

Prognostic Value of Early Treatment Response in Idiopathic Sudden Sensorineural Hearing Loss Treated with Hyperbaric Oxygen

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ABSTRACT

Background: The aim of this study is to evaluate the value of early treatment response in predicting the prognosis of patients with idiopathic sudden sensorineural hearing loss (ISSNHL) who received hyperbaric oxygen (HBO) treatment.

Methods: A total of 226 patients were available for evaluation and met the inclusion criteria. The patients were separated into 3 groups according to the degree of hearing loss: mild to moderate hearing loss <60 dB, severe hearing loss between 61 dB and 80 dB, and profound hearing loss ≥81 dB. An improvement of ≥10 dB in the pure tone audiogram (PTA) performed after the first 5 sessions compared to the pre-treatment audiogram was considered an early treatment response positive (ETR-P). No improvement or an improvement of <10 dB was considered an early treatment response negative (ETR-N).

Results: After the first week of HBO treatment, a total of 119 patients (52.6%) showed ETR-N and 107 patients showed (47.3%) ETR-P. A significant association was found between the degree of hearing loss and ETR-P and ETR-N ($\chi^2 = 7.24$, $P = .02$). Patients in the ETR-N group received significantly more HBO sessions than those in the ETR-P group (17.6 ± 3.4 vs. 13.3 ± 4.1 , $P = 0.02$). The pure tone average after treatment of the ETR-N patients (60.3) was higher than that of the ETR-P patients (45.2). There was a significant difference between pure tone average after treatment and ETR-P and ETR-N ($U = 4110$, $z = -4.59$, $P = .000$).

Conclusion: Patients who did not achieve sufficient treatment success in the first week of HBO therapy did not achieve good final hearing results.

Keywords: Early treatment response, hyperbaric oxygen, inner ear, pure tone audiometry, sensorineural hearing loss.

Introduction

Idiopathic sudden hearing loss (ISHL) refers to a type of sensorineural hearing impairment that arises abruptly, within a maximum of 3 days. It affects at least 3 frequencies, with a minimum threshold of ≥30 dB.¹ Factors such as viral infection, vascular insufficiency, membrane rupture, and immune inner ear disease have been proposed for the etiology of sudden sensorineural hearing loss.² Idiopathic sudden sensorineural hearing loss (ISSNHL) treatment remains an area of research.

A variety of treatment protocols have been used to treat ISSNHL. This diversity is due to both different etiologies and uncertainties in diagnosis. Corticosteroids still maintain a place

in the current treatment. Although the mechanism of steroid therapy has not been fully explained, it has been shown to be effective on inner ear ion mechanisms.³ In addition, it increases cochlear blood flow and down-regulates proinflammatory cytokines.⁴

In recent years, hyperbaric oxygen (HBO) has become a common adjunct to steroid therapy in primary or rescue therapy.^{5,6} Hyperbaric oxygen therapy may reduce ischemia-induced cochlear damage by increasing perilymph oxygenation.⁷ As reported by the American Academy of Otolaryngology-Head and Neck Surgery, HBO may be provided as a treatment option to patients with ISSNHL.⁸ However, discussions about the number of sessions to be given are still ongoing. Recent studies

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have shown that European hyperbaric centers provide a wide variation in the number of HBO sessions given to ISSNHL patients. Unnecessary use should be avoided because HBO therapy is expensive, causes labor loss, and there may be occasional complications such as barotrauma. Patients undergoing HBO therapy may experience complete or partial recovery, while unfortunately, some may not benefit from the treatment. If the prognosis of patients receiving HBO therapy could be predicted, unnecessary applications can be avoided for those who will not benefit from receiving extra HBO therapy.

Therefore, this study aimed to investigate the importance of early treatment response in predicting the prognosis of patients with ISSNHL who were treated with hyperbaric oxygen therapy.

Methods

Patient Selection

This study conducted a retrospective analysis of the medical records of 310 patients who received hyperbaric oxygen (HBO) treatment for sudden sensorineural hearing loss between January 2016 and March 2020 at the hyperbaric oxygen treatment center of our hospital. The study procedures were conducted in adherence to the principles outlined in the Declaration of Helsinki. The patients provided informed consent prior to their participation in the study. The study was approved by Trabzon Kanuni Training and Research Hospital (decision no: 2020/47 date: 17.09.2020).

