Original Article
Yonsei Med J
https://doi.org/10.3349/ymj.2024.0068
Yonsei Medical Journal
YMJ
pISSN: 0513-5796 · eISSN: 1976-2437

Risk Factors Associated with Middle Ear Barotrauma in Patients Undergoing Monoplace Hyperbaric Oxygen Therapy

Yoon Sung Lee[1], Sang Won Ko[1], Hyoung Youn Lee[2,3], Kyung Hoon Sun[4], Tag Heo[1,3], and Sung Min Lee[1,3]

[1]Department of Emergency Medicine, Chonnam National University Hospital, Gwangju;
[2]Trauma Center, Chonnam National University Hospital, Gwangju;
[3]Department of Emergency Medicine, Chonnam National University Medical School, Gwangju;
[4]Department of Emergency Medicine, College of Medicine, Chosun University, Gwangju, Korea.

Purpose: This study aimed to identify independent risk factors for middle ear barotrauma (MEB) symptoms in patients undergoing monoplace hyperbaric oxygen therapy (HBOT).
Materials and Methods: We analyzed data from a single-center study involving 296 patients who received monoplace HBOT. Through multivariable logistic regression analysis, we examined the relationship between various factors and the occurrence of MEB to identify significant independent risk factors.
Results: The multivariable logistic regression analysis indicated that an altered mental state was associated with increased odds of MEB occurrence [odds ratio (OR) 2.50; 95% confidence interval (CI): 1.13–5.51]. Furthermore, patients in the emergency treatment group for HBOT, as defined by the national health insurance in Korea, were found to be 6.75 times more likely to experience MEB (95% CI: 1.33–34.20).
Conclusion: This study identified altered mental status and classification in the emergency treatment group for monoplace HBOT as independent risk factors for MEB. These findings can aid in developing safer protocols for monoplace HBOT chamber operations.

Key Words: Middle ear barotrauma, hyperbaric oxygen therapy, monoplace chamber

INTRODUCTION

Hyperbaric oxygen therapy (HBOT) aims to saturate the patient's plasma with 100% oxygen by facilitating inhalation within a hyperbaric chamber, where the pressure exceeds twice the normal atmospheric pressure.[1] The primary mechanism of action is associated with the increased concentration of dissolved oxygen in the plasma under high pressure during HBOT.[2,3] This treatment is prevalently utilized for a variety of conditions, including decompression sickness, carbon monoxide (CO) poisoning, wound healing, and burns, along with applications in myonecrosis, necrotizing fasciitis, chronic refractory osteomyelitis, sudden sensorineural hearing loss, and cerebral air embolism.[4]

However, HBOT can induce a range of complications, from severe effects such as seizure or pulmonary toxicity to milder effects such as claustrophobia, anxiety, auditory changes, and visual disturbances. Notably, middle ear barotrauma (MEB) is recognized as a common complication associated with HBOT.[5-8] Post-treatment, MEB is believed to result from specific mechanisms, where a pressure differential exceeding approximately 60 mm H_2O between the ambient atmosphere and the middle ear (ME) may cause ear pain and a sensation of pressure. If

Received: April 15, 2024 **Revised:** September 13, 2024
Accepted: October 8, 2024 **Published online:** January 3, 2025
Corresponding author: Sung Min Lee, MD, PhD, Department of Emergency Medicine, Chonnam National University Medical School and Chonnam National University Hospital, 42 Jebong-ro, Dong-gu, Gwangju 61469, Korea.
E-mail: em00058@jnu.ac.kr

•The authors have no potential conflicts of interest to disclose.

this differential persists or increases, fluid infiltration into the ME is possible, and vascular damage could lead to hemorrhage within the ME. Moreover, the inability to execute pressure-equalizing maneuvers, such as the Valsalva, Toynbee, or swallowing, could precipitate eardrum rupture.

Achieving pressure equilibrium in the ME can be hindered by various factors. Indeed, certain individuals, such as pediatric or dementia patients or those with language barriers, may not fully grasp the techniques essential for ME pressure equalization. These challenges can lead to inefficient equalization technique application, causing primary eustachian tube dysfunction (ETD) by escalating ME pressure. Additionally, patients with conditions that diminish ME ventilation during pressurization, such as upper respiratory infections, allergies, or radiation-induced soft tissue injuries, may be more prone to secondary ETD due to inflammation-induced swelling in the nasopharynx and nasal passages, obstructing the opening to the eustachian tube (ET). Secondary ETD may also result from direct radiation-induced damage manifesting as gland fibrosis and scarring in the ET.

