Complications of Tympanostomy Tubes Inserted for Facilitation of Hyperbaric Oxygen Therapy

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Objective: To document the incidence of complications occurring secondary to placement of tympanostomy tubes in patients undergoing hyperbaric oxygen therapy.

Design: Retrospective chart review.

Setting: Tertiary referral center.

Patients: Forty-five patients referred to the Department of Otolaryngology for inability to tolerate hyperbaric oxygen therapy between January 1, 1990, and December 31, 1995.

Interventions: All patients underwent bilateral myringotomy and tube placement.

Outcome Measures: Charts were reviewed for complications of tube placement, including otorrhea, otalgia, hearing loss, persistent perforations, and tinnitus.

Results: Seventeen (38%) of 45 patients experienced complications, with most having more than 1. Most complications occurred after conclusion of hyperbaric oxygen therapy. Otorrhea was most common, occurring in 13 patients (29%). Persistent tympanic membrane perforations occurred in 7 patients (16%).

Conclusions: The rate of complications is higher than reported for placement of tympanostomy tubes in other patient populations. Coexisting illness, such as diabetes mellitus, may contribute to the development of complications in patients undergoing hyperbaric oxygen therapy. Alternative methods of tympanostomy, with emphasis on shorter duration of intubation, should be considered in this patient population.

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HYPERBARIC oxygen therapy (HBO) has become commonplace in many medical centers as clinical experience continues to document efficacy. The physiologic basis for the treatment is that the partial pressure of oxygen in the lungs will be increased in direct proportion to an increase in atmospheric pressure.1 Elevation of the partial pressure of oxygen in hypoxic tissues, to normal or even supranormal levels, enhances fibroblast proliferation, supports collagen deposition, stimulates angiogenesis and epithelialization, and enhances leukocyte bactericidal activity.2 Also, oxygen tension remains elevated in subcutaneous tissues for several hours after treatment, which further improves the healing process.3 These factors have led to the application of HBO as an adjunctive measure for treating conditions resulting from tissue hypoxia, such as clostridial myonecrosis, severe crush injuries with traumatic ischemia, necrotizing fasciitis, chronic osteomyelitis, and nonhealing wounds in diabetic patients and patients with peripheral vascular disease.4 In addition, HBO has emerged as the primary treatment modality for carbon monoxide poisoning, decompression sickness, and air embolism.5

Middle ear barotrauma is the most common adverse effect of HBO.6 As the ambient pressure within the chamber is increased to 2 atmospheres, a patient must be able to equalize the pressure within the middle ear by autoinsufflation. If a significant pressure gradient is allowed to develop, severe otalgia may occur, followed by hemorrhage or serous effusion. Additional reported complications of middle ear barotrauma include tympanic membrane perforation, ossicular chain disruption, or even oval or round window rupture, with resultant vertigo or sensorineural hearing loss.7

Instructing patients in proper autoinsufflation techniques during compression can minimize the risk of barotrauma during HBO.8 Adding oral and topical de-
congestants to the regimen is indicated when nasal congestion compromises performance of autoinsufflation. Some patients continue to experience difficulty despite these measures, resulting in the need for myringotomy and tympanostomy tube insertion to allow continuation of HBO.

Most tympanostomy tubes are inserted for sequelae of otitis media. The patients undergoing HBO represent a distinct subpopulation of all patients receiving tubes. Often, these individuals have no antecedent history of otitis media. The purpose of this study was to retrospectively examine the complication rate in patients who undergo tympanostomy tube insertion for facilitation of HBO.

