A prospective analysis of independent patient risk factors for middle ear barotrauma in a multiplace hyperbaric chamber

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Abstract

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Introduction: Middle ear barotrauma (MEBT) is the most common complication of hyperbaric oxygen therapy (HBOT). We wished to determine whether independent risk factors could predict which patients will require tympanostomy tubes in order to continue HBOT.

Methods: Data regarding demographics, medical history and physical examination were collected prospectively over one year. Multivariate logistic regression was used to analyse the data.

Results: One hundred and six patients were included. The cumulative risk of MEBT over the first five treatments was 35.8% and that for needing tympanostomy tubes was 10.3%, while that for needing tubes at any time was 13.2%. Risk factors for MEBT on bivariate analysis were older age, history of ENT radiation and anticoagulant use. Risk factors for requiring tympanostomy tubes included a history of cardiovascular disease and patients being treated for an infective condition. The adjusted multivariate logistic model identified history of difficulty equalising as the only characteristic significantly associated with MEBT during the first five treatments, adjusted odds ratio (AOR) (95%CI): 11.0 (1.1 – 111.7). Being female, AOR (95%CI): 24.7 (1.8 – 339.7), and having a history of cardiovascular disease, AOR (95%CI): 20.7 (2.0 – 215.3), were significantly associated with the need for tympanostomy tubes during the first five HBOT, but there was no significant association between any other characteristics and the need for tubes at any point.

Conclusion: Despite some significant risk factors for MEBT being identified, we were unable to predict accurately enough which patients needed tympanostomy tubes during their HBOT to recommend these being placed prophylactically in selected patients.

Key words

Ear barotrauma, hyperbaric oxygen therapy, risk factors, hyperbaric research, morbidity

Introduction

The most common and easily identifiable complication of hyperbaric oxygen therapy (HBOT) is middle ear barotrauma (MEBT).[1] MEBT occurs when there is a change in the ambient atmospheric pressure accompanied by an inability to equalise the pressure in the middle ear with the new atmospheric pressure. This process of equalisation occurs by the active opening of the Eustachian tube linking the nasopharynx to the middle ear, allowing the passage of air and therefore equalisation of pressure. It is abnormalities of anatomy and function along the Eustachian tube and poor equalization technique that lead to MEBT.

Pain is the primary symptom of MEBT. Complications of MEBT include otalgia, haemorrhage into or rupture of the tympanic membrane (TM), ossicular chain disruption and potentially conductive and/or sensorineural hearing deficit. More serious complications occur rarely.[2,3]

Previous studies have reported incidences of HBOT-related MEBT ranging from 8% up to 94% in specific populations.[4–14] This inconsistency in the reported rate of MEBT is thought to be multi-factorial and may include differing inter-observer experience and interpretation of grading and the use of different grading scales between centres.[15] Reported risk factors for HBOT-related MEBT include age over 61 years or less than 40 years, female gender, prior evidence of Eustachian tube dysfunction, patients with artificial airways and patients undergoing HBOT for delayed radiation injury of the nasopharynx.[5,8–12,16]

The Hyperbaric Medicine Unit (HMU) at the Townsville Hospital (TTH) receives referrals from throughout North Queensland, covering a population of greater than 650,000 people over an area of more than 600,000 km^2. Approximately 200 patients, with a wide variety of conditions, are referred each year. On average, each patient receives 30 daily treatments of HBOT. The current practice at TTH at the time of this study was that patients who were unable to successfully equalise pressure in the middle ear had placement of tympanostomy tubes performed under a general anaesthetic. Although a prioritized procedure, the process of referral for tympanostomy tubes to the Ear, Nose and Throat (ENT) Clinic and then awaiting access to theatre time can sometimes take several weeks or even months.

The aim of this prospective study was to determine whether a number of independent risk factors could predict which patients would require tympanostomy tubes. If possible, this would allow for prophylactic tube insertion, and could significantly reduce interruption and delay to HBOT and inconvenience to patients.

Methods

Approval for the study was granted by The Townsville Health Service District Human Research Ethics Committee. Every patient who received HBOT at TTH between 01 June 2009 and 31 May 2010 was enrolled into the study. The exclusion criteria were: age < 18 yrs; non-English speaking (or no interpreter available); and patients who already had tympanostomy tubes.

