

Comparison of Efficacy of Tinnitus Retraining Therapy versus *Ginkgo biloba* in the Management of Tinnitus.

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ABSTRACT

This study was done to compare treatment options for management of tinnitus (Tinnitus Retraining Therapy, *Ginkgo biloba*), to evaluate the quality of life of individuals who present with tinnitus before and after treatment and to analyse if severity of tinnitus has any implication on its treatment. A randomized prospective study was conducted on patients who presented to ENT outpatient department (OPD) with history of subjective tinnitus in the ear. Complete audiological profile was conducted after thorough clinical examination. Patients were asked to fill Tinnitus Handicap Inventory (THI) on their first visit and then divided into 2 groups for management. One treated with Tinnitus Retraining Therapy (TRT) and the other managed with *Ginkgo biloba*. Their THIs were filled after 1 week, 1 month and 2 months interval to assess the change in their THI scores. Of the 78 patients who participated in the study 19 were lost to follow up. Among the 59 who remained in the study 29 were in TRT group and 30 were treated with *Ginkgo biloba*. Among the 29 in TRT group 2 showed no improvement in THI scores, 1 showed increase in THI scores and 26 showed decline in THI scores. Among the 30 in *Ginkgo* group 1 showed no improvement in THI scores 4 showed increase in THI scores and 25 showed reduction in THI scores. The results obtained conclude that both simplified Tinnitus Retraining Therapy and *Ginkgo biloba* extract have beneficiary effects on reduction of tinnitus prevalence. And simplified TRT has better patient acceptance than *Ginkgo*.

INTRODUCTION

Tinnitus is defined as a perception of a sound without an external acoustic source. People with tinnitus often describe it as a perception of ringing, whistling or buzzing in one or both ears^[1]. It can be persistent, intermittent, or throbbing, depending on the cause. Subjective tinnitus has a neuro-physiological origin whereas objective tinnitus can be generated from vascular, muscular or respiratory sources and also from the temporomandibular joint^[1]. Population afflicted by tinnitus in many cases report consequential changes in quality of life and substantial modifications of behavior, including anxiety, irritability, depression and sleep disturbances.

Studies have shown that the prevalence of tinnitus in the general population appears to be 8–15% and it is suggested that 0.5–1% of the population has tinnitus to such a degree that their possibility of leading a normal life is affected^[2]. Absence of correlation between physical intensity of tinnitus, its acoustic characteristics and reported discomfort led to the use of questionnaire-based assessment methods like the Tinnitus Handicap Inventory (THI)¹. Approaches such as machine-aided acoustic therapies, electro stimulation, psychological therapy procedures, pharmacological therapies such as *Ginkgo biloba* and others, surgical procedures, hyperbaric oxygen

therapy have been made for the treatment of tinnitus^[3]. In this study we are mainly aiming at determining whether tinnitus retraining therapy or *Ginkgo biloba* extract will help in reducing the symptom of tinnitus in patients with chronic idiopathic tinnitus.

Tinnitus Retraining Therapy is one of the approaches for treatment of tinnitus. It involves two components – counseling and sound therapy. It has been said that since the first description of TRT in the 1990s, clinicians have modified and customised the method of TRT to suit their practice and their patients^[4]. While observational studies have reported significantly improved patient outcome after treatment with TRT, a review undertaken in 2000 of TRT studies found no convincing evidence that TRT was superior to other treatments^[2].

Because of these differences and unconvincing results another treatment option considered in this study is the prescription of *Ginkgo biloba* to patients with tinnitus. This constitutes of ginkgolides and bilobalides and a range of flavonoids. In older people, tinnitus occurs most often in conjunction with the hearing problems connected with ageing or it can be associated with general diseases.

MATERIAL AND METHODS

A prospective study was conducted between 1st May 2012 and 30th April 2013.

Inclusion criteria

A total number of 78 patients who presented to ENT outpatient department (OPD) with history of subjective tinnitus in the ear from 1st May 2012 to 30th April 2013 were included in the study.

Exclusion criteria

- Patients with history of vertigo associated with tinnitus.
- Patients diagnosed to have middle ear pathology or external ear pathology.
- Patients with objective tinnitus.

