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Intratympanic injection of steroids for treatment of tinnitus

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Abstract
Tinnitus has become one of the most challenging tasks faced by the medical field. It has a moderately negative impact on patient's quality of life. Different methods had been developed in medical science for managing tinnitus but none of these offered a permanent cure.
Objective: This study aims to evaluate the effect of intratympanic dexamethasone (8mg/2ml) injection in the treatment of refractory tinnitus associated with sensorinural hearing loss of cochlear origin.
Methods: Total number of patients involved in this study are thirty patients complaining of tinnitus with sensorineural hearing loss, which were confirmed further by pure tone audiometry. Their ages ranged from 20-65 years with a mean of 42.5 years, Twenty four had unilateral tinnitus and six had bilateral tinnitus, the duration of tinnitus ranged from 3 months to 5 years. Injection was given under otologic microscopic vision and some patients by sinuscope 0 degree through posteroinferior quadrant of tympanic membrane in weekly interval for 4 weeks. The evaluations were done by tinnitus handicap inventory (THI) for all patients befor and in three sessions after intratympanic injection of dexamethasone, first after the end of all injection then at 3 months after injection and 6 months after injection.
Results: Total percent of improvement of tinnitus after dexamethasone injection (76.7%), No improvment (23.3%).
Conclusion: Intratympanic dexamethasone injection could be a simple noninvasive and effective method for the control of subjective tinnitus associated with sensorinural hearing loss.

Keywords: inner ear drug delivery system, steroid targeting therapy, tinnitus, trans tympanic perfusion technique

Introduction
Tinnitus is a common and distressing symptom that is characterized by the perceived sensation of sound without a corresponding external stimulus. Tinnitus can take the form of buzzing, hissing or ringing, or a combination of these. It can be heard in one or both ears, but it can also be referred to the head. Tinnitus can occur continuously, intermittently, or have a pulsatile character [1].
It is derived from the Latin word tinnitus that means to ring. The condition usually is subjective and audible only to the patient. When tinnitus is slight, the patient may not notice the ringing during most of the day, however when tinnitus is continous and loud it can interfere with a person's quality of life and may be so annoying [2].
Although tinnitus is a significant health and economic problem, there are no FDA-approved drugs to treat tinnitus [3].
Shulman, treated tinnitus with intratympanic dexamethasone and obtained control of tinnitus in 50% of cases [4].
In 2002 Cesarani, described 54 patients treated with intratympanic dexamethasone injections, Of these patients, 34% experienced complete resolution of tinnitus, 40% experienced significant improvement, and 26% experienced no change [5].

Patients and Methods
A total number of 30 patients presented with tinnitus associated with sensorineural hearing loss (cochlear origin) attending to outpatient clinic to otorhinolaryngology department, Al azhar University Hospital at Assiut, starting from May 2018 to April 2019.

Patients
They were selected according to the following criteria:
- Both male and female were included.
- All Patients were complaining of tinnitus from 3 months to 5 years duration.
- All Patients had no history of systemic diseases.
- All Patients had no history of otologic surgery.
- All Patients had no history of acoustic trauma or barotraumas.
- All Patients had no history of acute otitis media or chronic otitis media on examination.
- All Patients had no history of ototoxic drug intake.

All subjects the study were submitted to
Full history taking, Otological examination, Pure tone audiometry (PTA), Speech audiometry, Acoustic impedance measurements, ABR to exclude retrocochlear affection in selected patients, Video-nystagmography or Electro-nystagmography in patient presented by tinnitus associated with vertigo to be excluded, C.T temporal bone and MRI in selected patients to exclude vascular tinnitus.

Tinnitus questionnaire (Tinnitus handicap inventory) (THI) (See Appendix A)
It is a self-administered, 25 item questionnaire that is scored on a 3-point scale (No = 0, Sometimes = 2 and Yes = 4). The total THI score is the sum of the scores for the following three subscales; functional, emotional and catastrophic. Based on the total THI score, tinnitus sufferers can be classified into five categories denoting handicap severity: slight handicap (0-16), mild handicap (18-36),

moderate handicap (38- 56), severe handicap (58-76) or catastrophic (78-100) [6]. Befor and after the end of injection and follow up at 3 and 6 months after the injection.

The evaluations were done in three sessions after intratympanic injection of dexamethasone. First after the end of all sessions of injection then at 3 months after injection and 6 months after injection by tinnitus handicap inventory (THI), PTA and Speech discrimination befor and after the end of all sessions of injections.

Materials used during the procedure were otoscope, microscope, 3 ml syringe, cannula needle number 22G, 10% xylocaine in cotton wick, aural speculum. The patients were made to lie supine with the head turned 45 degree to other side and the ear to be treated facing upward. Thorough microscopic examination of the ear to be injected was done. Any debris in external auditory canal was removed. A cotton wick soaked in 10% xylocaine was inserted in external auditory canal and left for 15 min. One milliliter of dexamethasone was loaded in 3 ml syringe and attached to a 22G cannula needle. Cotton wick removed, any remains of xylocaine solution was sucked out. The posteroinferior quadrant of tympanic membrane was focussed in microscope, The cannula needle was then slightly bend by fingers and introduce in the external auditory canal. In all the patients 1 ml of dexamethasone was introduce into the middle ear through posteroinferior part of tympanic membrane. The patient's head was then maintained as such for 30 min to allow concentration of drug in round window. The patients were instructed not to swallow their saliva to prevent escape of drug from Eustachian tube [7].

