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Efficacy of intratympanic dexamethasone injection in tinnitus management

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Abstract

Introduction: Tinnitus, from the Latin tinnire meaning to ring, is defined as the perception of sound without an external stimulus. Tinnitus is generally divided into two groups as objective and subjective. Subjective tinnitus is the most common form of tinnitus and can be detected in nearly 10% of the general population. The objective of our study was to determine the efficacy of intratympanic dexamethasone injection in management of chronic subjective tinnitus.

Materials and methods: A Prospective study was conducted for the patients admitted in the department of Otorhinolaryngology with chronic subjective tinnitus. The patients in study group received intratympanic (IT) steroid dexamethasone injections, once a week for four weeks. Tinnitus handicap questionnaire index (THI) score and tinnitus rating scale were performed before and after the treatment.

Results: Among 60 patients, 30 patients were studied in study group and 30 patients in control group. In the study group, pretreatment THI and post-treatment THI scores at first and three months were statistically significant whereas the same scores were not significant in the control group.

Conclusion: In this study, we found that intratympanic steroid treatment decreased both tinnitus rating scale and tinnitus handicap scores for patients with chronic idiopathic tinnitus. Early intervention, asymmetric hearing loss and unilateral tinnitus seem to be favorable factors for outcome of intratympanic dexamethasone injection.

Keywords: Tinnitus, Dexamethasone, Steroid, Intratympanic, Efficacy.

Introduction

Tinnitus is a disabling symptom that can occur alone or with other disorders such as hearing loss[1] and can be

defined as the perception of sound without an external stimulus[2]. Subjective tinnitus is the most common form of tinnitus and can be detected in nearly 10% of the general population[3]. The most common site for subjective tinnitus is the cochlea but other disorders within the auditory pathway may also be responsible. Among cochlear pathologies, the most common diagnosis includes presbyacusis followed by noise-induced hearing loss and endolymphatic hydrops[4].

Several different options have been described for tinnitus treatment, which include tinnitus retraining, tinnitus masking, biofeed-back therapy, various drug treatments, and more recently, intratympanic (IT) injection therapy[5]. The most frequently used drugs for intratympanic injections are aminoglycoside antibiotics and steroids. Steroids, which have anti-inflammatory and electrolyte modifying effects, are one of the most popular agents used for intratympanic treatment. Intratympanic dexamethasone treatment has been demonstrated as relatively safe compared to gentamicin and lidocaine[6,7]. The therapeutic effect of intratympanic drugs is thought to occur by diffusion through round window, annular ligament of oval window, capillaries, or through the lymphatics of the inner ear[8,9].

Recent literature recommends IT-steroid injection not only as an alternative to oral steroid in vulnerable subjects such as diabetic patients, but also for a salvage therapy after failure of initial therapy[10,11]. The objective of our study was to determine the efficacy of intratympanic dexamethasone injection in management of chronic subjective tinnitus.

Materials and methodology

Study design: A prospective study was conducted for the patients admitted in the department of Otorhinolaryngology with chronic subjective tinnitus. The study was done from January 2021 to March 2022.

Ethical clearance was obtained from Institutional ethical committee prior to the study. A written informed consent was obtained from the patients before their participation in the study.

Methodology

All cases of subjective idiopathic tinnitus meeting the selection criteria were included in the study by random sampling. After a detailed evaluation of the nature and duration of the tinnitus and past medical history, a complete otorhinolaryngology examination was performed in all patients. Also otomicroscopy and audiometric examination, including pure tone audiometry, impedence audiometry was carried out. The patients were also screened for blood cell count, serum electrolytes, glucose, lipid profile and thyroid function tests. Patients with otitis media, meniere's, otosclerosis and patients with sensorineural deafness and systemic diseases like hypertension, hypercholesterolemia, thyroid abnormalities and diabetes mellitus were excluded.

A total of 60 patients (38 males, 22 female) above 18 years of age with a mean age of 42.8 years who had chronic idiopathic tinnitus were included in this prospective study. Patients on medications prescribed for tinnitus were stopped 2 weeks prior to the procedure.

