HNO 2017 · 65:840–847
DOI 10.1007/s00106-017-0346-8
Published online: 30 March 2017


L. Di Rienzo Businco[1] · A. Di Mario[2] · M. Tombolini[2] · A. Mattei[3] · M. Lauriello[4]

[1] Otorhinolaryngology Unit, S. Spirito Hospital, Rome, Italy
[2] Otorhinolaryngology Unit, S. Volto Clinic, Rome, Italy
[3] Department of Life, Health and Environmental Sciences, University of L'Aquila, L'Aquila, Italy
[4] Department of Experimental Medicine, University of L'Aquila, L'Aquila, Italy

# Eustachian tuboplasty and shrinkage of ostial mucosa with new devices

## Including a proposal of a classification system

**Treatment of Eustachian tube dysfunction (ETD) is challenging, and further confounded by the lack of a classification system. ETD is often underestimated; the results of impedance audiometry and other oto-functional examinations may be inconclusive, and diverse case histories render classification difficult. An anatomoclinical classification of ETD termed "hypertrophy-degeneration-synechiae" (HDS) has been conceived to homogeneously and reproducibly classify patients, thus making comparative studies on the efficacy of proposed treatments at different clinical sites possible.**

## Introduction

Eustachian Tube Dysfunction (ETD due to obstruction is a pathologic condition frequently found in pediatric patients (incidence 1–5%; 40% of children aged up to 10 years, even if only temporary), but which may also persist into adulthood [1]. The large increase in air travel and the high-speed trains that are becoming widespread in Western countries in the third millennium have definitely favored the incidence of ETD cases, due to more frequent exposure to pressure changes and longer stays in confined spaces without air circulation, such as these modern means of transport. On the one hand, the characteristics of the latter have enabled the emergence of certain subclinical tube dysfunctions that were previously asymptomatic because of patients' lack of or limited exposure to sudden pressure changes, and on the other, they have led to an increased incidence of inflammation of the upper airways (caused by interhuman bacterial or viral infections, or hyper-reactivity), which triggers ETD manifestations.

The underlying causes of ETD [2] are numerous, including adenoid hypertrophy, chronic rhinitis, hypertrophic and hypersecretory causes, allergic or vasomotor triggers, recurrent or chronic infections of the upper respiratory tract, laryngopharyngeal reflux, changes in the development of the superior maxillary bone, outcomes of previous rhinopharyngeal or cleft palate surgery, results of rhinopharyngeal radiotherapy [3]. The main symptoms reported by patients are a feeling of auricular pressure, auditory fullness, and even actual earache. The most feared risks of Eustachian tube obstruction caused by poor ventilation of the middle ear are chronic otitis with effusion and possible cholesteatomatous evolution of the middle ear inflammation.

Treatment of ETD is still a challenge. One of the problems in treating this disease is the lack of a correct categorization. ETD is often underestimated: impedance audiometry and other routine oto-functional examinations are not always decisive, and the diverse case histories do not facilitate its correct classification [4]. Given the need for a classification system for ETD that is not yet available in the literature, the authors have conceived an anatomoclinical classification of ETD named hypertrophy-degeneration-synechiae (HDS), in order to allow correct categorization of patients and enable comparative studies to be performed on the efficacy of proposed treatments at different clinical sites using a homogeneous and reproducible classification method.

Although it is an anatomical description of the area, the authors believe that this classification provides very direct information regarding function. This is because the four anatomical conditions (hypertrophy, H; degeneration, D; synechiae, S; presence or absence of hypertrophy of the posterior portion of the inferior turbinate, IT) that compete for space determine anatomic and clinical conditions that accurately reflect the severity of the symptoms reported by the patient.

Medical treatments and thermal steam insufflations have been and are still used—with poor results on symptoms and, above all, with temporary efficacy [5]. Medication with topical or oral steroids cannot guarantee effective and

lasting results for the resolution of ETD symptoms.

Various tubal surgical techniques have been proposed over the years, but without general consensus regarding their efficacy [6]—transtubal insertion of gold threads [7], transmastoid shunt [8], laser tuboplasty [9, 10])—all characterized by invasive methods resulting in possible complications and, above all, in possible damage to the delicate nasotubal mucosa. Insertion of transtympanic ventilation tubes (grommets) has also been proposed to aerate the middle ear and stimulate tube opening via a nonphysiological mechanism and method; however, to be effective in chronic tube dysfunction, they almost invariably require repeated positioning or must be permanent (with the risk of persistent tympanic perforation [11]).

