

# Middle ear barotrauma after hyperbaric oxygen therapy - the role of insufflation maneuvers

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## Abstract

**Objective:** To analyze the association of insufflation maneuvers status before hyperbaric oxygen therapy with middle ear barotrauma. **Materials and Methods:** Forty-one patients (82 ears) admitted to the Department of Hyperbaric Medicine from May 2011 to July 2012. Assessments occurred: before and after the first session, after sessions with symptoms. During the evaluations were performed: otoscopy with Valsalva and Toynbee maneuvers, video otoscopy and specific questionnaire. Middle ear barotrauma was graduated by the modified Edmond's scale. Tubal insufflation was classified in Good, Median and Bad according to combined results of Valsalva and Toynbee maneuvers. Inclusion criteria: patients evaluated by an otolaryngologist before and after the first session, with no history of ear disease, who agreed to participate in the research (convenience sample). **Results:** Of the 82 ears included in the study, 32 (39%) had barotrauma after the first session. The rate of middle ear barotrauma according to tubal insufflation was: 17.9% (Good insufflation) 44.4% (Median insufflation) and 55.6% (Bad insufflation) ( $P = 0.013$ ). **Conclusion:** Positive Valsalva and Toynbee maneuvers before the first session, alone or associated were protective factors for middle ear barotrauma by ear after the first session.

**Keywords:** barotrauma, hyperbaric oxygenation, middle ear ventilation.

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## INTRODUCTION

The Hyperbaric Oxygen Therapy (HBOT) is an accepted treatment modality for primary and adjuvant treatment of various diseases<sup>1,2</sup>. HBOT is not without risks and the middle ear barotrauma (MEB) is its most common side effect<sup>3,4</sup>. MEB consists in the appearance of lesions on the tympanic membrane (TM) and/or tympanic cavity, secondary to pressure variation unable to be compensated by the Eustachian tube (ET). Its incidence ranges from 8 to 68.7% and achieves up to 91% in patients unable to auto-inflate their middle ear (ME)<sup>5</sup>.

Symptoms range from discomfort, ear pain, ear fullness, hearing loss, tinnitus and even otorrhagia<sup>2,3,6</sup>.

There are conflicting opinions regarding the role of the Eustachian tube (ET) in the occurrence of MEB<sup>7</sup>. Some authors advocate tube dysfunction as the primary risk factor for this condition<sup>1,8-10</sup>. Others minimize its influence<sup>2,11,12</sup>.

The role of self-insufflation maneuvers (Valsalva and Toynbee) status before HBOT is controversial and many authors have used tubal function tests instead, to try to predict MEB. Otoscopy persists as the most reliable method for detecting changes in the ME induced by HBOT<sup>2,7,12</sup>.

This research was conducted to analyze the relevance of insufflation maneuvers status before hyperbaric oxygen therapy in order to stratify patients into similar categories of MEB risk. It was attempted to make an otolaryngological profile of patients undergoing HBOT, in order to establish more accurate protocols for the prevention and treatment of MEB.

## METHODS

The study group consisted of 41 patients (82 ears) admitted to the Hyperbaric Medicine Department at Brasilia Armed Force Hospital, from May 2011 to July 2012, for the treatment of various diseases.

The study was approved by the Ethics Committee on Human Research of Brasilia Armed Force Hospital under protocol number 0009/2010/CEP/HFA.

Patients were evaluated before and after the first session. During the evaluations were performed: otoscopy with Valsalva and Toynbee maneuvers, video otoscopy and specific questionnaire.

Assessments were conducted within 2 hours after the procedures. When there were signs of MEB on otoscopy, self-inflating maneuvers were not realized after the sessions, to prevent pain or discomfort.