Methods of collection of data

A detailed history regarding the development, severity and previous medications for tinnitus was taken and a thorough clinical examination (ENT) was done. Their proforma was then filled which also included their contact number. To include the patients in the study which was of one year duration, their consent was taken. All the patients who attended the OPD consented to be included in the study. The patients were then asked to fill the Tinnitus Handicap Inventory (THI) to assess the severity of their tinnitus. The patients who were not able to follow English were made to understand and answer the questions of THI in the local language followed by them and so was the procedure in patients who were unable to read (illiterates). Following this, a thorough audiometric investigation was carried out to rule out any pathologic condition causing tinnitus. The patients were then randomly divided into two groups:

Group A who were managed by Tinnitus Retraining Therapy and

Group B with *Ginkgo biloba*.

Patients with severe hearing loss were given hearing aids in addition to the treatment option.

To avoid bias, the patients were not grouped based on their age, severity of their tinnitus or severity of their hearing loss. Post-treatment patient's symptoms were again evaluated using Tinnitus Handicap Inventory Score at 1 week, 1 month, 2 months and 1year after their 1st visit. Data was then analyzed.

Group A

Patients were given a combination of counseling and sound therapy(TRT). But this differed from the original Retraining Therapy where white sound generators were advised to the patients. Wherein in this study, the patients were asked to use accessible sound or music generators such as tape recorders and radios for habituation of the sound and the volume was asked to be set at the level at which their tinnitus would be camouflaged. This was accompanied with a course of counseling of 20 to 30 minutes during their first visit and the subsequent follow up visits. This included the explanation about the mechanism behind their tinnitus development, possible cause, advice about personal coping with tinnitus etc.

Group B

Patients were given 40mg of *Ginkgo biloba* extract to be taken thrice daily.

In case the patients were unable to attend the OPD for their follow up to assess their THI scores, the patients were contacted over phone and their THI scores were taken along with that a short duration of counseling was given.

The data which was collected during their 1st visit and subsequent visits was then assessed by the end of the study and results were tabulated.

RESULTS

A randomized prospective study was conducted between 1st May 2012 and 30th April 2013 to determine the efficacy of TRT and Ginkgo Biloba in the treatment of tinnitus. A total number of 78 patients who walked into ENT Department with complaints of subjective tinnitus were included in the study. Of these, 35 were males and 43 were females. The range of age was between 18 and 79 and most of the patients fell under the age group between 30 and 55. Detailed history regarding development of their tinnitus and previous medications was taken and thorough clinical (ENT) examination was done. None of them had any kind of previous treatment for tinnitus. The average duration of tinnitus ranged between 2 weeks and 10 years. Among the 78 patients, 32 patients had bilateral tinnitus, 25 had tinnitus in left ear and 21 had tinnitus in right ear. Consent was taken from the patients to include them in the study which was of one year duration. They were sent for audiology to assess their hearing ability. The audiogram gave information about the degree and frequency of hearing loss in the patient. Among the 78 patients, 29 had hearing loss and 49 patients had normal hearing. Most of the hearing loss patients had mild to moderate sensory-neural hearing loss mostly in the side corresponding to the side of tinnitus and very few had severe sensory-neural hearing loss. After audiology testing the patients were asked to fill a questionnaire (Tinnitus Handicap Inventory) which contained a total of 25 questions related to the severity of their symptoms and the effects of tinnitus on their quality of life. Their THI scores were then assessed. Among the 78 patients the highest THI score in 1st visit was 92 and the least score was 10. According to THI score prior to treatment, 18% patients had slight handicap, 28% patients had mild handicap, 31% patients had moderate handicap, 15% had severe handicap and 9% had catastrophic handicap. Patients were allotted to Group A or Group B based on the treatment plan. TRT and Ginkgo were given to group A and B patients respectively. Patients with severe hearing loss were given hearing aids in addition to the treatment. The patients of TRT were given a course of Counseling of 20-30 minutes duration to remove fears and anxiety associated with tinnitus which is a part of retraining therapy. Instead of sound generators used in original TRT, patients were asked to use any source of sound or music such as tape recorders, radio etc. for economic reasons, since the patients attending the OPD were of lower socio-economic status and hence could not afford to buy sound generators. The volume of music was asked to be set to the level at which their tinnitus volume was camouflaged. Patients of Ginkgo were asked to take regular medications, 40mg tablet with thrice daily dosage.