A method for balloon dilation of the cartilaginous Eustachian tube was developed a few years ago, based on positive experiences with balloon sinuplasty for sinusitis. A number of worldwide research group studies have reported its efficacy on ETD symptoms, with a possible beneficial interference on the pathophysiologic mechanisms of Eustachian tube submucosal inflammation [12–15]. However, besides the Seven-Item Eustachian Tube Dysfunction Questionnaire (ETDQ-7) and the Eustachian Tube Score 7 (ETS-7) [16–19], one of the main obstacles in the way of more widespread use of this method and evaluation of its actual and lasting efficacy is the lack of a homogenous classification of ETD patients across different centers, based on objective parameters that would also allow quantification of the degree of disease severity.

Since 2015, a new balloon device called AERA (Acclarent, Menlo Park, CA, USA) has been marketed, which further streamlines the tubal dilation technique and which the authors of the current paper have started using to treat ETD. Based on the cases and experience collected, the authors have developed a classification of the different variations of Eustachian tube nasopharyngeal opening with relevant increasing severity staging that they named HDS. HDS is based on certain easily identifiable endoscopic patterns seen during a simple ENT examination, in order to verify the possibility of treating patients with homogenous pathology according to the degree of severity, to promote the exchange of clinical data across different centers, and to evaluate the differences in terms of therapeutic success based on the different disease stages.

Herein, the authors report their experiences gained with a consecutive series of obstructive ETD patients treated using AERA-based balloon dilation of the Eustachian tube according to a previously described two-hand two-nostril technique combined with shrinkage of the rhinopharyngeal tubal ostial mucosa by means of quantic molecular resonance (QMR) using a dedicated "Mitto" hand piece (Telea, Sandrigo-Vicenza, Italy), in order to evaluate the efficacy and safety of the new balloon and, at the same time, validate the proposed HDS classification.

## Materials and methods

### Patient selection

From January 2015 to September 2015, following written informed consent, a prospective study was conducted on 102 consecutive patients (39 women, 63 men, mean age 45 years) who exhibited ETD. Medical history, complete clinical ENT examination, oto-functional examination (complete pure tone audiometry with Weber test to confirm conductive hypoacusia; complete impedancemetric examination; "swallowing-opening-Toynbee-Valsalva", SOTV test), were performed in all patients included in the study.

The criteria for inclusion in the study were the simultaneous presence of at least two of the following symptoms:

- pain or pressure/fullness in the ear in the presence of altitude or atmospheric pressure changes,
- improvement, even temporary, of symptoms when swallowing or with compensation maneuvers,
- perception of noise and auricular crepitation upon compensation maneuvers,
- subjective hypoacusia.

HNO 2017 · 65:840–847 DOI 10.1007/s00106-017-0346-8


L. Di Rienzo Businco · A. Di Mario · M. Tombolini · A. Mattei · M. Lauriello

# Eustachian tuboplasty and shrinkage of ostial mucosa with new devices. Including a proposal of a classification system


## Abstract

**Objective.** A new combined approach to Eustachian tube dysfunction (ETD) employing new minimally invasive devices is described.
**Study design.** An anatomoclinical classification of ETD was conceived to allow correct categorization of patients and enable comparative studies to be performed. Herein, the authors report on their experience with a consecutive series of obstructive ETD patients treated by balloon dilation of the Eustachian tube using AERA (Acclarent, Menlo Park, CA, USA), combined with a quantic molecular resonance (QMR)-mediated rhinopharyngeal tubal ostial mucosa shrinkage technique with a dedicated "Mitto" hand piece (Telea, Sandrigo-Vicenza, Italy).
**Methods.** A prospective study was conducted in 102 patients with ETD. Medical history, complete clinical ENT evaluation and oto-functional examinations were performed in all patients. In all cases, balloon dilatation of the Eustachian tube was performed via the transnasal approach under video-endoscopic control. This was followed by decongestion of the torus tubarius and the inferior turbinate by QMR, with immediate shrinkage of the mucosa of the turbinate and a reduction of the prolapse of the mucosal plica on the tubal ostium.
**Results.** Comparison of pre- and post-operative oto-functional examinations revealed a significant improvement. The postoperative hearing symptoms were reduced in a statistically significant manner on the visual analog scale (VAS). It was possible to perform the postoperative "swallowing-opening-Toynbee-Valsalva" (SOTV) test in a significant percentage of cases compared to the preoperative test.
**Conclusion.** The combined surgical procedure of balloon tubodilation with simultaneous QMR-mediated shrinkage of the tubal ostial mucosa and reduction of the posterior portion of the inferior turbinate was found to be an effective, safe, and complete treatment for tubal dysfunction in the majority of patients.



