RESEARCH ARTICLE

Proof of concept study using a modified Politzer inflation device as a rescue modality for treating Eustachian tube dysfunction during hyperbaric oxygen treatment in a multiplace (Class A) chamber

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ABSTRACT

Introduction: Eustachian tube dysfunction (ETD) and middle ear barotrauma (MEB) are the most common adverse effects of hyperbaric oxygen (HBO_2) treatments. Patients practice equalization maneuvers to prevent ETD and MEB prior to hyperbaric exposure. Some patients are still unable to equalize middle ear pressure. This ETD results in undesirable consequences, including barotrauma, treatment with medications or surgical myringotomy with tube placement and interruption of HBO_2. When additional medications and myringotomy are employed, they are associated with additional complications.

Methods: A device known as the Ear Popper® has been reported to reduce complications from serous otitis media and reduce the need for surgical interventions (myringotomy). Patients unable to equalize middle ear pressure during initial compression in the hyperbaric chamber were allowed to use the device for rescue. All hyperbaric treatments were compressed using a United States Navy TT9, or a 45-fsw hyperbaric treatment schedule. Patients with persistent ETD and the inability to equalize middle ear pressure were given the Ear Popper upon consideration of terminating their treatment.

Results: The Ear Popper allowed all patients to successfully equalize middle ear pressure and complete their treatments.

Conclusion: This study substantiates the use of this device to assist in allowing pressurization of the middle ear space in patients otherwise unable to achieve equalization of middle ear pressure during HBO_2 treatment in a multiplace chamber.

INTRODUCTION

Hyperbaric oxygen (HBO_2) treatment is associated with few significant adverse effects [1,2]. Eustachian tube dysfunction (ETD) and middle ear barotrauma (MEB) are the most frequent complications experienced when a patient is pressurized during HBO_2 treatment [3,4,5,6]. This complication often results in elective treatments being canceled and rescheduled due to the patient's inability to equalize middle ear pressure. Barotrauma potentially occurs, requiring treatment with certain pharmaceuticals and surgery, such as a myringotomy and placement of ventilation tubes [7]. Primary and secondary etiologies causing ETD and MEB have been described [5]. Equalizing the middle ear pressure is more complex than originally believed and involves a combination of simultaneous functions, including ventilation or opening of the Eustachian tube (ET), mucosal gas diffusion and the buffering effect supplied by the mastoid cells [8,9]. During HBO_2 treatments, a rapid change and increase in the atmospheric pressure places more demand at the orifice of the ET and subsequently can affect its ability to equalize pressure in the middle ear space via ventilation.

Similar ventilatory stress is placed on the ET during extreme atmospheric pressure shifts experienced when scuba diving, flying in a pressurized aircraft and pressure shifts also encountered in a hypo/hyperbaric chamber. During any of these rapid changes in the atmospheric pressure a significant demand is shifted to the ET to increase ventilation [10]. Various pathophysiologic mechanisms of ETD and MEB have been described in addition to the methods to reduce ETD and MEB

KEYWORDS: barotrauma; ear barotrauma; Eustachian tube dysfunction; hyperbaric oxygen; middle ear; ONeill Grading System; pressure

Table 1

Equalization methods and techniques	Description of the action
passive equalization	requires no effort
voluntary tubal opening	tense the throat and push the jaw forward
Toynbee maneuver	pinch the nostrils closed and swallow
Frenzel maneuver	pinch the nostrils closed and make the letter "K" sound
Lowery technique	pinch the nostrils closed, blow and swallow
Edmonds technique	pinch the nose and blow and push the jaw forward

adapted from Divers Alert Network

[5,11]. These comprise various methods, including changes in the rate of compression to allow attainment of treatment depth [12,13]. Additionally, various potential risk factors associated with the development of ETD and MEB in a multiplace hyperbaric chamber have been reported and defined below [14].

Prior to hyperbaric treatments patients are educated regarding ETD and MEB. They are taught various techniques to overcome rapid changes in atmospheric pressure during chamber pressurization [15]. The maneuvers listed in Table 1 are practiced by patients prior to treatment and are actively employed during chamber compression in our center. Additionally, the chamber pressure is reduced after a patient has had a hold, to allow the middle ear pressure to equalize. We use ascents in segments of 2 fsw as necessary to allow the patient to clear unassisted.

