

Early Intervention with Transtympanic Methylprednisolone Is Effective Therapy in Idiopathic Sudden Sensorineural Hearing Loss

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Conflict of interest: Nil

Abstract

Background: Idiopathic sudden sensorineural hearing loss is a not so uncommon condition affecting individuals with potential risk of permanent hearing loss if not treated on time. Steroids are the main stay of therapy and in recent years transtympanic steroid therapy is getting popular for its effectiveness in the management of Idiopathic SSNHL.

Aim: To evaluate efficacy of early intervention with transtympanic methylprednisolone in Idiopathic sudden sensorineural hearing loss

Methods: In a retrospective study over a period of 4 yrs, 32 patients with idiopathic sudden sensorineural hearing loss were treated with transtympanic methylprednisolone in combination with or without oral steroid therapy. Pretreatment and post treatment audiometric evaluation was done. Transtympanic methylprednisolone was given in the dose of 0.4 ml of 10 mg/ml alternate days for total 5 instillations.

Results: A statistically significant association was found between the time at which medical intervention in the form of transtympanic methylprednisolone was started and hearing improvement without any side effects of the drug. Amongst 32 patients, 25 pts showed significant improvement in the hearing [more than 20 db improvement on audiogram]. 14 of these pts was on only oral steroids but hearing improved significantly after starting transtympanic therapy. 7 patients who consulted in the first week got best results of 90% improvement in hearing and in the rest of the patient's percentage of recovery reduced by every passing day and week, with no improvement when intervention was made after one month of hearing loss. Notably almost all patients suggested improvement in tinnitus and aural pressure before hearing improvement.

Conclusion: Early diagnosis and intervention with transtympanic methylprednisolone has best results in Idiopathic sudden sensorineural hearing loss.

Keywords: Transtympanic Methylprednisolone, Idiopathic Sudden Sensorineural Hearing Loss.

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Introduction

Sudden sensorineural hearing loss [SSNHL] has been defined as hearing loss of 30 db or greater shift in bone conduction threshold in three consecutive frequencies occurring within 72 hours or less [1]. Others define it as a rapid onset sensorineural hearing loss that develop within 24 hours [4]. Hearing loss is usually unilateral and is frequently associated with tinnitus, vertigo and auricular fullness. True incidence of SSNHL in India is under evaluated because many patients go undiagnosed and live with permanent hearing loss on the affected side.

The term 'idiopathic' is coined by De Kleyn [1] in 1944 and this term is used when all the other causes of sudden hearing loss like trauma, infections, neoplastic, neurologic, metabolic disorders are

ruled out. The plausible theories in the etiology of Idiopathic SSNHL are viral infections, vascular compromise, and disruption of cochlear membrane [1]. Up to one-third of patients have upper respiratory tract prodrome preceding SSNHL suggesting role of viruses in the etiology [3]. The alterations in microcirculation of cochlea causing hypoxia or anoxia leading to cochlear injury is another suggested theory [3].

A significant hearing improvement is defined as at least 15db improvement in pure tone or 20% increase in speech discrimination [4]. Types of hearing loss pattern in pure tone audiogram were observed as ascending, descending, flat and total [3]. Several treatment protocols have been proposed for treating SHL. Corticosteroids,

antiviral agents, anticoagulants, vasodilators, anti-inflammatory drugs, and other approaches have been suggested; there are reports of some benefit from most of these therapies. At present, the most commonly accepted treatment is systemic corticosteroid therapy [2,3]. Corticosteroids are thought to improve idiopathic SSNHL by reducing inflammation and edema in the inner ear [9]. Systemic steroids as a treatment for SSNHL have been extensively studied since the hallmark work by Wilson et al. in 1980 [6]. However, as per a Cochrane work on this topic, first published in 2006 and most recently updated in 2013 [6], that included Randomised controlled trials [RCT], meta-analysis and other study reviews, Cochrane and clinical guidelines of the American Academy of Otolaryngology – Head & Neck Surgery (AAO-HNS) concluded that systemic steroids were not proven as either effective or ineffective [6]. No recommendation can therefore be made for or against their usage, but because of the potentially severe consequences of SSNHL, the AAO-HNS guideline suggested using them as an option.

