

# A retrospective study of the clinical characteristics and post-treatment hearing outcome in idiopathic sudden sensorineural hearing loss

Purushothaman Ganesan,<sup>1</sup> Purushothaman Pavanjur Kothandaraman,<sup>2</sup> Simham Swapna,<sup>3</sup> Vinaya Manchaiah<sup>4-6</sup>

<sup>1</sup>Expert Hearing Solutions, Wall Street Audiology Inc., Saskatoon, Saskatchewan, Canada; <sup>2</sup>Department of Otorhinolaryngology, SRM Medical College Hospital and Research Centre, Chennai, Tamil Nadu, India; <sup>3</sup>Hindu Mission Hospital, Chennai, Tamil Nadu, India; <sup>4</sup>Department of Speech and Hearing Sciences, Lamar University, Beaumont, TX, USA; <sup>5</sup>The Swedish Institute for Disability Research, Department of Behavioral Science and Learning, Linköping University, Linköping, Sweden; <sup>6</sup>Audiology India, Mysore, Karnataka, India

## Abstract

The purpose of this retrospective study was to analyze the clinical characteristics and document hearing recovery in patients with idiopathic sudden sensorineural hearing loss (ISSNHL). 122 patients diagnosed with unilateral ISSNHL, from March 2009 to December 2014, were treated with oral steroids and pentoxifylline. Hearing change was evaluated by comparing pre-treatment and post-treatment pure-tone average (PTA) (500, 1K, and 2K Hz), and categorized into complete, partial, and no recovery of hearing. T-test, Wilcoxon Signed Rank test and Regression analy-

sis were employed to analyze the statistical significance. Of the 122 patients, seventy-one (58%) had complete recovery and 34 (28%) had partial recovery. The average pre-treatment PTA was 78.3±16.9 dB whereas post-treatment average was 47.0±20.8 dB, showing statistically significant improvement ( $t=24.89$ ,  $P<0.001$ ). The factors such as presence of tinnitus ( $P=0.005$ ) and initial milder hearing loss ( $P=0.005$ ) were found to be significant predictors for hearing recovery. Conventional steroid regimes produced a recovery rate in ISSNHL, which exceeds the spontaneous recovery rate. The current study results highlight the importance of medical treatment in the management of ISSNHL.

Correspondence: Purushothaman Ganesan, Expert Hearing Solutions, Wall Street Audiology Inc., Saskatoon, Saskatchewan, Canada S7K 1N4.  
Tel.: +1.306.665.3443, +1.639.471.0501 - Fax: +1.306.665.9922.  
E-mail: puruaudio@gmail.com

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## Introduction

Idiopathic sudden sensorineural hearing loss (ISSNHL) is an often under-recognized medical emergency that the Otolaryngologists and Audiologists come across frequently. It is defined as sensorineural hearing loss of 30 dB or greater over at least three contiguous audiometric frequencies occurring over 72 hours.<sup>1,2</sup> The loss of hearing has been associated with the damage to the cochlea or auditory nerve, which without prompt treatment can leave patients with permanent hearing deficits. Patient evaluation should proceed promptly and expeditiously. Early presentation to a physician and early initiation of treatment improves the prognosis for hearing recovery.<sup>3</sup>

The incidence of ISSNHL has been estimated to range between 5 and 20 cases per 100,000 people per year.<sup>4</sup> There is no published data on incidence of ISSNHL in India. These figures are likely to be an underestimate since the symptoms are common and non-specific, spontaneous recovery of hearing may dissuade some patients from seeking medical attention and many people do not seek treatment immediately.<sup>1,5</sup> The causes of ISSNHL are putative and often multifactorial. The term idiopathic is used frequently,<sup>6,7</sup> because usually there is no definite or underlying cause that could be identified in (85-90%) of the patients at the time of presentation, and treatment decisions are generally made without knowledge of the etiology.<sup>3</sup> Audiological evaluation provides a criterion for the diagnosis of ISSNHL; in the case of retro-cochlear lesions, further investigations like imaging studies are necessary to rule out other causes like vestibular Schwannoma, cerebro-vascular accidents and the like. In case of sudden sensorineural hearing loss, treatment protocol as for ISSNHL can be initiated even without ruling out other causes, since early treatment is necessary for

recovery. If periodic audiological evaluation shows improvement in hearing level across frequencies, further evaluation for cause of the hearing loss would not be required. Characteristics of pre-treatment audiogram will form the baseline for treatment protocol.