### Sample Selection

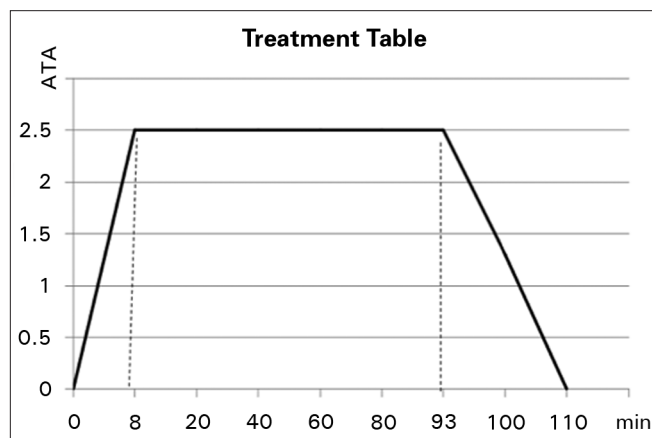
Inclusion criteria: all patients undergoing HBOT evaluated by an otolaryngologist before and after the first session, with no history of ear disease.

Exclusion criteria were: patients with MEB due to infection of the upper airways and acute allergic rhinitis after the first session; previously evaluated patients that didn't start the sessions, patients who required placement of ventilation tubes (VT) before the beginning of sessions, unconscious patients or those with artificial airways and patients with previous ear diseases.

Were considered ear diseases for purposes of exclusion: chronic otitis media, history of previous otologic operations such as tympanostomy, tympanoplasty or mastoidectomy.

The sample was selected by convenience respecting the free choice of the patient to participate (with signing of informed consent term). Were excluded 3 patients who required bilateral VT placement before the beginning of sessions and a patient who already had bilateral VT, totaling 4 exclusions.

The equipment used for HBOT was a Seaway Diver multiplace chamber with eight places, model A-240. It was adopted a standardized treatment protocol which consisted of one session per day (5 days per week) (Figure 1). Were included both inpatients and outpatients.



**Figure 1.** Pressurization pattern during HBOT (hyperbaric oxygen therapy). HBOT: Hyperbaric oxygen therapy.

In accordance with Bessereau et al., MEB was defined as a higher degree of TM lesion diagnosed by otoscopy compared to its state before HBOT session<sup>5</sup>. The MEB was graduated by Edmonds et al. modified scale (Figure 2).

Videotoscopy was performed and recorded with the intent of reducing the interobserver difference in the degree of evaluated barotrauma.

Tympanostomy with Ventilation tubes (VT) placement was held in MEB grades 3 and 4 and in cases of severe pain in grade 2.

### Valsalva and Toynbee Maneuvers

To perform the Valsalva maneuver, patients were instructed to pinch the nostrils and inflate the cheeks

Modified Edmonds et al. scale for MEB	
Grade	TM and ME findings
0	Normal
1	Redness of the TM
2	Redness + slight haemorrhage within TM
3	Gross haemorrhage within the TM or presence of ME effusion
4	Hemotympanum
5	TM perforation

**Figure 2.** Modified Edmonds et al. scale for MEB. MEB: Middle ear barotrauma.

through forced expiration with the mouth closed until a sensation of fullness was achieved in the ears. To accomplish the Toynbee maneuver, the patients were asked to swallow while pinching the nostrils. In both cases, the patient underwent maneuvers during otoscopy, allowing the examiner to assess the movement of the TM. During the Valsalva maneuver was expected lateralization of TM and during the Toynbee maneuver, its medialization. When these outcomes occurred maneuvers were classified as positive and otherwise as negative. The Toynbee and Valsalva maneuvers were analyzed by ear and by patient.

Besides the evaluation of each maneuver (Valsalva and Toynbee) separately, it was evaluated the result of the combined two maneuvers by ear. The following groups of ears were obtained: those with positive Valsalva and Toynbee maneuvers, those with only one positive maneuver (Valsalva or Toynbee), those with negative Valsalva and Toynbee maneuvers. Using these categories, the insufflation of each ear was rated respectively as: Good, Medium and Bad.

