Original Article

# Comparative Efficacy of Prochlorperazine and Promethazine for Acute Vertigo in the Emergency Department: A Randomized Clinical Trial

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## Abstract

**Background:** Vertigo represents a subset of dizziness, and the mainstay of pharmacotherapy in the emergency department (ED) is the use of vestibular suppressants. Numerous studies have demonstrated that antihistamines are effective vestibular suppressants and provide substantial relief for acute vertigo patients. However, no studies have evaluated the use of prochlorperazine for acute vertigo despite its common prescription in EDs. This study aimed to compare the efficacy of intramuscular prochlorperazine versus intramuscular promethazine for treating acute vertigo in the ED. **Methods:** A randomized, single-blinded study comparing 12.5 mg intramuscular prochlorperazine versus 25 mg intramuscular promethazine was conducted in adult patients who presented with acute vertigo. Patients were randomized using a random number of tables and a permutated block of four. Periodic assessment of the vertigo analogue score (VAS) was performed at 1- and 2-hour intervals. The primary outcome was the mean reduction in the VAS score. Side effects and drug evaluations were conducted within 2 hours of drug administration. **Results:** There was no statistically significant difference in the reduction in the mean VAS score between patients in the prochlorperazine and promethazine groups. The mean VAS scores for patients treated with prochlorperazine were 8.43 at 0 minutes, 5.00 at 1 hour, and 3.13 at 2 hours. In contrast, the mean VAS scores for patients who received promethazine were 8.81 at 0 minutes, 6.63 at 1 hour, and 4.94 at 2 hours. Seventy-five percent of patients in the prochlorperazine group were ready for discharge, compared to only 44% in the promethazine group. However, patients in the prochlorperazine group were 1.80 times more likely to develop orthostatic hypotension (relative risk [RR] = 1.80; 95% confidence interval [CI] = 0.97, 3.35). **Conclusion:** Intramuscular prochlorperazine demonstrated a nonsignificant trend toward superiority over intramuscular promethazine for acute vertigo management, providing better relief and increasing discharge readiness.

keywords: *acute vertigo, efficacy, prochlorperazine, promethazine*

## INTRODUCTION

Vertigo represents a subset of dizziness,[1] and is not uncommon in the emergency department (ED).[2] In fact, dizziness itself may be the most common non-pain-related physical complaint seen in the ED.[3]

Management of vertigo in the ED starts by differentiating it from peripheral or central vertigo, followed by symptomatic management. Disease-specific treatments and rehabilitations are managed by the respective specialties. The mainstays of pharmacotherapy in ED are vestibular suppressants and antiemetic drugs.[4] Examples of vestibular suppressants are antihistamines, anticholinergics, benzodiazepines and calcium channel blockers. [5]

Antihistamines such as diphenhydramine, dimenhydrinate and promethazine are among the most prescribed vestibular suppressants.[5] Benzodiazepines such as diazepam and lorazepam are also effective in treating vertigo with anxiety.[6] On the other hand, antiemetics such as prochlorperazine and metoclopramide are considered second-line drugs due to their adverse effects. [4]

Many studies have compared the efficacy of these pharmacotherapies, such as intravenous hyoscine versus diazepam,[7] promethazine versus lorazepam,[8,9] and lorazepam versus dimenhydrinate.[10] A recent systematic review and meta-analysis (SRMA) showed that antihistamines provide greater acute vertigo relief than benzodiazepines. The most common antihistamine involved in SRMA is dimenhydrinate, followed by cinnarizine, promethazine, betahistine and meclizine.[11]

However, to the best of our knowledge, there are no studies comparing promethazine with prochlorperazine for acute vertigo, although both are commonly prescribed in EDs in some countries, such as Malaysia and Singapore.[12] Nevertheless, a randomized clinical trial comparing these two drugs for uncomplicated vomiting showed that prochlorperazine works significantly better than promethazine.[13] The aim of this study was to compare the efficacy of intramuscular prochlorperazine versus intramuscular promethazine for acute vertigo in the ED.

