

## Original Research Article

# The role of intratympanic dexamethasone in sudden sensorineural hearing loss

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### ABSTRACT

**Background:** Present study was conducted to assess the efficacy of intratympanic dexamethasone in patients with sudden sensorineural hearing loss and to determine factor affecting treatment outcome for sudden sensorineural hearing loss.

**Methods:** Prospective study was conducted on 24 patients of sudden sensorineural hearing loss between October 2019 to February 2020 in the department of ENT, OPD, SPMC, Bikaner. Group A were given oral steroids: prednisolone 1 mg/kg/day (maximal dose is 60 mg/day) full dose 14 days, then tapered over next 14 days. Group B were given intratympanic dexamethasone 4 mg/ml, 0.5 ml into middle ear space (into the posterior inferior quadrant) every 7 days for a total of 4 weeks. Audiogram was performed at end of every week for 4 weeks.

**Results:** Overall, 58% (n=14) patients showed improvement in pure-tone average. For  $\leq 3$  days of presentation; out of total 6 patients, 83.33% cases recovered. For 4 to 7 days of presentation; out of total 10 patients, 80% cases recovered. For 8 to 14 days presentation; out of total 8 patients 12.5% cases recovered (p=0.005).

**Conclusions:** We suggest the treatment approach in which interaural time difference is used adjuvantly with oral steroids.

**Keywords:** Intratympanic dexamethasone, Sudden sensorineural hearing loss, Audiogram

### INTRODUCTION

Idiopathic sudden sensorineural hearing loss (SNHL) is defined as a decline in hearing over 3 days or less affecting 3 or more contiguous frequencies by 30 dB or greater with no identifiable etiology.<sup>1</sup> The hearing loss (HL) is nearly always unilateral and is commonly associated with tinnitus and aural fullness. Although this disorder is not one of the more common aetiologies for HL, disproportionate interest in sudden SNHL exists most likely because it is one of the few reversible (sensorineural) hearing losses encountered by clinicians.<sup>2</sup> Another potential reason for high interest level is that sudden SNHL is encountered by all otolaryngologists in

all areas of the country and treated as a true emergency often without the timeframe to allow for tertiary referral.

The aetiology, natural history and treatment of this disorder have been subjects of debate for many years. The actual number of patients recovering spontaneously from sudden SNHL without having sought medical attention is not known. High rate of spontaneous recovery, up to 65%, also confounds reviews as to the therapeutic efficacy.<sup>3</sup>

It occurs in 5 to 20 cases per 100000 population. This is approximately the same incidence as Meniere's disease (15 per 100000) and twenty times more common than acoustic neuroma (1 per 100000).<sup>2,4</sup> The true incidence of

idiopathic sudden sensorineural hearing loss (ISSNHL) is probably underestimated because many who recover hearing early are unlikely to seek medical therapy.

The treatment of patients with sudden SNHL remains varied among otologic centers with no standard protocol universally accepted. With no specific etiology and a short timeline for effective therapy realized, a technique termed “shotgun” therapy is often used. This therapy entails multiple therapeutic agents geared toward the hypothetical etiologies given at once, because the narrow therapeutic window prevents trials with each agent singly. Notwithstanding the timeframe in which maximum recovery may occur, from several days to possibly several months, also leads to errors in determining treatment efficacy versus natural history.<sup>5,6</sup>

This study was undertaken to assess the efficacy of intratympanic dexamethasone (4 mg/ml) in patients with Sudden sensorineural hearing loss and to study the factor affecting treatment outcome for Sudden sensorineural hearing loss.

## METHODS

This prospective study was conducted between October 2019 to February 2020 in the department of ENT OPD, SPMC, Bikaner.

### *Inclusion criteria*

Patients with sudden unilateral hearing loss of at least 30 dB across 3 contiguous frequencies occurring in less than 72 hours and presentation to OPD within 2 weeks of onset of hearing loss were included.

### *Exclusion criteria*

Patients with hearing loss history with onset over 2 weeks, history of ear surgery or ear disease in the past, evidence of retrocochlear disease, oncologic history with recent chemotherapy or radiation therapy, congenital cochlear malformations, Ménière’s disease, fluctuating hearing loss, acute or subacute otitis media with abnormal tympanometry, neurological disorders, recent use of ototoxic medications, recent trauma, consent refusal for treatment or to be a part of study were excluded.

### *Audiometric data*

Patients were all evaluated using standardized methods for pure-tone threshold audiometry by certified audiologists pre- and post-injection. Pure-tone average (PTA) was calculated as an average of the threshold measured at 0.5, 1.0 and 2.0 kHz (speech frequencies).

