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TO EVALUATE THE EFFECTIVENESS OF INTRATYMPANIC STEROID INJECTIONS IN SUDDEN SENSORINEURAL HEARING LOSS

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ABSTRACT

Sudden sensorineural hearing loss (SSNHL) is a rapid-onset condition characterized by unexplained hearing loss, often occurring within 72 hours. The aim and objectives of the study to evaluate the effectiveness of Intratympanic Steroid (Methyl Prednisolone) Injections in Sudden Sensorineural Hearing Loss. The objective of the study to check the safety and tolerability of Intratympanic Steroid (Methyl Prednisolone) Injection in Sudden Sensorineural Hearing Loss. The study was designed a Prospective, Comparative, Observational, Single Centre Study, it conducted in the deprtment of ENT at Medicover Hospitals, Hitech city, Hyderabad, in the periodof 6 months with population size was 25 patients. The result of the study on 25 population has Analysis by Intratympanic methylprednisolone (40 mg/ml), administered as 0.5 ccf via direct injection into the middle ear once a month for three consecutive months, patient-based outcomes revealed that 22 patients (88%) showed significant hearing improvement, while

3 patients (12%) showed no improvement. The procedure was well-tolerated, with minimal and transient side effects such as mild pain at the injection site (3 patients, 12%), dizziness (3 patients, 12%), and ear fullness (3 patients, 12%), while 16 patients (64%) reported no adverse effects. The study concludes that Intratympanic methylprednisolone injection is an effective, safe, and well-tolerated treatment for SSNHL, providing significant improvement in hearing outcomes with minimal adverse effects, and can serve as a primary or salvage therapy in the management of SSNHL.

KEYWORDS: SSNHL, Allergic rhinitis, Intratympanic methylprednisolone, Ear, 72 hours and prospective.

INTRODUCTION

1. INTRODUCTION ON SUDDEN SENSORINEURAL HEARING LOSS

Sudden sensorineural hearing loss (SSHL) is defined as an abrupt start of loss in hearing that is more than 30db of hearing loss in at least 3 consecutive audiometric frequencies appearing in 72 hours or less, SSNHL can present as unilateral or bilateral; Unilateral being most common.[1] The most common type of hearing loss was NHL, accounting for 3935 cases (39.3%)**.** Among these, 1436 cases (36.5**%)** were USNHL, and 872 cases (60.72%) had USNHL with the other ear being normal, forming the study group. This represented 8.72% of the 10,000 PTA cases and 22.16% of SNHL cases. The age of the patients ranged from 8 to 76 years, with a mean age of 39.5 years, and the male-to-female ratio was 1.6:1. Both ears were almost equally involved. Regarding severity, 35.6% of cases had profound hearing loss (>90 dB)**,** followed by 32.1% with mild hearing loss (25–40 dB).[2]

ETIOLOGY

The exact etiology and pathology of idiopathic sudden sensorineural hearing loss (ISSNHL) remain unknown. However, several vascular mechanisms have been proposed as possible contributors are Vascular Impairments, Cochlear Ischemia, Labyrinthine Artery Insufficiency and Inner Ear Damage.[3]

Understanding this arterial anatomy is crucial for addressing vascular-related ISSNHL.[4]

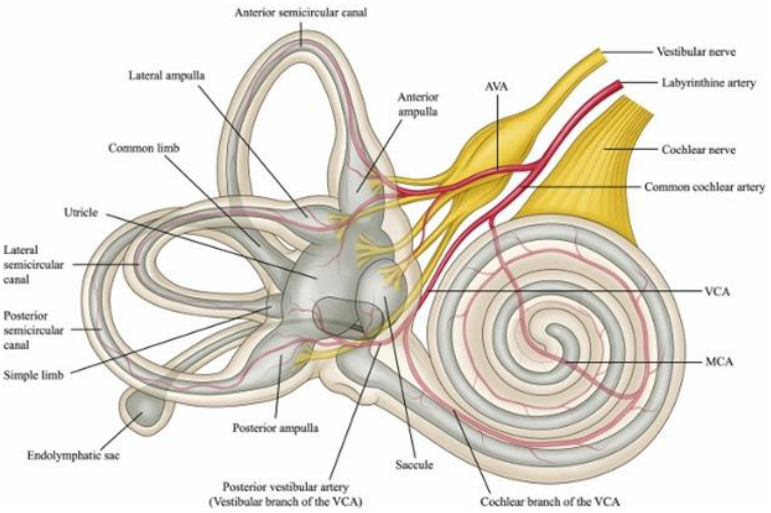

Fig. 1: Arterial anatomy and innervation of the inner ear.[5]

