Cukurova Medical Journal
ÇUKUROVA ÜNİVERSİTESİ TIP FAKÜLTESİ

Cukurova Med J 2021;46(4):1687-1693
DOI: 10.17826/cumj.996404

ARAŞTIRMA / RESEARCH

Efficacy of hyperbaric oxygen therapy in sudden unilateral idiopathic sensorineural hearing loss

İdiopatik unilateral ani işitme kaybında hiperbarik oksijen tedavisi etkinliği

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Cukurova Medical Journal 2021;46(4):1687-1693

Abstract

Purpose: We investigated the effectiveness of hyperbaric oxygen therapy (HBOT) in patients receiving medical treatment with the diagnosis of sudden unilateral idiopathic sensorineural hearing loss (ISSNHL).

Materials and Methods: The records of the patients referred to our hyperbaric oxygen therapy clinic between 2013 and 2019 were analyzed retrospectively. All patients' age was over 18 years old, and ISSNHL was diagnosed in the last 30 days with pure tone audiometry. averages of pure tone results of the patients were compared before and after HBOT according to variables of age, gender, hearing loss level before the treatment, and elapsed time to the treatment.

Results: A total of 135 patients were included, with 70 (51.86%) females and 65 (48.14%) males. The hearing gains were statistically significant in all age groups among males and statistically significant in 18-39 and 40-59 years old age groups among females. When cases were grouped according to elapsed time to HBOT, mean hearing gains of the 14-days group in males and both 14- and 30-days groups in females were statistically significant. Statistically significant hearing gains were detected in mild, moderate, moderate to severe, severe, and complete hearing loss groups in females, while only in moderate, severe, and complete hearing loss groups in males.

Conclusion: Consequently, we think that earlier received HBOT with medical treatment applied to the younger adults with more severe disease gained more improvement in the hearing levels. Consequently, our findings showed that early administration of HBOT with MT resulted in better clinical improvements in the younger adults with severe ISSNHL.

Keywords:. Hyperbaric oxygen therapy, sudden hearing loss, HBOT

Öz

Amaç: Çalışmamızda medikal tedavi alan ani idiopatik işitme kayıplı hastalarda (AISNIK) hiperbarik oksijen tedavisinin (HBOT) etkinliği ve tedavi sonuçlarını etkileyebilecek değişkenlerin etkileri araştırılmıştır.

Gereç ve Yöntem: Çalışmamızda 2013-2019 yılları arasında HBOT Merkezi'ne başvuran, son 30 gün içinde unilateral AISNIK tanısı odyolojik testle tespit edilmiş, HBOT ve medikal tedavi almış olan 18 yaş üstü hastaların dosyaları retrospektif olarak incelenmiştir. Yaş, cinsiyet, işitme kaybının derecesi ve semptomların başlangıç zamanından tedavinin başlangıcına kadar geçen süre değerlendirilmiştir. Tedavi öncesi ve tedavi sonrası saf ses ortalamaları bu değişkenlere göre karşılaştırılmıştır.

Bulgular: 135 hastanın 70 (%51,86)'i kadın, 65 (%48,14)'i erkekti. İşitme kazancı, erkek hastalarda tüm yaş gruplarında, kadın hastalarda ise 18-39 ve 40-59 yaş gruplarında yüksek bulunmuştur. Erkek hasta grubunda tedavi öncesi şiddetli ve tam işitme kayıp gruplarındaki HBOT sonrası iyileşme kazançları yüksek bulunmuştur. Kadınlarda ise başlangıç işitme kaybı gruplarının tamamında tedavi sonrası gerçekleşen iyileşme kazançları yüksek saptanmıştır. Erkeklerde 14 güne kadar olan başvurularda işitme seviyelerinde saptanan kazanç istatistiksel olarak anlamlı bulunurken kadınlarda 30 güne kadar olan başvuruların tamamında işitme seviyelerinde saptanan kazanç anlamlı bulunmuştur.