In the analysis of the Valsalva maneuver by patient, the subjects were classified into Inflaters and Non-inflaters. To be considered Inflater the patient should perform the Valsalva maneuver successfully in both ears. The group of Non-inflaters was then constituted by two subgroups: those who could not perform the Valsalva maneuver in both ears, and those who could do it unilaterally.

The analysis of the Toynbee maneuver by patient was similar. Patients were divided into three groups: those patients who could perform the maneuver Toynbee in both ears, those who could not perform the Toynbee maneuver in both ears, and those who could do it unilaterally.

The result of the combined Valsalva and Toynbee maneuvers was also evaluated by patient. It was obtained 4 maneuvers per subject that were categorized as: 4 positive maneuvers (Valsalva and Toynbee maneuvers positive bilaterally), 3 positive maneuvers and 1 negative,

2 positive and 2 negative maneuvers, 1 positive and 3 negative maneuvers, 4 negative maneuvers (Valsalva and Toynbee maneuvers negative bilaterally). Using these categories the insufflation of each patient was rated respectively as: Good, Medium (for 3 intermediate categories) and Bad.

The tubal insufflation by patient was also classified into symmetric and asymmetric. It was considered symmetric for the following combinations of maneuvers: 4 positive maneuvers (Valsalva and Toynbee maneuvers positive bilaterally); 4 negative maneuvers (Valsalva and Toynbee maneuvers negative bilaterally) 2 positive maneuvers on the following occasions: positive Valsalva or Toynbee maneuver bilaterally. Insufflation was considered Asymmetric for the following combinations of maneuvers: 1 positive maneuver (any combination), 3 positive maneuvers (any combination), 2 positive maneuvers on the following occasions: positive Valsalva and Toynbee maneuvers in different ears, positive Valsalva and Toynbee maneuvers in the same ear.

### Statistical Analysis

The database was organized using Excel® 2010 for Windows®. Analyses were performed using features of Excel® and SPSS® (Statistical Package for the Social Sciences, Chicago, IL) 13 for Windows®. Comparisons of means were made using the *Student t* test for independent measures or repeated measures according to the correspondence. Association between variables was made using the chi-square test. When appropriate it was calculated the odds ratio with its confidence interval. Correlation analyzes were carried out using the Spearman test. The level of statistical significance was set at 5% ( $P < 0.05$ ). All tests were two-tailed.

## RESULTS

The patients underwent a total of 1167 HBOT sessions during the study period. The number of sessions per patient ranged from 1 to 100 sessions, with an average of 28.46 sessions.

Twenty-eight patients were male (68.3%) and 13 females (31.7%). The average age was 53 years, ranging from 17 to 88 years.

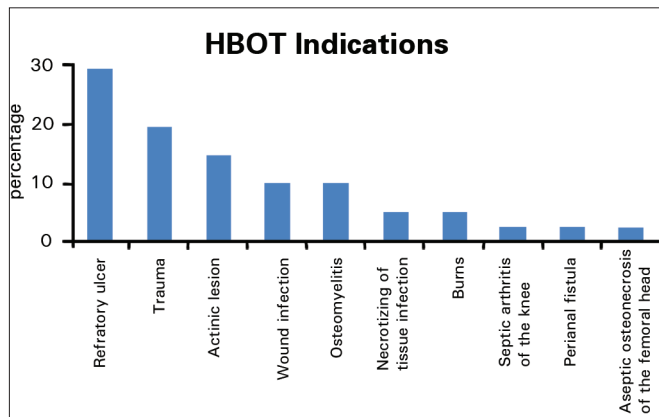
After the first session of HBOT, there were 22 patients with MEB (53.65%), 12 unilateral and 10 bilateral.

Of the 32 affected ears (39%) after the first session, 16 were grade 1 (50%); 6 grade 2 (18.7%); 8 grade 3 (25%) and 2 grade 4 (6.3%). There was no grade 5 barotrauma.

Of the 22 patients that presented MEB, 8 (36.3%) required tympanostomy with VT placement. Of these eight patients, six underwent VT placement after the first session (75%).

