

## Original Research Article

# Clinical study to compare the effect of intratympanic injection of lidocaine and dexamethasone in tinnitus of cochlear origin

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### ABSTRACT

**Background:** Due to various aetiologies and the less known mechanism involved in tinnitus no treatment modality gives consistent results. Here, we are comparing the efficacy of intratympanic injections of lidocaine and dexamethasone.

**Methods:** Out of 100 selected patients, consecutive patients who fulfilled the inclusion and exclusion criteria are randomly allocated into one of the 2 study groups (50 members each). Intratympanic injection of lidocaine and dexamethasone are given to respective group weekly for 3 consecutive weeks and response is assessed at 1 month and 2nd month of injection.

**Results:** In our study, maximum patients were in the age group of 56-65 yrs. When the effect of lidocaine and dexamethasone on tinnitus (based on THI-tinnitus handicap inventory questionnaire) is compared, dexamethasone is found to be more efficacious than lidocaine with a p value<0.005. Out of total, 96% of dexamethasone group and 68% of lignocaine group have got improved THI score during second follow up. While assessing the effect of lidocaine and dexamethasone on pure tone audiogram (PTA) it is found that, dexamethasone is showing more improvement when compared to lignocaine (p value<0.05). Regarding the adverse effects of injection, side effect is more with lidocaine (50%) than that of dexamethasone (36%), most common adverse effect which we came across was burning type of pain, followed by giddiness which last only for few seconds.

**Conclusions:** Dexamethasone is effective in reducing the overall THI score hence reduces handicap when compared with that of lidocaine with added advantage on hearing.

**Keywords:** Tinnitus, Lidocaine, Dexamethasone

## INTRODUCTION

Tinnitus has been defined as the conscious experience of a sound that originates in the head of the owner.<sup>1</sup> It is a common symptom among patients coming with ear complaints which may affects the functional and mental status of a person. Prevalence of tinnitus is found to be in direct proportion with that of hearing loss.<sup>2</sup>

Tinnitus has been one of the bugbears of humanity for as long as medical records have been kept: ancient babylonian clay tablets from more than 600 years BC contain multiple references to tinnitus together with

instructions on how to treat the condition using incantations and charms.<sup>3</sup>

Tinnitus is classified as, subjective ie; only be heard by the patient and objective which is heard by the examiner also. Subjective tinnitus is the most common type of tinnitus. Tinnitus can also be pulsatile as we see in some vascular anomalies like glomus tumour and palatal myoclonus.

Various therapeutic modalities are being discussed to treat tinnitus. But, none of the treatment modality gives consistent results. Systemic administration of drugs like

frusemide, caravarine and carbamazepine are notable. Frusemide, a loop diuretic was introduced by Risey et al. in 1995.<sup>4</sup> It was given as intravenous infusion. This drug act peripherally to reduce spontaneous firing of auditory afferents. Caraverine, a papaverine like drug which is a glutamate receptor antagonist was proposed by Denk et al in 1997.<sup>5</sup> Carbamazepine is an antiepileptic drug effective on neural membranes. It was given orally. Use of this systematically administered drug is much limited due to their significant side effects. This has triggered interest in intratympanic administration of drugs.

Here in this study, intratympanic treatment is opted. One of the principle advantages of the intratympanic therapy is the ability to deliver therapeutic concentration of the drug in a highly targeted fashion to the inner ear, thus avoiding systemic side effect.

Our study aims at evaluation and managing tinnitus of cochlear origin which is subjective, with or without sensorineural hearing loss. Here we have adopted intratympanic medication in an attempt to evaluate the efficacy of intratympanic 2% lidocaine and dexamethasone (8 mg/2 ml) in such cases of tinnitus, the outcome being assessed based on THI questionnaire and pure tone audiogram (PTA).

## METHODS

Source of data is from outpatient department of KIMS, Hubli over a period of eighteen months, from 2018 January-2019 September. Detailed history was taken and subjective assessment of the tinnitus was done using THI questionnaire which is an easy method of assessing subjective severity of tinnitus. Then routine ENT clinical examination was performed, aided with PTA and also imaging wherever required.