However, the early and late complications of systemic corticosteroid therapy are not rare and are well-known to otorhinolaryngologists; this has led to investigations of topical therapies in the inner ear for its conditions, including SHL. Intratympanic corticosteroid therapy may potentially provide organ-specific treatment, with high doses applied over the round window membrane, thereby avoiding the adverse effects of systemic corticosteroid therapy. As with other proposed treatments, the efficacy of intratympanic therapy for SHL needs to be determined; several studies have demonstrated favorable results, even after systemic therapy had failed [2,6]. On the other hand, there are studies that did not indicate any differences in hearing outcomes for intratympanic vs systemic corticosteroids in a first-line treatment of ISSNHL equivalent of a moderate to severe hearing loss [7]. However, there are other studies like, the meta-analysis by Qiang et al. [8] found a better recovery rate in a total of 225 pooled subjects who received a first-line treatment by trans-tympanic steroids compared to 226 pooled control subjects (systemic steroids), especially in subjects with mild to moderate hearing loss.

There are other studies on the use of trans-tympanic steroids as a salvage therapy which showed at least a tendency to obtain better results than control for PTA improvement and/or the rate of recovery [2,6]. In some of the studies which concluded that combination therapy with transtympanic and systemic steroids is more effective than systemic steroids alone [4]. There is unanimous conclusion in most of the studies which used either systemic steroids or transtympanic steroid or combination therapy that results are good if early diagnosis and

intervention is done within 72 hours [1,3]. Although its efficacy alone has not been proved definitively, intratympanic corticosteroid therapy for SHL is becoming more widely used. Use of intratympanic corticosteroids has given rise to three main protocols for the treatment of SHL [2]:

Primary Therapy - as the first treatment for SHL, without systemic corticosteroids;

Adjuvant Therapy - concomitantly with systemic corticosteroids, and;

Rescue therapy - started after systemic corticosteroid therapy has failed.

There are several advantages of using intratympanic corticosteroids like its an outpatient procedure, easily administered, can be administered soon after the diagnosis and is relatively painless. The procedure is well tolerated and relatively easy to perform. Most patients understand the concept of intratympanic therapy and accept it, since it may be administered in an outpatient setting under local (topical) anesthesia [2]. There are minor side effects like tympanic membrane perforation, Pain, Otitis media.

Dexamethasone and methylprednisolone are commonly used steroids for transtympanic steroid therapy [2,6,10]. Although Dexamethasone is considered to be absorbed well in middle ear, there are studies that suggest Methylprednisolone is more effective in hearing improvement [10]. Administration modes also differ: transtympanic needle injection, myringotomy, myringotomy with a ventilation tube [9,10], myringotomy with a special perfusion needle (Micromedics, Eagan, MN), and implantable infusion pumps in the middle ear (Round Window m-Cath; Durect Corp., Cupertino, CA) for continuous steroid release. The duration of treatment, the interval between injections, and the number of injections also differs among authors, ranging from a single dose to weekly transtympanic injections, [2,6] steroid solutions as drops applied by patients during several weeks, transtympanic injections several times a week, or implantable infusion pumps [2,6].

Myringotomy and Grommet insertion is a simple one time procedure in short GA or LA, steroid then can be instilled frequently through grommet conveniently [9].

Aim and Objective of the Study: To establish the effectiveness of transtympanic methylprednisolone in the treatment of Idiopathic SSNHL with emphasis on early diagnosis and immediate intervention for better outcome in this annoying condition with the potential risk of developing permanent hearing loss and tinnitus.

Materials and Methods

From January 2011 to December 2021, 32 patients with a diagnosis of Idiopathic sudden sensorineural hearing loss were seen at the otorhinolaryngology outpatient clinic. 18 patients were either received no treatment earlier or received antibiotic and NSAID therapy and 14 patients were already on oral steroid therapy.

A detailed clinical history was taken, followed by an otoneurological examination, and an initial audiological assessment by pure tone audiometry, impedance testing, laboratory tests, and an image exam (magnetic resonance imaging with contrast of the inner auditory canal). All patients were treated with transtympanic methylprednisolone given in the dose of 0.4 ml of 10 mg/ml alternate days for total 5 instillations.

