



## Intra-tympanic Dexamethasone for Sudden Sensory Neural Hearing Loss: A Multicentre Trial

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### Abstract

The sudden sensory neural hearing loss is a condition with considerable incidence and confers some risk factors behind. Use of systemic steroids is effective for the condition but with several adverse effects, so; use of local intra-tympanic injection of steroid is safer option warrants efficacy confirmation. This trial included 60 patients with the condition allocated into three arms according to steroid treatment; oral, local and combined. The patients were compared before and after and were assessed with pure tone audiometry. The result show statistically significant difference for each arm in before and after testing but not inter-groups comparison. This study adds evidence to enhance the use of steroid as an intra-tympanic topical therapy in managing sudden sensory neural hearing loss.

**Keywords:** sudden sensory-neural hearing loss, Siegel criteria, intra-tympanic injection.

## INTRODUCTION

### Background

The sudden sensorineural hearing loss (SSNHL) is a condition documented and described by De Kleyn for the first time in 1944. The definition suggested by the US National Institute on Deafness and Other Communication Disorders (NIDCD) is most widely accepted one. This definition states that SSHL is known as hearing loss greater than 30 dB HL reported in at three or more successive audiometric readings within 3 days or less.<sup>1,2</sup>

The condition is not rare, for instance; in the United States, the estimate of annual incidence for SSNHL is about 5-20 cases per 100,000 capita. In South Korea, a study found the mean annual incidence of unilateral (SSNHL) of 17.76 cases per 100,000 population with a slight male preponderance of 53% and a peak incidence in the sixth decade of life. While the onset of bilateral SSNHL shows predilection to younger age than the unilateral one.<sup>3-6</sup>

Anyhow, there is missing of reporting of considerable number cases in the studies as true surveillance figures are not available. Regarding the aetiology, many pathologies are being reported like autoimmune conditions, viral cochleitis, and rupture of the inner ear membrane.<sup>7</sup>

The viral and vascular aetiologies seem to be the most convincing etiopathogenetic mechanisms in most of cases. Anyhow, the natural background of SSNHL is still not understood; in addition, in almost 30% of cases; spontaneous recovery occurs and recovery mostly occurs within the first two weeks after the onset of SSNHL with partial response.<sup>8</sup> Recovery seems to be influenced by many factors including; the degree of hearing loss indicated by the audiogram result, concomitant symptoms, and the lag time to treatment as the probable most influencing factors.<sup>8</sup>

The treatment of SSNHL is still under controversy, the current practices are devoid of a universally accepted protocol. The only proven effective agent is systemic steroids, with a recovery rate of 49 to 89% in otherwise untreated patients.<sup>9</sup> Systemic steroids, anyhow, are associated with adverse effects and are contraindicated in certain conditions.

Intratympanic (IT) steroids treatment is applying topical medication, first invented in 1956 to control symptoms of Meniere's disease. IT steroids are increasingly prescribed nowadays, particularly in patients in whom systemic steroids are contraindicated or they have resistance to. Furthermore, in cases of failed regular treatments, IT steroids seem to be effective as a rescue treatment. Along with the widespread IT steroids therapy application, this medication could be used as a first-line therapy for SSNHL victims.<sup>10</sup>

None of other therapeutic interventions has been tried for SSNHL proved efficacy; including hyperbaric oxygen, vasodilator drugs, blood thinners and magnesium.<sup>8</sup>

It is important to note that excessive doses of steroids might have systemic effects, making them unsuitable for all patients. Corticosteroids exhibit several methods of action, including as anti-inflammatory effects, immunological suppression, membrane stability, enhanced perfusion, and modulation of ion balance.<sup>11</sup>

Silverstein H et al (1996) pioneered the practice of applying IT steroid as a perfusion therapy for the condition in 1996.<sup>12</sup> Numerous investigations on this therapeutic method have been published in scientific literature, while IT and systemic steroids combination has lately attracted the attention of doctors.<sup>13</sup>

Nevertheless, the variety of the findings and the scarcity of randomized controlled trials emphasize the necessity for further study in this area. The aim of this study was to comparatively evaluate the effectiveness of intra-tympanic installation, systemic, and combination steroid administration as an initial intervention for idiopathic sudden sensorineural hearing loss (ISSHL).

## Subjects and methods

Multicentre clinical trial investigated hearing test results of 60 patients with ISNHL attended the clinics of Department of Otorhinolaryngology in Benghazi Medical Centre, ALTAREK hospital, and Al Marj hospital during the period from January 2014 and April 2017.

### Selection criteria were:

- (1) Loss of 30 dB in audiometry over three successive frequencies in less than 72 h,
- (2) Normal ear examination by otoscope,
- (3) Free history for chronic otitis media,
- (4) Free history for trauma (mechanical, barometric, or acoustic),
- (5) Free history for conditions affecting inner ear; fluctuating hearing loss, hydrops, meningitis or Meniere's disease,
- (6) Free surgical history regarding ear,
- (7) Freedom of exposure for radiation or ototoxic medications.