A total of 226 patients were available for evaluation and met the inclusion criteria. The patients included were aged >18 years and had sensorineural hearing loss at 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz and 30 dB or more. Patients were excluded if they had not received oral or intravenous steroid therapy, there was a 30-day delay, if they had fully recovered in the first 5 sessions, or stopped the treatment before 10 sessions despite incomplete recovery, or if data were missing from the patient file.

Treatment Protocol

The treatment was administered once a day, 5 days a week, in a hyperbaric room. Each HBO session comprised a 10-minute compression period in air, followed by a period of treatment at 2.4 atmospheres absolute (ATA) for 90 minutes, and then a 10-minute decompression period with oxygen. All patients were planned to receive 20 sessions of HBO therapy. HBO treatment was discontinued only when patients showed complete recovery before the last session.

Main Points

- Patients who did not achieve sufficient treatment success in the first week of HBO therapy did not achieve good final hearing results.
- Research suggests that patients with a hearing gain of less than 10 dB after the 5th session of HBO therapy are unlikely to benefit from further sessions of HBO.
- Early treatment response can be used as a prognostic factor in patients who receive HBO treatment, and unnecessary use of HBO therapy can be avoided.

In addition, all patients received oral or intravenous corticosteroid therapy. HBOT was started immediately along with steroids.

Evaluation of Audiological Functions

The pure tone audiometry (PTA) and speech discrimination percentages of all patients were recorded before hyperbaric oxygen therapy. The final hearing results were evaluated in the third week of HBO treatment for all patients. Pure tone audiometry was determined as the mean of thresholds measured at 5 frequencies (250, 500, 1000, 2000, and 4000 Hz). Five frequencies (250, 500, 1000, 2000, and 4000 Hz) were used to calculate hearing gain. According to the international standard criteria, the World Health Organization (WHO) defines hearing loss as normal with an average pure sound of less than 26 dB, mild with 26-40 dB, medium with 41-60 dB, severe with 61-80 dB, and very severe with 81 dB or more. The patients who underwent hyperbaric oxygen therapy in this study were grouped based on their hearing loss severity into 3 categories: mild to moderate (less than 60 dB), severe (61-80 dB), and profound (81 dB or greater).

Outcome Measures

The Siegel criteria were utilized to evaluate the recovery of hearing.⁹ For the purposes of this study, "complete recovery" is defined as final hearing better than 25 dB, "partial recovery" as a hearing gain of greater than 15 dB with a final hearing between 25 and 45 dB, "slight improvement" as a gain of greater than 15 dB with a final hearing poorer than 45 dB, and "no improvement" as a gain of less than 15 dB with a final hearing poorer than 75 dB.

Evaluation of Early Treatment Response

An improvement of 10 dB or more in the PTA compared to the pre-treatment audiogram performed after the first 5 sessions was considered an early treatment response positive (ETR-P). No improvement or an improvement of less than 10 dB, was considered an early treatment response negative (ETR-N).

Statistical Analysis

The collected data were analyzed using SPSS version 26.0 software (IBM SPSS Corp.; Armonk, NY, USA) for statistical analysis. The chi-square test was used to analyze the qualitative variables, followed by the Kolmogorov-Smirnov test to assess their normality. As the quantitative variables did not show normal distribution, significant differences between each of the studied variables were examined with the Mann-Whitney test. We employed the MANOVA test to assess differences in pure tone average values before and after treatment in the 2 groups. We established test defaults due to the high sample size.

The 2-way ANOVA test was used to examine the significant difference between the final hearing loss variable and the degree of hearing loss variable in the groups with and without an early treatment response. Due to the abnormality of the final hearing loss variable, the value was standardized and then tested.

We presented continuous variables as mean $\pm$ SD and categorical data as number (n) and percentage (%). We regarded a value of $P < .05$ as statistically significant in our analyses.

