Eustachian tube balloon dilation in treatment of equalization problems of freediving spearfishermen

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Key words
ENT; Ear barotrauma; Diving; Treatment; Outcome

Abstract
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Background: Eustachian tube balloon dilation is a minimally invasive surgical procedure used to treat Eustachian tube dysfunction which is not responsive to conventional therapies.
Methods: In this cohort intervention series we report the results of balloon dilation in treating refractory equalization problems in 20 freediving spearfishermen; in 19 cases the problem was unilateral and in one case bilateral. All the patients had already received medical and insufflation therapy and four patients had also had nasal surgery. None of these treatments or procedures had achieved improvement. We used a 20 mm x 3 mm disposable balloon catheter inserted through a 70-degree guide catheter and inflated up to 12 ATM three times at three different depths of insertion within the Eustachian tube. Every inflation lasted 120 seconds.
Results: Fifteen out of 20 patients improved. Ten patients reported a complete resolution of equalization problems, five showed improvement with persistence of a slight equalization delay on the treated side. Five patients did not report any improvement. Two complications occurred: subcutaneous emphysema of the parotid region in one case; and a mild high frequency (4–8 KHz) sensorineural hearing loss in another patient.
Conclusion: Balloon dilation of the Eustachian tube is an effective therapy in the treatment of equalization problems with a good success rate.

Introduction

The Eustachian tube (ET) is a complex structure connecting the middle ear to the nasopharynx. It is approximately 44 mm in length and includes a medial cartilaginous portion (two thirds) and a lateral bony part (one third).[1] Normally the tube is collapsed at rest and it opens during swallowing thanks to the paratubal muscles, primarily tensor veli palatini and secondarily levator veli palatini.[2,3] This involuntary opening of the tube happens 1.4 times each minute for about 0.4 s and allows the middle ear pressure to be balanced with the ambient pressure.[4] It is also possible to voluntarily open the ET to counterbalance acute changes in ambient pressure by swallowing or yawning, and to increase or decrease nasopharyngeal pressure creating an air flow through the tube by maneuvers like Valsalva, Toynbee, Marcante-Odaglia, sniffing, etc.

ET dysfunction is defined by the presence of pressure dysregulation in the middle ear, with chronic dysfunction diagnosed when this is present for at least three months.[5] If the dysfunction is mild, symptoms like aural fullness, popping or pain occur. In more severe cases, other middle ear diseases may develop (e.g., otitis media with effusion, chronic suppurative otitis media, retraction pocket on the tympanic membrane (TM) and cholesteatoma). ET dysfunction during substantial barometric change, commonly seen with flying or diving,[5] can lead to barotrauma, which is damage to the middle or inner ear structures caused by ineffective equalization of middle ear pressure. There are many different tests for assessing ET function but evidence for their use is weak. There have also been also many attempts to develop objective tests but no single test has been found to be a reliable diagnostic tool.[1]

Tympanometry is the simplest and most widely available test. It uses the application of pressure in the external ear canal and records a chart called a tympanogram that displays TM compliance. Most commonly observed tympanogram types are the following: type A, considered normal; type B, most commonly considered expression of middle ear effusion; and type C, considered a manifestation of negative pressure in the middle ear usually due to ET dysfunction. The value of this test to diagnose ET dysfunction is poor

Table 1
Equalization problems (EP) score

Description	EP score
Perfect equalization	0
Equalization possible and effective but slight difference between the ears (no middle ear barotrauma reported even after many dives and/or many days of diving)	1
Equalization possible but ineffective (middle ear barotrauma after few dives)	2
Equalization not possible	3

since middle ear pressure varies considerably over time and, therefore, one single measure is of limited relevance.[6] When tympanometry is used to measure compliance changes after manoeuvres like Valsalva or Toynbee or after sniffing, sensitivity for ET dysfunction is reported to be higher.[7,8] The nine-step inflation/deflation test was found to be the most efficient test with the highest predictive value as a predictor of middle ear barotrauma, especially in scuba divers.[9] Other tests, such as tubomanometry and sonotubometry, although interesting, did not demonstrate optimal sensitivity and specificity and imaging techniques are not recommended as part of a routine assessment of ET function.[1]

