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Comparative Efficacy of Gingko biloba and Ashwagandha with Caroverine in the Treatment of Idiopathic Tinnitus: An Investigative Clinical Study

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ABSTRACT

Idiopathic tinnitus, a condition characterized by the perception of sound without external stimuli, significantly affects quality of life, causing distress, anxiety, and sleep disturbances. Current treatments show inconsistent efficacy due to the multifactorial nature of tinnitus, leading to interest in alternative therapies. This randomized controlled trial aimed to compare the efficacy of Gingko biloba and Ashwagandha combined with Caroverine in managing idiopathic tinnitus. Fifty patients were divided into two groups: Group 1 received Gingko biloba (60 mg/day) with Caroverine (20 mg/day), and Group 2 received Ashwagandha (300 mg twice daily) with Caroverine (20 mg/day). Outcomes were assessed using the Tinnitus Handicap Inventory (THI) at baseline, one month, three months, and six months post-treatment. Both groups demonstrated significant reductions in THI scores ($p < 0.05$) over six months, with improvements in tinnitus severity and its impact on daily life. While both treatments were effective, Ashwagandha offered comparable results to Gingko biloba, positioning it as a cost-effective alternative. These findings support the combined use of herbal supplements and Caroverine for managing tinnitus, providing new insights into complementary therapies for this challenging condition. Further studies are needed to explore long-term effects and psychological benefits in diverse populations

Keywords: *Idiopathic tinnitus, Gingko biloba, Ashwagandha, Caroverine, Tinnitus Handicap Inventory* .

1. INTRODUCTION

Idiopathic tinnitus, characterized by the perception of sound in the absence of external auditory stimuli, presents a significant challenge in clinical management due to its diverse etiologies and subjective nature. Tinnitus can range from a minor inconvenience to a debilitating condition, severely impacting the quality of life, leading to distress, anxiety, depression, and sleep disturbances [1]. The prevalence of tinnitus is reported to be between 2% and 32%, and it is often accompanied by hearing loss [2]. Despite extensive research, a universally effective remedy for tinnitus remains elusive, largely due to its multifactorial pathophysiology which includes auditory and non-auditory mechanisms. Current therapeutic strategies for tinnitus focus on various modalities such as pharmacotherapy, sound therapy, cognitive behavioral therapy and lifestyle modifications [3]. However, the efficacy of these treatments varies significantly among individuals and none have proven to be consistently effective. This inconsistency in treatment outcomes has spurred interest in alternative therapies, particularly those involving herbal supplements which are perceived to have fewer side effects compared to conventional pharmacological agents.

Two such herbal supplements, Gingko biloba and Ashwagandha, shown promise in the management of tinnitus symptoms. Gingko biloba, derived from the leaves of the ancient Gingko tree, has been used for centuries in traditional medicine and contains multiple pharmacologically active substances [4]. Although there is some disagreement regarding the effectiveness of Gingko biloba on tinnitus, it has gained popularity because some studies have found it effective, providing relief to tinnitus sufferers without the side effects associated with antidepressants or anxiolytics [5]. Ginkgo flavonoids (GF) and ginkgolides

(GL) in Gingko biloba, renowned for its antioxidant and vasodilatory properties, which are believed to enhance cochlear blood flow and protect against oxidative stress, both of which are implicated in the pathogenesis of tinnitus [6]. Numerous studies have suggested that Gingko biloba can reduce the severity of tinnitus symptoms, though results have been mixed and often dependent on dosage and formulation. Ashwagandha (Withania somnifera) belongs to the family Solanaceae, also known as Indian ginseng or winter cherry, is an adaptogenic herb traditionally used in Ayurvedic medicine [7]. It is acclaimed for its ability to modulate the body's response to stress, enhance cognitive function and provide neuroprotective effects [8]. The adaptogenic and neuroprotective properties of Ashwagandha suggest it may mitigate the distress associated with tinnitus, particularly in patients whose symptoms are exacerbated by stress and anxiety [9]. Research into Ashwagandha's role in tinnitus management is still emerging, but its broad spectrum of health benefits makes it a compelling candidate for further investigation. Caroverine, a synthetic amino acid derivative, is a known glutamate antagonist that has been investigated for its potential in treating tinnitus. Glutamate-induced excitotoxicity is a significant factor in the pathogenesis of tinnitus and by inhibiting glutamate receptors, Caroverine may help to reduce the hyperactivity in the auditory pathways that contributes to tinnitus perception [10]. Clinical trials have demonstrated that Caroverine can alleviate tinnitus symptoms, particularly in cases where tinnitus is linked to cochlear synaptic transmission anomalies [11]. The combination of Caroverine with herbal supplements like Gingko biloba and Ashwagandha offers a multifaceted approach to tinnitus treatment, targeting both the neurological and psychological aspects of the condition.

