

# Systemic steroids and intratympanic steroids perfusion as an initial therapy for idiopathic sudden sensorineural hearing loss, a comparative study

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## Objective

The objective of this study is to compare the efficacy of systemic steroids (SS) and the intratympanic steroids (ITS) in the treatment of idiopathic sudden sensorineural hearing loss (SSNHL).

## Study design

This is a prospective study.

## Material and methods

This study included 21 patients suffering from idiopathic SSNHL. They were divided into 2 groups according to the modality of treatment. Group A included 10 patients who were treated with SS and group B included 11 patients who were treated with ITS due to their refusal or contraindication to take SS. A pre-treatment pure tone audiometry (PTA) was performed for all patients at their first presentation for establishment of the diagnosis and assessment of the degree of the hearing loss. A post-treatment PTA was done at the follow up visit 2 weeks later for the assessment of the degree of hearing loss and hearing improvement. The data of both groups were compared together.

## Results

For group A the pre-treatment PTA average ranged from 37.5 to 113.3 db with a mean of  $72.3 \pm 25.11$  db and the post-treatment PTA average ranged from 13.3 to 113.3 db with a mean of  $49.24 \pm 33.72$  db. On comparing the means of the pre-treatment and the post-treatment PTA averages the difference was found to be statistically significant ( $P = 0.03$ ). The overall hearing improvement rate using SS was 60%. For group B the pre-treatment PTA average ranged from 50 to 115 db with a mean of  $77 \pm 18.98$  db and the post-treatment PTA average ranged from 26.6 to 101.8 db with a mean of  $50.05 \pm 23.3$  db. On comparing the means of the pre-treatment and the post-treatment PTA averages the difference was found to be statistically highly significant ( $P = 0.001$ ). The overall hearing improvement rate using ITS was 72.7%.

## Conclusion

Both SS and ITS have proven to be effective in the treatment of idiopathic SSNHL, however SS seems to have a better effect in terms of cure with complete recovery to normal hearing, while ITS exerts most of its effect in partial recovery.

## Keywords:

Sudden sensorineural hearing loss, systemic steroids, intratympanic steroids, hearing improvement

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## Introduction

Sudden sensorineural hearing loss (SSNHL) is an uncommon medical emergency that is typically diagnosed if there is greater than 20 db hearing loss in at least three consecutive frequencies on audiometric testing, with the hearing loss progressing within a 72-h period [1]. Despite the dramatic presentation, diagnostic testing fails to yield an identifiable cause in as many as 88% of patients; therefore, it is often referred to as idiopathic [2]. A list of potential etiologies has been suggested for SSNHL including viral infection, vascular disruption, autoimmune process, or cochlear membrane rupture, with reasonable support for each [1,3]. The viral-induced inflammation is considered to be the most

reasonably possible cause from gathering experimental, histopathologic, and clinical evidence [4,5]. Spontaneous recovery of function, although not established in a large number of patients, is variably reported to occur in up to 65% of patients with SSNHL [6].

The treatment of SSNHL is perhaps the most controversial aspect of this entity as there are various treatment agents and regimens. The use of more than one agent is very common and the choice of agents used varies considerably among clinicians. Currently, systemic steroids, either oral or intravenous, are the most commonly used treatment for SSNHL particularly among those suspecting a viral inflammatory

etiology [7]. Its efficacy in the treatment of SSNHL has been well established in double-blinded controlled-randomized clinical trials [8,9]. However, this efficacy is limited for patients with moderate to severe SSNHL [6,9]. The use of ITS for the treatment of SSNHL was proposed by Silverstein *et al.* [10]. Its main advantage lies in the markedly higher concentrations of steroids in the labyrinthine fluids as reported in animal studies [11,12]. Another value is the avoidance of the side effects of systemic steroids (SS), which enables its use when SS are contraindicated. Based on animal studies and the initial favorable clinical evaluations, the use of intratympanic steroids (ITS) have been embraced by many clinicians with several series of patients presented for this issue [13–16]. Other treatments including oral antiviral agents, carbogen gas inhalation, hyperbaric oxygen treatment, diuretics, plasma expanders, and agents designed to alter the blood flow or viscosity are not unusual, but perhaps less commonly used [7]. The aim of this study is to compare the efficacy of SS and the ITS in the treatment of SSNHL.

