

## Original Research Article

# A study to determine the incidence of otitic barotrauma during hyperbaric oxygen therapy

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## ABSTRACT

**Background:** Hyperbaric oxygen therapy (HBOT) is approved as a treatment modality for large number of indications and Middle ear barotrauma is one of its most common side effects.

**Methods:** A prospective study was done on 100 patients involving 1216 HBOT sessions for a period of 2 years on all those undergoing HBOT in our hospital.

**Results:** 19 patients which was 1.56 per 100 treatment sessions developed otitic barotrauma with severity from grades I to III, maximum in II and none in IV to V. All resolved with temporary break in HBOT and treatment conservatively. The incidence of barotrauma was significantly less, probably due to the proper counselling, pressure equalization techniques and precautions.

**Conclusions:** HBOT can be used as a safe treatment modality and the incidence of otitic barotrauma can be minimized with pressure equalization techniques and precautions during the therapy sessions.

**Keywords:** Otitic barotrauma, Hyperbaric oxygen therapy, Middle ear barotrauma, Compression chamber, Pressure equalisation

## INTRODUCTION

Barotrauma is caused by the difference in pressure between the air containing spaces of the ear and the outside environment. Since fluids do not compress under pressure, the fluid containing cavities of the ear do not alter their volume under the pressure changes of hyperbaric oxygen therapy (HBOT). However, the air containing spaces of the ear do compress, resulting in damage to the ear if the alteration in ambient pressure cannot be equalized.

These changes are dependent on speed of pressurization and ability to equalize pressure between middle ear and outside environment by various measures including

Valsalva, Toynbee, Frenzel, yawning and chewing gum.<sup>1</sup> Inability to equalize pressure can result in significant differential between middle ear pressure and external environment and/ or middle ear pressure and inner ear pressure. such situation can lead to otitic barotrauma.

Otitic barotrauma can cause various symptoms and signs, such as tinnitus, hearing loss, pain, fullness of ear and even tympanic membrane perforation.<sup>2</sup> It is one of the leading causes for discontinuation of HBOT. The treatment depends upon the severity of barotrauma and ranges from temporary cessation of therapy, nasal decongestants and occasionally middle ear surgery.<sup>3</sup> Early diagnosis is important to relieve symptoms and prevent disease progression.

This study was performed to determine the incidence of otitic barotrauma during hyperbaric oxygen therapy as a part of treatment of various illnesses and to determine various factors predisposing its development.

**METHODS**

A prospective study was done in INHS Asvini Mumbai, a tertiary care hospital setup where the Hyperbaric oxygen therapy was available. After the clearance of the hospital’s ethical committee, the study was conducted over a period of 2 years from October 2015 to September 2017.

**Inclusion criteria**

The study comprised of individuals undergoing hyperbaric oxygen therapy for various indications who consented or NOK consented (if individual was unable to give consent) were recruited into the study.

**Exclusion criteria**

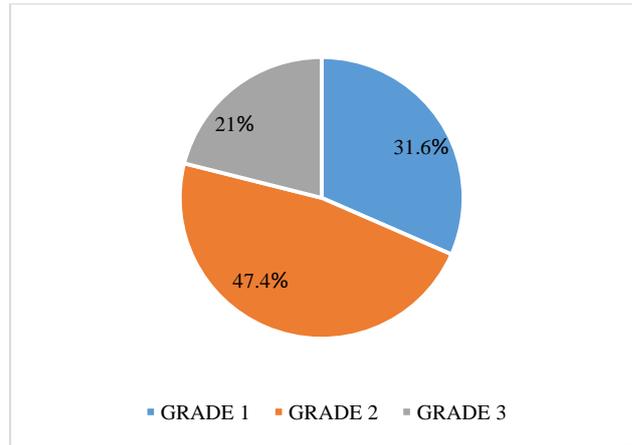
Patients where consent was not forthcoming to participate in the study, pre-existing middle ear pathology as diagnosed by pneumatic otoscopy, diagnosed nasal allergy or sino-nasal polyps or growths were excluded.

A total of 100 patients were evaluated. Pneumatic otoscopy was chosen to predict the eustachian tube function. Patients undergoing hyperbaric oxygen therapy were subjected to otoscopy and the tympanic membrane of these patients were evaluated prior to and immediately following the session of HBOT. Standard modified TEED grading system was used to grade the changes when noticed.<sup>4,5</sup> These changes were correlated with other variables of the patient such as age, underlying illness, comorbidities and general condition of the patient. Data collected was analyzed using IBM SPSS for Windows, Version 22.0, Armonk, NY Released 2013.