Sonuç: Bu çalışmada işitme kaybı yaşayan hastalarda HBOT etkinliği üzerine cinsiyetin etkisinin olmadığı, hasta yaşı ilerledikçe tedaviden elde edilen kazancın azaldığı, tedaviye erken başlamanın daha olumlu sonuçlandığı ve başlangıçta ileri düzey işitme kaybı olanların işitme kazançlarının daha fazla olduğu gösterilmiştir.

Anahtar kelimeler: Hiperbarik oksijen tedavisi, ani işitme kaybı, HBOT

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Geliş tarihi/Received: 17.09.2021 Kabul tarihi/Accepted: 03.11.2021 Çevrimiçi yayın/Published online: 23.11.2021

INTRODUCTION

Sudden sensorineural hearing loss (SSNHL) is defined as hearing loss of at least 30 dB affecting three or more consecutive frequencies within 72 hours [1-4]. It has an estimated incidence between 2 - 20 per 100,000 population per year[1]. SSNHL can be seen at a wide range of ages; however, it typically occurs between 43 and 53 years of age[2]. Despite all the examinations, no etiological explanation can be found in 85-90% of SSNHL cases. These cases are defined as idiopathic sudden sensorineural hearing loss (ISSNHL)[1]. Steroids, vasodilators, plasma expanders, antiviral and diuretic agents, low molecular weight heparin, and hyperbaric oxygen therapy (HBOT) are preferred in different combinations to reduce the inflammatory state increase the blood supply and/or oxygenation of the inner ear[3,5-7].

It is approved that HBOT has comprehensive effects on immunity, oxygen transport, and hemodynamics. It reduces hypoxia, edema and boosts the responses against infection and ischemia[4]. A Meta-analysis study showed that HBOT improved recovery in ISSNHL cases and was reported more effective, especially in patients with severe hearing loss[8]. According to the 2019 Clinical Practice Guidelines of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), HBOT and systemic steroid treatment can be administered within one month from the onset of the symptoms of ISSNHL cases. However, it has been reported that more positive results were obtained when administered within two weeks following ISSNHL[4]. Despite the positive results in the literature, there are also studies stating that HBOT is not an effective treatment modality for ISSNHL[9-11]. Patients are usually treated with 10-20 sessions of HBOT that were implemented one session per day. Therefore, HBOT is time-consuming due to the completion of treatment between 2 weeks to 1 month[9].

This study aimed to investigate the efficacy of HBOT in patients receiving medical treatment (MT) with the diagnosis of unilateral ISSNHL.

MATERIALS AND METHODS

We analyzed the records of patients diagnosed with hearing loss and were referred to the Hyperbaric Oxygen Therapy Clinic of the Eskisehir Yunus Emre State Hospital between 2013 and 2019.

Adult patients diagnosed with unilateral, idiopathic neurosensorial hearing loss and treated with MT and HBOT were included in our study. Patients who were younger than 18 years old (n=6) and had a diagnosis of bilateral (n=38), mixed type (n=13), or recurrent hearing loss (n=6) were excluded from the study. 2 patients could not continue the HBOT due to medical reasons (1 upper respiratory tract infection and 1 syncope). Thirteen patients who discontinued treatment before the 5th HBOT session were excluded from the study. So, 78 patients were excluded from the study, and 135 patients were included in our study.

Procedure

Evaluation of ISSNHL

As a routine procedure, patients who have a symptom of hearing loss are referred to the outpatient clinic of Ear Nose and Throat Diseases (ENT). Patients who applied directly to the HBOT clinic were referred to the ENT clinic for further medical evaluation. It has been investigated whether patients have any other pathology that may cause hearing loss. Therefore, patients' otorhinolaryngological and neurological histories were taken, and our hospital performed physical examinations. All patients were prescribed MT, including systemic steroids, by an otorhinolaryngologist unless they had contraindication for medications. All patients were evaluated with a pure tone audiometry (PTA) test before and after HBOT. The otorhinolaryngologist and audiologist who evaluated the patients and the PTA device (Interacoustics AC40, Denmark) (Figure-1) used to test the patients' hearing levels did not change during the study period.