## METHODOLOGY

This was a prospective, randomized, single-blinded, controlled trial. The randomization was performed using a random number of tables and a permutated block of four. Patients were assigned to the treatment group in sequential order according to the randomization code. Ethical approval was obtained from the Universiti Sains Malaysia (USM) Human Ethics Committee (Ref: USMKK/PPP/JEPeM [200.3(9). This study was carried out from 1st March 2009 until 31st August 2010. Despite being conducted a decade ago, the practice of administering these antivertigo medications remains routine in EDs throughout Malaysia.

The study was conducted in the emergency department (ED) of Hospital USM. Patients who presented with acute vertigo, defined as vertigo occurring within three days of presentation, were included. The inclusion criteria included patients who were triaged in the green or yellow zones, while those in the red zone were excluded due to hemodynamic instability and other critical conditions. The triage system in Hospital USM is based on a three-tier system of red, yellow, and green zones.[14] Additional inclusion criteria included adults (aged 18 years and older), ability to complete the visual analogue scale (VAS), and no allergies to prochlorperazine or promethazine. Conversely, exclusion criteria included pregnancy, use of antivertigo medication, hypoglycaemia, and anaemia. Patients diagnosed with orthostatic hypotension and those with a history of alcohol use were also excluded due to the potential for these conditions to mimic vertigo. Details of the inclusion and exclusion criteria are depicted in Figure 1.

Laboratory studies or imaging studies were obtained while the study was ongoing. All patients who presented with acute vertigo needed to have a minimum of 4 bedside tests, which included electrocardiography (ECG), capillary blood sugar (CBS) tests, full blood count (FBC) tests and blood pressure (BP) measurements during the supine and standing phases. These tests ruled out non-vertiginous dizziness.

The data were recorded 2 hours after medication administration. The disposition of patients depended on the managing doctors. Upon completion of the patient encounter, the managing doctor meticulously documented the required study data on the designated forms, which were subsequently segregated into a secure repository for comprehensive review and analysis by the research team. The final ED diagnosis and disposition were recorded. The performance of ancillary studies, such as head computed tomographic (CT) scans or lumbar punctures, was noted in addition to all other relevant studies. If the patient was admitted to the hospital, inpatient management was also reviewed.

The main study outcome was a reduction in vertigo sensation at 1 hour and 2 hours, based on the VAS score after receiving the antivertigo medication. Patients were asked to scale the level of vertigo sensation (10 was the maximum possible, and 1 was none). The sensation of vertigo while walking was chosen as the primary outcome measurement because it is more sensitive than lying in bed.[10] This is the most important outcome for disposition because patients should not be discharged home if they experience severe vertigo while ambulating. The risk of falls was also high. For the present study, vertigo was scored after 1 min in the supine, sitting, and standing positions, while the ambulation vertigo score was taken after 5 steps of walking