**RESULTS**

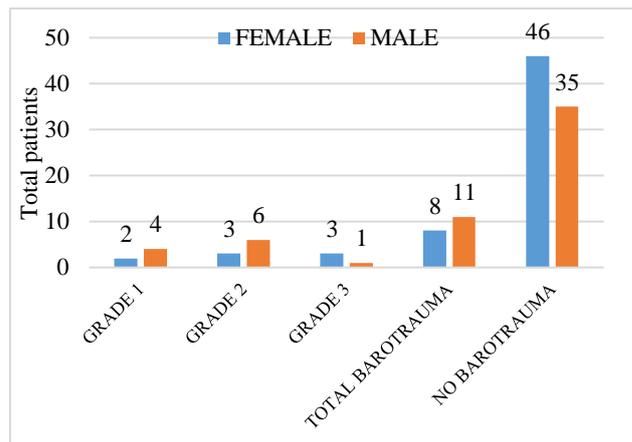
This study included 100 patients of which 46 (46%) were males and 54 (54%) were females. The study population comprised of all age groups with majority of population in age range of 45 to 65 years and the mean age being 47.1 years.

On further analysis of the study population, it was found that the indications for HBOT was radiation cystitis or prostritis in 44% patients, non healing wounds in 31% cases, sensorineural hearing loss in 17% patients and dental causes in 8% cases. The preexisting comorbidities among the study population was found as diabetes mellitus type II in 11 patients, deep venous thrombosis in 2 patients, hypertension in 2 and coronary artery disease in 1 patient. Rest of the patients did not have any significant comorbidity except for underlying illness for which HBOT was given.



**Figure 1: Incidence of otitic barotrauma as per the severity grading.**

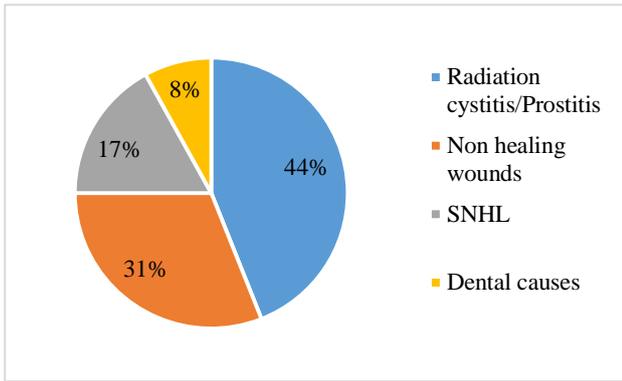
Of the 100 patients, 19 (19%) had otitic barotrauma during the hyperbaric oxygen therapy. Of these 19 patients, 6 patients had grade 1 otitic barotrauma, 9 patients had grade 2 otitic barotrauma and 4 patients had grade 3 otitic barotrauma (Figure 1).



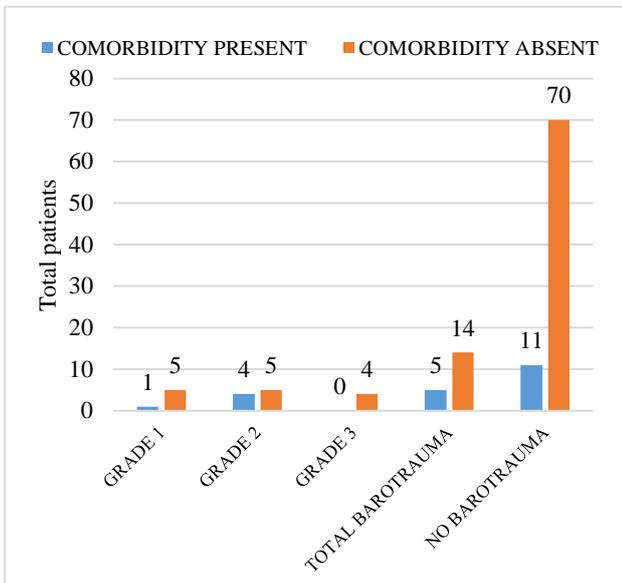
**Figure 2: Association of gender and otitic barotrauma in the study population.**

Among those with otitic barotrauma, 8 were females and 11 were males. Of the 8 females, 2 had grade 1 otitic barotrauma, 3 had grade 2 otitic barotrauma and 3 had grade 3 otitic barotrauma. Of the 11 males, 4 had grade 1 otitic barotrauma, 6 had grade 2 otitic barotrauma and 1 had grade 3 otitic barotrauma (Figure 2). The statistical analysis found the predilection of incidence of barotrauma among the 2 sexes to be insignificant ( $X^2=3.54$  or  $p=0.315$ ).

The barotrauma incidence as per the specific indications of the HBOT was found to be 5 among 17 SNHL patients, 2 among 8 dental causes, 7 among 31 non healing wound cases and 5 among 44 radiation cystitis patients (Figure 3). Again, the incidence of barotrauma was not significant in its association with the indications necessitating the HBOT ( $X^2$  value=1.63 or  $p=0.2$ ).



**Figure 3: Indications for HBOT.**



**Figure 4: Association of comorbidity and otitic barotrauma in the study population.**

The presence of comorbidities was analysed among those with and without barotrauma. Comorbidities were present in 1 of 6 patients with barotrauma severity grade 1, 4 of 9 with grade 2 barotrauma, none of 4 with grade 3 barotrauma and 11 among 81 with no barotrauma. The statistical analysis showed no significant association between the existence of comorbidity and incidence of otitic barotrauma.