Various theories have been proposed for the cause of the disease, the treatment of ISSNHL is based on one or another underlying hypothesis of the etiology and always remains debatable. Despite extensive research, there is no strong evidence regarding the efficacy of treatment preferences. Therapeutic strategies may vary, though a short course of corticosteroids is often prescribed either systematically or by intra-tympanic injection in most cases,<sup>8,9</sup> which reduces inflammation and edema in the inner ear. Vascular compromise is the most likely pathogenesis involved in ISSNHL. It is believed that pentoxifylline increases microvascular blood flow in the cochlea, although there is limited evidence supporting its effectiveness. Although many studies have reported on the effectiveness of steroids, the state of clinical equipoise about the use of corticosteroids for ISSNHL still exists.<sup>10-12</sup> Despite the lack of consistent data on treatment of ISSNHL, the American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) guidelines recommends that clinicians may offer corticosteroids as initial therapy to patients with ISSNHL.<sup>4</sup>

Several prognostic factors have been investigated in various studies, including age of the patient, presence of concomitant vestibular symptoms, degree of hearing loss, audiometric configuration, and time between the onset of hearing loss and initiation of treatment.<sup>3,13</sup> There is no consensus regarding the actual influence of these factors on the clinical outcome.<sup>14-18</sup> Since ISSNHL is still a medical dilemma, in terms of its associated symptoms, prognostic indicators and hearing recovery following treatment, there is a need to study these characteristics, for better understanding and management of this condition.

The aim of this retrospective study was to clinically characterize ISSNHL and document the hearing outcomes after a standardized combined systemic steroid and rheological therapy with pentoxifylline.

## Materials and Methods

### Study design and participants

A retrospective study design was performed for patients who underwent treatment for unilateral ISSNHL at two Tertiary Hospitals, between March 2009 and December 2014. 122 patients with ages ranging from 18 to 68 years had met the inclusion criteria (Table 1). The diagnosis of all the patients had been made by experienced Otolaryngologists. The study followed the principles of Declaration of Helsinki.

**Table 1. Inclusion criteria based on the information in case files.**

History of sudden, unilateral sensorineural hearing loss of at least 30 dB in three frequencies, demonstrable on a pure-tone audiogram at the time of presentation
No history of acoustic trauma
No other neurological signs
No demonstrable cause for the hearing impairment, which rules out Meniere's disease, autoimmune hearing loss, vestibular schwannoma, cerebello-pontine angle tumors, and other potential etiology for sensorineural hearing loss
Availability of pre-treatment audiogram and post-treatment audiograms done till 1 month
Treatment must include combination of systemic steroid and pentoxifylline

### Medical examination

A detailed profiling of the patient's medical history was performed, and the following variables were tabulated: demographic data, onset, and duration of hearing loss, associated symptoms, presence of cardiovascular risk factors and other co-morbid factors. Clinical examination had been conducted on all ISSNHL patients, and a demonstrable cause of hearing impairment had been ruled out in all cases. Routine blood investigations had also been conducted in all the patients, which included complete haemogram, serum electrolytes, thyroid function tests. All patients received an initial audiogram and were documented for further referral during follow-up to manage the course of treatment. Informed consent was obtained from all patients prior to hospitalization, and also for outpatient follow-up. Our standard medical treatment were oral administration of prednisolone (Wysolone; Wyeth, Mumbai, India): 60 mg/day for 5 days, 50 mg/day for 3 days, 40 mg for 2 day, 30 mg for 1 day, 20 mg for 1 day, 10 mg for 1 day, and 5 mg for 1 day, in combination with oral pentoxifylline (Trental; Sanofi Aventis, Mumbai, India) (400 mg twice per day) and Gingko Biloba (Bilovas; Zyduz Cadila, Mumbai, India). Tapering dose of prednisolone for fourteen days was administered, which is consistent with the AAO-HNSF clinical practice guidelines.<sup>4</sup>

