

# Indication for hyperbaric oxygen treatment as a predictor of tympanostomy tube placement.

F. W. FIESSELER<sup>1</sup>, M E. SILVERMAN<sup>1</sup>, R L. RIGGS<sup>2</sup>, P. A. SZUCS<sup>1</sup>

<sup>1</sup>Department of Emergency Medicine, Morristown Memorial Hospital, Morristown, New Jersey; <sup>2</sup>Department of Emergency Medicine, UMDNJ-RWJMS, New Brunswick, New Jersey

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Fiesseler F.W., Silverman M.E., Riggs R.L., Szucs P.A. Indication for hyperbaric oxygen treatment as a predictor of tympanostomy tube placement. *Undersea Hyperb Med* 2006; 33(4):231-235. Introduction: Hyperbaric oxygen therapy (HBO<sub>2</sub>) has been utilized for many years for a multitude of disease entities. One commonly encountered side-effect is otic barotrauma. Objective: To determine if patients with specific disease processes are at increased risk of requiring tympanostomy tubes during HBO<sub>2</sub>. Methods: Data was obtained from Jan. 2000 to Dec. 2004, retrospectively. The requirement for tympanostomy tubes during a course of HBO<sub>2</sub> was established. Results: 325 met inclusion criteria. Fifteen percent of patients overall (95% CI= 11-19%) required tympanostomy tubes. Tubes were required in: 5% necrotizing soft tissue infection (p=0.33); 10% failed/threatened graft (p=0.39); 15% problem wounds; 17% chronic refractory osteomyelitis (CRO) (p=0.64); 22% soft tissue radionecrosis (STRN)/ osteoradionecrosis (ORN) (p=0.02); 33% of crush injuries (p=0.10). Twenty-nine percent of nasopharyngeal radiation injury patients (p=0.001) and 10% of the non-nasopharyngeal radiation patients (p=0.36) received tympanostomy tubes. Conclusion: A significant increase in tympanostomy tubes were required in nasopharyngeal radiation injury patients.

## INTRODUCTION

HBO<sub>2</sub> has been recommended as treatment for a multitude of disease processes. As indications expand, so does the likelihood that patients will encounter this therapeutic modality. While complications are limited, otic barotrauma is encountered most frequently (1). Symptoms are variable and often delay/interrupt HBO<sub>2</sub> regimens. Patients with intractable Eustachian tube dysfunction may require myringotomy tube placement before initiating therapy, while others develop problems during therapy and ultimately need tubes to prevent further otalgia or permanent injury.

Previous literature on predisposing factors contributing to otic barotrauma is limited. Possible etiologies previously postulated include: upper respiratory infection; communication

problems; endotracheal intubation; Eustachian tube dysfunction; altered mental status; infants; elderly; stoic patients (2-6). Conjecturally, the pathophysiologic process is multifactorial in nature.

Using referral for tympanostomy tubes as an endpoint, we hypothesized that patients at increased risk can be identified prior to HBO<sub>2</sub> based on treatment indication. With this information, accurate patient expectations regarding probability of significant otalgia and the need for tympanostomy tubes will be better delineated. Our goal was to identify those who might benefit from prophylactic tympanostomy tubes preventing untoward discomfort and/or treatment interruptions saving time, resources, and revenue.

## METHODS

### Study design

This was a retrospective observational study.

### Setting

This study was conducted in a HBO<sub>2</sub> unit at a community-based tertiary care center in northern New Jersey, performing HBO<sub>2</sub> on both an emergent and non-emergent basis.

### Population

Information was obtained through a computerized tracking system. When information was incomplete a manual review of the chart was performed. Study population included all patients treated at our HBO<sub>2</sub> unit from January 2000 through 2004. Excluded were those who had tympanostomy tubes placed prior to initiation of therapy.

### Study Protocol

The requirement of tympanostomy tubes was initially considered in patients with persistent otic discomfort which interrupted their care. Ultimately, the decision to place tympanostomy tubes was determined by the treating hyperbaric physician in conjunction with an otolaryngologist. Statistical Analysis: Categorical data was analyzed by

Fisher Exact Tests. Ninety-five percent confidence intervals were calculated as appropriate. All tests were two-tailed with alpha set at 0.05.