## Keywords

Eustachian tube · Otitis · Inflammation · Ear, middle · Hypertrophy


# Tuboplastie der Eustachischen Röhre und Ostiumreduktion mit neuen Instrumenten. Einschließlich eines Vorschlags zu einem Klassifikationssystem


## Zusammenfassung

**Ziel.** Ein neuer kombinierter Ansatz zur Behandlung einer Funktionsstörung der Eustachischen Röhre („Eustachian tube dysfunction" [ETD]) unter Einsatz neuer minimalinvasiver Instrumente wird beschrieben.
**Studiendesign.** Eine anatomisch-klinische ETD-Klassifikation wurde entworfen, um eine korrekte Kategorisierung der Patienten und die Durchführung von Vergleichsstudien zu ermöglichen. In diesem Beitrag schildern die Autoren ihre Erfahrungen mit einer konsekutiven Serie von Patienten mit obstruktiver ETD, die einer Ballondilatation der Eustachischen Röhre mithilfe von AERA (Acclarent, Menlo Park, Kalifornien, USA) unterzogen wurden, kombiniert mit einem Quantic-molecular-resonance(QMR)-gestützten Verfahren zur Reduktion des rhinopharyngealen Tubenostiums unter Einsatz eines dezidierten „Mitto"-Handstücks (Telea, Sandrigo-Vicenza, Italien).
**Methoden.** Mit 102 ETD-Patienten wurde eine prospektive Studie durchgeführt. Bei allen Patienten erfolgten eine Anamnese, eine vollständige klinische Untersuchung von Hals, Nase und Ohren sowie eine Prüfung der Hörfunktion. In allen Fällen wurde eine Ballondilatation der Eustachischen Röhre über den transnasalen Zugang unter videoendoskopischer Kontrolle vorgenommen. Daran schloss sich ein Abschwellen des Torus tubarius und der unteren Nasenmuschel mithilfe der QMR an, mit unmittelbarem Rückgang der Mukosa der unteren Muschel und Reduktion des Schleimhautfaltenprolaps am Tubenostium.
**Ergebnisse.** Der Vergleich prä- und postoperativer Prüfungen der Hörfunktion ergab eine signifikante Verbesserung. Die postoperativen gehörbezogenen Symptome waren auf der visuellen Analogskala (VAS) statistisch signifikant verringert. Verglichen mit der präoperativen Situation war es postoperativ bei einem signifikanten Anteil an Patienten möglich, den Schluck-Öffnungs-Test nach Toynbee und Valsalva durchzuführen.
**Schlussfolgerung.** Das kombinierte chirurgische Verfahren mit Ballondilatation der Tuba Eustachii, simultaner QMR-gestützter mukosaler Reduktion des Tubenostiums und Reduktion des posterioren Anteils der unteren Nasenmuschel erwies sich bei der Mehrzahl der Patienten als wirksame, sichere und umfassende Therapie der ETD.



## Schlüsselwörter

Eustachische Röhre · Otitis · Entzündung · Mittelohr · Hypertrophie


Other diagnostic inclusion criteria were at least two of the following case histories:

- ENT diagnosis accompanied by impedancemetry of recurrent catarrhal otitis,
- otoscopic findings of a dull tympanic membrane or abnormalities (pockets, sclerosis, perforation),
- immobility of the tympanic membrane after Valsalva maneuver.

The impedancemetric examination was performed in all patients using a tubal function SOTV test in order to look for movement of the tympanometric pattern alternating between positive and negative values depending upon whether the Valsalva or Toynbee maneuver was performed. The test is not executable in the event of perforation, but none of the patients had tympanic perforation.

Of the 102 patients included in the study, 33 presented with monolateral tubal obstructive dysfunction, amounting to a total of 171 tubes that required treatment.

**Table 1** HDS classification

| | Absent | Mild | Severe |
|---|---|---|---|
| Hypertrophy (H) | 0 | 1 | 2 |
| Degeneration (D) | 0 | 1 | 2 |
| Synechiae (S) | 0 | 1 | 2 |

HDS anatomoclinical classification of the rhinopharyngeal torus tubarius: the sum of scores for each parameter determines the patient's stage: 0: no pathology, 1–2: stage I, 3–4: stage II, 5–6: stage III
In the presence or absence of hypertrophy of the posterior portion of the inferior turbinate (-it), e. g., stage II-it

The hearing symptoms were evaluated using the visual analog scale (VAS; 0–10, with increasing severity from 0 to 10) comparing the pre- and postoperative periods. A pre- and postoperative comparison was performed for all instrumental parameters examined at the time of inclusion in the study.

Patients presenting obstructive hypertrophy of the adenoids or chronic rhinosinusitis with or without polyposis reaching the choana were excluded from this study and sent for surgical treatment for the obstructive condition. Allergic rhinitis was not an exclusion criterion because the chronic inflammatory condition of the nasal mucosa is almost always at the root of the ETD.

