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Clinicoetiological pattern and pharmacotherapy practices in patients with new onset vertigo: findings from a prospective multicenter registry in India

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ABSTRACT

Background: The objective was to evaluate the clinicoetiological pattern and pharmacotherapy practices of new onset vertigo in India.
Methods: This multicentre, prospective, registry was conducted in adult patients across 37 centres. Enrolled patients were followed at week 1, month 1 and 3 to assess clinicoetiological characteristics, prescribed pharmacotherapy, safety and effectiveness of treatment.
Results: Of the 1520 patients enrolled, 1428 (93.95%) completed the study. The mean (SD) age was 50.2 (±15.37) years and 53.2% were women. Of 202 patients reporting co-morbidities, 55.4% had cardiovascular disease and 38.6% had diabetes mellitus. Peripheral causes were predominant in majority (74.3%); benign paroxysmal positional vertigo (BPPV) being the most frequent (67.58%). Migraine affected 68.9% (80/116) patients, .as the central cause. Betahistine (74.6%) and prochlorperazine (21.75%) were the top two drugs of choice irrespective of origin, preferred by all treating specialists. Both the drugs significantly prevented recurrence by week 1 (prochlorperazine: 76.6%; betahistine: 64.2%) ($p<0.001$) and over 3 months. A lower daily dose of betahistine (15.6±5.26 mg) was preferred. Almost half complained of nausea and vomiting; prochlorperazine significantly reduced recurrence of both within a week ($p<0.001$). The treatments were well-tolerated with no reported adverse drug reactions.
Conclusions: The study demonstrates vestibular vertigo, BPPV to be the dominant type in Indian patients with new onset vertigo. Betahistine and prochlorperazine top the physicians' preference list, with equal benefits in preventing recurrence. Prochlorperazine has an additional antinausea and antiemetic property, thereby may improve patient satisfaction. Prescription of a lower dose of betahistine calls for the need to sensitize physicians.

Keywords: Betahistine, Prochlorperazine, Registry, Vertigo, BPPV

INTRODUCTION

Vertigo refers to erroneous perception of movement of either one's own body, such as swaying or rotation, or of the surrounding, or both, and is often characterized by dizziness.[1-3] Secondary symptoms include postural instability, cold sweating, nausea, and vomiting.[4] Vertigo is among the most common reasons for a physician visit, with estimated lifetime prevalence between 20% and 30%.[5-7] An epidemiological study in France reported a considerably higher 1 year prevalence of 48.3%.[8] Healthcare burden of vertigo is enormous with relative under-reporting because of its nature and unpredictability of attacks.[4]

Vertigo has a multicausative etiology; the most common cause is vestibular disorders - benign paroxysmal positional vertigo (BPPV), Ménière's disease (MD), vestibular neuritis (VN), labyrinthitis, migraine and cervical migraine and anxiety disorders.[2,9] Peripheral vestibular diseases were reported to constitute a majority of the self-reported cases of vertigo during a 10-year period in Africa.[10] BPPV was the most common cause of vertigo reported in India.[11]

Patients are affected differently depending on the underlying cause. In BPPV, vertigo is of sudden onset, lasts for approximately 1 min and is typically induced by changes of the head or body position. However, attacks can last up to several hours in MD.[11] Vertigo becomes more prevalent with increasing age and the reported frequency is higher in women.[12-15] The subjective nature of vertigo demands clinicians to follow a multi-dimensional approach to management including attention to detailed history, vestibular assessment using otolaryngological diagnostics, and treatment algorithms.[3] With a fluctuating episodic pattern of symptoms, vertigo treatment aims to minimize or eliminate the number and severity of acute attacks, reduce tinnitus, and prevent impaired vestibular functions. Medications useful in treatment and prophylaxis include anticholinergics, antihistamines, benzodiazepines, calcium channel antagonists, dopamine receptor antagonists and H1 agonists.[1,16] The usage pattern and long-term effectiveness of these antivertigo drugs have not been widely reported in routine clinical settings. The unavailability of information on treatment effects on vertigo elucidated the need for such a large registry of new onset vertigo patients in India.

This study was conducted to determine the prevalent causes, clinical presentation, and management of vertigo, a relatively common condition in India. The study also reports pharmacotherapy practices as per etiological patterns and disease characteristics along with its safety and effectiveness.

METHODS

Study population

Men and women aged ≥18 years, diagnosed with new onset vertigo of known or unknown origin, were enrolled. Pregnant or lactating women, treatment-experienced patients, and individuals requiring hospitalization for any cause were excluded.

Study design

This was a multicenter, prospective, noninterventional, observational registry (CTRI/2016/01/006500) of patients with newly diagnosed vertigo, recruited at 37 centers (17 ENTs, 10 neurologists, and 10 consulting physicians between June-2015 and May-2016.

