

## A Study on Role of Intra Tympanic Steroids Vs oral Steroids on Sudden Sensorineural Hearing Loss in A tertiary Care Centre

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### Abstract

**Background:** Sudden sensory-neural hearing loss (SSNHL) is defined as loss of hearing within 3 days, more than 30 dB in consecutive 3 frequencies. It is an otological emergency for which a definitive aetiology is unknown in most of the cases and treatment remains controversial. Prompt diagnosis and management have shown to improve hearing outcomes.

**Methods:** In our study we assigned patients to 2 groups randomly selected from patients fulfilling the criteria of SSNHL. All the patients with SSNHL between the study periods were taken in the study. After applying the inclusion and exclusion criteria 60 patients were included in the study. Patients were divided into two groups randomly (30 in each group). Group 1 patients were given intra tympanic steroids and group 2 patients were given oral steroids.

**Result:** Our study showed that majority of the subjects reported hearing improved with intra tympanic steroids (90%), whereas, only 10% of the subjects reported hearing improved with oral steroids. These differences in proportions were statistically significant ( $p$  value < 0.001). This study also showed that the duration of SSNHL and hearing at 4 weeks of the study was significantly correlated with more than duration of SSNHL. More the duration of SNHL less improved was the hearing at 4 weeks ( $p$  value < 0.001).

**Conclusions:** Our study showed better hearing outcome with intra tympanic steroids than with oral steroid with lesser side effects in cases of SSNHL. The specific action of steroids in the cochlea is uncertain but their use has been based on their ability to decrease inflammation and edema and in most of the cases there are improvements of hearing. Intra tympanic steroids can be given safely where oral or systemic steroids are contraindicated. This is safe and office based procedure.

**Keywords:** Sudden Sensorineural Hearing Loss, SSNHL, Intra Tympanic Steroid, ITS.

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### Introduction

Sudden sensory neural hearing loss (SSNHL) is defined as loss of hearing within 3 days, more than 30 dB in consecutive 3 frequencies. It is an otological emergency for which a definitive aetiology is unknown in most of the cases and treatment remains controversial. But prompt diagnosis and management have shown to improve

hearing. Other accompanying symptoms include tinnitus and dizziness.

Idiopathic SSNHL is initially a clinical diagnosis supported by audiological evaluation, characterized by a sudden deafness of cochlear or retro cochlear origin in the absence of a clear precipitating cause. Its incidence has been estimated at 5 to 20 per

100,000 persons.[1,2,3] The true incidence of SSNHL may be higher than these estimates because affected individuals who recover quickly do not come for the medical advice [4]. Individuals of all ages can be affected but the peak incidence is between fifth and sixth decade of life. SSNHL occurs with equal incidence in males and females [5, 6]. Most of the cases are unilateral; less than 2 % patients have bilateral involvement [7].

Oral and systemic steroids have been used in the treatment of SSNHL for long period. There are some side effects in some patients. At present we are getting more patients of SSNHL with multiple co morbidities in our clinical practice. Treatments of these patients are really challenging. Considering these we carried out our study to know the effectiveness and side effects of steroid usage by intra tympanic and oral routes in SSNHL cases.

### Aims and Objectives

The study was conducted in the department of E.N.T. of North Bengal Medical College and Hospital, Siliguri, and district Darjeeling of West Bengal in all the adult patients with SSHNL between the study periods, 1st May 2019 to 30th June, 2020.

1. To evaluate the efficacy and to compare the recovery of intra tympanic steroid vs. oral steroid as initial therapy in SSNHL.
2. To compare the effects of oral steroid and intra tympanic steroid on reducing other symptoms associated with SSNHL like tinnitus, vertigo etc.
3. To compare the morbidity of both oral steroid and intra tympanic steroid among the study subjects.

### Materials and Methods

In our study we assigned patients to 2 groups randomly selected from patients fulfilling the criteria of SSNHL. All the patients with SSHNL between the study periods were taken in the study.