While the incidence of MEB post-HBOT is recognized, most research has concentrated on patients undergoing treatment in multiplace hyperbaric chambers. Some studies have suggested that the supine posture in monoplace chambers elevates central venous pressure, causing venous congestion, complicating ear pressure compensation and potentially leading to adverse effects.[9] However, the exact contributors and their overall impact remain to be fully elucidated. This study aimed to ascertain the incidence rates of MEB symptoms in patients receiving monoplace HBOT and identify associated factors to aid in developing safer operational protocols for monoplace HBOT applications.

MATERIALS AND METHODS

Study design

This study, conducted from May 2021 to December 2023, focused on patients treated in our institution's monoplace HBOT chamber (BARA-MED Monoplace Hyperbaric Chamber, ETC Biomedical Systems, Southampton, PA, USA). The typical session duration was 90 minutes, beginning with 15 minutes of compression and ending with 15 minutes of decompression. Furthermore, depending on the indication, the maximum treatment pressure was set at 2.0 atmospheres absolute (ATA) or 2.8 ATA, depending on the indication. Medical records were retrospectively collected and analyzed. Our primary aim was to assess the incidence of MEB among all treated patients. Secondly, we planned to identify the characteristics and risk factors associated with MEB occurrences by examining patient-side factors, such as demographic information, physiological signs, medical history, blood tests, and other pertinent data. We also considered secondary factors related to the HBOT protocol, including rates of decompression and compression, pressure metrics, treatment duration, and treatment indications. We used a video otoscope to detect MEB and evaluate its severity (INSIGHT-I, MEDIANA, Wonju, Korea). The modified O'Neill grading system, applied through video otoscopy, will help identify the risk factors for MEB within patient groups.[10] Furthermore, we intended to analyze the timing of complication occurrences. This analysis will enable us to define the groups experiencing MEB. Through multivariate analysis, we will then discern the differences between groups with and without complications to pinpoint occurrence risk factors.

The O'Neill grading system utilizes a video otoscope to capture a baseline image of the tympanic membrane (TM) before hyperbaric exposure. This image serves as a permanent record of the initial observations made by the physician, which can be referenced in any subsequent MEB episode, aiding in minimizing variations in grading.

The O'Neill grades are assigned as follows:

- Grade 0: Symptoms with no otologic signs of trauma
- Grade 1: Any increased redness of the TM when compared to baseline, presence of serous or slightly serosanguinous fluid, and/or trapped air behind the TM
- Grade 2: Frank bleeding in any location and/or perforation of the TM

This study was approved by the Chonnam National University Hospital Institutional Review Board (CNUH-2023-305). The need for informed consent has been waived owing to its retrospective nature.

Data collection

Age, sex, past medical history, and medication history: hypertension (HTN), diabetes mellitus (DM), cancer, pregnancy, liver cirrhosis, chronic kidney disease, cerebrovascular diseases, cardiovascular diseases, otitis media, rhinitis, and consciousness level. Operational protocol variables for HBOT: compression rate and time, decompression rate and time, and number of treatment sessions. Complications of HBOT: MEB, nasal sinus pain, ocular complication, and claustrophobia. Abnormal findings in post-HBOT otoscope examination: O'Neill scale grade. Indications for HBOT: 16 conditions covered by the national health insurance (NHI) in Korea.[11] Among these 16 conditions covered by NHI, 7 conditions, such as CO poisoning and decompression sickness, were classified as requiring emergency treatment group (Table 1).

Statistical analysis

Continuous variables are presented as the mean and standard deviation, as all continuous variables had a normal distribution. Continuous variables that did not satisfy the normality test are presented as median values with interquartile ranges (IQRs). Normality was evaluated using skewness and kurtosis. Categorical variables are presented as the frequencies with percentages. Continuous variables between independent

https://doi.org/10.3349/ymj.2024.0068

Table 1. Sixteen Indications of Hyperbaric Oxygen Therapy Covered by National Health Insurance in Korea[11]

