Section: ENT

Original Research Article

EFFICACY OF INTRATYMPANIC STEROID INJECTION VERSUS 4% LIGNOCAINE IN IDIOPATHIC TINNITUS

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Abstract

Background: Tinnitus is perception of sound without actual stimulus and is a common complaint. It has various somatic and psychological effects that interfere with the quality of life. It affects 7% of population. Even though there are different treatment methods available, there is no definite cure for tinnitus. Various studies have proven that intra-tympanic injection of various drugs have positive effect in those patients with no improvement with conservative treatment. Aim of this study is to compare outcomes of intra-tympanic injection of Dexamethasone with 4% Lignocaine for treating idiopathic tinnitus based on pre-treatment and post-treatment OAE's, THI and VAS. **Materials and Methods:** Eighty patients enrolled for study were randomly assigned to two groups; one group treated with intra-tympanic injection of 4% Lignocaine and second group with Dexamethasone. Pre injection and post injection Tinnitus Handicap Inventory (THI), Visual Analogue Scale (Loudness/ Annoyance) for Tinnitus (VAS-L/VAS-A) and OtoAcoustic Emissions (OAE) were noted. **Results:** The pre-injection THI scores, VAS-L/VAS-A scores and OAE's recorded. Post THI scores, VAS-L/VAS-A scores and OAE's recorded at 30 minutes,1 day and 1 week showed significant reduction in these levels for both groups. But the group treated with intratympanic dexamethasone had much significant reduction in scores when compared to lignocaine group at the end of 1 month. **Conclusion:** Both the drugs are effective in treating tinnitus but in our study comparing the effects of these two treatment modalities, intra-tympanic dexamethasone injection has better results compared to intratympanic 4% lignocaine injection- symptomatically and complication wise.

INTRODUCTION

Tinnitus is a buzzing or hissing auditory sensation in the absence of an external sound. Tinnitus can be either objective or subjective. In objective form real sound is generated by an internal biological activity, such as vascular turbulence or pulsations or spasm of the muscles in the middle ear, Eustachian tube or soft palate. Subjective tinnitus, the most common type and the subject of this review, refers to a phantom auditory sensation with no stimuli. Subjective tinnitus has also been called "tinnitus aurium", "non-auditory", or "non-vibratory" tinnitus.It has various somatic and psychological disorders that interfere with the quality of life. Psychological problems such as depression, anxiety, sleep disturbances, and concentration difficulties are common in those with tinnitus. There is no definitive cure for tinnitus. Vestibular sedatives, vasodilators, neuro-stimulants, nutrients and vitamins, centrally acting drugs can be used for medical management. Surgical treatment options include neurectomy/labyrinthine ablative procedures. Psychotherapy and rehabilitative measures also play a role in treatment. There are oral, parenteral and intratympanic routes for drug administration. Oral route has poor bioavailability. Intravenous route has systemic complications with narrow safety window and needs strict monitoring. Intra-tympanic route directly delivers drug into the target site and is absorbed by diffusion. Dexamethasone is a long acting glucocorticoid with anti-inflammatory, anti-edema effect and studies prove that dexamethasone acts by suppressing irritability or hypersensitivity of the sensory cells in the inner ear due to damage of cochlear hair cells, reduction of the inflammation caused by immune-mediated or autoimmune dysfunction in the inner ear, increase of inner ear vascularity, and/or direct effects on the inner ear neuroepithelium .Lignocaine is a local anaesthetic drug with voltage-gated sodium channel blocking property which helps in treating tinnitus. In our study we are aiming at comparing the

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efficacy of these two drugs against each other and observing the effectiveness of one over the other in managing tinnitus.

