ARTICLE IN PRESS



The Journal of Emergency Medicine, Vol. ■, No. ■, pp. 1–5, 2016 © 2016 Elsevier Inc. All rights reserved. 0736-4679/\$ - see front matter

http://dx.doi.org/10.1016/j.jemermed.2016.09.016

-
Rriet
Diici
D 1 -
Reports
MCPOI CS

DIAZEPAM AND MECLIZINE ARE EQUALLY EFFECTIVE IN THE TREATMENT OF VERTIGO: AN EMERGENCY DEPARTMENT RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL

Richard D. Shih, MD,* Brian Walsh, MD,† Barnet Eskin, MD,† John Allegra, MD,† Frederick W. Fiesseler, DO,†
Dave Salo, MD,† and Michael Silverman, MD†

*Department of Integrated Medical Science, Charles E. Schmidt College of Medicine, Florida Atlantic University, Boca Raton, Florida and †Department of Emergency Medicine, Morristown Medical Center, Morristown, New Jersey

Corresponding Address: Richard D. Shih, MD, Division of Emergency Medicine, Charles E. Schmidt College of Medicine, Florida Atlantic University, 777 Glades Road, BC-71, Room 307, Boca Raton, FL 33431-0991

☐ Abstract—Background: Vertigo is a debilitating disease that is commonly encountered in the emergency department (ED). Diazepam and meclizine are oral medications that are commonly used to alleviate symptoms. Objectives: We sought to determine whether meclizine or diazepam is superior in the treatment of patients with peripheral vertigo in the ED. Methods: We performed a double-blind clinical trial at a suburban, teaching ED. We randomized a convenience sample of adult patients with acute peripheral vertigo (APV) to diazepam 5 mg or meclizine 25 mg orally. Demographic and historical features were recorded on a standardized data form. Patients recorded their initial level (t0) of vertigo on a 100-mm visual analog scale (VAS) and after 30 min (t30) and 60 min (t60). The primary outcome parameter was the mean change in VAS score from t0 to t60. Differences between groups and 95% confidence intervals were calculated. Our a priori power calculation estimated that a sample size of 20 patients in each group was required to have an 80% power to detect a difference of 20 mm between treatment groups. Results: There were 20 patients in the diazepam group and 20 in the meclizine group. The two groups were similar with respect to patient demographics and presenting signs and symptoms. At t60, the mean improvements in the diazepam and meclizine groups were 36 and 40, respectively (difference -4; 95% confidence interval -20 to 12; p = 0.60). Conclusion: We

Reprints are not available from the authors.

found no difference between oral diazepam and oral meclizine for the treatment of ED patients with acute peripheral vertigo. © 2016 Elsevier Inc. All rights reserved.

☐ Keywords—benign paroxysmal positional vertigo; diazepam; meclizine; vertigo

INTRODUCTION

Vertigo is a debilitating disease that is commonly encountered in the emergency department (ED). There are approximately 500,000 medical encounters for the primary complaint of vertigo dizziness in the United States each year (1). Of these, approximately 20% occur in the ED and account for 3% of all ED visits (1–3).

Although preferable diagnostically and for guiding therapy, establishing a specific cause for vertigo is difficult in the ED (3–5). In addition, vertigo as a presentation of stroke or some other central etiologic cause adds to this diagnostic challenge (4–7).

A number of different treatments have been used for ED patients with cases of severe symptomatic vertigo. These include anticholinergics, antiemetics, benzodiazepines, and others (8,9). Of these medications, diazepam and meclizine are commonly used (8–11). Little information exists comparing the effectiveness of these

RECEIVED: 12 July 2016; FINAL SUBMISSION RECEIVED: 1 September 2016;

ACCEPTED: 8 September 2016

2 R. D. Shih et al.

agents in the treatment of vertigo. We found no previous study comparing these agents. Our objective was to determine whether meclizine or diazepam is more effective in the treatment of peripheral vertigo in the ED.