Statistical analysis

Data were analyzed and expressed in tables and charts using Statistical Package for Social Science (SPSS),categorical variables were described by number and percent (N, %), where continuous variables described by mean and standard deviation (Mean, SD). Compare between continuous variables by t-test and analysis of variance (ANOVA) tests. Continuous variables were tested for normal distribution using Kolmogorove Smirnov test and Q-Q Plots. A two-tailed $p < 0.05$ was considered statistically significant.

Results

Thirty patients complaining of tinnitus with sensorineural hearing loss were the subjects of this study. Their ages ranged from 20-65 years with a mean of 42.5 years and standard deviation of 11.44, Twenty four had unilateral tinnitus and six had bilateral tinnitus, the duration of tinnitus ranged from 3 months to 5 years with a mean of 37.2±21.34.

Table 1: Age distribution of the study samples

	Age (Years)
(Range) Mean ± SD	(20-65) 42.5± 11.44
Age groups: n (%)	
20-35 years	4 (13.3)
36-50 years	10 (33.3)
51-65 years	16 (53.4)

Result of table (1): The prevalence of tinnitus increase with age from 13.3% for persons 20-35 years of age to 33.3% for those 36-50 and 53.4% for those 51-65 years of age.

Table 2: Sex distribution of the study samples

Sex: n (%)	
Male	20 (66.7)
Female	10 (33.3)

Result of table (2): The prevalence of tinnitus more common in male than female.

Table 3: The side of sensorinural hearing loss distribution in the studied sample

SNHL: n (%)	
Bilateral	22 (73.3)
Unilateral	8 (26.7)

Table 4: The side of tinnitus of the study samples

Site of tinnitus: n (%)	
Bilateral	6 (20)
Left only	17 (56.7)
Right only	7 (23.3)

Result of table (4): prevalence of tinnitus more common unilateral (80%) than bilateral (20%) and left side (56.7%) more common than right side (23.3%).

Table 5: Outcome of tinnitus handicap inventory (THI) score of studied sample pre and at the last evaluation post dexamethasone injection

THI	**Pre injection n (%)**	**Post injection n**	
Catastrophic(78-100)	6 (20)	Catastrophic (no improvement)	1
		Sever handicap	0
		Moderate handicap	3
		Mild handicap	2
		Slight handicap	0
Sever handicap (58-76)	16 (53.3)	Catastrophic	0
		Sever handicap (No improvement)	2
		Moderate handicap	9
		Mild handicap	5
		Slight handicap	0
Moderate handicap (38-56)	5 (16.7)	Catastrophic	0
		Sever handicap	0
		Moderate handicap (no improvement)	2
		Mild handicap	2
		Slight handicap	1
Mild handicap (18-36)	3 (10)	Catastrophic	0
		Sever handicap	0
		Moderate handicap	0
		Mild handicap (no improvement)	1
		Slight handicap	2

The results of table (5): Tinnitus patients before injection had mainly severe or catastrophic handicap, but their scores reduced significantly after therapy to be slight, mild, or moderate handicap, Total percent of improvement of tinnitus after dexamethasone (76.7%), No improvment (23.3%).

Table 6: Mean (x), standard deviation (SD) and P level of pure tone average for the studied samples pre and post dexamethasone injection

Pure tone average: Mean ± SD	
Pre injection	45.2±21.7
Post injection	44.3±22.1
P-value	0.877

The result of table (6): There was no statistically significant difference between pure tone average between the study samples pre and post dexamethasone injection.

Table 7: Shows Mean (x), standard deviation (SD) and P level of speech discrimination of the studied samples pre and post dexamethasone injection

Speech discrimination: Mean ± SD	
Pre injection	70.2±24.2
Post injection	70.3±24.1
P-value	0.987

The result of table (7): there was No statistically significant difference for speech discrimination between the study samples pre and post dexamethasone injection.

Discussion

Tinnitus is a common and persistent symptom affecting 10-15% of the population and it varies with each population. Prevalence of tinnitus is much higher than the number of patients who seek treatment. It is often a feature of primary ear disease usually associated with hearing loss but may also occur in subjects with normal hearing [8].

Treatment of tinnitus had been a frustrating situation since the ancient times till date there is no single modality for treatment of tinnitus which can provide complete cure of tinnitus, universally different methods have been developed by different physician as pharmacological, psychotherapy, masking device, electrical and magnetic stimulation, herbal medicine etc., had been tried to various extend but none of these techniqu es provide promising result for the control of tinnitus [9].

Intratympanic dexamethasone perfusion technique, is assumed that the medicine that was introduced directly into the tympanic cavity acts on the plexus tympanicus, is absorbed through the round window, and acts on the inner ear. The mechanism of action of this therapeutic modality is multifactorial, including anti-informatory effect, a metabolic improving effect, an edema-relieving effect, and suppress the irritated or hypersensitive hair cells in the inner ear, which are believed to cause tinnitus [10].

Conclusion

Intratympanic dexamethasone injection could be a simple noninvasive and effective method for the control of subjective tinnitus associated with sensorinural hearing loss, reduction of their handicap and hence improving their quality of life and the best choice for low socioeconomic patients.

Compliance with Ethical Standards

Conflict of interest: The authors declare that they have no conflict of interest.

An approval of Al-Azhar Assuit faculty of medicine ethical committee was obtained before the start of this study,the aim of the study was explained to each participator before collection of data,verbal and written consent was obtained from those who agree to participate in the study.

Privacy of the data was assured.

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