Demographic data were collected prospectively from the documented past medical history and physical examination findings recorded by the admitting medical officer for all patients prior to commencing HBOT. These data included: age; gender; condition requiring HBOT; use of analgesics; a history of diabetes, cardiovascular or respiratory disease; psychiatric illness; other significant illness; smoking history; history of facial/ENT surgery; history of facial/ENT radiation; previous equalisation problems; previous scuba diving experience and previous HBOT problems.

Otoscopic examination of the TM was performed prior to commencing HBOT, following each of the first five treatments and as required after that. The Valsalva manoeuvre was described to all patients prior to commencing treatments and otoscopic examination was performed whilst the patient attempted to Valsalva to determine whether TM movement was visible or not. Dynamic assessment of TMs was not performed as it was not part of the standard pre-HBOT assessment at TTH at the time of the study.

TTH uses a triple-lock hyperbaric chamber (Fink Engineering Pty Ltd, Warana, Queensland, Australia) pressurised with compressed air. The majority of patients were compressed to 243 kPa at a rate of 14 kPa min^{-1}. Treatment at this pressure runs for 80 minutes with patients breathing 100% oxygen via a closed-circuit head hood. Two 5-minute air breaks occur during the treatment, and decompression occurs at a rate of 9.5 kPa min^{-1}. Other treatment tables used (e.g., for divers with decompression illness) included RN62 and Comex 30.

During treatments, patients were asked to report any symptoms of MEBT, and additional otoscopic examinations were performed during pressurisation by the inside chamber attendant, as indicated. If symptoms or signs of MEBT were found during pressurisation, they were managed as per current practice, including slowing the rate of compression, a trial of topical decongestants or cessation of treatment. MEBT was graded on a scale of 0 to 5 using the Edmonds classification (Table 1), which is interchangeable with the modified Teed scale, and is standard in most hyperbaric units in Australasia.[17,18]

The primary analysis was multivariate logistic regression, with barotrauma (yes/no) as the dependent variable and the demographic characteristics, history and physical findings as independent variables. Secondary endpoints included the need for tympanostomy tube placement at any point during the first five HBOT sessions, and the need for tube placement at any point during therapy.

Table 1
The Edmonds scale for middle ear barotrauma

Grade	Criteria
0	Symptoms with no signs
1	Injection of the tympanic membrane (TM)
2	Injection of the TM plus slight haemorrhage within the substance of the TM
3	Gross haemorrhage within the TM
4	Free blood in the middle ear, as evidenced by blueness and bulging
5	Perforation of the TM

Results

During the study period, 108 adult patients underwent HBOT at TTH; after excluding two subjects who already had tympanostomy tubes in place, 106 subjects were included in our analysis. The subjects were mostly males (67%), with a median (range) age of 62.0 (18–86) years. The incidence of MEBT after the first treatment was 22.6%, with a cumulative risk of 35.8% over the first five treatments, and 43.4% at any point during treatment.

The cumulative risk of needing tympanostomy tubes during the first five HBOT treatments was 10.3%. The cumulative risk of needing tubes at any time during the HBOT treatment regimen was 13.2%. Table 2 shows the demographic characteristics and indications for HBOT of subjects with and without MEBT, as well as those requiring tube placement within the first five treatments or at any time during their treatment.

On bivariate analysis, there was a positive association of developing MEBT with advancing age, history of ENT radiation therapy and anticoagulant use. Bubble-related indications, documented TM movement with Valsalva and scuba experience appeared protective against MEBT. Patients with a history of cardiovascular or psychiatric disease, patients with a tracheostomy tube in place and patients being treated for an infective condition were more likely than others to require tube placement at some point during their treatment.

