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Oral Prednisolone Vs Intratympanic Dexamethasone in Sudden Sensorineural Hearing Loss- A Comparative Study

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I. INTRODUCTION:

Idiopathic sudden sensorineural hearing loss is defined as reduction in hearing over 3 days or less, by 30 dB or greater, affecting 3 or more frequencies with no identifiable aetiology.[1,2]Factors like autoimmunity, vascular insult and viral infection have been postulated in the pathogenesis.[3] The hearing loss is mostly unilateral and may be associated with tinnitus and aural fullness. The true incidence of sudden sensorineural hearing loss is probably underestimated because of higher rate of spontaneous recovery.[1] The actual number of patients recovering spontaneously is not known.It is one of the few causes of reversible hearing loss seen all over the world and should be treated as a medical emergency by otologists. Multiple treatment protocols have been proposed to treat sensorineural hearing loss. Steroids, antiviral agents and vasodilators are some of the proposed therapeutic agents to treat SSNHL. The most accepted treatment remains with systemic corticosteroids. However systemic steroids have both short term and long term side effects. Hence it is important to study the efficacy of intratympanic steroid therapy for early improvement in hearing with minimal systemic side effects. Intratympanic steroid offers a chance to administer high concentration of drug into the inner ear, in a directed manner, with possible reduction in systemic side effects. The most common steroid used in intratympanic steroid treatment is dexamethasone, followed by methylprednisolone.[1] Treatment with topical steroids has been previously studied in refractory sensorineural hearing loss, labyrinthitis and Ménière's disease.[2,3,4,5,6,7,8]The intratympanic route creates significantly high perilymph concentration of steroids than that with intravenous or oral routes.[1,9]The efficacy of intratympanic steroid therapy in the treatment of SSNHL has not yet been established, although some studies have shown encouraging results if used in early course of treatment.[3,9] Some clinicians have used it only after failure of oral steroid therapy to treat refractory SNHL.[2,6,7,9]

Aims and Objectives:
To compare hearing improvement after treating with oral steroid and that with two doses of intratympanic dexamethasone injections.

Inclusion criteria:
1. 30 dB loss in three consecutive frequencies in <72 hours
2. Normal otoscopic examination
3. Age- 18- 55 years

Exclusion criteria:
1. Head injury
2. Ménière's disease or fluctuating hearing loss
3. Barotrauma
4. Noise induced hearing loss
5. Chronic otitis media
6. Exposure to ototoxic drugs
7. Post radiation hearing loss
8. Patients having absolute or relative contraindications to systematic steroids

II. MATERIALS AND METHODS:

Sample size: 30
Duration of study: 6 months

A prospective study was carried out on thirty patients presenting with sudden hearing loss. Hearing was assessed using pure tone audiometry (PTA) and those who fit in the definition of SSNHL were included in this study. Detailed clinical history and other associated symptoms were noted, which included tinnitus, aural fullness, vertigo etc. Patients were randomly divided into two groups of fifteen each. The pre-treatment hearing loss was classified into five grades using modified Siegel's criteria (grade 1: hearing threshold under 25 dB, grade 2: hearing threshold 26–45 dB, grade 3: hearing threshold 46–70 dB, grade 4: hearing threshold 71–90 dB, grade 5: hearing threshold over 90 dB).[10,11]The first group (group A) received treatment with oral steroid prednisolone (starting with 1mg/kg, tapered by 10mg every 7 days) and oral vasodilator for a period of six weeks. The second group (group B) underwent treatment with oral vasodilator for a duration of six weeks along with two intratympanic

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dexamethasone injections 24-hour apart, first being on the day of presentation. A written and valid consent was obtained from all the patients. Under all aseptic precautions and local anaesthesia, every patient of second group underwent myringotomy in supine position using a 26-G needle. Then 1 ml (2mg/ml) of microscopic intratympanic dexamethasone was injected in the posteroinferior quadrant of tympanic membrane. Patient's head was tilted 30 degrees to the healthy side for about 20 minutes so that the drug perfuses the round window adequately. Patients were observed for 30 minutes before being discharged. The same procedure was repeated the next day in out-patient setup. Patients from both the groups were followed up after six weeks of initiation of treatment to look for symptomatic improvement and hearing assessment using PTA.

