A Novel Method to Treat Obstructive Eustachian Tube Dysfunction in the Mucosal Type of Chronic Otitis Media

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Abstract

Introduction Treatment of Eustachian tube dysfunction has remained an enigma for a long time. Balloon tuboplasty, even though effective, is not considered by many, as it is invasive, expensive, and cumbersome. Hence, we tried to find some simple and inexpensive solution for the same in chronic otitis media. In this background, we evaluated the use of the Eustachian barotubometer to treat obstructive Eustachian tube dysfunction in mucosal chronic otitis media.

Materials and Methods The pilot study was undertaken in a tertiary referral hospital with 25 cases and 30 controls. Case group patients were administered Eustachian barotubometer therapy along with ciprofloxacin-dexamethasone ear drops and xylometazoline nasal drops until the recovery or up to 10 days. Control group patients received the same ear and nasal drops along with Valsalva maneuver for the same duration.

Results The recovery of the Eustachian tube was categorized as complete, partial, or nil. It was found that the case group had 60 and 32% complete and partial recovery, respectively, while it was 33.33 and 13.33% in the control group. The recovery was faster with Eustachian barotubometer therapy than with the Valsalva maneuver. No complications were observed with the new procedure.

Conclusion The Eustachian barotubometer is a simple, inexpensive device that can be used to treat Eustachian tube dysfunction in chronic otitis media. This device is particularly suitable for the peripheral health care centers of developing countries.

Keywords
- eustachian tube
- valsalva maneuver
- otitis media

Introduction

Prior treatment of Eustachian tube dysfunction (ETD) is crucial for the success of any middle ear surgery in chronic otitis media (COM). However, many physicians tend to ignore this as the treatment is cumbersome, expensive, or inaccessible. Balloon dilation, even though the standard of care, is expensive and not universally available, mainly in developing countries. There is a need to look for more straightforward and cheaper alternatives that are readily available. In this background, we evaluated the use of Eustachian barotubometer (EBT) (►**Fig. 1**) to treat obstructive ETD (OETD) in mucosal COM.[1,2]

Materials and Methods

This pilot study was undertaken in 1 year in a tertiary referral public hospital after obtaining the necessary clearance from the institutional review board (KIMS/EC/68/2019-20).

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Fig. 1 Prototype of the Eustachian barotubometer designed by the first author.

This study was also registered in the clinical trials registry of India (2020/10/037763). Written informed consent was taken from all the adult patients with mucosal COM (quiescent and dry stages only) for the study. All eligible patients were confirmed to have complete ETD using the EBT before assigning to the groups.[1]

Method of Testing Eustachian Tube Function with EBT

For the physiological opening test, the patient was in the sitting position; an earplug of the EBT was applied to the ear canal. Air pressure in the canal was raised up to 40 mm in the dial and the patient was asked to dry swallow voluntarily multiple times. If the air pressure fell in the dial of the EBT, it meant that the Eustachian tube opened physiologically and if the air pressure did not drop, it meant that the Eustachian tube was partially blocked.

For the forced opening test, a patient in the same sitting position was asked to do the Valsalva maneuver (VM) with pressure in the dial at zero. If the pressure in the dial of the EBT rose, it meant that the forced opening of the Eustachian tube was present. If the pressure dial did not raise, it meant that the forced opening of the Eustachian tube was absent and hence the Eustachian tube was completely blocked.

They all underwent diagnostic nasal endoscopy (DNE) to rule out persistent adenoids or any other mass in the nasopharynx or nasal cavity. They also underwent otoendoscopic evaluation to rule out cholesteatoma, granulation, and pus in the middle ear. Cases included those who underwent Eustachian barotubometer therapy (EBTT) twice a day, while controls performed VM with dry swallows 10 times a day. These exercises were performed every day for 10 days or until the Eustachian tube opened, whichever was earlier.

The Procedure of the EBTT

The patient was in the sitting position, and the pressure in the middle ear of the dysfunctional side was raised to 50 mm Hg by sealing the ear canal with the ear tip and maintaining the same force for one minute. The patient was asked to dry swallow multiple times after the procedure. EBT test was repeated between the therapy procedures to verify the opening of the Eustachian tube.

