

Original Research Article

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## Clinicoepidemiological profile and practices to manage dizziness in primary care setting: results from an Indian registry

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### ABSTRACT

**Background:** Dizziness is a common symptom encountered in primary care settings by general physicians and specialists. This study evaluated the clinicoepidemiological profile and management practices in patients with dizziness in an Indian primary care setting.

**Methods:** This prospective, multicentric, observational study was conducted between November 2018 and June 2019. Patients aged  $\geq 18$  years presenting with clinical features of dizziness were eligible. The study data included demographics and socioeconomic details, complete medical history, medication and concomitant medication use, and the cause and pattern of dizziness. Patients had a baseline visit and two follow-up visits at weeks 1 and 4.

**Results:** Overall, 1000 patients with a mean age of 45.1 years were included (women: 51.5%; men: 48.5%). Of these, 762 reported dizziness as a primary complaint; whereas, 238 reported it as a complaint associated with nausea, vomiting and light-headedness on visit 1, which reduced on subsequent visits. Around 34% of the patients were unemployed and 59% belonged to the upper-middle class. The most common co-morbidities were hypertension and diabetes mellitus (n=132, each). More than 50% of the patients presented with vestibular cause (n=577), followed by neurologic (n=179), metabolic (n=84) and psychiatric (n=61) etiologies. Betahistine (n=581) and prochlorperazine (n=312) were the commonly prescribed medicines for primary and associated complaints. The most commonly used concomitant medications were telmisartan (n=53), glimepiride plus metformin (n=40), metformin (n=32) and ondansetron (n=29).

**Conclusions:** Dizziness has a multifactorial origin necessitating a multifactorial treatment approach. Betahistine and prochlorperazine were the most commonly prescribed drugs in the primary care setting (CTRI/2018/11/016408).

**Keywords:** Betahistine, Clinicoepidemiological, Neurologic, Otologic, Prochlorperazine

### INTRODUCTION

Dizziness is one of the common medical issues and reason for frequent clinic visits. Dizziness could be a symptom and an indication of serious conditions such as tumors or stroke.<sup>1</sup> It is conventionally classified into vertigo (middle-aged), disequilibrium (frequent in elderly), presyncope and lightheadedness (younger adults) categories based on the medical history and

clinical presentation.<sup>2</sup> Nevertheless, the recent approach of classification includes acute prolonged spontaneous, recurrent spontaneous, recurrent positional, or chronic dizziness.<sup>3</sup> The common causal factors of dizziness are benign paroxysmal positional vertigo, Meniere disease, vestibular neuritis, and labyrinthitis. Moreover, it may be associated with other diseases, including migraine, motion sickness, anxiety, depression, or it could possibly be medication-induced.

The prevalence of dizziness is greater in women and highly dependent on age.<sup>4</sup> It has a deleterious effect on the quality of life of an individual. Functional impairment and disability due to recurrent falls impact the patients adversely.<sup>5</sup>

Diagnosis of dizziness is tough, costly, and highly prone to misdiagnosis.<sup>6</sup> The most common snags in the traditional approach for the diagnosis of dizziness include dependence on a symptom-quality approach and computed tomography, underusage of timing and triggers, lack of understanding of physical examination findings and medical history, and age-related and vascular risk factors to screen patients. Depending on the type of dizziness, patients are either treated in primary care or referred to specialist care.<sup>7</sup> The most common diagnostic approaches are physical, cardiac and neurologic examination, evaluation of nystagmus and Dix-Hallpike maneuver. However, laboratory findings and imaging techniques are not much useful.<sup>8</sup>

Treatment of dizziness depends on the etiology, whether it is central or peripheral type. The HINTS (involves head-impulse, nystagmus, a test of skew) investigation helps to differentiate between the etiology types. Central type requires prompt intervention.<sup>8</sup> Acute attacks of dizziness are treated effectively with drug therapy including vestibular suppressants and antiemetics.<sup>9</sup> Lifestyle changes such as salt restriction, avoiding intake of alcohol and coffee, and engaging in physical exercise are recommended.<sup>10</sup>

It is imperative to study the epidemiology and management practices of dizziness in primary care settings to improve clinical decision-making and optimal treatment. Similar studies have been conducted in primary care settings in countries such as United Kingdom and Brazil to determine the management pattern of dizziness.<sup>1,11,12</sup> However, there is a paucity of methodologically robust studies on etiology, prognosis and management of dizziness in primary care settings in India.

The objectives of the present study were to determine clinic epidemiological profiles of patients presenting with dizziness including epidemiology, frequency, and distribution of dizziness and assess management practices in primary care settings across multiple geographical locations in India.

## METHODS

### Study population

Patients of either sex aged  $\geq 18$  years presenting with the clinical features of dizziness in a primary care setting were eligible to participate in the study. Pregnant and lactating women and patients with dizziness requiring hospitalization were excluded from the study. Patients with any other condition that in the opinion of the

investigator did not justify the inclusion in the study were excluded.

