International Journal of Otorhinolaryngology and Head and Neck Surgery
Ilambarathi M et al. Int J Otorhinolaryngol Head Neck Surg. 2024 Jun;10(3):258-264
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937
DOI: https://dx.doi.org/10.18203/issn.2454-5929.ijohns20240950

Original Research Article

A prospective, multicenter study to evaluate the effectiveness and safety of prochlorperazine in patients suffering from vestibular migraine

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Received: 12 March 2024
Revised: 08 April 2024
Accepted: 09 April 2024

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ABSTRACT

Background: Prochlorperazine is commonly used for managing vertigo and dizziness-associated vestibular disorders. This study was designed to evaluate the effectiveness and safety of prochlorperazine in Indian patients with vestibular migraine.
Methods: In this prospective, multicenter, open-label, single-arm study, VM patients received 5 mg of prochlorperazine thrice daily for 5 days. The primary endpoint measured changes in clinical response using the scale for vestibular vertigo severity level and clinical response evaluation from baseline to days 6, 15, and 30. Secondary endpoints included symptom severity improvement and changes in SVVSLCRE from baseline up to day 30. Safety and tolerability were also assessed. Statistical analysis used the Wilcoxon signed-rank test and student-paired t-test.
Results: Out of 259 enrolled patients, 254 (98.1%) completed the study with a mean (standard deviation) age of patients was 42.22 (10.7) years; 72.2% were females. Significant improvements in clinical response and symptom severity were observed at all follow-up periods. 81.5% of patients showed VM symptom improvement by day 6, with 77.2% exhibiting moderate to good changes in SVVSLCRE scores. 83.4% experienced milder vestibular symptoms after 6 days. Furthermore, a significant difference ($p<0.001$) in mean values was observed from baseline at different follow-up periods. 11 (4.3%) adverse events (AEs) were reported, with headache being the most common (2, 0.8%); all AEs were unrelated to the study drug, and patients reported good tolerability.
Conclusions: Prochlorperazine showed significant improvement in clinical response and symptom severity with acceptable safety and tolerability in VM patients.

Keywords: Vestibular migraine, Prochlorperazine, Vestibular vertigo, Clinical response

INTRODUCTION

Vestibular migraine (VM) was described by Dieterich and Brandt in 1999.[1] VM is a type of migraine that connects vertigo with headache. Migraine is the most common cause of recurrent, primary headache disorder. It is involved with intense head pain among sufferers which is accompanied with a range of symptoms such as nausea, dizziness, lack of appetite, and disturbances of bowel function. Vertigo is a sensation of feeling off balance. Both vertigo and migraines are the two most common diseases with the highest prevalence in the general population.[2] Vertigo is 2-3 times more prevalent among migraine sufferers, especially those with aura, than in the

general population, indicating a link between the two conditions.[3] Furthermore, vertigo could be a component in both benign paroxysmal vertigo in children. Vertigo can also manifest as an aura symptom in migraine with brainstem aura.[4,5] VM, also known as migrainous vertigo or migraine-associated vertigo, migraine-associated dizziness, migraine-anxiety-associated dizziness, and migraine-related vestibulopathy, has been accepted by the International Classification of Headache Disorders (ICHD) as a general term that describes both vestibular and migrainous symptoms. The most common central cause of vertigo is VM.[4,5] Despite its high prevalence and established diagnostic criteria, VM remains underdiagnosed and undertreated.[6] This diagnostic challenge may be due to a wide range of symptoms, the absence of headaches in nearly half of them, a lack of understanding of the diagnostic criteria, and collaboration between the neurological and otolaryngological communities.[1,7]