After obtaining approval from an independent ethics committee, the study was conducted in compliance with the protocol, the Declaration of Helsinki (2000), International Conference on Harmonization-Good Clinical Practice guidelines, Indian Council of Medical Research ethical guidelines for biomedical research on human participants, amended Schedule Y, and other applicable regulatory guidelines. A written informed authorization was obtained from all the patients for voluntary participation. Study related information was recorded on the case report forms. At baseline, following data were collected: demography, history of vertigo with clinical presentation (including episodes and recurrence), co-morbid conditions, clinical diagnostics, physical examination findings, anti-vertigo treatment prescribed and concomitant medications. Patients were asked to attend a total of 3 follow-up visits for assessment of response to the prescribed anti-vertigo treatment at around week 1 and around months 1 and 3. During these clinic visits, data pertaining to effectiveness of the anti-vertigo treatment (prevention of recurrences) were recorded along with treatment change, if any. All patients were advised to visit the center anytime apart from the recommended visits for any health-related issues or adverse drug reactions (ADRs).

Study endpoints

Endpoints included clinico-etiological characteristics, preferred anti-vertigo treatment per the cause, and frequency of recurrence of symptoms from base-line. Reports of ADRs were accrued from the safety population.

Statistical analysis

All statistical analyses were performed using SAS® version 9.4 (SAS Institute Inc., Cary, NC, USA). Demographics and baseline characteristics, including patient's medical history, clinical presentation, causes of vertigo, and treatment prescribed, are summarized descriptively in terms of the number of patients (n), mean, standard deviation for continuous parameters, and count (n) and percentage (%) for categorical variables. Recurrence of vertigo at follow-up visits was analyzed for its association with cause and anti-vertigo treatment received, using chi-square or Fischer exact test at 5% level of significance.

RESULTS

Patient disposition

A total of 1520 patients were enrolled, of which 1428 (93.9%) patients completed the study (considered per protocol population); all 1520 were included in the intention to treat analysis. The most common reason for study discontinuation was loss to follow-up (4.21%) (Figure 1).

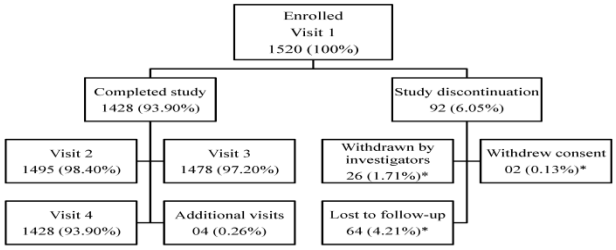


Figure 1: Patient disposition.

N: number of patients. *% out of N=1520.

Demographic and clinical profile

Table 1 summarizes the demographic and clinical characteristics of patients with mean age of 50.2 (±15.37) years. Nearly half (753, 49.5%) of the patients were aged over 51 years with numerically higher number of women (808, 53.2%). Of 202 (13.3%) patients with history of at least one significant medical condition, 112 (55.45%) patients reported cardio-vascular disease (CVD), with hypertension in 99 (88.4%) patients and dyslipidemia in 9 (8.04%) patients. Diabetes mellitus (DM) was the second most frequently reported co-morbidity, which was reported in about 78 (38.6%) patients.

Peripheral causes of vertigo were predominant in majority (1129, 74.3%) of the patients: BPPV (763, 67.58%), labyrinthitis (177, 15.68%), VN (91, 8.06%) and MD (56, 4.96%). Of 116 (7.63%) patients with central vertigo, migraine (80, 68.97%) was the most common cause.

Table 1: Demographic and clinical characteristics.

Variable	All patients (N =1520)
Age (years)	
Mean (SD)	50.2 (15.37)
Median (min, max)	50.0 (18, 88)
Age groups, n (%)	
≤30 years	191 (12.6)
31-40 years	268 (17.6)
41-50 years	308 (20.3)
≥51 years	753 (49.5)
Sex, n (%)	
Male	712 (46.8)
Female	808 (53.2)
Medical conditions	
At least 1 medical condition n (%)	**(N =202)**
Cardiovascular disease	112 (55.45)
Diabetes mellitus	78 (38.61)
Neurological disorder	15 (7.43)
Hormonal dysfunction	12 (5.94)
History of recent infections	7 (3.47)
Head and neck trauma	2 (0.99)
Psychological disorder	1 (0.50)
Other medical history	14 (6.93)
Causes of vertigo	**Total (N =1520)**
Peripheral causes, n (%)	1129 (74.3)
Benign paroxysmal positional vertigo	763 (67.58)
Labyrinthitis	177 (15.68)
Vestibular neuritis	91 (8.06)
Meniere's disease	56 (4.96)
Other	55 (4.87)
Central causes, n (%)	116 (7.63)
Migraine	80 (68.97)
Cerebrovascular disease	25 (21.55)
Multiple sclerosis	5 (4.31)
Other	6 (5.17)
Other causes, n (%)	275 (18.1)