### *Operative procedure of intratympanic injection*

The correct ear was confirmed for injection by patient response and audiometric review. The operative

procedure of intratympanic steroid injection was performed under a microscope and with patient in supine position. After confirming intact tympanic membrane and middle ear status, local anaesthesia was administered with a cotton ball soaked with 10% lidocaine (xylocaine), which was applied on the tympanic membrane for 10 to 15 minutes. While the patient tilted the head 45° to the healthy side.

**Table 1: Grading of severity of hearing loss.<sup>7</sup>**

Grade	
Mild	26-40 dB
Moderate	41-55 dB
Moderately severe	56-70 dB
Severe	71-90 dB
Profound	>90 dB

The dexamethasone solution of 4 mg/ml is checked and warmed to body temperature before injection. Before each procedure, the patients were counselled regarding the risks and expectations of the procedure and informed consent obtained.

A 25-gauge spinal needle was introduced into the postero-inferior portion of tympanic membrane and approximately 0.5 ml of dexamethasone (4 mg/ml) was injected into the middle ear.

The patients were asked to lie in the supine position with the head turned 45° away from the treated ear for approximately 20 minutes on average and avoid swallowing.

24 patients of either sex fulfilling inclusion and exclusion criteria were taken up for the study. Written informed consent was taken. Detailed evaluation of the patient was done including detailed history and complete ENT examination. All patients underwent PTA to confirm Sensorineural hearing loss. All patients underwent Gadolinium enhanced MRI brain and BERA to rule out retrocochlear pathology. Patients were allocated into 2 groups and each group consist of 12 patients.

Group A were given oral steroids. Prednisolone 1 mg/kg/d (maximal dose is 60 mg/day) full dose 14 days, then tapered over next 14 days. Audiogram was performed at end of every week for 4 weeks.

Group B were given intratympanic dexamethasone 4 mg/ml, 0.5 ml into middle ear space (into the posterior inferior quadrant) every 7 days for a total of 4 weeks via narrow-gauge spinal needle to fill middle ear. Patients also got prednisolone 1 mg/kg/day (maximal dose is 60 mg/d) full dose 14 days, then tapered over next 14 days. Audiogram was performed before each subsequent injection and at completion of treatment course.

**Treatment response**

**Complete:** If the follow-up PTA (dB HL) improved to within 10 dB of pre-sudden hearing loss hearing levels.

**Partial:** If the follow-up PTA (dB HL) improved to within 50% of pre-sudden hearing loss hearing levels.

**No recovery:** If the follow-up PTA (dB HL) was less than 50% of recovery of pre-sudden hearing loss hearing levels.

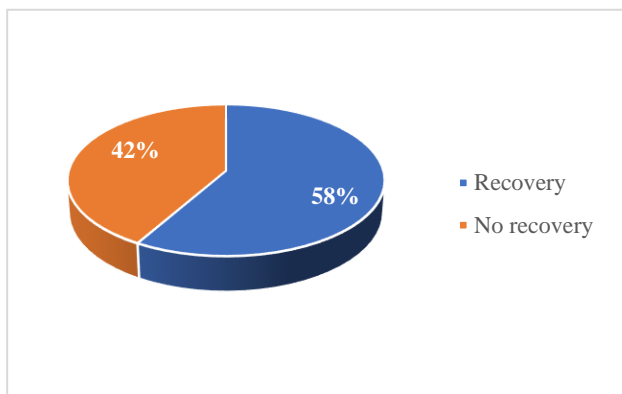
**Statistical analysis**

Data are presented in numeric and percent form. Categorical data analysis was performed using  $\chi^2$  (chi-square) techniques and ANOVA. A p value of less than 0.05 was considered statistically significant.

**RESULTS**

In present study, after meeting the requirements of inclusion exclusion criteria, 24 patients were available for study. Patients were divided in two groups consist of 12 patients in each group. The mean age at enrolment for all patients was 40.50 years with range from 24 to 70 years. The mean age for male was 44.50 years and for female 38.94 years. The mean age for group-A was 44.66 years, for group-B was 38.50 years.

In our study, out of 24 patients there were 13 (54%) male and 11 (46%) female. In group-A, there were 6 (50%) male and 6 (50%) female. In group-B, there were 7 (58%) male and 5 (42%) female.



**Figure 1: Overall hearing recovery.**

**Overall hearing recovery**

Twenty-four patients fit the criteria for inclusion in the study. Overall, 58% (n=14) patients showed improvement in PTA. Out of 14 recovered cases 8 were fully recovered and 6 were partially recovered and 42% (n=10) were not recovered (Figure 1). For those 58% patients showing improvement in PTA, the mean gain was 34.61 dB. In group-A, the mean gain was 38.85 dB. In group-B, it was

32.66 dB. Here, in group-A out of total 12 patients 50% (n=6) were recovered and in group-B, 66.67% (n=8) were recovered out of total 12 patients.