This is a descriptive comparative study, where a total of 100 patients were selected and studied during the study period. Patients of 16 yrs and above who had tinnitus of cochlear origin were included in the study and those who had suspected retro cochlear disease and those with local aural lesions were excluded. Consecutive patients were randomly allocated into one of the 2 study groups comprising of 50 members each. Intratympanic lidocaine injection was given to first group on weekly basis for 3 consecutive weeks. For second group, intratympanic dexamethasone injection has been given weekly for 3 weeks. Action of dexamethasone on cochlea are reduction of ischemia, increase in blood flow, reduction of inflammation and ability to modify the cochlear ion transport. It is postulated that increase in blood flow occurs 30 seconds after intratympanic injection of steroids.

Lidocaine, is a potent local anesthetic agent, widely used for different purposes all across the world. It acts by inhibiting voltage gated sodium channels without affecting the resting potential of the neuron.

Ethical approval was obtained from ethical clearance committee held in Karnataka Institute of Medical Sciences in 2017.

Following a brief explanation of the procedure to the patient, local anesthesia was achieved by LOX 10% spray. After 2 minutes, excess spray was suctioned off before giving the injection to avoid spillage of the same into the middle ear.

Patient's head was kept in extended position, slightly tilted towards the unaffected ear. Then patient was made in lying down position with head extended and slightly turned to the affected ear for half an hour.

## Statistical tool

Data was entered into microsoft excel and checked for errors. Continuous datas were summarised as mean (standard deviation) and median. Since the results of normality tests were significant for PTA and THI, these variables were tested for differences using various other tests like mann whitney test, chi-square test/fisher's Exact test etc. A p value less than or equal to 0.05 was considered as statistically significant.

## Statistical software

Softwares namely R software ver. 3.1, R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria & MH Program ver. 1.2, Uebersax JS. User guide for the MH program (ver. 1.2). Statistical methods for rater agreement. 2006 are used for analysis of data.

## RESULTS

During follow up period, dexamethasone injection gave better abolition of tinnitus when compared to that of lidocaine. Comparison of effect of lidocaine and dexamethasone in tinnitus shows in Table 1.

Dexamethasone resulted in better improvement of hearing on repeated intratympanic injection. Comparative effect of lidocaine and dexamethasone on PTA shows in Table 2.

Most common type of adverse effect we came across was a burning type of pain followed by transient giddiness. Type of adverse effect with lidocaine and dexamethasone shows in Figure 1.

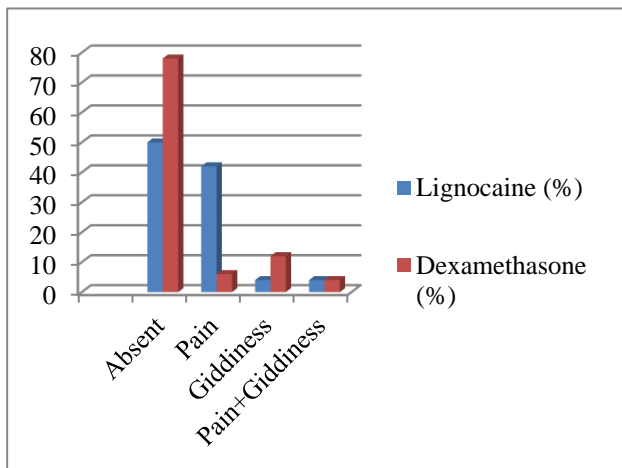
Maximum number of patients belong to the age group of 56 – 65years. Age distribution of patients included in the study shows in Table 3.

**Table 1: Comparison of effect of lidocaine and dexamethasone in tinnitus.**

THI (change)	Groups	N	Mean (SD)	Median (IQR)	Mann-Whitney test
From Pre injection to 1 Month Post injection.	Lidocaine	50	1.6 (6.64)	3 (-4 - 6)	Z =-2.787
	Dexamethasone	50	5.24 (3.7)	4 (2 - 8)	P=0.005 (Sig.)
From Pre injection to 2 Month Post injection.	Lidocaine	50	4.76 (9.11)	6 (-2 - 10)	Z =-4.279
	Dexamethasone	50	12.24 (6.29)	12 (8 - 16)	p<0.005 (Sig.)
From 1 Month Post injection to 2 Month Post injection	Lidocaine	50	3.16 (4.5)	4 (0 - 6)	Z =-3.766
	Dexamethasone	50	7 (4.36)	8 (4 - 10)	p<0.005 (Sig.)