### Audiological evaluation

Pure tone thresholds were obtained for air conduction at 500, 1000, 2000, 4000, and 8000 Hz and for bone conduction at 250, 500, 1000, 2000, and 4000 Hz (Arphi 500, Mumbai, India; Interacoustics AC 33, Middelfart, Denmark). In all cases, the hearing improvement was monitored by successive audiometric tests of pure tone audiometry on the day of presentation and weekly after treatment initiation until one month. The hearing improvement was evaluated based on the change in hearing threshold from the pre-treatment to the 1-month follow-up audiogram. Most patients did not have audiograms before the episode of ISSNHL, the hearing in unaffected normal ear as measured at the time of diagnosis was used as standard. Pure-tone average (PTA) was calculated using the three-frequency average (*i.e.*, 500, 1000 and 2000 Hz). In addition, we adapted Wilson's criteria<sup>19</sup> to categorize hearing recovery into: i) complete recovery: a post-treatment PTA that was  $\geq 90\%$  of the reference hearing level; ii) partial recovery: 50% to 89% improvement of the PTA but with a remaining hearing loss of  $> 10$  dB relative to the reference hearing level; and iii) no recovery:  $< 50\%$  improvement of PTA relative to the reference hearing level.

### Data analysis

The variables such as age, gender, vertigo, tinnitus, degree of hearing loss at presentation, and time to onset of treatment were evaluated and correlated with hearing recovery rates. Descriptive statistics were used to define patient demographics and pathological characteristics. T test and Wilcoxon Signed Rank test was used

to compare the pre and post audiometric test results. Logistic regression was used to study the predictor variables for hearing recovery. The significance level of 0.05 was used for all-purpose.

## Results

From 2009 to 2014, there were 122 patients with ISSNHL evaluated in two tertiary hospitals. Table 2 summarizes the demographics and clinical characteristics of the study population. The age of the patients ranged from 20 to 68 years, with the mean age being 40.5 years. A majority of the individuals fell between the age ranges of 31 and 40 years. It was noted that 64% (n=78) were males, 36% (n=44) were females. 47 (39%) of the affected ears were on the right side and 75 (61%) on the left side. Tinnitus and vertigo were present at the time of presentation in 79% and 24% of the patients, respectively. Audiometric testing showed that PTA ranged from 45 dB to 111 dB with an average of 78.30 dB.

It can be noted from Table 2 that moderately severe and severe degrees of hearing loss were the degrees that were most commonly observed (*i.e.*, 61%). 60% of them attained complete recovery. The audiogram pattern was ascending in 47 individuals followed by descending in 40 patients and flat in 19 and total deafness in 16 patients. The number of days from the onset of hearing loss to the initiation of treatment ranged from 0 to 28 days, with the majority of the patients (58%) starting treatment less than 10 days, among which 63% achieved complete recovery (Table 3).

## Hearing level recovery

The hearing level was measured at the time of consultation (*i.e.*, pre-treatment) and on a weekly basis until one month following the treatment initiation. The pre-treatment PTA was 78.3±16.9 and the post-treatment PTA was 31.2±24.0. An average hearing level recovery of 47.0 dB was noted. The t-test results showed a significant reduction in PTA post-treatment ( $t=24.89$ ,  $P\leq 0.001$ ). However, as the PTA recovery was not seen in all patients, the recovery was categorized according to Wilson's criteria. Out of 122 patients, 58% showed complete recovery, 28% had partial recovery, whereas 14% had no recovery. Table 3 provides the hearing outcomes according to patient's demographics. A Wilcoxon signed-rank test showed that statistically significant change ( $Z=-9.2$ ,  $P\leq 0.001$ ) in hearing level one month post-treatment.

## Factors contributing to recovery of hearing levels

Table 4 presents the linear regression model consisting of hearing recovery (pre vs post) as dependent variable and other factors (degree of hearing loss, gender, age, vertigo and tinnitus) as independent factors. This model was statistically significant ( $r=0.418$ ,  $P\leq 0.001$ ) and explained only 17.4% of the total variance. The factors such as pre-treatment degree of hearing loss and presence of tinnitus were found to be significant contributors to the hearing gain over time.

## Discussion

This retrospective study analyzed the clinical characteristics and documented hearing outcomes in patients with unilateral ISSNHL treated with a standardized treatment protocol. Our results showed a statistically significant positive outcome following the medical treatment. The factors such as presence of tinnitus and/or pre-treatment degree of hearing loss found to be significant predictors of the hearing recovery.

