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# The outcomes of hyperbaric oxygen therapy in patients with sudden hearing loss and analysis of the treatment outcome prediction value of early treatment response possible

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**Abstract**

Sudden hearing loss (SHL) is an otologic emergency. This study aimed to evaluate the outcomes of hyperbaric oxygen therapy (HBOT) in patients with SHL. Secondly, we aimed to assess whether early treatment response (ETR) of HBOT at the end of the 5th (5ETR) and 10th sessions (10ETR) could predict overall HBOT outcomes. Patients' files who underwent HBOT due to SHL between 01.01.2017 - 31.12.2018 were retrospectively analyzed. Patients without an audiogram before HBOT and who did not meet the SHL definition, who were under 18 years old were excluded. Demographic data, delay time to HBOT, the severity of SHL, etiology, steroid administrations, number of HBOT sessions, and audiograms were analyzed. A total of 51 patients were included. The mean number of HBOT sessions was 17.6±5.9. There was a statistically significant improvement in each frequency and pure tone average (PTA) at the end of HBOT ($p<0.001$). Twenty-four patients (47.1%) had no treatment response. 5ETR and 10ETR had a significant relationship with overall HBOT outcomes (respectively, $p<0.05$, $p<0.001$). However, only 10ETR was found to be the only independent predictive factor for overall HBOT outcomes according to logistic regression analysis ($p<0.05$). We found that the treatment outcome success probability with positive 10ETR was 12,5-fold higher than with negative 10ETR. ($p<0.05$). HBOT may help the improvement in patients diagnosed with SHL. 10ETR can be used as a predictive parameter for estimating HBOT outcomes.

**Keywords:** Hyperbaric oxygenation, hearing loss, time to treatment

## Introduction

Sudden hearing loss (SHL) was first defined in the 1940s, and nowadays, it is designated as at least 30 decibels (dB) of hearing loss in 3 consecutive frequencies in one or both ears, emerging in the last 72 hours, with sudden onset [1]. It is also an otologic emergency with an annual incidence of 5-27/100.000 [2]. Unfortunately, hearing loss puts a heavy social and economic burden on the individual and society.

Sudden hearing loss is usually idiopathic in etiology, although it can be secondary to non-idiopathic causes, such as leading vestibular schwannoma (acoustic neurinoma), stroke, malignancy, noise, and ototoxic drugs. Various theories, including viral infections, vascular problems (thromboembolism, vasoconstriction, blood hyper viscosity, and hypertension), cochlear membrane damage, immunity disorders, and toxic and metabolic causes, have been proposed for idiopathic patients [3,4]. Therefore, it is essential to clarify the etiology because its incomplete explanation poses a problem in effectively treating it.

There are many recommended and applied treatment options for SHL. Vasodilators, rheological agents, diuretics, vitamins, anticoagulants, herbal remedies, other complementary and alternative medicine treatments, middle ear surgeries, and only observation can be used alone or in combination with hyperbaric oxygen therapy (HBOT) and systemic and topical steroids being in the first place [5-8]. The administration of antiviral, thrombolytic, vasodilators, or vasoactive drugs has not been recommended routinely, even was included in the opposite strong recommendations group in the SHL guide published by the American Ear Nose Throat Academy in 2019 [2]. A clinically and statistically significant improvement in patients' hearing has been reported in many controlled studies when they received concurrent steroids and HBOT in the early period [6,7,9-11].

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With a poor vascular structure despite its high metabolism rate, the cochlea consists of structures, which require a high oxygen supply, especially the stria vascularis and organ of Corti [12]. Direct vascular supply to the Corti organ is minimal [13]. Oxygenation of structures inside the cochlea is supplied by diffusion from the cochlear capillary networks to the perilymph and endolymph [14]. Perilymph is the primary oxygen source for these intracochlear structures. HBOT is a treatment method applied by breathing 100% oxygen intermittently under pressures higher than 1 ATA (atmosphere absolute), providing high oxygenation levels [15]. An increase in perilymph oxygenation provided by HBOT forms the rationale for using this treatment method in SHL. Cochlear hypoxia has also been mentioned as one of the possible mechanisms of acute acoustic trauma (AAT). Decreased cochlear blood flow and cochlear hypoxia resulted from vasoconstriction due to noise exposure in AAT [16]. For this reason, we also recommend HBOT for patients with AAT.