A group Emergency treatment	B group Chronic treatment	C group Other
Carbon monoxide poisoning	Acute thermal burn injury	Idiopathic sudden sensorineural hearing loss
Decompression sickness	Peripheral arterial occlusive disease (Buerger's disease)	
Air or gas embolism	Compromised flaps/grafts, crush injury, and compartment syndromes	
Gas gangrene (clostridial myositis and myonecrosis), necrotizing soft infection	Replantation of an amputated digit	
	Delayed radiation injury	
Cyanide poisoning	Diabetic foot ulcer (Wagner grades ≥3)	
Central retinal artery occlusion	Osteomyelitis (refractory)	
Severe anemia	Intracranial abscess	

groups were compared using the t-test or Mann–Whitney U test depending on their normal distribution, while categorical variables were compared using the appropriate chi-square or Fisher's exact tests. Variables showing statistical significance (p<0.1) in the univariable analysis will undergo multivariable logistic regression analysis to ascertain whether factors are associated with MEB occurring in monoplace HBOT. Multicollinearity was assessed, and none of the variables had a variance inflation factor >5. The results of the logistic regression analyses were reported as odds ratios (ORs) with corresponding 95% confidence intervals (CIs). Moreover, we analyzed the probability of MEB occurrence as a function of the number of HBOT sessions using a restricted cubic spline graph. This analytical method enabled us to illustrate the nonlinear relationship between the number of sessions and the dependent variable. The solid line represents the predicted values, while the shaded area indicates the 95% CI. Data were analyzed using Stata/SE version 16.1 software for Windows (StataCorp, College Station, TX, USA). A two-sided p-value of 0.05 was considered significant.

RESULTS

A total of 296 patients received treatment, of whom 203 were male (68.6%). The average age was 49.00±17.20 years. Among the indications for HBOT, the most common was CO poisoning, affecting 160 patients (54.1%), followed by sudden sensorineural hearing loss in 102 patients (34.5%). The third most common indication was CO delayed neuropsychiatric sequelae, which occurred in 15 patients (5.1%). According to the NHI in Korea, 181 patients (61.2%) were categorized as emergency indications, and the time from symptom onset to treatment initiation averaged 190.20±704.10 hours. The majority, 221 patients (74.7%), commenced treatment within a week. Regarding the number of treatments, 231 patients (78.0%) had 1–5 sessions, 48 patients (16.2%) had 6–10 sessions, and 17 patients (5.7%) had more than 10 sessions. At admission, 52 patients (19.9%) presented with altered consciousness. Among the treated patients, 74 (25.0%) had a history of HTN, 52 (17.6%) had DM, 24 (8.1%) had heart disease, and 22 (7.4%) had cancer; 72 (24.3%) were smokers. Post-HBOT, general complications occurred in 180 patients (59.8%), with MEB affecting 166 patients (56.1%). According to the O'Neill Scale for MEB, 174 patients (58.8%) showed abnormalities on video otoscopy, and 8 (2.7%) patients with claustrophobia also experienced MEB. The pressurization rates for HBOT were 2.2 feet of seawater (FSW) in 120 patients (40.5%) and 4 FSW in 176 patients (59.5%) (Table 2).

The graph indicates the probability of MEB occurrence based on the number of treatments. As treatment sessions increased, the likelihood of MEB occurrence continuously decreased. There was a 60% chance of MEB occurring in the first session, which dropped below 20% from the fifth session. Notably, there were zero cases of MEB from the 18th session onwards (Fig. 1).

In the group comparison, the MEB occurrence group (grades 1 and 2 on the O'Neill scale) had an average age of 50.62±18.17 years, slightly older than the non-occurrence group. Patients with CO poisoning exhibited a higher rate of MEB at 62.6% compared to the other groups. The emergency treatment group based on the NHI had a higher MEB occurrence rate of 70.1%. Patients treated within 7 days showed a higher MEB occurrence rate. However, the MEB group had a shorter duration from symptom onset to treatment initiation, with a median of 7.01 (IQR: 2.83–121.08) hours. Altered consciousness was more prevalent (26.1%) in the MEB occurrence group. A higher MEB rate was observed in the group with a pressurization speed of 4 FSW/min (Table 3).

The univariable analysis demonstrated that the emergency treatment group A had an increased MEB rate, with an OR of 2.51 (95% CI: 1.55–4.05). Notably, the MEB rate was lower when treatment was initiated more than 7 days after onset. The patients with altered mental statues had higher MEB rates (OR: 3.18, 95% CI: 1.51–6.67) compared to those who were alert. Regarding compression speed, the MEB rate was higher (OR: 1.95, 95% CI: 1.21–3.13) at 4 FSW/min compared to 2.2 FSW/min. Multivariable logistic regression analysis confirmed that an altered mental state was associated with increased odds of MEB occurrence (OR: 2.50, 95% CI: 1.13–5.51), and the odds were 6.75 times higher (95% CI: 1.33–34.20) in the emergency treatment group for HBOT under the NHI of Korea (Table 4).

