

Predictors of middle ear barotrauma associated with hyperbaric oxygen therapy

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Key words

Ear barotrauma, ENT, morbidity, hyperbaric research

Abstract

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Introduction: Middle ear barotrauma (MEBT) is a relatively common complication of hyperbaric oxygen therapy (HBO₂). Many factors have been reported to increase the risk of this complication. This study investigates risk factors for MEBT associated with the initiation of HBO₂.

Methods: Patients scheduled for elective HBO₂ were recruited over a 12-month period. Possible risk factors for MEBT on history and examination were recorded prior to the initial HBO₂. During or immediately after this initial treatment, the presence of ear symptoms or new otoscopic tympanic membrane (TM) changes were determined as evidence of MEBT.

Results: Sixty subjects contributed data during the study period. The initial HBO₂ session was associated with mild MEBT in 43% of patients and in 32% of ears. There were no cases of free blood in the middle ear or perforated TM. MEBT was positively correlated with an immobile TM on otoscopy during the Valsalva manoeuvre. Multivariate logistic regression suggests the risk of MEBT can be predicted from the results of TM otoscopy during Valsalva manoeuvre and tympanograms before and after Valsalva (dynamic tympanogram).

Conclusions: MEBT is common in patients starting HBO₂. Patients can be stratified into low-, intermediate- and high-risk groups on the basis of the combined information from otoscopic visualisation of the mobility of the TM during Valsalva and dynamic tympanograms.

Introduction

The use of hyperbaric oxygen therapy (HBO₂) for diving-related conditions and various medical conditions has been increasing in Australia in recent years.¹ During the period 1 July 2001 to 30 June 2002, more than 23,000 HBO₂ treatments were administered to 1,349 patients in Australia.² The use of HBO₂ is generally safe and serious side effects are rare. However, HBO₂ is not without risks, and middle ear barotrauma (MEBT), also referred to as 'middle ear squeeze' or 'barotitis media', is by far the most common complication at the initiation of a course of treatments.³ The reported incidence of MEBT ranges from 2% in a military setting to 94% in a group of intubated patients.^{4,5} The incidence of MEBT in non-intubated medical patients ranges from 10% to 82%.^{6,7} We would, therefore, predict that between 130 and 1,100 patients suffer from this complication every year in Australia.

The considerable range in the reported incidence of MEBT is probably due in part to the wide manifestations of this complication and the failure to establish a standard clinical definition as to what constitutes MEBT. In mild cases, 'fullness only' may be reported, while otalgia is reported in moderate cases. Severe ear pain associated with tympanic membrane (TM) rupture occurs in the worst cases. Other symptoms include tinnitus, vertigo and conductive hearing loss.^{8,9} The severity of MEBT is assessable by otoscopy. In a previous study, we found that the most useful method for evaluating MEBT was if otoscopy was performed before

and after the first HBO₂. If this was not done, interpretation of any otoscopic findings after subsequent compressions was confusing as the timing of the changes could not be determined.¹⁰ In our experience, the majority of patients who have problems equalising will suffer from MEBT during the first HBO₂.

Many actual and potential risk factors for MEBT have been discussed previously. Analysis of case series data supports the following risk factors: the presence of an artificial airway (tracheostomy or endotracheal tube); the patient having a reduced level of consciousness; abnormal Eustachian tube (ET) function on history or testing; head and neck radionecrosis; nasal and paranasal disease; age over 55 years; and female sex (Table 1).^{5,7,11-14} Yet more putative risk factors are supported only by expert opinion, and include a previous history of middle ear surgery, ear infections or smoking.⁹

A number of investigations have been suggested as useful in the prediction of MEBT, but none appears to have been tested in the context of compression and HBO₂. Such investigations are largely aimed at assessment of middle ear pathology and ET function and include tympanometry, sonotubometry, tubo-tympano-aerodynamography, laser-doppler-vibrometry and ventilation capacity testing.^{3,15} Of these, tympanometry using a hand-held instrument is the simplest method. The instrument can be operated by staff with minimal training and has the capacity to produce reliable tympanograms.^{16,17}

TABLE 1
Risk factors for middle ear barotrauma during hyperbaric oxygen therapy

Artificial airway (endotracheal tube or tracheostomy)
Abnormal Eustachian tube function
Head and neck radionecrosis
Nasal and paranasal disease
Impaired consciousness
Age over 55 years
Female gender

Possible factors

History of middle ear surgery
History of ear infections
Smoking

In this study, we prospectively assessed multiple risk factors for the development of MEBT. We hypothesised that MEBT could be accurately predicted by the presence or absence of a small subset of possible historical or investigational factors previously considered.