The audiometric results were again recorded using the modified Siegel's criteria, where 'complete recovery' was defined as more than 30 dB hearing gain and as final hearing better than 25 dB, 'partial recovery' as more than 15 dB hearing gain and as final hearing between 25 and 45 dB, 'slight improvement' as more than 15 dB hearing gain but with a final hearing poorer than 45 dB, and 'no improvement' as less than 15 dB hearing gain and final hearing poorer than 75 dB.[10,11,12]

III. RESULTS:

Thirty patients met the inclusion criteria of the study. Sixteen males and fourteen females participated in the study with mean age (in years) of male 37.88 (+/- 5.58) and that of female 34.64 (+/- 7.20) at confidence interval of 95%. Onset of hearing loss ranged between 1-5 days for all the patients (mean- 2.23 days).

The demographic details of the patients are tabulated below.

Age (years)	Mean	36.26
	Range	19-55
Affected ear	Right	16
	Left	14
Sex	Male	16
	Female	14

Table 1. Demographic details

Thirteen out of thirty patients complained of other otological symptoms associated with hearing loss.

Symptom	Group A	Group B	*n
Tinnitus	3	4	7
Vertigo	1	1	2
Aural fullness	2	2	4

*n= Number of subjects

Table 2. Symptoms associated with hearing loss

All the patients (30/30) had unilateral presentation with normal otoscopic findings.

Pre-treatment audiometric results-

Hearing threshold for speech frequencies in affected ear ranged from 50-110dB for all the patients. Mean hearing threshold for speech frequencies was 75.5dB.

Mean hearing threshold for group A was 71.5dB. Mean hearing threshold for group B was 75.5dB.

Grade	n	%
3	11	55%
4	4	20%
5	5	25%

Table 3. Pre-treatment Siegel's grade of hearing loss-

Post-treatment hearing recovery-

Group A:

After four weeks of completion of treatment, hearing threshold ranged between 40dB and 95dB with mean threshold of 64dB. Decibel gained after treatment ranged between 0dB and 30dB with mean gain of 16.33dB. As per Siegel's

criteria, 20% of patients had partial recovery, 40% of patients had slight recovery and 40% of the patients had no recovery.

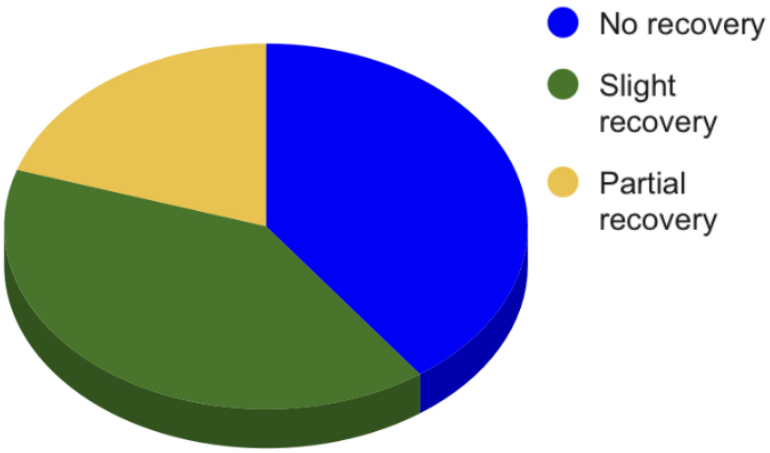

Fig.1. Recovery in Group A

Group B:

After four weeks of completion of treatment, hearing threshold in this group ranged between 25dB and 85dB with mean threshold of 58dB. Decibel gained after treatment ranged between 5dB and 40dB with mean gain of 21.67dB. As per Siegel's criteria, 6.67% of the patients had complete recovery, 33.33% of the patients had partial recovery, 40% of the patients had slight recovery and 20% of the patients had no recovery.