### Inclusion Criteria

1. Patient  $\geq 18$  years of age.
2. Has history of a unilateral SSNHL with or without associated symptoms that developed within 72 hours and was present for  $\leq 30$  days.
3. To the best of the participant's knowledge, hearing must have been symmetric prior to onset of SSNHL.
4. Patients who gave consent.

### Exclusion Criteria

1. Patients  $\leq 18$  years of age.
2. Patients who are having history of  $>30$  days of hearing impairment.

3. Patients who are very sick or have associated with other disabling morbid conditions like chronic kidney disease, autoimmune disease, previous otological surgery etc.
4. Patients having structural or retrocochlear pathology such as history of cerebrovascular accident, cerebellopontine angle space occupying lesions, or demyelinating diseases etc.
5. Patients who did not give consent

### Study Technique

In our study we assigned randomly selected patients fulfilling the criteria of SSNHL in 2 groups, 30 in each group. Group 1 patients were given intra tympanic medications (steroids, dexamethasone) and group 2 patients were given oral medications (steroids, prednisolone).

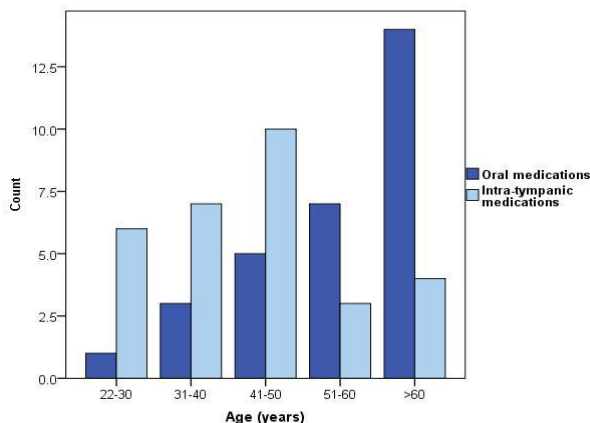
1. Intra tympanic steroids (0.3 ml dexamethasone) were given under microscope or with endoscope with 27 G spinal needle bi-weekly for 4 weeks. Oral steroids (prednisolone) were given at the dose of 1mg/kg/day and tapered off over 4 weeks.
2. Making a chart mentioning all the parameters like age, sex, duration of symptoms in the patients with SSNHL and associated symptoms like tinnitus, vertigo etc. encountered.
3. Another chart correlating the pure tone average, calculated as the arithmetic mean of the hearing thresholds at 500, 1000, 2000, and 4000 Hz in the affected ear.
4. Taking proper medical history of the patients including recording monitoring of parameters like BP, CBG etc. both pre procedural or medications.
5. Comparing post procedural or post medication PTA in the both groups as follow up case after 4 weeks of treatment with intra tympanic steroids or oral steroids.

### Statistical Analysis

Data were entered into MS Excel and analyzed using the SPSS version 20. Descriptive analysis was done in the form of proportion for categorical variables, mean or median for continuous variables. Data were checked for normal distribution using tests for normality and non-parametric test was performed accordingly. The difference between proportions was analyzed using Chi square test; p value of less than 0.05 was considered statistically significant.

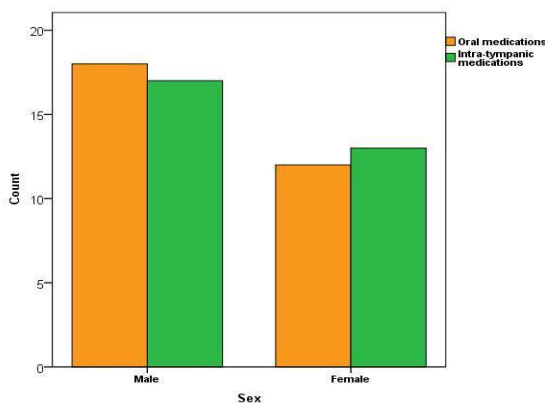
### Results

The present study was conducted among 60 patients with SSNHL (30 in each group receiving either oral or intra tympanic steroids).The results are described under following headings