The primary objective of this study is to compare the efficacy of Gingko biloba and Ashwagandha, each combined with Caroverine capsules, in the management of idiopathic tinnitus. The study employs the Tinnitus Handicap Inventory (THI) scoring system to evaluate and quantify the effectiveness of these interventions in alleviating tinnitus-related distress, depression, anxiety and sleep impairment. By utilizing a randomized controlled trial design, this research aims to provide robust evidence on the comparative benefits of these herbal supplements in conjunction with Caroverine, potentially offering new insights into effective tinnitus management strategies. In summary, this study seeks to elucidate whether the combination of Gingko biloba or Ashwagandha with Caroverine can offer a viable and effective treatment option for patients suffering from idiopathic tinnitus, as in Figure 1 thereby contributing to the broader understanding and management of this challenging condition.

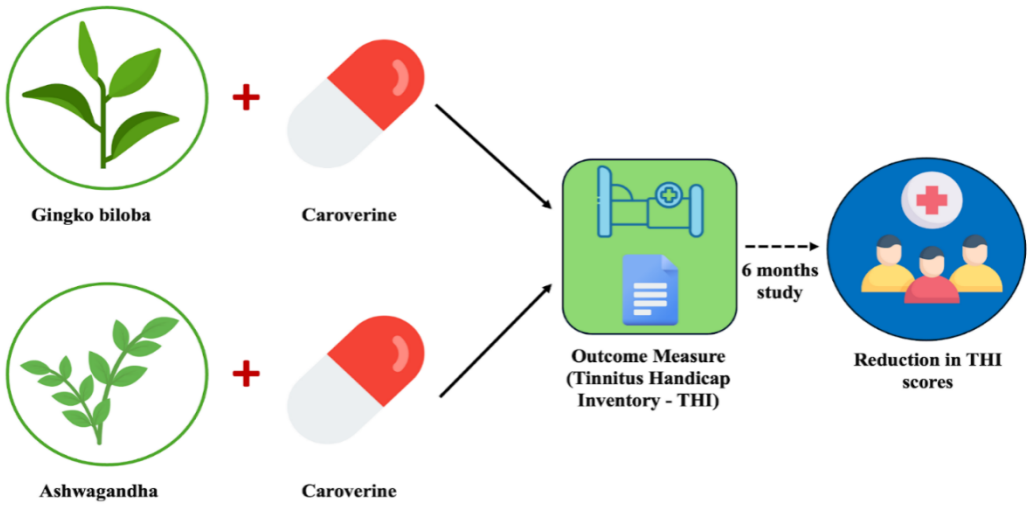


Figure 1: Ashwagandha and Gingko biloba in reduction of THI scores

2. MATERIALS AND METHODS

2.1. Study Design

This study was designed as a prospective randomized controlled trial conducted in the ENT outpatient department (OPD) atTertiary care centre, chennai . The trial period spanned six months, with follow-up assessments at baseline (T0), one month (T1), three months (T3) and six months (T6) post-treatment initiation. Participants were randomly assigned to one of two treatment groups to ensure balanced representation and minimize potential biases. The key elements of the study design and interventions are summarized in Table 1.

Table 1: Summary of Study Design and Interventions

Category	Details
Study Design	Prospective Randomized Controlled Trial
Study Population	**Age**: 20-60 years **Diagnosis**: Idiopathic tinnitus **Setting**: ENT OPD, Tertiary care centre,chennai
Sample Size	**Total:** 50 patients Group 1: 25 patients Group 2: 25 patients
Interventions	**Group 1**: Gingko biloba (60 mg once a day) Caroverine (20 mg once a day) **Group 2**: Ashwagandha (300 mg twice a day) Caroverine (20 mg once a day)
Outcome Measures	Tinnitus Handicap Inventory (THI) Score Baseline, 1 month, 3 months, 6 months
Statistical Analysis	Student's t-test for pre- and post-treatment THI scores p-value < 0.05 considered significant Software: SPSS 18.0

2.2. Study Population

The study enrolled 50 patients diagnosed with idiopathic tinnitus, aged between 20 and 60 years. Inclusion criteria required participants to have steady loudness (±5 dB between test and retest) and pitch of tinnitus perceived by the subject. The exclusion criteria included the presence of external or middle-ear diseases, fluctuating hearing loss, major psychiatric disorders and objective tinnitus due to vascular or neurological conditions. All participants provided informed consent before enrollment in the study.