Methods

The study was undertaken over a 12-month period following approval of the appropriate research and ethics committee. Adult patients presenting for elective HBO₂ were eligible for the study. Those patients who were unconscious, had existing TM rupture or middle ear ventilation tubes in situ, and those in whom the TM could not be visualised were excluded from the study.

Study participants were first assessed for risk factors for MEBT based on past medical history. The assessment was by questionnaire developed specifically for this study and included all potential risk factors identified following review of the existing literature and expert opinion. Following completion of the questionnaire, subjects were examined and otoscopy performed. To exclude evidence of pre-existing barotrauma, all subjects' TMs were graded for the presence of barotrauma according to the scheme of Edmonds et al, a modification of the Teed score (Table 2).^{8,18}

Following clinical examination, the subjects were instructed how to perform effective middle ear equalisation techniques by experienced hyperbaric attendant staff. Once the ability to perform the manoeuvre was demonstrated, the mobility or otherwise of the TMs during the Valsalva manoeuvre was observed by otoscopy and recorded. Subjects were assessed as able to successfully ventilate the middle ear if the TM was seen to 'bulge' toward the observer during a Valsalva manoeuvre, and this finding was assumed to indicate a patent, functional ET.¹⁹ This test result was then recorded as 'Mobile TM' if the TM was seen to be bulging and 'Immobile TM' if the TM did not move.

TABLE 2
The Edmonds classification of MEBT⁸

Grade 0: Symptoms without physical signs
Grade 1: Injection of the tympanic membrane (TM), especially along the handle of the malleus
Grade 2: Grade 1 plus slight haemorrhage within the substance of the TM
Grade 3: Gross haemorrhage within the substance of the TM
Grade 4: Free blood in the middle ear, as evidenced by blueness and bulging
Grade 5: Perforation of the TM

The subjects then underwent further assessment using a series of three tympanogram recordings for both ears using the Welch Allyn Microtympanometer (Welch Allyn, Inc., Skaneateles Falls, New York, USA). Tympanometry assesses TM, middle ear and ET function by interpretation of TM impedance to sound over a range of external auditory canal pressures. All tympanograms were classified as 'normal' if the maximal impedance was between -99 and +200 decapascals (daPa) and the static admittance less than 1.5 millimho (1 millimho = 10⁻⁸ m³.Pa⁻¹.s⁻¹), an A-type tympanogram according to Jerger's system.²⁰ All other tympanograms were classified as 'abnormal'.

The first tympanogram was performed before any attempt to actively ventilate the middle ear ('Static Tympanogram' Test). The subjects were then asked to perform a Valsalva manoeuvre and requested not to talk or swallow until a second tympanogram was completed on both ears. Subjects were then asked to swallow three times and a third tympanogram performed. The presence of normal ET function and correct performance of the manoeuvre were recorded if the peak pressure became more positive following the Valsalva manoeuvre and returned to baseline after swallowing. The result of this series of tympanograms was then recorded ('Dynamic Tympanogram' Test).²¹

Following this series of investigations, the subjects underwent their first HBO₂ session in a multiplace chamber supervised by a hyperbaric nurse attendant. The treatment consisted of pressurisation on air to 242 kPa (2.4 Ata) over 10 minutes followed by inhalation of 100% oxygen at 242 kPa for 90 minutes. The treatment was completed by slow decompression on oxygen over 10 minutes. The compression phase could be extended if patients complained of equalisation problems. Both the nurse attendant and supervising medical team attempted corrective strategies if any such difficulties were experienced.

Patients complaining of continuing difficulties were deemed 'unable to equalise' and were removed from the chamber after decompression to atmospheric pressure. Any symptoms referable to MEBT were recorded after specific questioning by a study investigator and included fullness in the ears,

pain, vertigo, dizziness and subjective hearing problems. A final otoscopy was performed and any barotrauma recorded using the same classification system used prior to compression. If changes of mild erythema (grade 1) were present on TM examination before HBO₂, the ear was subsequently classified only as a MEBT if there was an increase in the TM score. Finally, we recorded the successful completion or otherwise of the initial HBO₂ session.