## HDS rhinopharyngeal endoscopic classification

For the purpose of defining certain homogenous patterns shared between patients with different case histories, which combined the findings of otofunctional tests that are not always concordant with patients' ETD symptoms, an anatomoclinical classification was elaborated upon. This system is based on three parameters related to the torus tubarius and which contribute to the local clinical picture: hypertrophy, degeneration, and synechiae. A fourth parameter was then added to these initial three, depending on the presence or absence of hypertrophy of the posterior portion of the inferior turbinate (-it). Each of the three HDS parameters can obtain a score of 0, 1, or 2, based on the absence, or mild or severe presence of the pattern at the rhinoendoscopic examination. The sum of the scores obtained for each parameter represents a stage of increasing severity of three degrees (I: 1–2, II: 3–4, III: 5–6). The concomitant presence of hypertrophy of the inferior turbinate is indicated by adding the suffix "-it" after the stage (**Table 1**). In the authors' case history analysis, patients were characterized according to this classification in an attempt to correlate the results and the parameters with the described stage. In the authors' opinion, this classification is easy to use and aims at facilitating correct categorization of patients, to make them homogeneous in terms of the degree of disease severity, and therefore enable studies to be conducted comparing the efficacy of the different therapeutic treatments that are currently proposed. To date, in fact, the results of the different studies on ETD treatments are conflicting and not comparable.

## Surgical technique

Using the transnasal approach under videoendoscopic control, with a 3 mm rigid 45° endoscope (Karl Storz, Tuttlingen, Germany) inserted into the nasal fossa on the side opposite the tube to be dilated, the special tube balloon catheter (AERA) is introduced. This catheter is introduced through a dedicated angled cannula made of transparent plastic, which allows the catheter to slide and thus enter the Eustachian tube. Once the catheter has been correctly and completely introduced into the tube, it is then inflated with a physiologic solution (NaCl) to a pressure of 10 bar (7.501 mm Hg) for 2 min using a dedicated pressure pump (Acclarent). Once the dilation has been completed, the catheter is deflated and the introducer and the catheter are removed after retraction inside the cannula, all of which are performed under endoscopic control at 45° from the contralateral nasal fossa, so as to have an optimal view of the tubal ostium without obstacles in the maneuver that would occur using the same nasal fossa for endoscope and catheter (personal variation described previously [1]). Following tubal dilation, still under videoendoscopic control at 45° from the contralateral nasal fossa, decongestion of the inferior turbinate and of the torus tubarius is performed by means of insertion with a DRB (Di Rienzo Businco) Mitto QMR quantum-generator hand piece (Telea, Sandrigo-Vicenza, Italy). The shrinkage of the mucosa of the torus tubarius is achieved applying QMR for 4–5 s at a power of 3.5 Watt, with immediate shrinkage of the mucosa and reduction of the prolapse of the mucosal plica on the tubal ostium (personal technique).

The procedures were performed under intravenous anesthesia (total intravenous anesthesia, TIVA); they did not cause any bleeding and did not require insertion of nasal tampons in any of the patients treated.

The data obtained were analyzed with a statistical method.

## Statistical analysis

A descriptive analysis was conducted for all variables investigated using median and interquartile range (IQR) for quantitative variables, whereas categorical variables were described using frequency and percentage. The data were analyzed for normality of distribution with the Shapiro–Wilk test. Because the data were distributed non-normally, they were analyzed using nonparametric statistics. Thus, the Wilcoxon signed-rank or $\chi^2$ test were used to compare pre- and postoperative values according to the characteristics of data. The Mann–Whitney test was used to compare the mean differences between the two groups (group B: presence of allergic rhinitis, HDS=3, inferior turbinate hypertrophy; and group A: patients who do not simultaneously present the three conditions). Data considering the VAS score were also analyzed using the same test. A multivariate logistic regression was performed to determine the odds

**Table 2** Pre- and postoperative condition

| Outcome measure | Preoperative condition | Postoperative condition | *p*-value |
|---|---|---|---|
| Tympanogram amplitude ($cm^3$) | | | |
| Median (IQR) | 73 (69–79) | 152 (136–160) | 0.0001[a] |
| Retraction values ($mmH_2O$) | | | |
| Median (IQR) | –196 (–188–-205) | –152 (–136–-160) | 0.0001[a] |
| Movement of pattern, *n* (%) | | | |
| Absent<br>Present | 135 (78.95)<br>36 (21.05) | 107 (62.57)<br>64 (37.43) | 0.001[b] |
| Air-bone gap (dB) | | | |
| Median (IQR) | 41 (37–44) | 23 (21–27) | 0.0001[a] |