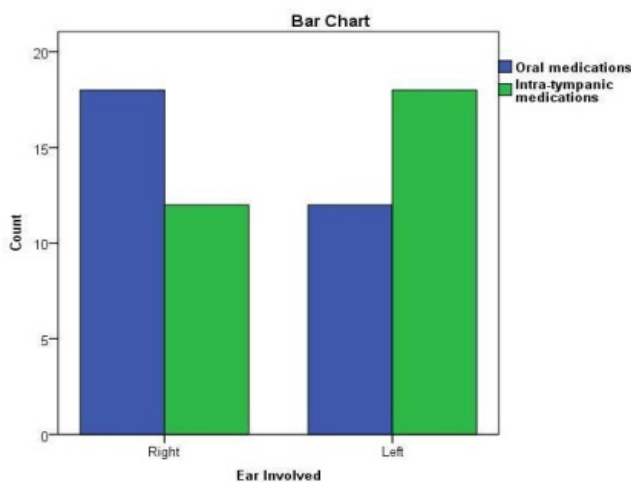
**Figure 1: Distribution of study subjects according to age (n=60)**

Figure 1 shows that among the patients receiving intra tympanic medication, most of the patients were in the age group of 22-30 years (85.7%), 31-40 years (70%) and 41-50 years (66.7%); whereas, among the patients receiving oral medications, most of the patients were in the age group of 51-60 years (70%) and more than 60 years (77.8%).



**Figure 2: Distribution of study subjects according to sex (n=60)**

Figure 2 shows the distribution of study subjects according to sex among the subjects.



**Figure 3: Distribution of study subjects according to ear involved (n=60)**

Figure 3 showing the distribution of study subjects according to ear involved among the subjects.

**Table 4: Distribution of study subjects according to duration of SSNHL (n=60)**

Duration of SSNHL (days)	Oral medication N=30 n%	Intra tympanic medication (n=30) n (%)	Total	$\chi^2$ value (df) p value
<7	9 (30)	14 (46.7)	23 (38.3)	1.763 (1) 0.184
>7	21 (70)	16 (53.3)	37 (61.7)	
Total	30(100)	30 (100)	60 (100)	

Table 4 shows that the difference in duration of SSNHL was not statistically significant among both the groups (*p* value 0.184).

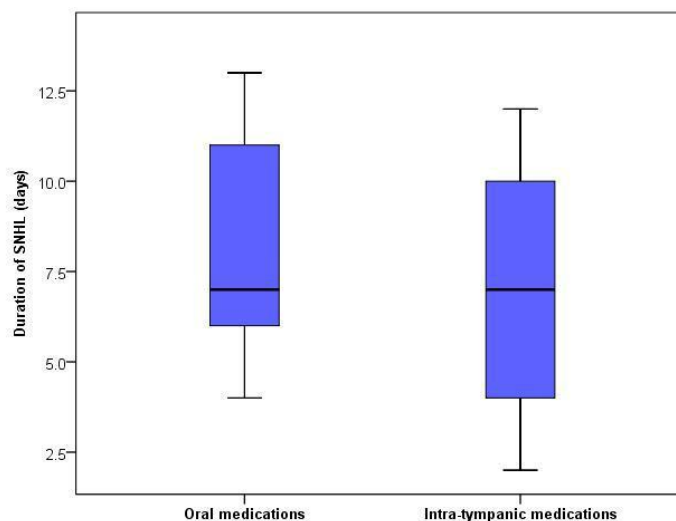
**Figure 5: Box Whisker plot showing the distribution of duration of SSNHL (days) among the study subjects (n=60)**

Figure 5 shows that the mean (SD) and median (inter quartile range) of duration of SSNHL (days) among the patients receiving oral medications were 8.33 (2.95) days and 7 (6, 11.25) days, and among the patients receiving intra tympanic medication, the corresponding were 6.80 (3.62) days and 7 (3.75, 10.25) days. This difference was not statistically significant [Mann Whitney U test, *p* value 0.053].