In the unadjusted model, having a bubble-related indication was associated with a decreased risk of MEBT during the first five treatments (odds ratio (OR) = 0.07). However, after controlling for confounding effects of other variables, this association was negated, (Adjusted odds ratio (AOR) (95% confidence intervals, CI): 0.13 (0.01–2.7); and difficulty with equalising ears was the only patient characteristic significantly associated with MEBT during the first five

Table 2
Association between patient demographics, indication for HBOT and middle ear barotrauma (MEBT); numbers of patients (%) experiencing MEBT or requiring tympanostomy tubes

	All subjects Day 1–5	No MEBT	MEBT		Tympanostomy tubes
			Rx 1–5	At any time	
	(*n* = 106)	(*n* = 68)	(*n* = 38)	(*n* = 10)	(*n* = 14)
Characteristic					
Mean age	57.2	53.0	64.5	62.4	62.6
95% CI	53.8–60.7	48.4–57.5	59.6–69.4	52.7–72.2	55.3–70.0
Male	71 (67.0)	47	24	5	7
Female	35 (33.0)	21	14	5	7
Indication for HBOT (some patients have multiple indications)					
Bubble injury	20 (18.9)	19	1	0	0
Infective condition	10 (9.4)	5	5	3	4
Radiation tissue damage	48 (45.3)	26	22	5	8
Wound problem	21 (19.8)	14	7	2	2
Other	7 (6.6)	4	3	0	0

Table 3
Multivariate logistic regression models for patients having HBOT who experienced middle ear barotrauma (MEBT) and those requiring tympanostomy tubes (within the first five treatments or at any time); only variables that reached or approached statistical significance are shown

Dependent variable	Independent variables	Odds ratio	95% CI odds ratio		*P*–value
			Lower	Upper	
MEBT	Difficulty equalising	11.0	1.1	111.7	0.042
Tympanostomy tube (Rx 1–5)					
	Female	24.7	1.8	339.7	0.016
	Cardiac history	20.7	2.0	215.3	0.011
	Documented TM movement	0.1	0.01	1.1	0.063
	Difficulty equalising	21.9	0.7	724.1	0.084
Tympanostomy tube (at any point)					
	Infectious indication	6.7	0.97	45.6	0.053

treatments, AOR (95% CI): 11.0 (1.1–111.7). Although intuitive, this finding should be viewed with some caution given the small number of patients who had difficulty with equalisation (*n* = 9). Table 3 shows the results of the multivariate logistic regression modelling.

Being female (OR = 9.9), a history of cardiovascular disease (OR = 25.2) and a documented immobile TM (OR = 0.07) were associated with the tube placement during the first five treatments in the unadjusted model. After adjusting for confounding variables, only being female, AOR (95%CI): 24.7 (1.8–339.7) and having a history of cardiovascular disease, AOR (95%CI): 20.7 (2.0–215.3) remained significantly associated with the need for tympanostomy tube placement during the first five treatments. There was no interaction effect between these two variables.

Only an infection-related indication was associated with the need for tube placement at any time during the course of treatment in the unadjusted model (OR = 5.7); however, after adjusting for confounding variables, this association was no longer significant, AOR (95%CI): 6.7 (0.97–45.6).

Discussion

The prevention and management of MEBT during HBOT includes education regarding equalisation techniques, slowing of pressurisation, avoidance of further HBOT until symptoms have resolved and, although the supporting evidence is limited, the use of systemic or topical decongestants.[19,20] The insertion of temporary tympanostomy tubes to create an artificial passage for equalisation to occur is a more invasive management option. This treatment has a number of risks, including otorrhoea, otalgia, infection, decreased hearing, persistent TM perforations and tinnitus.[3] Whilst MEBT rarely results in the cessation of HBOT, anecdotal reports from our region are that all of these management approaches can result in interruptions and delays to HBOT regimes.[15]

In Australia, HBOT is mainly available in hospitals located in large cities and regional centres.[21] Many patients live too far away from the hospital to permit daily travel for HBOT, resulting in a large proportion of patients having to relocate themselves and family members and needing to arrange long breaks from their usual occupations. Delays during HBOT,

therefore, can be both socially and financially costly for some patients. In our study the average delay to treatments in those patients with MEBT was 10 days, with a maximum delay of 40 days waiting for tympanostomy tube placement. Sadly this happened to be a patient who had travelled from out of town for their course of treatments.

Given our large catchment area for patient referrals and sometimes delayed referral times for tympanostomy tube placement, we chose to collect and analyse a wide list of variables in order to attain the best outcome to assist with managing our patients more efficiently. The ability to predict which patients will require tympanostomy tubes would allow for prophylactic insertion and minimum disruption to treatment and inconvenience to patients. Unfortunately, we could not accurately predict which patients will go on to suffer MEBT and which will need tubes. However, some key points should be noted.