$p > 0.05$: no statistically significant difference between pre- and postoperative was found; $p < 0.05$; statistically significant difference between pre- and postoperative was found
*IQR* interquartile range
[a]Wilcoxon signed-rank test for pre- and postoperative comparison
[b]$\chi^2$ test for pre- and postoperative comparison

**Table 3** Pre- and postoperative symptoms on the visual analog scale (VAS)

| VAS symptom | Preoperative | Postoperative | *p*-value |
|---|---|---|---|
| Fullness upon variations in pressure | | | |
| Median (IQR) | 9 (8–10) | 3 (2–3) | 0.0001 |
| Improvement in fullness after Valsalva maneuver | | | |
| Median (IQR) | 2 (2–3) | 9 (8–10) | 0.0001 |
| Auricular noises at the Valsalva maneuver | | | |
| Median (IQR) | 9 (8–10) | 2 (2–3) | 0.0001 |
| Recurrent subjective hypoacusia | | | |
| Median (IQR) | 9 (8–10) | 2 (2–3) | 0.0001 |

*p*-value: Wilcoxon signed-rank test for pre- and postoperative comparison; $p > 0.05$: no statistically significant difference between pre- and postoperative was found; $p < 0.05$; statistically significant difference between pre- and postoperative was found
*IQR* interquartile range

ratios (OR) with the corresponding 95% confidence interval (95% CI) to evaluate the possible associations between the severity of health conditions and the functional response to tuboplasty and VAS score. All tests were two-tailed and statistical differences were considered significant at $p < 0.05$ using the software STATA/IC 12.1 (StataCorp, College Station, TX, USA).

## Results

The surgical procedure with combined balloon tubodilation and tubal QMR shrinkage proved to be effective in most patients. Furthermore, despite the absence of a control group, the classification of patients allowed a correlation between the results obtained and the severity of the disease to be found, showing greater efficacy in stage III patients. It is likely that the greatest effectiveness of the treatment in this group is correlated with the presence of synechiae that are lysed by QRM, with a logical clinical benefit for the patient.

### Surgical technique

The surgical procedure was found to be easy to perform for a surgeon familiar with endoscopic techniques in a safe, autonomous mode (two hands for the two nostrils), and the absence of bleeding during balloon dilation and QMR mucosal shrinkage allows the entire procedure to be safely followed under endoscopic vision. In particular, introduction of the angled endoscope into the nasal fossa opposite the one receiving surgery, as previously described, further reduces the risk of possible injury to the mucosa, even during the rotation maneuvers of the introducer when seeking the correct angulation for the tubal entrance, which are, thus, facilitated.

Introduction of the hand piece for tubal shrinkage of ostial mucosa and performance of the maneuver under contralateral endoscopic control were found to be particularly simple and immediately effective in reducing the mucosal volume, absolutely safely and without side effects. The three-level action of the technique (tube, torus tubarius, and posterior portion of the inferior turbinate) is the key to the success of the proposed treatment for ETD.

Furthermore, no intra- or postoperative complications occurred either in the rhinopharynx or at the tympanic membrane; in particular, it should be emphasized that no pain occurred even in the immediate postoperative period and there was complete absence of bleeding during both tubodilation and decongestion of the torus tubarius.

### Clinical efficacy

Of the 102 patients included in the study, the majority presented with a severe Eustachian tube condition: 11.11% had preoperative stage I in the HDS classification, 29.82% stage II, and 38.24% stage III. Hypertrophy of the inferior turbinate was present in 84.21% of patients and was secondary to allergic rhinitis in 69%. This was predictable because chronic inflammation of the nasal mucosa is naturally connected with the ETD.

Three months after performing the combined procedures, a comparative re-evaluation of the preoperative parameters was performed. Comparison of pre- and postoperative oto-functional examinations revealed a significant audiometric reduction in the air-bone gap in frequencies between 250 and 2000 Hz.

The tympanometric examination revealed a significant increase in the tympanometric peaks, indicating an increase in tubotympanic ventilation, with a reduction in the retraction quota (**Table 2**).