The patients of both the groups were asked to come for follow up after 1 week, 1 month, 2 months and one year duration from their 1st visit. During these successive visits thorough clinical examination was done again and their THI scores were taken and the improvement of scores if present was noted. Patients of TRT were given successive counseling during their further visits. Among 78 patients, 19 were lost to follow up and among the 59 patients 29 were in TRT and 30 in Ginkgo group. Among these, 9 patients were lost to follow up under TRT and 10 patients under Ginkgo. This led to inclusion of 59 patients in the study to assess the primary objective of efficacy of different treatment options for tinnitus. These 59 patients included 29 patients under simplified TRT and 30 under Ginkgo treatment.

Among the 29 patients who had regular follow up after Retraining therapy, 2 patients showed no change in their THI scores, 1 patient showed increase in THI score after 1 week which remained the same after subsequent visits, whereas the remaining 26 Patients showed decline in THI scores after simplified TRT, indicating a decrease in subjective handicap produced by tinnitus. Most of the patients exhibited a decline of more than 6 after 1 week and more than 18 after 1 month, when compared to their scores during 1st visit. Among the 30 patients who had regular follow up after Ginkgo treatment, 1 patient showed no improvement in their THI score, 4 patients showed increase in THI score and 25 patient showed improvement in THI scores. Clinically a significant decline in THI scores was observed in patients before and after the treatment with TRT. But statistically there was no significant difference before and after the treatment since the calculated value was less than the tabulated value for paired t test. This may be probably due to the small sample size and short duration of study. Even under Ginkgo there was improvement in patient condition clinically but statistically there was no significant difference before and after the treatment. By the end of the study no significant relationship was found between the presence of tinnitus and other associated problems like Ischemic heart disease, hypertension etc. based on the detailed history taken during their visit.

The quality of life of the individuals could be assessed based on their THI score, whether it was a mild handicap, moderate handicap or severe handicap. And an improvement in quality of life was noted in 26 patients out of 29 on Retraining therapy and 25 patients showed improvement out of 30 who were given Ginkgo extract.

By the end of the study we could also note that, severity of tinnitus had no implications on its treatment as the treatment option and improvement in tinnitus did not vary based on the severity of tinnitus. According to the study, tinnitus was prevalent mostly in the middle aged group people (30-55 years) who are under the influence of constant stress.

DISCUSSION

Tinnitus Retraining Therapy (TRT) reflects the practical implementation of the neurophysiological model of tinnitus. The main principles of the neurophysiological model of tinnitus form the basis for TRT. Specifically,

- The limbic (emotional) and autonomic nervous systems are the primary and dominant systems for the development of tinnitus annoyance while surprisingly, the auditory system plays a somewhat secondary role in tinnitus manifestation,
- The brain demonstrates high levels of plasticity and is capable of habituating to any neutral signal, once negative associations with the signal (i.e. tinnitus) are neutralized,
- Hypersensitivity to sound (hyperacusis) should, and frequently does, coexist with tinnitus.

In practical terms, TRT is a method aimed primarily at habituating tinnitus-evoked reactions of the brain and body, and secondarily, at habituation of tinnitus perception. Consequently, successful TRT patients are not bothered by their tinnitus, even though they are aware of it. Additionally, the amount of time the successful TRT patient perceives tinnitus is decreased.

The two main components of TRT are;

- Educational counseling (which is intensive, individualized and interactive)
- Sound therapy.

Counseling sessions are aimed at the reclassification of tinnitus into a category of neutral signals. The second element of TRT is sound therapy. Constant low level broad band sound decreases the difference between tinnitus-related and background neuronal activity. This in turn decreases the negative reinforcement in the conditioned reflex arcs and permits blockage of the tinnitus signal within the subconscious part of the auditory pathways, i.e., habituation of tinnitus perception^[5]. In this study the counseling used was based on the counseling used in Ealing PCT Audiology Department on simplified form of retraining therapy in adults and this intended to reduce negative associations with the tinnitus, but was shorter in duration and simplified⁴. The duration of the initial counseling was only 20-30 minutes.

