

## Comparison Study Of Treatment Modalities In Sudden Onset Sensorineural Hearing Loss

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### ABSTRACT

**Objective** - In this study 2 modalities of treatment- Injection Dexamethasone and Oral Glycerol Versus Injection Dexamethasone Alone are compared in case of sudden sensorineural hearing loss. **Methods**- it is a randomized clinical study conducted in western U.P. on 100 patients with a history of fewer than 10 days and with no known cause. The patient is divided into 2 groups – 1. We administered systemic steroids (injection Dexamethasone) for 3 days, followed by oral deflazacort for 6 days with liquid glycerol, and 2. we administer systemic steroids alone, injection Dexamethasone 3 days, followed by oral deflazacort for 6 days. The study duration is 7 days and post-treatment was assessed by pure tone Audiometry and speech discrimination test at 0, 3, and 5,7 days. **Result**- There were 51 males and 49 females. Vertigo ( $P$  value  $< .00$ ) and diabetes mellitus ( $P$  value  $< .001$ ) had a negative prognostic influence on the recovery rate in both groups. The comparison revealed that group I in which patients received injection dexamethasone with oral glycerol had a higher recovery rate of 66% as compared to group II patients, in which patients received injection dexamethasone alone (recovery rate of 52% ). **Conclusion**- Vertigo and diabetes mellitus play a negative role in the recovery of SSNHL. The novel treatment protocol we used in group I patients that is liquid glycerol and systemic steroids was significantly better and more effective in treating SSNHL as compared to the group II treatment protocol of systemic steroids alone. Hence, we concluded that SSNHL is treatable too with a good recovery rate.

**Keywords:** sudden sensorineural hearing loss, systemic steroids, management, prognosis, outcome

### INTRODUCTION

Numerous studies and reviews have been conducted trying to formulate a valid definition and the best management protocol of SSNHL. The most accepted definition of SSNHL is sensorineural hearing loss of 30dB or greater over at least 3 contiguous audiometric frequencies occurring over 72 hours.<sup>1</sup>

The management of SSNHL depends upon whether it is idiopathic or of known etiology. Sensorineural hearing loss with known etiology has been postulated to be due to vestibular schwannoma, malignancies, and stroke.<sup>2</sup>

In 90% of patients, with SSNHL, the cause is not known (idiopathic) and pathogenesis in these patients is attributed to vascular, viral, cochlear membrane rupture, or multiple etiologies.<sup>3</sup>

In the last 2 decades, many researchers have recommended the use of intratympanic steroid therapy in patients with SSNHL as a rescue or salvage therapy and none of the conducted studies could demonstrate superior results in comparison to systemic steroids.<sup>4-6</sup>

The Management Of SSNHL Should Include Diagnostic MRI Scanning Of The Cerebellopontine Angle To Discard A Vestibular Schwannoma.

Systemic steroids act by their anti-inflammatory properties to improve clinical outcomes.

The use of the osmotic agent glycerol along with steroids in the management of SSNHL was with the ideology to utilize the osmotic property of this agent in effectively decreasing inner Ear fluid pressure.

Various Prognostic factor influence SSNHL such as the age and timing of presentation, An associated disorder like diabetes, and symptoms such as vertigo and tinnitus.<sup>7-9</sup>

## Material and Methods

This study was carried out from august 2021 to July 2022 on a total of 150 patients who presented to the department ENT and Head & Neck Center, Santosh medical college and hospital, Ghaziabad. Post obtaining informed written consent from all the patients with SSNHL who participated in the study, they were divided into 2 equal groups based on stratified randomization.

Ethical clearance was obtained from the institutional ethical committee.

Inclusion criteria - The Patients Presenting To OPD with Idiopathic SSNHL within 10 Days Of Symptom Of decreased Hearing Were Included In The Study.

Exclusion criteria- the patient with a previous history of decreased hearing, ear discharge, and vertigo.