Since the first ECHM (European Committee for Hyperbaric Medicine) consensus conference in Lille, France, in 1994, HBOT has been suggested as an optional indication for SHL patients [6, 7]. However, as the rate of spontaneous improvement in SHL ranges between 32-65%, it is difficult to assess the therapeutic efficacy of other treatment modalities as well as HBOT [1,3]. This study aimed to evaluate the treatment results of patients who applied HBOT due to SHL. Our secondary aim was to assess whether early treatment response (ETR) of HBOT at the end of the 5th and 10th sessions could predict the HBOT result.

## Materials and Methods

Patient files who were treated at Underwater and Hyperbaric Medicine Department of Health Sciences University (HSU)-Gülhane Training and Research Hospital with SHL diagnosis between 01.01.2017-31.12.2018 were retrospectively analyzed. Patients with SHL diagnosis more than 30 days, without an audiogram before HBOT, did not meet the SHL definition, were under 18 years old were excluded. Demographic data, delay time to treatment (starting HBOT:≤10 days or >10 days following the onset of the symptoms), severity classification of SHL (mild-moderate-severe-profound), etiological data, treatments applied other than HBOT, the number of HBOT sessions, and audiometry data at the end of every 5 HBOT sessions of the subjects were used in statistical analysis. The hearing loss severity at the admission was classified as "mild SHL" for audiograms with pure tone average (PTA)≤40 dB, as "moderate SHL" for audiograms with PTA 41-59 dB, as "severe SHL" for audiograms with PTA 60-84 dB and as "profound SHL" for audiograms with PTA≥85 dB. HBOT was ended when patients had a complete improvement or completed the 20th session. If there was a 20 dB or more improvement in the PTA at the end of the 20th session, an additional 20 sessions of HBOT were recommended.

Treatment (HBOT) outcomes were analyzed according to Siegel criteria. If a patient's final PTA was better than 25 dB, it was recorded as "complete recovery". If a patient had more than 15 dB gain and the final PTA was between 25-45 dB, this was recorded as "partial recovery". However, the patient has more than 15 dB gain, but the final PTA was poorer than 45 dB; it was defined as "slight improvement". On the other hand, "no improvement" was described as less than 15 dB gain with a final PTA poorer than 75 dB. For further statistical analysis, treatment outcomes were classified into two groups. Patients with a slight improvement, partial recovery and complete recovery were grouped as "recovery group", and those who showed no improvement or worsening complaints as "non-recovery group". Possible predictive parameters, considered to affect the treatment response, were determined as the use of steroid therapy (oral, systemic, intratympanic), the severity of hearing loss, age (≤50 years old, >50 years old), delay time to treatment (starting HBOT:≤10 days or >10 days following the onset of the symptoms), and is at the 5th and 10th session. PTA difference between pre-HBOT and the post-5th session was defined as the 5th session ETR (5ETR) and between pre-HBOT and post-10th session as the 10th session ETR (10ETR). Those with 10 dB or more improvement in PTAs (after the 5th or 10th session of HBOT) than baseline levels (pre-HBOT) were considered to have a positive ETR.

This study was approved by HSU-Gülhane Non-Interventional Research Ethics Committee on 22.10.2019 (Project/Decision No:19/313).

SPSS Statistics version 21 (IBM Corp., Armonk, NY) was used for statistical analysis. The data were given as n (%), mean ± standard deviation, or median (minimum-maximum) in the text. The Kolmogorov-Smirnov test was performed to determine the normal distribution of variables. "Pearson or Spearman Correlation Analysis" tests were used to evaluate the linear correlation between continuous variables. "Wilcoxon signed-rank test" was used for comparing paired data (audiograms before and after HBOT). "Chi-Square" and "Mann-Whitney U" tests were utilized to investigate the relationship between possible predictive parameters and HBOT outcomes (recovery and non-recovery groups). Then, the statistically significant predictive parameters were then analyzed with logistic regression analysis to determine the independent predictive parameter on the final HBOT outcome. A p-value of $<0.05$ was considered statistically significant.