Other (anxiety, anemia, and cervical spondylitis)	241 (87.64)	
Idiopathic causes	34 (12.36)	
Clinical features and frequency	**n (%)**	**Daily mean frequency (SD)**
Feel like spinning or turning right side	478 (31.4)	5.1 (11.06)
Feel like spinning or turning left side	245 (16.1)	5.4 (13.13)
Loss of balance or feel like falling on right side.	492 (32.4)	4.4 (8.76)
Loss of balance or feel like falling on left side	142 (9.34)	5.1 (11.20)
Loss of balance or feel like falling forward	161 (10.6)	3.6 (10.41)
Loss of balance or feel like falling backward	79 (5.20)	5.3 (10.33)
Blackouts	137 (9.01)	1.7 (1.52)
Feel lightheaded	292 (19.2)	4.3 (7.53)
Uncertainty	255 (16.8)	4.3 (4.10)
Feel like swaying	330 (21.7)	4.6 (8.15)
Ringing, buzzing, or stuffy feeling in ear(s) during an attack	87 (5.72)	3.5 (4.44)
Feel like going to faint or unconsciousness	44 (2.89)	4.3 (4.11)
Others	25 (1.64)	-

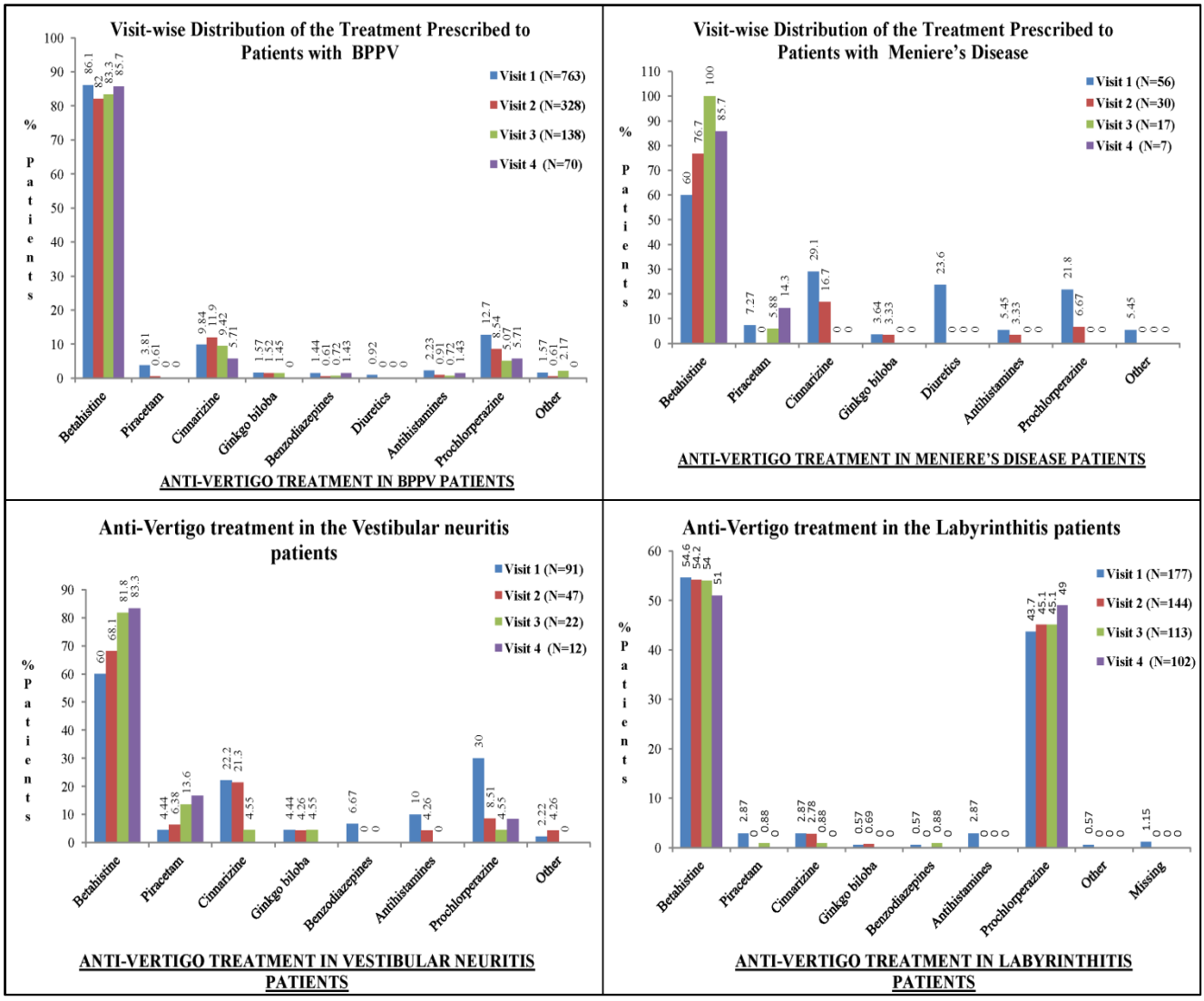
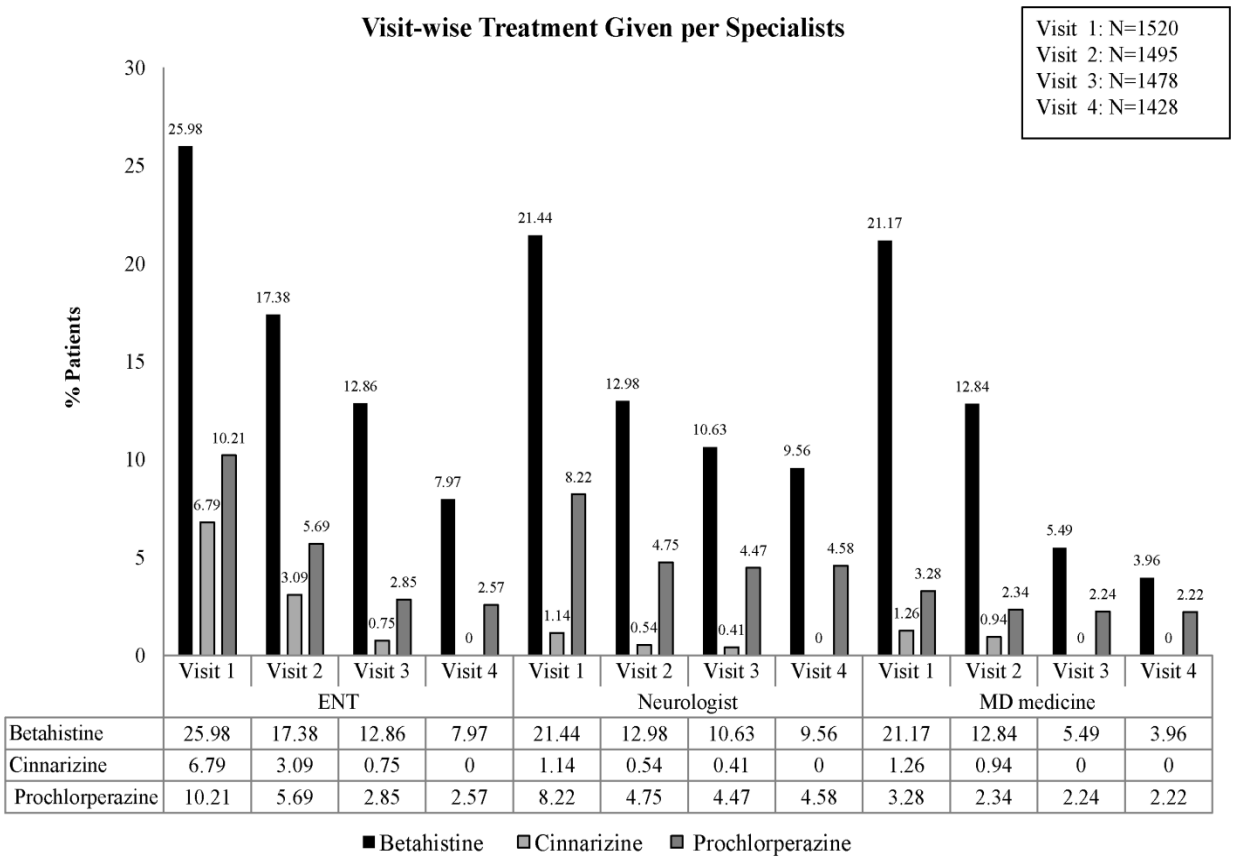