MATERIALS AND METHODS

Study was approved by the local ethics committee and conducted in accordance with the ethical principles. Written informed consent was obtained from all participants before the study. Eighty patients belonging to age group 20-50 with tinnitus for more than a year not responding to medical treatment at Government Coimbatore medical College and hospital were enrolled for the study from April 2021 to April 2022. These patients were randomly allocated to two groups of 40 members each. Exclusion criteria included patients with proven sensorineural hearing loss/on hearing aids, patients who respond to conventional treatment, patients with objective tinnitus, persons with other co-morbidities like Hypertension, CAD, thyroid disorders, arrhythmias, COPD, diabetes mellitus, chronic renal or hepatic disease cancer, hypercholesterolemia, obesity, bleeding diathesis, autoimmune disease, patients with contraindication to fore-mentioned drugs used in study. Patients with tinnitus not responding to drugs are thoroughly evaluated, detailed history, complete clinical examination including vitals recorded and examined for any primary ENT pathology. Audiological evaluations like pure tone audiometry (tinnitus frequency identified), Impedance audiometry, Otoacoustic emission (OAE) (including the tinnitus frequency measured) were measured. Temporal bone and brain imaging were done using high resolution CT to rule out organic inner ear /auditory/brainstem pathology. Basic baseline investigations like complete blood hemogram, coagulation profile, urine routine and microscopy, random blood sugar estimation, renal function test, thyroid profile, ECG, Chest X ray were done. Pre-injection scores of the tinnitus handicap inventory (THI, 0–100, higher number for greater handicap) to evaluate the quality of tinnitus and reported scores on visual analogue scale (VAS, 0 indicating no tinnitus, 10 indicating the worst imaginable degree of tinnitus) to evaluate its intensity. The ear to be injected depends on audiological report or patients' choice. From the bags of numbered double blinded drug covers (containing one of the two drugs – 4% lignocaine or dexamethasone) one bag is chosen for the patient. Injection done under microscopic guidance with or without local anesthesia. Patient is put in supine position and using operating microscope and aural speculum tympanic membrane visualized. Using loaded syringe (1cc) the drug is injected into the postero-inferior quadrant into the middle ear. Patient is advised to lie on the same position for an hour and not to strain/blow forcefully for a day (24 hours minimum). Patient is monitored for an hour for any vertigo or other immediate reactions. Tinnitus handicap inventory (THI, 0–100, higher number for greater handicap) to evaluate the handicap of tinnitus and visual analogue scale (VAS, 0 indicating no tinnitus, 10 indicating the worst imaginable degree of tinnitus) scores recorded to evaluate its intensity. A 30% reduction on the THI scale and a 50% reduction in VAS scores were considered clinically significant. THI and VAS scores were recorded immediately before the infusion, 30 minutes after injection, on Day 1, week 1 and a month after the injection. Otoacoustic emissions (DPOAEs) were also measured during the same interval. Analysis of THI, VAS and OAE will be done and p value is noted to compare if there is any statistical significance.

RESULTS

Present study includes 80 patients randomly divided into two groups, totally there were 46 males and 34 female patients., of which 40 were allotted to each group, including 23 males and 17 females in each. In our study maximum number of patients, 31patients (38.75%) were reported in age group 40- 50 and least number of patients in age group 30-40 years(17 patients-21.25%). In this study, intra-tympanic injections were given only in one ear (pathologic ear / ear with worse symptom in bilateral problem). Of the ears injected total of 48 injections were done in right ear (60 %) and 32 injections were done in left ear (40 %).

The mean pure tone averages of dexamethasone and lignocaine group were 23.91dB and 24.36 dB respectively. The median pure tone averages for dexamethasone and lignocaine group were 23.3 dB and 25dB respectively. The mean tinnitus frequencies of dexamethasone and lignocaine group were 1.88 kHz and 1.92 kHz respectively. The median tinnitus frequencies and modes for dexamethasone and lignocaine group were 2 kHz and 2 kHz respectively. The mean tinnitus intensity levels of dexamethasone and lignocaine group were 25.14 dB and 27.63 dB respectively. The median tinnitus intensity levels and modes for dexamethasone and lignocaine group were 25 dB and 25 dB respectively. The mean Pre injection THI scores of the dexamethasone and lignocaine group were 64.78 ± 10.86 and 64.94 ± 10.75 respectively. No statistical significance was observed at 30 minutes' post-injection between the THI scores of both the groups'- gender wise, but comparing the total population of each group the difference is statistically significant (p-value<0.001) at 30 minutes post injection. Gender-wise and total population THI scores post injection at 1 day,1 week and 1 month were statistically significant(p-value<0.001) amongst two groups. THI score has significant reduction in case of post injection 1 month from the pre-injection scores in dexamethasone group but in lignocaine group an increase in score was obtained at the end of 1 month (see Table 1).