### Intervention arms:

We allocated the selected participants into three arms: IT dexamethasone (GP-I), oral prednisolone (GP-II), and combined treatment (oral steroid and IT dexamethasone injection; GP-III).

### The operative procedure<sup>13</sup>:

**The intra-tympanic (IT) dexamethasone injection** was executed with aid of a microscopy and with patient in supine position. Confirming that tympanic membrane (TM) and middle ear are intact first, then administering topical anaesthesia using a cotton ball soaked with 10% lidocaine solution as a spray, applied to the TM membrane for twenty minutes. Then, after tilting the head of the patient tilted for 45° to the healthy side, a 25-gauge spinal needle was advanced into the posterior inferior area of TM to inject the steroid.

**Regimen of IT steroid therapy:** Dexamethasone, 5 mg/ mL applied twice a week for total of four doses (over two weeks).

**Regimen of the oral steroid group:** Prednisolone 60 mg per day tapered over two weeks.

### Outcome measurement and definitions:

Pure-tone audiometry (PTA) was used to assess the auditory function; the hearing levels were indicated by the mean of hearing thresholds at 0.5, 1, 2, and 3 kHz, according to the protocol recommended by the working guidelines.<sup>14</sup>

The measurements were taken twice; once before treatment and another one month after the treatment, Siegel's criteria were taken in consideration.<sup>15</sup>

Definitions of treatment response categories according to Siegel's criteria<sup>15</sup>:

Definition of complete recovery: gain in hearing higher than 30 dB with final hearing better than 25 dBs

Definition of partial recovery: gain in hearing higher than 15 dB with final hearing between 25 and 45 dBs.

Definition of slight improvement: gain in hearing higher than 15 dB with final hearing less than 45 dBs.

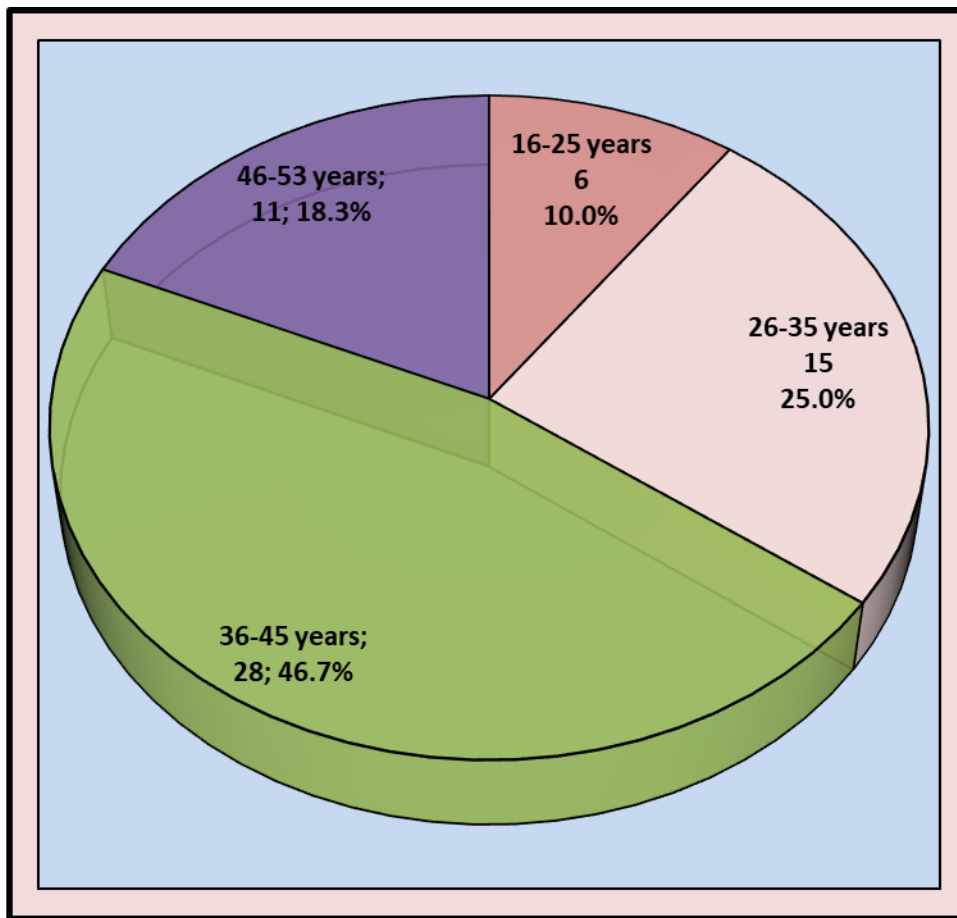
Definition of no improvement: gain in hearing lower than 15 dB with final hearing less than 75 dBs.

**Statistical analysis:** The software statistical package for social science (SPSS; version 23) was in charge. The graphs were created with Microsoft Excel software (version 2010). The numerical variables within arms were handled with paired samples test and three related groups with Friedman test. Differences were labeled statistically significant when P value  $\leq 0.05$ .