Table 2. Analysis of Characteristics of Patients Treated with Monoplace HBOT (n=296)

	Value
Age (yr)	49.00±17.20 (9–86)
Sex	
Male	203 (68.6)
Female	93 (31.4)
Indication of HBOT	
CO	160 (54.1)
CO DNS	15 (5.1)
SSNHL	102 (34.5)
DCS	1 (0.3)
AGE	1 (0.3)
Necrotizing fasciitis	3 (1.0)
Burn	2 (0.7)
Buerger's disease	1 (0.3)
Wound problem after radiation therapy	4 (1.4)
Diabetes mellitus foot	2 (0.7)
Chronic osteomyelitis	1 (0.3)
Compartment syndrome	1 (0.3)
Others	3 (0.8)
HBOT indication based on NHI	
Emergency treatment group A	181 (61.2)
Chronic treatment group B and C	115 (38.8)
Time from onset to treatment (hours)	11.00 (3.23–170.83)
<168 hours (7 days)	221 (74.7)
>168 hours (7 days)	75 (25.3)
Number of treatments based on HBO indication	
1–5	231 (78.0)
6–10	48 (16.2)
>10	17 (5.7)
Compression rate of HBOT	
2.2 FSW/min	120 (40.5)
4 FSW/min	176 (59.5)
Mental state (n=261)	
Alert	209 (80.1)
Altered mental status (verbal, pain, unresponsive)	52 (19.9)
GCS score (n=158)	15 (13–15)
Past medical history (no/yes)	
Cardiac disease	272 (91.9)/24 (8.1)
Hypertension	222 (75.0)/74 (25.0)
Diabetes mellitus	244 (82.4)/52 (17.6)
Cerebrovascular disease	289 (97.6)/7 (2.4)
Cancer	274 (96.0)/22 (7.4)
Chronic liver disease	288 (97.3)/8 (2.7)
Chronic renal disease	284 (96.0)/12 (4.0)
Rhinitis	291 (98.3)/5 (1.7)
Tinnitus	295 (99.7)/1 (0.3)
Hearing loss	293 (99.0)/3 (1.0)
ENT surgery	295 (99.7)/1 (0.3)
ENT radiation therapy	295 (99.7)/1 (0.3)
Psychiatric illness	259 (87.5)/37 (12.5)
Smoking history	224 (75.7)/72 (24.3)
Others	218 (73.7)/78 (26.3)
HBOT complication	
Middle ear barotrauma	166 (56.1)
Nasal sinus pain	2 (0.7)
Ocular complication	1 (0.3)
Claustrophobia	8 (2.7)
No complication	119 (40.2)
O'Neill grading scale	
0	122 (41.2)
1	167 (56.4)
2	7 (2.4)

HBOT, hyperbaric oxygen therapy; CO, carbon monoxide; DNS, delayed neuropsychiatric sequelae; SSNHL, sudden sensorineural hearing loss; DCS, decompression sickness; AGE, arterial gas embolism; FSW, feet of seawater; NHI, national health insurance; GCS, Glasgow Coma Scale; ENT, otorhinolaryngology. Data are presented as mean±standard deviation, n (%), or median (Q1–Q3).

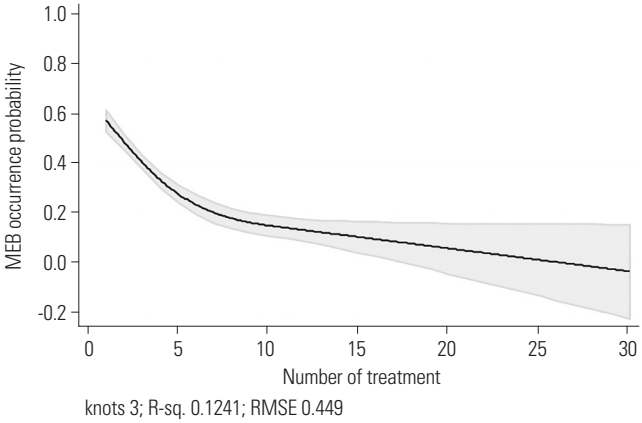

Fig. 1. The probability of MEB occurrence depending on the number of treatments. MEB, middle ear barotrauma.