The mean Pre injections Visual Analogue Scale for Tinnitus (VAS - L/VAS - A) scores of the

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dexamethasone and lignocaine group were 7 ± 1.01and 7.03 ± 0.97 respectively. There was no statistical significance noted at 30 minutes, 1day and 1 week post-injection between the VAS - L/VAS - A scores of both the groups'- gender wise and in total. But there is a statistically significant reduction in post injection 1-month VAS - L/VAS - A score dexamethasone group compared to lignocaine group. Also, there is a significant reduction in VAS - L/VAS - A score of post injection 1 month from the pre-injection scores in dexamethasone group. But in lignocaine group VAS - L/VAS - A scores reduces at 30 minutes, day one and week one but increases at 1-month post injection. (See Table 2).

The Distortion Product OtoAcoustic Emission values recorded for patients in both the group showed following features (1) The signal to noise ratio was completely absent or low (6, "pass" criteria) with positive recordings in the tinnitus frequency both for Dexamethasone and Lignocaine group. (4) The DPOAE recorded at 1-month post injection showed "pass" criteria for dexamethasone group in all frequency but in the lignocaine group it was "refer" criteria at tinnitus frequency for most patients, with los normal values for others. Other than the recordings mentioned above, four patients had acute severe vertigo immediately following lignocaine injection.

Table 1: Tinnitus Handicap Inventory(THI)

Variable			Dexamethasone group	Lignocaine group	P value
Male	Pre-injection		65.9 ±10.17	67.5±11.35	0.64
	Post-injection	½ hour	42.4 ± 6.14	51.8 ±10.42	0.00154
		Day 1	38.8 ± 5.21	50.6 ±10.32	<0.001
		Week 1	34 ± 6.93	52.8 ±11.58	<0.001
		Month 1	35 ± 10.21	66.4 ±10.27	<0.001
Female	Pre-injection		63.38 ± 11.86	61.75 ±9.52	0.67
	Post-injection	½ hour	42.25 ± 5.65	50.75 ±7.55	0.00121
		Day 1	39.25 ± 6.23	49.5 ± 7.71	<0.001
		Week 1	36 ± 7.59	51.63 ±7.46	<0.001
		Month 1	31.63 ± 14.54	62.25 ±9.18	<0.001
Total	Pre-injection		64.78 ± 10.86	64.94 ±10.75	0.94
	Post-injection	½ hour	42.33 ± 5.85	51.33 ± 9.15	<0.001
		Day 1	39 ± 5.61	50.11 ± 9.15	<0.001
		Week 1	34.89 ± 7.15	50.28 ± 9.85	<0.001
		Month 1	33.5 ± 12.25	64.56 ± 9.89	<0.001

Table 2: Visual Analogue Scale for Tinnitus (VAS - L/VAS - A)