The patients were divided according to their age groups as follows: age in years <30, 31 to 40, 41 to 50, 51 to 60. Patients were also divided - into early and late presenters.

Early presenters were the patients who presented between 0 and 3 days of experiencing hearing loss. late presenters were the ones who experienced hearing loss between 4 and 10 days.

Group I is given a Combination Of Steroids For A Total Of 7 Days. The Dosing Schedule Was Oral Glycerol (1g/Kg/D) Liquid In 4 Divided Doses For 7 Days And Injection Dexamethasone 8 Mg (Weight 50 Kg Or More) Daily For The First 3 Days, Followed By Oral Steroids In The Form Of Tablet Deflazacort 30 Mg (Weight 50 Kg Or More) Or 15 Mg (Weight < 50 Kg) Twice

A Day For Next 2 Days. Deflazacort Was Tapered To Once-Daily Dosing For Another 2 Days Before Discontinuing.

In Group II, Only Steroids Were Administered In The Same Manner As In Group 1 Only Difference Glycerol Is Not Given To Patients.

At The Time Of Presentation (0 Day), A Thorough History Is Taken, General Physical Examination, And Patients Underwent A Complete ENT Examination Including Microscopic Examination Of The Ear And Hearing Tests In The Form Of A Pure Tone Audiogram (PTA). The Hearing Tests Were Repeated At Follow-Up On The Third Day, 1 Week, And Third And Sixth Week. Next Step, Patients Underwent Magnetic Resonance Imaging Brain And Relevant Blood Investigations.

The Recovery Score For Every Patient Was Calculated Using The Definition Of Recovery (AAO-HNS),<sup>4</sup> Which Is The Improvement To 50% Of Baseline Difference Between The Treated And Untreated Ear Patients Divided Into 2 Categories: Complete Recovery And No Recovery. Both The Groups Were Studied For Side Effects If Any.<sup>10</sup>

Based On The Above Findings, Performa For Each Patient Was Filled In And Analyzed Statistically Using IBM SPSS Software (Version 20). The Chi-Square Test Was Used For Analysis And The Power Of The Study.

**Results**

The result is compiled compared to hearing gain outcome and the role of various factors such as age, sex, the timing of presentation, associated tinnitus, vertigo, and diabetes mellitus (DM).

Of the 100 patients with SSNHL, 51 males and 49 females, no significant differences were noted in both group, (group I: P ¼ .13; group II: P ¼ .20).

In group I and group II, the number of patients presenting in different divided age groups and genders were similar (P ¼ .49 not significant; Table 1 and II).

**Table 1. Patients Divided According to Their Age-Groups in Group I and Group II.**

Age group	Count and percentage	Group		
		Group I	Group II	Total
< 30		10 20%	12 24%	22 22%

31-40		12 24%	14 28%	26 26%
41-50		11 22%	10 20%	21 21%
51-60		17 34%	14 28%	31 31%
Total		50 100%	50 100%	100 100%

**Table 2. Patients Divided According to Their Gender in Group I and Group II**

Gender	Count Percentage	Group I	GROUP II	TOTAL
MALE		29 58%	22 44%	51 51%
FEMALE		21 42%	28 56%	49 49%
Total		50 100%	50 100%	100 100%

**Table 3. Chi-square test on age- groups**

	Value	Df	Asymp sig (2-sided )
Pearson chi-square test	2.145 <sup>a</sup>	4	.705
Likelihood ratio	2.169	4	.705
Linear-by-linear association	.470	1	.493
N for valid values	100		

**Table 4. Chi-square test on gender.**

	Value	Df	Asymp sig ( 2=sided )	Exact sig ( 2-sided )	Exact sig ( 1-sided)
Pearson chi-square	.027 <sup>b</sup>	1	.870		
Continuity correction <sup>c</sup>	.000	1	1.000		
Likelihood	0.027	1	0.870		
Fisher exact test				1.000	0.500
N for valid cases	100				

Abbreviations: Asymp, asymptotic; grp, group; Sig, significance.