**Table 2. Demographic and clinical characteristics of patients with idiopathic sudden sensorineural hearing loss.**

Variable	Number of patients (%)
Gender	
Male	78 (64%)
Female	44 (36%)
Affected ear	
Right	47 (38.5%)
Left	75 (61.5%)
Presence of concomitant symptoms	
Tinnitus	96 (79%)
Vertigo	29 (24%)
Degree of hearing loss	
Mild to moderate (<55 dB)	16 (13%)
Moderately severe and severe (56 to 90 dB)	74 (61%)
Profound (>91 dB)	32 (26%)
Pattern of hearing loss	
Ascending	47 (38.5%)
Descending	40 (32.8%)
Flat	19 (15.5%)
Total Deafness	16 (13%)
Interval between onset and treatment initiation	
<10 days	71 (58%)
11-21 days	34 (28%)
>21 days	17 (14%)
Recovery	
Complete recovery	71 (58%)
Partial recovery	34 (28%)
No recovery	17 (14%)

	Median, range
Age (years)	40.5 (20–68)
Hearing loss, initial (3PTA; dB)	78.3, 45–110
Hearing loss, final (3PTA; dB)	31.2, 11–95
Hearing gain (3PTA; dB)	47.0, 0–78

PTA, pure tone average.

**Table 3. Hearing outcomes according to demographic variables among idiopathic sudden sensorineural hearing loss patients.**

Prognostic factor	Complete recovery (%)	Partial recovery (%)	No recovery (%)
Gender			
Male	60	21	13
Female	55	29	16
Ear side			
Right	64	19	17
Left	55	33	12
Tinnitus			
Present	64	28	8
Absent	38	27	35
Vertigo			
Present	83	10	7
Absent	51	33	16
Degree of hearing loss			
<55dB	69	19	12
56 to 90 dB	60	32	8
>91dB	50	22	28
Interval between onset and treatment initiation			
<10 days	63	28	9
11-20 days	65	29	6
>21 days	24	23	53

A wide variety of treatment protocols are a result of the ongoing debate over the etiology, lack of superiority of any one-treatment protocol over the other, or over placebo. Till date, none of the clinical trials unequivocally document the effectiveness of any medication.<sup>3,11,12</sup> This uncertainty leads to investigation of efficacy of the commonly used agents, systemic steroids. Currently, standard treatment for ISSNHL is the early administration of tapering doses of systemic steroids. Steroids are strong anti-inflammatory agents which when administered; reduce the inflammatory assaults on the end organs, thereby reducing the ischemia in the tissues. However, an updated Cochrane systematic review based on 3 randomized controlled trials, as well as another recent review, both concluded that the importance of steroids in the treatment of ISSNHL remains unclear.<sup>11,12</sup> Even though, inconsistent results regarding the treatment success have been reported, steroid treatment is one of the treatment options that has shown efficacy. A non-randomized, retrospective review of patients with ISSNHL over a ten year period concluded significant hearing improvement in steroid therapy group compared to non-steroid therapy group ( $P < 0.01$ ).<sup>20</sup> Another retrospective study analyzed hospital records of 781 patients with ISSNHL and concluded that steroid therapy yielded significant hearing improvement in patients with non-diabetes and hypercholesterolemia group.<sup>21</sup>

In our study, the complete recovery of hearing level at one month follow up was seen in 58% (71/122) of participants, which is in accordance with other reports.<sup>1,21,22</sup> The observed average pre-treatment hearing loss was 78.3 dB, with the average hearing sensitivity recovery after treatment being 47.0 dB. The success rate reported in the literature varies between 5% and 89%.<sup>23</sup> However, these recovery rates have to be interpreted and compared across studies with caution given imperative differences in recovery definitions, tested audiometric frequencies, and inclusion criteria. For example, in Wittig *et al.* study,<sup>24</sup> inpatient treatment is intended if outpatient treatment fails to improve hearing within the first days after ISSNHL onset. Half of the study sample had unsuccessful outpatient treatment before admission for inpatient treatment. Also, a few studies have determined PTA using 5 to 6 frequencies (*i.e.*, 0.25, 0.5, 1K, 2K, 4K, and 6 KHz),<sup>24-26</sup> as opposed to the 3 frequencies that we have considered in our study. Research has shown that low frequency hearing loss tends to have higher rates of recovery (63% to 88%) as compared to high frequency hearing loss (19% to 38%).<sup>23</sup> Therefore, inclusion of higher frequencies in the calculation of PTA may have skewed the results to a lower average hearing gain.