RISK FACTORS

Risk factors for ischemic vascular disease, including cigarette smoking, hypertension, and hyperlipidemia, are risk factors for the development of idiopathic SSNHL, although others have found no association of these risk factors with idiopathic SSNHL.

DIAGNOSIS

The diagnosis is primarily clinical, clinical history audiometric evaluation, Tuning fork tests, Weber test, Rinne test, Magnetic Resonance Imaging (MRI), Hearing Ability in the Healthy Ear, $CHADS_2$ Score, Auditory brainstem response testing (ABR), cerebellopontine angle (CPA), internal auditory canal (IAC), MRI, electronystagmography (ENG) and Framingham risk score.

TREATMENT

The treatment of sudden sensorineural hearing loss (SSNHL) remains one of the most critical and debated issues in the field of otorhinolaryngology. Among available therapies, steroid treatment has emerged as the mainstay intervention, with various administration routes under evaluation for efficacy and safety. the treatment of idiopathic SSNHL including antiinflammatory agents, antimicrobials, calcium antagonists, vitamins, essential minerals, vasodilators, volume expanders, defibrinogenators, diuretics, hyperbaric oxygen, and bedrest.[6]

2. INTRODUCTION ON INTRATYMPANIC STEROID INJECTIONSANATOMY AND PHYSIOLOGY OF THE EAR RELEVANT TO INTRATYMPANIC DRUG DELIVERY

The drug delivery by the Tympanic Membrane, Middle Ear, Internal Ear and Intratympanic Drug Delivery and Clinical Implications.

MECHANISM OF ACTION

Intratympanically administered steroids primarily enter the scala tympani through the round window membrane (RWM). However, a significant proportion of the drug is lost via drainage through the Eustachian tube into the pharynx, thereby reducing the amount available for cochlear absorption. The RWM is a semi-permeable trilaminar membrane, comprising an outer squamous epithelial layer facing the middle ear, an inner mesothelial layer contiguous with the scala tympani, and a connective tissue core. Sterile aqueous suspension marketed as Depo-Medrol® 40 mg/mL, which contains methylprednisolone acetate a synthetic corticosteroid with potent anti-inflammatory and immunosuppressive properties.[7]

COMPLICATIONS OF INTRATYMPANIC STEROID INJECTIONS

There are some potential complications or side effects that must be considered and thoroughly discussed with the patient before undergoing the procedure. The complications of ITI include transient dizziness, injection pain, a burning sensation, increasing tinnitus, post-injection vertigo, tongue numbness, and a small perforation of the eardrum.[8, 9]

3. INTRODUCTION ON METHYLPREDNISOLONE

Methylprednisolone Acetate Injection I.P., a sterile aqueous suspension marketed as Depo-Medrol® 40 mg/mL, which contains methylprednisolone acetate a synthetic corticosteroid with potent anti-inflammatory and immunosuppressive properties. Methylprednisolone is an FDA-approved medication used for managing and treating various conditions, including allergic reactions, arthritis, asthma exacerbations, long-term asthma maintenance, and acute exacerbations of multiple sclerosis.[10, 11]

PHARMACODYNAMIC PROPERTIES

The pharmacodynamics of exogenous corticosteroids may show temporal variations. The susceptibility of the hypothalamic-pituitary-adrenal axis to suppression in humans, as measured by 17-hydroxy-corticosteroid excretion, varies within the circadian cycle. When

exogenous corticosteroids are administered between the hours of 8 AM and 4 PM, the hypothalamic-pituitary-adrenal axis suppression is either minimized or absent altogether.[12,13]