Inclusion Criteria

- Patients with sudden sensorineural hearing loss developed within two months.
- Patients in whom the cause has not been properly diagnosed.
- Patients in the age group of adults between 15 years and older.
- Patients with SSNHL who were already on systemic steroids, as salvage therapy

Exclusion criteria

- Hearing loss with recognizable cause. In the course of study, we found three cases of SSNHL who had Diabetes, one case of acoustic tumor and two cases of perilymph leak leading to SSNHL and vertigo, all of these were excluded from current study.
- Hearing loss which is purely conductive in

nature and/or chronic in nature.

Observation and Results

A total of 32 patients were selected for this study. The youngest patient was 21 years old and the oldest patient was 60 years old. All had undiagnosed unilateral sensorineural hearing loss without any obvious cause. In the study Audiogram was taken immediately after the patient presented with hearing loss and this was repeated in one month after initiation of treatment.

Myringotomy with Grommet was done in local anaesthesia [2% xylocain with adrenalin] in all the patients under aseptic precautions and first dose of steroid [0.4 ml Inj Methylprednisolone 125 mg in the concentration of 10mg/ml] was instilled in middle ear in the same sitting. This is demonstrated in image 1. Patients were asked to remain in the same operative position of supine and head tilted through 45 degree to opposite side for 30 more minutes to maximise exposure of round window to the medicine. Procedure was done on day care basis and they were discharged in 4 hrs with a course of pain killer and antibiotic.

Patients were advised to visit outpatient clinic every alternate day for endoscopic instillation of steroid with a needle and syringe through the grommet, we avoided the method of putting ear drops as mentioned in some studies because of possibility of blockade of grommet. Every time it is ensured that the solution has entered the middle ear by checking with the patient as some time grommet gets blocked and solution may not enter the middle ear. Most of the time patients say that solution entered the throat which is confirmatory.

DRUG, DOSE AND METHOD OF ADMINISTRATION :

- Methylprednisolone - 0.4 ml of 25mg/ml - Alternate days for 5 instillations

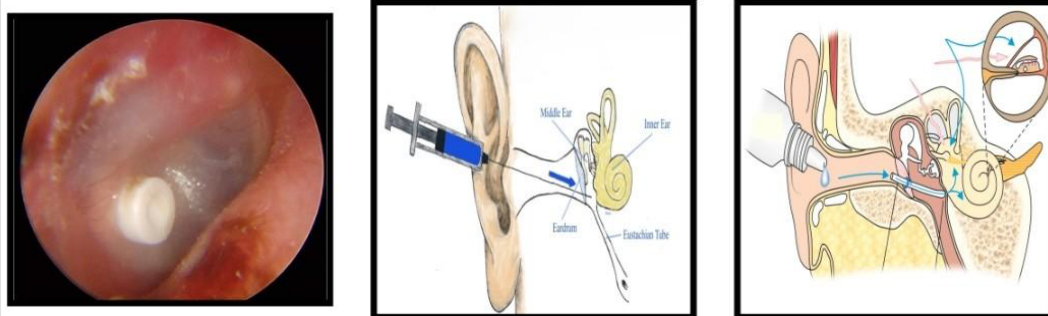


Figure 1:

None of the patients developed any complication related to the procedure or grommet insertion. Grommets got extruded from drum on its own in 6 to 8 months duration without any residual perforation.

Data Analysis:

Severity of SSNHL [3] is classified as

- Mild: 30–50 dB,
- Moderate: 51–70 dB,
- Severe: 71–90 dB
- Profound 90 dB HL.

Definition of Recovery:

The specific definition of what constitutes “improvement” or “recovery” after an SSNHL is not uniform among studies and reports [3].

Since most patients did not have audiograms before the SSNHL episode, the hearing in unaffected normal ear as measured at the time of diagnosis was used as standard.

There are two types patients, one group constituted patients who were directly put on transtympanic methylprednisolone therapy and no systemic steroids and the other group patients who were already receiving systemic steroids as salvage therapy with transtympanic Methylprednisolone. We avoided use of antivirals as there are studies that proved its ineffectiveness [11,12].