STATISTICAL ANALYSIS

Subjects were enrolled prospectively in an opportunistic way and no power calculations were made prior to commencement of enrolment. Results were recorded and analysed both as the number of individuals affected by MEBT, and the number of ears so affected. Fisher’s exact test was employed for univariate analysis, with chi-square test for trend when using data from both ears. Factors were included in a logistic regression if univariate analysis suggested a significant association (p <= 0.1), or previous publications suggested a significant association.

Beginning with all those factors included, we employed a backwards, stepwise elimination method to determine the most useful predictive model for MEBT. Using this method, the factor contributing least to the predictive value of the model is eliminated at each stage until such a removal significantly reduces that predictive value. Any differences between groups or association of risk factor with barotrauma

were considered statistically significant when the p-value was less than or equal to 0.05.

The performance of the tests for TM and ET function (examination for TM mobility and both static and dynamic tympanometry) were examined using sensitivity and specificity for the occurrence of barotrauma, along with positive predictive values (PPV) and likelihood ratios (LR). In the context of the present study, PPV is the probability that an individual who tests positive will experience MEBT, while the LR (+ve test) estimates how much the odds of an individual with a positive test have increased from baseline risk in the study group. All calculations were made using statistical software from StatsDirect, StatsDirect Ltd., version 2.2.3, 2002.

Results

Seventy eight subjects were enrolled in the study. Eighteen were excluded due to data loss through error or inability to perform all tympanograms required for meaningful analysis. Therefore, data from 60 subjects (120 ears) were available for analysis. One of the 60 did not complete the initial HBO₂ due to problems equalising and sustained grade 1 MEBT.

The subjects were aged from 22 to 92 years (mean 59). There were 41 males and 29 females. Six had never flown and none of the remaining 54 subjects reported problems equalising their ears during the descent of an aeroplane.

TABLE 3
Univariate analysis of potential risk factors for middle ear barotrauma (MEBT)

	MEBT	No MEBT	Odds ratio	95% confidence intervals	p-value
CLINICAL RISK FACTORS					
Age >55 years	18	19	1.78	0.54 - 6.06	0.42
Female gender	10	8	2.03	0.58 - 7.25	0.26
Scuba diver	0	4	0	0 - 1.93	0.13
Head and neck surgery	10	15	0.79	0.24 - 2.52	0.79
Head and neck radiation	11	10	1.76	0.53 - 5.88	0.41
Past middle ear infection	3	2	2.09	0.22 - 26.5	0.64
Middle/inner ear surgery	5	0	infinity	1.31 - infinity	0.01
Smoker	5	6	1.11	0.23 - 5.04	> 0.99
Upper respiratory tract infection in last month	8	10	1.07	0.30 - 3.72	> 0.99
TESTS					
At least one side abnormal:					
Tympanic Membrane (TM) Mobility	12	9	2.38	0.71 - 8.11	0.17
‘Static’ Tympanometry	5	3	2.46	0.42 - 17.3	0.28
‘Dynamic’ Tympanometry	23	24	3.19	0.69 - 20.0	0.12
Both sides abnormal:					
TM Mobility	6	2	4.8	0.74 - 51.8	0.07
‘Static’ Tympanometry	3	0	infinity	0.56 - infinity	0.08
‘Dynamic’ Tympanometry	12	11	1.79	0.55 - 5.85	0.30
PATIENTS	26	34			

This potential risk factor was therefore not analysed further. Three patients had received HBO₂ on a previous occasion and one of these reported ear problems at that time; however, none of these three experienced MEBT during this study.

Twenty six subjects (43%) had MEBT after the first HBO₂ in a total of 38 of 120 ears (32%). Seven subjects sustained grade 0 MEBT, 14 had grade 1 MEBT, three had grade 2 MEBT, and two had grade 3 MEBT. In terms of single ears, 13 had grade 0 MEBT, 18 ears had grade 1, three had grade 2, and four ears had grade 3 barotrauma. No ear had evidence of grade 4 or 5 barotrauma. The presence or absence of potential risk factors is summarised in Table 3, including the results of the univariate analysis.