## Results

A total of 51 patients were included in our study. The demographic data were examined in Table 1. The improvement at the end of treatment (post-HBOT) for each frequency and PTA are presented in Table 2.

The correlation analysis was conducted for possible predictive parameters. A negative moderate ($r=-0.391$) and statistically significant ($p=0.005$) linear correlation was found between delay time to HBOT and improvement in PTA at the end of the HBOT. Besides, there was a positive moderate ($r=0.679$) and statistically significant ($p<0.001$) linear correlation between 5ETR and PTA improvement at the end of HBOT (Figure 1). Also, a positive strong ($r=0.789$) and statistically significant ($p<0.001$) linear correlation between 5ETR and 10ETR was remarkable. Similarly, there was a positive strong ($r=0.922$) and statistically significant ($p<0.001$) linear correlation between 10ETR and the PTA improvement at the end of HBOT (Figure 2).

Treatment outcomes according to Siegel Criteria were demonstrated in Figure 3. Overall treatment outcomes were classified into two groups ("recovery group" and "non-recovery group") for further statistical analysis as explained in the Material-Methods section.

Steroid administration (systemic, intratympanic, oral), the severity of hearing loss at the administration, age, delay time for HBOT did not show any statistically significant relationship with overall HBOT outcomes (p>0.05) (Table 3). However, there was a statistically significant relationship between 5ETR and treatment outcomes. (p<0.05) (Table 4) Similarly, a statistically significant relationship was found between 10ETR and overall treatment outcomes (p<0.001) (Table 4).

According to these results, the logistic regression analysis was conducted for 5 ETR and 10 ETR (Table 5). The predictor variables were found to contribute to the model. The treatment outcome success probability of patients with positive 10ETR was 12,5-fold higher than patients with negative 10ETR (p<0.05).

**Table 1.** Characteristics of SHL patients (URTI: Upper Respiratory Tract Infection, HT: Hypertension, DM: Diabetes Mellitus, CAD: Coronary Artery Disease, SHL: sudden hearing loss, HBOT: hyperbaric oxygen therapy, PTA: pure tone average)

| | Mean ± SD or n (%) |
|---|---|
| **Age** | 42.9±15.2 |
| **Gender** | |
| Male | 28 (54.9 %) |
| Female | 23 (45.1 %) |
| **Affected ear** | |
| Right | 27 (52.9 %) |
| Left | 24 (47 %) |
| Bilateral | 0 (0%) |
| **SHL Etiology** | |
| Idiopathic | 37 (72.5 %) |
| URTI | 3 (5.8 %) |
| Acoustic trauma | 8 (15.6 %) |
| Trauma | 2 (3.9 %) |
| Lightning strike | 1 (1.9 %) |
| **Medical history** | |
| No features | 34 (66.6 %) |
| HT | 8 (15.6 %) |
| Asthma | 3 (5.8 %) |
| DM | 1 (1.9 %) |
| CAD | 1 (1.9 %) |
| **Severity of hearing loss** | |
| Mild | 11 (21.5 %) |
| Moderate | 14 (27.4 %) |
| Severe | 13 (25.4 %) |
| Profound | 13 (25.4 %) |
| **Delay time to HBOT** | |
| ≤10 days | 36 (70.5 %) |
| >10 days | 15 (29.4 %) |
| **Steroid therapy** | |
| Systemic steroid | 34 (66,6%) |
| Intratympanic steroid | 25 (49,0%) |
| Oral steroid | 19 (37.2 %) |
| **Number of HBOT sessions** | 17.6 ± 5.9 |
| **PTA (dB)** | |
| At the admission | 65.7 ± 28.6 |
| At the end of HBOT | 48.6 ± 29.9 |