We adopted following definition for recovery considering normal hearing contralateral ear as indicator of status of affected ear prior to hearing loss.

1. Complete (Type 1) recovery: The recovery of hearing to within 10 dB of contralateral ear hearing pure tone average. Complete recovery from tinnitus
2. Partial (Type 2) recovery: The recovery of hearing to within 50% or more of contralateral ear hearing loss pure tone average. Significant improvement in tinnitus.
3. Minimal (Type 3) recovery: Less than 10 to 20 db hearing improvement, relief from severity of tinnitus
4. No recovery in hearing

Results

Thirty-two patients with unilateral sudden onset sensoryneural hearing loss were included, 18 patients were directly put on trans tympanic methylprednisolone therapy and 14 were already receiving systemic steroids with partial or no hearing and/or tinnitus improvement. The mean age was 41 years (range 21–60). There were 17 women and 15 men. The right and left ears were affected in 20 and 12, respectively. Most of the patients complained of concomitant onset of tinnitus and aural fullness with hearing loss. We divided patients in four groups Group A: Included 7 patients who visited in the first week and received primary therapy directly as Transtympanic steroid therapy, Group B: 6 Patients who visited in the second week of presentation, Group C: 12 patients who visited after 15 days, 9 amongst them were already on oral steroid therapy and Group D: 7 patients visited approximately 1 month after starting of the hearing loss, 5 of which were already on oral steroid therapy. As per image 2.

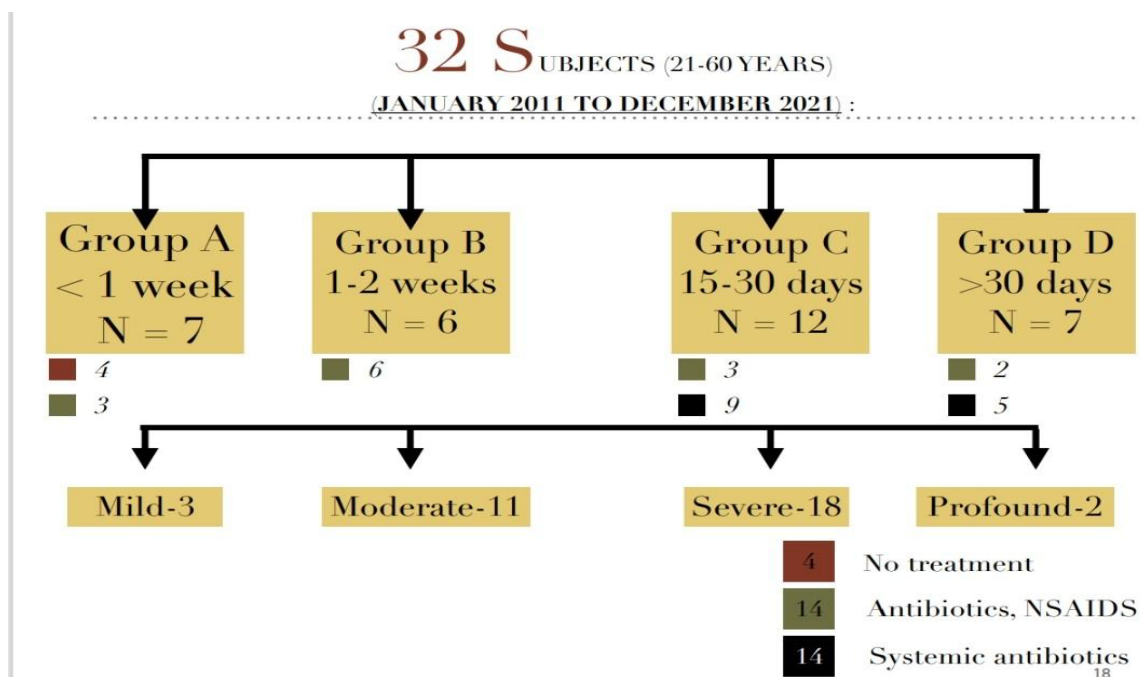


Figure 2:

All the 7 patients who received trans tympanic methylprednisolone in first week of onset of hearing loss recovered well with hearing improvement close to 90% of other normal ear [Figure 3], while those who received therapy in second week and within one month had variable hearing improvement from 20 to 40 db. And the rest 7 patients who presented after one month of onset did not show any improvement in hearing [Figure 4].

