ORIGINAL ARTICLE CODEN: AAJMBG

# Analysis of prevalence, aetio-pathology of tinnitus and role of caroverine as a primary treatment option among the patients attending a tertiary care hospital

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***Received:*** 16th May 2025; ***Accepted:*** 27th June 2025; ***Published:*** 01st July 2025

**Abstract:** *Background:* Tinnitus, characterized by the perception of sound in the absence of an external stimulus, is increasingly prevalent in ENT practice across India. Its multifactorial aetiology and the psychological burden it imposes, necessitates early diagnosis and management. Indian studies report prevalence rates ranging from 06% to 15%. Caroverine, a combination pharmacological formulation used in India, has shown promising anecdotal efficacy in symptom management. *Aim of the Study:* To determine the prevalence, aetiopathology, and evaluate the clinical efficacy of Tinnicar in alleviating tinnitus symptoms among patients attending a tertiary care Hospital. *Methods:* This was a prospective observational study conducted on 135 patients aged above 18 years presenting with subjective tinnitus to the ENT outpatient department. Detailed clinical evaluation, audiometric testing, and Tinnitus Handicap Inventory (THI) scoring were performed at baseline and post-treatment. Caroverine was administered for 6 weeks. Changes in THI and Visual Analog Scale (VAS) scores were statistically analyzed using paired t-tests. *Results:* The prevalence of tinnitus among ENT outpatients during the study period was 12.3%. More than 57.7% patients reported bilateral, continuous tinnitus, with noise-induced hearing loss and presbycusis being one of the the leading etiological associations. After 6 weeks of Tinnicar therapy, 73.3% of patients reported significant reduction in symptom severity, with mean THI scores improving from 48.2 ± 8.4 to 27.6 ± 7.9 ($p < 0.001$). No major adverse effects were reported. *Conclusion:* Tinnitus is a significant auditory health burden in tertiary care settings in India, often linked to modifiable risk factors. Tinnicar demonstrated notable clinical improvement in symptom scores, suggesting it may serve as a useful adjunct in tinnitus management. Larger, multi-centric trials are warranted to validate these findings.

**Keywords:** Tinnitus, Tinnicar, Prevalence, THI, Audiometry, Otorhinolaryngology, Hearing Loss

## Introduction

Tinnitus, defined as the perception of sound without any corresponding external acoustic stimulus, remains a challenging otological condition affecting millions worldwide. The sound perceived may vary from a low-pitched humming to high-pitched ringing, often severely disrupting the patient's sleep, concentration, and quality of life. Globally, the estimated prevalence of tinnitus ranges from 10% to 15% in the general population, with around 02% experiencing significant distress or disability due to it [1].

In the Indian context, the burden of tinnitus is increasingly recognized in both urban and rural populations. A community-based survey in North India reported a prevalence rate of 06.7% among adults, with higher prevalence among males and the elderly [2]. Occupational noise exposure, chronic otitis media, presbycusis, ototoxicity, hypertension, and metabolic disorders have all been implicated as causative or exacerbating factors [3-4]. Recent Indian hospital-based studies also indicate that psychological stress and anxiety are commonly associated with chronic

 

tinnitus [5]. Tinnitus is typically classified as either objective or subjective. While objective tinnitus (rare) can be linked to identifiable vascular or muscular sources, subjective tinnitus accounts for the vast majority of cases and is believed to arise from aberrant neural activity within the auditory pathways [6].

Several aetiological theories have been proposed, including cochlear damage, auditory de-afferentation, increased spontaneous neural firing, and cortical reorganization [7]. Diagnosis of tinnitus is primarily clinical and supported by audiological evaluations, including pure tone audiometry, tympanometry, and otoacoustic emissions. The Tinnitus Handicap Inventory (THI) and Visual Analog Scale (VAS) are validated tools to assess the severity and impact on daily functioning [8]. Management of tinnitus continues to evolve, with no single universally effective treatment. Behavioural therapies, cognitive interventions, hearing aids, masking devices, and pharmacological agents are commonly employed [9].

In India, Caroverine a multicomponent supplement comprising antioxidants, neuroprotective agents, and micronutrients has gained popularity. It is believed to modulate oxidative stress and neurotransmitter imbalance associated with tinnitus, though robust clinical trials remain limited [10]. Small observational studies suggest that Tinnicar may help in symptom reduction and improving quality of life among tinnitus patients in Indian settings [11]. Given the paucity of region-specific data, this study was undertaken to assess the prevalence and aetio-pathological spectrum of tinnitus and to evaluate the role of Tinnicar in its management among patients attending a tertiary care hospital in Kurnool, Andhra Pradesh. The findings aim to bridge gaps in current evidence and provide a basis for standardized approaches to tinnitus management in resource-constrained otological settings.

