Ist Tip Fak Derg 2016; 79: 4 J Ist Faculty Med 2016; 79: 4 http://dergipark.ulakbim.gov.tr/iuitfd http://www.journals.istanbul.edu.tr/iuitfd

# SYMPTOMATIC MIDDLE EAR AND CRANIAL SINUS BAROTRAUMAS AS A COMPLICATION OF HYPERBARIC OXYGEN TREATMENT

# HİPERBARİK OKSİJEN TEDAVİSİ KOMPLİKASYONU: SEMPTOMATİK ORTA KULAK VE KRANYAL SİNUS BAROTRAVMASI

# Bengüsu MİRASOĞLU\*, Aslıcan ÇAKKALKURT\*, Maide ÇİMŞİT\*

#### **ABSTRACT**

**Objective**: Hyperbaric oxygen therapy (HBOT) is applied for various diseases. It is generally considered safe but has some benign complications and adverse effects. The most common complication is middle ear barotrauma. The aim of this study was to collect data about middle ear and cranial sinus barotraumas in our department and to evaluate factors affecting the occurrence of barotrauma.

**Material and methods:** Files of patients who had undergone hyperbaric oxygen therapy between June 1<sup>st</sup>, 2004, and April 30<sup>th</sup>, 2012, and HBOT log books for the same period were searched for barotraumas. Patients who were intubated and unconscious were excluded. Data about demographics and medical history of conscious patients with barotrauma (BT) were collected and evaluated retrospectively.

**Results:** It was found that over eight years and 23,645 sessions, 39 of a total 896 patients had BT; thus, the general BT incidence of our department was 4.4%. The barotrauma incidence was significantly less in the multiplace chamber (3.1% vs. 8.7%) where a health professional attended the therapies. Most barotraumas were seen during early sessions and were generally mild. A significant accumulation according to treatment indications was not determined.

**Conclusion:** It was thought that the low barotrauma incidence was related to the slow compression rate as well as training patients thoroughly and monitoring them carefully. It can be said that when applied in these conditions, HBOT is safe for ears and cranial sinuses.

Key words: Hyperbaric oxygen; barotraumas; patient training.

# ÖZET

Amaç: Hiperbarik oksijen tedavisi (HBOT) genel olarak güvenli bir tedavi yöntemidir ancak her yöntem gibi bazı komplikasyonları ve yan etkileri vardır. En sık görülen komplikasyon orta kulak barotravmasıdır. Tedavi merkezimizdeki barotravma sıklığını belirlemek ve ortaya çıkmasına neden olan faktörleri araştırmak üzere retrospektif bir çalışma planlandı.

Gereç ve Yöntem: Merkezimizde 1.06.2004 ve 30.04.2012 tarihleri arasında HBOT alan hastaların dosyaları ve aynı döneme ait HBOT kayıt defterleri barotravma açısından tarandı. Barotravma geçirdiği belirlenen hastalar saptandı. Tedavi sırasında entübe ve bilinci kapalı olan hastalar çalışmadan dışlandı. Hastaların demografik bilgileri ile medikal özellikleri kaydedildi ve değerlendirildi.

**Bulgular:** Sekiz yılda 23.645 seans HBOT yapıldığı ve bu sürede tedavi edilen 896 hastanın 39'unda semptomatik barotravma oluştuğu saptandı. Merkezimizdeki genel BT insidansı %4,4 idi. Bir sağlık görevlisinin tedaviler sırasında hastalara eşlik ettiği çok kişilik basınç odalarında barotravma insidansı (% 3,1) tek kişilik basınç odasına (% 8,7) göre anlamlı şekilde daha azdı. Barotravmaların pek çoğu hastaların tedaviye ilk başladığı dönemlerde oluşmaktaydı ve genel olarak hafif seyirliydi. HBO tedavisine alınma endikasyonu ile barotravma arasında bir ilişki izlenmedi.

**Sonuç:** Yavaş kompresyon hızı ile birlikte hastaların tedavi öncesi eğitilmesi ve tedavi sırasında yakın gözlemin barotravma oluşma sıklığını azalttığı düşünüldü. Bu koşullarda uygulandığında HBO tedavisinin kranyal sinüs ve orta kulak barotravmaları acısından güvenli olduğu söylenebilir.