Variable			Dexamethasone group	Lignocaine group	P value
Male	Pre-injection		7.1 ± 1.21	6.85 ± 0.88	0.46
	Post-injection	½ hour	1.95 ± 0.76	1.45 ± 1.32	0.15
		Day 1	1 ± 0.92	1 ± 0.86	1
		Week 1	1 ± 0.73	1.65 ± 0.93	0.0189
		Month 1	1.35 ± 0.88	5.8 ± 1.28	<0.001
Female	Pre-injection		6.88 ± 0.72	7.25 ± 1.07	0.25
	Post-injection	½ hour	2.13 ± 0.89	2.13 ± 1.15	1
		Day 1	0.75 ± 0.86	1.63 ± 1.20	0.0252
		Week 1	0.63 ± 0.81	2.38 ± 1.20	<0.001
		Month 1	1.19 ± 1.05	5.94 ± 1.57	<0.001
Total	Pre-injection		7 ± 1.01	7.03 ± 0.97	0.91
	Post-injection	½ hour	2.03 ± 0.81	1.75 ± 1.27	0.27
		Day 1	0.89 ± 0.89	1.28 ± 1.06	0.096
		Week 1	0.83 ± 0.78	1.97 ± 1.11	<0.001
		Month 1	1.28 ± 0.94	5.86 ± 1.40	<0.001

DISCUSSION

Tinnitus, the phantom perception of sound, represents a highly prevalent and distressing condition. Although most cases of tinnitus derive from deprivation of auditory input, it goes beyond the classical definition of an otologic illness, since it encompasses a range of symptoms that are likely to place a huge burden on patients and significantly impair quality of life.[5] This can include irritability, agitation, stress, insomnia, anxiety, and depression. In fact, for one in 100 adults, tinnitus affects their ability to lead a normal day-to-day life.[6] The generation of tinnitus have been linked to damage to the central and peripheral auditory systems, even in cases where an impairment could not be detected by audiometry.[7-9] The numbers of patients suffering from tinnitus are increasing day by day and those patients seeking medical advice to alleviate this problem is increasing geometrically across the globe. The treatment of choice for tinnitus is retraining therapy,[10] but there is a group of patients who does not get sufficient alleviation with it. Certain similarities exist between tinnitus and chronic pain,[11] and they can be ameliorated with the same pharmacological agents, such as steroids, tricyclic antidepressants,[12] anticonvulsants,[13] and the local anaesthetic lignocaine at anticonvulsant doses.[14] In our study we used dexamethasone, a corticosteroid and lignocaine, an anti-arrhythmic/local anaesthetic

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agent intra-tympanically to avoid systemic complications and for dose effectiveness. There is no significant age or gender based association between the study population and tinnitus occurrence nor did it affect the study outcome. Both the ears are equally affected by tinnitus with no side predilection in the study population. The THI scores of the dexamethasone group drastically reduced from the pre-treatment scores (with a statistical significance) with no increase in the post injection 1 month scores compared to that of lignocaine group, where there was an increase in THI score at 1 month post injection implying that with time the effect of lignocaine injection tends to wane off, which may be faster than dexamethasone injection. This was similar to the study by Antonio cesarani et al,[15] where 74% of the study population had improvement of symptoms following intra-tympanic injection of dexamethasone. The VAS-L/VAS-A scores of the dexamethasone group has also reduced in accordance with the THI scores with sudden fall after 30 minutes post injection with gradual fall with time with a statistical significance. Whereas in lignocaine group the scores decreased post injection but had a rise after 1 month, which implies unconvincing effect after a month with lignocaine injection. This was similar to the study by Laurikainen EA et at,[4] where lignocaine effects wane off after hours to days post injection. The OAE recordings at the above mentioned interval also shows that there is positive response at tinnitus frequency from "refer" criteria to "pass" criteria with most patients in dexamethasone injection, but only with very few such response in lignocaine group. It implies that the drugs act at a cellular level similar to the study conducted by R. Salvi et al.[3] Finally, there were few complications with the intratympanic injection, which was mostly following lignocaine injection. Four patients had severe vertigo, settled following vestibular sedatives administration. No other untoward complications recorded.

CONCLUSION

The present study shows that among intratympanic injections of dexamethasone and lignocaine used for treatment of idiopathic tinnitus, with the available data from the study dexamethasone injection has a favourable outcome than lignocaine (with statistical significance) and prolonged effect without any complications. Although both the drugs act at molecular level the exact mechanism and site of action is yet to be researched upon for better targeted treatment modalities

Conflicts of Interest Statement

We hereby declare that we have no financial interests or personal conflicts that may affect the study in this article.

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