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EFFICACY OF HBOT AND INTRATYMPANIC DEXAMETHASONE IN SUDDEN ONSET IDIOPATHIC SNHL

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ABSTRACT

BACKGROUND

Idiopathic sudden sensorineural hearing loss (SSNHL) is an otologic emergency. While intratympanic steroids are standard, adjunctive hyperbaric oxygen therapy (HBOT) may improve outcomes.

METHODS

In this prospective, open-label, single-arm trial, 39 adults (age 18–70) with SSNHL (≥30 dB loss at ≥3 contiguous frequencies within 3 days) received IT dexamethasone (0.5 mL of 4 mg/mL solution) daily for 5 days plus HBOT at 2.4 ATA for 60 minutes daily (10 sessions). Pure tone averages (PTA) at 500–4000 Hz were measured at baseline and 1 month. The primary endpoint was mean PTA change; secondary endpoints included tinnitus, and adverse events. Sample size (n=34) was calculated to detect a 10 dB PTA difference (α=0.05, β=0.8).

RESULTS

Thirty-nine patients (22M/17F; mean age 42.3 ± 11.7 years) completed treatment. Mean baseline PTA was 71.8 ± 14.6 dB, improving to 54.6 ± 18.3 dB at 1 month (mean gain 17.2 ± 10.4 dB; 95% CI, 13.6–20.8; p<0.001). Early treatment (≤5 days) yielded greater gains (20.9 ± 9.1 dB) than later treatment (11.3 ± 7.4 dB; p=0.004). Seventy percent achieved a delayed ≥15 dB gain. Tinnitus improved in 65.4%. Two patients (5.1%) experienced mild middle ear barotrauma.

CONCLUSION

Adjunctive HBOT with IT dexamethasone is safe and associated with clinically meaningful hearing improvement, particularly when initiated early. Randomized controlled trials are warranted.

KEYWORDS

sudden sensorineural hearing loss; hyperbaric oxygen therapy; intratympanic dexamethasone; audiometry; clinical trial

INTRODUCTION

Sudden onset idiopathic sensorineural hearing loss (SSNHL) is defined as a hearing loss of at least 30 decibels (dB) affecting 3 or more contiguous frequencies and occurring during 3 days without a known cause. SSNHL is an emergency entity in Otolaryngology practice, with an incidence of 5 to 20 cases per 100,000 per year. It is frequently accompanied by tinnitus and/or vertigo. SSHL is considered idiopathic, although different pathophysiological theories have been proposed. These include viral infection, vascular causes, rupture of the cochlear membrane and autoimmunity.

Corticosteroids are commonly used to treat SSNHL and can be given systemically (i.e., oral, intravenous [IV]) and Intratympanic [IT].

Review Process: Double blind Peer Reviewed by Reviewer Board Members

HBOT (Hyperbaric Oxygen Therapy) which was first used in the treatment of idiopathic SSNHL in 1960s, increases perilymph oxygenation and relieves ischemia into the inner ear by delivering high pressure oxygen. The guidelines for SSNHL which were updated in 2019, state that HBOT can be administered as an initial therapy in combination with steroids within 2 weeks of the onset of SSNHL and within 1 month as a salvage therapy.

The aim of the present study was to determine the efficacy of Intratympanic steroid in combination with HBOT for the management of idiopathic SSNHL. We hypothesized that adjunctive HBOT plus IT dexamethasone would yield ≥15 dB greater PTA gain than historical controls treated with steroids alone. Because delayed treatment has no yield, so any therapy should be directed as early as possible.

MATERIALS AND METHODS:

Study design:

The study was a prospective, controlled, interventional clinical trial to assess the efficacy of intratympanic steroid in combination with HBOT for the management of idiopathic SSNHL.

Inclusion criteria: Adults aged between 18 to 70 years presenting to our OPD with the history of sudden onset audiometrically proven hearing loss ≥ 30 dB were included in the study.Informed written consents were obtained from all participants of the study. All patients attending the hospital between January 2020 and December 2024 were included in the study.

Exclusion criteria: Patients with systemic diseases like diabetes mellitus and hypertension along with those with specified causes of SSNHL such as labyrinthitis, meniere's disease, trauma, etc were excluded from the study.

Sample size: Based on detecting a 10 dB difference in PTA improvement (SD=12 dB), with α=0.05 and power 80%, 34 patients were required. We enrolled 39 to account for dropouts.