Anahtar kelimeler: hiperbarik oksijen; barotravma; hasta eğitimi

Date received/Dergiye geldiği tarih: 23.09.2016 – Date accepted/Dergiye kabul edildiği tarih: 15.11.2016
\*Istanbul University, Istanbul Faculty of Medicine, Department of Underwater and Hyperbaric Medicine, Istanbul

# INTRODUCTION

Hyperbaric oxygen therapy (HBOT) is a treatment where patients breathe 100% oxygen at a pressure higher than sea level. It is applied in sealed chambers, which are either monoplace or multiplace. Its mechanism depends on the increase in tissue oxygenation after the rise of dissolved oxygen due to higher pressure. HBOT is used as the actual or adjuvant therapy for many diseases that have a hypoxic component.

HBOT, which is generally considered as safe with minor adverse effects such as transient myopia, can also lead to complications like many other therapies. The most frequent complication is barotrauma (BT). Barotrauma is a pressure-related injury caused by nonequalization of pressure between body cavities and with environment pressure (1). Middle ear and cranial sinuses are the structures most affected by pressure changes; hence, not surprisingly, middle ear barotrauma (MEB) is the most common event. Barotrauma incidence ranges between 8 and 68.7% in previous reports, but it is seen more frequently in unconscious patients (2). Barotrauma symptoms include a feeling of fullness in the ears, pain, hearing loss or vertigo, depending on the level of injury. Objectively, BTs can be evaluated by otoscopic examination and graded according to Teed classification (1). Healing can take a few hours or several weeks, again depending on the injury. Very rarely, serious cases require surgery.

In our department, where many patients have been treated and thousands of sessions performed since 1990, data for complications other than the seizure rate due to hyperoxygenation is limited (3). We conducted this retrospective study in order to collect our own data, and also to investigate the importance of pre-treatment training, close monitoring, and slow compression.

# MATERIAL AND METHODS

Treatment and applications

In our center, HBOT indications are adopted according to the reimbursement by the Ministry of Health. In Turkey, air trapping lesions of the lungs, severe cardiac failure, and a history of untreated pneumothorax are accepted as contraindications for hyperbaric oxygen. In addition, upper respiratory infections are considered to be relative contraindication; patients are not admitted to the chamber until the infection subsides. The only exception is in cases of emergencies such as gas embolism, carbon monoxide intoxication, and gas gangrene.

Before initial HBOT, every patient undergoes otoscopic examination and is thoroughly informed and trained about ear equalization by a doctor or a hyperbaric nurse. All sessions are attended by a doctor or a nurse who helps and instructs the patients to perform the necessary maneuvers at the appropriate time during compression and carefully monitors them. A chamber operator watches the entire session via video cameras. If a patient reports ear pain or discomfort during compression, the compression is halted and pressure is decreased until the discomfort relieves. Then the chamber is pressurized again at a slower rate. If the pain persists despite two

attempts, the patient is taken out and examined again with an otoscope. In case of necessity, systemic or nasal decongestants may be prescribed and HBOT is discontinued for one to five days. Prophylactic use of these medications and routine myringotomy are not approved in our practice.

Patient data

Data were collected with the help of the Information Technologies (IT) department of Istanbul Faculty of Medicine. Files of patients who had undergone hyperbaric oxygen therapy between June 1<sup>st</sup>, 2004, and April 30<sup>th</sup>, 2012, and had HBOT log books for the same period were searched for BTs.

Patients who reported ear or sinus pain or discomfort and had to leave the chamber were considered to have suffered BT. Positive findings with otoscopic examination for middle ear BT and radiologic findings for sinus BT were also recorded for these patients. From the logbooks and files of these patients, age, sex, diagnosis, treatment details, pre- and post-treatment otoscopic examination findings, and factors that could predispose for BT such as head/neck radiotherapy were extracted. Patient distribution among the monoplace and multiplace chambers and treatment protocols were recorded. Also, symptoms regarding the ear or sinus were searched, including information about the session during which these occurred and the layover time. MEBs were classified as mild, intermediate, or advanced according to the symptoms and otoscopic findings. Session interruption for 1-2 days or Grade 1 or 2 BT according to the Teed scale were classed as mild BT, whereas an interruption for 3-5 days or Grade 3 BT was considered an intermediate BT. Longer interruption or higher grades were classified as severe BT.