Globally, VM affects approximately 1%-2.7% of the general population, about 10% of patients in dizziness clinics, and at least 9% of patients in migraine clinics.[8] It appears to affect both men and women, but it predominantly afflicts women at a ratio of up to 5:1, with a mean age between 30 and 40 years.[2,9] There is some evidence to suggest hereditary susceptibility, as VM may be more prevalent among those with a family history of migraines or vestibular problems.[10] Vertigo and headache do not always manifest simultaneously. VM affects approximately up to 30% of patients in specialized vertigo or headache centres.[2] The presentation of vestibular symptoms does not follow a consistent pattern during episodes of headache. Typical complaints encompass abrupt bouts of vertigo lasting from seconds to days, along with feelings of imbalance, spatial disorientation, light-headedness, a sensation of swimming, heaviness in the head, tingling sensations, and heightened susceptibility to motion sickness. Moreover, transient fluctuating hearing loss, aural fullness, tinnitus, and mild sensorineural hearing loss on audiograms are not uncommon occurrences. Given the variable duration of symptoms, this condition has the potential to mimic other causes of vertigo.[8] In the Indian setting, it has been reported that 5% of VM patients consult a general physician and about 10% of patients visit neurologists and ENT specialists.[11] VM is an underdiagnosed disorder but an increasingly recognized condition. Its propensity to become the leading cause of vertigo is noted in different literature. A study in a tertiary vertigo center demonstrated that although VM was finally diagnosed in 20.2% of patients, it was suspected by the referring doctor in fewer than 2% of patients.[12] Another study showed that only 20% of VM patients were correctly diagnosed after visiting a doctor.[13] There are no standardised guidelines to treat VM, which leads to a reduction in the quality of life, with only a few patients finding relief from their symptoms. Approximately 40% of patients with VM have reported missing work because of their symptoms, which demonstrates the impact of this disease on daily activities and quality of life.[7]

VM trials are limited and treatment recommendations rely on migraine guidelines. Moreover, there still exists a lack of awareness in the medical community that leads to misdiagnosis and subsequently reduces the quality of life.[13] The use of vestibular suppressants is the mainstay of treatment for VM. Prochlorperazine is an antiemetic with vestibular-suppressing properties.[14] It exerts therapeutic effects via a complex mechanism of action. The primary mechanism of prochlorperazine involves blocking dopamine receptors in the brain, specifically the D2 receptors. This dopamine receptor antagonist activity helps regulate dopamine neurotransmission, which is involved in various brain functions. The mechanism of action by which neuroleptics like prochlorperazine relieve headaches is likely related to dopamine D2 receptor antagonists. Prochlorperazine can relieve symptoms of various conditions, such as dizziness, nausea, and vomiting, by its multireceptor action; antihistaminergic and antidopaminergic.[15] Additionally, it exhibits antagonistic effects on serotonin receptors, particularly the 5-HT3 receptor, and has anticholinergic properties. These combined actions contribute to its antiemetic effects and neurotransmitter signaling modulation, ultimately reducing symptoms such as dizziness, nausea, vomiting, and anxiety.[16,17] Prochlorperazine has a long history of being used in VM.[18] Despite clinical success, data on the clinical safety and effectiveness of prochlorperazine are inconsistent and limited. Given the lack of data regarding the use of prochlorperazine in VM, the present prospective, multicenter, open-label, single-arm study was designed to evaluate its effectiveness in improving clinical symptoms, overall clinical response, and safety of prochlorperazine in Indian patients with VM.

METHODS

Study design

A prospective, multicenter, open-label, single-arm, investigator-initiated study was conducted from 29th September 2022 to 30th June 2023 across the following five institutions in India: IGNET Clinic, Chennai, Tamil Nadu, India, Sree Krishna ENT Care Center, Chennai, Tamil Nādu, India, Yashwantrao Chavan Memorial Hospital, Pune, Maharashtra, India, NEO Clinic, Ghaziabad, Uttar Pradesh, India and AMRI Hospital, Kolkata, West Bengal, India. This trial was registered with the Clinical Trials Registry of India on 13th October 2022. Before enrolling each patient in the trial, written informed consent was obtained. All eligible patients were prescribed 5 mg of prochlorperazine three times a day (TID) for five days and were followed up on days 6, 15 and 30. The study was performed according to the protocol, and ethical principles originating from the Declaration of Helsinki, which are consistent with

ICH/GCP and applicable government regulations, and institutional research policies and procedures.

Study population

Patients aged 18-65 years of either sex who had been diagnosed with VM based on the ICHD-3 criteria were included in the study. Key exclusion criteria were patients on prochlorperazine or any other anti-vertigo medication in the 30 days before enrolment, patients with a history of psychiatric illness in the past 6 months, patients with a history of cardiovascular, kidney, or liver disorders, or hypersensitivity to phenothiazine derivatives, patients on antipsychotics or antidepressants in the past 6 months, patients requiring hospitalization, patients with suspected or confirmed subcortical brain damage, with or without hypothalamic damage, as well as pregnant or nursing women, or those of childbearing potential not employing reliable contraceptive methods.