According to the level of initial hearing loss,

patients were divided into four classes of hearing loss. Moderate hearing loss was detected in 3 (8.8%), moderate-severe hearing loss in 11 (32.3%), severe hearing loss in 18 (52.9%) and profound hearing loss in 2 (5.8%) patients.

However almost all patients who visited in first 30 days showed significant improvement in tinnitus however only 3 three patients who presented after 30 days showed partial improvement in tinnitus and rest 4 patients did not show any improvement in tinnitus.

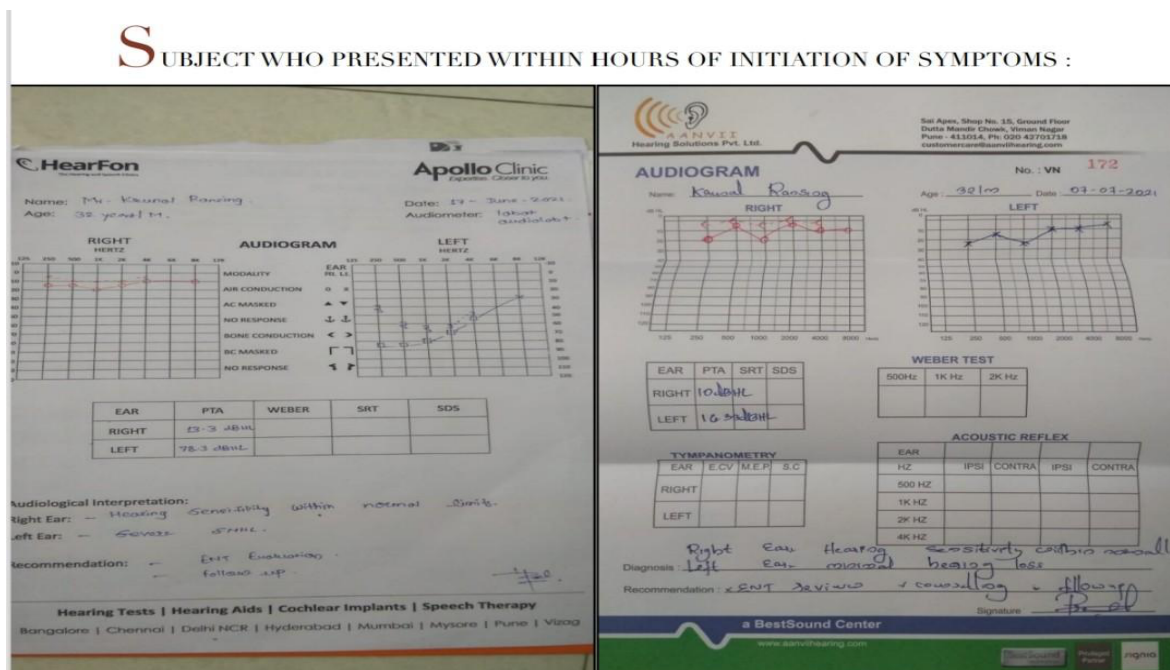
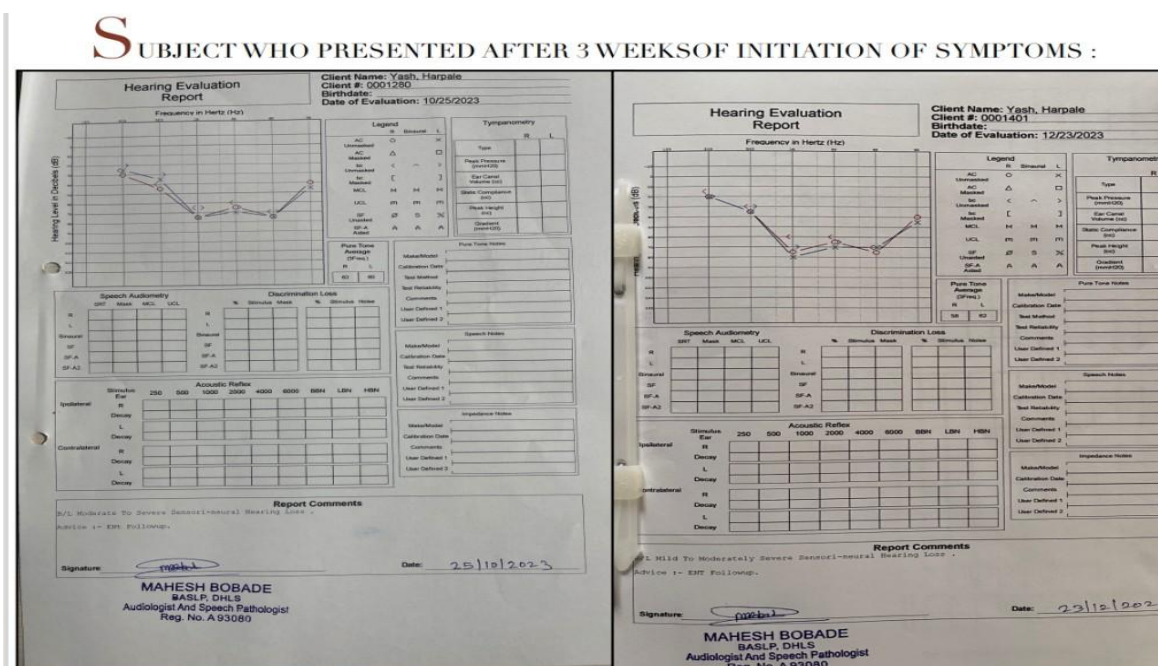