## RESULTS

Three hundred and forty patient records were screened. Fifteen patients were excluded due to having received prophylactic tympanostomy tubes, leaving three hundred and twenty-five for analysis. Median age was fifty-eight (SD  $\pm$  17) and males comprised 63% of enrollees. Overall, fifteen percent of patients (95% CI= 11-19%) had significant barotrauma requiring tubes. Fifteen percent (30/205) of males compared to 17% of females (20/115), required tubes ( $p=0.52$ ). Mean age of those requiring tympanostomy tubes was 57.6 (SD  $\pm$  18), compared to 58.7 (SD  $\pm$  17) who did not ( $P=NS$ ).

Subset analysis regarding indication demonstrated the following. Tympanostomy tubes were not required with: air embolism (0/1); CO poisoning (0/23); gas gangrene (0/3); decompression sickness (0/3); arterial insufficiency (0/2). Tubes were required in: 5% necrotizing soft tissue infection (1/20) ( $p=0.33$ ); 10% failed/threatened graft (5/52) ( $p=0.39$ ); 15% problem wounds (9/60) ( $p=1$ ); 17% CRO (7/40)

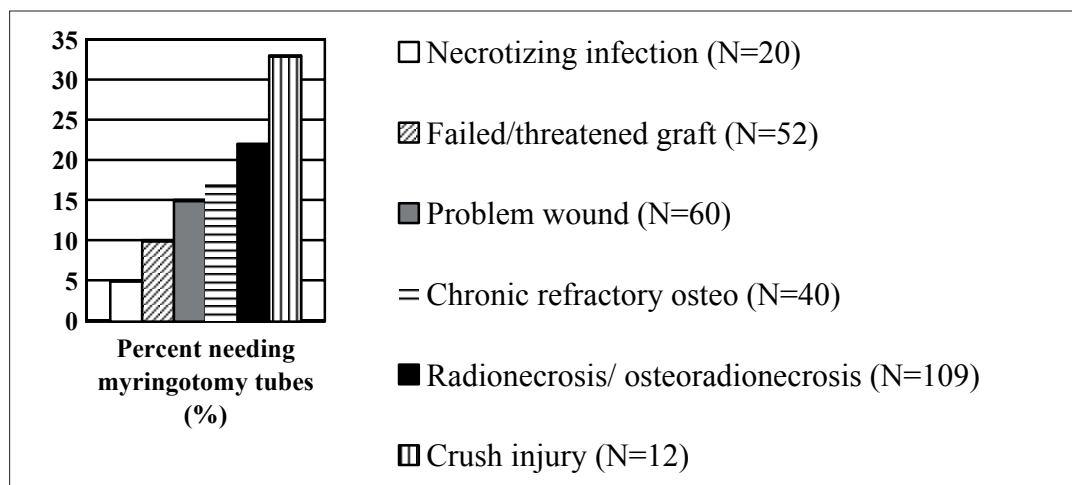


Fig. 1. Percent of patients requiring tympanostomy tubes based on diagnosis.

( $p=0.64$ ); 22% STRN/ORN (24/109) ( $p=0.02$ ); (4/12) 33% of crush injuries ( $p=0.10$ ). (Figure 1)

Of the one hundred and nine delayed radiation injury patients, 69 had involvement of the nasopharynx. Of these, 29 % ultimately required tympanostomy tubes (20/69) ( $p=0.001$ ). The requirement for tympanostomy tubes between STRN and ORN of the nasopharynx was 30% (6/20) and 29% (14/49) ( $P=NS$ ), respectively. Only 10% of non-nasopharyngeal radiation injury patients required tubes (4/40) ( $p=0.36$ ).

Depth of treatment was evaluated according to those patients at 2.0 ATA ( $R=158$ ) and those treated at greater than 2.0 ATA (typically 2.5 ATA) ( $R=164$ ). Sixteen percent (25/158) and 15% (25/164) of patients required tympanostomy tubes, respectively ( $P=1.0$ ).

## DISCUSSION

HBO<sub>2</sub> is generally considered safe, but it is not without morbidity. Side effects are mostly limited to anxiety, oxygen toxicity and barotrauma. Barotrauma can be further divided based on anatomical location. While pneumothorax, sinus squeeze, dental pain, and inner ear squeeze are rare; middle ear barotrauma is common (7). Most cases of otic barotrauma are mild, but delays in treatment occur in 10-40% of patients with these complications (2,8). This emphasizes the clinical importance of otic barotrauma and confirms the need for proper treatment of middle ear injury with active prevention and cautionary measures.