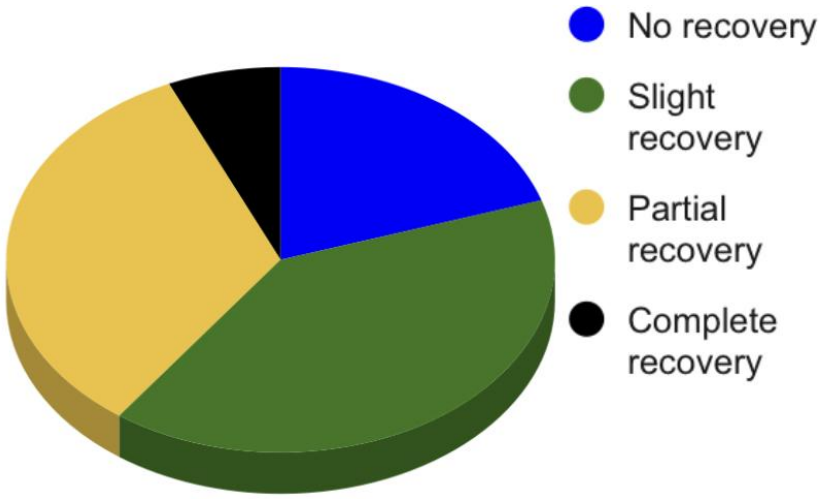

Fig.2. Recovery in Group B

The null hypothesis stated that hearing improvement in group B was not better than that in group A.

In this study, the p value obtained was 0.0406 which is statistically significant. Hence group B was proved to have better hearing improvement at the end of four weeks of completion of treatment. The pre-treatment Siegel's grade of hearing did not seem to be related with the post treatment hearing gain.

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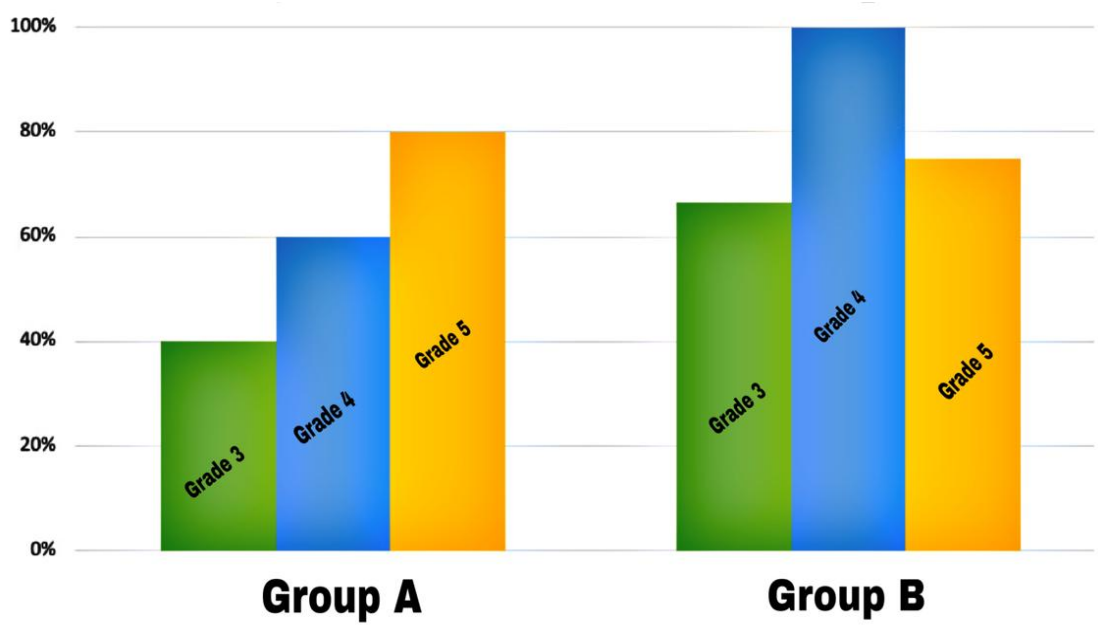

Fig.3. Recovery in various Siegel's grades in both the groups

Symptom improved	Group A	Group B
Tinnitus	3/3 (100%)	3/4 (75%)
Vertigo	1/1 (100%)	1/1 (100%)
Aural fullness	2/2 (100%)	2/2 (100%)