DISCUSSION

This study provides valuable insights into the occurrence of MEB among patients undergoing HBOT in monoplace hyperbaric chambers, with a focus on the implications of altered mental status and emergency treatment indications under the NHI of Korea. Our findings indicate a substantial incidence of MEB, with 56.1% of the patients affected, corroborating the well-established association between HBOT and MEB. Notably, patients with CO poisoning exhibited the highest rate of MEB occurrence (62.6%), which aligns with previous research emphasizing the vulnerability of this patient group due to the acute and severe nature of CO poisoning, often requiring rapid intervention with HBOT. The emergency treatment group, classified under NHI, demonstrated a significantly higher OR (6.75,

https://doi.org/10.3349/ymj.2024.0068

Table 3. Comparison of Factors Related to MEB after Monoplace HBOT

	MEB (O'Neill grading scale)		
	Scale 0 (n=122)	Scale 1–2 (n=174)	*p* value
Age (yr)	46.70±15.49	50.62±18.17	0.053
Sex			0.933
Male	84 (68.9)	119 (68.4)	
Female	38 (31.1)	55 (31.6)	
HBOT indication			0.002
CO	51 (41.8)	109 (62.6)	
CO DNS	6 (4.9)	9 (5.2)	
SSNHL	56 (45.9)	46 (26.4)	
DCS	0 (0.0)	1 (0.6)	
AGE	0 (0.0)	1 (0.6)	
Necrotizing fasciitis	1 (0.8)	2 (1.1)	
Burn	2 (1.6)	0 (0.0)	
Buerger's disease	0 (0.0)	1 (0.6)	
Wound problem after radiation therapy	2 (1.6)	2 (1.1)	
Diabetes mellitus foot	0 (0.0)	2 (1.1)	
Chronic osteomyelitis	1 (0.8)	0 (0.0)	
Compartment syndrome	1 (0.8)	0 (0.0)	
Others	2 (1.6)	1 (0.6)	
HBOT indication based on NHI			<0.001
Emergency treatment group A	59 (48.4)	122 (70.1)	
Chronic treatment group B and C	63 (51.6)	52 (29.9)	
Number of HBOT			0.135
1–5	89 (73.0)	142 (81.6)	
6–10	26 (21.3)	22 (12.6)	
>10	7 (5.7)	10 (5.8)	
Time from onset to treatment (hours)	84.96 (5.17–219.17)	7.01 (2.83–121.08)	0.001
<168 hours (7 days)	82 (67.2)	139 (79.9)	
>168 hours (7 days)	40 (32.8)	35 (20.1)	
GCS score (n=158)	15.00 (15.00–15.00)	15.00 (12.00–15.00)	0.005
Mental state (n=261)			0.002
Alert	90 (90.0)	119 (73.9)	
Altered mental status (verbal, pain, unresponsive)	10 (10.0)	42 (26.1)	
Past medical history (no/yes)			
Cardiac disease	114 (93.4)/8 (6.6)	159 (90.8)/16 (9.2)	0.413
Hypertension	92 (75.4)/30 (24.6)	130 (74.7)/44 (25.3)	0.892
Diabetes mellitus	97 (79.5)/25 (20.5)	147 (84.5)/27 (15.5)	0.268
Cerebrovascular disease	119 (97.5)/3 (2.5)	170 (97.7)/4 (2.3)	>0.999
Chronic pulmonary disease	118 (96.7)/4 (2.3)	172 (98.9)/2 (1.1)	0.234
Cancer	117 (95.9)/5 (4.1)	157 (90.2)/17 (9.8)	0.067
Chronic liver disease	119 (97.5)/3 (2.5)	169 (97.1)/5 (2.9)	>0.999
Chronic renal disease	115 (94.3)/7 (5.7)	169 (97.1)/5 (2.9)	0.219
Rhinitis	120 (98.4)/2 (1.6)	171 (98.3)/3 (1.7)	>0.999
Tinnitus	121 (99.2)/1 (0.8)	174 (100.0)/0 (0.0)	0.412
Hearing loss	120 (98.4)/2 (1.6)	173 (99.4)/1 (0.6)	0.571
ENT operation history	121 (99.2)/1 (0.8)	174 (100.0)/0 (0/0)	0.412
ENT radiation	122 (100.0)/1 (0.8)	172 (98.9)/2 (1.1)	0.514
ENT trauma	121 (99.2)/1 (0.8)	174 (100.0)/0 (0/0)	0.412
Psychiatric illness	110 (90.2)/12 (9.8)	149 (85.6)/25 (14.4)	0.246
Smoking history	97 (79.5)/25 (20.5)	127 (73.0)/47 (27.0)	0.198
Other underlying disease	93 (76.2)/29 (23.8)	125 (71.8)/49 (28.2)	0.399

Table 3. Comparison of Factors Related to MEB after Monoplace HBOT (continued)