Figure 2: Treatment prescribed for peripheral causes of vertigo per study visits.

N: number of patients



	ENT				Neurologist				MD medicine			
	Visit 1	Visit 2	Visit 3	Visit 4	Visit 1	Visit 2	Visit 3	Visit 4	Visit 1	Visit 2	Visit 3	Visit 4
Betahistine	25.98	17.38	12.86	7.97	21.44	12.98	10.63	9.56	21.17	12.84	5.49	3.96
Cinnarizine	6.79	3.09	0.75	0	1.14	0.54	0.41	0	1.26	0.94	0	0
Prochlorperazine	10.21	5.69	2.85	2.57	8.22	4.75	4.47	4.58	3.28	2.34	2.24	2.22

Figure 3: Treatment prescribed by specialists at different visits.

ENT: Ear-Nose-Throat; MD: Doctor of Medicine; N: number of patients. % out of total N for the visit.

Two-thirds of the patients presented with either "feeling like falling on right side" and/or "feeling like spinning or turning right side" as the 2 most common vertigo symptoms (492, 32.4% and 478, 31.4%, respectively). The mean daily frequency of episodes was ~5 episodes for the most frequently reported symptoms as shown in Table 1. "Loss of balance or feeling like falling forward" was more often reported in women (p=0.0058). Of 934 (61.4%) patients reporting triggering factors for vertigo onset (a sudden specific action), the 2 most frequent triggers were "sudden turning of the head" (786, 51.7%) and "standing up" (502, 33.0%) (data not shown).