Fitzpatrick et. al. retrospectively evaluated risks associated with “symptomatic” barotrauma. He utilized a multiplace chamber and excluded patients exposed to pressures greater than 2.4 ATA. Thirty-five percent of patients suffered from significant barotrauma defined as otic or sinus pain requiring discontinuation of compression. Fitzpatrick

was unable to demonstrate a significant difference based on treatment indication (3).

Ueda et. al. evaluated the otological complication rate of 898 patients. Treatment indications included: sudden deafness; idiopathic bilateral sensorineural hearing loss; Bell’s palsy; various other diseases. Though 143 patients developed grade 3 or 4 barotrauma, 116 ears were punctured or incised and only 5 ears required tympanostomy tubes. This study sets itself apart with its unique population and philosophy regarding treatment (9).

Blanchard et. al. reported a 29% incidence of tympanostomy tubes, with delayed radiation injury of the nasopharynx being the only statistically significant diagnosis. Enrollment included only 82 patients and utilized a multiplace chamber with inside tender. All nine nasopharyngeal radiation injury patients required tubes during HBO<sub>2</sub> treatment (10). This paper’s small enrollment numbers and utilization of different equipment differentiates our studies. Though our conclusions were similar, our 29% myringotomy rate was far less than the 100% they reported for nasopharyngeal radiation patients.

Previous studies have demonstrated that those with abnormal Eustachian tubes or those unable to autoinflate the middle ear are at increased risk of otic complications (2,5,11). It is presumed that patients with delayed nasopharyngeal radiation injury acquire anatomical dysfunctions that predispose them to otic complications. While these patients can benefit greatly from HBO<sub>2</sub>, it is not without complications.

Nasopharyngeal late radiation injury remains a common HBO<sub>2</sub> treatment indications and our retrospective study conclusively demonstrates that this group is at risk of requiring tympanostomy tubes when compared to the mean complication rate of 15% (49/325) ( $P= 0.001$ ). This finding is independent of the fact that most radiation injury patients

are treated at greater depths (2.5ATA). We hope that this additional knowledge will help better delineate expectations regarding otic barotrauma based on indication. Further studies investigating prophylactic treatment protocols (i.e. prophylactic tympanostomy tubes prior to HBO<sub>2</sub>), thereby preventing interruptions in treatment regimens, are warranted. Such protocols instituted in select patients could potentially save valuable resources and revenue.

## LIMITATIONS AND REMAINING QUESTIONS

There are limitations in data that are collected retrospectively. However, since two independent physicians determined the necessity for myringotomy tube placement, an objective endpoint, we do not feel this affected our conclusions. Analysis based on “minor” otic barotrauma was not analyzed since kappa values between observing physicians regarding TEED classifications is unknown. Also, analysis of medications to prevent otic barotrauma (prophylaxis) was not monitored, but by protocol, the patients were started on topical sympathomimetics if otic barotrauma was suggested clinically or if the patient had an upper respiratory tract infection. Minor otic trauma was ameliorated in some patients, while in others it was not. Previous studies have not validated improvement in outcomes based on utilization of sympathomimetics (1). Hence, this most likely did not affect our conclusions. One could speculate that those patients undergoing treatment for delayed radiation injury had a greater number of treatments, increasing the risk of otalgia, however, most barotrauma occurs in the early stages of treatment, and moreover, non-nasopharyngeal delayed radiation injury did not have a significant requirement of tympanostomy tubes.

It is also notable that the highest

incidence of tympanostomy tubes was in the crush injury group. The effect of repetitive surgery and post anesthesia Eustachian tube dysfunction has not been addressed and is highly relevant to this group. Future studies are needed to confirm if crush injury patients might benefit from simultaneous tympanostomy tube placement at the time of surgery since their incidence was 33%. The numbers of patients within categories of AGE; CO; gas gangrene; crush injury; DCI and arterial insufficiency is low, which limited the power of this study to depict risks accurately in these patients.

## CONCLUSIONS

Overall, a moderate number of patients in this series required tympanostomy tube placement during their HBO<sub>2</sub>. Radiation injury of the nasopharynx was associated with a “significant” increase in risk. Further research is needed to identify which patients in this and other groups might benefit from prophylactic tympanostomy tube placement before HBO<sub>2</sub> therapy.

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