	MEB (O'Neill grading scale)		
	Scale 0 (n=122)	Scale 1–2 (n=174)	*p* value
Compression rate of HBOT			0.006
2.2 FSW/min	61 (50.0)	59 (33.9)	
4 FSW/min	61 (50.0)	115 (66.1)	
HBOT common complication			<0.001
Middle ear pain	0 (0.0)	166 (95.4)	
Nasal sinus pain	0 (0.0)	2 (1.2)	
Ocular complication	1 (0.8)	0 (0.0)	
Claustrophobia	5 (4.1)	3 (1.7)	
No complication	116 (95.1)	3 (1.7)	

MEB, middle ear barotrauma; HBOT, hyperbaric oxygen therapy; CO, carbon monoxide; DNS, delayed neuropsychiatric sequelae; DCS, decompression sickness; AGE, arterial gas embolism; SSNHL, sudden sensorineural hearing loss; NHI, national health insurance; GCS, Glasgow Coma Scale; ENT, otorhinolaryngology; FSW, feet of seawater.

95% CI: 1.33–34.20) for MEB occurrence, underscoring the challenges of managing unstable patients in urgent settings where rapid pressurization may exacerbate middle ear pressure imbalances. The ET, connecting the ME to the pharynx, is vital for maintaining pressure equilibrium, especially under elevated pressures. Dysfunction or blockage of the ET represents a primary risk factor for MEB, as it impedes pressure equalization during the compression and decompression phases of HBOT.[9]

Moreover, altered mental status emerged as a significant predictor of MEB, with an OR of 2.50 (95% CI: 1.25–5.96). Patients with cognitive impairments or unconsciousness may struggle with voluntary pressure regulation techniques, such as the Valsalva maneuver, thus increasing their susceptibility to MEB. This finding highlights the need for specialized care protocols for patients with altered mental status, including enhanced monitoring and the potential use of adjunctive measures to mitigate the risk of MEB during HBOT.

This study also highlights the importance of early intervention. Our results showed that after the initial HBOT session, 60% of patients exhibited abnormal findings on video otoscopy. Other studies have also observed higher rates of MEB findings during the early stages of HBOT.[12] Interestingly, patients treated within 7 days of symptom onset had a higher incidence of MEB, suggesting that the acuteness of the condition might influence the likelihood of barotrauma. This is likely due to patients adjusting to the pressure changes and learning effective ear pressure equalization techniques at the onset of treatment. Patients usually adapt better to the pressure changes as treatment progresses and become more familiar with methods to regulate ear pressure, such as the Valsalva maneuver, potentially reducing MEB incidence as therapy advances.

Our analysis indicates that MEB incidence in a monoplace chamber is significant. For instance, a review of patient data from a level 1 trauma center reported an overall MEB incidence of 43.2%.[13] In our study, 58.8% of patients showed MEB abnormalities on video otoscopy, possibly due to the positional limitations in a monoplace chamber. Patients lie supine during treatment, which increases central venous pressure and leads to venous congestion, complicating ear pressure compensation. The increase in blood and middle ear oxygen partial pressures during HBOT can cause negative pressure in the middle ear and fluid transudation.[9,14] However, this situation reflects a decrease in the ET's ventilatory function, not merely the absorption of O_2 by the ME.[15–17] The vulnerability of ME chemoreceptor tissues to hyperoxia, akin to that observed in the carotid body, explains the failure of the pressure regulation mechanism in the ME.[18]

When the compression rate was 4.4 FSW/min, MEB occurrence nearly doubled compared to treatments at 2.2 FSW/min. Other studies have also shown that reducing pressurization rates can decrease MEB occurrences.[19] Rapid environmental pressure increases during compression, without active equalization, can overwhelm the pressure regulation capabilities of the ME.[20] Most MEB cases occur within the first 10 meters of compression, equivalent to 2.0 ATA in HBOT.[21] This finding suggests that more gradual pressurization may allow for better adaptation of the middle ear pressure regulation mechanisms, thereby reducing the risk of barotrauma. These results reinforce the need for carefully tailored compression protocols, particularly in vulnerable patient populations.