The study protocol was approved by Independent ethics committee (IEC) or institutional review board (IRB) of the respective sites. Study principles were followed as per the declaration of Helsinki and International council for harmonization-good clinical practice (ICH-GCP). Written informed consent was obtained from each patient before enrolment in the study. The study is registered on a publicly accessible database of clinical trials in India with registration number CTRI/2018/11/016408.

### Study design

This prospective, multicenter observational study was conducted at 28 sites across India between November 2018 and June 2019. The etiology of dizziness was considered as per the investigator's clinical judgment based on the clinical examination and patient interview. This study involved a baseline visit and two follow-up visits at week 1 and week 4. In case the patient did not visit the clinic, they were followed up telephonically at weeks 1 and 4. Patients were not followed up if they were referred to a specialist by the investigator or if they consulted a specialist out of their own accord (when contacted at weeks 1 or 4).

### Study outcomes

The primary endpoint of the study was to determine clinic epidemiological profile of patients with dizziness, which included socio-demographic characteristics (age, gender, lifestyle habits, occupation, and socioeconomic status), clinical characteristics (BMI, the onset of dizziness, and co-morbidity burden), the proportion of patients presenting with dizziness as a "primary complaint" or an "associated complaint" with other symptoms (nausea, vomiting, anxiety and others), clinical presentation of dizziness including the type of dizziness, frequency of dizziness, and disability score due to dizziness, and possible causes of dizziness as diagnosed by the treating primary care physician. The secondary endpoints were to determine the management practices, the proportion of patients advised with lifestyle modification, pharmacotherapy, and/or referred to specialists for further management. Furthermore, exploratory objectives included evaluation of the profile of patients being prescribed with prochlorperazine and investigation of effectiveness and safety of different drugs prescribed for dizziness in primary care.

### Statistical analysis

Considering the nature of the registry, no formal sample size calculation was employed. A total of 1000 patients were considered sufficient to arrive at conclusive findings. The data are presented using descriptive statistics. Categorical variables are presented using numbers and/or percentages, whereas continuous

variables are summarized using mean, standard deviation (SD), median, and range. There was no change in the protocol or planned analysis. All statistical analyses were performed using SAS® version 9.4 software package for Windows (SAS Institute Inc. Cary, NC, USA).

## RESULTS

A total of 1000 patients fulfilling the inclusion criteria were enrolled in the study. The mean (SD) age was 45.1 (12.9) years and the number of women (n=515) was

slightly higher than that of men (n=485). Around 34% (n=336) patients were unemployed, whereas 19% (n=191) were skilled workers. According to Kuppuswamy classification of socioeconomic status, around 60% patients were from the upper-middle class (n=591). Of the 1000 patients, 209 patients presented with various co-morbidities. Hypertension and diabetes mellitus were the most common co-morbidities followed by hyperthyroidism, hyperlipidemia, dyslipidemia, and others (including asthma, benign prostatic hyperplasia, asthma etc) (Figure 1).

**Table 1: Summary of sociodemographic and clinical characteristics of enrolled patients.**

| Parameters  | Total (n=1000) N (%) |
|---|----------------------|
| <b>Age (years), mean (SD)</b>                           | 45.1 (12.9)          |
| <b>Sex, Women</b>                                       | 515 (51.5)           |
| <b>Education</b>  |                      |
| Illiterate  | 59 (5.9)             |
| Primary (up to 8 <sup>th</sup> class)                   | 121 (12.1)           |
| Secondary (8 <sup>th</sup> -12 <sup>th</sup> )          | 344 (34.4)           |
| Graduate  | 412 (41.2)           |
| Post-graduate   | 64 (6.4)             |
| <b>Occupation</b>                                       |                      |
| Profession  | 116 (11.6)           |
| Semi-profession   | 155 (15.5)           |
| Clerical/shop owner                                     | 105 (10.5)           |
| Skilled worker  | 191 (19.1)           |
| Unskilled worker  | 97 (9.7)             |
| Unemployed  | 336 (33.6)           |
| <b>Socioeconomic status (Kuppuswamy classification)</b> |                      |
| Lower (<5)  | 8 (0.8)              |
| Upper lower (5-10)                                      | 148 (14.8)           |
| Lower middle (11-15)                                    | 131(13.1)            |
| Upper middle (16-25)                                    | 591(59.1)            |
| Upper (26-29)   | 122 (12.2)           |
| BMI (kg/m <sup>2</sup> ), mean (SD)                     | 26.2 (3.62)          |
| <b>Type of dizziness</b>                                |                      |
| Dizzy feeling   | 604 (60.4)           |
| Vertigo   | 366 (36.6)           |
| Floating  | 13 (1.3)             |
| Fainting  | 12 (1.2)             |
| Imbalance   | 5 (0.5)              |
| <b>Duration of dizziness</b>                            |                      |
| For 2-3 days  | 227 (22.7)           |
| Since last 2 weeks                                      | 461 (46.1)           |
| Up to 1 month   | 140 (14.0)           |
| Up to 6 months  | 111 (11.1)           |
| ≥ 6 months  | 61 (6.1)             |
| <b>Concomitant medication (&gt;10)</b>                  |                      |
| Telmisartan   | 53 (53.0)            |
| Glimepiride: Metformin                                  | 40 (40.0)            |
| Metformin   | 32 (32.0)            |
| Ondansetron   | 29 (29.0)            |
| Rabeprazole   | 26 (26.0)            |
| Levothyroxine   | 26 (26.0)            |
| Glimepiride   | 21 (21.0)            |