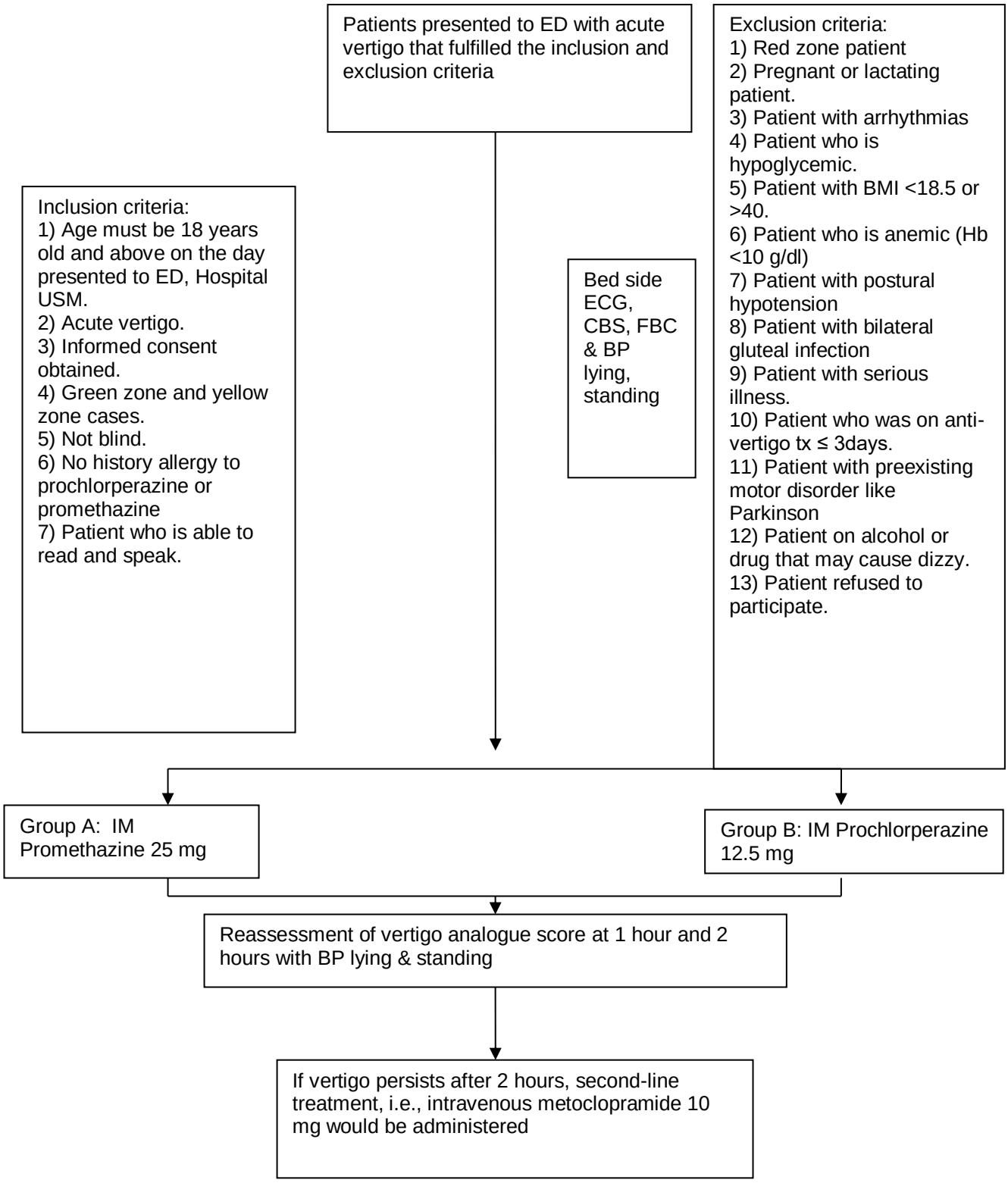


**Figure 1**: Flow chart of the methodology

Patients were randomly assigned to receive either 12.5 mg of prochlorperazine mesylate (Stemetil) or 25 mg of promethazine hydrochloride (phenergen). Both were common and frequently prescribed parenteral symptomatic treatments for acute vertigo at Hospital USM and throughout Malaysia. Dosages and routes were chosen based on recommendations from the British National Formulary (BNF). Based on recommendations, both medications should be given via deep intramuscular injection in the upper outer quadrant of the gluteal region, and the dosage should not depend on the body weight.[15] The dosage and route of administration are slightly different from those used in uncomplicated vomiting studies, where patients were administered 10 mg of prochlorperazine and 25 mg of promethazine intravenously.[13]

The secondary outcome of this study was the readiness of patients to return home post treatment, Orthostatic hypotension was also assessed as a side effect of the treatment. Patients were asked by the treating doctor if they were ready to return home after completing the treatment. Orthostatic hypotension (OH) was measured at 1 and 2 hours post treatment. Orthostatic hypotension is defined as a reduction in systolic blood pressure (SBP) of 20 mmHg or more, a reduction in diastolic blood pressure (DBP) of 10 mmHg or more, or an increase in pulse rate of 20 beats/minute (bpm) or more upon standing.[12] Blood pressure was measured after 10 minutes in the supine position or after 1 minute in the standing position.

Side effects were defined as patient complaints regardless of any changes in cardiovascular status. Some of the signs and symptoms that were asked about and observed included extrapyramidal symptoms (EPS), difficulty breathing, giddiness, nausea, vomiting and abdominal pain. Treatment failure is determined by the need for further antivertigo medication within 2 hours or the development of EPS, such as acute dystonia. No other medication was allowed during the 2-hour observation period post medication unless there was any emergency event that required intervention. If vertigo still persisted and was severe, 10 mg intravenous metoclopramide was given as a rescue medication. Intravenous procyclidine hydrochloride (10 mg) was given if any of the patients developed EPS. These patients were classified into the treatment failure group. Figure 1 summarizes the flow chart of the methodology.