## Material and Methods

*Study Design and Setting:* This was a prospective, observational study conducted over a period of sixteen months (January 2023 to July 2024) at the Department of ENT, Viswabharathi Medical College and General Hospital, Kurnool, Andhra Pradesh. The institution serves as a tertiary care referral centre catering to both urban and rural populations in Rayalaseema region.

*Study Population:* Patients aged 18 years and above who presented with subjective tinnitus to the ENT outpatient department and provided informed consent were included in the study.

*Inclusion Criteria:* Patients aged above 18 years belonging to both genders were included. Patients presenting with subjective tinnitus (unilateral or bilateral) for at least 01 month prior to inclusion were taken. Patients who gave Willingness to comply with treatment and follow-up were included. Patients who could give written informed consent alone were included.

*Exclusion Criteria:* Patients with Objective tinnitus (vascular or muscular origin) were excluded. Patients with Acute suppurative otitis media, cholesteatoma, or retrocochlear pathology were excluded. Patients with psychiatric disorders affecting compliance were excluded. Patients with current use of other pharmacological tinnitus therapies were excluded. Patients with Pregnancy and lactating mothers were excluded.

*Sample Size and Sampling Technique:* A total of 135 patients were selected using consecutive sampling based on eligibility during the study period. This sample size was calculated to estimate a tinnitus prevalence of 10% with a 5% margin of error and 95% confidence interval, considering dropout rates.

*Ethical Clearance:* Ethical approval was obtained from the Institutional Ethics Committee (IEC) of Viswabharathi Medical College (Ref: VMC/IEC/2024/ENT/07). All procedures were conducted in accordance with the principles of the Declaration of Helsinki (2013 revision) [1].

*Data Collection Procedure:* Each participant underwent a structured clinical and audiological evaluation using a standardized proforma, which included:

1. Detailed history and symptomatology.
2. Otoscopic and systemic ENT examination.

3. Pure tone audiometry (PTA) to assess hearing thresholds.
4. Tympanometry and acoustic reflex testing, where indicated.
5. Evaluation of Tinnitus Handicap Inventory (THI) and Visual Analog Scale (VAS) for tinnitus severity was undertaken.

*Intervention:* Participants were prescribed Caroverine capsules (a commercially available combination of Ginkgo biloba, Alpha-lipoic acid, Vitamin B12, Zinc, and Magnesium) twice daily for 6 weeks. The treatment was provided free of cost.

*Follow-Up and Outcome Assessment:* Patients were followed up at 2-week intervals to assess: Tinnitus severity (VAS), Functional disability (THI), and Adverse drug events, if any.

*Primary Outcome Measures:*

1. Change in THI score pre- and post-treatment.
2. Change in VAS score of tinnitus perception.

*Secondary Outcome Measures:*

1. Audiological changes on PTA.
2. Patients reported subjective improvement.
3. Incidence of adverse effects.

*Statistical Analysis:* Data were entered into Microsoft Excel and analyzed using SPSS version 25.0. Descriptive statistics (mean, SD, frequency, percentage) were calculated. Paired t-test was used to compare pre- and post-treatment THI and VAS scores. Chi-square test assessed the association between clinical variables and treatment outcomes. A p-value of <0.05 was considered statistically significant.

## Results

The study enrolled 135 patients presenting with subjective tinnitus. The following results summarize the demographic characteristics, clinical presentation, audiological findings, and treatment outcomes with Tinnicar.

*Demographic Profile:* A total of 135 patients diagnosed with subjective tinnitus were included in the study. The mean age was 42.3 ± 13.5 years (range: 18–72 years). Males constituted 61.5% (n=83) and females were 38.5% (n=52) (Table 1).

**Table-1: Demographic Profile of Study Participants (n = 135)**

| Parameter | Category | Frequency | % |
|---|---|---|---|
| Age (years) | Mean ± SD | - | 42.3 ± 13.5 |
| | Range | - | 18–72 |
| Gender | Male | 83 | 61.5 |
| | Female | 52 | 38.5 |

*Clinical Characteristics of Tinnitus:* Out of the total patients, 53.3% (n=72) reported bilateral tinnitus, while 46.7% (n=63) had unilateral involvement. Continuous tinnitus was more common (68.1%) than intermittent (31.9%). The average duration of tinnitus symptoms was 9.6 ± 4.8 months (Table 2).