Continued.

| Parameters       | Total (n=1000) N (%) |
|------------------|----------------------|
| Olmesartan       | 15 (15.0)            |
| Paracetamol      | 15 (15.0)            |
| Amlodipine       | 15 (15.0)            |
| Insulin glargine | 12 (12.0)            |
| Atorvastatin     | 12 (12.0)            |
| Rosuvastatin     | 10 (10.0)            |

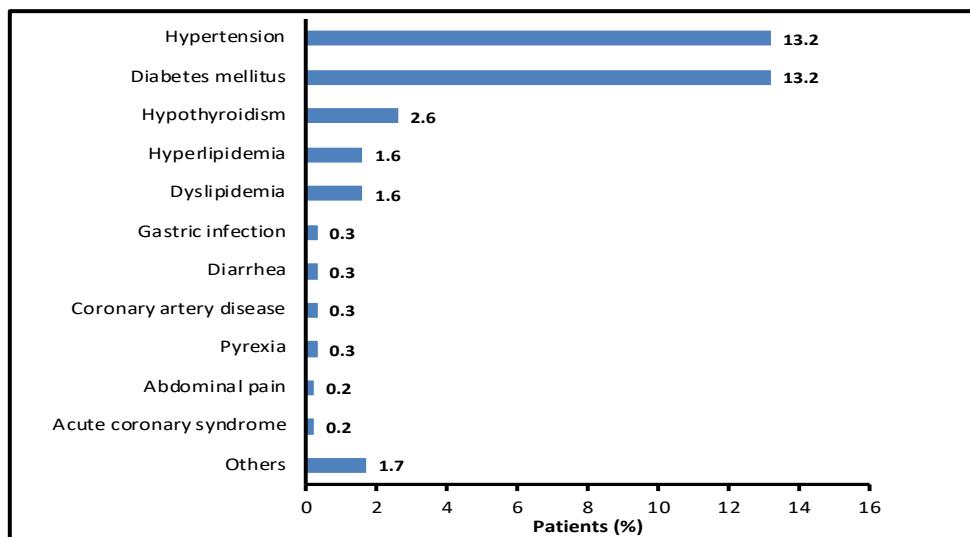


Figure 1: Co-morbidities observed in patients with dizziness.

Table 2: Patients presenting with dizziness as a primary complaint or an associated complaint.

| Parameters  | Visit 1    | Visit 2    | Visit 3    |
|---|------------|------------|------------|
|   | N (%)      | N (%)      | N (%)      |
| <b>Primary complaint</b>  | 762 (76.2) | 743 (74.3) | 734 (73.4) |
| <b>No complaint (primary)</b>   | -          | 19 (2.5)   | 9 (1.2)    |
| <b>Associated complaint</b>   | 238 (23.8) | 230 (23.0) | 230 (23.0) |
| <b>No complaint (associated)</b>                                      |            | 8 (3.4)    | -          |
| <b>Associated symptoms (frequency once-in-a week/day/hour/minute)</b> |            |            |            |
| Nausea  | 147 (61.8) | 146 (63.5) | 143 (62.2) |
| Week  | 54 (36.7)  | 82 (56.2)  | 98 (68.5)  |
| Day   | 89 (60.5)  | 64 (43.8)  | 44 (30.8)  |
| Hour  | 3 (2.0)    | -          | -          |
| Minute  | 1 (0.7)    | -          | -          |
| <b>Vomiting</b>   | 95 (39.9)  | 88 (38.3)  | 83 (36.1)  |
| Week  | 26 (27.4)  | 49 (55.7)  | 53 (63.9)  |
| Day   | 69 (72.6)  | 39 (44.3)  | 29 (34.9)  |
| <b>Anxiety</b>  | 39 (16.4)  | 35 (15.2)  | 35 (15.2)  |
| Week  | 4 (10.3)   | 17 (48.6)  | 23 (65.7)  |
| Day   | 30 (76.9)  | 18 (51.4)  | 12 (34.3)  |
| Hour  | 2 (5.1)    | -          | -          |
| Minute  | 3 (7.7)    | -          | -          |
| <b>Other</b>  | 24 (10.1)  | 20 (8.7)   | 20 (8.7)   |
| Week  | 1 (4.2)    | 4 (20.0)   | 6 (30.0)   |
| Day   | 21 (87.5)  | 16 (80.0)  | 7 (35.0)   |
| Hour  | 1 (4.2)    | -          | -          |
| Minute  | 1 (4.2)    | -          | -          |