Patient questionnaires offer an attractive method to assess the symptoms that are seen in ET dysfunction. The ETDQ-7 was developed by assessing the differences between the answers to a set of questions between cases with ET dysfunction and controls.[10] A German translation of ETDQ-7 showed very high sensitivity and specificity that outperformed any of the objective tests described.[11]

Therapy for ET dysfunction is not completely standardized yet. Currently, no medical therapies have shown efficacy[12] even though the use of antibiotics and/or steroids as first-line treatment is very common. Despite the widespread use of ventilation tubes (grommets), there are no studies published evaluating their efficacy.[12] LASER tuboplasty and balloon dilation of the nasopharyngeal entrance of the ET are two surgical procedures that are becoming increasingly popular, with many published series reporting good results and a low complication rate.[13–17] A comparison between the two techniques concluded that both procedures can improve symptoms of ET dysfunction but could not clarify if there is one that provides greater benefits.[18]

In this paper, the results are reported of balloon dilation in treating equalization problems of 20 freediving spearfishermen. To our knowledge, this is the first study conducted on this particular patient population.

Methods

From October 2012 until May 2015, balloon catheter dilation of the cartilaginous portion of the ET was offered to 20 freediving spearfishermen who complained of equalization problems (EP) during freediving and had experienced multiple episodes of middle ear barotrauma. All the patients were amateurs who used to dive at least twice a week, all year long and were symptomatic for at least for one year, but did not show any symptoms in their everyday life. Exclusion criteria were age less than 18 and more than 65 years, evidence of other diseases that could explain the complaint and the impossibility of follow up of the patient and/or to collect a detailed history.

All 20 patients had been treated medically (oral and/or intravenous antibiotics and steroids) already and received insufflation therapy (Politzer, catheter insufflation, Otovent®) without improvement. Four patients had also received surgical treatment; inferior turbinate reduction in two cases, septoplasty and inferior turbinate reduction in one case and a combined procedure including septoplasty, inferior turbinate reduction and endoscopic sinus surgery in the fourth case. In all four, surgery did not provide symptom relief, whilst the patient who had the combined surgery experienced worsening of the symptoms, with fullness and the presence of a Type C or B tympanogram even in daily life.

In 19 cases, the problem was unilateral (left side in 11 cases and right in eight) and in one bilateral case. Patients' ET function was scored using a four-stage system (0 – normal equalization, to 4 – equalization not possible, Table 1) called the *EP score*. A diagnosis of middle ear barotrauma was only accepted when made by a physician.

Before the intervention, all the patients were evaluated with a detailed interview, a complete ear, nose and throat (ENT) examination using a microscope to assess the TM and a fiberoptic flexible endoscope to assess the nasal cavities, nasopharynx and ET orifices. All patients also had a hearing test, tympanometry, an acoustic reflexes test and a tympanometric assessment of ET function using the nine-step inflation/deflation test.

At this preoperative assessment, all but two patients had normal hearing, type A tympanogram on tympanometry, normal acoustic reflexes and no pathology on clinical examination. One patient had bilateral conductive hearing loss from otosclerosis. The patient who had undergone the combined surgery and came to our attention for left-sided equalization problems had slight left conductive hearing loss, a B tympanogram on the left side, left TM retraction and inferior turbinate asymmetry (left > right) from the previous surgery. This patient also had a high frequency sensorineural hearing loss on the right side from a previous (three years before) inner ear barotrauma. Interestingly he did not report equalization problems on that side except for that particular

Table 2
Results of clinical assessment of 20 patients. TM = tympanic membrane; R = right; L = left