Outcomes

The primary endpoint of the study was the proportion of patients with VM achieving improvement in clinical response using the scale for vestibular vertigo severity level and clinical response evaluation (SVVSLCRE) from baseline (day 0) to days 6, 15, and 30 (end of treatment). Secondary endpoints were; the proportion of patients with symptom improvement assessed using SVVSLCRE from baseline to days 6, 15, and 30 and the mean change in SVVSLCRE score from baseline to days 6, 15, and 30. Safety and tolerability endpoints were; proportion of patients with adverse events (AEs) and serious AEs (SAEs) and tolerability assessment by patients and investigators on days 6, 15, and 30.

Study assessments

Demographic details such as age, sex, height, weight, body mass index (BMI), and vital characteristics including pulse rate, respiratory rate, temperature, blood pressure, and medical history were collected at baseline. The SVVSLCRE was used to assess vertigo symptoms such as faintness, headache, hearing loss, nausea, vomiting, and tinnitus and their severity. Symptom severity was graded as follows: Level I (scores 0-2): Absent vertigo/very mild, Level II (scores >2-4): Mild, Level III (scores >4-6): Moderate, Level IV (scores >6-8): Severe and Level V (scores >8-10): Very severe vertigo. Clinical response was evaluated based on the change in the severity of vertigo symptoms from baseline to days 6, 15, and 30. The responses were characterized as follows: Worsening: Increase by one level, No change: If levels remained unchanged from the baseline, Moderate: If levels changed from V to IV, IV to III, III to II, or II to I, Good: If levels changed from V to III, IV to II, or III to I, Very good: If levels changed from V to II or IV to I and Excellent: If the level changed from V to I. Tolerability was assessed by patients and the investigators on a 5-point scale and rated as excellent (no adverse effects and patients able to tolerate the drug), good (minimal side effects not interfering with patients' daily activities), moderate (some side effects and minimal interference in patients' daily activities), poor (significant side effects and significant interference in patients' daily activities), or worst (patient not able to tolerate the drug at all due to adverse reactions or effects) on Days 6, 15, and 30.

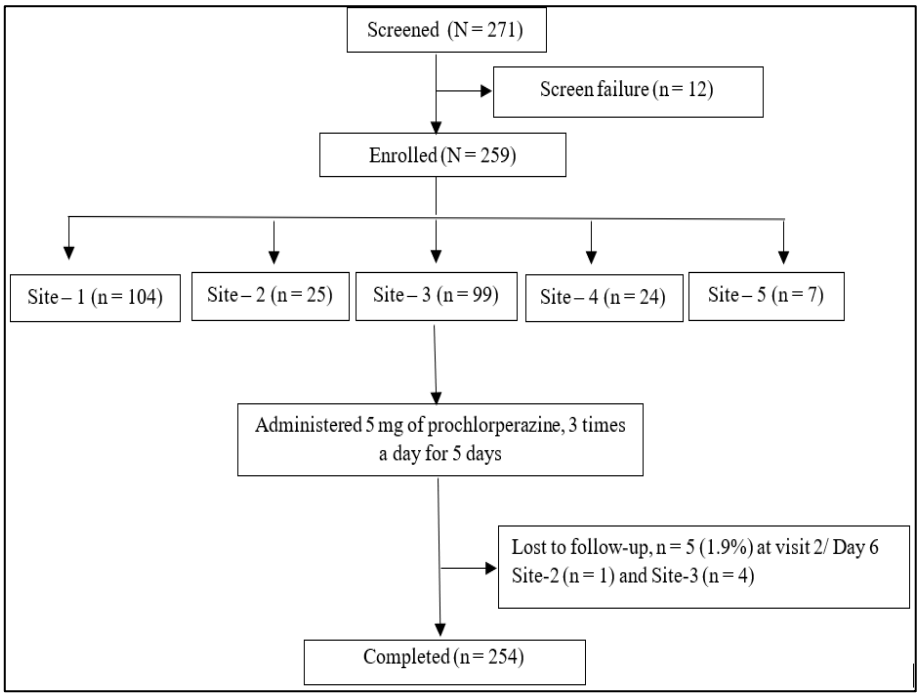

Figure 1: Patient disposition of study participants.

Statistical analysis

Continuous variables were summarized as n, mean, and standard deviation (SD). Categorical variables were summarized as N and %. The differences in SVSLCRE scores at baseline and days 6, 15, and 30 were assessed using a paired t-test at a 5% significance level. All statistical processing was performed using IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp. Released 2011. Assuming a confidence level of 95%, precision level of 0.05, the expected proportion of patients experiencing symptom improvement (primary endpoint) of 80%, and an attrition rate accounting for potential dropouts of 5%, 259 patients were needed to be enrolled in the study.