Statistical analysis was performed using the Statistical Package for Social Science (SPSS) version 12.0 software. All the variables were categorical variables, descriptive data were expressed as percentages and frequencies and presented as tables. A repeated measure analysis of variance (RM ANOVA) was used to compare vertigo VAS while walking at baseline, 1 hour, and 2 hours between the prochlorperazine and promethazine, A multiple paired t with Bonferroni correction was done manually to determine within group difference. A Chi square test was used to compare readiness of the patient to go home and to determine the association of OH. Furthermore, by using Chi square risk estimate test, the relative risk (RR) of developing OH among prochlorperazine group had been calculated.

## RESULTS

A total of 32 patients were enrolled in the study. All participants were Malay except one who was Indonesian. Females were more common, representing 78.1% (n=25) of the patients. Sixteen (50.0%) patients were randomized to the prochlorperazine group, and 16 patients (50.0%) were randomized to the promethazine group. Neck movement (44.5%) was the most common associated symptom, followed by vomiting (34%), upper respiratory tract infection (8.5%) and others. The mean VAS score for vertigo with ambulation at presentation was 8.43 for the prochlorperazine group and 8.81 for the promethazine group (Table 1). The most common diagnosis for both groups was BPPV. Only one patient who presented with mild unilateral upper motor neuron 7$^{th}$ nerve palsy and ataxia was diagnosed with central vertigo. The CT brain of this patient was normal, and the final diagnosis was brainstem stroke.

There was no statistically significant difference in the reduction in the mean VAS score between patients who were treated with either prochlorperazine or promethazine (P = 0.078). The mean VAS score for patients who were treated with prochlorperazine was 8.43 at baseline, 5.00 at the 1$^{st}$ hour and 3.13 at the 2$^{nd}$ hour. The mean VAS score for patients who received promethazine was 8.81 at baseline, 6.63 at the 1$^{st}$ hour and 4.94 at the 2$^{nd}$ hour (Table 4). Figure 2 shows the estimated mean VAS score between patients treated with prochlorperazine or promethazine from baseline to the 2$^{nd}$ hour. The mean reductions in the VAS score for patients treated with prochlorperazine and promethazine between baseline and the 1$^{st}$ hour, between baseline and the 2$^{nd}$ hour, and between the 1$^{st}$ hour and the 2$^{nd}$ hour were significant (Table 2).

**Table I**: Sociodemographic and clinical characteristics of the two different groups

| Variables | Treatment Group | | |
|---|---|---|---|
| | **Prochlorperazine** (n=16) | **Promethazine** (n=16) | **p value** |
| | Mean (SD)/n (%) | Mean (SD)/n (%) | |
| Age (years old) | 51 (13.7) | 52 (11.1) | |
| BMI (kg/m²) | 24 (2.8) | 25 (2.0) | |
| Gender | | | |
| Male | 4 (25) | 3 (19) | |
| Female | 12 (75) | 13 (81) | |
| VAS score | | | |
| Mean (SD) | 8.43 (1.34) | 8.81 (1.21) | |
| Associated sx* | | | |
| vomiting | 1.38 (0.50) | 1.38 (0.50) | 1.000 |
| a/w neck mv | 1.06 (0.25) | 1.31 (0.48) | 0.740 |
| hearing loss | 1.81 (0.43) | 1.94 (0.25) | 0.300 |
| tinnitus | 1.87 (0.34) | 1.87 (0.34) | 1.000 |
| URTI | 1.87 (0.34) | 1.81 (0.40) | 0.640 |
| Diagnosis | | | |
| BPPV | 14 (87.5) | 14 (87.5) | |
| Labyrinthitis | 1 (6.25) | 0 (0) | |
| Meniere's | 1 (6.25) | 1 (6.25) | |
| Central vertigo | 0 (0) | 1 (6.25) | |
| OH at 1 hour+ | | | |
| Yes | 2 (12.5) | 0 (0) | 0.242[a] |
| No | 14 (87.5) | 16 (100) | |
| OH at 2 hours+ | | | |
| Yes | 4 (25.0) | 2 (12.5) | 0.327[a] |
| No | 12 (75.0) | 14 (87.5) | |
| Readiness to go home+ | | | |
| Yes | 12 (75.0) | 7 (44.0) | 0.074[a] |
| No | 4 (25.0) | 9 (56.0) | |