**Table 2.** The change at the beginning and end of the HBOT according to frequencies and PTA (Variables were not normally distributed and Wilcoxon signed rank test was used for statistical analysis) (HBOT: hyperbaric oxygen therapy)

| Frequencies | PreHBOT (dB) median(Min-Max) | PostHBOT (dB) median(Min-Max) | P- value |
|---|---|---|---|
| **250 Hz** | 65 (5-110) | 50 (5-110) | <0.001* |
| **500 Hz** | 60 (5-120) | 45 (5-120) | <0.001* |
| **1000 Hz** | 65 (10-120) | 45 (5-120) | <0.001* |
| **2000 Hz** | 65 (10-120) | 55 (5-120) | <0.001* |
| **4000 Hz** | 80 (5-120) | 65 (5-120) | <0.001* |
| **6000 Hz** | 90 (15-120) | 80 (15-120) | <0.001* |
| **PTA** | 60 (25-120) | 42 (5-120) | <0.001* |

**Table 3.** The relationship between possible outcome predictive parameters and overall HBOT outcomes. (SHL:sudden hearing loss, HBOT:hyperbaric oxygen therapy)

| | | Overall HBOT outcomes | | |
|---|---|---|---|---|
| | **Patient number** | **Non-recovery (n=24)** | **Recovery (n=27)** | **P-value** |
| **Steroid administration** | | | | |
| **Systemic steroid** | | | | |
| **(+)** | 34 | 15 (62.5%) | 19 (70.4%) | 0.552 |
| **(-)** | 17 | 9 (37.5 %) | 8 (29.6%) | |
| **Intratympanic steroid** | | | | |
| **(+)** | 25 | 12 (50%) | 13 (48.1%) | 0.895 |
| **(-)** | 26 | 12 (50%) | 14 (51.9%) | |
| **Oral steroid** | | | | |
| **(+)** | 19 | 10 (41.7%) | 9 (33.3%) | 0.539 |
| **(-)** | 32 | 14 (58.3%) | 18 (66.7%) | |
| **SHL severity** | | | | |
| **Mild** | 11 | 5 (20.8%) | 6 (22.2%) | 0.197 |
| **Moderate** | 14 | 8 (33.3%) | 6 (22.2%) | |
| **Severe** | 13 | 8 (33.3%) | 5 (18.5%) | |
| **Profound** | 13 | 3 (12.5%) | 10 (37.0%) | |
| **Age** | | | | |
| **>50years old** | 16 | 9 (37.5%) | 7 (25.9%) | 0.374 |
| **≤50years old** | 35 | 15 (62.5%) | 20 (74.1%) | |
| **Delay time to HBOT** | | | | |
| **≤10 days** | | 17 (70.8%) | 19 (70.4%) | 0.971 |
| **>10 days** | | 7 (29.2 %) | 8 (29.6 %) | |

**Table 4.** The relationship between 5ETR, 10 ETR and HBOT outcomes. (5ETR= early treatment response at the end of the 5th HBOT session, 10ETR= early treatment response at the end of the 10th HBOT session, HBOT=hyperbaric oxygen therapy)

| | | Overall HBOT Outcome | | |
|---|---|---|---|---|
| | **Patient number (n)** | **Recovery group** | **Non-Recovery Group** | **P-value** |
| **5 ETR** | | | | |
| **5 ETR (-)** | 29 (61.7 %) | 11 (45.8%) | 18 (78.3%) | 0.022* |
| **5 ETR (+)** | 18 (38.3%) | 13 (54.2%) | 5 (21.7%) | |
| **Total** | 47 | 24 | 23 | |
| **10 ETR** | | | | |
| **10 ETR (-)** | 22 (50%) | 6 (24%) | 16(84.2%) | <0.001* |
| **10ETR (+)** | 22 (50%) | 19 (76%) | 3 (15.8%) | |
| **Total** | 47 | 25 | 19 | |