HBO therapy

Aerospace medicine specialists who treated the patients, the HBOT chamber (Hypertech Zyron12, Multiplace Chamber Turkey) (Figure -1), and the HBOT protocol did not change during the study period. The chamber was pressurized to a constant level of 2.4 atmospheric pressures (ATA), and pure oxygen was administered through a tight-fitting oronasal mask with an on-demand type oxygen regulator. Every HBOT session lasted for 120 minutes. Our center's routine clinical practice

consisted of 20-40 sessions of HBOT delivered to ISSNHL patients in 4 - 8 weeks (once a daily in 5 consecutive days). If there was no improvement of at least 20 dB in average threshold scores after the 20th session, the treatment was considered unsuccessful, and no more HBOT sessions were applied to the patient. HBOT was terminated earlier than the prescribed number of sessions if normal hearing levels were achieved and detected by the audiometric test in the early treatment period.

Figure 1. Audiometry and hyperbaric oxygen therapy devices used during the study period.

All patients who will receive HBOT are informed about the treatment, and the patients read and signed the consent form before the treatment. All stages of the study were carried out according to the principles of the Declaration of Helsinki. The University of Health Sciences, Gulhane Ethics Board approved the study (2021/60). Following the principle of corporate information security of the Turkish Ministry of Health, all information resources are protected by using all kinds of technical, administrative, and legal methods.

Data selection

The patients' demographic data like age, gender, hearing loss level before the treatment, elapsed time to the treatment, and the number of HBOT sessions were recorded. Patients were grouped according to their age, as 18-39, 40-59 years old, 60 years and older. Following the American Speech and Hearing Association guidelines, hearing loss level was defined as mild (20–39 dB HL), moderate (40–54 dB HL), moderate to severe (55–69 dB HL), severe (70–89 dB HL) and profound (>90 dB HL) [3]. After HBOT, the hearing gain in pure tone averages below 10 dB or final hearing threshold more than 90 dB were regarded as 'no clinical improvement'; whereas hearing gain more than 10 dB in PTA or hearing threshold that reached within normal limits (< 25 dB) were considered as 'clinical improvement achieved'[12-14].

Statistical analysis

Data were compiled in the Microsoft Excel program, and IBM SPSS Statistics was used for statistical analysis. P< 0.05 was considered statistically significant. Descriptive statistics for patients were presented as frequency, percentage, mean and standard deviation. The normality of the distributions of the parameters in the groups was analyzed with the Kolmogorov Smirnov test. "Chi-Square Test" was used for testing relationships between categorical variables. Our study analyzed the distribution of the pre-treatment hearing loss levels within gender groups by the "Chi-Square Test". "Independent Samples T-Test" was used to compare the means between two unrelated normally distributed groups. In our study, means of age within gender groups were analyzed by "Independent Samples T-Test". "Mann Whitney U Test" was used to compare differences between two independent groups when the dependent variable is either ordinal or continuous but not normally distributed. In our study, means of pre/post-treatment hearing thresholds, elapse time to HBOT, and total treatment sessions within gender groups were analyzed by " Mann Whitney U Test". "Wilcoxon Signed-Rank Test" was used to compare two sets of scores from the same group. Our study analyzed the comparison of pre-and post- threshold scores by the "Wilcoxon Signed-Rank Test".

RESULTS

One hundred thirty-five patients were included, with 70 (51.86%) females and 65 (48.14%) males. Clinical improvement in hearing loss was detected in 61.5% of females and 58.6% of males after HBOT (p= 0.725). Mean values of the variables of age, the number of the sessions, hearing loss levels before the treatment, and elapsed time to–HBOT onset were showed similar results when grouped by gender (p> 0.05) (Table-1).

Table 1. Comparison of the variables of "Age, number of the sessions, hearing threshold before and after the treatment, elapsed time to the treatment" according to gender.