RESULTS

During the study period, more than 1000 patients received HBO, yielding an approximate 4% incidence of patients requiring tube placement. Of the 45 patients identified, 25 were female (56%) and 20 were male. Their ages ranged from 20 to 86 years, with a mean of 59 years. The indications for HBO were as follows:

<table>
<thead>
<tr>
<th>Disease Process</th>
<th>No. (%)</th>
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<tbody>
<tr>
<td>Diabetic foot ulcer</td>
<td>30 (67)</td>
</tr>
<tr>
<td>Venous stasis ulcer</td>
<td>7 (16)</td>
</tr>
<tr>
<td>Osteoradionecrosis</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Necrotizing fasciitis of the neck and face</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Gluteal abscess</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Carbon monoxide poisoning</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Clostridial myonecrosis</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Pharyngocutaneous fistula</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Osteomyelitis of the sternum</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

Only 1 patient with a history of otitis media was identified. This individual had a chronic perforation in one ear, while the other ear was normal.

Twenty-one patients (47%) had no follow-up in otolaryngology clinics. Included in this number are 4 patients who died of their disease within 6 months of receiving HBO. An additional 10 patients did not complete the planned course of HBO and were unavailable for follow-up. Because of the advanced age and the severity of illness of some of these patients, additional deaths owing to disease may have occurred. Seven patients were followed up only in hyperbaric medicine and reported no complaints referable to the ear over a 3- to 14-month period after tube placement. The final status of the tympanic membrane is not known in all of these patients, but for calculations in this report, these patients were assumed to have no complications.

Complications, which developed in 17 (38%) of the 45 patients, were as follows: otorrhea (13 patients), otalgia (11 patients), decreased hearing (10 patients), perforation of the tympanic membrane (7 patients), and tinnitus (2 patients). Multiple complications occurred in most patients. An average of 4 additional clinic visits were required for treatment (range, 1-10 additional clinic visits). No patients reported only otalgia or tinnitus. Complications became evident an average of 9 months after tube placement (range, 1 week to 48 months after tube placement).

Four patients developed drainage within the first month of tube placement, giving an incidence of early postoperative otorrhea of 9%. The remainder occurred 2 to 20 months after the HBO was completed. Otorrhea was bilateral in 5 of 13 cases. Treatment with topical antibiotics was initiated in all patients, and was successful in 10 of 13 cases. The remaining patients required systemic antibiotic therapy for resolution. Tube removal was necessary for eradication of infection in 4 patients.

Persistent perforations after tube extrusion developed in 7 patients. Bilateral perforations occurred in 1 patient. All perforations were present a minimum of 6 months after tube extrusion or removal. The duration of intubation in these cases was less than 3 months in 4 ears, 6 months in 1 ear, and 1 year in 1 ear. The exact duration of intubation was not certain in 2 patients who presented with large perforations (and no tube) more than 18 months after tube placement. Otorrhea had occurred in all but 1 of the ears with persistent perforation. One of these perforations subsequently healed.

At the last examination, 7 ears had perforations, the tubes remained in place in 32 ears, and the tympanic membrane was intact in 20 ears. Thirty ears were not examined, and 1 ear had a perforation before HBO was initiated. Thus, only 20 (74%) of 27 tympanic membranes healed completely after tube removal or extrusion. There were no attempts at surgical closure of the perforations. Reasons not to pursue surgical intervention included patient refusal, poor medical condition, and subsequent unavailability for follow-up. Persistent perforations were often the cause of hearing loss. The magnitude of additional hearing loss was not quantified, as formal audiometry was not performed in all cases. Individuals developed as much as 30 dB of conductive loss.

Interestingly, patients with diabetes mellitus had a higher incidence of complications. Fifteen (45%) of 33 patients with diabetes mellitus developed complications. In contrast, only 2 (17%) of the 12 patients without diabetes developed complications (P=.08).

COMMENT

Tympanostomy tubes are required for continuation of HBO in 1% to 21% of patients. Factors that may increase the incidence of barotrauma, and thus the need for tubes, include endotracheal intubation, preexisting eustachian tube dysfunction, and altered anatomy of the eustachian tube or nasopharynx. Patients with severe neurologic disease or mental retardation are also likely to develop barotrauma owing to an inability to learn proper autoinsufflation techniques. Treatment with topical and oral decongestants is thought to provide some benefit in alleviating symptoms of nasal congestion, allowing improved autoinsufflation.

