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RESEARCH ARTICLE

A COMPARATIVE STUDY ON EFFICACY OF ORAL AND INTRATYMPANIC STEROIDS IN SUBJECTIVE IDIOPATHIC TINNITUS

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Abstract

Background: Tinnitus is a common and annoying symptom caused by an abnormal spontaneous activity from within the auditory system. Corticosteroids is used as an empirical treatment in the oral form or as intratympanic injection for the treatment of this chronic condition.

Aim of the study: To evaluate the efficacy of Intratympanic dexamethasone injection and oral prednisolone in the treatment of subjective idiopathic tinnitus. Materials and Methods: This is an interventional study carried out at Madurai Medical College for a period of one year. A total of 60 patients with subjective idiopathic tinnitus were included of which 30 patients were subjected to Intratympanic Dexamethasone injection and 30 patients were given oral prednisolone. Improvement in the symptom of tinnitus was assessed by means of subjective evaluation with the help of Tinnitus Handicap Inventory (THI) before and after 1 week, 1 month and 3 months of treatment.

Results: There was a significant reduction in the mean THI SCORE and the grade of THI at 1 month and 3 months after treatment with both oral steroids and intratympanic steroids.

Conclusion: Intratympanic steroids and oral steroids can be considered as viable options for the treatment of subjective idiopathic tinnitus although intratympanic steroid is a better alternative as it bypasses the systemic side effects of steroids.

Introduction:-

Tinnitus is an auditory perception caused by an abnormal spontaneous activity from within the auditory system, which could be any altered state of excitation or inhibition. The term “tinnitus” derived from the Latin word 'Tinnire' has the literary meaning “to ring” [1]. It is seen in any age and sex and has a prevalence of 6 to 17%. This sound perception,that can range from a mild annoyance to an exasperating chronic condition, [2] is not a well-defined disease, but a symptom of many pathologies, otologic or non-otologic. It may or may not be associated with hearing loss. Neurologic, metabolic or psychogenic disorders constitute the non otologic causes of subjective tinnitus [3].

Several different options have been described for tinnitus treatment like tinnitus retraining, tinnitus masking, biofeed back therapy, and pharmacotherapy. [3, 4] But still there is a lack of approved treatments for this annoying chronic condition. This could be due to the insubstantial understanding of the pathophysiology of tinnitus or due to the diversity of affected population. [5]

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Corticosteroids have been used as an empirical treatment for various diseases like sudden sensorineural hearing loss (SSNHL), Meniere's disease, and autoimmune-induced hearing loss. These can be given in systemic form or as an intratympanic injection. [6] Intratympanic injection of steroid (Dexamethasone) is used for the treatment of tinnitus by introducing the drug through the tympanic membrane. This results in reduced systemic toxicity and a higher perilymph steroid level. [7,8] The proposed mechanism of action of intratympanic steroids are its anti-inflammatory action, increase in cochlear blood flow and evidence of steroid receptors in the inner ear. [9]

In this study, we evaluate the efficacy of intratympanic injection of dexamethasone and oral prednisolone in patients with subjective idiopathic tinnitus.

Materials And Methods:-

This is a prospective interventional study carried out at Madurai Medical College, Madurai, Tamilnadu, India for a period of one year from March 2021- March 2022. Ethical Clearance was obtained from the Institutional Ethics Committee.

Inclusion and exclusion criteria:

60 patients with subjective idiopathic tinnitus within 15 to 50 years of age were included in the study. Patients having any middle ear diseases were excluded from the study.

All cases underwent a detailed clinical examination which included otoscopic examination, tuning fork tests and otoendoscopic examination. Pure tone audiometry, impedence audiometry, radiological investigations like HRCT Temporal bone was also done.