	Female		Male		p-value
	N	Mean±SD	N	Mean±SD	
Age	66	46.47±12.15	62	47.50±17.50	* 0.701
Pre-treatment threshold (dB)	70	55.83±24.03	65	63.72±25.06	** 0.066
Post-treatment threshold (dB)	70	38.62±27.53	65	39.63±27.09	** 0.693
Elapsed time to HBOT (Days)	57	9.12±6.51	50	9.84±6.81	** 0.612
Number of sessions	70	16.27±7.03	65	16.71±5.93	** 0.345

* Independent Samples T-Test ** Mann-Whitney U Test; SD: Standard Deviation, N: Number, dB: Decibel

Hearing loss levels before the treatment were showed similar distribution when grouped by gender (p= 0.511). (Table-2).The mean hearing threshold before and after the treatment was compared in males and females in different age groups. The hearing gains were found statistically significant in all age groups (18-39, 40-59, and above 60 age groups) among males and statistically significant in "18-39" and "40-59" years old age groups among females (p< 0.05). (Table-3)

Table 2. Distribution of hearing loss onset levels by gender.

Hearing loss level group	Female		Male		p-value
	N	%	N	%	
Mild (20-39 dB)	20	28.6	11	16.9	* 0.511
Moderate (40-54 dB)	16	22.9	17	26.2	
Moderate to Severe (55-69 dB)	14	20.0	12	18.5	
Severe (70-89 dB)	13	18.6	15	23.1	
Profound (>90 dB)	7	10.0	10	15.4	

* Chi-square Test; N: Number, dB: Decibel

Table 3. Comparison of hearing thresholds before and after the treatment in different age groups among males and females.

Age Group (Years)		Female			Male		
		Pre-Treatment threshold (dB)	Post-Treatment threshold (dB)	p-value	Pre-Treatment threshold (dB)	Post-Treatment threshold (dB)	p-value
18-39	N	19	19	0.005*	23	23	0.001*
	Mean±SD	53.90±21.75	30.16±25.91		67.61±24.26	40.96±33.03	
40-59	N	39	39	<0.001*	21	21	<0.001*
	Mean±SD	56.52±26.83	40.84±28.52		59.79±25.82	35.05±20.03	
> 60	N	8	8	0.176*	18	18	0.019*
	Mean±SD	60.25±19.61	47.63±29.85		64.67±24.36	47.11±26.03	

* Wilcoxon Signed-Rank Test; SD: Standard Deviation, N: Number, dB: Decibel

When cases were grouped according to elapsed time to-HBOT onset, mean hearing gains of the 14-days group among males and both 14- and 30-days groups among females were found statistically significant (p< 0.05). (Table-4).Among females, statistically significant hearing gains were detected in all hearing loss groups, and statistically significant hearing gains were detected in moderate, severe, and complete hearing loss groups among males (p< 0.05) (Table-5).

Table 4. Comparison of hearing thresholds before and after the treatment according to elapsed time to HBOT among males and females.

Treatment Onset (Days)		Female			Male		
		Pre-Treatment threshold (dB)	Post-Treatment threshold (dB)	p-value	Pre-Treatment threshold (dB)	Post-Treatment threshold (dB)	p-value
0 - 14	N	43	43	<0.001*	36	36	<0.001*
	Mean±SD	57.45±24.21	36.06±28.49		67.13±22.96	37.11±23.93	
15 - 30	N	14	14	0.033*	14	14	0.755*
	Mean±SD	53.36±30.71	42.14±28.73		65.21±33.34	61.57±29.45	

* Wilcoxon Signed-Rank Test, ; SD: Standard Deviation, N: Number, dB: Decibel

Table 5. Comparison of the mean hearing thresholds before and after the treatment according to hearing loss levels among males and females.