Both the groups were also treated with Ciprofloxacin Dexamethasone ear drops (Ciplox-D, Ciprofloxacin 0.3% w/v, dexamethasone sodium phosphate 0.1% w/v, and benzalkonium chloride 0.01% w/v manufactured by Cipla Ltd., Village Sachana, Viramgam Taluk, Ahmedabad - 382150, Gujarat, India) and Xylometazoline nasal drops (Xylomist, xylometazoline hydrochloride 0.1% w/v, benzalkonium chloride 0.022% w/v manufactured by Zydus Healthcare Ltd., 75/1, GIDC, Valsad District, Vapi - 396195, Gujarat, India) thrice a day. Number of days taken for opening of Eustachian tube among cases and controls was noted. If the ET opened partially (only forced opening present) or completely (both forced and physiological opening present), then the outcome was considered a success. If the Eustachian tube failed to recover even at the end of 10 days, the outcome was considered a failure.

The data were entered in SPSS software version 17 and analyzed using independent "t" test and chi-square test with a confidence interval of 95%.

Results

Twenty-five cases and 30 controls with COM and ETD were enrolled for the study. The demographic characteristics of the patients are given in ►**Tables 1** and **2**. All of them underwent DNE and the findings were not significantly different between the groups (►**Table 3**). The number of patients who recovered completely from ETD was more than those who recovered partially in both groups. The success rate of the cases was 92%, while it was 46.66% for the controls and this difference was highly significant (►**Table 4**). The average

Table 1 Sex distribution of the cases and controls

Patients	Cases	Controls	Total
Males	6	8	14
Females	19	22	41
Total	25	30	55

Chi-squared test *p*-value: 0.83.

Table 2 Analysis of age in cases and controls

Groups	Number	Mean	SD	Min-max	*p*-Value
Cases	25	29.9	13.0	11–63	0.83
Controls	30	30.7	16.1	7–70	

Abbreviation: SD, standard deviation.
Independent *t*-test, *p*-value—not significant.

Table 3 Diagnostic nasal endoscopy findings in the cases and controls

DNE findings	Cases, *n*	Controls, *n*	Total, *n*
Adenoid grade 1	7	2	9
DNS	16	16	32
Inferior turbinate hypertrophy	4	9	13
Nasal allergy	0	1	1

Abbreviations: DNE, diagnostic nasal endoscopy; DNS,deviated nasal septum.
Chi-squared test *p*-value = 0.12.

Table 4 Recovery status of the cases and controls in 10 days

Recovery status of ET	Cases, *n*	Controls, *n*	Total, *n*
Complete recovery	15 (60%)	10 (33.33%)	25
No recovery	2	16	18
Partial recovery	8 (32%)	4 (13.33%)	12
Total	25	30	55

Abbreviation: ET, Eustachian tube.
Chi-squared test *p*-value: 0.001.

number of days taken for partial recovery was 4.2 and 5.3 days for cases and controls, respectively. For complete recovery, it was 5 and 7.9 days. The time taken for the recovery of the Eustachian tube was compared between the cases and controls for partial and complete responses in ►**Tables 5** and **6**, respectively. Again, the difference between the cases and controls for complete recovery was highly significant, suggesting that the recovery was much faster with EBT than with VM. No complications were observed with EBTT.

Discussion

ETD remains a poorly understood disease whose management is unclear.[3] Among the general population in the United States, ETD has a prevalence of 4.6% among adults and 6.1% among the children.[4] There can be 3 types of ETD and diagnosis has to be based on history and clinical examination: (1) dilatory or OETD, (2) bar-challenge-induced ETD, and (3) patulous ETD.[3,5] Dilatory ETD can be further broken down into (A) functional obstruction, (B) dynamic obstruction (muscular failure), and (C) anatomical obstruction.[5] There is a wide range of Eustachian tube function tests; however, none can be considered a "gold standard."[6] Although many are reported to determine Eustachian tube function with a reasonable degree of accuracy, the optimal assessment tool for the complex spectrum of ETD disorders lies in a combination of objective clinical tests and patient-reported measures.[6] Mucosal edema at the Eustachian tube orifice has been noted in 83% of patients with ETD.[7] There is also a strong correlation between mucosal inflammation and laryngopharyngeal reflux and allergic rhinitis.[8] Because of this association, it is a common practice to prescribe nasal steroids as the first-line treatment for ETD.[3]

Even though this disorder is quite common, opinions differ widely among otolaryngologists on managing these patients.[3] There is no doubt that OETD needs to be treated before any middle ear surgery for COM.[9,10] Conservative