Results

The study included a total of 226 patients (mean age (SD): 47.8 ± 14.05 years; range: 8-78 years), representing 226 ears (119 right ears, 52.7%; 107 left ears, 47.3%) with hearing loss. The mean delay time was 15.1 ± 7.7 days (range: 1 to 30 days). Mean baseline PTA value was 71.8 ± 24.3 dB (range: 30-120 dB). While 87 patients (38.5%) had mild-to-moderate hearing loss, 55 (24.3%) had severe hearing loss, and 84 (37.2%) had profound hearing loss. The mean number of HBO sessions per patient was 14.5 ± 4.9 (range: 7 to 60). Following the completion of HBO therapy, the improvement in hearing loss according to Siegel's criteria was "slight improvement" in 62 patients (27.4%), "partial recovery" in 47 (20.8%), "full recovery" in

32 (14.2%), and "no improvement" in 85 (37.6%) patients. Table 1 presents the patient characteristics and improvements in hearing.

Following the first week of HBO therapy, a total of 107 patients (47.3%) displayed ETR-P and 119 showed (52.7%) ETR-N. The 2 groups were well matched for age, sex, affected ear, and hearing improvement (Table 2). A chi-square test of independence was performed to examine the relationship between Siegel's criteria and ETR-P and ETR-N. There was a significant relationship between the variables ($X^2 = 75.08$, $P = .000$) (Figure 1). There was a significant correlation between the severity of hearing loss and ETR-P as well as ETR-N, ($X^2 = 7.24$, $P = .02$) (Figure 2).

Table 1. Descriptive Statistics of Variables

Variable	N	Mean	SD	Minimum	Maximum
Age	226	47.8	14.05	8	78
Interval between hearing loss and HBO (days)	226	15.1	7.7	1	30
Hyperbaric O ₂ received	226	14.5	4.9	7	60
Pure ton average before treatment	226	71.8	24.3	30	120
Degree of hearing loss	226	1.9	.87	1	3
Pure tone average after 5th session	226	60.2	25.7	10	120
Hearing gain after 5th session	226	12.5	13.7	0	70
Pure tone average after 10th session	226	55.7	25.6	5	120
Hearing gain after 10th session	226	5.5	9.2	0	90
Pure tone average after 15th session	191	58.8	23.1	8	110
Hearing gain after 15th session	191	2.3	4.7	0	30
Pure tone average after 20th session	46	56	23.9	10	110
Hearing gain after 20th session	46	2.6	5.5	0	27
Pure tone average after treatment	226	53.2	24.7	5	110
Final hearing gain	226	19.2	17.02	0	75
		Frequency		Percent	
Gender					
Woman		99		43.8	
Man		127		56.2	
Affected ear					
Right		119		52.7	
Left		107		47.3	
Siegel's criteria					
No improvement		85		37.6	
Slight improvement		62		27.4	
Partial recovery		47		20.8	
Full recovery		32		14.2	
Degree of hearing loss					
Mild to moderate		87		38.5	
Severe		55		24.3	
Profound		84		37.2	

Table 2. Investigation Significant Difference Between Variables and Groups

		Early Treatment Response Negative (ETR-N) (119)	Early Treatment Response Positive (ETR-P) (107)	P
Gender				
	Woman	56 (47.1)	43 (40.2)	.2
	Man	63 (52.9)	64 (59.8)	
Affected Ear				
	Right	63 (52.9)	56 (52.3)	.9
	Left	56 (47.1)	51 (47.7)	
Siegel's Criteria				
	No improvement	75 (63)	10 (9.3)	<.001
	Slight improvement	22 (18.5)	40 (37.4)	
	Partial recovery	18 (15.1)	29 (27.1)	
	Full recovery	4(3.4)	28 (26.2)	
Degree of hearing loss				
	Mild to moderate	54 (45.4)	33 (30.8)	.02
	Severe	30 (25.2)	25 (23.4)	
	Profound	35 (29.4)	49 (45.8)	
Mean (SD) within group				
Age		49.3 (13.6)	46.2 (14.4)	.1
Interval between hearing loss and HBO (days)		16.4 (8.1)	13.7 (7)	.01
Hyperbaric oxygen intake session		17.6 (3.4)	13.3 (4.1)	.02
Final hearing gain		9.5 (10.1)	30.1 (16.5)	.000
Pure tone average before treatment		68.8 (24.2)	75.2 (24.1)	.06
Pure tone average after treatment		60.3 (23.7)	45.2 (23.5)	<.001
5th HBOt session		67.64 (24.97)	51.95 (24.03)	<.001
Mean (SD) within group				
		Interval between hearing loss and HBO <15 days	Interval between hearing loss and HBO >15 days	
Hearing gain		21.47 (17.6)	15.65 (15.45)	.008