The postoperative hearing symptoms were reduced in a statistically significant manner on the VAS (**Tables 3**, **4** and **5**). In particular, the best results were obtained in group B, as if the most se-

**Table 4** Group A vs. group B for functional response. Comparisons of postoperative value pairs and comparisons between differences

| | Group A $n = 134$ | | | Group B $n = 37$ | | | *p*-value | *p*-value |
|---|---|---|---|---|---|---|---|---|
| | Pre | Post | Δ | Pre | Post | Δ | Group A vs. group B (value pairs post) | Group A vs. group B (Δ pairs) |
| Tympanogram amplitude ($cm^3$) | | | | | | | | |
| Median (IQR) | 73 (69–78) | 134 (143–159) | 72 | 73 (70–81) | 160 (150–171) | 85 | 0.0001[a] | 0.0009[a] |
| Retraction values ($mmH_2O$) | | | | | | | | |
| Median (IQR) | –196 (–188–-204) | –145 (–136–-160) | –49 | –196 (–187–-205) | –156 (–140–-164) | –53 | 0.125[a] | 0.2380[a] |
| Movement of pattern, *n* (%) | | | | | | | | |
| Absent<br>Present | 109 (81.34)<br>25 (18.66) | 86 (64.18)<br>48 (35.82) | –92[c] | 26 (70.27)<br>11 (29.73) | 21 (56.76)<br>16 (43.24) | –45[c] | 0.0001[b] | 0.0001[b] |
| Air-bone gap (dB) | | | | | | | | |
| Median (IQR) | 41 (38–44) | 23 (21–27) | 16 | 40 (37–44) | 25 (21–29) | 15 | 0.540[a] | 0.42[a] |

Group A: HDS<stage III; allergic rhinitis present or absent; inferior turbinate hypertrophy present or absent
Group B: HDS= stage III; allergic rhinitis present; inferior turbinate hypertrophy present
Δ median (post–pre)
$p > 0.05$: no statistically significant difference; $p < 0.05$: statistically significant difference
[c]Δ %, increased percentage
[a]Mann–Whitney test for comparison of postoperative value pairs and between the two groups
[b]$\chi 2$ test
*IQR* interquartile range

**Table 5** Group A vs. group B for visual analog scale (VAS) comparisons of postoperative value pairs

| | Group A $n = 134$ | Group B $n = 37$ | Group A vs. Group B *p*-value[a] |
|---|---|---|---|
| VAS symptoms | | | |
| Fullness upon variations in pressure | | | |
| Median (IQR) | 3 (2–3) | 2 (2–3) | 0.535 |
| Improvement in fullness after Valsalva maneuver | | | |
| Median (IQR) | 9 (8–10) | 9 (8–10) | 0.986 |
| Auricular noises at the Valsalva maneuver | | | |
| Median (IQR) | 2 (2–3) | 3 (2–3) | 0.012 |
| Recurrent subjective hypoacusia | | | |
| Median (IQR) | 3 (2–3) | 2 (2–3) | 0.266 |

Group A: HDS<stage III; allergic rhinitis present or absent; inferior turbinate hypertrophy present or absent
Group B: HDS=stage III; allergic rhinitis present; inferior turbinate hypertrophy present
[a]Using Mann–Whitney test for comparison of postoperative value pairs between group A and group B
$p > 0.05$: no statistically significant difference; $p < 0.05$; statistically significant difference

rious cases were benefitting most from the combined treatment.

It was possible to perform the postoperative SOVT test in a significant percentage of cases compared to the preoperative test.

The movement of the pattern shows a 92% increase in group A (from 18.66 to 35.82%) and a 45% increase in group B (from 29.73 to 43.24%; ◘ **Table 4**).

The estimation of ORs performed in order to evaluate the associations between severity of the health conditions, functional response, and perceived symptoms (VAS) reveals statistically significant associations with respect to tympanogram amplitude and reduction of auricular noises at the Valsalva maneuver, which are the two most reliable parameters (◘ **Table 6**).

No patients complained of complications or problems during the postoperative period; particularly appreciated by the patients were the absence of pain and bleeding, even during the first few hours after the operation.

## Discussion

The combined surgical procedure of balloon tubodilation and simultaneous QMR-mediated tubal shrinkage and shrinkage of the mucosa of the posterior portion of the inferior turbinate presented herein was found to be an effective minimally invasive and complete treatment for tubal dysfunction in the majority of patients. This was accomplished by means of a combined action on the three obstructive components of the pathogenesis of the clinical disorder, which is particularly effective in the most severe cases of disease. This observation, although absent in the literature, leads the authors to believe that hypertrophy of the inferior turbinate, when present, plays a crucial role in the pathogenesis and persistence of ETD, and the positive outcome of ETD therapy cannot leave aside the treatment of turbinate pathology. Balloon tubodilation is effective not