Anti-vertigo treatment prescribed

Betahistine (1134, 74.6%) and prochlorperazine (330, 21.75%) were the 2 most frequently prescribed drugs irrespective of the origin (peripheral, central or idiopathic). Cinnarizine was prescribed in about 9.14% of patients. The mean daily dose and frequency for betahistine were 15.6 (±5.26) mg and 2.2 (±0.69); for prochlorperazine were 6.5 (±5.00) mg and 1.9 (±0.76) mg respectively. Betahistine was the preferred drug for treatment initiation followed by prochlorperazine in BPPV (86.1%; 12.7%), MD (60%; 21.8%), and VN (60%; 30%). In labyrinthitis, betahistine and prochlorperazine were prescribed equally (54.6% vs. 43.7%). Irrespective of the peripheral cause, the number of patients requiring treatment with betahistine or prochlorperazine reduced considerably month-on-month. (Table 2 and Figure 2). The prescription practices were similar across all specialists, preferring betahistine and prochlorperazine as the top 2 drugs of choice (Figure 3). There were no reported changes in the prescription pattern at subsequent follow-up visits.

Effectiveness outcomes

Symptom reduction and recurrence

Percentage changes (reductions) in each symptom are shown in Figure 4 (comparison at each visit versus baseline). Both betahistine and prochlorperazine showed significant benefits in preventing a recurrence of all symptoms at subsequent visits from baseline (p<0.001) (Table 3). The mean improvements in all symptoms were numerically larger in the first month with gradual and consistent reductions until month 3. Prochlorperazine prevented recurrence in 73% (241/330) of patients at week 1. Betahistine also showed a significant improvement (no recurrence) in all symptoms within 1 week of treatment in 62.9% (713/1134) patients (p<0.001). A further statistically significant symptom

reduction occurred at month 1 with only 2 patients reporting recurrence (p<0.001). However, higher recurrence was reported in patients on cinnarizine, 42.4% (59/139) compared with prochlorperazine and betahistine.

The overall reductions in each symptom were consistent in men and women and across the diagnostic categories of peripheral causes including BPPV, labyrinthitis, VN, and MD (data not shown). Symptoms with the highest mean daily frequencies of ~5 episodes reduced to ~3 episodes per day by week 1. Symptoms of feeling like falling backward, blackouts, feeling like swaying, uncertainty, and stuffy feeling in the ear got resolved completely at month 3 (Figure 5).

Table 2: Summary of antivertigo treatment at different visits.

Antivertigo treatment		Visit 1 (N=1520)	Visit 2 (N=1495)	Visit 3 (N=1478)	Visit 4 (N=1428)
Betahistine	n (%)	1134 (74.6)	646 (43.2)	428 (28.96)	310 (21.47)
	Dose (mg) mean (SD)	15.6 (5.26)	14.5 (4.39)	14.5 (3.75)	15.5 (2.76)
	Daily frequency mean (SD)	2.2 (0.69)	1.9 (0.82)	2.1 (0.51)	2.7 (0.54)
	Duration in days mean (SD)	23.3 (31.09)	46.5(38.58)	76.5 (29.40)	88.8 (9.94)
Prochlorperazine	n (%)	330 (21.71)	191 (12.78)	141 (9.54)	135 (9.45)
	Dose (mg) mean (SD)	6.5 (5.00)	6.0 (4.26)	5.2 (1.75)	5.1 (0.44)
	Daily frequency mean (SD)	1.9 (0.76)	1.2 (0.45)	2.0 (0.29)	2.9 (0.29)
	Duration in days mean (SD)	38.3 (39.44)	75.9 (29.85)	87.7 (13.11)	90.0 (0.00)
Cinnarizine	n (%)	139 (9.14)	68 (4.55)	17 (1.15)	4.0 (0.28)
	Dose (mg) mean (SD)	26.3 (11.75)	24.3(7.10)	21.9 (4.48)	15.0 (0.00)
	Daily frequency mean (SD)	2.3 (0.59)	2.0(0.53)	2.0 (0.35)	2.0 (0.00)
	Duration in days mean (SD)	8.6 (6.01)	18.8 (5.63)	20.0 (14.14)	0

n: number of patients in a given category; N: number of patients in a specific main category; SD: standard deviation

Table 3: Summary of recurrence of vertigo by treatment at different visits.