The impact of tinnitus on patient's life was evaluated using Tinnitus Handicap Inventory (THI). It is a set of 25 questions with the responses - Yes (4 points), sometimes (2 points) and No (0 points). The sum of all the responses is the THI Score. With the THI Score, patient's symptom were graded as Grade 1 to Grade 5 i.e., Grade 1: 0-16 (Slight), Grade 2:18-36 (Mild), Grade 3: 38-56 (Moderate), Grade 4: 58-76 (Severe), Grade 5: 78-100 (Catastrophic). [10]

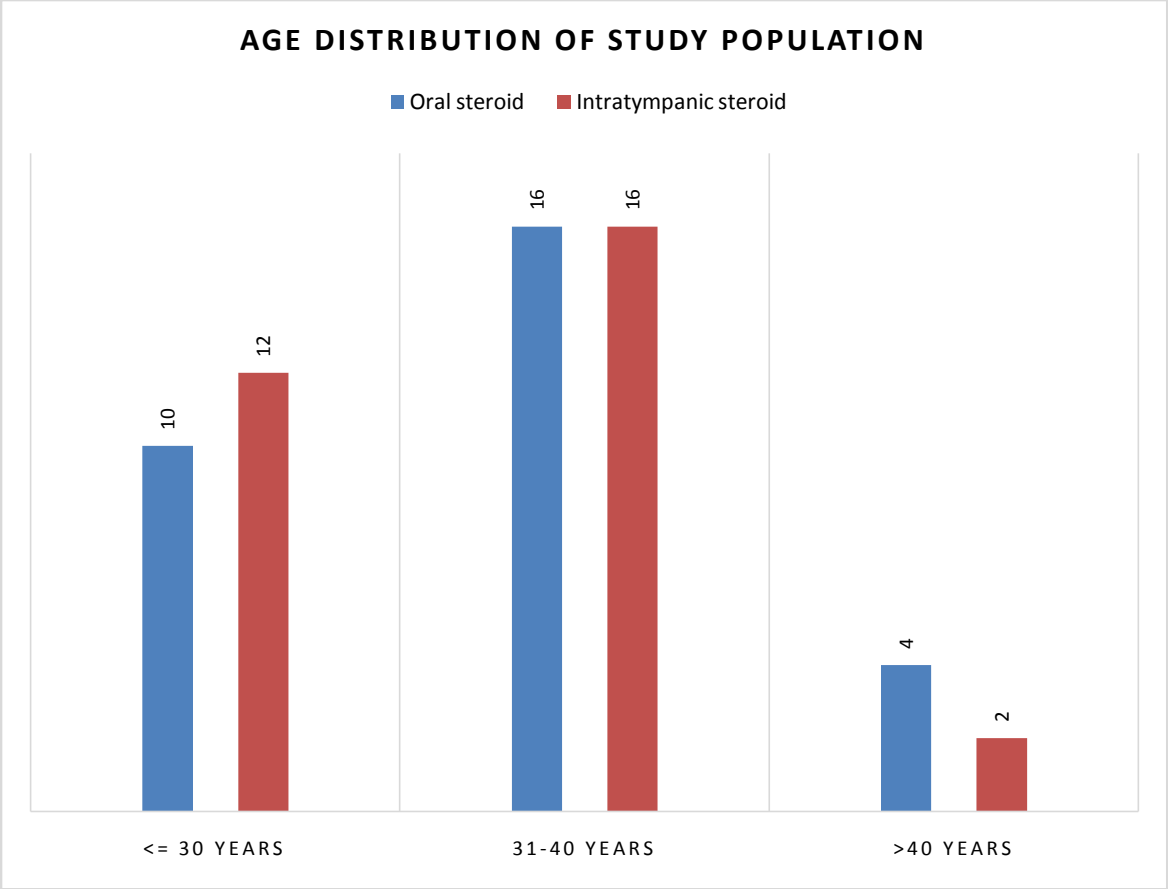
Out of 60 patients of subjective idiopathic tinnitus selected for the study, 30 patients who consented for intratympanic injection of steroids were administered the same. Other 30 patients were given oral steroids.