**Table 6** Multivariate logistic regression to evaluate the possible associations between severity of health conditions and the functional response to tuboplasty and the VAS score

| Postoperative results | OR | CI 95% | *p*-value |
|---|---|---|---|
| Tympanogram amplitude | 1.06 | 1.03–1.09 | 0.001 |
| Retraction values | 1.02 | 0.99–1.05 | 0.087 |
| Movement of pattern | 1.76 | 0.78–3.93 | 0.171 |
| Air-bone gap | 1.02 | 0.95–1.11 | 0.553 |
| VAS symptoms | | | |
| Fullness at the variations in pressure | 0.93 | 0.65–1.35 | 0.713 |
| Improvement in fullness after Valsalva | 0.96 | 0.69–1.34 | 0.823 |
| Auricular noises at the Valsalva maneuver | 1.48 | 1.04–2.10 | 0.029 |
| Recurrent subjective hypoacusia | 0.89 | 0.62–1.27 | 0.509 |

$p > 0.05$: no statistically significant difference; $p < 0.05$; statistically significant difference
*VAS* visual analog scale, *OR* odds ratio; *CI* confidence interval

only because of the mechanical action of the balloon, but, as reported by Poe et al, because a change also occurs in the tubal mucosa at the histologic level, with a reduction of the immune-mediated inflammatory disease. Likewise, a change in histology, always with a reduction in the immune-mediated hyper-reactivity of the mucosa of the torus tubarius and the posterior portion of the turbinate, is also supported by the action of the QMR applied during shrinkage.

The authors believe that the key to the success of their technique is the global approach to the pathological condition: balloon dilation of the Eustachian tube and reduction of the inflammation underlying the tubal dysfunction, not only at the level of the tubal mucosa itself, but also at the other points that are crucial for its correct functioning i.e., the tubal ostium and the posterior portion of the inferior turbinate. Thus, the novelty proposed herein is to combine the action of balloon dilation and reduction of inflammation on the tube [20] with the regenerative and anti-inflammatory action of QMR on the tubal ostium and inferior turbinate [21]. With a single surgical approach, it is possible to dilate the cartilaginous tract of the tube, to relieve its distal ostium at the rhinopharyngeal level, and to treat hypertrophy and hyper-reactivity of the inferior turbinate. However, because of the lack of a control group, it is difficult to say which of these components is more effective for achievement of therapeutic success; furthermore, it would be interesting to compare our results with those obtained with balloon tubal dilatation alone.

However, in the authors' opinion, QMR-mediated shrinkage of the tubal ostial mucosa is helpful in all cases of ETD and represents the natural completion of tubal dilation when taking into consideration the inflammatory hyperplasia of the rhinopharyngeal mucosa—which often involves the torus tubarius—that is almost always associated with persistent stenosis with chronic inflammatory states.

In the authors' experience, the HDS classification allows a simple and homogenous definition of the different rhinopharyngeal endoscopic patterns, which is concordant with the severity of the symptoms.

The comparative analysis of clinical and instrumental results, together with the proven safety of the procedure in the absence of adverse events [1], indicates that this is a first-choice candidate in the treatment of persistent tubal dysfunction syndromes associated with tube stenosis, particularly if with hyperplasia of the torus tubarius.

The clinical evaluation at long-term follow-up of the patients in order to confirm the stability of the results obtained over time is still in progress. However, no abnormal scarring or mucosal damage has been observed at the in the postoperative visits.

The classification of patients enrolled according to our proposed classification allows comparative studies to be conducted on the different techniques proposed today and, in the context of the same study, it allows comparison of the results obtained with the different degrees of disease severity. The results obtained using a specific treatment could, in fact, be different depending on the severity of the disease being treated. Without a universal classification of the disease itself, it would be difficult to compare the efficacy of the different treatments. The lack of a diagnostic classification of the patient is responsible for treatment failures in ETD patients.

The classification proposed herein could thus pave the way for new studies on how tubal stenosis and the severity of the disease can affect the health of the middle ear or, rather, the stability of surgical treatments for middle ear pathology.

It is still unknown whether there is a connection between staging and the indication for surgery, and this is why the authors hope for dissemination of their HDS classification, in order to stimulate further studies that will help to confirm this correlation and validate the classification.

## Conclusion

**Balloon tubodilation and simultaneous QMR-mediated shrinkage of the mucosa of the torus tubarius and the posterior portion of the inferior turbinate is an effective minimally invasive treatment for ETD. The technique represents a global approach to the pathology: balloon dilation of the Eustachian tube and reduction of the inflammation underlying tube dysfunction, both at the level of the tube itself and at other sites critical for its functioning. Its safety and the absence of adverse events indicates that this is a first choice for treatment of persistent tubal dysfunction syndromes associated with tube stenosis, particularly in the presence of torus tubarius hyperplasia. The proposed HDS classification could pave the way for comparative studies on ETD treatments.**

## Corresponding address

**Prof. L. Di Rienzo Businco**
Otorhinolaryngology Unit, S. Spirito Hospital
Lungotevere in Saxia, 1, 00193 Rome, Italy
ldirienzo@businco.net