**Association between recovery and sex**

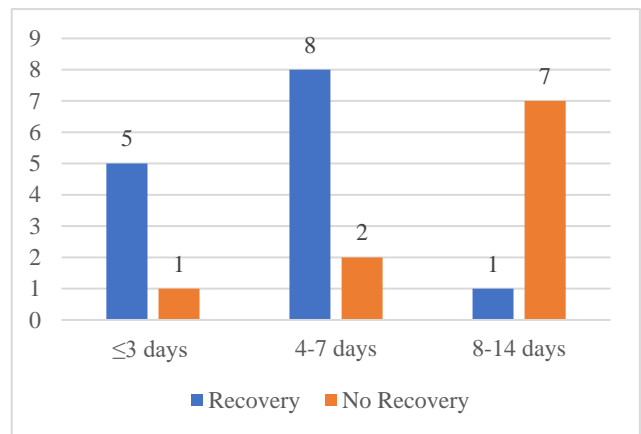
Out of 13 male patients, 62% (n= 8) were recovered and among 11 female patient 55% (n=6) were recovered. Out of 6 males and 6 females, 50% were recovered in both males and females in group-A. In group-B, out of 7 male patients 71% (n=5) were recovered, while 60% (n=3) female patients recovered out of 5 (p value=0.4175).

**Association between recovery and age**

In our study, hearing recovery related to patient’s age was studied. 79% (n=19) patients were under 60 years of age and had an overall recovery rate of 57.89%. 21% (n=5) patients were 60 years of age or older and had an overall recovery of 60%. For age <60 years, in group-A recovery rate was 50%, in group-B it was 66.67%. For age  $\geq$ 60 years, in group-A recovery was 50%, in group-B it was 66.67% (p value=0.099).

**Recovery related to time of onset of symptoms**

For  $\leq$ 3 days of presentation; out of total 6 patients, 83.33% cases recovered. For 4 to 7 days of presentation; out of total 10 patients, 80% cases recovered. For 8 to 14 days presentation; out of total 8 patients 12.5% cases recovered (p value=0.005) (Figure 2).



**Figure 2: Recovery related to time of onset of symptoms.**

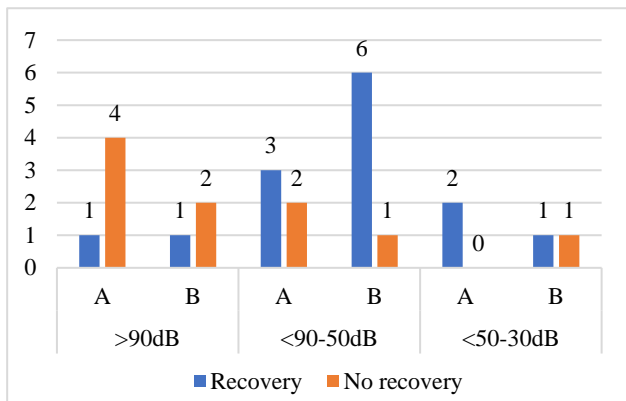
**Table 2: Mean time of onset of symptoms.**

Group	Recovery		No recovery	
	Time of onset of symptoms (days)		Time of onset of symptoms (days)	
	Mean	SD	Mean	SD
<b>Group-A</b>	4.30	2.01	8.38	3.07
<b>Group-B</b>	3.90	2.16	11.80	2.38

The average number of days from onset of symptoms to treatment was  $6.01 \pm 3.17$  days with a range from 1 to 14 days. For recovered cases, the mean days of presentation in group-A was 4.30 days, in group-B it was 3.90 days (p value=0.001) (Table 2).

**Recovery related to severity of hearing loss**

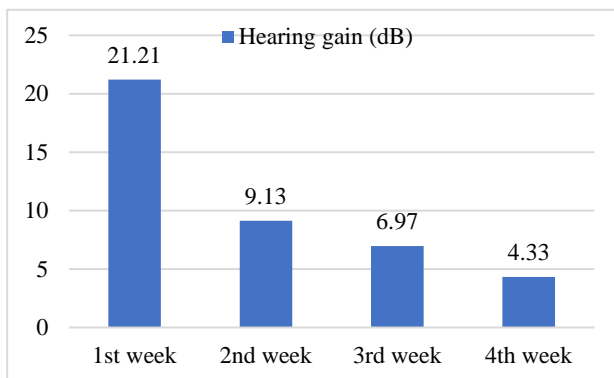
For hearing loss >90 dB, there were total 8 patients with recovery rate of 25% (n=2). For hearing loss <90-50 dB, there were total 12 patients with recovery rate of 75% (n=9). For hearing loss <50-30 dB, there were total 4 patients with recovery rate of 75% (n=3) (p=0.0081) (Figure 3).