After complete evaluation, the patients in intratympanic steroids group were taken for intratympanic injection of steroid by endoscopic method under local anesthesia. The patient was placed in supine position with the head turned about 45 degrees away from the surgeon. Topical anesthesia of the external auditory canal and tympanic membrane was done using 10% lignocaine spray. Using a 2 ml syringe and a spinal needle of size 26 gauge, 0.5 ml of dexamethasone solution of dose 4 mg/ml was administered under direct vision using an endoscope in the posteroinferior quadrant of the tympanic membrane. The patient was asked to remain in the same position for about 20 minutes. Patient was asked not to swallow for that time. It helps for longer duration stay of injected steroids in the middle ear. A total of 3 injections were performed, 1 injection per week. THI was again administered after first week, first month and three months of treatment. [6]

Thirty patients received oral prednisolone at a dose of 1 mg/kg body weight for first seven days. It was reduced by half strength weekly and continued for four weeks. THI was administered on first week, first month and at three months of treatment. [11]

Results:-

The study population had a total of 60 subjects of age between 15 and 50 years. Majority of the population belonged to the age group of 31 – 40 years (53.33%) [Table/Fig-1].



Table/Fig 1:- Age distribution of the study population.

There was no sex predilection as male and female population was equal in number.

Over all comparison of the mean values of THI SCORES before treatment and after 1 week, 1 month and 3 months of intratympanic and oral therapy is as shown in Table 2. The mean THI SCORE has been significantly reduced in 1 month and 3 months after the treatment in both intratympanic steroid group and oral steroid group. (Table/Fig 2).

Table/Fig 2:- Comparison of the mean values of THI SCORES before and after treatment in intratympanic steroid group.

	INRATYMPANIC STEROID		**ORAL STEROID**	
	Mean +/- Standard deviation	p value	Mean +/- Standard deviation	p value
PRETREATMENT	50.06 +/- 16.94	-	50.42 +/- 16.22	-
1 WEEK AFTER TREATMENT	43.26 +/- 14.97	0.105	42.49 +/- 14.66	0.121
1 MONTH AFTER TREATMENT	35.73 +/- 12.24	<0.001	36.82 +/- 13.98	<0.001
3 MONTHS AFTER TREATMENT	26.93 +/- 11.33	<0.001	25.28 +/- 12.87	<0.001

Table/Fig 2: Comparison of the mean values of THI SCORES before and after treatment

Student paired t test was used. $P < 0.05$ considered significant

Comparing the values of grades of THI scores before treatment and after 1 week, 1 month and 3 months of intratympanic and oral steroid therapy showed that there was a statistically significant improvement in the grades of THI scores after the treatment in both the groups. (Table/Fig 3).

Table/Fig 3:- Comparison of the mean values of grades of THI before and after treatment.

	INTRATYMPANIC STEROID		**ORAL STEROID**	
	Mean +/- Standard deviation	P value	Mean +/- Standard deviation	P value
PRETREATMENT	3.06 +/- 0.91	-	3.12 +/- 0.88	-
1 WEEK AFTER TREATMENT	2.77 +/- 0.82	0.184	2.85 +/- 0.84	0.22
1 MONTH AFTER TREATMENT	2.33 +/- 0.66	<0.001	2.51 +/- 0.69	<0.001
3 MONTHS AFTER TREATMENT	1.90 +/- 0.61	<0.001	1.95 +/- 0.64	<0.001

Table/Fig 3: Comparison of the mean values of grades of THI before and after treatment
Student paired t test was used. $P < 0.05$ considered significant

Discussion:-

The present study was a prospective interventional study carried out at Madurai Medical College involving 60 patients with complaints of tinnitus. Most of the study patients presented with tinnitus belonged to the age group of 31-40 years. The study by Sayoo et al had 50% of their study sample in the age group of 21-40 years [12]. In the study by Weshahy et al, the mean age was found to be 45 years. [2]

Tinnitus Handicap Inventory questionnaire helped in evaluating the various characteristics of tinnitus [10]. This questionnaire helped to direct towards the diagnosis and also helps to assess the severity of tinnitus to decide on the modality of treatment to be considered. The severity of tinnitus was graded in the questionnaire based on the degree of tinnitus.