**Table 6: Distribution of study subjects according to presence of vertigo (n=60)**

Vertigo	Oral medication N=30 n%	Intra tympanic medication (n=30) n (%)	Total	$\chi^2$ value (df) p value
Absent	30(100)	28(96.7)	58(98.3)	1.052(1) 0.305
Present	00	1(3.3)	1(1.7)	
Total	30(100)	30 (100)	60 (100)	

Table 6 shows that vertigo was present more among the patients receiving oral medications than patients receiving intra tympanic medication, and this difference was not statistically significant (*p* value 0.711).

**Table 7: Distribution of study subjects according to mean hearing at 4 weeks of the study subjects**

Hearing at 4 weeks (dB)	Oral medication N=30 n%	Intra tympanic medication (n=30) n (%)	p value
Mean (SD)	44.03 (9.91)	34.63 (12.91)	<b>0.002*</b>
Median (IQR)	40 (37, 50.50)	32.50 (23, 41.50)	

\*Independent t test

Table 7 shows that the mean (SD) hearing at 4 weeks was better with lesser mean among the study subjects receiving intra tympanic medications than patients receiving oral medications, and this difference was statistically significant (*p* value 0.002).

**Table 8: Distribution of study subjects according to subjective improvement of hearing**

Subjective improvement of hearing	Oral medication N=30 n%	Intra tympanic medication (n=30) n (%)	Total	$\chi^2$ value (df) p value
No	27 (90)	07 (23.3)	34 (56.7)	27.149 (1) <0.001
Yes	03 (10)	23 (76.7)	26 (43.3)	
Total	30(100)	30 (100)	60 (100)	

Table 8 shows that majority of the subjects reported hearing improved with Intra tympanic medication (90%), whereas, only 10% of the subjects reported hearing improved with oral medications, and these differences in proportions were statistically significant ( $p$  value<0.001).

**Table 9: Distribution of study subjects according to post intervention morbidities developed**

Variables	Oral medication N=30 n%	Intra tympanic medication (n=30) n (%)	Total	$\chi^2$ value (df) p value
<b>G I upset</b>				
No	21 (70)	30 (100)	51 (85)	10.588 (1) <b>0.001</b>
Yes	09 (30)	<b>00</b>	09 (15)	
Total	30(100)	30 (100)	60 (100)	
<b>Raised blood pressure</b>				
No	26 (86.7)	30 (100)	56(93.3)	4.286 (1) <b>0.038</b>
Yes	04 (13.3)	<b>00</b>	04 (6.7)	
Total	30(100)	30 (100)	60 (100)	
<b>Hyperglycemia</b>				
No	18 (93.3)	30 (100)	<b>58</b> (96.7)	2.069 (1) <0.150
Yes	02 (6.7)	<b>00</b>	02 (3.3)	
Total	30(100)	30 (100)	60 (100)	

Table 9 shows that 30%, 13.3% and 6.7% of the patients developed gastrointestinal upset, raised blood pressure and hyperglycaemia respectively among the patients with oral medications, whereas, none of the patients reported similar morbidities or complaints among intra tympanic medications.

**Table 10: Correlation between duration of SSNHL and hearing outcome at 4 weeks of the study subjects (n=60)**

		Duration of SSNHL	Improved hearing at 4 weeks
Duration of SSNHL	Pearson correlation	<b>1</b>	0.466**
	Sig. (2-tailed)		0.000
Improved hearing at 4 weeks	Pearson correlation	0.466**	<b>1</b>
	Sig. (2-tailed)	0.000	

\*\*. Correlation is significant at the 0.01 level (2-tailed)

Above table shows that the duration of SSNHL and hearing at 4 weeks of the study subjects was significantly correlated. More the duration of the SSNHL less improved is the hearing at 4 weeks ( $p$  value <0.001).