**Table 5.** The logistic regression analysis of the HBOT outcome prediction estimation of 5ETR and 10ETR. Constant defined overall HBOT outcomes as "recovery" and "non-recovery" group. (5ETR= early treatment response at the end of the 5th HBOT session, 10ETR= early treatment response at the end of the 10th HBOT session)

| | B | SE | Odds Ratio | 95% CI | P-value |
|---|---|---|---|---|---|
| **5ETR** | 0.902 | 0.914 | 2.464 | 0.410-14.787 | 0.324 |
| **10ETR** | 2.520 | 0.853 | 12.431 | 2.336-66.133 | 0.003* |
| **Constant** | -1.257 | 0.554 | 0.284 | | 0.023* |

N = 40, R2 =0,340 (Cox-Snell), R2 =0,455 (Nagelkerke)

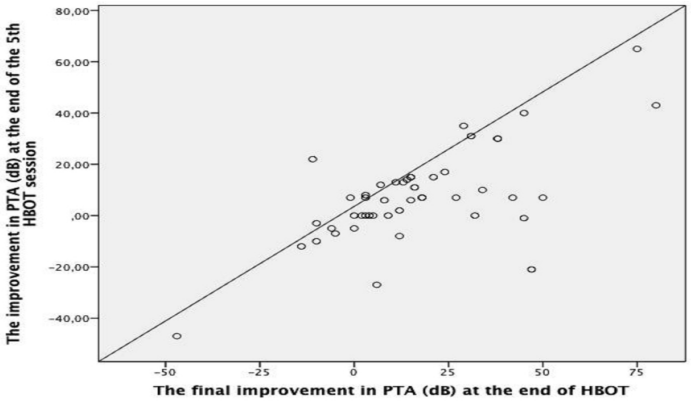


**Figure 1.** Linear correlation between 5ETR and PTA improvement at the end of HBOT (correlation coefficient r=0.679)

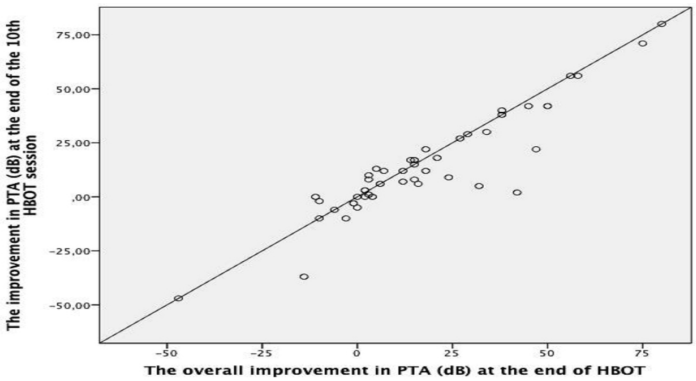


**Figure 2.** Linear correlation between 10ETR and PTA improvement at the end of HBOT (correlation coefficient r=0.922)

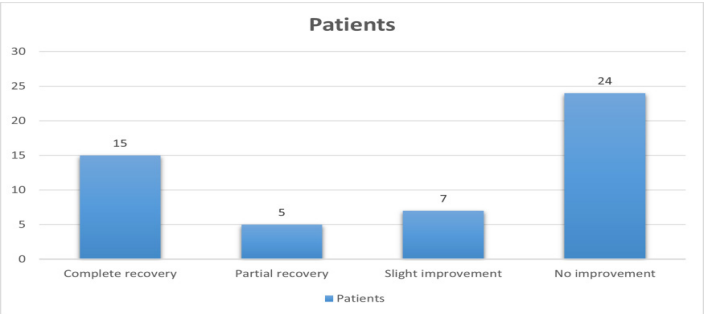


**Figure 3.** Treatment outcomes according to Siegel Criteria

## Discussion

In this study, while a positive response to treatment was obtained in 27 patients (52.9%) (recovery group), 24 patients (47.1 %) (non-recovery) did not respond to treatment. When the patients' first and last audiometry values were compared, the changes in PTA were found to be statistically significant (Table 3). Only 10ETR was the only independent predictive factor for overall HBOT outcomes ($p<0.05$).

