



TO COMPARE THE EFFICACY OF CAROVERINE AND PIRACETAM IN THE TREATMENT OF TINNITUS

Otorhinolaryngology

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ABSTRACT

Subjective tinnitus is characterised by the perception of sound or noise in the absence of any internal or external acoustical stimulation. Treatment may range from a very simple to a complex strategy and may require a multidisciplinary approach that takes into account both physical and psychological aspects of tinnitus. **Materials And Methods:** All patients who are suffering from subjective tinnitus after detailed investigations to rule out any cause of objective tinnitus were taken for study. The patients are divided into two groups, with each group containing 30 patients. A detailed examination with relevant investigations was done. One group of patients was treated with piracetam (800mg BD) and the other group with caroverine (20mg BD) for 3 months. The patient underwent a THI questionnaire and PTA. Pre- and post-treatment were followed up for a period of 3 months for improvement in symptoms. **Results:** The THI score showed significant improvement between pre- and post-treatment in patients treated with caroverine, with a P value of 0.001 at the end of 3 months, and minimal improvement in patients treated with piracetam, which was not statistically significant. There was no difference found in PTA values pre- and post-treatment in both groups of patients. **Conclusion** – In this study, it was found that caroverine was a more efficacious drug compared to piracetam in the treatment of tinnitus.

KEYWORDS

tinnitus, piracetam, caroverine, THI questionnaire, PTA

BACKGROUND

The term 'tinnitus' is derived from the Latin word *tinnire*, meaning 'to ring'. [1] Tinnitus is a phantom auditory perception, or head noise, defined as a sound perceived for more than 5 minutes at a time due to aberrant spontaneous activity arising from an altered state of excitation or inhibition within the auditory system in the absence of any external acoustic or electrical stimulation of the ear and not occurring immediately after exposure to loud noise. [2] In 1–2% of the general population, this condition causes a considerable amount of distress and interferes seriously with the individual's ability to lead a normal life.

Seen in any age and sex, it is one of the most common distressing problems. Causing various somatic and psychological disorders, affecting the ability of a person to lead a normal life.

Subjective tinnitus is characterised by the perception of sound or noise in the absence of any internal or external acoustical stimulation [3].

Treatment may range from a very simple to a complex strategy and may require a multidisciplinary approach taking into account both physical and psychological aspects of tinnitus. [4]

Tinnitus treatments can be divided into three categories, depending on their aim:

- 1) treating the underlying cause by medical or surgical means,
- 2) directly reducing the intensity of tinnitus and
- 3) relieving the annoyance and distress associated with tinnitus [2].

The various treatment options for tinnitus include Pharmacotherapy, which can include antidepressants, GABA analogues, glutamate receptor antagonists, calcium antagonists, antiepileptics, prostaglandin analogues, and lidocaine. Psychotherapy, which includes cognitive behavioural therapy and biofeedback, sound devices like wearable masking devices, electrical and magnetic stimulation, use of herbal medicines like ginkgo biloba [1].

Methods

Source Of Data:

Those patients of either sex in the age group of 20 to 60 years attending ENT OPD are selected at Chigateri district hospital and Bapuji hospital, teaching hospitals attached to J.J.M. Medical College Davanagere.

Sample Size:

60 patients attending OPD with symptoms of tinnitus who fulfilled all inclusion and exclusion criteria were selected.

Sampling Procedure:

All patients who are suffering from ringing sensations in their ears are taken for the study. Patients were divided into two groups, with each group containing 30 patients. A detailed clinical history, including history of the presenting illness, past history, and other relevant history, is taken, as is a general physical examination, systemic examination, and ENT examination. Investigations like PTA and the subjective THI questionnaire were used in this study to evaluate the efficacy of caroverine and piracetam.

Patients were divided into two groups. One group of patients received Piracetam 800mg BD, and another group of patients were treated with Caroverine 20mg BD. Both groups of patients were followed up for 3 months, and PTA and THI scorings were repeated at the end of the 3rd month, and values were documented.

Study Of Design: prospective, comparative, and follow-up studies

Inclusion Criteria:

1. Patients between 20 years and 60 years of both sexes.
2. Patients with tinnitus of minimum 3 months
3. Tinnitus with SNHL, mixed hearing loss, noise induced hearing loss

Exclusion Criteria:

1. Patients with severe systemic disease.
2. Patients with meniere disease, vestibular schwannoma or cerebellopontine angle tumors
3. Tinnitus occurring due ototoxic drugs 4. Tinnitus occurring due to external ear and middle ear diseases

Table 1 Age Distribution

Variables	Statistics	
	Piracetam group	Caroverine group
Age		
No. of patients	30	30
Mean ± SD	44.60 ± 11.78	41.83 ± 11.99
Median	48.00	40.00

Q1 : Q3	31.5 : 55.0	30.8 : 52.5
Min : Max	24.0 : 60.0	21.0 : 59.0

Inference – There are 30 patients in each group. Caroverine group has age distribution of 24 to 60 years with mean age 44.60 ± 11.78years. Piracetam group has age distribution of 21 to 59 years with mean age 41.83 ± 11.99 years.