**Table 3: Summary of clinical presentation, diagnostic test, and management.**

| Parameter                              | Visit 1<br>N (%) | Visit 2<br>N (%) | Visit 3<br>N (%) |
|--|------------------|------------------|------------------|
| <b>Frequency of dizziness</b>          |                  |                  |                  |
| 1-2 times a week                       | 143 (14.3)       | 568 (56.8)       | 675 (67.5)       |
| 3-5 times a week                       | 399 (39.9)       | 90 (9.0)         | 21 (2.1)         |
| Once a day                             | 121 (12.1)       | 76 (7.6)         | 36 (3.6)         |
| Many times, a day                      | 97 (9.7)         | 9 (0.9)          | 2 (0.2)          |
| All the time                           | 2 (0.2)          | 0                | 0                |
| <b>Vital signs, mean (SD)</b>          |                  |                  |                  |
| Pulse rate                             | 79.2 (7.9)       | 78.0 (5.5)       | 76.2 (3.9)       |
| SBP (mmHg)                             | 125.3 (8.1)      | 123.6 (5.9)      | 122.5 (5.1)      |
| DBP (mmHg)                             | 83.0 (5.9)       | 82.1 (4.3)       | 82.4 (4.2)       |
| Temperature (c)                        | 37.0 (0.2)       | 36.9 (0.2)       | 37.0 (0.3)       |
| Respiratory rate (breaths/min)         | 16.7 (2.3)       | 17.0 (2.6)       | 16.9 (1.8)       |
| <b>Diagnostic test</b>                 |                  |                  |                  |
| Dix-Hallpike test                      | [n=83]           | [n=48]           | [n=46]           |
| Negative/normal                        | 79 (7.9)         | 48 (4.8)         | 46 (4.6)         |
| Positive/abnormal                      | 4 (0.4)          | 0 (0.0)          | 0 (0.0)          |
| Romberg's test (negative/normal)       | [n=93] 93 (9.3)  | [n=72] 72 (7.2)  | [n=49] 49 (4.9)  |
| Cardiac testing (negative/normal)      | [n=3] 3 (0.3)    | [n=2] 2 (0.2)    | [n=2] 2 (0.2)    |
| Audiometry (positive/abnormal)         | 1 (0.1)          | 0 (0.0)          | 0                |
| EEG (negative/normal)                  | 0                | 1 (0.1)          | 0                |
| <b>Therapy of management</b>           |                  |                  |                  |
| Pharmacotherapy                        | 915 (91.5)       | 700 (70.0)       | 415 (41.5)       |
| Non-pharmacotherapy                    | 85 (8.5)         | 300 (30.0)       | 585 (58.5)       |
| <b>Pharmacotherapy</b>                 |                  |                  |                  |
| Prochlorperazine                       | 312 (34.1)       | 209 (29.9)       | 119 (28.7)       |
| Bethistine                             | 581 (63.5)       | 476 (68.0)       | 280 (67.5)       |
| Cinnarizine Dimenhydrinate             | 57 (6.2)         | 36 (5.1)         | 32 (7.7)         |
| Other                                  | 4 (0.4)          | 1 (0.1)          | 0                |
| <b>Non-pharmacotherapy</b>             |                  |                  |                  |
| Lifestyle modification                 | 79 (92.9)        | 264 (88.0)       | 517 (88.4)       |
| Referral to specialist                 | 1 (1.2)          | 0                | 0                |
| Advanced assessment                    | 0                | 0                | 1 (0.2)          |
| <b>Others</b>                          |                  |                  |                  |
| Physiotherapy                          | 1 (20.0)         | 27 (75.0)        | 38 (56.7)        |
| Advised to follow same                 | 0                | 5 (13.9)         | 14 (20.9)        |
| <b>Life modification</b>               |                  |                  |                  |
| Prochlorperazine stopped               | 0                | 2 (5.6)          | 12 (17.9)        |
| Advised to continue metoprolol therapy | 0                | 1 (2.8)          | 1 (1.5)          |
| Diet                                   | 1 (20.0)         | 1 (2.8)          | 1 (1.5)          |
| Exercise                               | 1 (20.0)         | 0                | 0                |
| Repaglinide stopped                    | 1 (20.0)         | 0                | 0                |
| Rizatriptan stopped                    | 0                | 0                | 1 (1.5)          |
| Ramipril stopped                       | 1 (20.0)         | 0                | 0                |

Unless otherwise specified. DBP, diastolic blood pressure; SBP, systolic blood pressure; EEG, electroencephalogram.