Patient	Affected side	Clinical assessment	Hearing test	Tympanometry and acoustic reflex test	Eustachian tube function test	EP score on affected side
1	Right	Nothing to report	Normal hearing	Bilateral type A Normal reflexes	Right dysfunction	2
2	Left	Nothing to report	Normal hearing	Bilateral type A Normal reflexes	Left dysfunction	2
3	Bilateral	Nothing to report	Normal hearing	Bilateral type A tympanogram	Bilateral normal	3 (bilateral)
4	Right	Nothing to report	Normal hearing	Bilateral type A Normal reflexes	Bilateral normal	2
5	Right	Nothing to report	Normal hearing	Bilateral type A Normal reflexes	Bilateral normal	2
6	Left	Nothing to report	Normal hearing	Bilateral type A Normal reflexes	Bilateral normal	2
7	Right	Nothing to report	Normal hearing	Bilateral type A Normal reflexes	Bilateral normal	2
8	Left	Nothing to report	Bilateral conductive loss (otosclerosis)	Bilateral type A Absent reflexes	Left dysfunction	2
9	Left	Nothing to report	Normal hearing	Bilateral type A Absent reflexes	Left dysfunction	2
10	Left	TM retraction L>R Inferior turbinate asymmetry L>R	Mild L conductive hearing loss R high frequency sensorineural loss.	Type C/B on L Type A on R	Left dysfunction	3
11	Right	Nothing to report	Normal hearing	Bilateral type A	Right dysfunction	2
12	Right	Nothing to report	Normal hearing	Bilateral type A	Right dysfunction	2
13	Left	Nothing to report	Normal hearing	Bilateral type A	Left dysfunction	2
14	Left	Nothing to report	Normal hearing	Bilateral type A	Bilateral normal	2
15	Right	Nothing to report	Normal hearing	Bilateral type A	Right dysfunction	2
16	Left	Nothing to report	Normal hearing	Bilateral type A	Bilateral normal	2
17	Left	Nothing to report	Normal hearing	Bilateral type A	Bilateral normal	2
18	Right	Nothing to report	Normal hearing	Bilateral type A	Bilateral normal	3
19	Left	Nothing to report	Normal hearing	Bilateral type A	Left dysfunction	2
20	Left	Nothing to report	Normal hearing	Bilateral type A	Left dysfunction	2

Figure 1
The guide catheter is directed toward the nasopharyngeal Eustachian tube orifice under endoscopic control. **a.** Nasopharynx. **b.** Eustachian tube orifice. **c.** Guide catheter

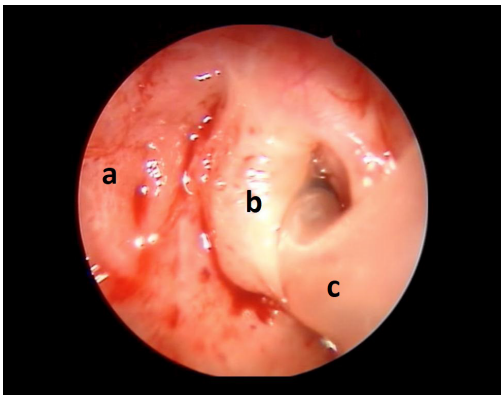


Figure 2
Balloon catheter inflated inside the Eustachian tube. **a.** Nasopharynx. **b.** Eustachian tube orifice. **c.** Guide catheter. **d.** Inflated balloon

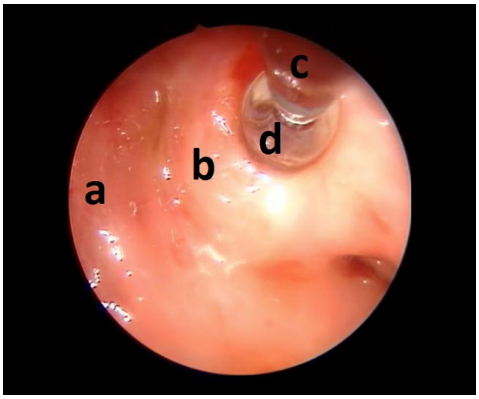
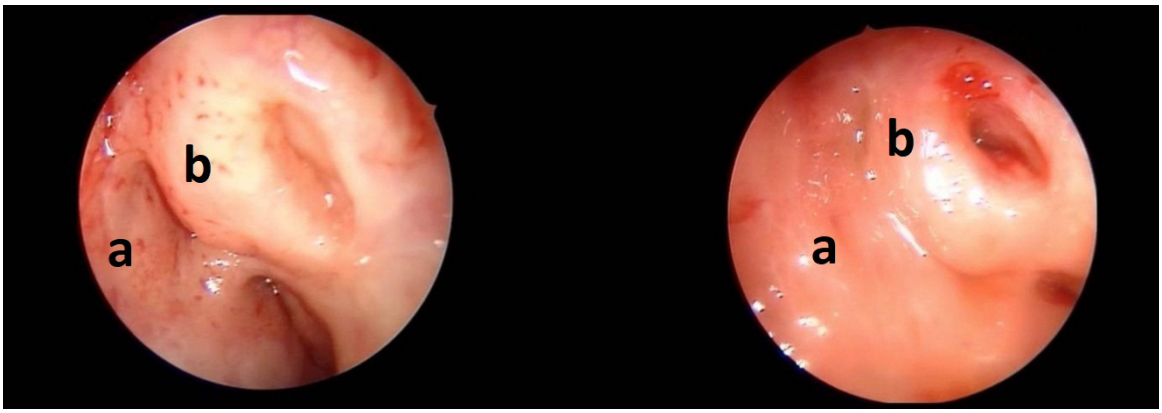