## Materials and methods

This study was carried out on 21 patients with SSNHL. The patients were selected from among those attending the outpatient otolaryngology and audiology clinics in Kasr ElAini University Hospital and the new Kasr ElAini teaching hospital during the period from January 2010 till December 2012. All patients were subjected to an assessment of full medical history, with a focus on the onset and course of the hearing loss and the presence of tinnitus and vertigo. A complete otolaryngological examination was performed. A baseline PTA was performed upon presentation for establishment of the diagnosis and assessment of the degree of the hearing loss. SSNHL was diagnosed when there was 20 db or more sensorineural hearing loss in three consecutive frequencies or less. Other inclusion criteria were previous subjective bilateral normal hearing, no history of chronic ear disease, normal otoscopic examination, and unidentified cause for the SSNHL. The study was approved by the committee of ethics and research related to the otolaryngology head and neck surgery department in Cairo University. All patients had a preformed consent for participating in the study signed by them.

According to the modality of treatment, the patients were divided into two groups. Group A included 10 patients with SSNHL who were treated with SS in the form of oral prednisolone (5 or 20 mg tablets) at a dose of 1 mg/kg/day for 1 week in two divided doses, and then the dose was tapered gradually over a period of 2 weeks. Omeprazole was administered during the

treatment with oral prednisolone. Group B included 11 patients with SSNHL who were treated by ITS perfusion because of either patient refusal to take SS (five patients) or the presence of a contraindication for treatment with SS (6 patients). These contraindications were diabetes (three patients), hypertension (one patient), peptic ulcer (one patient), and osteoporosis (one patient). The ITS perfusion was performed by anesthetizing the tympanic membrane with a topical anesthetic (EMLA gel) for 45 min. One milliliter of dexamethasone (8 mg/2 ml) was injected slowly into the middle ear space using a 27-G needle syringe through the posteroinferior quadrant of the tympanic membrane over the region of the round window. The procedure was carried out using the microscope with the patient lying supine with the head tilted to the opposite side. After the perfusion, the patient's head was elevated 45° upward and maintained in this position for 30 min to allow inner ear perfusion. The patient was asked to refrain from swallowing for the duration of the perfusion to prevent escape of the solution in the Eustachian tube. This procedure was carried out once daily for 3 successive days.

## Audiological assessment

A pretreatment PTA was performed for all patients at their first presentation. The frequency range of 250–6000 and 500–4000 Hz at intervals was used for air and bone conduction, respectively. The severity of hearing loss as determined by air conduction PTA average 500–4000 Hz was considered as follows: (a) mild hearing loss for values between 20 and 40 db hearing loss, (b) moderate hearing loss for values between 40 and 70 db hearing loss, (c) severe hearing loss for values between 70 and 90 db hearing loss, and (d) profound hearing loss for values more than 90 db hearing loss. The post-treatment PTA was performed at the follow-up visit 2 weeks later. The hearing improvement was assessed as follows:

- (a) Cured, if the final hearing was better than 20 db,
- (b) Marked recovery, if there is more than 30 db hearing gain at the tested frequencies,
- (c) Slight recovery, if there is 10–30 db hearing gain at the tested frequencies, and
- (d) No recovery, if the hearing gain is 10 db or less at the tested frequencies.

## Statistical analysis

Descriptive and analytic statistics were calculated using the statistical package of social scienc program version 16 designed for windows IBM Corporation, Chicago, USA. The one-sample and paired-sample Student (*t*) test was used for the analysis of numerical values for comparison of

the means. The Pearson  $\chi^2$ -test was used for the analysis of categorical variables. Significance was set at a *P* value less than or equal to 0.05.

## Results

The demographic and clinical characteristics including age, sex, presence of vertigo and tinnitus, and the time interval from the onset of hearing loss till the start of treatment are shown in Table 1. The mean age of the patients was 38.7 and 42.5 years for group A and group B, respectively. The mean time from the onset of hearing loss till the start of treatment was 5 and 7.5 days for group A and group B, respectively. There was no statistically significant difference between the two groups in these variables.

