66.
10. Saris-Baglama RN, Dewey CJ, Chisholm GB. (2004). SF Health Outcomes™ Scoring Software User's Guide. Lincoln, RI, USA: QualityMetric Inc.
11. SF-36v2™. Scoring SF-36 Scales. Lincoln, RI, USA: QualityMetric Inc.; 2000.
12. Zigmond AS, Snaith RP. (1983).The Hospital Anxiety and Depression Scale.Acta Psychiatr Scand. 67, 361–370.

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