Figure 3
Eustachian tube appearance before (left) and after (right) the procedure. **a.** Nasopharynx. **b.** Eustachian tube orifice



episode. Tympanometric assessment of ET function revealed dysfunction on the affected side in 11 patients and normal function in nine (Table 2).

All patients were fully informed about the procedure and signed an informed consent approved by our hospital. We used a 20 mm x 3 mm disposable balloon catheter inserted through a 70-degree guide catheter (Spiggle & Theis, Overath, Germany). The procedures were carried out as follows:

- general anaesthesia induction;
- introduction of 4.0 mm diameter, 45 degree view endoscope in the contralateral nasal cavity and nasopharyngeal ET orifice visualization;
- guide catheter introduction in the ipsilateral nasal cavity;
- introduction of the balloon catheter in the ET (Figure 1);
- execution of three 12 ATM (balloon pressure) dilations at three different depths (balloon catheter completely inserted and no more visible at the orifice level; balloon catheter completely inserted but visible at the orifice level; balloon catheter partially inserted) of 120 seconds each (Figure 2);
- balloon catheter removal and final check (Figure 3).

Results

All the patients were discharged the day after surgery with an oral antibiotic and steroid therapy, mostly prednisone 25 mg daily and amoxicillin/clavulanic acid 875/125 mg twice daily for one week and re-examined after 7–10 days postoperatively. All were advised not to dive until after the postoperative examination but they were allowed to perform delicate Valsalva manoeuvres many times a day.

Eighteen patients had an uncomplicated postoperative recovery. One patient had subcutaneous emphysema of the parotid region on the first postoperative day following a Valsalva maneuver. The patient was temporarily forbidden from performing Valsalvas again and the emphysema resolved after four days without additional treatment. The patient who presented with a preoperative left B tympanogram and a right sensorineural hearing loss developed acute otitis media on the treated (left) side two

Table 3
Results of Eustachian tube balloon dilation in 20 freedivers

Case	Affected side	Pre-op EP score	Post-op EP score
1	Right	2	0
2	Left	2	0
3	Bilateral	3, 3	3, 3
4	Right	2	1
5	Right	2	1
6	Left	2	0
7	Right	2	2
8	Left	2	0
9	Left	2	2
10	Left	3	1
11	Right	2	0
12	Right	2	1
13	Left	2	0
14	Left	2	0
15	Right	2	1
16	Left	2	2
17	Left	2	0
18	Right	3	0
19	Left	2	2
20	Left	2	0

days after the procedure. This resolved within seven days with medical therapy but resulted in tinnitus and slight high frequencies (4–8 KHz) sensorineural hearing loss exactly the same as on the contralateral side. Neither prolonged intravenous and oral steroid therapy nor hyperbaric oxygen therapy were effective.

Fifteen out of 20 patients showed improvement or resolution of the equalization problems (Table 3). Ten patients reported complete resolution of the problem; nine patients went from an EP score of 2 to a score of zero and one from EP score 3 to a score of zero. Five patients reported an improvement with persistence of a slight equalization delay on the treated side, four going from EP 2 to 1 and one from 3 to 1 (the patient with preoperative B tympanogram and EP score 3 who suffered from postoperative acute otitis media). After the procedure he exhibited a type A tympanogram. Five patients did not report any improvement; four with a preoperative EP score of 2 and one preoperative score of 3 (Table 3).

After a follow-up period ranging from 19 to 50 months, the above reported results remained stable.