Two cells (20.0%) have an expected count of less than 5. The minimum expected count is 4.50.

B Zero cells (.0%) have an expected count of less than 5. The minimum expected count is 36.50.

C Computed only for a 2 \_ 2 table.

The effect of age on the recovery rate was noted. In group, I, the recovery pattern in all the divided age groups was similar ( $P \frac{1}{4}$  .304; Table 5). in group II, the recovery score of younger patients was much better as compared to the older age-group patients ( $P < .05$  significant; table 5).

**Table 5. Recovery Score in Group I and Group II According to the Days of Presentation. a**

GROUP	PRESENTATION DAY	COUNT PERCENTAGE	NO RECOVERY	COMPLETE RECOVERY	TOTAL
GROUP I	0-3		3	12	15
	3-5		7	11	18
	5-7		8	9	17
	TOTAL		18	32	50
GROUP II	0-3				
	3-5				
	5-7				
	TOTAL		22	28	50

The relationship between the time of presentation and its effect on the recovery score was noted. In group I, we found that there was no significant difference in the recovery of patients presenting early or late ( $P > .05$ ). On the contrary in group II, a significant impact of days of presentation on the recovery score was found.

Another factor analyzed concerning its impact on the recovery rate of SSNHL was the presence of vertigo and tinnitus. Patients presenting with vertigo as an accompanying symptom with SSNHL had a poor recovery rate.

**Table 6. Recovery Score in Group I and Group II According to Different Age-Groups**

Group	Age group	Count Percentage	Recovery rate		
			No recovery (0)	Recovery (1) ( complete )	Total
Group I	<30	3 6%	7 14%	10 20%	
	31-40	5 10%	7 14%	12 24%	

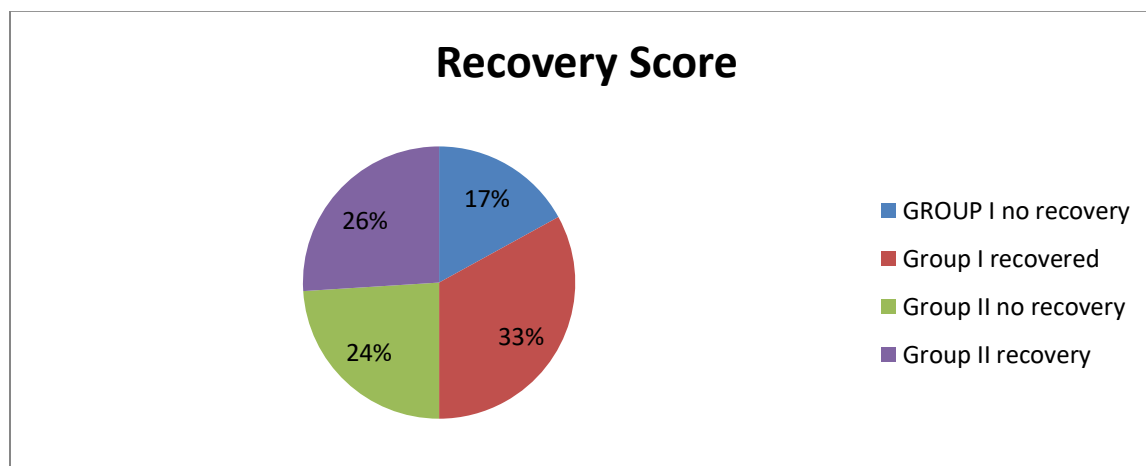
	41-50		4 8%	7 14%	11 22%
	51-60		5 10%	12 24%	17 34%
	Total		17 34%	33 66%	50 100%
Group II	<30		6 12%	6 12%	12 24%
	31-40		7 14%	7 14%	14 28%
	41-50		5 10%	5 10%	10 20%
	51-60		6 12%	8 16%	14 28%
Total			24 48%	26 52%	50 100%

Abbreviation: grp, group.