PHARMACOKINETIC PROPERTIES

Pharmacokinetics of methylprednisolone (MP) is a intravenous doses of 20, 40 and 80 mg methylprednisolone sodium succinate (MPSS) and an oral dose of 20 mg methylprednisolone as 4 x 5 mg tablets. Pharmacokinetic properties are local absorption and distribution, duration of action and systemic exposure as per The mean values (+/- s.d.) of half-life, mean residence time (MRT), systemic clearance (CL) and volume of distribution at steady state (Vss) of MP following intravenous administration were 1.93 +/- 0.35 h, 3.50 +/- 1.01 h, 0.45 +/- 0.12 lh-1 kg-1 and 1.5 +/- 0.63 1 kg-1, respectively.[14]

AIM AND OBJECTIVE

The aim and objective To evaluate the effectiveness of Intratympanic Steroid (Methyl Prednisolone) Injections in Sudden Sensorineural Hearing Loss.

METHODOLOGY

The study design is a Prospective, Comparative, Observational, Single Centre Study. It was conducted study site at Department of ENT at Medicover Hospitals, Hitech city, Hyderabad. The duration of the study was conducted for a period of 6 months. It was approved by the Institutional Ethical Committee of Medicover Hospitals, Hitech city, Hyderabad. The sample size of a population in research study has performed with 25 patients. The volunteers are enrolled in the study based on criterias such as inclusion criteria are Sudden sensorineural hearing loss of at least 30 dB in three consecutive frequencies, initiating within a 72 hours, No previous treatment had been received, Unilateral hearing loss and Patients Aged >18yrs to <60yrs and exclusion criteria there are Acute or chronic otitis media, Previous otologic surgery, Trauma and Meniere's disease or history of fluctuating hearing. The study was statistically used on microsoft word by using tables, figure, pie diagrams and sum of calculation of percentage yield while followed a 23.0 version software.

RESULTS

A Prospective observational study was undertaken to evaluate the effectiveness of Intratympanic steroid injection in treating SSNHL among patients seeking care in out-patient settings, alongside an investigation into the prevailing treatment patterns. This research study aims to evaluate the effectiveness of Intratympanic steroid injection in treating SSNHL. The

data was extensively collected from the patients with SSNHL presented to out-patient, from Medicover Hospital, Hi-Tech City, Hyderabad.

Over the course of study, a total of 25 patients prescribed with Intratympanic steroid injection were observed. This study was done for 6 months. The data was collected from ENT department of Medicover Hospital, Hi-Tech City, Hyderabad. We will be considering 25 patient's data while analyzing the results to evaluate the effectiveness of Intratympanic steroid injection in treating SSNHL.

The following results were observed from this study.

Table 1: Distribution of patients according to age group.

Age Group	No. of Patients	Percentage of patients(%)
30-39	8	32
40-49	7	28
50-59	6	24
60-69	3	12
70-79	1	4
Total	**25**	**100**

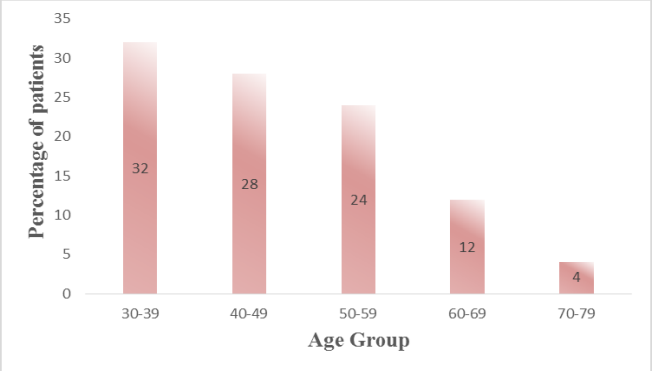

Fig 1: Distribution of patients according to age group.

Among 25 patients observed, their ages were categorized into 5 groups. From the table and graph, itwas observed in the 30–39 age group 8 patients (32%), followed by the 40–49 age group 7 patients (28%). Together, individuals aged 30–49 years constituted 15 patients(60%) of the study population. It is observed that age 50 and above constituted 10 patients (40%) of study population.

Table 2: Distribution of patients according to Gender.