**DISCUSSION**

Middle ear barotrauma is one of the most common side effects of HBOT. Reported incidences of middle ear barotrauma range from 8 to 68.7%. However, it has been reported to rise to 91% in patients who are unable to auto-inflate their middle ear.<sup>6</sup> Known risk factors for otitic barotrauma include older age, artificial airways, history of Eustachian tube dysfunction and the inability to auto-inflate the middle ear. Slower compression is a known protective factor for otitic barotrauma.<sup>6</sup>

In our study of 100 patients, it was found that the incidence of necessity for HBOT at this centre among males and females was almost equal. Age group 35 to 65 formed the maximum of around 70% of the study population. This suggests that the indications for HBOT occur equally in both sexes commonly in the 4<sup>th</sup> to 6<sup>th</sup> decade of life. 19 of the 100 patients (19%) in the total 1216 HBOT sessions reported symptoms of barotrauma, with an overall rate of 1.56 cases per 100 treatments. Of those 19 patients, around 58% were males and rest females. There was no influence of age or gender of the patient on the incidence of otitic barotrauma.

Fitzpatrick et al retrospectively evaluated the relationship of multiplace chamber compression rates and the influence of several predisposing factors on the risk of symptomatic barotrauma.<sup>7</sup> A total of 35 patients among the total 111 patients reported symptoms of barotrauma, with an overall rate of 3.05 cases per 100 treatments. The most frequently affected area was the ears (95%) with objective findings noted in 18% of patients reporting fullness compared to 39% of patients reporting pain. Referral diagnosis was not related to the incidence of barotrauma. Although the overall risk of symptomatic barotrauma increased as the compression rate increased, it was not significant. Female patients were at significantly increased risk compared to males, and patients less than age 40 were at higher risk than those age 40 and older.

In our study, around half of those who had otitic barotrauma had the severity of grade II, with none having grade IV or V. The incidence of otitic barotrauma is important for patients undergoing HBOT because it can lead to interruption of treatment or delay in commencement of treatment. HBOT was interrupted temporarily till barotrauma was resolved and was re-started with counselling of patient and ongoing topical and systemic treatment. None of these patients required myringotomy, tympanostomy tubes or abandoning of the HBOT. Otitic barotrauma though being the most common complication of HBOT, more severe grades are of very minimal incidence if done with proper precautions.

Ueda et al evaluated the otological complication rate of 898 patients.<sup>8</sup> Treatment indications included Sudden deafness, Idiopathic bilateral Sensorineural hearing loss, Bell’s palsy and various other diseases. Though 143 patients developed grade 3 or 4 barotrauma, 116 ears underwent myringotomy and only 5 ears required tympanostomy tubes. Thus 27% of patients developed grade 3 or 4 barotrauma. This study set itself apart with its unique population and philosophy regarding treatment.

The overall incidence of middle ear barotrauma in our study (19% and 1.56 per 100 treatment sessions) was found to be lower as compared to other studies conducted worldwide. The multiplace chamber at our centre is manned by Professional divers, in addition to trained personnel specialising in hyperbaric and undersea

medicine. They being trained divers, have personal experience and expertise regarding pressure equalisation techniques, decompression, recompression and barotrauma. They were therefore well suited to appropriately counsel and guide the patients with regards to pressure equalisation techniques. In our study, all the patients always received explanations and education on HBOT and were taught how to perform effective pressure equalisation. They were informed about the risks for otitic barotrauma and told to report to the attendant in case of any symptoms of ear pain or discomfort. In cases of difficulties with pressure equalization, patient was assisted out of the chamber by the attendant. This is probably the main contributory factor for low incidence and grades of barotrauma in our study as compared to other studies.

Incidence of middle ear barotrauma is also related to the rate of compression of HBOT chamber. Kindwall et al mentioned in his study on middle ear barotrauma that a rate of compression of 2 psi per minute was adequate in preventing the occurrence of middle ear barotrauma and compression at any slower rate did not add to the reduction in number of cases of middle ear barotrauma.<sup>9</sup> In our centre, the compression rate at HBOT chamber was 2 psi per min and this commensurate with compression rate described in other studies.

The analysis of the correlation of the otitic barotrauma with the indication necessitating the HBOT, we found increased incidence in patients with sensorineural hearing loss than the others. However, it was statistically insignificant. The given literature also does not provide any basis for it. The presence of comorbidity was also found to have no correlation with the incidence of otitic barotrauma in these patients.

## CONCLUSION

Middle ear barotrauma continues to be the commonest complication of HBOT. However, pre-procedure screening for eustachian tube function, rigorous and meticulous instructions to the patients with regards to pressure equalization techniques and monitored and gradual increase of pressure in HBOT chamber seem to keep the incidence of otitic barotrauma low. The significantly lower incidence of otitic barotrauma in our study suggests that the incidence may be significantly reduced by utilization of professionally well trained manpower added with those having personal experiences in diving. The indications and comorbidities of the patient having no correlation in the occurrence of otitic barotrauma, HBOT may be given safely to patients across all the existing indications.

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