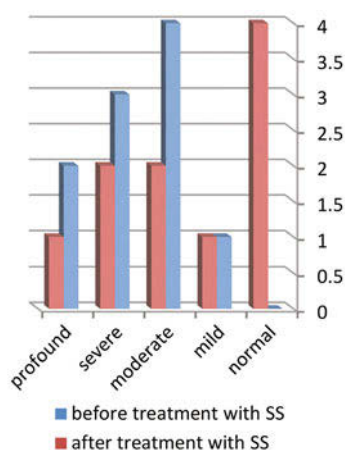
### Hearing results of group A

The pretreatment PTA average ranged from 37.5 to 113.3 db, with a mean of  $72.3 \pm 25.11$  db. The post-

**Table 1 Demographic and clinical pretreatment data**

	Group A SS	Group B ITS	<i>P</i> value
Age (years)			
Range	23–58	30–55	0.39
Mean $\pm$ SD	$38.7 \pm 11.1$	$42.5 \pm 8.9$	
Sex [ <i>n</i> (%)]			
Male	7 (70)	8 (72.7)	0.63
Female	3 (30)	3 (27.3)	
Vertigo [ <i>n</i> (%)]			
Yes	2 (20)	6 (54.5)	0.12
No	8 (80)	5 (45.5)	
Tinnitus [ <i>n</i> (%)]			
Yes	6 (60)	9 (81.8)	0.27
No	4 (40)	2 (18.2)	
Time since onset			
Range	2–12	2–14	0.18
Mean	5	7.5	

**Figure 1**



Pretreatment and post-treatment degree of hearing loss with SS.

treatment PTA average ranged from 13.3 to 113.3 db, with a mean of  $49.24 \pm 33.72$  db. The difference between the pretreatment and the post-treatment PTA average representing the hearing improvement ranged from 0 to 91.7 db, with a mean of  $23.09 \pm 29.1$  db. On comparing the means of the pretreatment and the post-treatment PTA averages, the difference was found to be statistically significant (*P* = 0.03). The pretreatment and post-treatment degrees of hearing loss in this group are shown in Fig. 1. The overall hearing improvement rate using SS was 60% (six of 10 patients). Four patients (40%) were cured, two patients (20%) achieved slight recovery, and four patients (40%) showed no recovery.

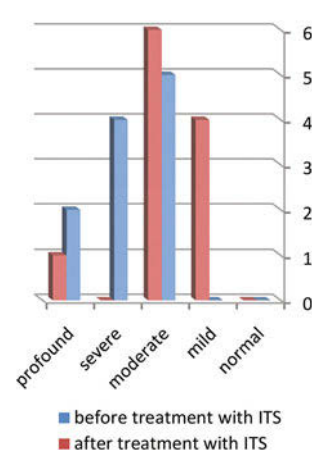
### Hearing results of group B

The pretreatment PTA average ranged from 50 to 115 db, with a mean of  $77 \pm 18.98$  db. The post-treatment PTA average ranged from 26.6 to 101.8 db, with a mean of  $50.05 \pm 23.3$  db. The difference between the pretreatment and the post-treatment PTA average representing the hearing improvement ranged from 1.66 to 56.67 db, with a mean of  $26.95 \pm 20.25$  db. On comparing the means of the pretreatment and the post-treatment PTA averages, the difference was found to be statistically highly significant (*P* = 0.001). The pretreatment and post-treatment degrees of hearing loss in this group are shown in Figure 2. The overall hearing improvement rate using ITS was 72.7% (eight out of 11 patients). Five patients (45.5%) showed marked recovery, three patients (27.5%) showed slight recovery, and three patients (27.5%) showed no recovery. None of the patients in this group were cured.

## Discussion

SSNHL is a rare otologic emergency with a controversial treatment. The use of SS is considered to

**Figure 2**



Pretreatment and post-treatment degree of hearing loss with ITS.