RESULTS

Disposition of patients

A total of 271 patients were screened for eligibility, of which, 259 were enrolled at baseline (visit 1/day 0) to receive 5 mg of prochlorperazine three times a day for five days. All the patients were followed up on Day 6 (visit 2), Day 15 (visit 3), and Day 30 (visit 4). A total of 5 (1.9%) patients were lost to follow-up on Day 6: one patient (0.4%) at site 2 and four (1.5%) at site 3 (Figure 1).

Table 1: Demographic and baseline characteristics of enrolled patients (n=259).

Characteristics	Observations
Gender, N (%)	
Males	72 (27.8)
Females	187 (72.2)
Age (years), mean (SD)	42.2 (10.7)
BMI (kg/m^2), mean (SD)	26.2 (4.4)
Pulse rate (bpm), mean (SD)	77.1 (7.6)
Respiratory rate (breaths/min), mean (SD)	16.1 (2.2)
Temperature (°F), mean (SD)	96.4 (2.4)
Systolic BP (mmHg), mean (SD)	
Supine	127.3 (13.1)
Sitting	125.9 (12.3)
Diastolic BP (mmHg), mean (SD)	
Supine	81.6 (8.3)
Sitting	81.0 (8.0)
Personal history	
History of alcohol	
Current	9 (3.5)
Former	1 (0.4)
Never	249 (96.1)
History of smoking	
Current	5 (1.9)
Former	1 (0.4)
Never	253 (97.7)
History of tobacco	
Current	1 (0.4)
Former	1 (0.4)
Never	257 (99.2)
Medical history	
Endocrine and metabolic	34 (13.13)
Cardiovascular	25 (9.65)

Demographics and baseline characteristics

Table 1 shows the baseline and demographic summary of the study participants. The majority of patients were female 187 (72.2%); the mean (SD) age of the study population was 42.2 (10.7) years; median (range), 42.0 (18.0-65.0) years and mean (SD) body mass index (BMI) was 26.2 (4.4) kg/m^2 median (range), 25.0 (14.6-42.0) kg/m^2. Vital signs, including pulse rate, respiratory rate, temperature, and blood pressure, were also recorded at baseline. Mean (SD) systolic blood pressure (SBP) in the supine position was 127.3 (13.1) mmHg and that in the sitting position was 125.9 (12.3) mmHg. Mean (SD) diastolic blood pressure (DBP) in the supine position was 81.6 (8.3) mmHg and that in the sitting position was 81.0 (8.0) mmHg. The mean (SD) pulse rate was 77.1 (7.6) bpm, the mean (SD) respiratory rate was 16.1 (2.2) breaths/min, and the mean (SD) temperature was 96.4

(2.4)°F. Data on personal history was collected in terms of alcohol consumption, smoking, and tobacco usage. Among the entire population assessed, 96.1% had never consumed alcohol, 97.7% had never smoked, and 99.2% had never used tobacco or other substances. Current users of the same were 3.5%, 1.9%, and 0.4%, respectively. In all, 0.4% of the participants had a previous history of smoking and tobacco/substance use. In addition, the medical history of the study participants was documented. We found 34 (13.1%) of them with endocrine and metabolic disorders and 25 (9.7%) with cardiovascular disorders.

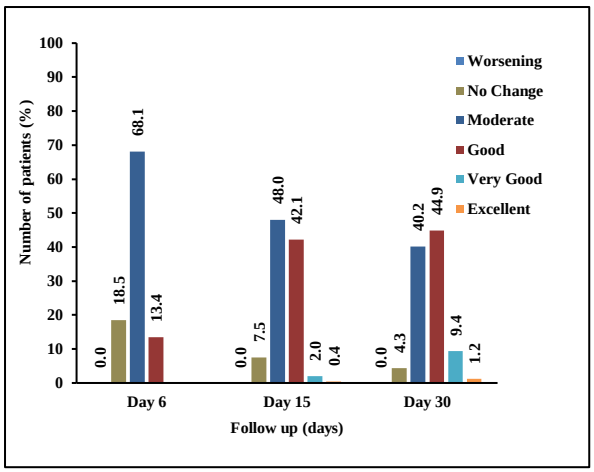

Figure 2: Clinical response based on changes in SVVLCRE score at different time points.