Various etiologies for the inability to equalize pressure in the middle ear space despite using these maneuvers are multifactorial and are categorized as Type I and Type II ETD [5]. For this paper, Type I is defined as ETD caused solely by the increased atmospheric pressure and inability to ventilate the middle ear space without any contributory pathologic Type II processes. Upper respiratory infections, potential soft tissue damage of the ET related to prior radiation therapy, and throat surgery encompassing the ET orifice are all examples of Type II pathologies that may have a negative effect on ventilation of the ET and middle ear space. Type I ETD is caused by the inability of the ET to overcome the extreme changes in atmospheric pressure. Patients may not be able to comprehend, cooperate and perform the equalization maneuvers required to ventilate the middle ear space. Excluding all Type II ETD etiologies, Type I ETD may be due to various levels of anxiety and apprehension associated with the first days of treatment. Equalizing middle ear pressure is most common during the first three treatments [5]. Identification of ETD prior to treatment does not predict a patient's ability or inability to equalize middle ear pressure during treatment [16].

Adam Politzer was a Hungarian-born physician (1835) and graduated from medical school in Vienna, Austria (1859). He is considered one of the fathers of otology [17]. The Politzer maneuver which bears his name is the act of forcing air up the nostrils while swallowing for the purpose of opening the ET and ventilating the middle ear space and sinuses. The Ear Popper® (Popper) is a device that simplifies this maneuver. The device is manufactured by Summit Medical, Inc. The Popper was compared for efficacy in a prospective analysis versus the Toynbee and Valsalva maneuvers in a study by Hidir in 2011. There was no statistical significance identified between the three maneuvers. However, when groups were separately compared, the Popper was more effective in those with a completely normal tympanic membrane (TM) and ventilation prior to the study [15]. Additionally, Silman and Arick used the Politzer-inspired device to manage serous otitis media with success and decrease the need for surgical intervention in the pediatric population [20,21].

These positive results in the pediatric population suggested a potential use for the Popper as a rescue device for patients unable to equalize middle ear pressure during hyperbaric treatment. The device could prove useful to overcome Type I ETD after all the usual ventilation maneuvers are exhausted and treatment termination imminent. The Popper might allow patients to be rescued from treatment termination, achieve required treatment depth and preserve the treatment schedule in doing so. Additionally, the success of the Popper may reduce the incidence of MEB and the unnecessary use of pharmaceutical and surgical modalities typically ordered to prevent Type I ETD.

Based on this, we set out to demonstrate proof of

The Ear Popper® manufactured by Summit Medical isenergized with 4 AAA non-offgassing batteries enclosed in a hard plastic casing.

Photo demonstrating the correct use of the Popper.

concept. Using the Popper would be beneficial in achieving ventilation of the middle ear space in patients otherwise having difficulty equalizing middle ear pressure during routine hyperbaric treatment compression to 45 fsw (U.S. Navy Treatment Table 9) in a multiplace chamber environment.

MATERIALS AND METHODS

All patients being treated in our multiplace hyperbaric chamber facility were included in this proof-of-concept study. Those patients having difficulty equalizing middle ear pressure on compression were allowed to use the Popper, shown in Photo 1.

All 12 patients were considered to have Type I ETD, as they had no additional pathologies to cause ETD. The device is powered using 4 AAA batteries, enclosed in a plastic casing, and considered safe for multiplace hyperbaric operations in our chamber. Our team evaluated the device for safety and function in the hyperbaric chamber, employing our usual safety protocols for new devices introduced to the hyperbaric environment. The device is intended for one-patient use by the company; however, the tips are removable, disposable and replaceable. One Popper disposable head was assigned to each patient throughout their treatments and maintained in a plastic sealed bag identified with the patient's name. After use, the Popper head was removed and placed into the patient's identification bag at the end of treatment. Poppers were not shared by any other patient during that treatment. The Popper itself was cleaned and sanitized with PDI germicidal disposable wipes and/or benzalkonium chloride antiseptic towelettes after each treatment.

Patients hold the Popper in one hand and tamponade the nasal opening on one side with the disposable head, while tamponing the other nostril with a finger of the opposite hand, whereby closing off the nares. They then close the mouth tightly and swallow while activating the Popper. This is accomplished easily by pressing a button with the hand supporting the popper. A higher pressure burst of air is continuously released as the patient swallows. For those patients who cannot accomplish the task, the Popper can be held and operated by the inside observer while the patient is encouraged to swallow. All 12 patients who initially used the device could operate it without inside observer assistance.