## Clinical History

In the present study, the refractory ulcers were the main indication for HBOT (29.3%) (Figure 3). There was no statistically significant association between treatment indication and MEB ( $\chi^2 = 5.644$ ,  $df = 9$ ,  $P = 0.775$ ).



**Figure 3.** HBOT indications during the study. HBOT: Hyperbaric oxygen therapy.

There was no correlation of reported nasal obstruction before the first session with MEB after the first session. ( $\chi^2 = 4.583$ ,  $df = 1$ ,  $P = 0.057$ ).

There was an inverse correlation of reported diagnosis of allergic rhinitis and MEB ( $\chi^2 = 13.254$ ,  $df = 1$ ,  $P = 0.001$ ).

There was no correlation of previous smoking ( $P = 0.42$ ), or alcohol intake ( $P = 0.75$ ) with MEB.

## Valsalva and Toynbee Maneuvers

The Toynbee and Valsalva maneuvers were performed in all 82 ears before the first session.

In 45 ears (54.9%) the Valsalva maneuver was classified as positive and in 37 (45.1%) as negative. There was a statistically significant correlation with the presence of positive Valsalva maneuver and absence of MEB ( $\chi^2 = 6.400$ ,  $df = 1$ ,  $P = 0.014$ ) (OR: 3.24; CI: 95% [1.3-8.03]).

In the classification of Valsalva maneuver by patient, no significant association was found between the category of insufflation (Inflaters and Non-inflaters) and MEB after the first session ( $\chi^2 = 3.913$ ,  $df = 2$ ,  $P = 0.141$ ).

In 38 ears (46.3%) the Toynbee maneuver was classified as positive and in 44 (53.7%) as negative. There was a statistically significant correlation with the presence of positive Toynbee maneuver and absence of MEB ( $\chi^2 = 4.807$ ,  $df = 1$ ,  $P = 0.041$ ). (OR: 2.8; CI: 95% [1.12-7.03]). In the classification of Toynbee maneuver by patient, no significant association was found between the category of insufflation and MEB after the first session ( $\chi^2 = 4.359$ ,  $df = 2$ ,  $P = 0.113$ ).

There was statistically significant association between the classification of insufflation and the development of MEB after the first session (Table 1) ( $\chi^2 = 8.706$ ,  $df = 2$ ,  $P = 0.013$ ).

**Table 1.** Contingency table for the variables insufflation and MEB after the first session ( $n = 82$  ears).

Insufflation	MEB by ear after the first session		
	No	Yes	Total
Good	23 82.1%	5 17.9%	28 100%
Median	15 55.6%	12 44.4%	27 100%
Bad	12 44.4%	15 55.6%	27 100%
Total	50 61.0%	32 39.0%	82 100%

MEB: Middle ear barotrauma.

In the analysis of tubal insufflation by patient it was not demonstrated a significant association between the type of insufflation and MEB ( $\chi^2 = 9.159$ ,  $df = 4$ ,  $P = 0.057$ ).

Further analysis tested whether the insufflation categorized as symmetric or asymmetric had any association with MEB (Table 2). The statistical significance of this test was marginal ( $\chi^2 = 4.143$ ,  $df = 1$ ,  $P = 0.052$ ). However, the odds ratio showed that patients with MEB have greater chances of having asymmetric insufflation (OR: 4.44, 95% CI: 1.06 to 18.69).

**Table 2.** Contingency table for the variables insufflation (symmetric or asymmetric) and MEB after the first session ( $n = 41$  patients).

Insufflation	MEB after the first session		
	No	Yes	Total
Asymmetric	3 23.1%	10 76.9%	13 100%
Symmetric	16 57.1%	12 42.9%	28 100%
Total	19 46.3%	22 53.7%	41 100%

MEB: Middle ear barotrauma.

## DISCUSSION

### Clinical History

As in the present study, Díaz Caparrós<sup>10</sup> reported that the refractory ulcers constituted the major indication for HBOT in his sample (73.8%).