Dizzy feeling was the most predominant type of dizziness symptom reported by 60.4% patients, followed by vertigo (36.6%), floating (1.3%), fainting (1.2%), and imbalance (0.5%). Nearly 46% patients reported dizziness in the previous 2 weeks, while 22.7% patients reported dizziness in the previous 2-3 days. Around 14% patients were experiencing dizziness for one month, while 111

(11.1%) patients presented with the history of dizziness for 6 months. The summary of sociodemographic and clinical characteristics is presented in Table 1.

More than half of the patients presented with otologic cause (57.7%) followed by neurologic condition (17.9%). Other etiological conditions presented were

metabolic/endocrine (8.4%), psychiatric (6.1%), postural (4.7%), cardiovascular (2.2%), infectious (1.2%), and others (1.8%). The commonly used concomitant medications were telmisartan (n=53), glimepiride plus metformin (n=40), followed by metformin (n=32) and ondansetron (n=29).

Some patients had a history of smoking (n=48) and alcohol consumption (n=35), of which 30 were current smokers and 18 were former smokers, while 25 were former alcohol consumers and 10 patients were current consumers. In addition, approximately 99% of the patients reported no change in physical activity or exercise.

Of the 1000 patients, hematology test results were available for 15 (1.5%) patients with mean (SD) hemoglobin of 12 (2.2) g/dL, which was abnormal for 7 (46.7%), but clinically significant for 3 (42.9%) patients. No clinically significant observations were recorded in other hematological parameters. The liver function test was normal. Of the 18 patients with the renal tests, 2 patients had abnormal serum creatinine with clinical significance in 1 patient. Fasting blood sugar was abnormal in 36 patients, which was clinically significant in 33 patients. Similarly, 32 patients had an abnormal postprandial blood sugar, of which 30 were clinically significant. The majority of the patients were vegetarian (n=741) and 86.4% had less than four meals per day.

The number of patients presenting with dizziness as a primary complaint or an associated complaint with symptoms are summarized in Table 3. Among the 1000 patients, 76.2% patients reported dizziness as primary complaint at visit 1, which subsequently decreased to 74.3% patients at visit 2 and 73.4% patients at visit 3. Further, 23.8% patients reported dizziness as an associated complaint on visit 1, which reduced to 23.0%

on visit 2 and continued until visit 3. The associated symptom was nausea in 147 patients at visit 1, 146 patients at visit 2, and 143 patients at visit 3. Further, 95 patients reported vomiting at visit 1, which decreased at visit 2 (n=88) and at visit 3 (n=83). Thirty-nine patients had anxiety as an associated symptom at visit 1, while 35 patients reported anxiety at visit 2 and continued until visit 3. An episode of each symptom for most patients was either once a day or once a week.

Frequency of dizziness for most patients (39.9%) was 3-5 times a week, which reduced to 1-2 times a week at visit 2 (56.8%), and at visit 3 (67.5%). The vital signs like pulse rate, systolic blood pressure, diastolic blood pressure, temperature, and respiratory rate were recorded at visits 2 and 3; they did not deviate from the observations recorded at visit 1.

Out of 1000 patients, the Dix-Hallpike test was performed on 83 patients of whom 4 patients had an abnormal report at visit 1, which was found to be normal at visits 2 and 3. The Romberg's Test was performed on 93 patients and cardiac test on 3 patients; none of the results were positive or abnormal. However, one patient had a positive/abnormal audiometry test at visit 1.

For the management of dizziness, pharmacotherapy was recommended to 915 patients at visit 1, which was reduced to 700 and 415 patients at visit 2 and 3, respectively. Non-pharmacotherapy recommendations including lifestyle modifications such as changes in smoking habit or alcohol consumption, diet, exercise and physiotherapy was suggested to 85 patients at visit 1, which increased to 585 patients by visit 3. Lifestyle modification was the most common non-pharmacological advice given to the patients at visit 1, 2, and 3 (Table 4). Betahistine (n=581, 63.5%) and prochlorperazine (n=312, 34.1%) were the two most frequently prescribed drugs, followed by cinnarizine (n=57, 6.2%).