### Discussion

Wilson et al. conducted a double blind placebo controlled study that demonstrated a statistically significant benefit of systemic corticosteroids for hearing recovery in patients with SSNHL [8]. Chen and Halpin had also shown the benefit of systemic corticosteroid therapy for hearing loss recovery in SSNHL patients [9]. In our study the 10 percent of the group of patients receiving oral corticosteroids had subjective hearing improvement after 4 weeks follow up (Table 8). However, a few researchers like Byl and Mattox have published discouraging results as to the benefits of systemic corticosteroids

compared to placebo.[1,10] On the other hand, studies of Silverstein (1996), Shirwany (1998) and Hennawi (2005) had shown that intra tympanic corticosteroids are safe and did not appear to cause any histological changes.[1,11,12]. In our study we found better results with intra tympanic steroids.

Studies of Araujo and Oliveira showed that in patients with tinnitus intra tympanic dexamethasone was not effective for relieving symptoms like tinnitus, but had no adverse effects against cochlear function, as evidenced in otoacoustic emissions.[13] On the other hand, studies by Spandow et al have suggested that intra tympanic corticosteroids might not be beneficial in the treatment of hearing loss. These authors suspected that there was a potential risk of decreased cochlear function because of intra tympanic therapy.[14] Studies by Nordang and Linder showed that intra tympanic therapy has also

been charged with causing inflammation to reach the round window.[15] However, in our study we did not find any such complications of intra tympanic steroid therapy.

Chandrasekhar and Rubinstein showed that intra tympanic steroids administration may attain high concentrations in the perilymph, higher than intravenous or oral administration [16]. Saijo and Salt using markers such as phenyl-ammonia (TMPA) and peroxidase, had demonstrated a non-uniform distribution, where higher concentrations of corticosteroids reached close to the round window.[17,18]. Salt showed that substances could reach the vestibule by means of extracellular pathways between scalae and through the spiral ligament [18, 19]. These studies and those of Parnes[20] suggested that there was a non-linear flow and interscala pathway for substances administered intra tympanically. In our study the patients in the group receiving intra tympanic steroids showed better hearing outcome than oral steroids group (Table 7 and Table 8). It indicates that the bioavailability of drugs (steroids) in the inner ear might be key factor in determining outcome in SSNHL patients.

Silverstein (1996) published the first report of intra tympanic corticosteroid use for the treatment of SSNHL.[21] followed by Parnes (1999).[20] Several other researchers published their results, mostly after 2001[18,22,23,24,25]. Most of these papers reported on the benefits of intra tympanic corticosteroids for the treatment of SSNHL in patients where systemic therapy failed. Battista and Lauterman's study had described studies in which patients were given intra tympanic corticosteroids as the therapy of choice or as adjuvant therapy with oral corticosteroid therapy with greater benefits.[26,27]. This is similar to our study (table 7 and table 8).

Gouveris[28] treated 40 patients with intra tympanic corticosteroids in a prospective study of patients in which systemic therapy was unsuccessful. Efficacy was lower in patients with profound hearing loss or high frequency loss or patients who were given intra tympanic steroid therapy more than 4 weeks after SSNHL set in. Shaia and Sheehy noted a significant improvement in patients treated within a week of the onset of hearing loss. However, some patients who were given treatment after 3 months also recovered (10%).[6] This finding was also in accordance to our study which showed more the duration of hearing loss lesser is the hearing outcome at 4 weeks in both groups (table 10).

Lauterman et al. (2005)[27] reported the results of a prospective study in which a group of SSNHL patients were treated with intra tympanic methyl prednisolone as the first treatment and was then

compared with another group undergoing systemic therapy (rheological agents and prednisolone). There was no difference in the efficacy of both treatments. In comparison we also started intra tympanic steroids and oral steroid as initial treatment but found significantly better outcome with intra tympanic steroids than with oral steroids.

Ho et al. (2005) [29] published a randomized placebo controlled study of 39 SSNHL patients in which 29 (74%) did not benefit from systemic therapy and were then randomized into two groups; fifteen patients were given intra tympanic corticosteroids and 14 were given systemic therapy. The recovery rate of hearing in the intra tympanic therapy group was 53%, while it was 7.1% in patients given systemic therapy. The improvement criterion was a 30 dB gain in PTA.