Our reported total cumulative incidence of MEBT of 43.4% is higher than many other published rates.[4–14] This may be because the Edmonds classification has a lower threshold for diagnosing MEBT since it grades symptoms without signs (Grade 0), which the original Teed scoring system does not.[21] The incidence of MEBT in our study population is also higher than the 13.6% reported in a study published just after our data collection had been completed.[4] This probably reflects the different population groups in the two studies: MEBT in the acute setting versus mainly non-acute patients with radiation tissue damage and wound problems in our population. This is also reflected in the different average ages between the two studies: 37.5 years versus 62.0 years in our study.

Patients being treated for bubble injury, those in whom TM movement can be visualised, and those with scuba experience appear less likely to suffer MEBT or to need tubes. 18.9% of the patients in this study were treated for bubble injury, all of which were diving-related and not iatrogenic. This suggests that the knowledge and experience of TM movement that comes with scuba diving is a protective factor.

In previous studies, patients with delayed radiation injury in the head and neck region were at increased risk of suffering MEBT or of requiring tympanostomy tubes.[16,22] Our study only partially supports this in that patients who had previously undergone ENT radiation treatments were more likely to suffer MEBT at some point during their first five HBOT, but they were not more likely to require tube placement.

When controlling for other factors, the best predictor of MEBT during the first five treatments was difficulty equalising ears (AOR = 11.0), but the small number of patients (nine) with such difficulty means this statement should be viewed with caution. This finding does, however, correlate with previous studies. MEBT correlates positively with an immobile TM on otoscopy during the Valsalva manoeuvre; patients who are unable to autoinflate the middle ear have been reported to have a higher incidence and greater severity of barotrauma than patients who are able to autoinflate.[7,10]

When controlling for all other factors, although women were at increased risk of requiring tube placement during their first five treatments compared to men (AOR = 24.7, five of 35 women), other similar-sized studies on gender as a risk factor for MEBT have been conflicting, suggesting that this is not a reliable predictor.[4,9] The most striking (and non-intuitive) finding, was the association between a history of cardiovascular disease and the need for tube placement during the first five treatments. Again, however, this increased risk is relative; only seven of 35 patients with a cardiovascular history required tubes and, when looking at whether patients ever needed a tube, including treatments beyond the first five, this association disappears. An interesting recurring theme was the relationship between MEBT and delayed radiation to the nasopharynx. Given the high numbers of these patients treated with HBOT, further studies could be aimed specifically at these patients to look at differences between total radiation doses, midline versus asymmetric radiation, and length of time since radiation.

All three of our patients with artificial airways required tubes. Having an artificial airway in place during HBOT has been identified previously as a risk factor for MEBT.[12] Of 28 patients with artificial airways in a study of 267 patients, 27 required tympanostomy tubes.[12] Our centre certainly does not treat sufficient patients with artificial airways to draw any useful conclusions, but it seems logical to prophylactically place tubes in these patients.

Since this study was completed, practice has changed at TTH and tympanostomy tubes are now being placed under local anaesthesia, a less time-consuming process, tolerated by patients. Staff confidence and ability to assess and grade MEBT has increased since completing the study. Audit of MEBT is part of the Australasian-wide documentation of clinical indicators by the Hyperbaric Technicians and Nurses Association. Another limitation to our study may have been the variability in accurately grading the degree of MEBT given that it is a subjective assessment and that we asked all chamber attendants and medical officers to participate. Pre-study education and reference material as well as ongoing supervision was provided by the authors.

Conclusions

Patients with a scuba diving history and those whose TMs could be visualized to move on otoscopic examination have decreased risks of MEBT and the need for insertion of tubes. Although these two factors appear to be protective, other risk factors for MEBT are more difficult to quantify. We cannot accurately predict which patients will require tubes

during their HBOT and, therefore, are unable to recommend prophylactic placement. On multivariate analysis, only difficulty equalising was a risk factor for MEBT and being female and having a history of cardiovascular disease were risk factors for early tube insertion. Infectious indications for HBOT may be a risk factor for tube placement at any time during HBOT. These groups of patients should be monitored closely during their course of HBOT to enable early diagnosis and intervention where appropriate.

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