**Table 4: Patients being advised to pharmacotherapy among those presenting with primary complaint and associated complaint.**

| Pharmacotherapy / Drug                                 | Primary Complaint                |            |                    | Associated Complaint |                                  |            |
|--|----------------------------------|------------|--------------------|----------------------|----------------------------------|------------|
|  | Visit 1<br>(Baseline)<br>(N=683) |            | Visit 2<br>(N=497) | Visit 3<br>(N=236)   | Visit 1<br>(Baseline)<br>(N=232) |            |
|  | N (%)                            | N (%)      | N (%)              | N (%)                | N (%)                            | N (%)      |
| <b>Betahistine</b>                                     | 431 (63.1)                       | 342 (68.8) | 163 (69.1)         | 115 (49.6)           | 115 (56.7)                       | 104 (58.1) |
| <b>Prochlorperazine</b>                                | 214 (31.3)                       | 138 (27.8) | 59 (25.0)          | 62 (26.7)            | 52 (25.6)                        | 47 (26.3)  |
| <b>Betahistine + prochlorperazine</b>                  | 14 (2.1)                         | 4 (0.8)    | 3 (1.3)            | 19 (8.2)             | 12 (5.9)                         | 7 (3.9)    |
| <b>Cinnarizine + dimenhydrinate</b>                    | 23 (3.4)                         | 11 (2.2)   | 9 (3.8)            | 27 (11.6)            | 19 (9.4)                         | 17 (11.7)  |
| <b>Betahistine + cinnarizine + dimenhydrinate</b>      | 1 (0.2)                          | 2 (0.4)    | 2 (0.9)            | 1 (0.4)              | 1 (0.5)                          | 1 (0.6)    |
| <b>Prochlorperazine + cinnarizine + dimenhydrinate</b> | 0                                | 0          | 0                  | 4 (1.7)              | 3 (1.5)                          | 3 (1.7)    |
| <b>Rizatriptan</b>                                     | 0                                | 0          | 0                  | 4 (1.7)              | 1 (0.5)                          | 0          |

**Table 5: Level of disability due to dizziness.**

| Parameter   | Visit 1 (Baseline)<br>(n=1000) | Visit 2<br>(n=1000) | Visit 3<br>(n=1000) |
|---|--------------------------------|---------------------|---------------------|
|   | N (%)                          | N (%)               | N (%)               |
| <b>No disability; negligible symptoms</b>   | 66 (6.6)                       | 220 (22.0)          | 473 (47.3)          |
| <b>No disability; bothersome symptoms</b>   | 258 (25.8)                     | 577 (57.7)          | 435 (43.5)          |
| <b>Mild disability; performs usual work duties, but symptoms interfere with outside activities</b>        | 582 (58.2)                     | 195 (19.5)          | 92 (9.2)            |
| <b>Moderate disability; symptoms disrupt performance of both usual work duties and outside activities</b> | 94 (9.4)                       | 8 (0.8)             | 0                   |

The visit-wise summary of patients on various pharmacotherapies indicated that majority of the patients were prescribed betahistine for the management of dizziness as a primary complaint or associated complaint at all the visits, followed by prochlorperazine, a combination of cinnarizine and dimenhydrinate, and combination of betahistine, cinnarizine, and dimenhydrinate (Table 4). Table 5 depicts the summary of level of disability score due to dizziness. Out of 1000 patients, 66 patients showed negligible symptoms on visit 1 which was further increased to 220 patients at visit 2 and 473 patients at visit 3. Two hundred fifty-eight patients showed no disability but bothersome symptoms at visit 1 which increased to 577 patients at visit 2 and further reduced to 435 patients at visit 3. Mild disability was reported by 582 patients at visit 1 which reduced to 195 patients at visit 2 and 92 patients by visit 3. There was a significant reduction in the level of disability score in prochlorperazine (mean Change: -0.7105; 95% CI: -0.81 to -0.62; P<0.0001) and betahistine treatment groups (mean Change: -0.5673; 95% CI: -0.62 to -0.52; P<0.0001) at visit 2 as compared to baseline visit.

Out of 1000 patients, 39 (6.7%) patients receiving betahistine reported relapse of dizziness as a primary complaint within 1 week of treatment; while four patients receiving betahistine reported relapse with dizziness as an associated complaint (nausea (1 [0.1%]), vomiting (2 [0.2%]), anxiety (1 [0.1%])). There were no adverse events (AE) and serious adverse events (SAE) reported throughout the study duration.

## DISCUSSION

The American Academy of Otolaryngology and Head and Neck defines dizziness as an illusory sense of motion without any real movement in relation to gravity.<sup>13</sup> Clinical practice guidelines are devised to ensure efficient diagnosis and management of vertigo, minimize the cost, and improve the quality of life.<sup>14,15</sup> However, there is limited real-world data from primary care to show compliance with such guidelines. Therefore, the objective of the present observational study was to understand the clinic epidemiological profile of Indian patients presenting with dizziness, in addition to the management practices (including pharmacotherapy) being followed for treating these patients in a primary care setting.