Patients who had diving history, took HBO treatment before, and who underwent more than fives sessions were were defined as experienced patients.

Demographic data are expressed in means  $\pm$  standard deviation and percentages where appropriate. Categorized data are given in percentages. Statistical analyses were performed using Medcalc® for Windows (version 11.2.1.0). "N-1" Chi-square tests were used to compare proportions. An ROC curve analysis was used to evaluate the relation of BT occurrence with the number of sessions. Significance was accepted in all cases at p<0.05.

#### RESULTS

During the study period, 896 patients were treated in 23,645 sessions attended by a nurse or a doctor after October 2008. Of these, 299 (33.4%) patients were female and 597 (66.6%) were male. Two hundred eight patients were treated in monoplace chambers and 688 in a multiplace chamber. Detailed information about chambers used and treatment protocols is presented in Table 1.

It was found that 39 patients had BT; thus, the general BT rate for our department was 4.4%. BT incidence was 3.5% for males and 6% for females. MEB was seen in 35 patients (14 females / 21 males), whereas sinus barotrauma was seen in only 4 patients (3 females / 1 male). The average age of these patients was  $45.1\pm18.1$ 

# Barotrauma as a HBO complication

years (range, 7-75 years). There were no predisposing factors for BT.

Patients with radionecrosis and avascular bone necrosis were the major groups who experienced BT.

Distribution of all patients according to indications and number of BTs seen in each are shown in Table 2.

Table 1: Details of chambers and treatment protocols

Chamber	Monoplace (Kurnichev® BLKS-303 MK)	Monoplace (Sechrist®)	Multiplace (Hypertech® Zyron)
Treatment protocol	100% $O_2$ at 2.0ATA 60 min	100% O <sub>2</sub> at 2.0 ATA 60 min	$3x \ 25 \ min \ 100\% \ O_2 + 2x5$ min airbreak $2.4 \ ATA$
Total time	80 minutes	80 minutes	115 minutes
Compression rate	1 m per min	1 m per min	1 m per min
Number of patients treated	177 (19.8%)	31 (3.4%)	688 (76.8%)

Table 2: General and barotrauma patient distribution by indication (RAO: retinal artery occlusion, OM: osteomyelitis, DCS: decompression sickness, ATI: acute traumatic ischemia [crush, compartment, risky flaps, graft], NSTI: necrotizing soft tissue infections) The Non-healing wound category comprises diabetic, vascular, vasculitic, and all other chronic ulcers.

Indication	Patients (n)	Barotrauma	BT rate in this indication
Non-healing wound	319	19	6
Sudden hearing loss	121	4	3.3
Chronic OM	85	5	5.9
RAO	67	-	
Radionecrosis	67	6	9
Avascular necrosis	47	4	9
ATI	50	-	
CO intox	41	1	2.4
DCS	24	-	
Other (e.g., NSTI, extravasation)	75	-	

The average total number of sessions all patients underwent was 28.4±23 (median: 24). The average total number of BT sessions patients underwent was 45±40 (median: 6). Barotraumas were mostly seen in the early sessions, but occurrence in later sessions was not rare. A little less than half of the BTs (48%, n=19) were seen in the first five sessions, eight of them in the first session.

The latest occurrence was a case in the 51<sup>st</sup> session. BT occurrences according to sessions can be seen in Figure 1. A ROC curve analysis revealed 15 sessions as a threshold for the decrease in the risk for barotrauma (Area under curve 0.714 +/- 0.041; p<0.001; sensitivity for the threshold 72%, specificity 61% (Fig 2). None of the patients experienced repetitive BT.

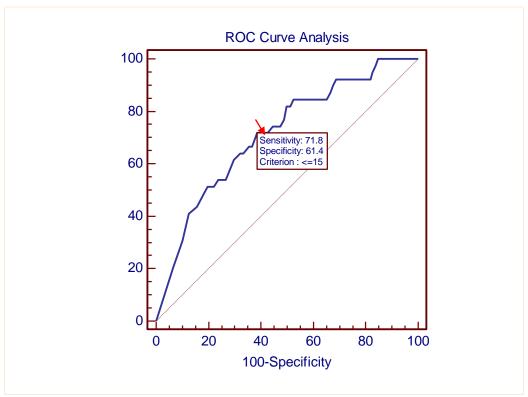


Figure 1: ROC curve analysis. Arrow shows the threshold session (session 15) for BT occurrence.