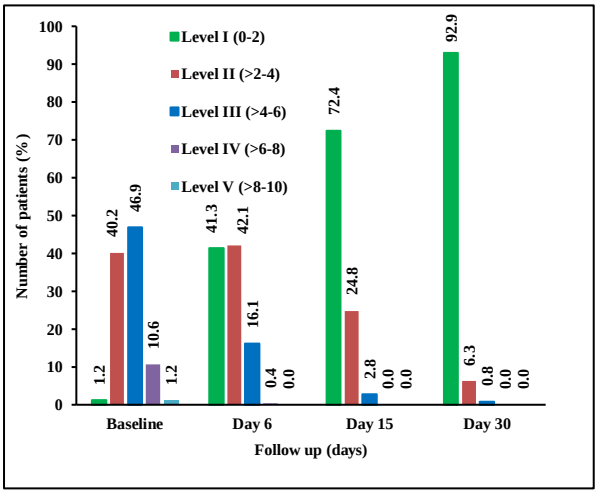

Figure 3: Changes in symptom severity level at different time points.

Effectiveness of prochlorperazine

Clinical response was assessed using the SVVSLCRE score, which demonstrated varying degrees of improvement in patients with VM. On day 6, 0.4% of patients exhibited an excellent clinical response and this proportion increased to 1.2% on day 30. A very good clinical response was observed in 2% of patients on day 15, and this proportion increased to 9.4% on day 30. A good clinical response was observed in 13.4% of patients on day 6, 42.1% on day 15, and 44.9% on day 30. Following, on day 6, 68.1% of patients experienced a moderate reduction in VM symptoms. This proportion decreased to 48.0% on day 15 and further to 40.2% on day 30. At the beginning of the observation period, on day 6, 18.5% of patients showed no change in their VM symptoms. This proportion decreased to 7.5% on day 15 and further to 4.3% on day 30 (Figure 2).

The severity of vestibular vertigo symptoms was graded using the SVVSLCRE. At baseline, 10.6% and 1.2% of patients experienced symptoms of severity level IV and level V, respectively; these proportions subsequently decreased to 0.4% and 0% on day 6; on days 15 and 30, none of the patients had level IV and level V symptoms. Moreover, shifting of patients predominantly to level 1 provided evidence that prompt intervention within the study population facilitated the resolution of milder symptoms in a relatively short time frame (Figure 3). Significant differences were observed between mean symptom scores at baseline and the follow-up periods, i.e., days 6, 15, and 30 ($p<0.001$), indicating that prochlorperazine was effective in reducing mean symptom scores at different time intervals (Table 2).

Table 2: Difference in mean change from baseline to follow-up periods (n=254).

Symptom severity score	Change from baseline; mean (SD)	95% CI of mean difference	P value*
Day 6	2.0 (1.1)	1.9-2.2	<0.001
Day 15	3.0 (1.3)	2.9-3.2	<0.001
Day 30	3.8 (1.5)	3.6-4.0	<0.001

*Paired sample t-test.

Table 3: Summary of adverse events (n=259).

Characteristic	Day 6 N (%), E	Day 15 N (%), E	Day 30 N (%), E
Any adverse event	9 (3.1), 9	1 (0.8), 2	0 (0), 0
Headache	1 (0.4)	1 (0.4)	0 (0)
Nausea	1 (0.4)	0 (0)	0 (0)
Pain and swelling	1 (0.4)	0 (0)	0 (0)
Itchy and red skin rash	1 (0.4)	0 (0)	0 (0)
Tingling of the hands or feet	1 (0.4)	0 (0)	0 (0)
Acidity	1 (0.4)	0 (0)	0 (0)
Runny nose	1 (0.4)	0 (0)	0 (0)
Heartburn	1 (0.4)	0 (0)	0 (0)
Muscle spasm/pain	1 (0.4)	0 (0)	0 (0)
Ear infection	0 (0)	1 (0.4)	0 (0)

E, event

Safety and tolerability of prochlorperazine

The criterion for the safety evaluation was the overall incidence of drug-related adverse events. The safety analysis was carried out on all patients at all follow-up visits, i.e., day 6, day 15, and day 30. A total of 11 adverse events were reported by 10 (3.9%) patients throughout the study. On day 6, a total of nine adverse events were reported by 9 patients (3.5%), including headache, nausea, pain and swelling, skin rash with itching, tingling of the hands or feet, acidity, runny nose, heartburn, muscle spasm/pain and ear infection. On day 15, only two adverse events were reported; one case of recurrent headache, and one of ear infection. All these events were assessed as non-serious, mild in severity, and not related to the study drug. They were resolved with appropriate treatment (Table 3). Patients and investigators reported similar tolerability for prochlorperazine. Excellent tolerability was reported by an increasing number of patients and by investigators for an increasing number of patients from day 6 to day 15, and day 30 (Table 4).