A total of 1000 patients were enrolled based on the eligibility matrix of inclusion/exclusion criteria, with a mean age of 45.1 years, which is in accordance with earlier studies.<sup>16,17</sup> Although school children have also shown the incidence of dizziness and vertigo, which was comparable to adults, limited studies are conducted in adolescents.<sup>18-20</sup> In this study cohort, dizziness was presented slightly higher in women at inclusion (men vs. women 485 [48.5%]: 515 [51.5%]). The earlier studies have reported higher enrolment of women with dizziness.<sup>21,22</sup> Kurre et al. reported that men with vertigo, dizziness, or unsteadiness were more likely to be depressive than women.<sup>17</sup>

A similar study conducted in the Nigerian elderly population revealed the incidence of dizziness in the majority of the patients living in rural-suburban regions (79.6%), with no formal education (54.1%), and with more than two-thirds (67.0%) of the population belonging to low economic status.<sup>23</sup> This is contradictory to the findings of this study, which showed that the majority of the patients with dizziness belonged to the upper-middle class, but the occurrence was higher in unemployed patients.

Furthermore, clinical evidence reported dizziness to have a multifactorial origin, of which otologic disorder is reported to be the most predisposing etiological factor for dizziness.<sup>24</sup> Similar findings were obtained in the current study in which ~58% of patients experienced dizziness due to otological conditions.

The co-morbidities reported by most of the patients in this study were hypertension and metabolic disease. Some patients showed abnormal fasting and postprandial glucose levels. This is in accordance with the previous studies conducted by Martins et al.<sup>25</sup> in Brazilian patients and Maarsingh et al. in elderly patients from the Netherlands.<sup>26</sup> It is important to monitor blood glucose levels more stringently to avoid adverse events due to diabetes. Maarsingh et al. also showed an independent association of dizziness with cerebrovascular disease. In the geriatric population, depression, sleeping disorders, fatigue, and recurrent falls were frequently associated with dizziness.<sup>26</sup> At visit 1, 16.4% of the patients with anxiety showed dizziness as an associated symptom. At visits 2 and 3, 15.2% of the patients with anxiety showed

dizziness as an associated symptom, which was comparable to the results of Kurre et al.<sup>17</sup> They predicted that co-morbid anxiety might have developed at a later period in patients with dizziness.

Moreover, this investigation has also recorded different lifestyle factors among Indian patients with dizziness. Most of the patients never smoked (95.2%) or consumed alcohol (96.5%). Evidence suggests physical inactivity as a risk factor for dizziness and vertigo, especially in women; nevertheless, smoking and alcohol did not show any strong association with the incidence of dizziness.<sup>27,28</sup>

Signs and symptoms play a crucial role in determining the prognostic approach. Consequently, various signs and symptoms of dizziness were recorded in this study cohort. Dizziness is generally associated with secondary symptoms such as nausea, vomiting, postural instability, and cold sweating; however, vertigo is a spinning sensation of either one's own body and/or surrounding which is generally characterized by dizziness. A similar observation has been reported by the study conducted by Neuhauser and co-workers.<sup>29</sup> The majority of the patients in the present study complained of dizziness accompanied by frequent episodes of nausea followed by vomiting and anxiety. All these symptoms were normal presentations in almost 50% of cases in the reported investigation by Kameswaran et al.<sup>30</sup> Additionally, among the different types of dizziness, dizzy feeling was the most prevalent type reported by ~61% patients, followed by vertigo reported by 36.6 %. Other types of dizziness reported minimally included floating, fainting, and imbalance. Notably, the associated symptoms of the underlying disease were not being considered as AE/SAE during the study.

Vital signs such as pulse rate, blood pressure, temperature, and respiratory rate were analyzed, and no clinically significant abnormalities were observed in any patients. Dix-Hallpike test and Romberg's test were conducted only in a few patients. Dix-Hallpike test is a gold standard test in the diagnosis of vertigo, yet contraindicated in patients with neck pathology.<sup>31,32</sup> Hence, there is a need to educate physicians to make the correct diagnosis.

Dizziness can be managed by medicines, physical therapy, and behavioral therapy, and a few cases may entail surgical therapy.<sup>33</sup> This study also recorded management practices for dizziness.

This study's key finding revealed that the majority of the patients reported dizziness as the primary complaint with a frequency of 3-5 times a week, and most had a vestibular cause. The primary drug of choice prescribed in the clinical care settings was betahistine, followed by prochlorperazine, consistent with the published literature.<sup>30,34-36</sup>

Betahistine, an H3 receptor antagonist, is an approved drug in many countries for Ménière's disease and dizziness of vestibular origin. Prochlorperazine is an antiemetic with a vestibular suppressing effect. It has been approved by the FDA in 1956 and recommended for severe nausea and vomiting. It has a long history of being used in vertigo pharmacotherapy for dizziness. Data indicate a complete clearance of vertigo symptoms on long-term treatment without any safety concern in Indian patients.<sup>36</sup>