Table 5 Duration required for the partial recovery of the Eustachian tube in the study groups

Duration in days	Cases	Controls	Total	*p*-Value
4	1	0	1	0.05
5	1	0	1	
6	1	0	1	
7	3	2	5	
> 7 < 10	2	1	3	
10	0	1	1	
Total	8	4	12	

Table 6 Duration required for the complete recovery of the Eustachian tube in the study groups

Duration in days	Cases	Controls	Total	*p*-Value
3	1	0	1	< 0.001
4	4	0	4	
5	3	0	3	
6	4	0	4	
7	3	8	11	
> 7 < 10	0	0	0	
10	0	2	2	
Total	15	10	25	

methods like VM and others have been tried before, both to confirm the diagnosis of patency of Eustachian tube and force open an obstructed tube.[11] However, these maneuvers have their limitations. They are challenging to be performed in children who represent a significant chunk of the cases of COM. Besides, the pressure built up inside the Eustachian tube voluntarily is often unreliable and inadequate, especially in children. Also, when both eardrums are perforated in a patient, these maneuvers are even more challenging to perform. Hence, we thought upon the EBT inflation-deflation therapy to overcome many of these drawbacks.[1,2] Besides, it is cost-effective, portable, noninvasive, is not driven by power and hence can be used quickly and conveniently without anesthesia. It can be used even by a layperson with some training in both adults and children in the peripheral health care setup. To the best of our knowledge, there is no such study reported in the literature so far.

Our procedure does not risk facilitating the regurgitation of the nasopharyngeal and nasal infections into the middle ear unlike the VM. Since our procedures were performed only in the quiescent and dry stage of mucosal COM, the mucosal edema inside the Eustachian tube was absent and hence there were very few failures in the case group. The failures were primarily due to the noncompliance by the patient, who was unduly sensitive to the pressure build-up inside the middle ear. The air leak at the earplug tip was yet another problem. Sometimes the tips would have to be changed repeatedly to achieve an air seal. A DNE ruled out enlarged adenoid as a confounding factor before the procedure.

Balloon Eustachian tuboplasty is a popular tool used widely for OETD. Several studies have been performed and reported in the past justifying its use.[9,12–14] The clinical

consensus statement on balloon dilation of Eustachian tube found no scientifically proven or standard medical therapy for OETD.[15] They also concluded that the modified VM was appropriate to test the function of the Eustachian tube.[15] Han et al, in their study, concluded that VM could be the first-line therapeutic modality in otitis media with effusion in adult patients who demonstrated successful maneuver results on otoendoscopic examination.[16] Hence, we chose this maneuver as a control in our study.

Transtympanic balloon dilation has also been tried and tested successfully.[17] The results of balloon dilation of Eustachian tube and medical treatments were 51.8 and 62.2% at 6 and 12 weeks, respectively, while in controls (medical therapy alone), it was 13.9 and 8.5% in the same period.[18] These results are comparable with that of ours. However, balloon dilation requires preoperative high-resolution computed tomography of the temporal bone of the patient. Besides the procedure itself is invasive, requires general anesthesia, operation theatre setup, and has its own complications.[19] It is also expensive and cannot be repeated due to patient morbidity. The procedure also does not address the obstruction in the bony part of the Eustachian tube. McCoul et al, in their study, concluded that the dilation of the Eustachian tube carried a substantial financial expense. Hence, there was a need to develop alternative therapeutic procedures to mitigate invasive procedures.[20] The device of our study overcomes all these disadvantages and is also both diagnostic and therapeutic.

Further studies with a larger sample size are required to verify the duration of this therapeutic effect in the long term. Studies are also needed to check the optimum pressure needed for the best outcome. Randomized studies could also be performed along with balloon dilation to compare their effects on middle ear surgery. However, the disadvantage of this device is that the Eustachian tube can be treated only in the presence of a perforation in the tympanic membrane and also, the procedure needs to be repeated multiple times for an apparent therapeutic effect.

Conclusion

The EBT is a simple, inexpensive device that can be easily used to treat OETD in quiescent and dry stages of mucosal COM. The net success rate (partial and complete recovery) was 92%. The therapeutic effect of this device is faster and superior to that of the VM (success rate—46.66%) and comparable with balloon tubal dilation. The device is particularly suitable for the developing countries at the rural and peripheral health care centers where expensive diagnostic and therapeutic equipment may not be available.