Patients were randomized by simple randomization to two groups, study group of 30 patients and control group of 30 patients to receive intratympanic dexamethasone or the same amount of isotonic solution respectively. The injections were administered once a week for four weeks.

Procedure: Under aseptic precautions, Patients were administered 0.5 mL intratympanic injections of either 4 mg/mL dexamethasone or isotonic solution. Following xylocaine spray application to achieve topical

anaesthesia, the patients were placed supine with their heads turned about 45° to the opposite side. Using a 25-gauge needle, the assigned solution was injected through the posteroinferior quadrant of the tympanic membrane, and the patients stayed in the same position for about 10 minutes.[12]

The patients were evaluated using the tinnitus severity rating scale and Tinnitus Handicap

Questionnaire (THI). THI is a highly reliable test, which is not affected by age, gender, or hearing loss. The test gives clear measurements and can be applied easily. There are three options for each question in the THI: "yes," "no," and "sometimes" with points 4, 0, and 2, respectively. (13, 14) The patients were asked to complete the tinnitus handicap questionnaire and tinnitus rating scale. Pretreatment and post treatment results were compared to assess the efficacy of IT steroid dexamethasone treatment for chronic subjective tinnitus patients.

Statistical analysis: Data were pooled and analysed using Statistical Package for the Social Sciences (SPSS) v20 software.

Results

The study population had a total of 60 patients; all the patients were above 18 years of age. Most of the patients presented with tinnitus belonged to the age group of 31-40 years, with a mean age of 42.8 years. Our study showed male preponderance with 38 (63.3%) patients and female patients in 22 (36.7%) cases.

Patients were randomized into two groups, study group of 30 patients received intratympanic dexamethasone and control group of 30 patients to receive the same amount of isotonic solution.

In the study group, 18 patients had tinnitus on the right ear, 12 had tinnitus on the left. In the control group, tinnitus was right sided in 20, left sided in 10. Only patients with unilateral tinnitus were included in the study. The duration of tinnitus in the study group ranged from 12 to 120 months with a mean duration of 35.28±22.67 months.

According to the tinnitus rating scale scores, 14 patients' tinnitus rating scale scores did not change after IT steroid treatment. After treatment, seven patients gave 3 point, four patients gave 2 points and five patients gave 1 point. For overall patients, there was a statistically significant decrease in tinnitus rating scale scores after treatment ($P < 0.001$). (Table 1).

THI questionnaire helped in evaluating the various characteristics of tinnitus. 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.

The handicap questionnaire given before and after the IT steroid treatment of the patients was evaluated with a score of 100 points. In this survey, 3 answers were obtained as "yes, no, and sometimes". Calculation results were evaluated as, no handicap between 0 and 16, mild handicap between 18 and 36, moderate handicap between 38 and 56, and severe handicap between 58 and 100 points. Accordingly, 9 (30%) patients had mild handicap, 14 (46.6%) patients had moderate handicap, 7 (23.4%) patients had severe handicap, before treatment. After treatment, there was no handicap in 8 (26.6%) patients, mild handicap in 14 (46.6%) patients, moderate handicap in 5 (16.6%) patients, and severe handicap in 3 (10%) patients

Overall comparison of the mean values of THI scores before treatment and after one month and three months of intratympanic therapy is as shown in Table 2. The mean

THI score was significantly reduced from 50.067±16.942 before treatment to 35.733±12.247 in one month and 26.933±11.335 in three months after the treatment. This reduction in THI scores was found to be significant. (Table 2).

The mean pre-treatment and post-treatment at first month and pre-treatment and post-treatment at three months THI scores of the control group were 57.96±24.39, 58.04±22.73, 58.68±23.25, and 56.77±23.13 respectively. The comparison of the THI scores between the groups revealed significantly lower scores at the first and third month in the study group whereas the same scores were not significantly different in the control group. (Table 3).