**Table 2: Comparative effect of lidocaine and dexamethasone on PTA.**

PTA (change)	Groups	N	Mean (SD)	Median (IQR)	Mann-Whitney test
From pre injection to 1-month post injection	Lidocaine	50	0.3 (2.63)	0 (-1.75 - 2)	Z = -2.891
	Dexamethasone	50	1.81 (2.66)	1.5 (0 - 3.25)	P = 0.004 (Sig.)
From pre injection to 2-month post injection	Lidocaine	50	1.47 (4.29)	0.63 (-1.75 - 4)	Z = -3.145
	Dexamethasone	50	4.29 (5.1)	4.5 (1 - 6.5)	P = 0.002 (Sig.)
From 1-month post injection to 2-month post injection	Lidocaine	50	1.18 (2.37)	1 (-0.5 - 2.7)	Z = -2.188
	Dexamethasone	50	2.48 (3.39)	1.75 (0.5 - 4)	P = 0.029 (Sig.)



**Figure 1: Type of adverse effect with lidocaine and dexamethasone.**

**Table 3: Age distribution of patients included in the study.**

Age in years	Dexamethasone		Lidocaine		Total	
	N	%	N	%	N	%
16-25	2	4	3	6	5	5
26-35	7	14	11	22	18	18
36-45	14	28	11	22	25	25
46-55	8	16	13	26	21	21
56-65	19	38	12	24	31	31
<b>Total</b>	<b>50</b>	<b>100</b>	<b>50</b>	<b>100</b>	<b>100</b>	<b>100</b>

**DISCUSSION**

Tinnitus is becoming a common auditory complaint nowadays. There are different treatment modalities proposed for tinnitus with varying degrees of success.

Till now no treatment option is found to be fully satisfactory.

In our present study, the effect of lidocaine and dexamethasone on THI was compared, dexamethasone was found to be more efficacious than lidocaine with a p value of <0.005. Dexamethasone started showing improvement in tinnitus by its 1st or 2nd dose whereas lidocaine was having a delayed effect. Out of total, 96% of dexamethasone group and 68% of lidocaine group have got improved THI (tinnitus handicap questionnaire) score during second follow up. This was similar to the study by Antonio Cesarani et al where 74% of the study population had improved with intra-tympanic injection of dexamethasone.<sup>6</sup>

In the current study, the effect of lidocaine and dexamethasone on PTA (pure tone audiogram) was compared, over three time period- Pre injection versus first month follow up, preinjection versus second month follow up and first follow up versus second follow up. In all three-time period, dexamethasone was found to have better effect on PTA when compared to lidocaine with p value 0.004, 0.002 and 0.029 respectively. Yilmaz et al studied intratympanic dexamethasone injection in 40 patients and reported a significant improvement in hearing (based on PTA) which is agreeing with our results.<sup>7</sup>

Regarding the side effect of intratympanic injection, Coles et al in 1992 reported that abolition of tinnitus has been noted in about two-thirds of patients treated with a single or weekly-repeated injection through the tympanic membrane using either dexamethasone or lidocaine and has also stated that dexamethasone had showed only few side-effects, whereas lidocaine had given 5 patients no lasting benefit but violent vertigo for several hours.<sup>8</sup> In

our study, it is concluded that the side effect was more with lidocaine (50%) when compared with that of dexamethasone (36%), the most common adverse effect which we came across was burning type of pain which may be attributed to the preservatives. Giddiness lasted for only a few seconds which had subsided completely with rest without any definitive interventions. Exact mechanism of post injection giddiness is not known, but possible explanations are, irritation of round window by the drug, which makes a micro perilymph fistula on it or it can be because of a caloric response provided the patient is having a semicircular canal fistula (possibility of which is excluded here by the absence of vertigo during every injections).

When we considered the role of age at which the onset of tinnitus is noted, it seems to be variable and not predictable. In our study, maximum patients were in the age group of 56-65 yrs which is almost similar to the study done by Sakata et al. Mean age of patients in our study was 45.84 for lignocaine group and 47.48 for dexamethasone group. According to literature, Sakata et al also stated that, cochlear tinnitus was seen frequently in the age group of 50-60 years of age, a relatively older population.<sup>9</sup>

## CONCLUSION

Hence, we would like to conclude that as far as intratympanic injections are considered, these are safe because it acts locally but having no definitive systemic side effect. In our study, we found that dexamethasone is effective in reducing the overall THI score hence reduces handicap. Even though lidocaine also leads to improvement in THI score, the efficacy is inferior to that of dexamethasone. Also, a positive shift in hearing was noted with intratympanic dexamethasone but not with lidocaine. Hence, this study has helped us to find out a cost-effective remedy for subjective tinnitus using cheap and easily available drugs without much side effect.

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