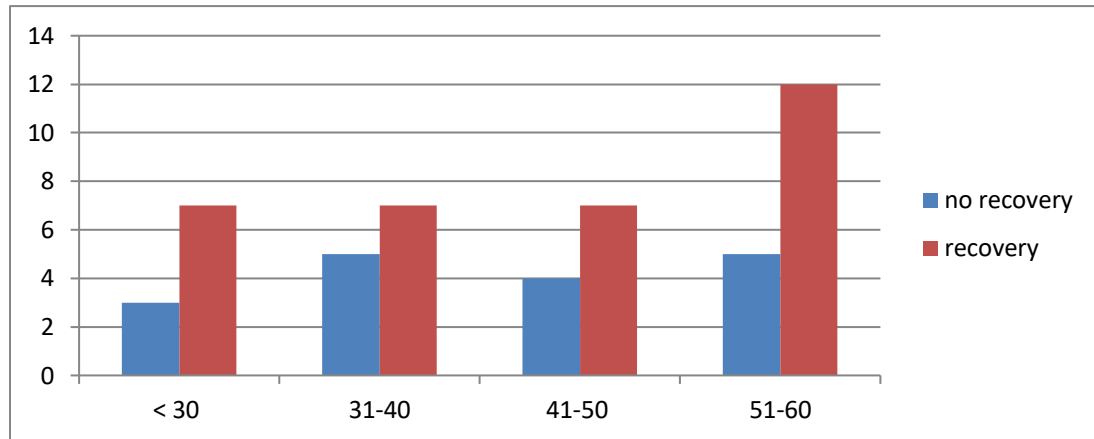
A Where 0 signifies no recovery. 1 signifies complete recovery. Chi-square test group I  $\chi^2$  0.304 (not significant).

Chi-square test group II  $\chi^2$  0.01 (significant).

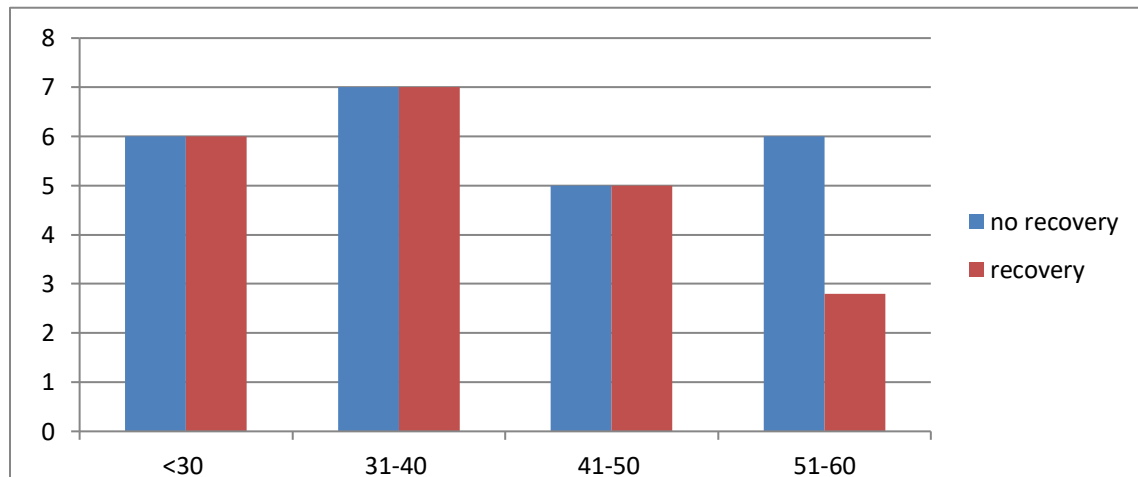
**Diagram 1-Recovery Score percentage**



**Diagram 2-Group I recovery score**



**Diagram3- Group II recovery score**



In group I, a total of 4 patients experienced vertigo and none recovered from SSNHL ( $P < .001$  highly significant). In group II, a total of 6 patients experienced vertigo and none of them recovered too ( $P < .001$  highly significant).