Criteria for improvement or response to treatment used in articles on SHL are quite different from each other [2,3,17-19]. The guide published by the American ENT Academy in 2019 suggested 10 dB or less hearing recovery not to be classified as an improvement [2]. However, no change in PTA at the end of treatment has been evaluated as "no treatment response," 0-10 dB recovery as "low treatment response," 10-20 dB recovery as "moderate treatment response," and >20 dB recovery as "complete/obvious treatment response" in many studies in the literature [20-22]. Accordingly, many studies have found the response rate to treatment in HBOT-applied SHL patients above 70% [20-22]. The rate of patients benefiting from HBOT was 52.9% in our study; it is low compared to other studies. Likely, Karatop-Cesur et al., also assessed treatment response based on Siegel Criteria and obtained a similar treatment response with a ratio of 53.8% [23]. We think that the low rate of treatment response in our study may have resulted from the 15 dB improvement to be considered "non-recovery/ no improvement" according to Siegel Criteria.

It has been recommended to start HBOT early (in the first two weeks following the onset of symptoms) in SHL patients [2]. Total PTA improvement rates due to HBOT in Arslan et al.'s study were significantly higher in the first seven days of SHL onset [24]. In a retrospective study of 59 patients, a mean PTA improvement of 23.5 dB and 22.9 dB for those who were applied HBOT within the first seven days and with a delay of 7-14 days was detected, respectively; there was no significant difference between the groups in level of improvement. In addition, only 5 dB improvement in PTA was observed in those who started HBOT between 2-4 weeks after SHL occurrence, and a statistically significant difference was found ($p=0.024$) [25]. Similarly, Capuona et al. reported a significantly reduced PTA improvement in those treated with HBOT after 14 days of SHL diagnosis [26]. Suzuki's study showed a significant negative correlation between the time to start treatment and improvement in audiograms [27]. On the other hand, Karatop-Cesur et al., established no significant difference between patients who started treatment between 0-7 days and 8-15 days after SHL emergence. In the present study, treatment was initiated for most patients (70.5%) within the first ten days following the onset of symptoms [21]. There was also no significant difference in PTA improvement between those who started treatment in the first ten days and after ten days. In contrast, a negative moderate ($r= -0.391$) and statistically significant ($p=0.005$) linear correlation was found between delay time to HBOT and improvement in PTA at the end of the HBOT. Strikingly, it was observed that the shorter the delay to HBOT, the more increased the PTA gain achieved. A review pointed out that the most successful outcome for SHL was achieved when treatment was started within the first two weeks, especially in patients with severe hearing loss where combined steroid and HBOT therapy were applied [22].

The effects of initial hearing level on treatment outcomes have also been investigated. Fujimura et al.'s study with 130 patients reported a significant improvement in those with more than 80 dB hearing loss in the subgroup analysis of the HBOT-receiving

group [11]. Similarly, in Ohno et al.'s study, HBOT yielded a significant improvement in patients with severe hearing loss [28]. When patients who received HBOT in Liu's study were evaluated, a significant improvement in those with moderate to severe hearing loss was detected [29]. In another study, supporting the study mentioned above, a statistically significant improvement with HBOT in those with a hearing loss of 60 dB and above was observed [7]. Korpınar et al. also observed in their study a significant improvement with treatment in patients with more than 90 dB hearing loss [20]. No statistically significant difference was found in our study between the severity of SHL and overall HBOT outcome. However, the group benefiting the most from HBOT were those with profound hearing loss (n=13), consisting of 10 people (76,9%) (Table 3). Accordingly, coverage of relatively fewer patients in the current study than in other studies and their examinations in 4 different groups may have affected statistical significance.

