

## DETERMINE THE EFFICACY AND SAFETY OF BETAHISTINE IN TREATING VERTIGO AMONG PATIENTS AT TERTIARY CARE HOSPITAL.

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### Abstract

**Aim:** to determine the efficacy and safety of betahistine in treating vertigo among patients at tertiary care hospital.

**Materials and Methods:** the present open label interventional study was conducted on 50 patients of confirmed peripheral vertigo visited the department of ENT, Nalanda Medical College and Hospital, Patna, Bihar, India. Patients received 48mg betahistine (16mg, TDS) for 21 days, and were followed up on day 0, 7 and 21. Safety and effectiveness were assessed based on clinical response (scale for vestibular vertigo severity level and clinical response evaluation (SVVSLCRE)).

**Results:** mean age of the study population was 42.16 years and majority of them were females. Betahistine was found to be effective at 16mg TDS, given up to 21days, by demonstrating a significant reduction in vertigo severity ( $p < 0.0001$ ), as assessed by changes in score of vestibular vertigo severity level and clinical response evaluation (SVVSLCRE) level.

**Conclusions:** Betahistine was found to be effective in controlling vertigo and easily tolerated in the study population with no major adverse effect.

**Keywords:** Betahistine, Vertigo, Safety, Nausea

### Introduction

Vertigo is one of the most common symptoms which patients present to physicians. It has been estimated that the annual prevalence of vertigo is 4.9% for the general population, and the lifetime prevalence of vertigo is ~ 20–30%.<sup>i,ii</sup>

Vertigo is reported ~ 1.7-times more often by women than by men, and visits to the doctor's office because of vertigo increase with age. Vertigo always reflects dysfunction at some level of the vestibular system, and, according to the topographic origin of the disturbance, it may be classified as peripheral or central.<sup>iii</sup>

The most common causes of vertigo are peripheral vestibular disorders, but central nervous system disorders must be thoroughly assessed and excluded in each patient. Epidemiologic studies indicate peripheral causes of vertigo are responsible for almost three-quarters of the vertiginous attacks experienced by patients, while one-quarter may be related to central or mixed causes.<sup>1-3</sup>

Betahistine is a histamine modulatory drug used for the treatment of vertigo and other disorders of vestibular origin.<sup>iv</sup> It was first introduced for the symptomatic treatment of vascular and vasomotor disorders such as cluster headaches and vascular dementia.<sup>v</sup> Subsequently it was used in Ménière's disease and has been explored in

other vertigo disorders of central and peripheral origin such as multiple sclerosis and motion sickness.<sup>vi,vii</sup>

Betahistine has not been shown to be better than placebo in many clinical studies.<sup>viii</sup> Hence, its clinical efficacy and safety is still questionable. The present study was conceived with the aim to determine its efficacy and safety in treating vertigo among patients at tertiary care hospital.

### Materials and Methods

The present open label interventional study was conducted on patients visited the department of ENT, Nalanda Medical College and Hospital, Patna, Bihar, India.

**Inclusion Criteria:**

1. Patients above 18 years of age of either sex
2. Patients diagnosed with vertigo
3. Those who give informed consent

**Exclusion Criteria**

1. Patients who are medically unfit i.e. suffering from acute and chronic systemic illness
2. Patients already taking the drug under study
3. Patients who have not signed the informed consent

The study protocol was reviewed by the Ethical Committee of the Hospital and granted ethical clearance. After explaining the purpose and details of the study, a written informed consent was obtained.

### Sample selection

The sample size was calculated using a prior type of power analysis by G\* Power Software Version 3.0.1.0 (Franz Faul, Universitat Kiel, Germany). The minimum sample size was calculated, following these input conditions: power of 0.80 and  $P \leq 0.05$  and sample size arrived were 44 participants. Final sample achieved was 50.

### Methodology

After taking detailed history and recording demographic data and thorough clinical examination was carried out. All the eligible patients were advised to take 48 mg per day of oral betahistine (Vertin, Abbott India Ltd) 16mg three times daily for 21 days.

### Follow-up

All the patients were followed at Baseline- day-0, at day-7 and day 21 following betahistine treatment to check its effectiveness using scale vestibular vertigo severity level and clinical response evaluation (SVVSLCRE).

### Statistical Analysis

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. The variables were assessed for normality using the Kolmogorov Smirnov test. Descriptive statistics included computation of percentages, means and standard deviations. Level of significance was set at  $p \leq 0.05$ .

### Results

**Table 1:** demographic profile of the study population

Age (years)	42.16±6.61
Gender (M/F)	14 (28.0%) /36 (72.0%)
BMI	26.21±2.01

**Table 2:** mean change in score of vestibular vertigo severity level and clinical response evaluation over different time intervals

SVVSLCRE	Day 0	Day 7	Day 21
Mean	4.32	3.14	2.01
SD	1.21	1.56	0.81
p-value	-	0.021 (Sig.)	0.001 (Sig.)

Test applied: paired t-test

**Table 3:** adverse effects reported

Adverse effects	N (%)
Nausea	3 (6.0%)
Headache	1 (2.0%)
Dry mouth	1 (2.0%)
Gastritis	1 (2.0%)

### Discussion

The clinical efficacy of betahistine in the treatment of vertigo was evidenced in many studies where most of them were focused on subjective scales with vertigo as the main symptom, and/or on questionnaires on self-evaluation of quality of life.<sup>ix</sup>

In the present study, betahistine was found to be effective at 16mg TDS, given up to 21days, by demonstrating a significant reduction in vertigo severity ( $p < 0.0001$ ), as assessed by changes in score of vestibular vertigo severity level and clinical response evaluation (SVVSLCRE) level.

Similar results were obtained in multi-national, observational review, where betahistine treatment was given at a dose of 48mg/day, and a significant change in vertigo severity was noted.<sup>x</sup>

A double-blind, multicentre and parallel-group randomized study with 144 patients showed that Betahistine had a significant effect on frequency, intensity and duration of vertigo attacks.<sup>xi</sup>

Present study reported few adverse effects like nausea (6%) followed by headache of mild intensity (2%), dry mouth (2%) and gastritis (2%) but no serious adverse effects were reported. This indicate the easily tolerable safety profile of betahistine at 16mg TDS. Similarly another study also reported no serious adverse effects.<sup>xii</sup> In another study gastritis was reported in a patient receiving betahistine.<sup>xiii</sup> Few more studies supported results of current study that betahistine treatment has shown minimal side-effects and have a positive safety profile in patients with vertigo.<sup>xiii,xiv</sup>

### Conclusion

It can be concluded that betahistine therapy may be considered for the treatment of acute peripheral vertigo in the Indian population. Betahistine was found to be effective in controlling vertigo and easily tolerated in the study population with no major adverse effect.

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