Table 1: Tinnitus rating scale, before and after treatment of IT Dexamethasone

Scoring (points)	Before treatment	After treatment
1		5
2		4
3		7
4	7	3
5	5	2
6	4	2
7	2	1
8	2	2
9	4	1
10	6	3

Table: 2. Comparison of the mean values of THI grades before and after IT Dexamethasone

Grades	Pretreatment	Post treatment 1 month	Post treatment 3 months
Grade 1	2	2	7
Grade 2	4	17	19
Grade 3	15	10	4
Grade 4	8	1	0
Grade 5	1	0	0
Mean	57.33±24.94	35.733±12.247	26.933±11.335
P value		<0.001	<0.001

Table: 3. Comparison of the mean values of THI grades in study and control group

Mean	Study group (30)	Control group (30)
Mean value Pre treatment	57.33±24.94	57.96±24.39
Mean value after first month	35.733±12.247	58.68±23.25
Mean value after three months	26.933±11.335	56.77±23.13
P value	<0.001	0.655

Discussion

Treatment of tinnitus currently includes hearing aids with masking, tinnitus retraining therapy, and oral medications which have limited efficacy. Intratympanic treatment with various agents is an emerging treatment option for inner ear disorders currently. This treatment has been used in sudden sensorineural hearing loss, Meniere's disease, tinnitus associated with these disorders, and idiopathic tinnitus[8,9,15]. The most important factors that determine the efficacy of the intratympanic treatment of tinnitus is time and drug dose. Intratympanic perfusion time and frequency is one of the key factors determining the effectiveness of treatment[16].

In 1956, Schuknecht first introduced IT aminoglycosides (streptomycin) for the treatment of Meniere's disease. (17) Gentamicin as a treatment for Meniere's disease was later reported by Beck and Schmidt in 1978 and quickly gained popularity because vertigo control was achieved with acceptable preservation of hearing.[18]

The present study carried out was involving 60 patients with complaints of tinnitus. Most of the study patients presented with tinnitus belonged to the age group of 31-40 years. In the study by Shetty S et al., the mean age was found to be 38.6 years[19]. The study by Sayoo C and Kumar S had 50% of their study sample in the age group of 21-40 years[20].

In this study, it was found that after completing four doses of intratympanic injection of dexamethasone, at the follow-up that is one month after the last injection, there was a mild improvement in the tinnitus. At the later visit, that is three months after the last injection, there was statistically significant improvement in the tinnitus.

This was similar to the study by Yener HM et al., which reported that the effect of intratympanic dexamethasone injection in tinnitus patients was statistically significant[12]. 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[21]. Sakata et al.[22] treated 1,214 tinnitus patients with intratympanic dexamethasone injections (ITDI). They found that 77% of the patients' symptoms decreased immediately and 68% after six months. Shim et al. found that IT steroid treatment was effective for both patients with idiopathic tinnitus and acute noise-induced tinnitus.[26]Elzayat et al. presented that adding lidocaine to dexamethasone increased the effectiveness of IT treatment for patients with idiopathic tinnitus.[24] Whereas Araujo MF et al[9] concluded that there was no improvement immediately after last treatment.

In our study, temporary ear pain was seen in 47.8% of patients and self-limited vertigo was seen in 30.4% of patients. This treatment protocol decreases both tinnitus rating scale scores and handicap scores for patients with chronic idiopathic tinnitus patients.

Conclusion

Currently, IT dexamethasone injection treatment of tinnitus requires more evidence provided by randomized controlled trials, but when the therapeutic target is limited to tinnitus in the acute phase, IT steroid injection may be a treatment option worth considering justified on the rational knowledge of mechanism, on the minimal potential for side effects, and on the result of a prospective study which showed a better clinical outcome. Although asymmetric hearing loss and unilateral tinnitus seems to be favorable factors for the outcome with IT steroid dexamethasone injection, patients with bilateral tinnitus or symmetric decreases in hearing thresholds should not be excluded in IT steroid injection treatment.

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