Hearing Loss Onset Levels		Female			Male		
		Pre-Treatment	Post-Treatment	p-value	Pre-Treatment	Post-Treatment	p-value
Mild (20-39 dB)	N	20	20	0.005*	11	11	0.074*
	Mean ± SD	29.77±6.28	21.03±9.54		31.55±5.96	23.64±11.10	
Moderate (40-54 dB)	N	16	16	0.010*	17	17	0.042*
	Mean ± SD	44.44±3.99	28.25±19.33		46.53±4.95	37.94±15.34	
Moderate to Severe (55-69 dB)	N	14	14	0.039*	12	12	0.135*
	Mean ± SD	61.64±3.99	46.29±23.81		62.08±4.14	42.0±24.88	
Severe (70-89 dB)	N	13	13	0.019*	15	15	0.001*
	Mean ± SD	79.31±5.41	51.23±35.14		80.11±6.52	28.13±18.17	
Profound (>90 dB)	N	7	7	0.018*	10	10	0.022*
	Mean ± SD	101.14±10.24	73.86±23.41		105.70±8.04	74.50±38.68	

* Wilcoxon Signed-Rank Test; SD: Standard Deviation, N: Number, dB: Decibel

DISCUSSION

Although the pathogenesis of ISSNHL is not entirely understood, the most widely accepted theory is hypoxia of the cochlea due to total or partial occlusion of the cochlear artery. Edema occurs in the hairy cells of the inner ear and subsequently becomes dysfunctional giving rise to hypoxia[15]. Clarifying the etiology of ISSNHL will facilitate the decision of which treatment modalities should be used.

Stachler et al. have defined that the spontaneous recovery rate of ISSHL is 32% to 65%[4]. However, the maximum spontaneous complete recovery percentage was reported %35-39 by Bayoumy et al. in 2018. That study stated that most of the improvements occur within the first 24 hours after hearing loss [16]. Since the spontaneous recovery rates vary and the percentage of patients with unhealed hearing loss is still high in the studies, most patients were treated with MT [4]. Steroids, vasodilators, plasma expanders, antiviral and diuretic agents, low molecular weight heparin, and HBOT are preferred in different combinations to reduce the inflammatory state and increase the blood supply and/or oxygenation of the inner ear[3,5-7].

HBOT increases physically dissolved oxygen in the blood, and it also raises the level of PO_2 levels in the inner ear by diffusing through the round window, and subsequently dissolved oxygen increases in the labyrinthine fluids. The improved oxygenation of the inner ear activates cell metabolism and the Na^+/K^+ pump, and it leads to a repair of the ionic balance and the electrophysiologic functions of the cochlea[17].

Age, elapsed time to treatment onset, the severity of hearing loss before the treatment are declared critical prognostic criteria of the ISSNHL[5,18]. Our study also investigated these prognostic criteria, and these variables' distribution was similar when grouped by gender.

Korpinar et al. studied 97 patients with ISSNHL and investigated the effect of gender on healing. The authors found that there was no significant difference between male and female patients' improvement[6]. Our study found that the main hearing gain provided by HBOT was 17.21 dB among women and 27.09 dB among men. Clinical improvement was 61.5% in females and 58.6% in males in the hearing thresholds after HBOT. Consistent with the literature, our study found no significant difference between the genders regarding clinical improvement.

In a retrospective study, Satar et al. compared the hearing gains between ages groups (younger and older than 50) in 54 patients treated with MT and HBOT. In this study, it was found that hearing gains did not show a significant difference between age groups[12]. In a study by Cekin et al., MT and HBOT success was compared between young and old (>50 years old) patients, and no significant difference was found in clinical improvements between these age groups [13]. Hosokawa et al. studied 334 patients in 2016 and reported that treatment success in patients younger than 60 years old is higher than in patients older than 60 years old[18]. In another study conducted by the same authors in 2018, no significant difference was found between the improvement rates of 161 patients who were grouped as below or above 60 years old and treated with systemic steroids and HBOT[19]. In 2 different studies, patients with ISSNHL were treated with MT and HBOT. The hearing gain in patients younger than 50 years old was found significantly higher than in patients older than 50 years old[5,7]. In our study, consistent with the published literature, hearing gains diminished with increasing age in both genders and were found statistically significant in "18-39" and "40-59" years old age groups among females, but the hearing gains were statistically significant in all age groups (18-39, 40-59 and above 60 age groups) among males.