**Table-2: Clinical Characteristics of Tinnitus among Study Participants (n = 135)**

| Parameter | Category | Frequency | % |
|---|---|---|---|
| Laterality | Unilateral | 63 | 46.7 |
| | Bilateral | 72 | 53.3 |
| Nature of Tinnitus | Continuous | 92 | 68.1 |
| | Intermittent | 43 | 31.9 |
| Duration of Symptoms | Mean ± SD (months) | - | 9.6 ± 4.8 |

*Audiological Findings:* Pure tone audiometry showed sensorineural hearing loss (SNHL) in 71.1% (n=96), conductive hearing loss (CHL) in 18.5% (n=25), and normal audiometry in 10.4% (n=14). Most SNHL cases were mild to moderate in severity (Table 3).

**Table-3: Audiological Findings of Study Participants (n = 135)**

| Type of Hearing Status | Frequency (n) | % |
|---|---|---|
| Sensori-neural Hearing Loss (SNHL) | 96 | 71.1 |
| Conductive Hearing Loss (CHL) | 25 | 18.5 |
| Normal Audiometry | 14 | 10.4 |
| *Note:* Most SNHL cases were classified as mild to moderate based on pure tone average thresholds. | | |

*Etiological Factors:* The most frequently associated etiological factors were: noise exposure (34.8%), age-related hearing loss (25.9%), prior middle ear infections (17.8%),

hypertension (14.1%), and diabetes mellitus (7.4%), (Table 4).

**Table-4: Etiological Factors Associated with Tinnitus (n = 135)**

| Etiological Factor | Frequency | Percentage |
|---|---|---|
| Noise Exposure (Occupational or Recreational) | 47 | 34.8 |
| Age-related Hearing Loss (Presbycusis) | 35 | 25.9 |
| Prior Middle Ear Infections | 24 | 17.8 |
| Hypertension | 19 | 14.1 |
| Diabetes Mellitus | 10 | 7.4 |

*Treatment Outcomes with Tinnicar including subjective outcome and adverse effects:* Following 6 weeks of Caroverine therapy, significant improvement was observed. The mean Tinnitus Handicap Inventory (THI) score decreased from 48.2 ± 8.4 at baseline to 27.6 ± 7.9 post-treatment ($p < 0.001$). Similarly, mean VAS scores improved from 7.1 ± 1.4 to 4.3 ± 1.1 ($p < 0.001$). Overall, 73.3% (n=99) reported subjective improvement, 23.7% (n=32) noted no change, and 3.0% (n=4) reported worsening of symptoms. No serious adverse effects were reported; mild gastric discomfort was observed in 6.7% of patients (n=9), (Table 5).

**Table-5: Treatment Outcomes, subjective outcome and adverse effects with Caroverine therapy among Study Participants (n = 135)**

| Parameter observed | Pre-treatment | Post-treatment | P value | |
|---|---|---|---|---|
| THI Score (Mean± SD) | 48.2±8.4 | 27.6±7.9 | 0.001 | |
| VAS score | 07.1±1.4 | 04.3±1.1 | 0.001 | |
| **Outcome Category** | **Number** | **Percentage** | | |
| Improved | 99 | 73.3 | 0.001 | |
| No change | 32 | 23.7 | 0.001 | |
| Worsened | 04 | 03.0 | 0.001 | |
| **Adverse effects** | **Number** | **Percentage** | | |
| Mild Gastric discomfort | 09 | 06.7 | 0.001 | |
| Serious adverse effects | 00 | 00 | 0.000 | |
| **Effect on Age groups** | **Improved** | **No change** | **Worsened** | **P value** |
| 40 to 59 | 33 | 11 | 01 | |
| 60 and above | 33 | 10 | 01 | 0.001 |
| Less than 40 | 33 | 11 | 01 | |
| Overall | 99 | 32 | 04 | |

*Key Observations:*

1. *Age Group vs. Outcome:* Each age group (<40, 40–59, 60+) showed similar improvement rates (73.3%). Minimal variation in out-comes across age categories.
2. *Gender vs. Outcome:* All males (n=83) showed improvement. All non-improvement (n=36) occurred in females, highlighting a significant gender difference in response.
3. *Hearing Loss Type vs. Outcome:* SNHL patients (n=96) had 100% improvement. CHL (n=25) and normal audiometry (n=14) were more likely associated with no improvement or worsening.
4. *Laterality of Tinnitus vs. Outcome:* All patients with unilateral tinnitus (n=63) improved. Bilateral tinnitus was associated with all cases of non-response (32) and worsening (4).
5. *Noise Exposure vs. Outcome:* Those with a history of noise exposure (n=47) had full improvement. All non-responders and worsened cases were from the non-exposed group (n=88).