In accordance with this study, Igarashi et al.<sup>11</sup> and Fitzpatrick et al.<sup>13</sup> found no correlation between HBOT indications and MEB.

Pinna et al.<sup>7</sup> reported 38.1% of patients with allergic rhinitis, a rate similar to the present study, 34.1%. Unlike this study, these authors found no influence of history of allergic rhinitis in MEB. As the diagnosis of allergic rhinitis was based on patients self-reporting, it is subject to bias, which may have result in this unexpected finding of inverse correlation with MEB.

In this study there were 39% of patients with a history of smoking. Vahidova et al.<sup>3</sup> reported 30.9% of smoking in their sample, but did not correlate this with MEB. Uzun<sup>14</sup>, in a study of MEB in divers, found no association between smoking and MEB.

### Valsalva and Toynbee maneuvers

In the present study there was a correlation with both positive Valsalva or Toynbee maneuvers before the first session with the absence of MEB after the first session. As expected, the correlation of the Valsalva maneuver ( $P = 0.014$ ) was much more relevant than the Toynbee maneuver ( $P = 0.041$ ) because of the more significant pressure variation that the first maneuver is capable of inducing. By grouping the results of the two tests, the correlation was even better ( $P = 0.013$ ) with good differentiation of MEB rates by ear between the three categories of tubal insufflation.

Igarashi et al.<sup>11</sup> evaluated the findings of the Valsalva maneuver prior to the beginning of HBOT (easy or difficult maneuver) and found no correlation with MEB. Bessereau et al.<sup>5</sup> reported the same incidence of MEB in patients who did or didn't perform the Valsalva maneuver. They attribute this finding to patients who perform ineffective Valsalva maneuvers, which would be under increased risk of MEB.

Beuerlein et al.<sup>1</sup>, in a prospective study, compared MEB incidence in auto-inflaters (which could lateralize the TM during the Valsalva maneuver attested by otoscopy) and non-inflaters (comatose patients with artificial airways or patients who failed to perform Valsalva maneuver). They found 37% of MEB in the group of auto-inflaters and 91% in the non-inflaters. The authors conclude that the non-inflaters have increased risk for MEB and therefore recommends prophylactic VT placement in patients with artificial airways and in patients with tubal dysfunction who do not respond to medical therapy.

Pinna et al.<sup>7</sup>, in a prospective study, made similar comparison and reported 38.9% of MEB in auto-inflaters and 66.6% in non-inflaters. But the finding was not statistically significant given the small number of non-inflaters ( $n = 3$ , 2 intubated patients and 1 with tracheostomy).

In the studies of Beuerlein et al.<sup>1</sup> and Pinna et al.<sup>7</sup> most of non-inflaters were unconscious or had artificial airways.

In this study patients were divided into auto-inflaters (by similar criterion used by Beuerlein et al.<sup>1</sup>) and non-inflaters (patients who could not perform the Valsalva maneuver). Unlike the studies of Beuerlein et al.<sup>1</sup> and Pinna et al.<sup>7</sup> in which almost all non-inflaters were unconscious or had artificial airways, in the present study all non-inflaters were aware and without airway alterations. There are insufficient studies to evaluate the risk of MEB in non-inflaters without airway alterations or altered state of consciousness. In the studies evaluated it hasn't been described if the auto-inflator can perform the Valsalva maneuver successfully in both ears or in just one. In this study, to be considered auto-inflater, the patient should perform the Valsalva maneuver successfully in both ears.

Although no association has been found between asymmetric tubal insufflation and increased MEB rate, there was a strong tendency in this direction that can be further investigated in future studies. Counteracting the opinion of several authors, it is believed that the capacity of self-insufflation (by Valsalva and Toynbee maneuvers) is relevant and should be evaluated before HBOT.

## CONCLUSION

Positive Valsalva and Toynbee maneuvers before the first session, alone or associated were protective factors for middle ear barotrauma by ear after the first session. Clinical history was not associated with MEB.

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