Treatment prescribed	Visit 1 (N =1520)	Recurrence at visit 2, n (%)	Visit 2 (N =1495)	Recurrence at visit 3, n (%)	Visit 3 (N =1448)	Recurrence at visit 4, n (%)
Prochlorperazine	330	78 (23.6)*	191	1 (0.52)*	141	0 (0.0)
Ginkgo biloba	22	7 (31.8)	9	0 (0.0)	3	0 (0.0)
Betahistine	1134	408 (36.0)*	646	2 (0.31)*	428	0 (0.0)
Antihistamines	49	19 (38.8)	9	0 (0.0)	2	0 (0.0)
Benzodiazepines	20	8 (40.0)	3	0 (0.0)	2	0 (0.0)
Piracetam	51	21 (41.2)	7	0 (0.0)	5	0 (0.0)
Cinnarizine	139	59 (42.4)	68	0 (0.0)	17	0 (0.0)
Diuretics	20	11 (55.0)	0	0 (0.0)	0	0 (0.0)
Other	33	11 (33.3)	6	0 (0.0)	3	0 (0.0)

n: number of patients in a given category; N: number of patients in a specific main category; Percentage (%) represents row percentage; Statistically significant (p<0.001).

Other associated symptoms and treatment

At baseline, 764 (50.3%) and 299 (19.7%) patients reported nausea and vomiting, respectively. Prochlorperazine was the preferred drug in 201 (13.2%) patients with nausea and 114 (7.50%) patients with vomiting. Both these symptoms improved significantly within 1-week treatment with no reported recurrence of nausea and vomiting in 156/201 (77.61%) and 94/114 (82.46%) patients, respectively (p<0.001). patients with nausea and 114 (7.50%) patients with vomiting. Both these symptoms improved significantly within 1-week treatment with no reported recurrence of nausea and vomiting in 156/201 (77.61%) and 94/114 (82.46%) patients, respectively (p<0.001).

Few patients were also prescribed other medications such as rabeprazole (42), domperidone (13), pantoprazole (06), and ondansetron (07) for nausea, and 5 patients received treatment with ondansetron (2) and esomeprazole, pantoprazole, and rabeprazole (1 each) for vomiting.

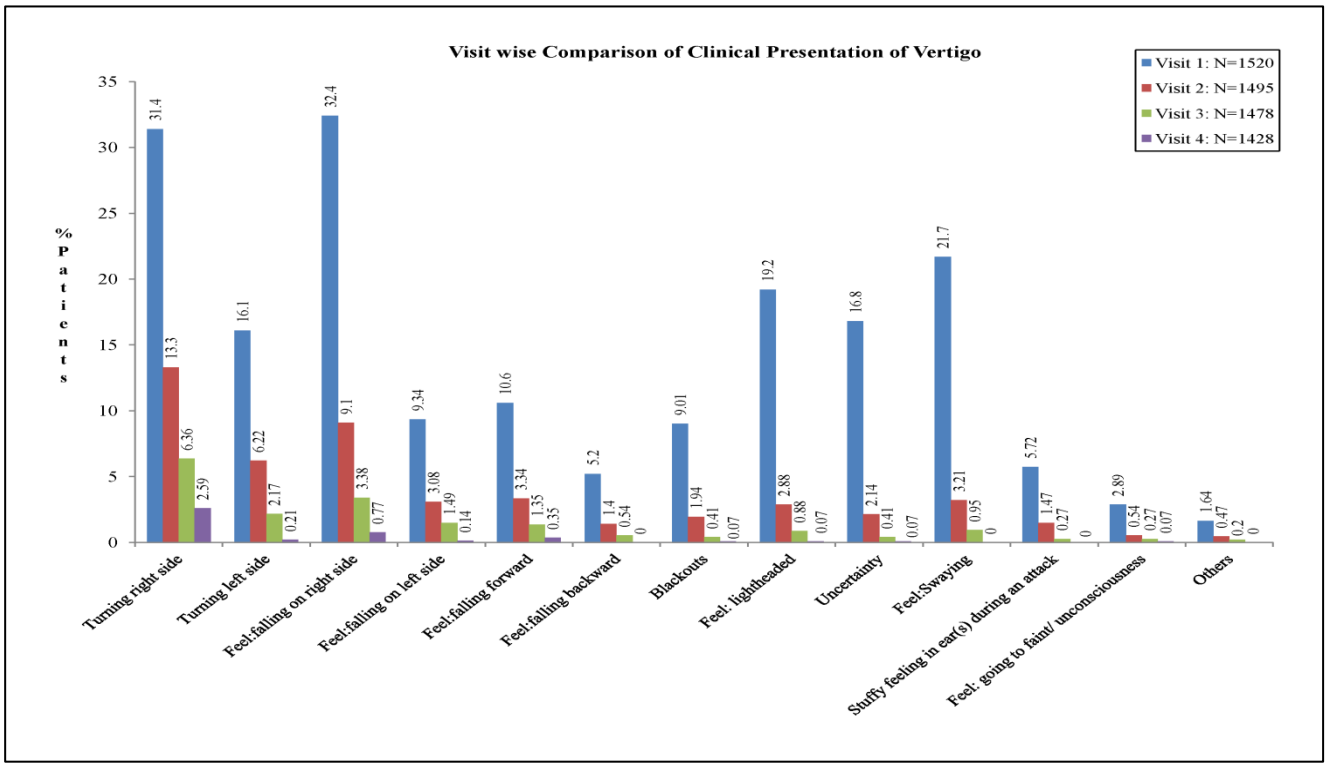


Figure 4: Visit-wise comparison of percentage of patients with each symptom.