UNIVARIATE RISK FACTOR ANALYSIS

The results of the univariate analysis are summarised in Table 3. None of the divers sustained MEBT, while 26 of 56 (46%) 'non-divers' did so. All subjects with a history of ear surgery developed MEBT resulting in the odds ratio reaching infinity. This was the only statistically significant historical risk factor for MEBT on the univariate analysis.

Details of the characteristics of the three tests used (TM Mobility, 'Static Tymp' Test and 'Dynamic Tymp' Test) taken in isolation are given in Table 4. Figure 1 illustrates the probability for MEBT as the number of abnormal tests

TABLE 4
Comparison of Immobile Tympanic Membranes (TMs), 'Static Tymp' and 'Dynamic Tymp' tests as single predictors of middle ear barotrauma

Predictor	Immobile TMs (one or both)	Static Tymp (any side abnormal)	Dynamic Tymp
+ve predictive value*	0.57	0.63	0.49
-ve predictive value*	0.64	0.60	0.77
Sensitivity	0.46	0.19	0.89
Specificity	0.73	0.91	0.29
Likelihood ratio# (+ve test)	1.70	2.18	1.25
Likelihood ratio# (-ve test)	0.73	0.89	0.39

* Proportion of abnormal tests associated with barotrauma (+ve) and of normal tests associated with absence of barotrauma (-ve).

The increase in the odds of barotrauma if the test is abnormal (+ve test), or decrease in the odds of barotrauma if the test is normal (-ve test).

per patient increases. Each of the three tests is analysed separately for trend across the possible values of no abnormal ear (score 0), unilateral abnormal ear (score 1) or bilateral abnormal ears (score 2). On this analysis, only immobile TM on otoscopy is associated with a significant trend to increasing prediction of MEBT with increasing score (chi-square test for linear trend 3.88, DF = 1, p = 0.049).

MULTIVARIATE ANALYSIS

Logistic regression was employed to investigate the predictive power for MEBT of several factors in combination. The risk factors 'diver' and 'ear surgery' were excluded from the regression as these have an odds ratio of zero and infinity respectively (no divers got MEBT and all subjects with a history of ear surgery got MEBT). Hence neither would contribute in a meaningful way to a multivariate model.

Beginning with a model including the factors age over 55, gender, head and neck radiation, and the results of TM Mobility, 'Static Tymp' Test and 'Dynamic Tymp' Test, we used an elimination stepwise method for determination of the best predictive model for MEBT. The best model (chi-square test for predicted likelihood ratio 7.15, DF = 2, p = 0.03), included the results of the dynamic tympanometry (normal or either ear abnormal) and the presence or absence of immobile TMs (normal or either ear abnormal) according to the equation:

$$\ln [P/1 - P] = -2.0 + 1.6 \times \text{Dynamic Tymp} + 1.2 \times \text{Immobile TMs}$$

where P is the proportional response predicted by the model, that is, if the predicted proportion of subjects with MEBT is b out of n subjects, then P = b/n.

Solving this equation for the different combination of results for the 'Dynamic Tymp' Test and TM Immobility gives the probability of an individual subject experiencing MEBT as shown in Table 5. From this table it can be seen that if the 'Dynamic Tymp' Test is normal and both TMs are mobile, the calculated probability of MEBT from the first HBO₂ is 12%; while if both predictors are abnormal, the risk of MEBT rises to 70%.

Discussion

We describe an analysis of potentially predictive factors for MEBT. Based on a review of the literature, we chose to include only clinical factors and three bedside tests designed to assess TM and ET function. All three are simple, non-invasive and easy to perform in the clinical setting. In our small sample, only three potential risk factors were sufficiently associated with MEBT on univariate analysis to be included in the initial multivariate model (history of middle ear surgery, TM Mobility Test and 'Static Tymp' Test). Of these, ear surgery was an 'all or none' predictor and could not meaningfully be included in a logistic

TABLE 5

The calculated probability of middle ear barotrauma (MEBT) from the initial hyperbaric oxygen treatment using different combinations of the results from two tests, ‘Dynamic Tymp’ and TM Mobility (see text for explanation; TM - tympanic membrane)

Dynamic Tymp	TM Mobility	Probability of MEBT
Normal	yes	0.12
Normal	no	0.32
Abnormal	yes	0.40
Abnormal	no	0.70

regression model. Based on our assessment of the literature, we also chose to include age, gender, previous head and neck irradiation and ‘Dynamic Tymp’ Test in our initial model. All of these factors have been previously identified in prospective studies as significantly associated with MEBT.^{6,7,12}

We examined subjects only in relation to their first HBO₂ session for two reasons. First, we wanted to avoid potential confusion over the significance of tests for the individual treatment under study. For any compression following the first, subjects were likely to enter the chamber with pre-existing TM abnormalities making interpretation of post-treatment tests problematic.²² This is particularly likely

following extended oxygen breathing at pressure.¹⁹ Second, it is our clinical experience that most barotrauma occurs during the first compression.