Twelve adults, – seven males and five females – were the first patients to use the Popper. They had a mean age of 65 years (range 36-81 years) and required the use of the modified Politzer device (Popper) in an attempt to rescue their hyperbaric treatment rather than the alternative of canceling treatment. Baseline pretreatment photographs of the TM and then video of TM mobility during ventilation maneuvers were completed for all patients treated as per our usual and customary protocol using the O'Neill grading system for ETD and MEB [5].

The usual compression rate was set at 3 feet per minute (15-minute compression to 45 fsw). The usual protocol also included an immediate halt in compression for any patient experiencing equalization difficulty. If compression is halted, the patient is allowed the opportunity to equalize middle ear pressure using various ventilation maneuvers commonly employed (Toynbee, Frenzel, Valsalva, etc.). The maneuvers determined best for each individual patient were based on the subjective sensation of effective and successful ventilation at atmospheric pressure prior to compression. Their specific equalization maneuvers were repeated following a 2-fsw

Table 2. Pressure changes and their effects on the tympanic membrane

feet of seawater (fsw)	EFFECT OF INCREASED ATMOSPHERIC PRESSURE ON THE TYMPANIC MEMBRANE AND MIDDLE EAR SPACE
1 fsw	At 1 foot below the surface, water pressure against the outside of your eardrums is 0.445 psi more than on the surface air pressure on the inside. They flex inward, and you feel pressure in your ears.
4 fsw	At 4 feet the pressure difference increases to 1.78 psi. Your eardrums bulge into your middle ears; so do the round windows and oval windows between your middle and inner ears. Nerve endings in your eardrum are stretched. You begin to feel pain.
6 fsw	At 6 feet the pressure difference is 2.67 psi. Your eardrum stretches further. Its tissues begin to tear, causing inflammation that will last up to a week. Small blood vessels in your eardrums may expand or break, causing bruising which will last up to three weeks. Your Eustachian tubes are now locked shut by pressure, making equalization impossible. Pain increases.
8 fsw	At 8 feet the pressure difference is 3.56 psi. If you are lucky, blood and mucus is sucked from surrounding tissues and begins to fill your middle ear. This is called middle ear barotrauma. Fluid, not air, now equalizes pressure on your eardrums. Pain subsides, replaced by a feeling of fullness in your ears which will remain for a week or more until the fluid is reabsorbed by your body.
10 fsw	At 10 feet the pressure difference is 4.45 psi. If you aren't so lucky – if your descent is very fast, for example –your eardrums may break. Water will flood your middle ear. The sudden sensation of cold against your balance mechanism (vestibular canals) may cause vertigo, especially if only one eardrum ruptures. Suddenly, the world is spinning around you, though the sensation will probably stop when your body warms up the water in your middle ear. Or, if you try to equalize by blowing hard and long against pinched nostrils, you may rupture the round window membrane between your middle and inner ears. This is called inner ear barotrauma. Perilymph fluid drains from the cochlea into the middle ear. Temporary or sometimes permanent, hearing loss may result.

adapted and modified from Divers Alert Network

chamber ascent for equalization difficulty. When these methods failed to achieve adequate ventilation and equalization of middle ear pressure after three attempts, the study device (Ear Popper) was employed prior to the decision to terminate the patient's treatment and return to normal atmospheric pressure.

RESULTS

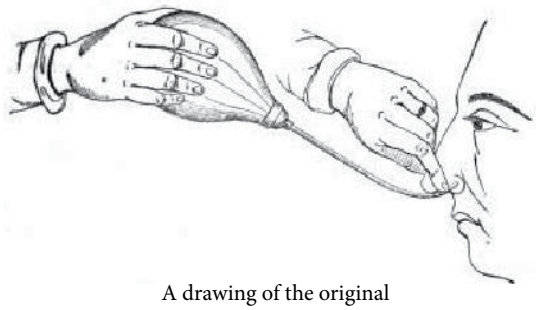
The proof of concept for using the Ear Popper as a rescue device to facilitate ventilation of the middle ear space was realized after its use on the first 12 patients. All 12 patients met the established study protocol described for using the rescue device.

Prior to terminating a treatment for failure to equalize middle ear pressure, all 12 patients were able to effectively clear the pressure in the middle ear space using the device. Treatment termination was successfully avoided by using the device, and all 12 patients completed their treatments uneventfully. Based on this observation and considering study ethics [20], the rescue device had an apparent 100% effectiveness without adverse outcomes or secondary effects. We are continuing to collect additional information on the use of this device, such as its continued efficacy, cost and secondary effects. Our group determined its short-term efficacy was significant enough to continue using it as a rescue device. It appears more suitable than the usual and customary equalization maneuvers used in our ETD protocol after stopping compression as described previously. The early results demonstrated by using the device on these first 12 patients seemed apparent that the device served well to alleviate ETD andMEB, rescuing all of them from treatment termination.