**Table 4. Linear stepwise regression analysis of prognostic factors with hearing sensitivity recovery among idiopathic sudden sensorineural hearing loss patients.**

Variable	Hearing level recovery model, $r=0.418$		
	Coeff	S.E.	P*
Constant	38.84	9.34	<i><math>\leq 0.001</math></i>
Age	-0.24	0.20	0.209
Gender	-5.61	3.65	0.127
Degree of hearing loss (pre-treatment)	17.60	6.11	<i>0.005</i>
Vertigo	-1.70	6.05	0.770
Tinnitus	-20.33	7.15	<i>0.005</i>
Interval between onset and treatment initiation	5.69	6.02	0.347

\*All significant items ( $P < 0.05$ ) are in italics.

Prognosis of ISSNHL has been known to depend on various factors, including: patient's age, gender, accompanying tinnitus and vertigo, pre-treatment degree of hearing loss, audiogram characteristics, and time interval between onsets of symptoms to initiation of treatment. The association between tinnitus and hearing improvements in ISSNHL is controversial; some reports claim a negative effect,<sup>23</sup> some show a positive effect.<sup>15,27</sup> Another European retrospective study concluded that complete hearing recovery and tinnitus remission are three times more frequent in mild-moderate cases than in severe-profound cases.<sup>28</sup> In our study, presence of tinnitus was associated with better outcome, corroborating previous studies.<sup>27,29</sup> It is postulated that presence of tinnitus after inner ear injury would indicate that hair cells are still viable.<sup>27</sup>

In clinical practice, most spontaneous improvement in hearing occur during the first 2 weeks; in a similar manner, greatest hearing recovery occurs with systemic steroids within 2 weeks.<sup>1,4</sup> This early recovery rate is therefore, a predictor of the final hearing outcome. Severity of initial hearing loss and audiometric configuration tend to have an impact on the prognosis. It is generally agreed that recovery rate decreases in proportion to the severity of initial hearing loss. In our study, of the 32 patients with profound loss, 16 of them had complete hearing recovery, similar to previous study.<sup>1</sup> Wilson *et al.*<sup>19</sup> suggested that a mild hearing loss yielded a satisfactory prognosis regardless of whether the treatment was initiated or not. On the other hand, Wen *et al.*<sup>30</sup> conducted a retrospective analysis of 2,185 ISSNHL patients and concluded that poorer initial hearing is a negative determinant of prognosis. We speculate that those with poorer initial hearing might have more room to improve with prompt treatment, thus significantly boosting the average hearing gain in our study.

In our study, there was no statistically significant impact of age, gender, vertigo, and interval between onset and treatment initiation, on hearing recovery. However, there was a trend of a superior performance in the age group of 31-50 years, and in patients who presented within 10 days of onset of hearing loss, which is in accordance with other studies.<sup>1</sup>

This study was a retrospective analysis, which presents limitations on interpretation due to the nature of the research design. This investigation involved relatively small number of patients without a control group, so any improvement measured in this study may be the result of combination of intervention and spontaneous recovery. Treatment fidelity could not be assessed due to the nature of this design. Moreover, patients were followed up for a relatively short period of limited. Intra-tympanic steroid therapy and hyperbaric oxygen therapy were not considered for patients who had no recovery post-treatment, as per AAO-HNSF guidelines.<sup>4</sup> Finally, further prospective randomized controlled studies involving a greater number of patients using various treatment protocols with longer follow-up are warranted to clarify the debate.

## Conclusions

This retrospective data from 122 patients was analyzed to determine hearing outcomes after tapering doses of oral steroids and pentoxifylline. Overall, normal or complete hearing recovery occurred in 58% of patients. Statistical analyses revealed significant improvement in hearing sensitivity post treatment. Presence of tinnitus and pre-treatment degree of hearing loss found to be significant predictors of hearing sensitivity recovery. ISSNHL is one of the difficult clinical conundrums encountered in otologic and audiologic rehabilitation. Though this condition is commonly encountered in clinical practice, its importance lies in the fact that it is a reversible type of sensorineural hearing impairment. As evi-

dence suggests that permanent hearing loss in ISSNHL is a result of delay in initiation of treatment, awareness should be created among the general population so that early diagnosis can be made and prompt treatment can be given.

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