Fifty-four patients' records were divided into three groups according to treatment onset of HBOT as 1-7 days, 8-14 days, and 14-28 days in the study of Yildirim et al. This study showed that the hearing gains of the patients whose treatments were started in the first 14 days from the onset of hearing loss symptoms were higher than those who were not[20]. Hosokawa et al. also found that the success of the HBOT in patients whose treatments were started within seven days was higher[18]. In our study, hearing gains diminished with increasing elapsed time to HBOT in both genders, and mean hearing gains of 14 days group were found statistically significant in males; however, mean hearing gains were found statistically significant up to 30-days in females.

In a study conducted by Capuano et al., the effects of initial hearing loss levels on hearing gain were investigated in a patient group treated with MT and HBO. The hearing gain of the patients with severe and complete hearing loss was higher than those with less hearing loss[14]. Similarly, Korpinar et al. found that the patients with severe hearing loss had higher clinical improvement rates in their study[6]. Consistent with the literature, in our study, hearing gains increased when the initial hearing loss level was severe in both genders, and statistically significant hearing gains were detected in moderate, severe, and complete hearing loss groups among males. However, statistically significant hearing gains were detected in all hearing loss groups in females.

In this study, no effect of gender was found on clinical improvement. Hearing recovery rates diminished in both genders as the patient's ages increased and decreased with increasing elapsed time to treatment. However, hearing gains were found higher in the patients with severe hearing loss onset.

The Turkish Ministry of Health approved HBOT in patients diagnosed with ISSNHL, so HBOT is routinely administered in addition to MTs to all AISNIK patients in our hospital. Because of the legislation and ethical principles, no patient group in our hospital is treated solely with HBOT or MTs.

In conclusion, HBOT is a safe and beneficial treatment modality for sudden unilateral idiopathic sensorineural hearing loss when applied with MT. Our findings are valuable because more cases were analyzed in our study than in many other published studies, and pre-treatment patient evaluation, MT, and HBOT protocols were highly standardized in our study. Consequently, our findings showed that early administration of HBOT with MT resulted in better clinical improvements in the younger adults with severe ISSNHL.

Yazar Katkıları: Çalışma konsepti/Tasarımı: EE, ZK, SE, BE; NÖM; Veri toplama: EE, ZK, SE, BE; Veri analizi ve yorumlama: EE, ZK, SE, BE; Yazı taslağı: EE, ZK, SE, BE; İçeriğin eleştirel incelenmesi: EE, ZK, SE, BE; Son onay ve sorumluluk: EE, ZK, SE, BE; Teknik ve malzeme desteği: EE, ZK, SE, BE; Süpervizyon: EE, ZK, SE, BE; Fon sağlama (mevcut ise): yok.
Etik Onay: Bu çalışma için Sağlık Bilimleri Üniversitesi Gülhane Bilimsel Araştırmalar Etik Kurulundan 11.02.2021 tarih ve 2021-60 sayılı kararı ile etik onay alınmıştır.
Hakem Değerlendirmesi: Dış bağımsız.
Çıkar Çatışması: Yazarlar çıkar çatışması olmadığını beyan etmişlerdir.
Finansal Destek: Yazarlar finansal destek almadıklarını beyan etmişlerdir.

Yazarın Notu: Çalışma daha önce sunulmamıştır.
Author Contributions: Concept/Design : EE, ZK, SE, BE; Data acquisition: EE, ZK, SE, BE; Data analysis and interpretation: EE, ZK, SE, BE; Drafting manuscript: EE, ZK, SE, BE; Critical revision of manuscript: EE, ZK, SE, BE; Final approval and accountability: EE, ZK, SE, BE; Technical or material support: EE, ZK, SE, BE; Supervision: EE, ZK, SE, BE; Securing funding (if available): n/a.
Ethical Approval: For this study, ethical approval was obtained from the Gülhane Scientific Research Ethics Committee of the University of Health Sciences with the decision dated 11.02.2021 and numbered 2021-60.
Peer-review: Externally peer-reviewed.
Conflict of Interest: The authors have no conflicts of interest to declare.
Financial Disclosure: The authors have stated that they have not received financial support.
Acknowledgement: The study has not previously been presented.

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