BMI= Body mass index, sx = symptoms, a/w neck mv = associated with neck movement, URTI = upper respiratory tract infection, BPPV = benign paroxysmal positional vertigo, OH = orthostatic hypotension

*Independent-samples t test, p<0.05, significant at the 95% CI. SD: standard deviation

+Chi-square test, p<0.05 significant at the 95% CI

[a] Fisher's exact test

**Table 2**: Comparison of vertigo VAS scores between prochlorperazine and promethazine over time.

| Comparison | **Prochlorperazine** | | | **Promethazine** | | |
|---|---|---|---|---|---|---|
| | **T statistic** | **Mean diff (95%-CI)** | **p-value*** | **t statistic** | **Mean diff (95%-CI)** | **p-value*** |
| **VAS in bed** | | | | | | |
| Baseline-1st hour | 7.22 | 2.63 (1.85, 3.40) | <0.001 | 4.48 | 2.06 (1.08, 3.04) | <0.001 |
| Baseline-2nd hour | 7.06 | 4.25 (2.97, 5.53) | <0.001 | 9.14 | 3.63 (2.78, 4.47) | <0.001 |
| 1st-2nd hour | 4.10 | 1.63 (0.78, 2.47) | 0.001 | 4.16 | 1.56 (0.77, 2.36) | 0.001 |
| **VAS while sitting** | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Baseline-1st hour | 6.16 | 3.31 (2.17, 4.46) | <0.001 | 4.67 | 2.13 (1.15, 3.10) | <0.001 |
| Baseline-2nd hour | 7.89 | 5.06 (3.69, 6.43) | <0.001 | 8.96 | 3.56 (2.72, 4.41) | <0.001 |
| 1st-2nd hour | 3.96 | 1.75 (0.81, 2.69) | 0.001 | 3.62 | 1.44 (0.59, 2.28) | 0.003 |
| **VAS while standing** | | | | | | |
| Baseline-1st hour | 6.42 | 3.56 (2.38, 4.75) | <0.001 | 3.79 | 2.06 (0.90, 3.22) | 0.002 |
| Baseline-2nd hour | 8.35 | 5.25 (3.91, 6.59) | <0.001 | 9.07 | 3.75 (2.86, 4.63) | <0.001 |
| 1st -2nd hour | 3.72 | 1.69 (0.72, 2.65) | 0.002 | 4.06 | 1.68 (0.80, 2.57) | 0.001 |
| **VAS with ambulation** | | | | | | |
| Baseline-1st hour | 3.44 | 3.44 (2.24, 4.64) | <0.001 | 3.73 | 2.19 (0.94, 3.44) | 0.002 |
| Baseline-2nd hour | 8.51 | 5.31 (3.98, 6.64) | <0.001 | 8.88 | 3.88 (2.94, 4.80) | <0.001 |
| 1st -2nd hour | 3.82 | 1.88 (0.83, 2.92) | 0.002 | 3.88 | 1.69 (0.76, 2.61) | 0.001 |