Tinnitus on the other hand did not show any significant impact on the recovery rate of patients with SSNHL (group I  $P = .15$  not significant, group II  $P = .12$ ).

The mean PTA score on the day of presentation (day 0) and at the end of 6 weeks was also compared in both groups. In group, I, the mean PTA value on the day of the presentation was 61.40 and at the end of 6 weeks was 30.31 ( $P$  value  $< .001$  highly significant). In group II, the mean PTA value on the day of presentation was 61.36 and at the end of 6 weeks was 43.05



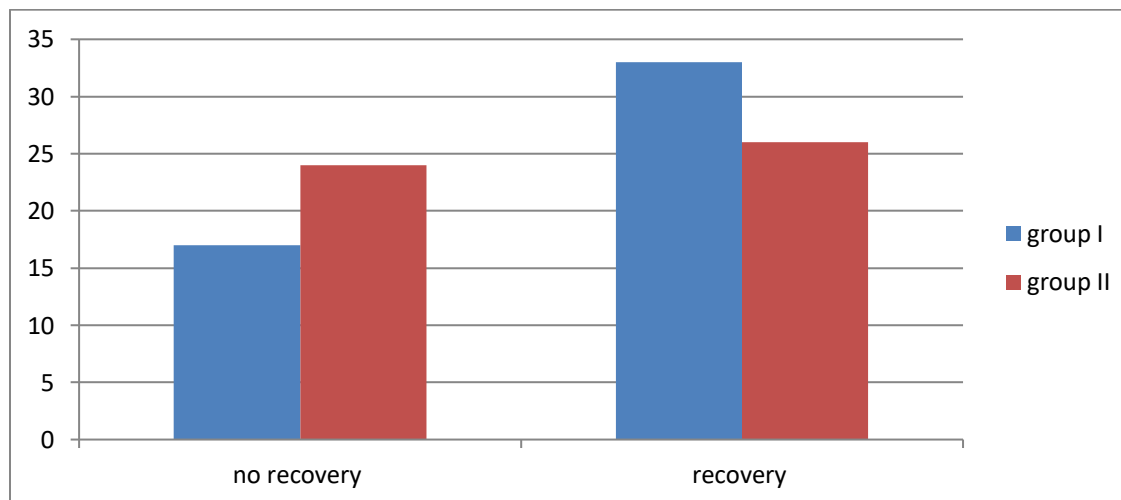
(Table 5).

The comparison of recovery rates in group I (glycerol & steroid) and group II (steroid alone) showed a significantly higher recovery rate (66%) in group I as compared to group II (52%;  $P < .001$ ; Table 5).

**Table 7. Comparison of Recovery Score in Group I and Group II.**

		Group I	Group II	Total
Recovery score	0	17 17%	24 24%	41 41%
	1	33 33%	26 26%	59 59%
Total		50 50%	50 50%	100

**Diagram 4-Comparison of Recovery Score in Group I and Group II.**



**Discussion**

A plethora of studies have been conducted in the past testing various modalities of treatment like intratympanic steroids, hyperbaric oxygen, and magnesium, however, every study had its limitation.<sup>11</sup>

Many authors have advocated the use of intratympanic steroids and various treatment regimens, ranging from its use as primary therapy, adjuvant therapy with systemic steroids, or rescue or

salvage has been studied. The outcome of intratympanic steroids is similar to the use of systemic steroids alone without additional benefits. Also, patients are more comfortable with less invasive techniques.<sup>4-6</sup>

This study was done to find effective management of SSNHL and also to identify various factors which influence the outcome of treatment.