2.3. Sample Size

A total of 50 subjects with idiopathic tinnitus were recruited and randomly divided into two groups. Group 1 consisted of 25 patients who received Gingko biloba capsules (60 mg once a day) in combination with Caroverine capsules (20 mg once a day). Group 2 included 25 patients who received Ashwagandha capsules (300 mg twice a day) in combination with Caroverine capsules (20 mg once a day). The sample size was determined based on preliminary data suggesting sufficient power to detect significant differences in treatment outcomes, accounting for a potential 20% dropout rate.

2.4. Interventions

Subjects in Group 1 received Gingko biloba (60 mg once a day) and Caroverine (20 mg once a day). Subjects in Group 2 received Ashwagandha (300 mg twice a day) and Caroverine (20 mg once a day). Both treatments were administered for six months, with adherence monitored through monthly follow-up visits.

2.5. Outcome Measures

The primary outcome measure was the Tinnitus Handicap Inventory (THI) score. The THI is a validated 25-item questionnaire assessing the impact of tinnitus on daily life. Each item is scored as 0 (none), 2 (sometimes), or 4 (always), with a total score ranging from 0 to 100. Higher scores indicate greater perceived handicap due to tinnitus. THI scores were recorded at baseline (T0), one month (T1), three months (T3), and six months (T6) post-treatment initiation.

2.6. Statistical Analysis

Statistical analyses were performed using SPSS version 18.0. The primary analysis involved comparing pre- and post-treatment THI scores within each group and between the two groups. A paired t-test was employed to assess the significance of differences in THI scores, with a p-value of less than 0.05 considered statistically significant. Descriptive statistics

summarized baseline demographic and clinical characteristics.

3. RESULTS

The severity and intensity of tinnitus in study participants were assessed using the 25-item Tinnitus Handicap Inventory (THI) questionnaire. This validated tool provided a robust measure of the impact of tinnitus on daily life. Patients were thoroughly briefed on how to complete the THI questionnaire to ensure accurate and consistent responses. The questionnaire offered three response alternatives for each item: 0 (none), 2 (sometimes), and 4 (always). The total THI score was calculated by summing the responses to all items, with possible scores ranging from 0 to 100. Higher scores indicated a greater perceived handicap from tinnitus.

3.1. Baseline Characteristics

Table 2. presents the baseline characteristics of the study population, including age, sex, pre-treatment THI scores and the degree of condition.

Table 2: Tinnitus Handicap Inventory (THI) pre-treatment scores and their degree of condition:

Degree of Condition	THI Score Range	Number of Patients (n)	Mean Age (Years)	Sex Distribution (M/F)
Mild	0–36	11	45.5	4 / 7
Moderate	38–56	25	35.8	15 / 10
Severe	58–76	11	36.4	6 / 5
Catastrophic	78–100	3	44.7	2 / 1
Total	—	**50**	**39.3 (overall)**	**27 / 23**

3.2. THI Score Evaluation

The total THI score was utilized as the primary outcome measure to assess the effectiveness of the treatments. The questionnaire is designed to cover various aspects of tinnitus impact, including functional, emotional, and catastrophic domains. The possible score range is from 0 to 100, with higher scores indicating more severe tinnitus impact. Scores from 0 to 16 indicate a slight impact, 18 to 36 indicate a mild handicap, 38 to 56 indicate a moderate handicap, 58 to 76 indicate a severe handicap, and scores from 78 to 100 indicate a catastrophic impact on daily life.

3.3. Statistical Analysis

Statistical analysis was performed using Student's t-test to compare the differences between pre- and post-treatment THI scores within each group and between the two groups. Values of $p < 0.05$ were considered statistically significant. All analyses were conducted using SPSS version 18.0 to ensure rigorous and reliable statistical processing.

3.4. Treatment Outcomes

Treatment with Gingko biloba and Caroverine (Group 1) and Ashwagandha and Caroverine (Group 2) resulted in significant improvement in THI scores from pre- to post-treatment. Both treatment groups demonstrated statistically significant reductions in THI scores ($p < 0.05$) over the six-month study period, as detailed in Table 3.