Table 2 THI Score Comparison Between The Groups

Variable s	Piracetam group	Caroverine group	Mean Difference	t statistic	95 % CI	P value
Thi score Before Rx			0.40	0.18	(-4.15, 4.95)	0.861
N	30	30				
Mean ± SD	27.27 ± 8.57	26.87 ± 9.02				
Min : Max	08.0 : 40.0	08.0 : 42.0				
Thi score After Rx			4.20	2.05	(0.10, 8.30)	0.045
N	30	30				
Mean ± SD	27.07 ± 7.96	22.87 ± 7.89				
Min : Max	10.0 : 42.0	10.0 : 38.0				

Inference - Improvement in THI questionnaire score in Piracetam group before treatment ranges with minimum to maximum value from 8 to 40 (mean 27.27 ± 8.57) before treatment to 10 – 42 (mean 27.07 ± 7.96) after treatment. Similarly in caroverine group from 8 - 42 (mean 26.87 ± 9.02) before treatment to 10 – 38 (mean 22.87 ± 7.89) after treatment.

Table 3 PTA Comparison Before And After Treatment Between Groups

Variable s	Piracetam group	Caroverine group	Mean Difference	t statistic	95 % CI	P value
PTA Before Rx-Right			-1.00	-0.19	-11.45, 9.45)	0.849
N	30	30				
Mean ± SD	32.35±2.03	33.35±2.04				
Min : Max	9.0 : 82.5	11.5 : 90.0				
PTA Before Rx-Left			-1.00	-0.45	(-12.65, 7.98)	0.652
N	30	30				
Mean ± SD	33.50±1.71	35.84±2.44				
Min : Max	9.0 : 66.3	8.0 : 90.0				
PTA After Rx-Right			-0.61	-0.12	(-11.00, 9.79)	0.907
N	30	30				
Mean ± SD	32.29±2.03	32.90±2.02				
Min : Max	9.0 : 82.5	11.0 : 90.0				
PTA After Rx-Left			-2.54	-0.50	(-12.81, 7.73)	0.622
N	30	30				
Mean ± SD	33.20±1.70	35.74±2.34				
Min : Max	9.0 : 66.3	8.0 : 90.0				

Inference - Two sample t test was performed to compare mean age, Mean Thi score (separately for Before and After Rx), Mean PTA (Separately for Before and After Rx , Left and Right). Only post THI score is significant between Piracetam and Caroverine group.

Table 4 Comparison Of Parameters(Thi and PTA improvement) Between The Groups

Variables	Piracetam group	Caroverine group	Chi square Value	P value
Thi Improvement			2.55	0.312*
Equal	06 (20.0 %)	03 (10.0 %)		
Improvement	13 (43.3 %)	19 (63.3 %)		
Negative	11 (36.7 %)	08 (26.7 %)		
PTA Improvement			0.48	0.488**
Equal	26 (86.7 %)	24 (80.0 %)		

Improvement	04 (13.3 %)	06 (20.0 %)	
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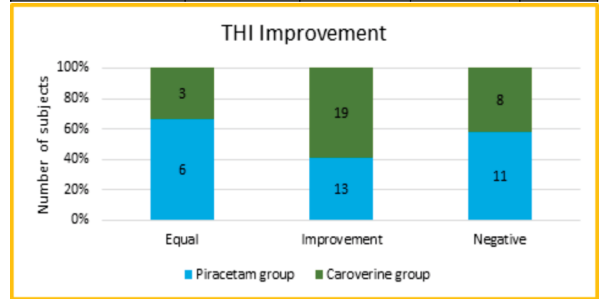


Figure 1

THI scorings- In Piracetam group 13(43.3 %) patients has improvement, 6(20.0 %) has equal, and 11(36.7 %) has no improvement after 3 months.

In Caroverine group 19 (63.3%) patients has improvement, 3(10.0 %) has equal, and 8(26.7 %) has no improvement after 3 months. Which is statistically significant.

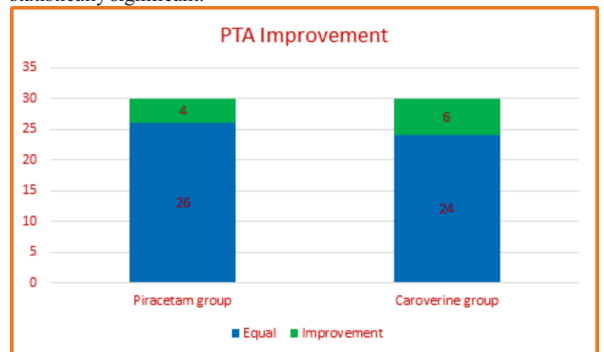


Figure 2

Inference –

PTA – 4 patients has improvement in Piracetam group, 6 patients improved in caroverine group after 3 months. . It was found to be not significant.