A combination of drugs like glycerol and systemic steroids was given for 7 days. Glycerol, an osmotic agent, was added in addition to steroids given its effect of reducing the inner ear pressure. Associated symptoms of vertigo and tinnitus were also studied as they are known to influence the recovery of SSNHL. Hearing recovery was seen concerning various parameters like age, the timing of presentation, and diabetes.

Although age is an important factor that has a bearing on hearing recovery and in many studies advancing age (51-60 yrs) has been universally correlated with decreased rates of hearing recovery and lower absolute threshold gains.<sup>3,8</sup>

In patients of group I where glycerol was added, the patients of all age groups whether young or old had significantly good recovery; whereas in group II patients, we noticed that with the increasing age there was a decreasing trend in the recovery rate (Table 2; Figures 1A and B). So patients of advancing age can benefit from the administration of glycerol along with steroids in the case of SSNHL.

Early presentation of patients less than a week after onset of SSNHL correlates with improved odds of hearing recovery.<sup>12-16</sup>

In the present study, the cutoff point of patients presenting with hearing loss was 10 days, so no patient presenting beyond the above period was included.

Early presentation to a physician (less than a week) after the onset of SSNHL correlates with improved odds of hearing, with chances of complete hearing recovery decreasing after that time.<sup>12-16</sup>

In the present study both early and late presenters, who were administered glycerol in addition to steroids, had a notably good hearing gain (Table 3 and Figure 2A) Results of my study shows a definitive role of oral glycerol for better outcome irrespective of age and time of presentation. The role of glycerol in addition to steroids is due to its anti-inflammatory action of steroids on hair cells. This effect of glycerol and systemic steroids on cochlea could be the reason to explain the improvement in hearing even in old age patients and late presenters.

Diabetes is one of the systemic disorders known to be associated with SSNHL, and previous studies show that recovery is not good with any of the treatment modalities. Min-Beom Kim et al studied the effect of diabetes on sensorineural hearing loss and found that the rate of hearing loss in participants with normal glucose levels, prediabetes, and DM was 1.8, 3.1, and 9.2, respectively, per 1000 person-years and concluded that patients with DM having a moderately increased risk of future hearing loss.<sup>17</sup>

In The Present Study, the Number of Diabetics Included 10 Diabetic Patients In Group I And 6 In Groups II. It Was Observed That Only 6 Patients in Glycerol Plus Steroid (Group I) and None in Steroids Group (Group II) Had Any Recovery.

A Negative Impact Of Vertigo On SSNHL Was Found In The Study, Vertigo Occurs Due To Disease In Vestibular Part Of The Inner Ear. The Involvement Of Both The Parts Of Inner Ear That Is Vestibular And Cochlea In Cases Having Associated Vertigo With SSNHL Has Poor Outcome As Compared To Involvement Of Only Cochlea In SSNHL Without Vertigo.

A Study Conducted By Moskowitz Et Al Who Reported the Association Of Vertigo With SSNHL With Poor Prognosis As They Noticed That Only 14% Of Patients With Vertigo Achieved A Complete Recovery.<sup>8,15,16,18</sup>

Tinnitus as an accompanying symptom of SSNHL has variable reviews, some authors found it to be a positive prognostic factor, 20 others as a negative prognostic factor, 21 and many of them found its presence to be insignificant in patients with SSNHL.<sup>8,13</sup>

A study conducted by Nosarti-Zarenoe et al<sup>14</sup> found that the presence of tinnitus as an accompanying symptom did not show any significant influence on hearing recovery score which was similar to the results of our study, where no effect of tinnitus on hearing recovery was seen in both the groups.<sup>8, 13</sup>

A comparison of hearing recovery scores showed 66% recovery in patients receiving glycerol in combination with Steroids and only 52% recovery in patients receiving steroids alone (P < .001 highly significant; Table 7 and Figure 3).

According to my study glycerol and steroid is the Answer in patients with SSNHL to achieve a good hearing Recovery. The limitation of our study is the small sample size which was calculated based on a statistical analysis of a pilot feasibility study conducted on 100 patients in our center.

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