The incidence of complications after the insertion of tympanostomy tubes has been widely studied. Early postoperative otorrhea develops in approximately 5% to 10% of patients. Several authors have noted an increased incidence when active infection is present at the time of tube placement, as indicated by culture or mucoid effusion. Otorrhea may occur at any time during intubation in approximately 20% of patients. Large-bore tubes and increasing duration of intubation are associated with a greater incidence of otorrhea. Luxford and Sheehy noted a lower incidence of otorrhea...
in patients with patulous eustachian tubes. Persistent perforations occur after tube extrusion in approximately 3% of patients.\textsuperscript{11,12,15} A greater incidence is also seen with large-bore tubes and Goode T tubes, both of which have a longer average duration of intubation than grommets, and with increasing atelectasis of the tympanic membrane.\textsuperscript{16-18}

In most of the reports cited, otorrhea could be controlled with topical antibiotics and occasional tube removal. Perforations have often been noted to spontaneously close with a longer period of observation. These studies conclude that minimal morbidity is associated with the procedure and that most complications resolve with limited treatment.

The above-mentioned studies, in general, focused on patients requiring tympanostomy tube insertion as treatment for middle ear infection. Failure of conservative treatment measures is necessary before operative intervention is considered; thus, individuals with greater impairment of eustachian tube function or recalcitrant infection become surgical candidates. Under these circumstances, development of recurrent infection in some patients is not surprising. In contrast, the patients in our study were usually free of middle ear infections before HBO was initiated. One might predict the incidence of otorrhea to be low, given the absence of a history of otitis media. However, this was not the case, as the incidence of otorrhea and persistent perforations was greater in nearly all of the above-mentioned studies. Our assumption, that patients who did not report problems or that those who were unavailable for follow-up remained free of complications, would have the effect of understating the actual incidence of complications.

Increased morbidity owing to chronic illness has been reported in patients with tympanostomy tubes.\textsuperscript{19,20} Patients with chronic otitis media with effusion associated with head and neck malignancies have a much greater incidence of persistent otorrhea after tympanostomy tube placement. In many cases, tube removal is necessary owing to unremitting drainage. Investigators have concluded that complications were more severe and more common in patients with head and neck malignancies and have advocated expectant management as an alternative treatment modality.\textsuperscript{19,20} Expectant management, however, is not an option in patients who require HBO and then experience eustachian tube dysfunction. Symptomatic relief must be provided to allow therapy to continue.

Unfortunately, complications as a result of tube placement occurred more often in patients treated for barotrauma than in patients who had otitis media with effusion. The rate of complications in patients who undergo HBO may be even greater than reported herein, as all patients without documented follow-up are assumed to be free of problems. Concurrent illness, such as diabetes mellitus, may be a factor in the increased complications seen in patients who undergo HBO. Patients with diabetes are predisposed to the development of infections and are known to display poor wound healing.\textsuperscript{21,22} An increased risk of complications in diabetic patients undergoing otologic surgical procedures has not been confirmed. However, animals with chemically induced or congenital diabetes that undergo partial excision of the tympanic membrane have a greater incidence of otorrhea and exhibit delayed closure of the perforation.

The duration of intubation may also play a role in the development of complications. Patients undergoing HBO develop eustachian tube dysfunction secondary to the treatment, but they require assistance with middle ear ventilation only for the duration of the therapy. At our institution, HBO averages 4 weeks. Most of the complications in this series became evident after the completion of HBO. Thus, the application of hyperbaric oxygen is not thought to play a role in the development of complications. A shorter duration of intubation may be beneficial in reducing complications of tympanostomy in this patient population. We are currently performing a prospective trial of short-term tympanostomy techniques to address this issue.

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REFERENCES