Discussion

In this paper the results are presented of ET balloon dilation in 20 freediving spearfishermen with equalization problems, of whom 18 had normal hearing and were completely asymptomatic in their everyday life. To our knowledge, this paper is the first to consider this particular population, since other authors have enrolled only patients with chronic symptoms and who were not subject to fast barometric pressure changes.

ET balloon dilation is a minimally invasive procedure used to treat ET dysfunction that is not responsive to conventional, non-invasive therapies. The procedure is carried out through the nasal cavities with endoscopic visualization of the nasopharyngeal ET orifice and introduction of a balloon catheter, which is inflated up to variable pressures of 5–12 ATM and left in place for a varing time; most surgeons performing each dilation for 30–120 seconds at 10–12 ATM balloon pressure.[19,20,21] A success rate of 70–87% and stable results up to three years have been reported.[17,20,22] The procedure is fast, easy and safe since the only complication, rarely reported, is subcutaneous emphysema that resolves spontaneously.[22,23] Extratubal structural damage or a patulous ET have not been reported in cadaveric or in clinical studies.[17,19,24,25]

No particular preoperative radiological examination is necessary, based on the evaluation of CT scan images of 1,000 patients (2,000 temporal bones).[26] No internal carotid artery anomalies or defects of the osseous portion of the ET were found.[26] However, a very detailed interview, clinical examination, hearing test, tympanometry and ET function tests are mandatory. Making a correct diagnosis of ET dysfunction is difficult because of the lack of a test with high levels of specificity and sensitivity.[1] For this reason diagnostic questionnaires have been developed with the ETDQ-7 being the most popular and reliable.[10,11] The ETDQ-7 was not a good tool for our study since it considers symptoms that are present in everyday life and not just during a specific activity like freediving. When administered to these 20 patients, it was inconclusive. Therefore, a new four-step scoring system was devised (the 'EP score') to categorize equalization difficulties during freediving.

Although LASER tuboplasty has shown good results, balloon dilation was chosen because of our familiarity with the routine use of balloons in endoscopic sinus surgery. Also, the formation of peritubal adhesions are sometimes reported after LASER tuboplasty,[13] but never after balloon dilation. Using a 20 x 3 mm balloon catheter inflated to 12 ATM to perform three consecutive dilations at different depths within the ET, 120 seconds for each dilation appears to be an adequate time to obtain a good dilation without risking mucosal ischaemia. The three dilations at different depths ensure the treatment of the cartilaginous portion of the ET for its entire length. The 75% success rate

(15 of 20 divers) is similar to that reported by other authors in treating patients with ET dysfunction and chronic symptoms.[20,22,25]

However, there were more complications in this series than was hoped for, with both a case of subcutaneous emphysema and one of acute otitis media which resulted in a high frequency sensorineural hearing loss and tinnitus on the treated side. In both cases the procedure was straightforward and no difficulties were noted during balloon insertion. The subcutaneous emphysema could be explained by a small unseen mucosal tear as already reported by other authors,[27] but it is not clear how the otitis media and the resulting hearing loss could occur. A barotrauma caused by a Valsalva manoeuvre performed by the patient in the postoperative period or by an inadvertent movement of the inflated balloon during the procedure could explain this. Indeed, this patient had a contralateral inner ear barotrauma three years before, which resulted in a sensorineural hearing loss identical to the one experienced on the treated side after the surgery. Why this patient developed inner ear damage is not clear since a CT scan performed after the surgery did not highlight any temporal bone anomaly. Also, although he suffered from multiple middle ear barotrauma on the affected side, there was never inner ear involvement. Even if a sensorineural hearing loss after balloon dilation is considered an exceptional event, it should always be kept in mind during the procedure and patients should be informed of this potential complication.

Conclusion

Although this study has some limitations, such as a relatively small number of patients and questionnaire-based results, balloon dilation of the Eustachian tube appears to be an effective therapy in the treatment of persistent equalization problems in divers. However, it is an invasive procedure that may have complications. This should be considered especially when treating patients who are, in the majority of cases, symptom-free in their everyday life. Therefore, ET balloon dilation should be reserved for patients who have failed to respond to alternative non-invasive therapies. It should be performed by experienced surgeons in the most delicate and atraumatic way.

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