N: number of patients.

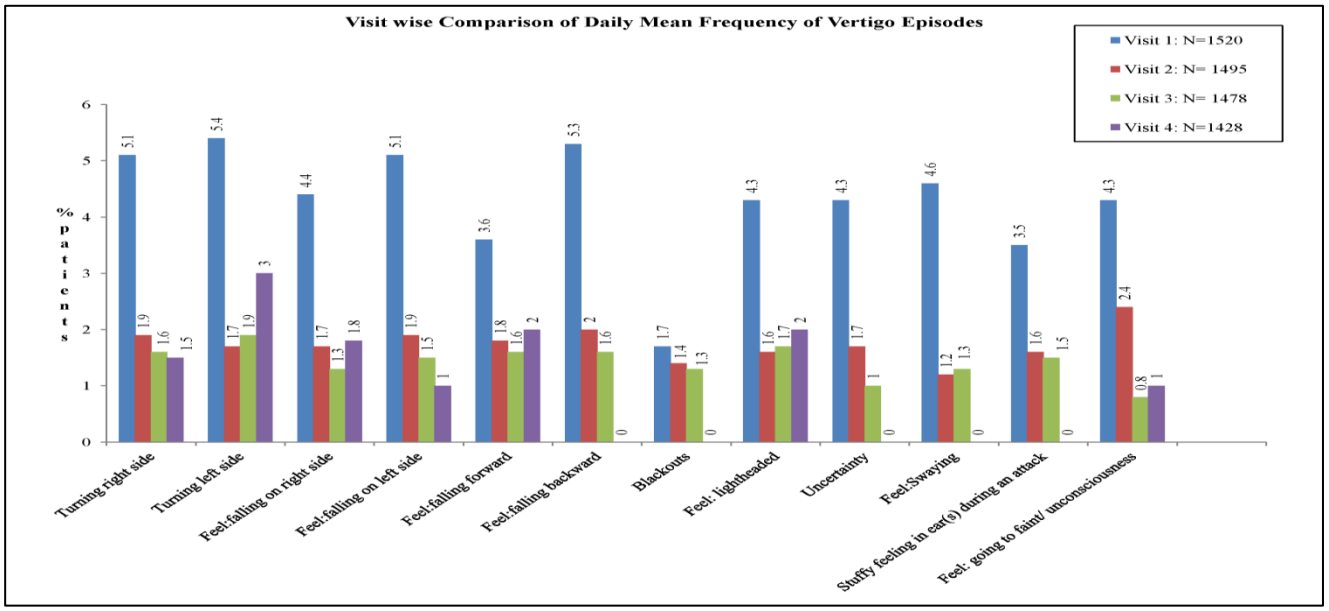


Figure 5: Visit-wise comparison of daily mean frequency of vertigo episodes.

N: number of patients.

Of 95 (6.25%) patients with migraine/headache, 29 (30.5%) were prescribed treatment; very few reported headache recurrence (2 patients at week 1 and 1 patient at month 1). Twenty patients received treatment for anxiety and the drug of choice for half of the patients was alprazolam.

Safety and tolerability

No ADRs, serious adverse events, or deaths were reported during the study.

DISCUSSION

This registry study in the Indian population with new onset vertigo demonstrates the dominance of peripheral causes in 74.3% of the population, with the BPPV variant comprising two-thirds of these cases. Migraine was the most common cause among the central causes. BPPV and migraine are reported as the 2 most common causes of vertigo globally.[17] Accurate diagnosis with quantification of vertigo of vestibular or central origin plays a key role for selecting and tailoring antivertigo management in primary care. The occurrence of vertigo is frequent in real-world settings and is associated with a substantial individual and healthcare burden.[1,18,19] Vertigo due to vestibular origin accounts for a large percentage of this burden, which necessitates optimum treatment. This large-scale pan-India registry helped to generate data regarding the entire spectrum of clinical presentation of vertigo, emphasizing importance of detailed history taking of vertigo attacks - duration and frequency of episodes at baseline and also for evaluating the effectiveness of antivertigo treatment.