Agarwal et al.'s study did not provide sufficient evidence of the efficacy of steroids and vasoactive vasodilators in SHL treatment [5]. The main goal of steroid therapy in SHL patients is to activate all glucocorticoid receptors in the cochlea [30]. In a randomized controlled prospective study, HBOT was applied to all patients (n=58); besides, only 20 patients were given systemic steroid therapy, while combined (systemic and intratympanic) steroid therapy was administered to 38 patients. As a result of the statistical analysis, no significant difference existed in treatment response between the two groups [31]. In another study, HBOT was started in all 48 patients in the first 15 days, the efficacy of systemic and intratympanic steroid therapy was compared. Although there was a significant difference in improvement in those with severe hearing loss (intratympanic 83%– systemic 53%), it was not statistically significant [32]. In the study of Alimoglu et al., patients were treated in 4 different protocols; oral steroid was applied to the first group, intratympanic steroid to the second group, only HBOT to the third group, and combined HBOT and oral steroid to the fourth group. Comparing the results of these protocols indicated that the highest success was achieved in the HBOT and oral steroid combined therapy group with a 42.6% rate of complete improvement [9]. In Suzuki's study of 196 patients, steroid, or prostaglandin E1 (PGE1) and HBOT were administered in combination. There was no statistically significant difference in terms of treatment success in both treatment groups. However, the authors have noted that in patients who cannot receive steroid therapy or who have side effects, PGE1 can be applied as an alternative to steroid therapy [33]. HBOT was also applied to all patients in our study, and those who received systemic and intratympanic steroid treatment were compared among recovery and non-recovery groups, but no significant difference was found in treatment responses. (Table 3)

It is thought that the patients' age may also affect the treatment outcomes. In their retrospective study with 522 patients, Murakawa et al. applied HBOT to all patients and reported the treatment response to be worse in the presence of starting treatment after 14 days, advanced age, and vertigo [34]. In another study evaluating the efficacy of HBOT, it was observed that the improvement in individuals under 50 years old was statistically more successful [24]. Topuz et al.'s study demonstrated better results in SHL patients receiving HBOT when they were over 50 years of age and with a loss of > 60 dB [7]. Korpınar et al. evaluated 97 SHL patients and could not find a statistically significant difference between age and treatment response [20]. Again, similarly, no significant difference between age and response to treatment was determined in another study [21]. Likely, in our study, we established no significant difference between age and overall HBOT outcomes (Table 3). As shown in the literature, although generally better results have been reported in younger patients, there are also studies where better results are achieved in the elderly, and no significant difference emerged between age and response to treatment.

Another critical point is whether responses obtained in the early period of treatment have a prognostic value. In this regard, early treatment response (ETR) was evaluated one week after HBOT initiation in Karatop-Cesur et al.' study, and those with >10 dB improvement was accepted as positive ETR, those with 10 dB or minor improvement as negative ETR. ETR is a new approach for prognosis prediction. A considerably significant relationship was found between negative ETR and unresponsiveness to treatment [21]. In the present study, the treatment outcome success probability of patients with positive 10ETR was 12,5-fold higher than patients with negative 10ETR. ($p<0.05$) This suggests that, in cases where no improvement was seen at the end of the 10th session, termination of treatment will be more significant. We may conclude that a patient with positive 10ETR would have better outcomes than a patient who showed no ETR in the 10th session. As a result, it appears that the treatment response in the 10th session may be used as a predictive factor.

The primary limitation of our study is data loss since it is a retrospective study. These parameters could not be evaluated since we could not significantly reach especially vertigo and tinnitus query data. The present study does not have a control group, and long-term follow-up data after HBOT was not available.

## Conclusion

HBOT could help the improvement in patients diagnosed with SHL at all frequencies. Unfortunately, a plausible conjecture is that HBOT does not benefit every patient. In line with the results obtained in our study, we think that ETR at the 10th session can be used as a valid and worth parameter in predicting HBOT outcomes. Thus, unnecessary treatments can be prevented in health expenditures, and we can give more objective information to patients. However, before being used as a treatment termination criterion in the clinic, randomized prospective controlled studies with common/standard assessment methods are also recommended to perform in this area.

**Conflict of interests**

*I (we) certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.*

**Financial Disclosure**

*All authors declare no financial support.*

**Ethical approval**

*This study was approved by HSU-Gülhane Non-Interventional Research Ethics Committee on 22.10.2019 (Project/Decision No:19/313).*

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