Table 4: Global tolerability assessment as reported by patients and investigators (n=254).

Response	Excellent N (%)	Good N (%)	Moderate N (%)
Patient assessment			
Day 6	118 (46.5)	133 (52.4)	3 (1.2)
Day 15	167 (65.7)	87 (34.3)	0
Day 30	181 (71.3)	73 (28.7)	0
Investigator assessment			
Day 6	118 (46.5)	133 (52.4)	3 (1.2)
Day 15	167 (65.7)	87 (34.3)	0
Day 30	180 (70.9)	74 (29.1)	0

DISCUSSION

The current study was designed to evaluate the effectiveness and safety of prochlorperazine in Indian patients with VM. Of 259 enrolled patients, 254 (98.1%) completed the study. We found that prochlorperazine was effective from baseline to the end of treatment (day 30/week 4) with a significant improvement in clinical response and a reduction in symptoms as measured by SVVSLCRE.

In a prospective, multicenter, single-arm study by Haldipur et al 5 mg of prochlorperazine given three times daily to 500 patients with dizziness resulted in a significant decrease in the episodes of dizziness from baseline to end of week 1. Moreover, significant improvements in nausea, vomiting, and headache were reported.[18] Prochlorperazine (100%) was found to be more effective than cinnarizine (97.14%) in a comparative study comprising 133 Indian patients treated with vertigo.[19] Our findings were similar to those of the study conducted by Kameswaran et al where the authors assessed the effectiveness and safety of prochlorperazine in patients experiencing acute vertigo. The improvement of clinical response from baseline to day 15, and day 30 in our study involving patients with VM was similar to that of 1716 patients with acute vertigo in the study by Kameswaran et al where significant changes in clinical response (91.9%) were observed at day 6 ($p<0.0001$) using SVVSLCRE.[20] Dizziness accompanied by nausea and vomiting is a common presentation in vestibular disorders that can cause disability.[21] Prochlorperazine is a safe and effective treatment for vertiginous disorders associated with nausea, vomiting, and dizziness.[20] Approximately 50% of patients experienced nausea and vomiting; prochlorperazine, when used as an antinausea and antiemetic supplement, significantly reduced the recurrence of both these symptoms during the first week of treatment thereby improving patient satisfaction ($p<0.001$).[22] In line with these reports, the current results confirmed the effectiveness of prochlorperazine in reducing symptoms associated with VM such as faintness, headache, hearing loss, nausea, vomiting, and tinnitus.

Kameswaran et al demonstrated that both the oral and intramuscular formulations of prochlorperazine were effective and well-tolerated, with good safety profiles and no extrapyramidal symptoms.[20] In the study by Haldipur et al only 3 adverse drug reactions, namely, headache, asthenia, and somnolence were reported with prochlorperazine use; all of these reactions were minor in severity and resolved with appropriate treatment.[18] Consistent with these previous reports, the current study found good tolerability and an acceptable safety profile of prochlorperazine. Moreover, no serious adverse events were reported in the entire study. Our study has several strengths. It was conducted across five centers in India, providing a representation of effectiveness across various geographical locations in India and diverse age groups. However, the study also has some limitations, including an open-label design, the absence of a control group, a lack of randomization, and a modest sample size. Therefore, further well-designed, comparative studies with a large sample size will be beneficial in this regard.

CONCLUSION

Prochlorperazine was found to be an effective and safe drug in VM. The positive effect of prochlorperazine may be attributed to its ability to block dopamine receptors in the brain, leading to its antiemetic and vestibular-suppressing properties. Further, prochlorperazine caused a significant reduction in symptom severity from baseline to the end of the treatment. In addition, prochlorperazine exhibited good tolerability according to patients and investigators. Out of the limited available options for VM, prochlorperazine seems to be a promising option.

ACKNOWLEDGEMENTS

The authors would like to thank Alpha MD Pvt. Ltd. for providing writing support.

Funding: Abbott Healthcare Pvt. Ltd.
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Ilambarathi M, Yeolekar A, Roy D, Saxena S, Kumar S. A prospective, multicenter study to evaluate the effectiveness and safety of prochlorperazine in patients suffering from vestibular migraine. Int J Otorhinolaryngol Head Neck Surg 2024;10:258-64.