There are various empirical treatment modalities that have been tried in patients with subjective idiopathic tinnitus like labyrinthine sedatives, microvasodilators, antipsychotic drugs, neurotropics and antioxidants, antihistamines etc. Other non-pharmacological treatment options includes hearing aids with masking and tinnitus retraining therapy. Apart from all these options, Intratympanic treatment with steroid is an emerging treatment option for idiopathic tinnitus. There have also been few studies which observed the effectiveness of oral steroids in alleviating tinnitus especially when associated with hearing loss. [13, 14] In this study, it was found that after completing three doses of intratympanic injection of Dexamethasone, at the first follow up that is 1 week after the treatment, there was no significant improvement in tinnitus. These results were similar in the oral steroid group also.

At 1 month after the last injection, there was a mild improvement in the tinnitus. At 3 months after the last injection, there was statistically significant improvement in the tinnitus. This was similar to the study by Yener et al which reported that the effect of intratympanic dexamethasone injection in tinnitus patients was statistically significant [15]. The study by Hoda E et al reports that intratympanic dexamethasone injection is a simple and effective treatment where the tinnitus could be markedly decreased and easily tolerated [16].

The study Slattery WH et al has concluded that a 14 da course of oral prednisolone is effective in the treatment of tinnitus associated with idiopathic sudden hearing loss. [17] Evidence based medicine has shown a 50 % recovery, in sudden sensorineural hearing loss and associated symptoms like tinnitus, by oral steroids and placebo. [18]

The advantage of intratympanic steroid injection over oral steroids is that the adverse effects of the systemic administration of the drug can be avoided which makes it suitable to be used in diabetic patients as well [19]. However local side effects may include injection site pain, dizziness, infection, persistent perforation of the membrane. In this study, no significant side effects were noted. Sufficient warming of the drug, the use of fine needles and appropriate local anesthesia, a gentle rate of injection and avoidance of excessive volume of injection are the key factors for good local tolerance.

In this study the improvement in tinnitus which was evaluated by the THI scores and grades, were similar with both intratympanic steroids an oral steroids. This shows that intratympanic steroids is a better alternative to oral steroids while bypassing the systemic adverse effects of steroids.

Conclusion:-

Tinnitus is a disabling symptom that can occur alone or with other disorders such as hearing loss. It is not a disease but a symptom of any possible underlying pathologies. Patients with tinnitus should be evaluated comprehensively and the underlying factors should be determined. In most of the cases, patients present to the hospitals or clinics with tinnitus only when it starts to bother or disturb them.

Different modalities can be taken into consideration in the treatment of tinnitus while keeping in mind the etiological diagnosis and the objective of achieving the greatest clinical relief. Specific medical or surgical methods of treatment should be used when the causes are treatable. The goal of treatment in cases with incurable cause is to lessen the distress brought on by tinnitus by reducing its intensity and thereby raising one's standard of living.

Intratympanic injection of Dexamethasone is considered to be a simple and effective method for controlling Subjective Idiopathic Tinnitus. Tinnitus will be reduced, making it easier for the patient to manage their condition and thereby enhancing their quality of life. In the current study, the treatment efficacy of both Intratympanic injection of Dexamethasone and oral prednisolone on tinnitus severity was found to be similar and statistically significant ($p < 0.001$). There was significant improvement in tinnitus at 1 month and 3 months after treatment. Hence it is concluded that intratympanic steroids and oral steroids can be considered as viable options for the treatment of subjective idiopathic tinnitus although intratympanic steroid is a better alternative as it bypasses the systemic side effects of steroids.

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