Conflict of Interest
None declared.

References

1 Bhat VK, Kumar PR, Nag M, Hegde J. Comparison of a eustachian barotubometer with a tympanometer to evaluate eustachian tube function in chronic suppurative otitis media. J Otolaryngol Head Neck Surg 2009;38(4):456–461

2 Bhat VK, Marimuthu GS, Herur K, Yadav M. Evaluation of Eustachian tube function in mucosal chronic otitis media: a cost-effective method for developing countries. Ann Otol Neurotol. 2018; 1 :111–114

3 Lafferty DJ, McKinnon BJ. To balloon or not to balloon, the current state of management of Eustachian tube dysfunction. Ear Nose Throat J 2021;100(10):696–697

4 Shan A, Ward BK, Goman AM, et al. Prevalence of Eustachian tube dysfunction in adults in the United States. JAMA Otolaryngol Head Neck Surg 2019;145(10):974–975

5 Schilder AG, Bhutta MF, Butler CC, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. Clin Otolaryngol 2015;40(5):407–411

6 Smith ME, Tysome JR. Tests of Eustachian tube function: a review. Clin Otolaryngol 2015;40(4):300–311

7 Poe DS, Gopen Q, Eustachian tube dysfunction. In: Ballenger's Textbook of Otolaryngology. Shelton, Conn.; Hamilton, Ont.; London: People's Medical Pub. House/B C Decker; 2009 201–208

8 Poe DS, Abou-Halawa A, Abdel-Razek O. Analysis of the dysfunctional eustachian tube by video endoscopy. Otol Neurotol 2001;22(5):590–595

9 Hsieh CY, Chang CJ, Sun CH, et al. Tympanoplasty with or without balloon Eustachian tuboplasty for chronic suppurative otitis media with obstructive Eustachian tube dysfunction. Otol Neurotol 2020;41(8):1077–1083

10 Dave V, Ruparel M. Correlation of Eustachian tube dysfunction with results of tympanoplasty in mucosal type of chronic suppurative otitis media. Indian J Otolaryngol Head Neck Surg 2019;71(1):10–13

11 Stangerup SE, Klokker M, Vesterhauge S, Rea P, Harcourt J. Methods to improve the efficacy of autoinflation procedures and to classify Eustachian tube patency. Archives of Medical Case Reports and Case Study. 2021;4(1):1–5

12 Cutler JL, Meyer TA, Nguyen SA, O'Malley EM, Thackeray L,Slater PW. Long-term outcomes of balloon dilation for persistent Eustachian tube dysfunction. Otol Neurotol 2019; 40 (10):1322–1325

13 Dai S, Guan GF, Jia J, et al. Clinical evaluation of balloon dilation eustachian tuboplasty surgery in adult otitis media with effusion. Acta Otolaryngol 2016;136(8):764–767

14 Singh T, Taneja V, Kulendra K, Farr M, Robinson J, Rejali D. Balloon Eustachian tuboplasty treatment of longstanding Eustachian tube dysfunction. J Laryngol Otol 2017;131(7):614–619

15 Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical consensus statement: balloon dilation of the Eustachian tube. Otolaryngol Head Neck Surg 2019;161(1):6–17

16 Han JJ, Park JM, Kim DK, Park SY, Park SN. A pilot study to investigate the therapeutic effect of Valsalva maneuver on otitis media with effusion in adults. Auris Nasus Larynx 2019;46(1):34–37

17 Kapadia M, Tarabichi M. Feasibility and safety of transtympanic balloon dilatation of Eustachian tube. Otol Neurotol 2018;39(9):e825–e830

18 Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: a randomized controlled trial. Laryngoscope 2018;128(5):1200–1206

19 Ramakrishnan N, D'Souza R, Kadambi P. A systematic literature review of the safety and efficacy of Eustachian balloon tuboplasty in patients with chronic Eustachian tube dysfunction. Indian J Otolaryngol Head Neck Surg 2019;71(3):406–412

20 McCoul ED,Weinreich HM, Mulder H, Man LX, Schulz K,Shin JJ. Utilization of invasive procedures for adult Eustachian tube dysfunction. Otolaryngol Head Neck Surg 2020; 163 (5):963–970