INTERVENTION:

Intratympanic Dexamethasone: Under sterile conditions, 0.5 mL of 4 mg/mL dexamethasone was injected via a 25-gauge spinal needle into the middle ear daily for 5 consecutive days. Patients remained supine with head rotated 45° to the other side for 45 minutes after each injection.

HBOT: Delivered at 2.4 ATA for 60 minutes per session, once daily, five days per week, totalling 10 sessions over two weeks, starting on the same day.

The improvements following treatment were assessed based on audiometric findings, comparing pre and post-treatment pure tone averages, and subjective improvements.

OUTCOME AND FOLLOW-UPS:

Primary Endpoint: Change in pure tone average (PTA) at 500, 1000, 2000, and 4000 Hz from baseline to 1 month.

Secondary Endpoints: Proportion with ≥15 dB gain, tinnitus and vertigo improvement (subjective), and adverse events.

Audiometry was performed at baseline, day 10, and 1 month by a blinded audiologist.

Randomization and Blinding: As a single-arm study, no randomization was performed. Audiologists conducting follow-up testing were blinded to treatment timing.

Statistical Analysis: Data were analyzed using SPSS v27. Normality was assessed via Shapiro–Wilk. Continuous variables are mean ± SD or median (IQR); categorical as counts (%). Paired t-tests or Wilcoxon signed-rank tests compared PTA changes. Chi-square tested proportions. A p-value <0.05 was significant.

RESULTS

Patient Demographics and Clinical Characteristics

A total of 39 patients met the inclusion criteria and completed the study protocol. The cohort included 22 males (56.4%) and 17 females (43.6%), with a mean age of 42.3 ± 11.7 years (range: 19–69 years). Most patients (61.5%) presented within 5 days of symptom onset, and the rest within 7–14 days.

Variable	Value (n = 39)
Mean Age (years)	42.3 ± 11.7
Gender (M/F)	22 / 17
Time to Treatment (days)	4.9 ± 2.3
Mean Initial PTA (dB)	71.8 ± 14.6
Presence of Tinnitus	26 (66.7%)
Side of Hearing Loss	Right: 21 (53.8%), Left: 18 (46.2%)

Table 1: Baseline Characteristics of Participants

Audiometric Improvement

The primary outcome was the change in pure tone average (PTA) across 500, 1000, 2000, and 4000 Hz frequencies. The mean pre-treatment PTA was 71.8 ± 14.6 dB, and post-treatment PTA was 54.6 ± 18.3 dB, indicating a mean improvement of 17.2 ± 10.4 dB ($p < 0.001$).

p-value: < 0.001

Audiometric Parameter	Pre-Treatment (dB)	Post-Treatment (dB)	Mean Change (dB)
PTA (500–4000 Hz)	71.8 ± 14.6	54.6 ± 18.3	17.2 ± 10.4
High Freq (2k–4k Hz)	75.1 ± 13.2	60.4 ± 17.1	14.7 ± 9.8
Low Freq (500–1k Hz)	68.4 ± 15.3	48.2 ± 16.5	20.2 ± 11.6

Table 2: Audiometric Changes Following Treatment

Subgroup Analysis by Severity

Patients were divided into three groups based on initial hearing thresholds:

- - Mild to Moderate (≤60 dB): 9 patients
- - Severe (61–90 dB): 20 patients
- - Profound (>90 dB): 10 patients

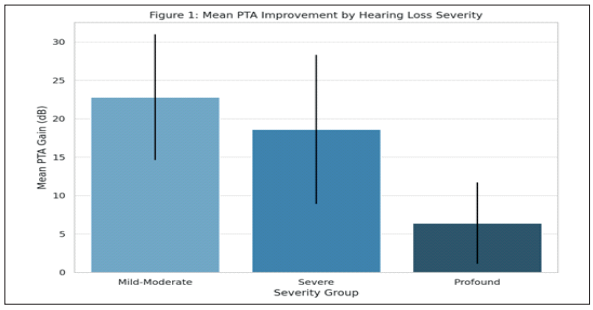


Figure 1: Mean PTA Improvement by Hearing Loss Severity Group.