**Figure 3: Recovery related to severity of hearing loss.**

**Hearing gain with treatment**

In our study, the hearing gain after 1 week was 21.21 dB, in 2nd week gain was 9.13 dB, in 3rd week it was 6.97 dB and in 4<sup>th</sup> week gain was 4.33 dB (Figure 4).



**Figure 4: Hearing gain with treatment.**

**DISCUSSION**

The sudden SNHL is considered as an otologic emergency and it severely impairs patient’s quality of life and social interaction, but, if treated at correct time, it can be potentially reversed. Considering the high rate of spontaneous recovery, it is difficult to determine if any therapeutic intervention actually improves the hearing.

The natural history of untreated patients with ISSNHL states that the recovery rates varies from 31% to 65%, while the hearing recovery in treated patients ranges from 35% to 89%.<sup>1,4,6,8</sup> Such a result may be related to different factors: the variable treatment protocols, the type of steroid used, the length of therapy, the patient data, the severity of hearing loss, the duration from onset of symptoms to treatment, the method of statistical analysis.

Usually, intratympanic steroids are used in three main protocols, as initial treatment, as adjunctive treatment given concomitantly with systemic steroids and as salvage treatment after failure of standard therapy.

In our study, patient age, interval from hearing loss onset to treatment and severity of hearing loss were not different between the two groups, making comparison of therapeutic effects relatively straightforward.

On review of the studies published to date in intratympanic steroids, it is clear that studies in the literature also differ on the definition of “success” for significant improvement after therapy. No definitive criteria exist to define recovery in patients with sudden SNHL. The criteria to which the authors define recovery range from any improvement in PTA or SDS to an improvement in 10-dB PTA or 10% SDS to the criteria described by Wilson et al that describes recovery as >50% of the initial loss.<sup>1,8,9</sup> They showed a statistically significant benefit with systemic steroids in recovery of hearing in patients with sudden SNHL.<sup>1</sup> Other studies have also demonstrated the benefit of systemic steroids in hearing recovery in sudden SNHL.<sup>5,11</sup> On the contrary, systemic steroids were shown to be of little benefit in the treatment of sudden SNHL in several other studies.<sup>6,12,13</sup>

Results of our study were consistent with those of Byl who found that increasing incidence with increasing age, with a peak incidence of 47/100 000 in patients 45 years and older.<sup>4</sup>

The increase in the incidence of SSNHL with increasing age may be due to differences in the etiology between younger and older patients.

Results of the current study were consistent with those of Fuse et al. noted that the majority of patients who recovered completely after treatment with oral steroids did so within 7 to 10 days after administration of steroids. In long-term follow up of 3 months to 2 years, none of the patients with no recovery or partial recovery recovered to normal hearing levels. They noted that patients resistant to steroids with regard to early outcome continued to have poor hearing recovery during long-term follow up.<sup>13</sup> Lefebvre reported that 100% of patients treated with steroids for sudden SNHL recovered within 7 days.<sup>15</sup>

In our study, dexamethasone related side effects are very less and they include ear fullness, slight otalgia during

injection and transient dizziness post injection. Majority of these events are technique related, very short term and self-resolving.

Availability of dose of dexamethasone (more than 4 mg/ml) is limiting factor in our country.

## CONCLUSION

Difficulty in proving safety and efficacy of a single modality of steroid treatment is present in all studies on ISSNHL, due to a multiple treatment protocols, a variable rate of recovery and a high rate of spontaneous recovery. Moreover, the hearing losses less than 90 dB, the involvement of the low frequencies and the earlier treatment seem to influence positively the hearing recovery, although the success could be attributed to the natural history of the disease.

More well-controlled clinical trials and standard criteria of hearing recovery are required to document the real efficacy of this option in the treatment of ISSNHL and to determine the most appropriate use and the correct timing and dosage of this therapeutic modality in the emerging field of inner ear medicine delivery.

We can affirm, according to the retrospective and prospective studies examined, that interaural time difference (ITD) has not been shown to be systemically absorbed at a clinically significant level and has not been shown to lead to systemic and severe cortisol related adverse events. It is therefore suitable to suggest that ITD therapy is a safe and reasonable procedure and that dexamethasone injected intra-tympanically is not absorbed systemically and does not carry risks of cortisol related metabolic or endocrine side effects.

Finally, we suggest the treatment approach in which ITD is used adjvantly with oral steroids.

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