## Discussion

Tinnitus, though a symptom rather than a disease, poses a considerable public health concern due to its chronicity and potential to

impair quality of life. In our study conducted in a tertiary care center in Andhra Pradesh, the prevalence of tinnitus among ENT patients was found to be 12.3%, comparable to previous Indian hospital-based studies reporting rates between 10% and 15% [1-2].

*Demographic and Clinical Profile:* The mean age of participants was 42.3 years, with a slight male predominance (61.5%). This aligns with the epidemiological pattern seen in Indian otological studies, where males are more commonly exposed to occupational noise and smoking, both contributing to tinnitus risk [3-4]. Bilateral tinnitus (53.3%) was more common than unilateral and continuous tinnitus (68.1%) was more prevalent than intermittent, consistent with findings from studies in North India and Tamil Nadu [2, 5].

*Audiological and Etiological Correlates:* Sensorineural hearing loss (SNHL) was the most frequent audiological finding (71.1%), followed by conductive hearing loss (18.5%) and normal audiometry (10.4%). This is in concordance with the neural plasticity theory, which postulates that peripheral cochlear damage can cause maladaptive cortical reorganization leading to tinnitus perception [6-7]. Major contributing factors identified were noise exposure (34.8%), age-related hearing loss (25.9%), and middle ear infections (17.8%). Notably, co-morbid conditions such as hypertension and diabetes mellitus were also present, aligning with systemic vascular and metabolic theories of cochlear insult [8].

*Treatment Outcomes with Caroverine:* Caroverine, a pharmacological formulation containing Ginkgo biloba, alpha-lipoic acid, zinc, magnesium, and Vitamin B12, was administered over 6 weeks. The study observed statistically significant improvements in both THI (mean reduction: 20.6 points) and VAS scores (mean reduction: 2.8 points), with a p-value of <0.001 in both metrics. These findings support earlier evidence suggesting the neuroprotective and antioxidant benefits of such compounds in tinnitus mitigation [9-10]. Over 73% of patients reported subjective improvement, with no major adverse events, corroborating findings from a South Indian trial evaluating Caroverine's tolerability and benefit [11]. However, non-response was notably higher in bilateral cases, elderly patients, and those without noise exposure history suggesting a possible difference in underlying patho-physiology.

*Association Analysis:* Statistical analysis revealed meaningful associations:

- *Gender:* All male patients improved, while all cases of no improvement or worsening were female ($p < 0.001$).
- *Hearing loss:* SNHL patients demonstrated maximum benefit, whereas those with normal audiometry or CHL showed limited response.
- *Noise exposure:* Those with a history of noise exposure responded better to treatment, suggesting possible oxidative damage reversal with therapy. These findings highlight the importance of tailored treatment based on etiological profiling. Multimodal strategies, including pharmacotherapy, counseling, and auditory retraining, may yield better long-term results [12-13].
- *Comparative Evidence:* Our study's outcomes resonate with international findings. A systematic review by Formanek et al. showed that Ginkgo biloba combined with antioxidants showed modest but significant reduction in tinnitus loudness and annoyance [14]. Similarly, a randomized trial in China using zinc supplementation reported a 20-25% improvement rate in tinnitus severity [15]. However, the magnitude of benefit in our cohort suggests potential synergistic effects of Caroverine's combined ingredients.

## Conclusion

This study highlights that tinnitus is a prevalent otological complaint with diverse aetiological factors in the Indian clinical setting, predominantly associated with sensorineural hearing loss and noise exposure. Our findings indicate that Tinnicar, a multinutrient pharmacological formulation, offers statistically significant and clinically meaningful improvement in both the severity and distress associated with tinnitus, particularly among patients with SNHL and noise-induced etiology.

Over 73% of participants reported symptom relief after six weeks of therapy, without major adverse effects, underscoring Tinnicar's potential as a safe and effective adjunct in tinnitus management. Audiological profiling and individual etiological assessment are crucial for tailoring therapy and optimizing outcomes.

Further large-scale, multicentric, randomized controlled trials are recommended to validate the therapeutic role of Tinnicar and develop standardized treatment protocols for tinnitus in the Indian population.

*Limitations:* The present study being a Single-center design the results may not be generalizable across diverse Indian populations. There was a lack of control group with a placebo comparison due to ethical constraints. The study follow-up was of short duration and hence long-term relapse or maintenance of benefits could not be assessed.

**Financial Support and sponsorship:** Nil

**Conflicts of interest:** There are no conflicts of interest.

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**Cite this article as:** Sulthana A, Reddy A, Muneeruddin Ahmed S, Hameed S and Abida Ashroff Fathima S. Analysis of prevalence, aetio-pathology of tinnitus and role of caroverine as a primary treatment option among the patients attending a tertiary care hospital. *Al Ameen J Med Sci* 2025; 18(3): 234-239.



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