Gender	No. of Patients	Percentage of Patients(%)
Male	15	60
Female	10	40
Total	**25**	**100**

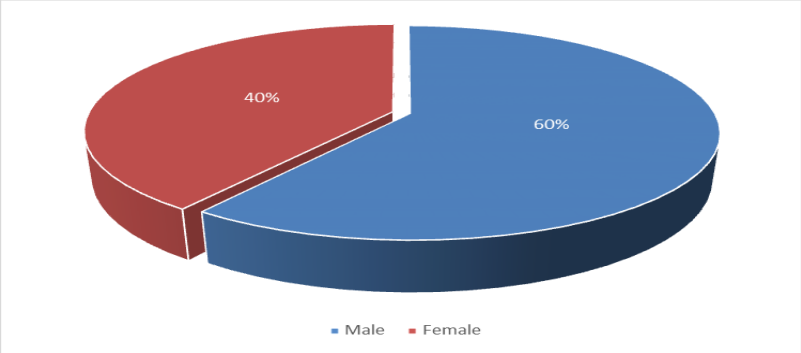

Fig 2: Distribution of patients according to Gender.

Among the 25 patients observed in the study, from Table 2 and Fig 2, it was observed that 60% were male (n=15) and 40% were female (n=10), indicating a male predominance in the occurrence of SSNHL.

Table 3: Distribution of patients based on associated symptoms.

S.no.	Associated symptoms	No. of Patients	Percentage of Patients(%)
1	Tinnitus	9	36
2	Sudden deafness	6	24
3	Ear Fullness	5	20
4	Ear AOLT	3	12
5	Muffled sounds	2	8
	Total	**25**	**100**

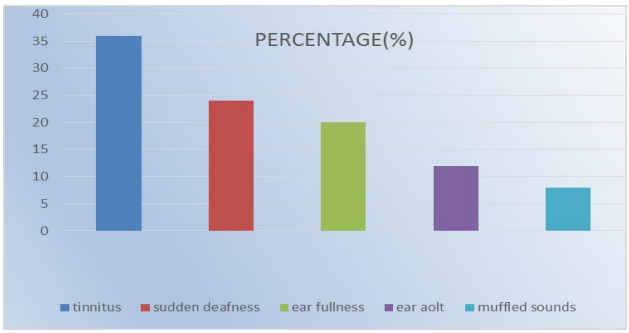

Fig. 3: Distribution of patients based on associated symptoms.

The distribution of patients based on associated symptoms is presented in Table 3 and Fig 3. The most commonly reportedsymptom in patients with SSNHL was tinnitus, observed in 9 patients (36%) of cases, followed by sudden deafness6 patients(24%) and ear fullness 5 patients (20%). Other symptoms included ear AOLT/ ear pain /ear ache 3 patients (12%) and muffled sounds 2 patients(8%).

Table 4: Distribution of patients based on their drug related side effects.

S.no.	Associated symptoms	No. of Patients	Percentage of Patients(%)
1	Pain at injection site	3	12
2	Dizziness	3	12
3	Ear fullness	3	12
4	No side effects	16	64
	Total	**25**	**100**

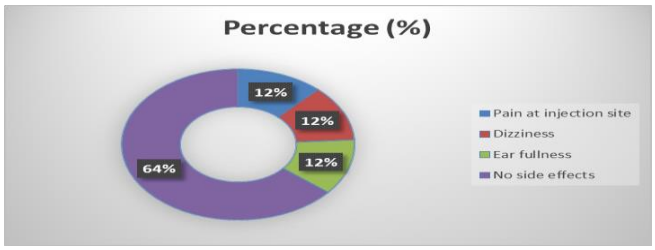

Fig 4: Distribution of patients based on their drug related side effects.

Based on Table 4 and Fig 4, it was observed that 16 (64%) of patients reported no drug-related side effects, 12 (36%) of patients experienced mild side effects, with pain at the injection site 3 (12%) patients, dizziness 3 (12%) patients, and ear fullness 3 (12%) patients being the most commonly reported adverse effects.

Table 5: Distribution of Diagnostic tests.

S.no.	Diagnostic Test	No. of Patients
1	Pure Tone Audiometry	25
2	Tympanometry	7
	Total	25

Fig. 5: Distribution of Diagnostic tests.