In our study we followed similar random sampling among patients presenting with SSNHL. Our result table 8 shows that majority of the subjects reported subjective hearing improved with intra tympanic steroids (90%), whereas, only 10% of the subjects reported hearing improved with oral steroids. These differences in proportions were statistically significant ( $p$  value < 0.001). So, our study had a result similar to the study of these authors where recovery rate of hearing in the intra tympanic therapy group was better than in patients who were given oral or systemic steroid therapy.

As the natural history of SSNHL suggest high recovery rates, it is difficult to establish whether interventions really increase these recovery rates. Mattox, Wilson and Chen's respective studies also showed that the natural history of untreated SSNHL patients had recovery rates ranging from 31% to 65% [13, 28, 29]. Several reasons may explain these different published rates. The best one may be the possibility that each author measured successful recovery differently.

A review of studies published shows that the definition of success or post therapy improvement may differ significantly between authors. There are no established criteria for defining recovery in SSNHL patients, especially in those cases of secondary recovery after failure of the first treatment. Recovery criteria may range from any improvement in 10 dB improvements in the PTA or more.

A meta analysis of the literature would be complicated by the huge variation in protocols and data presentation of patients. Our recovery rate is similar to that in other studies that applied the same criteria for defining improvement in hearing. As mentioned previously, table 8 shows that majority of the subjects reported subjective hearing improved with Intra tympanic medication (90%), whereas, only 10% of the subjects reported hearing improved with oral steroids.

In our study 9 out of 30 patients in our group receiving oral steroids complained of gastrointestinal symptoms like heartburns and bloating sensation in stomach. 2 of these cases of the same group complained of weakness and increased glycaemic levels during treatment. 4 of these patients of the same group also had increased blood pressure which was not controlled on previous anti-hypertensive medications. The recovery rate in these patients was similar to non-diabetic subjects in this group. However, among the 30 patients treated by intra tympanic steroids, they did not complain any gastrointestinal intolerance, increased glycaemic levels, weakness and dizziness. There were no complications in this group of patients. Among the 2 who had increased glycaemic levels during treatment in the oral corticosteroids group, one had history of pre diabetic glucose levels and other had type 2 diabetes mellitus on medication (Table 9). So, we can inference the better safety profile of intra tympanic steroid in pre diabetic and diabetic patients. Chandrasekhar et al in their study found that 3 of 3 diabetic SSNHL patients were improved with intra tympanic therapy. This was opposite to the general feeling of diabetic SSNHL patients would feel worse than non-diabetic subjects [30].

We opted for bi-weekly intra tympanic injections (0.3 ml dexamethasone) for 4 weeks based on the reflections of other authors like Silverstein, Chandrasekhar and Plontke who ended their studies unsatisfied with single injection therapy and recommended continuous infusion or multiple injections in subsequent studies. In the oral steroids group we started oral steroids (prednisolone) at the dose of 1mg/kg/day and tapered off over 4 weeks.

### Limitations

SSNHL may be mild to severe cases and therapeutic regimens may have varied according to disease severity. The method of steroid administration and therapy duration differed among different studies. These differences influence the comparability of various study cases and cause confounding bias. These factors may affect reported outcome. Substantial proportion of patients with SSNHL experience spontaneous recovery, therefore the benefits of intra tympanic steroids or oral steroids may not have been accurately evaluated. The limitations mentioned in this systematic review should be considered when evaluating its outcomes.

### Conclusion

The current study was undertaken to know the role, efficacy and adverse effects if any of both intra tympanic steroids and oral steroids in cases of SSNHL. In our study we tried to shed light on the effect and role of steroids on SSNHL by oral and intra tympanic administration steroids and their

associated side effects. The specific action of steroids in the cochlea is uncertain but their use has been based on their ability to decrease inflammation and edema and in most of the cases there are improvements of hearing. Thus, our study shows better hearing outcome with intra tympanic steroids than with oral medications with lesser side effects. We also observed that outcomes were better in cases received early treatment. The clinician should decide the risks and benefits of any specific treatment, intra tympanic steroids or oral medications according to the patient's individual medical status. Intra tympanic steroids can be given safely where oral or systemic steroids are contraindicated. This is safe and office based procedure.

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