The counseling was based on explanation of the nature of tinnitus and how to manage it. Its aims were:

- To reassure patients that the annoyance from tinnitus would gradually reduce with the passage of time following the natural process of habituation;
- To inform them that reduction in annoyance and distress caused by the tinnitus would promote habituation to the tinnitus and reduction of the tinnitus itself;
- In cases of tinnitus combined with hearing loss to explain that if they could not hear properly, this was most likely because of their hearing loss and not the tinnitus; and
- To advise them to avoid silence by using sound enrichment^[4].

The sound therapy used with simplified TRT for each patient category was essentially the same as for TRT, except that wearable sound generators were not recommended, instead accessible sound or music generators such as tape recorders and radios for habituation of the sound was insisted and the volume was asked to be set at the level at which their tinnitus would be camouflaged. According to Hashir Aazhet, al TRT is an established method of treating tinnitus patients and typically results in a decline (improvement) in THI scores of 25 to 35 points after 12-24 months of treatment. Studies on the psychometric adequacy of the THI questionnaire suggest that a decline

in THI score of 20 points or more can be considered as a statistically significant improvement in perceived tinnitus handicap^[4].

Ginkgo biloba extract, is a powerful glutamate antagonist which acts as a strong anti-oxidant within the cochlea, helping to minimize damage caused by free radical build-up but not proven results are demonstrated in tinnitus treatment. Smith et al uncritically lumped together studies of different *Ginkgo biloba* preparations irrespective of their quality and dosage^[6].

This study aimed at comparing the efficacy of simplified TRT and Ginkgo for treatment of tinnitus. The absolute mean reduction in THI score was 12 for simplified TRT and 14 for Ginkgo after 2 months of treatment.

Our results revealed that the THI score declined by approximately 10-20 points under both the categories within 1-2 months of treatment and follow up. Clinically there was considerable decrease in scores but when statistically analysed it did not show any significance. Those who seek help for tinnitus may have more complex tinnitus sounds, higher degree of hearing loss and greater psychological effects than those who do not seek help^[7]. This study indicates that patients of tinnitus were benefitted from the TRT intervention as well as Ginkgo extract for tinnitus. This improvement could already be observed within one month after their 1st consultation in both the interventions.

According to studies done by Claire gudex et.al^[2], HashirAazh et.al^[4], Phillips JS et al^[8] and many other studies, TRT is much more effective as a treatment for patients with tinnitus at a relatively low cost. But a review undertaken in 2000 of TRT studies found no convincing evidence that TRT was superior to other treatments^[2]. At the same time Alexander von Boetticher showed that in the treatment of tinnitus *Ginkgo biloba* had significant superiority of the active treatment over placebo^[9]. Whereas in California a review of pharmacological therapy for tinnitus was done by Patterson MB and Balough BJ which revealed no compelling evidence suggesting its efficacy for tinnitus treatment^[10].

In the present study, in case of retraining therapy the improvement was not only in the reduction of their tinnitus perception but it also made the patients emotionally strong to bare and cope up with their tinnitus and have a better social life because of the counseling given. Apart from these it was more cost effective and convenient for patients than Ginkgo extract. Whereas in patients who were given Ginkgo also showed decreased perception of tinnitus but patients found the medications expensive. Because of the same reason many patients discontinued their medications and were later included under lost to follow up cases (to assess secondary objectives). These findings make a major difference in the Indian scenario, where most of the patients attending Medical College Hospital OPD are of lower socio-economic status and are not capable to take costly medications. At the same time some patients were not cooperative when they were given the treatment with TRT as they felt that there was no actual medication (i.e drugs) given to them for their tinnitus. This led to patients being non-compliant to the treatment. Though both the interventions showed improvement in the patient condition, by the end of the study it was found that TRT was better accepted by the patients than Ginkgo due to economic reasons.

CONCLUSION

From the present study, the results obtained conclude that both simplified Tinnitus Retraining Therapy and *Ginkgo biloba* extract have beneficiary effects on reduction of tinnitus prevalence. And simplified TRT has better patient acceptance than Ginkgo. It also concludes that severity of tinnitus has no implications on its treatment as the treatment option and improvement in tinnitus did not vary based on the severity of tinnitus.

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