Table 5 and Fig. 5 illustrate the distribution based on Diagnostic tests. It shows that all 25 patients underwent Pure Tone Audiometry to measure hearing threshold. 7 patients underwent Tympanometry to rule out the conductive hearing loss and confirm the diagnosis.

Table 6: Distribution of patients based on Ear Affected.

Ear Affected	No. of Patients	Percentage
Left Ear	11	44
Right Ear	14	56
Total	**25**	**100**

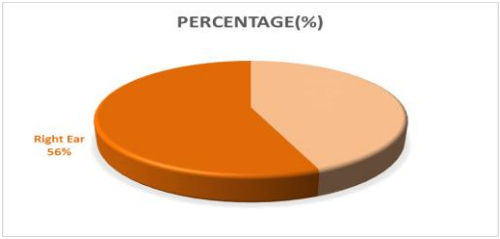

Fig. 6: Distribution of patients based on Ear Affected.

Table 6 and Fig. 6 illustrate the distribution of patients based on affected ear. It shows that all 25 patients are affected unilaterally, and the right ear was more commonly affected in SSNHL cases, with 14 (56%) of patients experiencing hearing loss in the right ear compared to 11 (44%) in the left ear.

Table 7: Distribution of Patients based on PTA Grading.

Grade	Pre Treatment (n=25)	Post Treatment (n=25)	
		1st month	2nd month
1	4	12	22
2	11	9	1
3	7	3	1
4	3	1	1

Table 8: PTA values Pre and Post Treatment.

Patient No.	Pre treatment	Post treatment	
		1 Month	2 Months
1	**103.3**	78.2	25.7
2	**51.7**	35.1	14.8
3	**68.3**	14.5	-
4	**61.7**	46.7	23.3
5	**65.4**	49.6	26.7
6	**52.8**	44.8	22.1
7	**40**	15.6	-
8	**65**	51.2	26.2
9	**73.3**	73.3	24.6
10	**40**	27	12.2
11	**35**	14.6	-
12	**103.3**	78.2	-
13	**54.2**	42.4	21.4
14	**40**	15.6	-
15	**50**	25	-
16	**50.6**	32.8	16.8
17	**47**	13.1	-
18	**48.33**	31.8	13.7
19	**68.9**	48.6	25.01
20	**50.9**	34.2	16.7
21	**61.7**	47.2	19.4

22	**48.3**	26.8	-
23	**46.7**	23.3	-
24	**55**	55	-
25	**98.3**	98.3	-

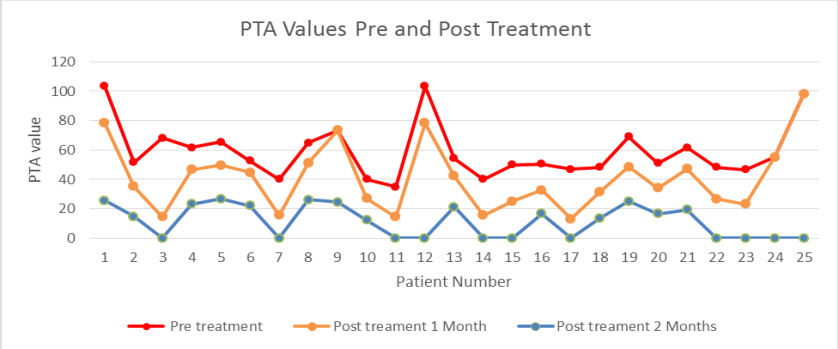

Fig. 7: PTA values Pre and Post Treatment.

The PTA values were recorded before treatment, at the 1st month, and at the 2nd month follow-up. After the first month of treatment, 22 out of 25 patients showed noticeable improvement in PTA values, indicating a positive response to the initial dose. Only 3 patients did not show any improvement. Among the responders, a smaller subset (14 patients) proceeded to receive the second dose, and further improvement was observed in this group by the 2nd-month follow-up.

Table 9: Distribution of patients based on Improvement.