This study has several limitations. First, this study utilized a retrospective design, meaning that some data may be missing or inaccurately recorded. Second, this study was conducted at a single institution; therefore, caution must be exercised when generalizing the results. Multicenter studies involving various institutions may be necessary. Third, all patients were treated in a monoplace hyperbaric chamber, limiting the applicability of the study's results to multiplace chamber settings. Fourth, variables such as previous health conditions of patients or existing ear problems may not have been fully controlled in the study. Lastly, the research did not assess the long-term outcomes or complications related to MEB occurrences, highlighting the need for additional studies to understand the long-term im-

https://doi.org/10.3349/ymj.2024.0068

Table 4. Logistic Regression Analyses of Middle Ear Barotrauma Outcomes in HBOT Patients

Variables	Univariable		Multivariable	
	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Age	1.01 (1.00–1.03)	0.054	1.02 (1.00–1.03)	0.057
Sex				
Male	1 (Reference)			
Female	1.02 (0.62–1.68)	0.933		
HBOT indication based on NHI				
Chronic treatment group B and C	1 (Reference)	<0.001	1 (Reference)	0.021
Emergency treatment group A	2.51 (1.55–4.05)		6.75 (1.33–34.20)	
Time from onset to treatment (hours)	1.00 (1.00–1.00)	0.563		
<168 hours (7 days)	1 (Reference)		1 (Reference)	
>168 hours (7 days)	0.52 (0.30–0.88)	0.014	1.09 (0.51–2.35)	0.825
Mental state				
Alert	1 (Reference)		1 (Reference)	
Altered mental status (verbal, painful, unresponsive)	3.18 (1.51–6.67)	0.002	2.50 (1.13–5.51)	0.023
GCS score (n=158)	0.86 (0.74–1.00)	0.046		
Past medical history [No disease=1 (References)]				
Cardiac disease	1.44 (0.60–3.49)	0.415		
Hypertension	1.04 (0.61–1.77)	0.892		
Diabetes mellitus	0.71 (0.39–1.30)	0.270		
Cerebrovascular disease	0.93 (0.21–1.90)	0.929		
Chronic pulmonary disease	0.34 (0.06–0.48)	0.221		
Cancer	2.53 (0.91–7.07)	0.076	1.96 (0.63–6.13)	0.246
Chronic liver disease	1.17 (0.28–5.01)	0.829		
Chronic renal disease	0.49 (0.15–1.57)	0.228		
Rhinitis	1.05 (0.17–6.40)	0.956		
Tinnitus	-	-		
Hearing loss	0.35 (0.03–3.87)	0.389		
ENT operation history	-	-		
ENT radiation	-	-		
ENT trauma	-	-		
Psychiatric illness	1.54 (0.74–3.30)	0.248		
Smoking history	1.44 (0.83–2.49)	0.199		
Others	1.26 (0.74–2.14)	0.399		
Compression rate of HBOT				
2.2 FSW/min	1 (Reference)			
4 FSW/min	1.95 (1.21–3.13)	0.006	0.27 (0.06–1.32)	0.105

OR, odds ratio; CI, confidence interval; HBOT, hyperbaric oxygen therapy; NHI, national health insurance; GCS, Glasgow Coma Scale; ENT, otorhinolaryngology; FSW, feet of seawater.
The multiple logistic regression model included all variables with a *p*-value<0.1 in the univariable analyses, except for variables presumed to interact with other variables.

pact of MEB.

In conclusion, this study underscores the high incidence of MEB in patients undergoing HBOT, particularly among those with emergency indications and altered mental status. These findings suggest that individualized treatment protocols, including careful pre-evaluation, patient education, and adjusted pressurization rates, are crucial in minimizing the risk of MEB. However, further research is warranted to refine these strategies and to explore their applicability in diverse clinical settings.

ACKNOWLEDGEMENTS

This work was supported by a grant (20025162) of the Regional Customized Disaster-Safety R&D Program funded by the Ministry of the Interior and Safety (MOIS, Korea).

AUTHOR CONTRIBUTIONS

Conceptualization: Yoon Sung Lee and Sung Min Lee. Data curation: Yoon Sung Lee and Sang Won Ko. Formal analysis: Yoon Sung Lee.

Funding acquisition: Sung Min Lee. Investigation: Yoon Sung Lee and Sang Won Ko. Methodology: Kyung Hoon Sun and Sung Min Lee. Project administration: Sung Min Lee. Resources: Sung Min Lee and Hyoung Youn Lee. Software: Hyoung Youn Lee. Supervision: Tag Heo and Sung Min Lee. Validation: Kyung Hoon Sun and Sung Min Lee. Visualization: Yoon Sung Lee and Sung Min Lee. Writing—original draft: Yoon Sung Lee and Sung Min Lee. Writing—review & editing: Hyoung Youn Lee and Sung Min Lee. Approval of final manuscript: all authors