*Bonferroni correction

**Table 3:** Comparison of vertigo visual analogue scores among prochlorperazine and promethazine based on time.

| Time | Treatment Group | Mean vertigo score | 95%Confidence Interval |
|---|---|---|---|
| **VAS in bed** | | | |
| Baseline | Prochlorperazine | 6.75 | 5.78, 7.72 |
| | Promethazine | 7.81 | 6.85, 8.78 |
| 1st hour | Prochlorperazine | 4.13 | 2.86, 5.39 |
| | Promethazine | 5.75 | 4.48, 7.02 |
| 2nd hour | Prochlorperazine | 2.50 | 1.48, 3.52 |
| | Promethazine | 4.19 | 3.17, 5.21 |
| **VAS while sitting** | | | |
| Baseline | Prochlorperazine | 8.06 | 7.12, 9.00 |
| | Promethazine | 8.19 | 7.25, 9.13 |
| 1st hour | Prochlorperazine | 4.75 | 3.41, 6.09 |
| | Promethazine | 6.06 | 4.73, 7.40 |
| 2nd hour | Prochlorperazine | 3.00 | 1.84, 4.16 |
| | Promethazine | 4.63 | 3.47, 5.78 |
| **VAS while standing** | | | |
| Baseline | Prochlorperazine | 8.31 | 7.44, 9.18 |
| | Promethazine | 8.56 | 7.69, 9.43 |
| 1st hour | Prochlorperazine | 4.75 | 3.36, 6.14 |
| | Promethazine | 6.50 | 5.11, 7.89 |
| 2nd hour | Prochlorperazine | 3.06 | 1.89, 4.23 |
| | Promethazine | 4.81 | 3.64, 5.98 |
| **VAS with ambulation** | | | |
| Baseline | Prochlorperazine | 8.43 | 7.55, 9.32 |
| | Promethazine | 8.81 | 7.93, 9.70 |
| 1st hour | Prochlorperazine | 5.00 | 3.56, 6.44 |
| | Promethazine | 6.63 | 5.19, 8.06 |
| 2nd hour | Prochlorperazine | 3.13 | 1.97, 4.28 |
| | Promethazine | 4.94 | 3.78, 6.10 |

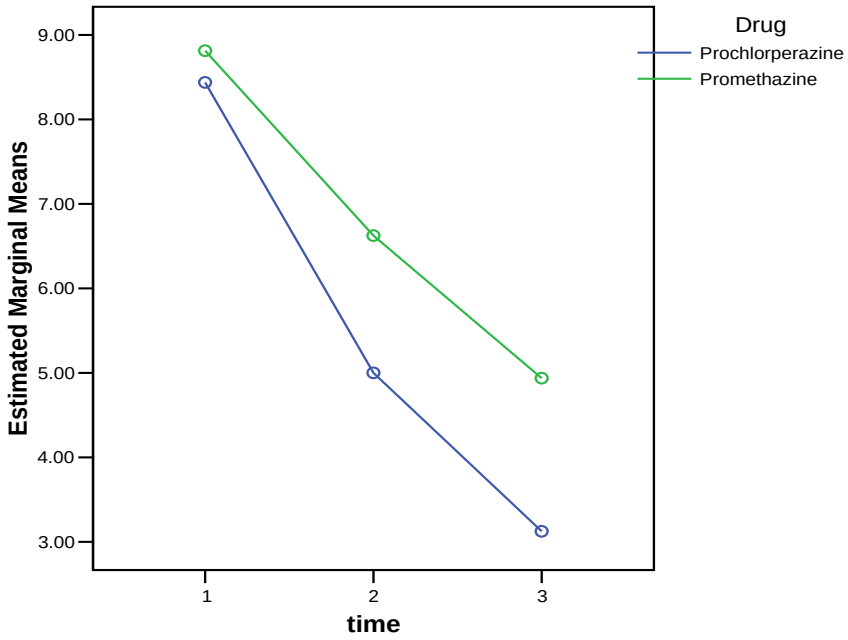


**Figure 2**: Vertigo visual analogue scale (VAS) scores of the treatment groups over time

**Table 4:** Comparison and relative risk (RR) of orthostatic hypotension within 2 hours posttreatment between prochlorperazine and promethazine

| | Orthostatic hypotension | | Total | RR (95% CI) | p value* |
|---|---|---|---|---|---|
| | Yes (%) | No (%) | | | |
| Prochlorperazine | 6 (37.5) | 10(62.5) | 16 | 1.80 (0.97, 3.35) | 0.110[a] |
| Promethazine | 2 (12.5) | 14 (87.5) | 16 | | |
| Total | 8 | 24 | 32 | | |

*Chi-square test, p<0.05 significant at the 95% CI

[a] Fisher's exact test

OH was experienced by 37.5% of patients who received prochlorperazine, whereas it was experienced by 12.5% of patients in the promethazine group as a known side effect of phenothiazine. However, the risk of developing orthostatic hypotension in both groups was tested by using the chi-square risk estimate test and was found to be non-significant (RR=1.80 with 95% CI 0.97, 3.35). (Table 4). In this study, no patients were classified into the treatment failure group. All patients enrolled were able to complete the 2-hour study. None of the patients developed EPS.

