Original Research Article

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A study on the outcome of various methods of administration of intratympanic dexamethasone in tinnitus of cochlear pathology

M. Vivek¹, M. Gowri Shankar²*, N. Ponraj Kumar³, V. Suresh²

Department of ENT, ¹Madras Medical College, ²Stanley Medical College, ³Government Medical College, Government Omandurar Estate, Chennai, Tamil Nadu, India

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*Correspondence:

Dr. M. Gowri Shankar,

E-mail: gowrishankarmurari@rediffmail.com

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ABSTRACT

Background: The aim of the study was to compare the outcome of various methods of injecting intra tympanic steroids in patients with tinnitus of cochlear pathology.

Methods: A prospective study was conducted on 56 patients with subjective tinnitus of cochlear pathology who were then divided into three groups. After thorough otological and audiological evaluation using standard questionnaire, ENT examination, pure tone audiometry, tone decay test, tinnitogram, CT scans of temporal bone and brain. Each patient underwent one of the three chosen methods of intra tympanic steroids administration randomly. The methods are 1-Tympanomeatal flap elevationand application of steroid soaked gelfoam sponge; 2-Transtympanic steroid injection; 3-Grommet insertion followed by steroid administration. These methods were performed for subjects with tinnitus of cochlear pathology from 2009 to 2011 at a neurotological clinic at Chennai. After following up on 1st, 3rd and 6 months the observations were statistically analysed.

Results: Success rate for techniques viz tympanomeatal flap was 70%, transtympanic - 63%, grommet - 50%. But when comparing statistically all the three methods were equally successful.

Conclusions: Intratympanic steroids for tinnitus (cochlear pathology) are a safe, simple and promising treatment option. Though all the methods of intra tympanic steroids injection had similar success rate, the tympanomeatal flap elevation method may be preferred since it can be done in a single sitting. However transtympanic injection remains the easiest and cost effective compared to the other two methods.

Keywords: Subjective tinnitus, Cochlear pathology, Intratympanic steroids, Dexamethasone

INTRODUCTION

Tinnitus has been defined as the conscious experience of a sound that originates in the head of the owner.¹ Subjective tinnitus is characterised by an individual perception of a sound in the absence of any physical sound and of course this cannot be heard by the observer.² The effect of tinnitus on an individual person varies, and the degree of annoyance is not directly related to the perception of tinnitus. Studies have indicated that inescapable and escapable pain involved different lamina of the (PAG) periaqueductal gray and the hypothalamic

midbrain neural circuits.³⁻⁵ Objective assessment of tinnitus is by tinnitogram which is a psychoacoustic measurement which is divided into a pitch-match test, loudness-match test.⁶⁻⁹ The inner ear is found to be immunoresponsive. So the ability to deliver medications to inner ear provides more target specific treatment.¹⁰ First study for intratympanic (IT) steroids for tinnitus was done by Sakata et al which was a retrospective study, reported 75% improvement immediately after treatment.¹¹ Recent animal study done by Lee et al has concluded that intra cochlear concentration of IT steroids is much more than that of the systemic steroids.¹² It has

been described that cochlear damage occurs due to various causes such as ototoxic agents, microvascular ischemia, virus, noise by inflammatory cytokines and reactive oxygen species. ¹³ Anti-inflammatory and immuno suppressive actions of glucocorticoids would help in described conditions. Our study aims at evaluation and managing tinnitus which is subjective, with progressive sensorineural hearing loss (not sudden) and of cochlear type. We have adopted intratympanic medication by dexamethasone, which is one of the efficient method of management as our protocol and compare with its different methods.

METHODS

We did a prospective study on 56 patients who attended Neurotology OPD from 2009 to 2011 at Madras Medical College, Chennai - with subjective tinnitus of cochlear pathology underwent various methods of intra tympanic steroids viz tympanomeatal flap elevation, transtympanic injection, grommet insertion followed by steroid injection.

Patients who had subjective tinnitus with cochlear hearing loss and duration of tinnitus more than three months, age group 20 to 70 years, tinnitus that affects the daily routine, tinnitus with moderate to severe degree of hearing loss, patients with intact tympanic membrane patients willing to return for multiple repeat injections were included in the study.