## Results

Out of 60 cases, the ratio of males to females was 1:1.4. Less than half of the sample had an age range of 36-45 years (figure 1).

The study population consisted of four age groups: 16-25 years, representing 10%, 26-35 years, accounting for 25%, 36-45 years, accounting for 46.7%, and finally 46-53 years, accounting for 18.3%, as shown in figure 1.



**Figure (1): Age interval of the cases of audiometry**

We found that before the intra-tympanic injection, none of them had a hearing rate of 20-45 dBs, and after the injection, 8 (40%) had a hearing rate of 20-45 dBs.

The number of 12 (60%) whose hearing rate was 46-70 dBs became 9 (45%) after the injection.

The number of people whose hearing rate was >70-90 dBs before the intra-tympanic injection was 8 (40%), and after the injection it was 3 (15%).

The mean hearing for this arm was  $67.7 \pm 8.9$ . The difference between before and after treatment hearing improvement was also a statistically significant.

For the arm treated with oral prednisolone, the difference before and after treatment in the rate of hearing improvement was statistically significant.

There was also a statistically significant difference for the group that was treated with the combination treatment (intra-tympanic injection with oral steroid).

**Table (1) shows the frequency of the pre-and post- interventions differences across study arms. Table (1): frequency of the pre-and post- interventions differences among neurosensory deafness cases at Benghazi medical center.**

Threshold level category (in dBs)	GP-I		GP-II		GP-III	
	Pre-	Post-	Pre-	Post-	Pre-	Post-
	N/20 (%)	N/20 (%)	N/20 (%)	N/20 (%)	N/20 (%)	N/20 (%)
I (20-45)	0 (0)	8 (40)	0 (0)	11 (55)	1 (5)	10 (50)
II (46-70)	12 (60)	9 (45)	14 (70)	7 (35)	8 (40)	6 (30)
III (71-90)	8 (40)	3 (15)	6 (30)	2 (10)	7 (35)	4 (20)
IV (>90)	0 (0)	0 (0)	0 (0)	0 (0)	4 (20)	0 (0)
<b>Mean ± SD</b>	67.7 ± 8.9	51.0 ± 16.5	64.9 ± 6.8	43.5 ± 15.3	73.1 ± 15.5	44.7 ± 15.4
<b>Mean ± SD For differences in dBs</b>	21.39 ± 10.75		16.73 ± 10.38		28.36 ± 12.75	
<b>P for difference</b>	<i>P</i> < 0.001		<i>P</i> < 0.001		<i>P</i> < 0.001	

SD = Standard deviation, dBs = decibels, GP-I = Arm of oral prednisolone, GP-II = Arm of intra-tympanic dexamethasone injection, GP-III = Arm of combined therapy.

There are statistically significant differences before and after treatment for the three groups, and the amount of improvement was greater in favor of the third group (oral steroid and intra-tympanic steroid injection), as the mean was 28.360 + 12.753 dBs. Comparing the treatment outcome of the three treatment modalities of the three groups found no statistical significance between them as the P value >0.05.

## Discussion

According to literature including Wilson WR et al (1980) 16 and Cinamon U et al (2001) 17; the use of steroids to treat SSNHL is an old school. Nevertheless, Gheriani H et al (2008) 18 stated that and until the time of their publication, no enough robust evidence based on clinical trials supporting the use of steroids in treating SSNHL. More recently, Filipino R et al (2013) 13, and Chen SL et al (2024) 3 added more piece of supporting evidence to the use of local steroids in such a condition. This work is a new evidence could be added to the practice of treatment of SSNHL. This was a trial included 60 cases with the ratio of males to females of 1:1.4 and less than half of the sample had an age range of 36-45 years. The study included three arms; first treated with only oral prednisolone, the second treated with IT dexamethasone injection and a third arm with combined therapy. There was statistically significant improvement in rates of hearing threshold categories as well as mean hearing threshold for the three arms, and the amount of improvement was greater in favor of the third group (oral steroid and intra-tympanic steroid injection), as the mean was 28.360 + 12.753 dBs. Anyhow, despite apparently different; comparing the final treatment outcome of the three treatment modalities of the three groups found no statistical significance between them as the P value >0.05. The results of the current study are congruent with a retrospective study by Chen SL et al (2024) 3. They included 89 cases of diabetic patients with SSNHL with mean age of 49.31 ± 16.26 years; the response to IT steroid injection was a gain in mean speech reception threshold (SRT) of 15.78 ± 32.16 dBs, with a rate for complete recovery of 8.98 % and for partial recovery of 15.73 %. Anyhow, they found that advanced age and profound hearing loss at the initial assessment were independent negative predictive factors for recovery. 3 The present study needs further investigation to suggest selection criteria for steroid intervention.

## Conclusion

Use of intra-tympanic dexamethasone for cases with sudden sensorineural hearing loss is equally effective as systemic steroids and should be considered instead to avoid their adverse effects.

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#### CITATION

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