Table 3: Summary of Pre- and Post-Treatment THI Scores and Outcomes

Treatment Group	No. of Patients (n)	Mean THI at 1 Month	Mean THI at 3 Months	Mean THI at 6 Months	Most Common Outcome After 6 Months
Gingko biloba (60 mg OD) + Caroverine (20 mg OD)	26	44.4	38.0	29.5	Mild
Ashwagandha (300 mg BD) + Caroverine (20 mg OD)	24	42.3	36.3	27.7	Mild
Overall	**50**	**43.4**	**37.2**	**28.7**	**Mild**

3.5. Comparative Efficacy

Both Gingko biloba combined with Caroverine and Ashwagandha combined with Caroverine were found to significantly

reduce the THI scores, indicating a marked improvement in tinnitus symptoms. The efficacy of Ashwagandha in combination with Caroverine was found to be comparable to that of Gingko biloba in combination with Caroverine (Figure 2 and Figure 3), suggesting that Ashwagandha is a viable and cost-effective alternative for the management of idiopathic tinnitus.

Figure 2: Pre-Treatment Distribution of Patients According to Tinnitus Severity Levels

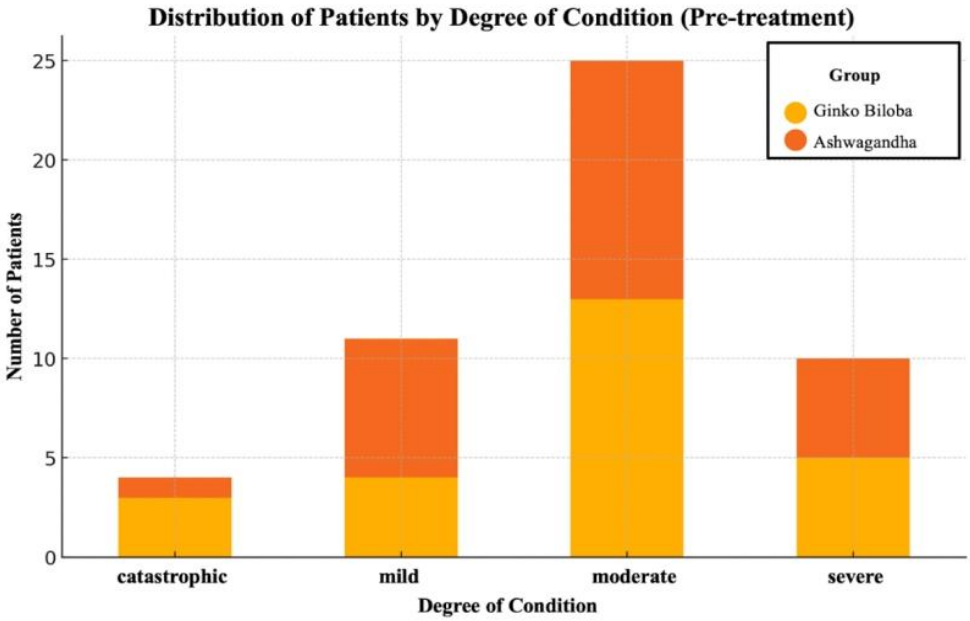
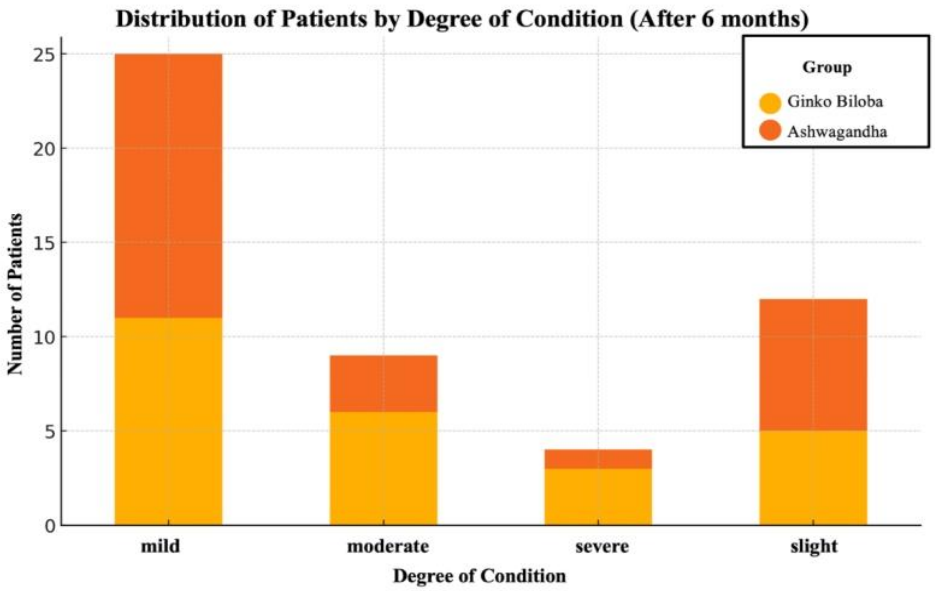