Patients with age less than 20, greater than 70, patients with otosclerosis or conductive hearing loss and other infectious conditions of external and middle ear, patients with retrocochlear, vestibular pathology, hypertension, diabetes mellitus, thyroid hormone imbalance, patients who are likely to be affected from noise pollution and ototoxic drugs, patients allergic to steroids, patients with other clinical conditions in which steroids are contraindicated, patients not willing for procedure and patients with only hearing ear were excluded from the study.

After a six month of follow up (1st month, 3rd month and 6th month) the values were noted and master chart prepared and statistical analysis done using SPSS 22 version software.

Preworkup procedure

Detailed initial patient assessment with history and the severity of tinnitus is graded accordingly. ¹⁴ Mild - When it only bothers the subject in quiet environment, is not persistent and does not disturb sleep. Moderate - When it is constantly present, occasionally disturbs sleep and interferes with concentration. Severe –When it is constantly present inhibits sleep, prevents concentration and incapacitates the subject.

Patients were asked to fill up the following Tinnitus questionnaire (Annexure-I) both before and after the procedures. 15

General examination, local examination including ENT examination, otomicroscopic examination, temporomandibular joint examination, systemic examination including cardiovascular system, respiratory system, central nervous system, per-abdomen were done routinely.

Investigations such as complete blood count, renal function test, chest X ray, electrocardiogram, pure tone audiometry, impendence audiometry, tinnitogram, special audiological tests, computered tomography and MRI brain (to rule out retrocochlear pathology), Oto acoustic emission, brainstem evoked response audiometry in certain indicated cases were done.

Patient work up such as informed written consent, injection tetanus toxoid intramuscularly started one day before procedure, injection 2% xylocaine test dose were performed.

Accessibility to middle ear can be either of the following procedures

- 1. Direct injection (IM-22G needle) through tympanic membrane (posteroinferior quadrant)
- 2. Tympanomeatal flap elevation and placing gelfoam soaked in dexamethasone 0.5 ml (single sitting) at round window niche.
- 3. Placing grommet in posteroinferior quadrant.

Procedure

Patient positioned and EAC infiltration given and with operating microscope and endoscopic guidance and by accessing the middle ear by previously described methods, intratympanic steroids (Dexamethasone 4 mg/ml) 0.5 ml or 2 mg at 2 weeks intervals for 4 sittings. Patient is instructed to swallow as little as possible to stay still for 15 minutes. Any side effects were noted immediately recorded. Results were analysed on the basis of pre and post treatment audiogram, tinnitogram and with patient questionnaire (2-improved, 1-not improved, 0-worsened). Positive result is considered mainly according to the symptomatic improvement in tinnitus and by other means such as tinnitogram.

RESULTS

Age distribution

Majority cases were in the fourth and fifth decade of life (Figure 1). Among them 20 were male and 36 were female.

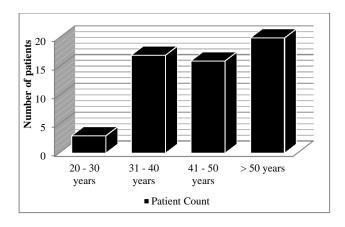


Figure 1: Age distribution.

Tinnitogram comparision

When comparing the pre and post tinnitogram, the reduction in tinnitus in terms of frequency (Hz) is statistically significant to that of the amplitude (dB). However in our study the main outcome measure was done by Tinnitus questionnaire because the Post treatment tinnitogram didn't correspond with the subjective improvement of tinnitus severity (Tables 1-4).

Table 1: Paired sample statistics - tinnitogram frequency.

	Mean	Standard deviation
Pre-treatment tinnitogram frequency (Hz)	2.58	0.989
Post treatment tinnitogram frequency (Hz)	2.38	0.837

Table 2: Paired sample test - tinnitogram frequency.

Wilcoxon signed ranks test	Pre and post treatment frequency (KHz)
Sig (2-tailed)	0.028

Table 3: Paired sample statistics – tinnitogram amplitude.

	Mean	Standard deviation
Pre-treatment tinnitogram amplitude (dB)	43.19	7.241
Post treatment tinnitogram amplitude (dB)	41.96	10.118

Table 4: Paired sample test -tinnitogram amplitude.