DISCUSSION

Attempts at seeking solutions to prevent ETD and MEB are rarely reported despite the frequency and commonality in which they are encountered by patients traversing a course of hyperbaric oxygen treatment. Divers Alert Network has nicely and simply outlined the physiologic and anatomic effects of various depths and pressures associated with ETD and MEB, as shown in Table 2.

Dr. Adam Politzer
https://en.wikipedia.org/wiki/Ádám_Politzer



A drawing of the original
Politzer method.
https://en.wikipedia.org/wiki/Politzerization

As hyperbaric team members, we frequently teach the usual and customary methods to facilitate ventilation of the middle ear space, including various maneuvers such as the Valsalva (developed in 1704), and the Toynbee maneuver (1853). Another commonly taught method to alleviate middle ear pressure is the Frenzel maneuver, developed in 1938.

All the conventional maneuvers to facilitate middle ear ventilation and treatment of otitis media are nicely outlined in a publication by Stangerup in 1998 [9]. All equalization modalities currently used as the mainstay of circumventing ETD and MEB during hyperbaric oxygen treatment have not been evaluated by formal scientific studies such as randomized controlled trials (RCTs) despite their apparent efficacy in clinical practice. We continue to teach our patients these modalities despite the lack of evidence linked to their efficacy as the anatomy and mechanics make sense and there is relatively little else to offer them.

Background

The Politzer maneuver was initially developed by Dr. Adam Politzer in 1853 [17] (pictured). In honor of Dr. Politzer, his name is associated with the International Society of Otology, founded in 1978 as described by Dr. Albert Mudry in a historical publication entitled 'The Role of Adam Politzer' (1835-1920) in the *History of Otology* [17]. In his writings, Politzer covered all areas of otology known at the time, although his favorite was the anatomical pathology of the ear. He first described a maneuver which entailed forcing air into a patient's nostrils through a tube connected to a bulb syringe; the air flow out from the nostrils was occluded while the patient swallowed. In his day, this was referred to as the "Politzerization" method and is depicted in Figure 1 [17].

Dr. Politzer's method was modified by Drs. Arick and Silman in 2000 through the development of a portable device they called the Ear Popper [21]. The device was quite successful in preventing the need for surgical intervention (ventilation tubes) and improving hearing thresholds in pediatric patients with serous otitis. Arick and Silman performed a two-part study looking at the non-surgical treatment of middle ear effusion (serous otitis). The findings demonstrated that their modified Politzer device was significantly effective in improving hearing and decreasing the need for surgery in this group of children. This further supports its use to overcome middle ear space ventilation difficulty, most often experienced by children [22].

This physiologic concept of positive pressure facilitating the opening of the ET and increasing middle ear pressure is not new. Adding to Dr. Politzer's experiments is the concept similar to that seen with patients receiving continuous positive airway pressure (CPAP). CPAP has also been demonstrated to cause a significant rise in middle ear pressure (positive middle ear pressure) by opening the orifice of the ET and forcing positive pressure into the middle ear space [23]. This device creates similar physiologic changes in middle ear pressure as demonstrated by both Politzer and pulmonary physiologists of modern day. The modified Politzer device creates an easy and modified way to reproduce these actions and facilitates middle ear positive pressurization.

CONCLUSION

Our group attempted to prove the concept of utilizing a modified Politzer device to rescue patients from hyperbaric treatment termination due to their inability to equalize middle ear pressure. We demonstrated the concept of using the device to be successful in all 12 patients requiring its use to compress and overcome ETD, representing a 100% efficacy rate among these 12 patients. As we continue our ongoing proof-of-concept data collection using this device as a rescue modality for our hyperbaric patients, we will continue to update and report our findings.

In the meantime, its relatively low cost per patient as compared to the alternatives (treatment termination, medication and surgery) appears to justify its continued use as a rescue device. As technology continues to improve we must investigate its potential to better assist our patients. We cannot become complacent as hyperbaracists. We need to continue providing our patients with better and more beneficial alternatives to patient care. This includes simple solutions such as using a modified Politzer device to improve middle ear ventilation.

This study has demonstrated the potential benefit offered by this device, making middle ear equalization less difficult during hyperbaric pressurization in a multiplace chamber and potentially decreasing the number of aborted hyperbaric treatments due to ETD.

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The authors report that no conflicts of interest exist with this submission.

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