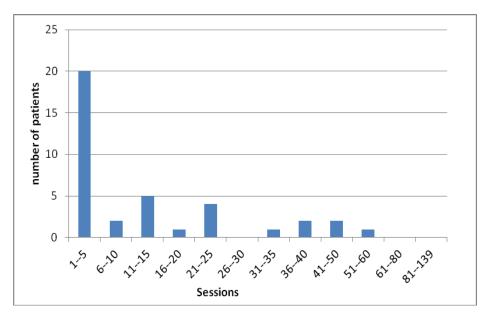


Figure 2: Patient distribution according to session with occurrence of BT

Almost all MEBs were mild to intermediate and the average break time was 2.6 sessions. Twenty-two patients had to suspend treatment for up to three days; the suspension/rest time was only one day in 14 of these patients.

MEB and sinus BT incidences in a monoplace chamber were found significantly higher than those in the multiplace chamber (p=0.003). MEB occurred in 18 and sinus BT occurred in 2 patients in monoplace chambers, so the overall BT rate was 8.7% in monoplace chambers. During multiplace chamber treatments, 19

patients had MEB and 2 patients had sinus BT. The total number was 21 and the incidence was 3.1%.

# **DISCUSSION**

In our study, we analyzed data from 896 patients regarding middle ear and cranial sinus BTs and factors that may be related to the development of BT. The BT incidence in our department was 4.4 %. This is one of the lowest reported to date (4,5). The main reason for this could be the patient population of the present study. In our study, only conscious patients were included.

# Barotrauma as a HBO complication

However, BT incidence of unconscious patients is always high. In 1994, Presswood reported a 94% incidence of MEB in unconscious patients (6). In Besserau's study, MEB incidence was found as 23.4% in unconscious patients, whereas it was 12.4% in conscious ones.

However, even when studies evaluating conscious patients are taken into account, our incidence is still lower than many others' (7,8). In this case, other factors that have also been reported in other studies should be considered, including slow compression rate, patient training, and following patients inside and from outside of the chamber.

A slow compression rate is accepted as one of the protective factors for barotrauma. In studies showing a slower compression rate, barotrauma incidences are generally lower. Vahidova et al, comparing MEB rates under standard compression (2.8 m per min) and slow compression (1.1 m per min), found that MEB was significantly less frequent with slow compression (9). Our compression rate, 1 m per minute, which is slower than the slow compression rate in that study, is also one of the slowest reported. So, this procedure is effective for keeping incidences low.

It has already been emphasized that when patients are well-informed and trained thoroughly about inflation techniques, fewer barotraumas are seen (10,11). However, close monitoring and helping the patent in the chamber is equally important. In the study by Ambiru et al., where patients were trained repeatedly and accompanied by a physician, BT incidence was 9.7%, one of the lowest. Similarly, in our department the overall incidence was significantly lower for multiplace chambers. The presence and help of an attendant must be associated with the observed lower incidence in multiplace chambers because all patients were informed in the same way. It can be said that watching new patients closely can reduce BT incidence.

Another factor to account for this difference may be the BT criteria. Our BT diagnosis was based on the patient's reports. Patients who had to quit the session due to pain or discomfort and had a positive findings with otoscopy were accepted to have symptomatic middle ear BT. To ascertain sinus BT, pain or discomfort around the sinus areas was questioned. In a study where middle-ear BT incidence was found as 43%, patients were examined otoscopically before and after each treatment and any change on the tympanic membrane was accepted as barotrauma, regardless of symptoms. However, it is controversial as to whether all of these cases should be accepted as BT because an exact definition for BT is not available (12).

In our practice, most BTs occurred in early sessions of HBOT. Even though fifteen sessions constituted a threshold after which BT occurrence significantly decreased, 41% of all BTs were seen in the first three and almost 60 percent in the first ten sessions. This is similar to the previously repored rates reported. In studies by Lima et al., Ambiru et al., and Lehm et al., about 40% of the BTs were seen during the first session, and Commons et al. found the cumulative risk of BT over the first five sessions to be 35.8% (13). We think

that despite all training, inexperience must still play an important role in early occurrence, because none of the patients were defined as experienced in our study reported BT in the early sessions.