be an accepted treatment choice, but is still debatable in terms of the dose and duration of treatment [15]. The background of its use is based on two prospective randomized clinical trials conducted by Wilson *et al.* [9] and Moskowitz *et al.* [8] that showed a statistically significant improved rate of recovery from SSNHL for steroid-treated patients compared with placebo. The therapeutic effect of SS is related to its general anti-inflammatory and immunosuppressive action [17]. A more recent postulated mode of action of SS is its local effect on inner ear tissues through its action on glucocorticoid receptors that have been detected in the inner ear [18]. This effect primarily includes ion homeostasis through affection of Na-K Atpase system [19]. However, the systemic use of steroids may have serious side effects, and may be contraindicated in patients with peptic ulcer, diabetes, hypertension, osteoporosis, glaucoma, and pregnancy. Therefore, the use of ITS in SSNHL appears to be an attractive method of management that achieves the benefits of systemic steroids without the side effects. The main advantage of ITS is its capability to perfuse in the cochlear fluids with a higher concentration compared with SS [11]. The limitation of ITS is the incapability to achieve systemic anti-inflammatory and immunosuppressive effects in addition of having no access to the more central portions of the cochlear nerve [20]. In this study, we compared the hearing improvement among patients with SSNHL treated with either SS or ITS. It is noteworthy that our patients treated with ITS were selected according to the presence of a contraindication to the use of SS because of medical reasons or patient refusal to receive SS owing to the possible side effects. We did not use ITS as a first line of treatment because it is well documented that SS are effective in the management of SSNHL [2,9]; thus, we considered it unethical to replace the first-line SS with ITS. Similarly, none of the studies investigating the ITS therapy in SSNHL used it as a first-line treatment [14,16,21]. An important issue in comparing various methods of management of SSNHL is the high spontaneous recovery rate that is claimed to occur in 32–65% among untreated cases within the first month after the event [2,22]. Even more a recent report found that almost 22% showed spontaneous hearing improvement beyond the first month following the onset of symptoms [23]. This natural course of the disease makes the comparison of different treatment methods difficult.

In this study, the overall hearing improvement rate with SS was 60%. This is comparable with the 61% reported by Wilson *et al.* [9]. Other investigators reported comparable results even with more aggressive SS regimens in terms of the dose and duration of steroid therapy [24,25]. The overall hearing improvement in our

group of patients treated with ITS was 72.7%. Several studies investigating the ITS treatment for SSNHL reported hearing improvement rates ranging between 38 and 77.27% [10,11,13,15,16,21]. The patients treated with ITS in these studies either failed to improve after SS or could not receive SS for medical reasons. The better overall hearing improvement rate among the ITS group compared with the SS group in our study cannot be considered an absolute better efficacy of ITS in the management of SSNHL as 40% of patients treated with SS were cured with a normal hearing level following treatment; in contrast, among those who improved with ITS, none of them achieved normal hearing. The better cure that could be achieved with SS could be attributed to the dual systemic and local effects on the inner ear structures exerting a dramatic effect that could revert hearing to normal whereas the ITS therapy exerts only a local action that could partially improve hearing as observed in our study. The mean PTA improvement after treatment of both groups was approximately similar: 23.09 and 26.95 db for patients treated with SS and ITS, respectively, without a statistically significant difference between both groups ( $P = 0.726$ ).

The patients' demographic data as well as the pretreatment degree of hearing loss did not show a statistically significant difference. Therefore, comparison of the hearing improvement is possible and sound. The only drawback was the bias in patient selection for the type of treatment. Blind randomization may be considered unethical, owing to the proven efficacy of SS in the treatment of SSNHL. Therefore, we limited the treatment with ITS for patients with a contraindication or refusal for SS therapy.

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## Conclusion

The results of the present study suggest that SS and ITS therapy are reasonably effective treatments in SSNHL. SS seems to have a better effect in terms of cure, with complete recovery to normal hearing, whereas ITS exerts most of its effect in partial recovery. ITS treatment in SSNHL is thus considered a safe and effective alternative when SS is contraindicated, failed, or refused by the patient. Blind randomized studies are still needed for adequate comparison between SS and ITS in the treatment of SSNHL (Table 2).

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## Acknowledgements

### Conflicts of interest

No conflict of interest.

**Table 2 Audiological data of the two groups**

Group	Pretreatment PTA average	Post-treatment PTA average	PTA difference (improvement)
<b>Group A SS</b>			
Range	37.5–113.3	13.3–113.3	0–91.7
Mean	72.3	49.24	23.09
SD	25.11	33.72	29.1
<i>P</i> value	0.03		
<b>Group B ITS</b>			
Range	50–115	26.6–111.8	1.66–56.67
Mean	77	50.05	26.95
SD	18.98	23.3	20.25
<i>P</i> value	0.001		
<i>P</i> value			0.726

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