ORCID iDs

Yoon Seong Lee https://orcid.org/0009-0005-8965-8945
Sang Won Ko https://orcid.org/0000-0002-3128-040X
Hyoung Youn Lee https://orcid.org/0000-0002-3730-6754
Kyung Hoon Sun https://orcid.org/0000-0001-5473-9781
Tag Heo https://orcid.org/0000-0002-2333-2169
Sung Min Lee https://orcid.org/0000-0002-6310-3475

REFERENCES

1. Gill AL, Bell CN. Hyperbaric oxygen: its uses, mechanisms of action and outcomes. QJM 2004;97:385-95.
2. Fife CE, Buyukcakir C, Otto GH, Sheffield PJ, Warriner RA, Love TL, et al. The predictive value of transcutaneous oxygen tension measurement in diabetic lower extremity ulcers treated with hyperbaric oxygen therapy: a retrospective analysis of 1,144 patients. Wound Repair Regen 2002;10:198-207.
3. Rollins MD, Gibson JJ, Hunt TK, Hopf HW. Wound oxygen levels during hyperbaric oxygen treatment in healing wounds. Undersea Hyperb Med 2006;33:17-25.
4. Moon RE. Hyperbaric oxygen therapy indications. 14th ed. North Palm Beach (FL): Undersea and Hyperbaric Medical Society; 2019.
5. Jain KK. Indications, contraindications, and complications of HBO therapy. In: Jain KK, editor. Textbook of hyperbaric medicine. 4th revised and expanded edition. Cambridge (MA): Hogrefe & Huber Publishers; 2004. p.73-8.
6. Kindwall E. Contraindications and side effects to hyperbaric oxygen treatment. In: Kindwall EP, Whelan HT, editors. Hyperbaric medicine practice. 2nd ed (revised). Flagstaff (AZ): Best Publishing Company; 2002. p.83-97.
7. Clark J. Side effects and complications. In: Feldmeier JJ, editor. Hyperbaric oxygen 2003: indications and results: the Hyperbaric Oxygen Therapy Committee report. Kensington (MD): Undersea and Hyperbaric Medical Society; 2003. p.137-41.
8. Beard T, Watson B, Barry R, Stewart D, Warriner R. Analysis of adverse events occurring in patients undergoing adjunctive hyperbaric oxygen treatment: 2009-2010. Undersea Hyperb Med 2011; 38:455.
9. Lima MA, Farage L, Cury MC, Bahamad F Júnior. Update on middle ear barotrauma after hyperbaric oxygen therapy-insights on pathophysiology. Int Arch Otorhinolaryngol 2014;18:204-9.
10. O'Neill OJ, Weitzner ED. The O'Neill grading system for evaluation of the tympanic membrane: a practical approach for clinical hyperbaric patients. Undersea Hyperb Med 2015;42:265-71.
11. Ministry of Health and Welfare. Partial revision of the details on the criteria and methods for health insurance benefits–criteria for coverage of hyperbaric oxygen therapy (Notice No. 2018-254). Sejong: Ministry of Health and Welfare; 2019.
12. 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;87:684-8.
13. Heyboer M 3rd, Wojcik SM, Grant WD, Chambers P, Jennings S, Adcock P. Middle ear barotrauma in hyperbaric oxygen therapy. Undersea Hyperb Med 2014;41:393-7.
14. Shupak A, Attias J, Aviv J, Melamed Y. Oxygen diving-induced middle ear under-aeration. Acta Otolaryngol 1995;115:422-6.
15. Shupak A, Tabari R, Swarts JD, Bluestone CD, Doyle WJ. Effects of middle ear oxygen and carbon dioxide tensions on eustachian tube ventilatory function. Laryngoscope 1996;106(2 Pt 1):221-4.
16. Shupak A, Tabari R, Swarts JD, Bluestone CD, Doyle WJ. Effects of systemic hyperoxia on eustachian tube ventilatory function. Laryngoscope 1997;107:1409-13.
17. Buckingham RA, Stuart DR, Geick MR, Girgis SJ, McGee TJ. Experimental evidence against middle ear oxygen absorption. Laryngoscope 1985;95:437-42.
18. Eden AR, Gannon PJ. Neural control of middle ear aeration. Arch Otolaryngol Head Neck Surg 1987;113:133-7.
19. 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;120:446-9.
20. Neuman TS, Thom SR. Physiology and medicine of hyperbaric oxygen therapy. 1st ed. Philadelphia (PA): Elsevier; 2008.
21. Uzun C, Adali MK, Tas A, Koten M, Karasalihoglu AR, Devren M. Use of the nine-step inflation/deflation test as a predictor of middle ear barotrauma in sports scuba divers. Br J Audiol 2000;34:153-63.