About half (49.5%) of the registry patients were older, which was consistent with other studies showing increased incidence with advanced age.[13,15,20,21] Unlike earlier studies that reported women dominance, men and women were almost equally affected in this study.[21-23] More than half of the patients suffered from either CVD (55.45%) and/or DM (38.61%). The registry to evaluate the burden of disease in vertigo reported CVD in approximately 46.3% of patients and hormonal dysfunction like diabetes in 17.2%.[23]

The recommended management for vertigo includes medications, physical therapy, and psychotherapy; a few limited cases may require surgical treatment.[3] Vertigo treatment depends specifically on the etiology; however, symptomatic relief has a substantial impact especially on patient's daily activities, regardless of the etiology.[14,24] Medications prove to be most beneficial for treating acute vertigo that lasts from a few hours to several days.[25] In our registry patients, substantial improvements (in symptoms and frequency with no recurrence) were seen with both betahistine and prochlorperazine. The primary drugs of choice prescribed in the clinical care to 74.6% and 21.71% of the patients, respectively. The choice of drugs was consistent among all specialists.

Prochlorperazine demonstrated a favorable clinical outcome by week 1 in 73% of the patients ($p<0.0001$) irrespective of gender or vertigo types. Similarly, betahistine showed maximum benefit in 62.9% of the patients within the first week of treatment with no reported recurrence ($p<0.0001$); this effect remained consistent across all types of vertigo and gender. Within 3 months of treatment, feeling like falling backward, blackouts, feeling like swaying, uncertainty, and stuffy feeling in ear(s) resolved completely (Figure 4).

Over the years, the clinical efficacy and safety of betahistine has been well established.[26] A recent meta-analysis also provided robust evidence regarding the beneficial effects of betahistine in MD and vestibular vertigo.[27] Betahistine was found to be more effective in BPPV when given to patients in whom the manifestation was not noticeable for long, which is reflected in our registry patients with all types of new onset vertigo.[28] Betahistine provided accelerated symptom relief within the first month in BPPV and 3-month use also proved its overall benefit in all the causes including MD. Early betahistine pharmacotherapy with active concomitant vestibular rehabilitation is highly recommended for early recovery compared with treatment alone.[29-31] This synergistic effect could not be elicited from the study data. Although the recommended dose of betahistine in vertigo is 48 mg per day, physicians prescribed a lower daily dose of betahistine, ~16 mg (average dose: 15.6±5.26 mg) in our study. This has been reported from trials included in a recent meta-analysis with total daily dose ranging from 16 mg to 48 mg for 14 days to 3 months.[9] Use of lower dose was also safe with no reported ADRs during 3 months' period. This finding suggests a gap related to the prescribing practice of physicians not choosing the recommended dose of 48 mg/day. However, a positive effect with respect to significant prevention of vertigo recurrence was evident at this lower dose.

Prochlorperazine has a long history of being used in vertigo pharmacotherapy. Prochlorperazine was reported to be superior to cinnarizine in the treatment of vertigo irrespective of the central or peripheral vertigo, in a study conducted in Indian patients.[20] Wheatley reported drowsiness in 8% patients on cinnarizine and in only 3% receiving prochlorperazine.[32] In our registry patients, prochlorperazine provided immediate relief in BPPV and long-term benefits in MD.

Dizziness with associated nausea and vomiting is a common presentation with vestibular disorder, which can be debilitating.[33] Prochlorperazine was safe, effective, and suitable for treating dizziness associated with nausea and/or vomiting in vertiginous disorders.[34] Approximately half of the registry patients had accompanied nausea and vomiting; prochlorperazine with supplemental antinausea and antiemetic properties significantly reduced recurrence of both these symptoms in the first week of treatment initiation ($p<0.001$).[35] It should be noted that associated symptoms were reported by a large proportion of patients. This highlights the need to improve overall vertigo management practices, giving due importance to associated symptoms being reported by large number of patients, which is important for overall patient satisfaction.

Our study has a few limitations: the synergistic effect of vestibular rehabilitation and antivertigo medication could not be analyzed; a control group was absent; and formal compliance assessment and safety issues with the prescribed doses of betahistine could not be evaluated.

Regardless of the limitations, this registry collected large-scale data from physicians with a good follow-up until 3 months with only 6% dropouts. This study also highlighted that primary care physicians prefer a lower dose of betahistine than the higher recommended dose of 48 mg per day. Further awareness is required among physicians for the use of the optimal dose. However, lower dose of betahistine showed a clinically significant benefit and was safe and well tolerated. Thus, this calls for additional research to understand if the sustained effect is seen with lower doses. Prochlorperazine showed an equivalent antivertigo effect with additional benefits in terms of providing relief from nausea and vomiting, yet it was second in the order of prescription preference.

CONCLUSIONS

This registry could generate nationally representative large scale data and insight into clinical profile and effectiveness of pharmacotherapy in new onset vertigo patients in real life settings. The study demonstrates that BPPV accounts for a considerable percentage of the overall burden of vertigo. Associated with a major impact on health care, early treatment of vertigo is important in primary care. Physicians preferred betahistine and prochlorperazine to treat majority of the patients with peripheral causes of vertigo. Both betahistine and prochlorperazine showed equally beneficial effects in preventing recurrence and improved treatment outcome. With anti-emetic property, prochlorperazine has an added advantage in anti-vertigo management. Both these drugs proved to be safe and well-tolerated.

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