MATERIALS AND METHODS

We performed a prospective randomized controlled trial at a suburban ED with an annual patient census of 80,000. All patients between 18 and 65 years of age with a chief complaint of vertigo were eligible if the treating emergency physician diagnosed an episode of vertigo that was peripheral in nature. Patients with mild vertigo (visual analog scale [VAS] score <40 mm on a 0-100mm scale) or those requiring parenteral therapy were excluded. In addition, any patients with a focal neurologic deficit, presentation consistent with a central cause of vertigo, presentation consistent with syncope or cardiac event, orthostatic hypotension, known pregnancy, presentation consistent with drug-induced vertigo, a known adverse reaction to diazepam or meclizine, or history of recent ingestion (within 24 hours) of a sedative, antihistamine, antipsychotic, or opioid were excluded.

After the patient examination, physicians completed a standardized data collection instrument that included demographic, historical, and clinical questions. Patients recorded their initial level (t0) of vertigo on a 100-mm VAS.

Patients were allowed to refuse or withdraw from participation in the study at any time. After enrollment, patients were randomized to the diazepam or meclizine group by computer randomization in a double blind fashion. Allocation to each group was concealed. The diazepam group received 5 mg orally, while the meclizine group received 25 mg orally. A study pharmacist prepared all the pills so that they looked identical and maintained a locked code of which drug was given to each study participant. The patient, study investigators, and treating physicians were blinded to the study medication used. In addition, this code was not unlocked until the completion of study enrollment and data collection.

Patients recorded the severity of their symptoms on the VAS after 30 min (t30) and 60 min (t60). The primary outcome parameter was the mean change in VAS score from t0 to t60. Differences between groups and 95% confidence intervals (CIs) were calculated. Our a priori power calculation estimated that a sample size of 20 patients in each group was required to have an 80% power to detect a difference of 20 mm between treatment groups in the mean change in VAS scores. We chose 20 mm on a 100-mm scale as a clinically important difference we wished to show.

Data were entered into Excel for Windows (Microsoft, Redmond, WA) and transferred into SPSS for Windows (IBM, Armonk, NY) for statistical analysis. Categorical

variables were analyzed by chi-square, interval data using the Mann-Whitney U test, and continuous variables using the Student's t-test. All tests were two-tailed, with alpha set at 0.05. The study was approved by the institutional review board.

RESULTS

Forty eligible patients were consented and enrolled in this study, 20 in the diazepam group and 20 in the meclizine group. The two groups had similar patient demographics (Table 1). The median age of all enrolled patients was 44.0 years (95% CI 37–50 years; interquartile range 34.2–53.7 years), and the mean duration of symptoms were 6.5 and 6.25 h, respectively.

There were no statistically significant differences in proportions between the groups with respect to headache (0.15; 95% CI -0.15 to 0.45; p=0.53), nausea (0.05; 95% CI -0.21 to 0.31; p=1), hearing changes (0.20; 95% CI -0.01 to 0.41; p=0.18), worsening symptoms with movement, (-0.05; 95% CI -0.21 to 0.411; p=1), and nystagmus (-0.25; 95% CI -0.54 to 0.04; p=0.19). The mean t0 score was 55 mm for the diazepam group and 62 mm for the meclizine group (-6.7; 95% CI -18.2 to 4.8; p=0.24).

Both agents were associated with rapid significant improvement (p < 0.001) in vertigo scores (t0 to t60 VAS scores). However, no significant differences were seen when comparing mean decrease in VAS between diazepam versus meclizine at any time points (Table 2). At t60, the mean improvement in the diazepam and meclizine groups were 36 mm and 40 mm, respectively (difference -4, CI -20, 12; p = 0.60).

DISCUSSION

There are a number of etiologies for vertigo. Peripheral causes include benign paroxysmal positional vertigo (BPPV), Meniere's disease, labyrinthitis, and bilateral vestibular paresis. Central nervous system causes include migraine, stroke, transient ischemic attack, tumors, and

Table 1. Study Demographics

	Diazepam	Meclizine
No. Age (mean ± SD) Female sex (n)	20 42.7 ± 13.2 11	20 42.9 ± 11.0 14
Median duration of symptoms in hours (range)	6.5 (2–72)	6.25 (2–72)
Initial to VAS score in mm (95% CI)	55.3 (46–63.6)	62.0 (53.5–70.4)

CI = confidence interval; SD = standard deviation; VAS = visual analog scale.

Download English Version:

https://daneshyari.com/en/article/5653847

Download Persian Version:

https://daneshyari.com/article/5653847

<u>Daneshyari.com</u>