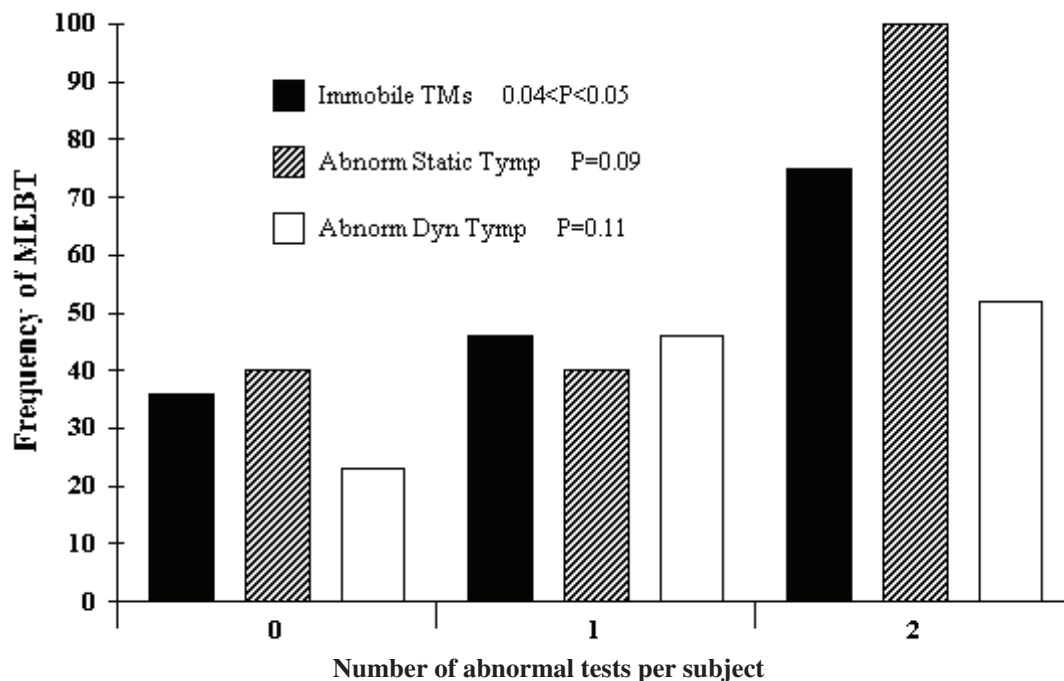
The current study found an overall MEBT incidence of 43% of patients and in 32% of ears with the first HBO₂. None of the patients sustained the most serious grades, 4 and 5, of MEBT in this series, probably attesting to good practice and supervision by the inside attendant. The incidence in this series lies between other reported figures ranging from 10% (retrospective review) to 82% in Fernau’s prospective study of 33 patients over 20 treatment sessions.^{6,7}

The incidence of MEBT in any study will probably depend on vigilance in looking for this complication, the patient population and compression practice. The relatively high incidence in this study is probably a consequence of actively seeking symptoms and signs of MEBT. In our study group none of the patients who were classified as divers suffered MEBT. Intuitively, this is not an unexpected finding as this patient group is expected to be proficient at equalising middle ear pressure. In contrast, all five patients with a history of middle ear or inner ear surgery sustained MEBT with the first HBO₂. This was the only statistically significant historical risk factor. We are unaware of any other studies demonstrating ear surgery to be a predictor of MEBT, but such a finding makes pathophysiological sense.