Figure 3:



According to classification for extent of recovery, complete recovery (Type 1) was seen all patients who consulted in first week and therapy was started immediately (7 out of 7,100%), partial recovery (Type 2) was seen in patients who were intervened after one week of onset of hearing loss [5 out of 9,55.5 %], 8 had type three recovery [8 out of 13, 60 %] and there was no recovery in hearing in rest of 7 patients in who either consulted late in the month or after one month of onset of symptoms (Type 4). 28 out of 32 patients showed complete to partial improvement in tinnitus [87.5%], here too patients who consulted in first week had near total recovery from tinnitus and thereafter recovery was less with time passage. For the purpose of statistical analysis, complete recovery and partial recovery groups are combined in recovery group. 25 patients in study group showed improvement in hearing [78.12%]

Discussion

In this retrospective study, we found that early diagnosis and intervention with trans tympanic methylprednisolone is highly effective in improving not only hearing loss but improvement of tinnitus as well. Even in the salvage group of patients who received systemic steroid, trans tympanic methylprednisolone had added benefit and patients hearing improved further 15 to 20 db in most of the patients. All 7 patients who were started therapy in first week itself had near 100 % recovery, thereafter hearing improvement went down by every passing day and week and by the end of one month and after one month, intervention with trans tympanic methylprednisolone was having negligible recovery or no recovery. Intratympanic steroids have only minor local

morbidities, and their efficacy as first-line therapy without systemic steroid in SSNHL has been shown. A higher concentration of therapeutic agent in the cochlea is associated with greater hearing recovery in animal studies (4). According to studies in guinea pigs, when medication is administered through the trans tympanic route, a much higher concentration of steroids is achieved compared with systemic administration (4). It has been shown in animal models that intratympanic steroids cause no morphologic or functional compromise, although there are some reports of tympanic membrane perforations and otitis media secondary to the perfusion process in human studies (4,9). It has also been shown that the chance of salvaging hearing decreases if the time interval between the insult and the administration of intratympanic steroid therapy after oral steroid failure increases [4]

Conclusion

Transtympanic methylprednisolone is a very effective therapy in isolated cases of Idiopathic sudden sensorineural hearing loss provided the therapy is started as early as possible, preferably in the first week itself. Timely intervention not only prevents the disability of permanent hearing loss but also recovers the precarious tinnitus that can haunt and disturbs the psychological wellbeing of the patients.

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