On the other hand, BT was also seen during later sessions where inexperience was not expected to be a problem. Upper respiratory tract infections may be a reason for BT occurring in later sessions (1). Other than that, inadequate equalizing technique may be a factor. Unsuccessful auto-inflation does not necessarily take place in earlier sessions. It was seen that patients who were able to perform required maneuvers at the beginning may fail to do so in later sessions (14).

In our study, we did not analyze risks or predictive factors, but when we compared our results with other studies, we found some differences. In most risk analysis studies, female sex was found as a risk factor for BT (10,11,12). Though most of our patients with BT were male, when all treated patients were considered, BT incidence was lower for males (3.5% vs. 6%). Thus, in line with other studies, our female patients tended to have more BTs. Other than sex, we saw no accumulation in parameters that have previously been identified as possible risk factors (10,12,13).

This study found that the incidence of BT in our department was very low. It is important to note that patients evaluated were conscious, but this low incidence is mostly related to the slow compression rate as well as informing patients thoroughly and monitoring them carefully. It can be said that when applied in these conditions, HBOT is safe regarding ears and cranial sinuses.

# REFERENCES

- 1. Hamilton-Farrell M, Bhattacharyya A. Barotrauma. Injury 2004;35(4):359-70.
- 2. Bessereau J, Tabah A, Genotelle N, Français A, Coulange M, Annane D. Middle-ear barotrauma after hyperbaric oxygen therapy. Undersea Hyperb Med 2010;37(4):203-8.
- 3. Yildiz S, Aktas S, Cimsit M, Ay H, Toğrol E. Seizure incidence in 80,000 patient treatments with hyperbaric oxygen. Aviat Space Environ Med. 2004;75(11):992-4.
- 4. Camporesi EM. Side effects of\_hyperbaric\_oxygen therapy. Undersea Hyperb Med 2014;41(3):253-7.
- Plafki C, Peters P, Almeling M, Welslau W, Busch R. Complications and side effects of hyperbaric oxygen therapy. Aviat Space Environ Med 2000;71(2):119-24.
- Presswood G, Zamboni WA, Stephenson LL, Santos PM. Effect of artificial airway on ear complications from hyperbaric oxygen. Laryngoscope 1994;104(11 Pt 1):1383-4.
- 7. Karahatay S, Yilmaz YF, Birkent H, Ay H, Satar B. Middle ear barotrauma with hyperbaric oxygen therapy: incidence and the predictive value of the nine-step inflation/deflation test and otoscopy. Ear Nose Throat J 2008;87(12):684-8.
- 8. Lima MA, Farage L, Cury MC, Bahmad F Jr. Middle ear barotrauma after hyperbaric oxygen

# HBO komplikasyonu: Barotravma

- therapy the role of insuflation maneuvers. Int Tinnitus J 2012;17(2):180-5.
- 9. Vahidova D, Sen P, Papesch M, Zein-Sanchez MP, Mueller PH. Does the slow compression technique of hyperbaric oxygen therapy decrease the incidence of middle-ear barotrauma? J Laryngol Otol. 2006;120(6):446-9.
- Ambiru S, Furuyama N, Aono M, Otsuka H, Suzuki T, Miyazaki M. Analysis of risk factors associated with complications of hyperbaric oxygen therapy. J Crit Care 2008;23(3):295-300.
- 11. Fitzpatrick DT, Franck BA, Mason KT, Shannon SG. Risk factors for symptomatic otic and sinus

- barotrauma in a multiplace hyperbaric chamber. Undersea Hyperb Med 1999;26(4):243-7
- 12. Lehm JP, Bennett MH. Predictors of middle ear barotrauma associated with hyperbaric oxygen therapy. South Pacific Underwater Medicine Society(SPUMS) Journal 2003;33(3):127-33
- 13. Commons KH, Blake DF, Brown LH. A prospective analysis of independent patient risk factors for middle ear barotrauma in a multiplace hyperbaric chamber. Diving Hyperb Med 2013;43(3):143-7.
- 14. Beuerlein M, Nelson RN, Welling DB. Inner and middle ear hyperbaric oxygen-induced barotrauma. Laryngoscope 1997;107(10):1350-6.