- Mild-Moderate: 22.8 ± 8.2 dB
- Severe: 18.6 ± 9.7 dB
- Profound: 6.4 ± 5.3 dB

Significant improvement (≥15 dB gain) was observed in:

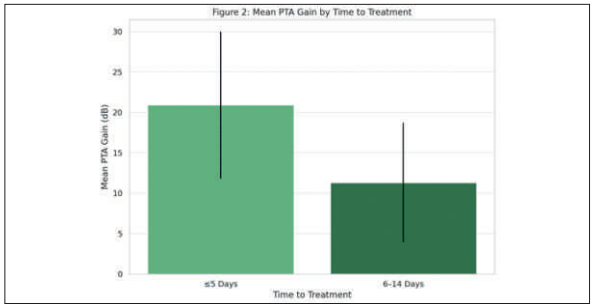
- 7/9 (77.8%) of mild-moderate group
- 13/20 (65%) of severe group
- 1/10 (10%) of profound group

Effect of Time to Treatment

Patients initiating therapy within 5 days had significantly greater improvement than those treated after 5 days.

Time to Treatment	Mean PTA Gain (dB)	% with ≥15 dB Gain
≤5 Days	20.9 ± 9.1	76.2%
6–14 Days	11.3 ± 7.4	38.5%

p = 0.004



Other Observations

- Tinnitus resolved or improved in 17/26 patients (65.4%)
- No major side effects of intratympanic injections or HBOT were observed

- Mild middle ear barotrauma was reported in 2 patients (5.1%), managed conservatively

DISCUSSION:

Stamatia Dova et al concluded that the addition of hyperbaric oxygen therapy as initial therapy to the conventional systemic steroid treatment does not provide any supplementary benefit to the outcome of patients with idiopathic sudden sensorineural hearing loss. Furthermore, the combined therapy did not lead to significantly better results in patients suffering with severe to profound hearing loss compared to systemic steroid therapy. The presence of a descending curve audiogram shape has a negative prognostic value as well as time interval to initiation of treatment. 1

In contrast, Aslan et al found that the addition of HBOT to the conventional treatment significantly improved the outcome of sensorineural deafness, especially in patients younger than 50 years. Additional HBOT provides limited benefit in patients older than 50 years and no benefit in patients older than 60 years.2

D Piotr H et al did not find a difference in hearing outcomes between patients treated with glucocorticoids and those treated with glucocorticoids in combination with HBOT. He suggested a prospective, controlled, and randomized study would provide more reliable knowledge of the role of HBOT in treating SSNHL.3

Yeji Ahn et al concluded that patients with idiopathic sudden sensorineural hearing loss above 80 dB are less likely to recover hearing even after oral plus intratympanic plus HBOT. However, this treatment initially accelerates recovery in patients with a hearing loss below 80 dB. Therefore, they suggested a review of the appropriate indication for HBOT benefits in patients with severe or profound ISSNHL.4

HBOT may be considered in pediatric patients with idiopathic SSNHL. However, Murat Salihoglu et alcould not rule out spontaneous improvement of hearing in their patients. They further remarked the need for high vigilance for potential side effects as aprerequisite for HBO treatment in pediatric patients since they may fail to follow instructions properly. Routine otoscopic examination of patients before each HBO session was recommended to avoid middle ear barotrauma.5

Muzzi et al concluded that salvage hyperbaric oxygen therapy improved patients' pure tone hearing thresholds, particularly at low frequencies. Positive results were postulated to be likely with increased patient age and reduced delay in receiving hyperbaric oxygen therapy.6

Tarun Sahni et al noted that the addition of HBOT to conventional therapy significantly improved outcome in patients of SSNHL if started within 14 days. Improvement was best at frequencies above 500 Hz and in hearing loss of above 70 dB. HBOT was found more effective in patients younger than 50 years of age. 7

According to Ebru Topuz et al the addition of HBOT to conventional treatment modalities significantly improves the outcome of Idiopathic Sudden Sensorineural Hearing Loss, especially at the frequencies of 250, 500, 1,000 and 4,000 Hz and in hearing loss of above 61 dB. Furthermore, HBOT was found to be more effective in patients younger than 50 years. 8

This single-arm trial demonstrates that IT dexamethasone plus HBOT yields a mean PTA gain of 17.2 dB, exceeding the minimal clinically important difference of 10 dB. Early initiation (≤5 days) was associated with superior outcomes, supporting guideline recommendations.

CONCLUSION

Adjunctive HBOT with IT dexamethasone is safe and yields clinically meaningful hearing improvements in idiopathic SSNHL, especially when started early. Further research to identify patients with sudden sensorineural hearing loss

for whom hyperbaric oxygen therapy would be most cost-effective, is encouraged.

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Conflict of Interest: None declared.

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