Pair 1	Pretreatment tinnitogram - loudness (dB) - post treatment tinnitogram –loudness (dB)
Sig (2-tailed)	0.100

Tinnitus severity distribution

In our study majority patients were having mild to moderate tinnitus (Figure 2).

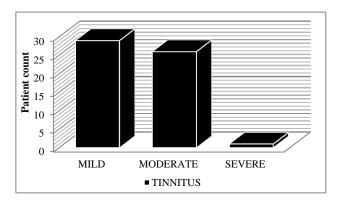


Figure 2: Tinnitus severity distribution.

Frequency distribution among intratympanic steroid group

Among the intratympanic groups transtympanic IT steroid was done in 11 patients, TM flap in 17 patients and grommet in 28 patients.

Frequency distribution of treatment outcomeintratympanic dexamethasone

Out of the 56 patients 33 got improved, 12 were not improved and 11 got worsening of the symptoms (Figure 3).

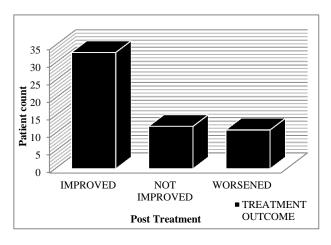


Figure 3: Treatment outcome - intratympanic steroid.

Comparison within intratympanic steroid group (Table 5 and 6)

Success rate for tympanomeatal flap was 70%, transtympanic was 63% and grommet was 50%.

But when comparing statistically all the three methods had the same effect.

Table 5: Crosstab – method of IT steroid vs. results.

IT steroid method		Results		Total (0/)	
		Worsened (%)	Not improved (%)	Improved (%)	Total (%)
Transtympanic	Count% of total	1 (1.8)	3 (5.4)	7 (12.5)	11 (19.6)
Grommet	Count% of total	8 (14.3)	6 (10.7)	14 (25)	28 (50)
TM flap	Count% of total	2 (3.6)	3 (5.4)	12 (21.4)	17 (30.4)
Total count and	% of total	11 (19.6)	12 (21.4	33 (58.9)	56 (100)

Table 6: Chi square test – intratympanic steroid methods.

	Value	Asymptomatic significance (2- sided)
Pearson Chi square	3.398 ^a	0.494

a: 4 cells (44.4%) had expected count less than 5, minimum expected count is 2.16.

DISCUSSION

Intratympanic therapy is becoming an important treatment modality for many inner ear disorders. The current therapies aimed at Meniere's disease, sudden sensorineural hearing loss (SSHL), noise induced hearing loss (NIHL); however intratympanic steroid therapy for cochlear tinnitus represents an evolutionary step in treatment modality. In our study 33 of 56 (59%) patients showed improvement in the outcome; 2 cases had disappearance of tinnitus. Even though it seems that 40-50 years age group responded well for intratympanic steroid therapy but it was not statistically significant. Post treatment tinnitogram was not corresponding with the subjective improvement of tinnitus severity therefore we considered the tinnitus history and questionnaire as the main mode of treatment outcome. Among the three methods of intratympanic steroids which all had equal effects, dexamethasone soaked gelfoam placement is a single time procedure.

One of the previous studies by She et al observed that intratympanic steroid injection has a positive effect on subjective tinnitus and may be considered to be an alternative treatment to subjective tinnitus. ¹⁶ On comparing our study we had a positive effect in the control of subjective tinnitus (59%). Another study by Shulman, Goldstein observed that intratympanic drug therapy with steroid has resulted in both short- and long-term tinnitus relief in 7 of 10 patients (70%) identified to have a predominantly cochlear-type tinnitus. ¹⁷ On comparing our study 33 of 56 (59%) patients showed varying degrees of relief from tinnitus and 2 cases had disappearance of tinnitus.

CONCLUSION

In our study, intratympanic dexamethasone was effective in subjective tinnitus of cochlear pathology. Age and sex of the patients had no influence on the methods of ITS treatment. The three methods of intratympanic dexamethasone (transtympanic, grommet insertion, tympanomeatal flap elevation) methods had equal outcome, noteworthy is the gelfoam soaked with

dexamethasone which is a single time procedure. However transtympanic injection remains the easiest and cost effective compared to the other two methods.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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