The pretreatment pure tone average of ETR-N patients (68.8) was lower than that of ETR-P patients (75.2). There was no statistically significant difference between the groups ($P = .06$). The pure tone average after treatment was statistically significantly higher for the ETR-N patients (60.3) than for the ETR-P patients (45.2) ($P = .000$). The Mann-Whitney test indicates a significant difference between the final hearing gain and ETR-P and ETR-N ($P = .000$). The final hearing gain of ETR-N patients (9.5 dB) was lower than that of ETR-P patients (30.1 dB).

There was a statistically significant difference between ETR-P and ETR-N patients in respect to mean pure tone average values ($P = .000$).

There was a significant interaction between ETR-P and ETR-N and final hearing gain ($P = .000$). A statistically significant interaction was found between the degree of hearing loss and

the final gain in hearing ($P = .000$). There was no significant interaction found between the combination of groups and the degree of hearing loss with regard to the final hearing gain ($P = .112$).

There was a statistically significant difference between the time from onset to treatment for ETR-P and ETR-N ($P = .01$). The time from onset to treatment was longer for the ETR-N patients (16.4 days) than for the ETR-P patients (13.7 days). The ETR-N group received a significantly higher number of HBO sessions than the ETR-P group (17.6 ± 3.4 vs. 13.3 ± 4.1 , $P = .02$).

The patients were divided into 2 groups based on the duration of hearing loss and the number of HBO treatment days, with one group receiving HBO for less than 15 days and the other for 15 days or more. A significant correlation was observed

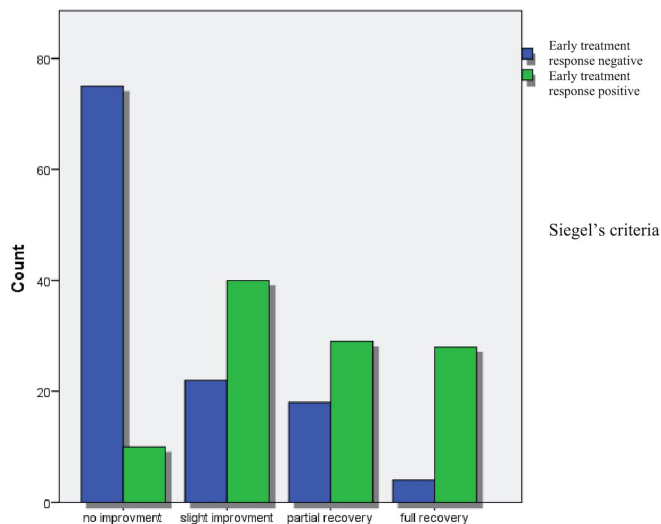


Figure 1. Siegel's criteria and patients' treatment response.

between the final improvement in hearing and the duration from the onset of hearing loss, as well as the number of days the patient was administered HBO therapy ($P=.008$).

There was a significant interaction between ETR-P and ETR-N and final hearing gain ($F(1, 226)=119.2, P=.000$). A statistically significant interaction was found between the degree of hearing loss and the final gain in hearing ($F(1, 226)=16.2, P=.000$). There was no significant interaction found between the combination of groups and the degree of hearing loss with regard to the final hearing gain ($F(1, 226)=2.2, P=.112$).