Table 3. Post-treatment symptomatic improvement

IV. DISCUSSION:

Sudden sensorineural hearing loss should be considered a true emergency and prompt diagnosis should be made. Early treatment with steroids has shown significant improvement in hearing and other associated symptoms.[2,3,6,7,9] The actual benefit of various treatment modalities cannot be studied due to high rate of spontaneous recovery of hearing. However systemic corticosteroids have been shown to produce significant improvement in hearing in double-blind, placebo controlled, randomised clinical trials.[13]The exact mechanism in which steroids may improve hearing is not known. The effects of steroids are mediated through both glucocorticoid and mineralocorticoid receptors that are found within the cytoplasm of inner ear cells. It is proposed that the steroids help in synthesis of proteins and increase cochlear blood flow, thus avoiding ischaemia. They act on stria vascularis, which maintains Na^+/K^+ secretion to regulate endocochlear potential.[1,9,14,15,16] Steroids are known to have many long term as well as short term side effects. Thus intratympanic dexamethasone can be used as an alternative therapy for SSNHL. This route aims to concentrate the drug into perilymphatic fluid. Steroid diffuses through the round window opening; thus creating adequate concentration into the perilymph.[1-8,17]This technique could reduce adverse effects and complications associated with systemic steroids. Chandrasekhar.[3] and Parnes et al.[17]in their studies measured much higher inner ear concentrations with intratympanic administration compared with oral or intravenous administration in the guinea pig model. Both these studies reported successful results with intratympanic steroid therapy in SSNHL.

Three main protocols have been proposed for treatment of SSNHL:

1. As a primary therapy without systemic steroids in patients who cannot tolerate systemic steroids;
2. As an adjunctive therapy along with systemic steroids; and
3. As salvage therapy after failure of systemic steroids in refractory cases.[9]

In majority of the studies the most rewarding results were obtained after failure of primary treatment with systemic steroids.[2,3,6,7,8,9]Chandrasekhar treated 10 patients with 2-4 mg/mL dexamethasone intratympanically, which showed increased inner ear absorption, 73% to 80% improvement in hearing and absence of systemic side effects.[3] Silverstein carried out a retrospective study on 46 patients who were treated with transtympanic steroids for a inner ear disorders, where 8 patients had SSNHL. He found that speech reception threshold and tinnitus improved significantly in 41% and 47%, respectively. However patients with tinnitus and bilateral sensorineural hearing loss did not benefit from this treatment.[8]Berjis and Soheilipour in their similar comparative study showed that hearing improvement rate was 84% in patients who received oral methylprednisolone and was 64% in those who received intratympanic dexamethasone injections.[12]Parnes et al. treated 37 patients of inner ear disorders with intratympanic steroids; 13 of which had SSNHL. Patients with immune-mediated hearing loss and SSNHL showed the most significant improvement in hearing, while patients with cochlear hydrops and those with sudden deterioration in pre-existing hearing loss did not show any success.[17] Lefebre and Staeker treated 6 patients with SSNHL with microcatheter infused methylprednisolone for 8 to 10 days, in patients refractory to systemic steroids. All these patients showed 16.25 to 25 dB improvement in hearing thresholds.[19]Five of the 6 patients treated by Kopke et al. with methylprednisolone using implanted microcatheter showed improved hearing, with 4 returning to base line hearing levels. All the 6 patients initiated treatment within 6 weeks of symptom onset. No patients who initiated treatment 6 weeks after the onset showed any improvement.[6]Gianoli in 2001 found encouraging results in patients with failed systemic steroid therapy, however the average hearing improvement in these patients was 15.2 dB only.[2]However Battista[13] and Lauterman[18] in their individual studies found no benefit after addition of intratympanic steroids to the primary oral steroid therapy.

In our study the mean decibel gain in patients who received oral prednisolone in tapering dose along with oral vasodilator (group A) was 16.33 dB. The mean decibel gain in patients who received two injections of intratympanic dexamethasone along with oral vasodilator (group B) was 21.67 dB, which was clearly more than the first group. The p value obtained in this study was 0.0406 which is statistically significant, showing that group B had better hearing improvement at the end of four weeks of completion of treatment. The Siegel's criteria for recovery of hearing loss takes into consideration the decibel gain as well as the final threshold for hearing, after completion of treatment. Only one patient in this study showed Modified Siegel's 'complete recovery' who had received intratympanic dexamethasone injection. There was no significance difference in the improvement with other associated symptoms like tinnitus, aural fullness, vertigo etc.

V. CONCLUSION:

Both oral and intratympanic steroids are effective in treatment of SSNHL. In this study intratympanic dexamethasone resulted in higher degree of improvement, symptomatically as well as on audiometric analysis. This route can help reduce steroid-associated adverse effects. However prompt diagnosis, appropriate subject selection and early initiation of treatment should be emphasised to establish intratympanic steroid therapy as mainstay of treatment in SSNHL.

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