* p value is derived from Pearson chi square test

** p value is derived from Fisher's Exact test–

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RESULTS

There are 30 patients in each group. The caroverine group has an age distribution of 24 to 60 years, with a mean age of 44.60 11.78 years. The Piracetam group has an age distribution of 21 to 59 years, with a mean age of 41.83 11.99 years, as shown in Table 1.

The improvement in THI questionnaire score in the Piracetam group before treatment ranges from a minimum to a maximum value of 8 to 40 (mean 27.27 8.57) before treatment to 10 to 42 (mean 27.07 7.96) after treatment. Similarly, in the caroverine group, from 8–42 (mean 26.87 9.02) before treatment to 10–38 (mean 22.87 7.89) after treatment, as shown in Table 2,

A two-sample t test was performed to compare the mean age, mean Thi score (separately for before and after Rx), and mean PTA (separately

for before and after Rx, left and right). Only the post-THI score is significant between the piracetam and caroverine groups, as shown in Table 3.

As shown in Table 4 and figure 1 & 2, in the piracetam group, 13 (43.3%) patients have improved, 6 (20.0%) have equal improvement, and 11 (36.7%) have no improvement after 3 months.

In the Caroverine group, 19 (63.3%) patients have improved, 3 (10.0%) have equal improvement, and 8 (26.7%) have no improvement after 3 months. Which is statistically significant.

PTA: 4 patients have improved in the piracetam group; 6 patients have improved in the caroverine group after 3 months. It was found not to be significant.

* The p value is derived from the Pearson chi-square test.
The ** p value is derived from Fisher's exact test.

DISCUSSION

Abha Kumari et al conducted a clinical study on role of caroverine in the management of tinnitus suggestive of significant improvement was noted in patients with symptoms of tinnitus who treated with caroverine (20mg BD x 3 months) compared to placebo group. THI scoring and tinnitus frequency matching was used to evaluate Subjective relief and objective improvement in patient with tinnitus. Similarly in our study caroverine group has improvement compared to Piracetam group [5].

Shruthi ByranahalliChannarayana Gowda et al Comparative study between caroverine and piracetam in management of the cochlear synaptic tinnitus. study suggestive of significant reduction in THI score, tinnitus frequency and intensity noted after treatment with caroverine which is administered as controlled IV infusion f/b oral route compared to piracetam which was administered orally. So caroverine is effective in treatment of patients with cochlear synaptic tinnitus over piracetam. In accordance with this study our study also found significant improvement in THI scoring in patients treated with caroverine [6].

VijayendraSimha. Net al A Comparative study to determine the efficacy of piracetam over carbamazepine in the treatment of idiopathic tinnitus. Study suggestive of use of piracetam helps in decrease the symptoms of ringing sensation and also improves SNHL in patient with tinnitus after treatment with piracetam compared to carbamazepine. Patients were assessed pre and post treatment using THI (tinnitus handicap inventory) questionnaire and PTA. In this study we compared the efficacy of caroverine with piracetam using THI questionnaire [7].

Doris-Maria Denket al caroverine in tinnitus treatment. Study showed that caroverine is most effective in treatment of cochlear synaptic tinnitus, which shows significant reduction in symptoms of tinnitus in subjective rating and tinnitus matching immediately after infusion and also after 1 week of follow up compared to placebo. Similar results found in our study that caroverine is most effective in management of tinnitus [8].

Klaus Ehrenberger et al Topical administration of caroverine in somatic tinnitus treatment. Study suggestive of non invasive use of caroverine (drug containing cotton strip in contact with tympanic membrane placed in EAC of affected ear) shows effective improvement in patient with menier's and sudden hearing loss associated with tinnitus and its related symptoms. Numerical rating scale (0-10) used for assessment. Reduction of 2 points is considered as improvement. As in accordance with this study our study also shows improvement in patients group treated with caroverine [9].

Ravinder raja et al a clinical study of tinnitus. Study suggestive of significant improvement in ringing sensation and hearing after taking caroverine, Gingko biloba and multivitamin in management of tinnitus. As shows in this study our study used caroverine and piracetam for treatment of tinnitus and symptomatic improvement [10].

Sachin jainet al comparative study of the efficacy of oral caroverine versus oral Gingko biloba in the treatment of cochlear synaptic tinnitus. Study suggestive of Gingko biloba is found to have more

effective in treatment of cochlear synaptic tinnitus for long duration (3 months), is also easily available, cost effective, less adverse effect compared to oral caroverine. In our study also it is found to be significant improvement in caroverine group [11].

Our study shows that there is improvement in patients treated with caroverine compared to piracetam.

CONCLUSION:

In this prospective, comparative and follow up study THI score showed statistical improvement of pre and post treatment in patients treated with caroverine with P value <0.001 at the end of 3 months compared to patients treated with Piracetam, which shows improvement not statistically significant.

There was no difference found in PTA value pre and post treatment in between both the group of patients i.e caroverine and piracetam.

Hence it shows Caroverine was found to be more efficacious drug compared to Piracetam in the treatment of tinnitus and symptoms associated with it.

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