Discussion

Hyperbaric oxygen therapy has become an additional treatment method to get better hearing in ISSNHL patients. The origins of this treatment method can be traced back to the 1970s, and it has since been employed as both primary and salvage therapy.¹⁰ Hyperbaric oxygen therapy has been investigated as a treatment modality for SSNHL. Studies have explored the use of HBOT as both salvage treatment and initial therapy for patients with SSNHL. The American Academy of

Otolaryngology-Head and Neck Surgery (AAO-HNS) guideline suggests that HBOT can be provided as either initial or salvage treatment when combined with steroid therapy.¹¹ Additionally, HBOT, in combination with steroid therapy, has been recognized as a primary treatment for SSNHL within 2 weeks of onset or as salvage therapy within 1 month of onset.¹² Furthermore, the combination of HBOT and steroids is accepted as the initial treatment within the first 2 weeks and as a rescue therapy when started within 1 month.¹³

Research has shown that the benefit of HBOT is greater in groups with severe-to-profound hearing loss at baseline, where HBOT is used as a salvage treatment.¹⁴ In cases of refractory SSNHL after steroid combined therapy, salvage HBOT has shown a significant effect on hearing gain and recovery rate.¹⁵ Moreover, adjuvant HBOT may be beneficial when used with steroid salvage therapy for patients with an inadequate response to the initial treatment, particularly for those with severe-to-profound hearing loss.¹⁶

Herein, the combination of HBOT and steroids was administered as a standard treatment for all patients. It was accepted as the initial therapy when used within the first 2 weeks and as a salvage therapy when started within 1 month.

According to reports, the concurrent administration of HBO and steroids results in a considerable enhancement of hearing outcomes when compared to the use of steroids alone.^{17,18} Hyperbaric oxygen therapy is mainly used in SSNHL due to the vascular theory of the disorder. This theory suggests that the cause of hearing loss is cochlear hypoperfusion as a result of vascular impairment.¹⁹ It is assumed that HBO therapy increases oxygen perfusion in the inner ear, thereby reducing inflammation and helping to heal damaged cochlear sensory structures.²⁰

In this study, the role of age, gender, degree of hearing loss, starting time of HBO therapy, and early treatment response in predicting the prognosis of hearing loss was investigated. There was no statistically significant difference observed between ETR-P and ETR-N patients in terms of their age and gender. Thus, it has been shown that patients with hearing improvement of less than 10 dB after 5 sessions of HBO treatment are rarely likely to advantage from extra HBO sessions. Therefore, HBO therapy can be discontinued in these patients. A previous study demonstrated that patients who experienced an increase in hearing of more than 10 dB during the first 2 weeks of steroid treatment achieved a higher average gain in hearing by the third month.²¹ The study conducted by Karatop et al indicated that patients who experienced a hearing improvement of 10 dB or more in the first week of HBO treatment showed better long-term hearing gain.²²

In the current study, when the ETR-P and ETR-N patients were evaluated according to Siegel's criteria, statistically significantly better hearing recovery was determined in the ETR-P group. It was demonstrated by Choi and colleagues that HBO therapy was more advantageous in patients with severe and profound hearing loss.²³ The study found a significant relationship between the degree of hearing loss and ETR-P and ETR-N. Patients with severe-to-profound hearing loss had a better response rate to early treatment.

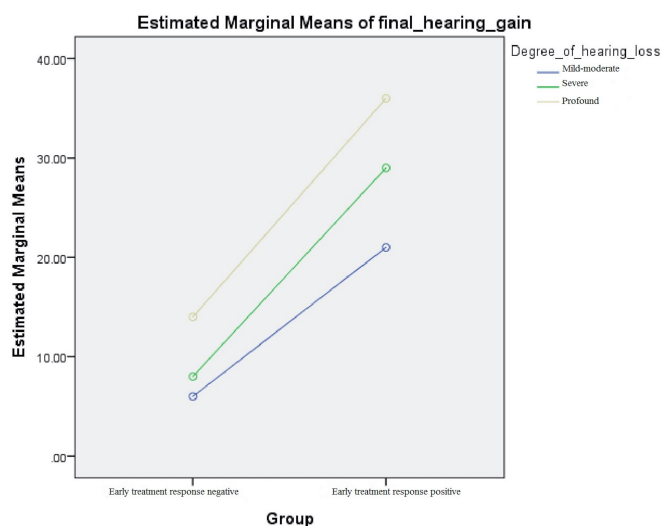


Figure 2. Degree of hearing loss and early treatment response.