A comparative study of prochlorperazine and cinnarizine by Singh et al. demonstrated the superiority of prochlorperazine in terms of efficacy and safety for the treatment of vertigo. Cinnarizine showed almost similar efficacy to prochlorperazine; however, the drug dosage was higher and side effects, such as drowsiness and sedation, were observed more with cinnarizine.<sup>36</sup>

Yardley et al reported that vestibular rehabilitation improves symptoms, postural stability, and dizziness-related handicap in patients with chronic dizziness.<sup>37</sup> Vestibular suppressants/antivertigo drugs (including anticholinergics, antihistamine, and benzodiazepine class of drugs) and antiemetics such as phenothiazines including prochlorperazine and promethazine, are the mainstay of treatment of acute vestibular episodes. These provide symptomatic relief as the cause is difficult to identify to provide curative therapy but needs to be done judiciously and cautiously. Vestibular suppressants decrease the nystagmus due to vestibular imbalance and calm the hyperactive vestibule leading to a decrease in symptom intensity and frequency of vertigo.<sup>38,39</sup> Prochlorperazine, an effective antiemetic is also the most preferred vestibular suppressant in acute vertigo that acts by vasodilation of the stria vascularis of the inner ear and blocks the chemoreceptor trigger zone.<sup>40,41</sup> It is a potent drug used for a very short course to relieve symptoms in acute vertigo with nausea and vomiting. Once the patient gets stabilized, prochlorperazine is discontinued within three days and the further condition is managed using pharmacotherapy, vestibular rehabilitation, maneuver, and surgery depending on the discretion of the treating physicians. The standard principles for treatment are expedited vestibular compensation through physical therapy to restore the balance. Furthermore, the concomitant psychological and cognitive impairment should be treated with a holistic approach for complete recovery.<sup>42</sup>

In a postal survey of general practitioners, prochlorperazine (58.9%), betahistine (35.4%), and cinnarizine (12.4%) were the commonly prescribed drugs for dizziness. Other drugs, such as propranolol, diazepam, and aspirin, were also prescribed.<sup>11</sup> Combination therapies would be more beneficial, leading to a marked improvement in patients' symptoms even in chronic conditions.<sup>43</sup>

A comprehensive method for management is essential for faster relief, to avoid reoccurrence, management of associated conditions and treating anxiety to prevent delayed recovery. An exact diagnosis of the causes of dizziness is mandatory and proper referral is imperative for appropriate disease management. An accurate history and physical examination are paramount for making a correct diagnosis in patients with dizziness. A comprehensive management method is essential for faster relief, avoiding reoccurrence, managing associated conditions, and treating anxiety to prevent delayed recovery.<sup>44</sup>

Non-pharmacological treatments for dizziness, especially in the elderly, have been studied, and they include vestibular rehabilitation exercises, cognitive-behavioral therapy, and manual therapy.<sup>45,46</sup> Lifestyle modifications, like regular sleep, diet, and exercises, and avoiding vertigo triggers, have proven to benefit in dizziness.<sup>47</sup> Initially, in the present study, most patients were advised pharmacotherapy and later a few patients shifted to non-pharmacotherapy, primarily lifestyle modification. By visit 3, it was observed that majority of the patients incorporated lifestyle changes to attain maximum clinical benefit in dizziness.

Disability can be a consequence of dizziness, particularly in the elderly, and depending upon the levels, the quality of life of individuals and their work activities may be affected.<sup>48</sup> According to the literature, 8% of the affected individuals interrupt their activities due to the symptom.<sup>49</sup> In the present study, a change in disability was determined, which indicated a low level of disability for ~90% of the patients after the treatment, which was in accordance with the previous study by Bittar et al.<sup>1</sup> A significant reduction ( $p < .0001$ ) in the level of disability score was observed in both the treatment groups (prochlorperazine and betahistine) at visit 2 as compared to the baseline visit. Dizziness relapsed within one week in 39 patients on betahistine, while those treated with prochlorperazine did not show any relapse. This finding is consistent with a recent real-world safety surveillance study from India by Haldipur et al. that revealed good tolerability of prochlorperazine in the management of acute dizziness with significant improvement in associated vomiting and nausea.<sup>44</sup>

This study did not analyze medication for other dizziness subcategories. However, this is the first of its kind extensive observational study focusing on the clinic epidemiological profiles as well as management practices for dizziness in the primary care setting in a large Indian population.

## CONCLUSION

Dizziness has a multifactorial origin necessitating a multifactorial treatment approach. Betahistine and prochlorperazine were the most commonly prescribed drugs. However, an improvement in the disability scores

with no relapse was reported with prochlorperazine. Further research is warranted to evaluate the effectiveness of betahistine and prochlorperazine. Additionally, focus on an accurate diagnosis of dizziness and emphasis on the pharmacological and non-pharmacological interventions for the management of dizziness or vertigo, especially targeting women and elderly, is imperative.

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