## Compliance with ethical guidelines

**Conflict of interest.** L. Di Rienzo Businco, A. Di Mario, M. Tombolini, A. Mattei, and M. Lauriello declare that they have no competing interests and there was no financial support.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

## References


1. Di Rienzo Businco L, Laurino S, Cipriani O, Bucci P, Lauriello M (2012) Balloon dilation tuboplasty and tubaric ostium shrinkage in the treatment of Eustachian tube obstruction. Int Adv Otol 8:354–359
2. Bluestone CD, Klein JO (1996) Otitis media, atelectasis, and Eustachian tube dysfunction. In: Bluestone CD, Stool SE, Kenna MA (eds) Pediatric otolaryngology, 3rd edn. WB Saunders, Philadelphia, pp 182–187
3. Poe DS (2007) Diagnosis and management of the patulous Eustachian tube. Otol Neurotol 28:668–677
4. Odd NW (2000) There are no accurate tests for eustachian tube function. Arch Otolaryngol Head Neck Surg 126:1041–1042
5. Luu K, Remillard A, Fandino M, Saxby A, Westerberg BD (2015) Treatment effectiveness for symptoms of patulous Eustachian tube: a systematic review. Otol Neurotol 36(10):1593–1600 (Dec)
6. Sudhoff H, Schroder S, Reineke U, Lehmann M et al (2013) Therapy of chronic obstructive Eustachian tube dysfunction: evolution of applied therapies. HNO 61:477–482
7. Lieberum B, Jahnke K (1996) Golden tube wire for temporary or permanent implantation. HNO 44(3):140–142
8. Goode RL, Glasscock M (1975) The tympano-frontal shunt: a procedure for the treatment of chronic Eustachian tube insufficiency. Laryngoscope 85(1):100–112
9. Caffier PP, Sedlmaier B, Haupt H et al (2011) Impact of laser Eustachian tuboplasty on middle ear ventilation, hearing, and tinnitus in chronic tube dysfunction. Ear Hear 32:132–139
10. Poe DS, Grimmer JF, Metson R (2007) Laser Eustachian tuboplasty: two-year results. Laryngoscope 117:231–237
11. Norman G, Llewellyn A, Harden M, Coatesworth A, Kimberling D, Schilder A, McDaid C (2014) Systematic review of the limited evidence base for treatments of Eustachian tube dysfunction: a health technology assessment. Clin Otolaryngol 39(1):6–21
12. Schroder S, Lehmann M, Ebmeyer J, Upile T, Sudhoff H (2015) Balloon Eustachian tuboplasty: a retrospective cohort study. Clin Otolaryngol 40:629–638
13. Poe DS, Silvola J, Pyykko I (2011) Balloon dilation of the cartilaginous eustachian tube. Otolaryngol Head Neck Surg 144:563–569
14. Tisch M, Maier S, Maier H (2013) Eustachian tube dilation using the Bielefeld balloon catheter: clinical experience with 320 interventions. HNO 61:483–487
15. Ockermann T, Reineke U, Upile Ebmeyer J et al (2010) Balloon dilatation Eustachian tuboplasty (BET): a feasibility study. Otol Neurotol 31:1100–1103
16. Van Roeyen S, Van de Heyning P, Van Rompaey V (2016) Responsiveness of the 7-item Eustachian tube dysfunction questionnaire. J Int Adv Otol 12(1):106–108
17. Zirkler J, Rahne T, Lautenschläger C, Honigmann R, Plontke SK (2016) Balloon dilatation of the Eustachian tube during middle ear surgery: study planning and first experiences during recruitment. HNO 64(4):237–242
18. McCoul ED, Anand VK, Christos PJ (2012) The Eustachian Tube Dysfunction Questionnaire (ETDQ-7). Laryngoscope 122(5):1137–1141. doi:10.1002/lary.23223
19. Schröder S, Lehmann M, Sauzet O, Ebmeyer J, Sudhoff H (2015) A novel diagnostic tool for chronic obstructive eustachian tube dysfunction – the Eustachian tube score. Laryngoscope 125(3):703–708. doi:10.1002/lary.24922
20. Kivekäs I, Chao WC, Faquin W, Hollowell M, Silvola J, Rasooly T, Poe D (2015) Histopathology of balloon-dilation Eustachian tuboplasty. Laryngoscope 125(2):436–441
21. Di Rienzo Businco L, Di Rienzo Businco A, Ventura L, Laurino S, Lauriello M (2014) Turbinoplasty with quantic molecular resonance in the treatment of persistent moderate-severe allergic rhinitis: Comparative analysis of efficacy. Am J Rhinol Allergy 28(2):164–168