It is believed that the earlier ISSHL treatment is started, including HBO therapy, the better the prognosis for the disease. When considering the timing of HBOT initiation in conjunction with steroid treatment for SSNHL, several studies provide insights. Olex-Zarychta suggests that the most favorable outcomes are seen when HBOT is implemented within 14 days of the occurrence of hearing loss, particularly in patients with a medium or deep level of hearing loss.²⁴ Kim et al found that combining HBOT with corticosteroids as the initial therapy for SSNHL resulted in better outcomes when HBOT was administered at a higher pressure.¹¹ Additionally, Lee et al suggest that adjuvant HBOT may benefit patients with severe-to-profound hearing loss who do not respond adequately to initial treatment.¹⁶

The timing of HBOT initiation in conjunction with steroid treatment for sudden sensorineural hearing loss is critical. Initiating HBOT within the first 14 days of hearing loss onset appears to yield more favorable outcomes, especially in patients with medium to deep levels of hearing loss. Combining HBOT with corticosteroids as the initial therapy may provide better results, particularly when HBOT is administered at a higher pressure. In light of these studies, we started HBO treatment immediately together with steroids.

It has been claimed that patients who start treatment early have better results.²⁵ Yildirim et al compared patients with HBO treatment initiation times of 1-7 days, 8-14 days, and 15-30 days, and the hearing gains were reported to be 23.55 dB, 22.92 dB, and 5 dB, respectively.²⁶ Capuona et al stated that if treatment is started after the first 14 days of hearing loss, the rate of recovery decreases.²⁷ In the current investigation, a statistically significant variation was observed between patients who commenced treatment within the first 15 days and individuals who initiated the procedure after the fifteenth day. Furthermore, the duration between the onset of symptoms and treatment was significantly longer for the ETR-N group than the ETR-P group. In contrast, Karatop et al compared the response to early treatment in positive and negative cases and did not find any significant differences between the 2 groups regarding the time taken to start treatment.²²

Hyperbaric oxygen treatment was discontinued only when patients showed complete recovery before the last session, and not for any other reason. In the study by Imsuwansri et al, it was mentioned that when patients demonstrated normal hearing during specific sessions of HBOT, the remaining sessions were considered unnecessary and canceled.²⁸ The decision to continue or cancel HBOT sessions based on the patient's response in terms of hearing improvement underscores the individualized approach that can optimize treatment outcomes in SSNHL patients.

Patients with hearing loss who recovered after 5 days of HBO therapy were excluded from further treatment due to their recovery within a short timeframe.

While many causes of SSNHL can lead to permanent hearing loss, studies have shown that a considerable percentage of patients, ranging from 45% to 66%, can experience spontaneous recovery to functional hearing levels without any specific treatment.²⁹ The spontaneous recovery rate for SSNHL

is estimated to be around 30%.³⁰ This spontaneous recovery most commonly occurs within the first 2 weeks after the onset of hearing loss.³⁰

This study can be considered valuable as a retrospective with a relatively large case series. It is possible that ETR-P plays a role in predicting the outcome of patients with ISSNHL and may play a role in preventing additional unnecessary HBO therapy. Discontinuation of HBO therapy in ETR-N patients will both reduce costs and avoid these patients from wasting time. It will also prevent complications related to unnecessary HBO therapy.

This study has some limitations, such as the need for more extensive prospective studies for the assessment of the relationship between ETR and predicting the prognosis of patients. In addition, the long-term effects of HBO treatment are not known, as the follow-up period was short.

The study results revealed that patients who did not attain satisfactory therapy outcomes in the early stage of HBO therapy did not achieve good final hearing results. Early treatment response can therefore serve as a prognostic indicator in patients receiving HBO treatment and can help avoid the unnecessary use of HBO therapy.

Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author.

Ethics Committee Approval: This study was approved by the Ethics Committee of Trabzon Kanuni Training and Research Hospital (Approval No: 2020/47, Date: 17.09.2020).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – G.Ç.; Design – E.S.; Supervision – E.S., G.Ç.; Resource – E.S., G.Ç.; Materials – G.Ç.; Data Collection and/or Processing – G.Ç., E.S.; Analysis and/or Interpretation – E.S.; Literature Search – G.Ç., E.S.; Writing – E.S.; Critical Review – E.S., G.Ç.

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