MEBT is caused by the expansion and contraction of small volumes of air within the middle ear in accordance with Boyle’s law. With reductions in ambient pressure during the ‘ascent’ phase of HBO₂ the gas in the middle ear will

FIGURE 1

Frequency of middle ear barotrauma (MEBT) when none (0), one (1) or both (2) ears tested abnormal for each of three clinical tests (Tympanic Membrane (TM) Mobility, ‘Static Tymp’ and ‘Dynamic Tymp’)



expand. This expanding gas generates a relatively positive middle ear pressure and opens the ET passively to equalise ambient and middle ear pressures. During compression, however, the ET is usually only capable of opening for equalisation with active manoeuvres.²³ Muscle contraction by swallowing, yawning or by the Valsalva manoeuvre is usually successful in opening the tubal lumen via the actions of the tensor and levator muscles of the palate.

These manoeuvres become increasingly difficult if the pressure gradient is allowed to increase as the ambient pressure is elevated. When the gradient reaches 80–90 mmHg (0.11–0.12 atm abs) the cartilaginous portion of the ET collapses and further attempts to equalise are futile.²⁴ The failure to equalise the pressure in the middle ear before this ‘point of no return’ during compression may be caused by poor function of the ET as a result of congenital, anatomic or pathophysiological factors or by poor technique.

Poor ET function with subsequent MEBT can be overcome by ventilation of the middle ear through the TM by the insertion of temporary tympanostomy tubes or formal grommets. However, as this is an active intervention not entirely without risks, it is desirable to identify the patients at higher risk of MEBT before deciding on this procedure. For example, several studies have demonstrated a very high risk of MEBT in unconscious patients.^{5,11} We believe this risk warrants the routine insertion of ventilation tubes before HBO₂ in these patients.

In awake patients, most cases of MEBT are relatively benign and even a TM rupture is likely to heal spontaneously with little morbidity expected. However, the animal and human diving literature does describe serious middle and inner ear damage from barotrauma, including oval/round window rupture, perilymph fistula and hearing loss. Inner ear damage, although rare, could be catastrophic, with potential for lifelong hearing damage.^{3,11}

Assessing ET function accurately at the bedside is not an easy task. Several previous authors have discussed the problems. Beuerlein employed visualisation of the TM during the Valsalva manoeuvre to classify the patient as an ‘autoinflator’ or ‘noninflator’ as a means of predicting MEBT.¹¹ We used the ‘Static Tymp’ Test in a previous study¹⁰ and found that all patients with an abnormal test developed MEBT. However, if the test was normal, the result was unhelpful in predicting MEBT. The current series found a 63% positive predictive value (abnormal ‘Static Tymp’ Test) but confirmed the poor sensitivity of this test. Both this and our previous study of the ‘Static Tymp’ Test show a poor sensitivity. Static tympanometry may be better suited to detect middle ear effusions.³

Dynamic ET function testing can be done in several ways. The best known is the 9-step inflation/deflation test described by Bluestone and used in the previously mentioned study by Fernau where patients were categorised

as ‘autoinflators’ or ‘noninflators’.⁷ Fernau found that this test was best at predicting subjects at increased risk of MEBT if it was performed after the first HBO₂. Our ‘Dynamic Tymp’ Test is a similar, but simpler, version of the same test using the Welch Allyn Microtymp instrument. In our study, this test (‘Dynamic Tymp’, one or both sides abnormal) has a high sensitivity (0.89) but a low specificity (0.29) for MEBT.

From our regression analysis, we introduce a novel concept of combining two tests (TM Mobility and ‘Dynamic Tymp’) to stratify patients for risk of MEBT. Because of the complementary combination of a low-sensitivity, high-specificity test (TM Mobility) and a high-sensitivity, low-specificity test (‘Dynamic Tymp’), risk of MEBT at the first HBO₂ can be stratified into low (12%), intermediate (32–40%) and high (70%) groups.

With identification of patients at increased risk of all grades of MEBT, it may be possible to decrease patient and middle ear morbidity by intensifying patient education, maximising equalisation practice and advocating selective insertion of tympanostomy tubes. It may also prevent the rare case of serious inner ear damage. A decrease in ear morbidity will also result in fewer delays and cancellations of treatments and may also decrease the compression times for multiplace treatment sessions.

Conclusions

We propose that the combination of two simple, clinical tests can stratify patients into three risk categories for MEBT. This stratification may be useful in directing educational efforts and identifying patients at increased risk of MEBT during the first HBO₂. Further studies are required to validate this concept.

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