Figure 3: Post-Treatment Distribution of Patients According to Tinnitus Severity Levels at the 6-Month Follow-Up



4. DISCUSSION

This study investigated the efficacy of Gingko biloba and Ashwagandha, each combined with Caroverine, in the management of idiopathic tinnitus by employing the internationally validated Tinnitus Handicap Inventory (THI) scoring system. The use of self-reported measures, such as the THI, to assess patients' functional status is of great significance in conditions like tinnitus, where subjective perception plays a crucial role. The THI, by capturing the emotional and functional impact of tinnitus, provides a comprehensive assessment that aligns well with the complex nature of tinnitus, which often involves both molecular and systemic alterations. The findings demonstrated that both treatment regimens significantly improved THI

scores, indicating a reduction in tinnitus severity and its impact on daily life. Specifically, patients treated with either Gingko biloba or Ashwagandha in combination with Caroverine showed marked improvements in THI scores from baseline to the six-month follow-up. This improvement supports the therapeutic potential of these interventions in tinnitus management.

The beneficial effects observed in this study align with previous literature on the individual components of the treatments. Gingko biloba, with its antioxidant and vasodilatory properties, has been shown to enhance cochlear blood flow and mitigate oxidative stress, factors implicated in tinnitus pathophysiology [11]. Ashwagandha, an adaptogenic herb, has demonstrated neuroprotective and stress-modulating effects, which are particularly relevant given the established correlation between tinnitus perception and emotional impact [12]. Interestingly, the improvement in THI scores was significant across both the emotional and functional subscales, reflecting a broad-based benefit of the treatments. However, the catastrophic subscale did not show a comparable level of improvement. This discrepancy may be due to the more stable personality traits captured by the catastrophic subscale, such as feelings of having a terrible disease and lack of control. These traits may require a longer follow-up period to observe significant changes. The mean improvement in the THI total score observed in our study corresponds to the minimal clinically relevant change, suggesting that the treatments not only statistically but also clinically ameliorated tinnitus symptoms. Given that THI scores have been shown to predict depression, anxiety, and stress, the reduction in THI scores likely reflects an overall improvement in psychological well-being, though further investigation into these psychological knock-on effects is warranted.

The results are consistent with studies highlighting the role of antioxidants in managing tinnitus and related auditory dysfunctions. For instance, the antioxidant properties of Gingko biloba and Ashwagandha, along with Caroverine's role as a glutamate antagonist, provide a multifaceted approach to addressing both oxidative stress and excitotoxicity in tinnitus. The study by [11] supports the results indicating that higher antioxidant intake is associated with better auditory outcomes, particularly in reducing oxidative damage within the cochlea [11].

The results of this study suggest that Ashwagandha, in particular, is a viable and cost-effective alternative to Gingko biloba for managing idiopathic tinnitus. This finding is significant given the growing interest in integrative and complementary therapies for chronic conditions. Future studies should aim to include larger, more diverse populations and incorporate objective measures alongside self-reported outcomes to validate and expand upon these findings.

5. CONCLUSION

Managing idiopathic tinnitus remains a significant clinical challenge due to its complex and multifactorial nature. This study aimed to assess the efficacy of Gingko biloba and Ashwagandha, each combined with Caroverine, in the management of idiopathic tinnitus, using the Tinnitus Handicap Inventory (THI) as the primary outcome measure. The results indicate that both treatment regimens led to significant reductions in THI scores over a six-month period, demonstrating their effectiveness in alleviating tinnitus symptoms. The comparable efficacy of Ashwagandha to Gingko biloba highlights its potential as a cost-effective and accessible treatment option. Ashwagandha's neuroprotective and stress-modulating properties make it particularly beneficial for patients whose tinnitus is influenced by psychological factors. This study underscores the importance of a comprehensive approach to tinnitus management that addresses both the neurological and psychological dimensions of the condition. The inclusion of Caroverine, a glutamate antagonist, further enhances this approach by targeting excitotoxicity mechanisms implicated in tinnitus. In summary, this research supports the use of herbal supplements like Gingko biloba and Ashwagandha, combined with Caroverine, as effective treatments for idiopathic tinnitus. These findings provide a foundation for improved patient care, offering clinicians additional options to enhance the quality of life for individuals suffering from this challenging condition.

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Conflict of interest:

The authors have no conflicts of interest to declare

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Ethical approval:

The questionnaire and methodology for this study was approved by the Human Research Ethics committee of the University of Saveetha Medical College and Hospital Institutional Ethics Committee (SMCH-IEC) (Ethics approval number - ECR/724/Inst/TN/RR-10)

Informed consent:

Informed consent was obtained from all individual participants included in the study

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