## DISCUSSION

Based on demographic data, more than ¾ of the patients were female, and their ages were approximately 50 years. These findings are comparable with those of a German study on the prevalence and age of patients.[16] Furthermore, female sex is also related to benign positional paroxysmal vertigo (BPPV),[17-19] which was also the most common cause of acute vertigo in this study. Continuous degradation of the maculae of the sensory otolith organs of the vestibule may be involved in the pathogenesis of BPPV in middle-aged or elderly patients.[20]

Both groups showed a statistically significant difference in vertigo scores between baseline and the 1st hour, between baseline and the 2nd hour, and between the 1st hour and the 2nd hour. This finding is comparable to those of studies comparing the effectiveness of promethazine versus diazepam and of promethazine versus lorazepam.[8,9] However, both studies showed the superiority of promethazine compared to benzodiazepines in reducing the severity of vertigo.

Repeated measures analysis of vertigo scores in bed, sitting, standing and while ambulating also revealed that the difference between the two treatment groups was not statistically significant. Therefore, there was no significant difference between prochlorperazine and promethazine in terms of the reduction in vertigo score for the treatment of acute vertigo in the ED. Nevertheless, compared with promethazine, prochlorperazine had a better mean VAS score, as shown in Figure 2.

OH is known as one of the side effects of both groups of medications. As shown in Table 4, orthostatic hypotension occurred more often in the prochlorperazine group than in the promethazine group, even though the difference was not statistically significant. Prochlorperazine has alpha adrenergic blockade properties that result in orthostatic hypotension. In cases of peripheral vertigo, the symptoms may be so intense that the associated nausea and vomiting may lead to volume depletion. Patients with volume depletion who received prochlorperazine may have aggravated OH. However, the volume status and intravenous fluid were not considered in this study.

Within 2 hours of treatment (Table 4), there were 6 patients who developed OH in the prochlorperazine group compared with only 2 patients in the promethazine group. Based on the chi-square test, patients in the prochlorperazine group were 1.80 times more likely to develop OH (RR=1.80 with 95% CI=0.97, 3.35).

After 2 hours of administering antivertigo medications—either prochlorperazine or promethazine—patients were evaluated for discharge readiness (Table 1). Remarkably, 75% of the patients in the prochlorperazine group were ready to go home, compared to only 44% in the promethazine group. This finding likely accounts for the prevalent prescription of prochlorperazine by ED doctors across Malaysia, who clearly recognize its superior efficacy in clinical practice.

Nevertheless, based on the current trend of managing vertigo, emphasis is also given to canalith repositioning manoeuvres as part of the treatment, particularly for BPPV. This manoeuvre has become increasingly recommended as an effective treatment measure.[18] The Third Guideline for Reasonable and Appropriate Care in the Emergency Department (GRACE-3) also emphasizes proper diagnosis and the use of the Epley manoeuvre for patients diagnosed with posterior canal BPPV.[21] This guideline is designed to reasonably reduce wasteful testing, provide explicit criteria to reduce foreseeable risk, and define sensible and prudent medical care. Emergency doctors are also required to receive training to conduct head impulse, nystagmus and test of skew (HINTS) examinations to exclude the central cause of vertigo. [21,22]

The present study was limited by its small sample size and the involvement of participants from only one ethnic group in Malaysia, except one Indonesian participant. Consequently, the study was likely underpowered to detect a significant difference. Additionally, the observation period of 2 hours was probably insufficient to determine the overall efficacy and side effects of both medications.

## CONCLUSION

Intramuscular prochlorperazine demonstrated a nonsignificant trend toward superiority over intramuscular promethazine for acute vertigo management, providing better relief and increasing discharge readiness. Despite a higher incidence of OH, no patients experienced EPS, highlighting prochlorperazine as a well-tolerated option for the treatment of acute vertigo.

## CORRESPONDENCE

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## DECLARATION OF INTEREST

The authors who participated in this randomized controlled trial declared no known conflicts of interest.

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