Conclusion	No. of Patients	Percentage of patient
Improved	**22**	**88**
Unimproved	**3**	**12**
	25	**100**

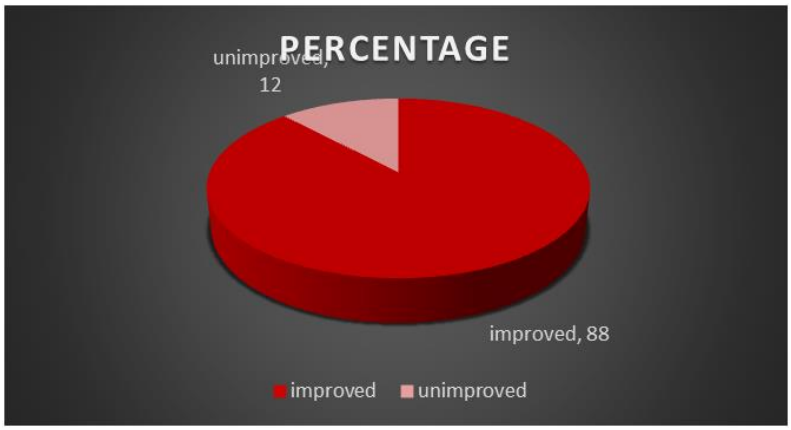

Fig. 7: Distribution of patients based on Improvement.

Table 9 and Fig. 7 illustrate the Distribution of patients based on Improvement Out of 25 patients treated for SSNHL, 22 patients (88%) showed improvement, while 3 patients (12%) did not improve.

DISCUSSION

Intratympanic methylprednisolone injections are increasingly used in the treatment of sudden sensorineural hearing loss (SSNHL), a condition characterized by sudden onset of hearing loss, often accompanied by tinnitus and dizziness, with a largely idiopathic etiology. In this prospective observational study conducted on 25 patients with idiopathic SSNHL, the efficacy and safety of Intratympanic methylprednisolone injections were evaluated. The study highlighted key findings regarding the demographics, clinical presentation, and treatment outcomes among the patients.

The age group of 30–49 years constituted 15 patients (60%) of the study population, indicating that this age group is more susceptible to developing SSNHL. Additionally, there was male predominance with 15 patients (60%) in the study, aligning with existing literature suggesting that males may have a higher prevalence of SSNHL.

The right ear was affected in 14 patients (56%), more commonly than the left ear in 11 patients (44%), consistent with similar studies. The most commonly associated symptom was tinnitus in 9 patients (36%), followed by sudden deafness in 6 patients (24%) and ear fullness in 5 patients (20%).

Analysis of the treatment outcomes revealed that 22 out of 25 patients (88%) showed improvement in hearing thresholds, indicating a high effectiveness of Intratympanic steroid injections in managing SSNHL, even in cases unresponsive to systemic steroids.

The procedure was well-tolerated, with minimal and transient side effects reported in a few patients, including pain at the injection site in 3 patients (12%), dizziness in 3 patients (12%), and ear fullness in 3 patients (12%), while 16 patients (64%) reported no adverse effects, demonstrating the safety and tolerability of the procedure.

The mechanism of action of Intratympanic steroids involves achieving higher local concentrations in the inner ear by bypassing the blood-labyrinth barrier, thus providing anti-inflammatory effects while minimizing systemic side effects, making it a suitable treatment option, especially for patients with contraindications to systemic steroids.

Comparing the findings with existing literature, this study aligns with the results of Xenellis et al. (2006), Lavigne et al. (2015), and Han et al. (2009), which highlighted the effectiveness and safety of Intratympanic steroids in improving hearing outcomes in SSNHL.

The findings of this study emphasize the importance of early intervention and the potential of Intratympanic steroid therapy as a primary or salvage treatment option for SSNHL, providing significant improvement in hearing outcomes with minimal adverse effects, thereby improving the quality of life in affected patients.

CONCLUSION

In this study, a reliable treatment for sudden sensorineural hearing loss (SSNHL) with maximum effectiveness and minimal side effects was assessed. This prospective observational study evaluated the effectiveness of Intratympanic methylprednisolone injections in patients with SSNHL in an Indian tertiary care setting. The study concludes that Intratympanic methylprednisolone injection is an effective, safe, and well-tolerated treatment for SSNHL, providing significant improvement in hearing outcomes with minimal adverse effects, and can serve as a primary or salvage therapy in the management of SSNHL.

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CONFLICT OF INTEREST

The author were no the conflict of interest.

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