

RESEARCH ARTICLE

Balloon eustachian tuboplasty for patients with chronic eustachian tube dysfunction: a novel method for Iranian samples

Mahnaz Mohamadi^{1,2*}, Masoud Motasaddi Zarandy^{1,2}, Mojtaba Mohammadi Ardehali^{1,2}, Mina Motasaddi Zarandy³

¹- Otorhinolaryngology Research Center, Tehran University of Medical Sciences, Tehran, Iran

²- Department of Otolaryngology, Head and Neck Surgery, Amir A'lam Hospital, Tehran University of Medical Sciences, Tehran, Iran

³- Department of Neurology and Neurosurgery, Montreal Neurological Institute, McGill University, Montreal, Canada

Received: 3 Aug 2020, Revised: 9 Sep 2020, Accepted: 16 Sep 2020, Published: 15 Oct 2020

Abstract

Background and Aim: Balloon eustachian tuboplasty (BET) is a recently developed and approved method for management of chronic eustachian tube dysfunction (ETD). In the present study we aimed to evaluate the safety and efficacy of this method in Iranian samples.

Methods: In this prospective case-series study, we included 15 adult patients with chronic ETD who were resistant to previous medical managements and/or ventilation tube use. All patients underwent baseline audiometry (pure tone audiometry and tympanometry), Valsalva maneuver, EDT questionnaire-7 (ETDQ-7), and physical examination. Three to six months after the BET procedure, all patients underwent four evaluation methods again.

Results: We found a significant improvement in the mean ETDQ-7 scores comparing pre- and post-test scores ($p < 0.0001$). There was also a statistically significant decrease in the average air-bone gap from 40.55 at baseline to 27.22 after treatment ($p < 0.001$). In the Valsalva test, 17 out of 18 study ears (92.3%) had a positive result

after the surgery. Under tympanographic evaluation, 9 ears (50%) reported a conversion from type B to type A after treatment, 2 ears (11%) had a conversion from type B to C, and 7 ears (39%) showed no any change and stayed in type B after BET.

Conclusion: As a novel method in Iran, BET can be an alternative safe treatment option for chronic ETD.

Keywords: Balloon eustachian tuboplasty; eustachian tube dysfunction; Iranian

Citation: Mohamadi M, Motasaddi Zarandy M, Mohammadi Ardehali M, Motasaddi Zarandy M. Balloon eustachian tuboplasty for patients with chronic eustachian tube dysfunction: a novel method for Iranian samples. *Aud Vestib Res.* 2020;29(4):204-8.

Introduction

The eustachian tube (ET) is a narrow canal with a length of 31–38 mm in adults which connect the nasopharynx to the middle ear. It consists of two parts including a permanently open osseous part and a cartilaginous part. It is normally closed (at rest) but opens transiently during yawning, chewing, swallowing, and Valsalva maneuver.

* **Corresponding author:** Otorhinolaryngology Research Center, Tehran University of Medical Sciences, Tehran, 1145765111, Iran. Tel: 009821-66703037, E-mail: drmmohamadi@yahoo.com

The ET has the following physiologic functions: a) protecting middle ear from nasopharyngeal secretions and acoustic pressure; b) clearance of middle ear secretions into the nasopharynx; and c) equalizing middle ear pressure with atmospheric pressure [1-3]. Until now, there have been uncertainty in defining ET dysfunction (ETD); however, according to an international consensus, ETD refers to any manifestations related to ventilatory dysfunction of the ET caused by middle ear pressure dysregulation [2,4]. Clinical manifestations of ETD include: muffled hearing, ear fullness, pressure dysregulation in the middle ear, ear pain, tinnitus, and dizziness. Unsatisfactory treatment of ETD may lead to chronic complications such as otitis media with effusion, eardrum perforation, middle ear atelectasis, adhesive otitis, and probably cholesteatoma formation [5].

Medical management of ETD including the local or systemic use of steroids, antihistamines, and anti-inflammatory compounds has failed to treat ETD properly [6]. Laser eustachian tuboplasty combined with medical management is an effective therapy for ETD patients [7]. Another method for chronic ETD treatment is Balloon Eustachian tuboplasty (BET), which was introduced for the first time by Ockermann et al. [8]. Concerns regarding possible occurrence of ear barotrauma during BET procedure have been addressed in a cadaveric study [9]. The effectiveness of BET in treatment of ETD has been evaluated by two systematic reviews with conflicting results necessitating further studies with better designs such as randomized placebo-controlled clinical trials [5,10]. Randrup and Ovesen in a systematic review of 9 case series, found out that these studies had low quality and were at high risk of bias [5]. In another systematic review and meta-analysis by Huisman et al., conducted on 15 case series, it was reported that all the studies had short-term effect and some of them had long-term effects in improving initial symptoms [10]. There are also studies confirming long-term effect of BET on ETD treatment [11-15]. Two randomized controlled trials showed the safety and effectiveness of this technique in chronic ETD treatment [16,17]. In a study of

more than 400 patients who underwent BET, almost four out of five patients reported subjective benefits from BET [18]. Considering the effectiveness of BET and the need to evaluate the feasibility and effect of this technique in our setting, we aimed to conduct this prospective case-series study on BET in department of otorhinolaryngology, Amir A'lam Hospital. Since our access to the BET device was limited (not covered by the insurance) and we had a group of adult patients with chronic ETD resistant to medical management, we planned to conduct this study with three-six months of follow-up.

Methods

Patients

Patients were 15 adults with chronic ETD. Inclusion criteria for them were: age 20–60 years, having ETD for more than six months, not responding to medical management or use of ventilation tube, type B or C tympanogram, and air-bone gap ≥ 20 dB (average at 1, 2, and 4 kHz) under pure tone audiometry (PTA). Those with contraindication to general anesthesia, history of nasopharyngeal cancer and receiving radiation therapy, perforated tympanic membrane, cholesteatoma or severe pars tensa atelectasis, severe adenoid tissue hypertrophy, and history of nasal polyps were excluded from the study. All patients signed an informed consent form prior to study. This study obtained its ethical approval from the Research Ethics Committee of Tehran University of Medical Sciences (Code: IR.TUMS.REC.1394.954). Pre- and post-BET evaluations were Eustachian tube dysfunction questionnaire-7 (ETDQ-7) [19], PTA, tympanometry, performing Valsalva maneuver (considered positive when resolved ear fullness), and the physical appearance of tympanic membrane and middle ear. The time interval for post-BET evaluation was three to six months.

Procedure

For BET, under general anesthesia and using a topical decongestant for nasal mucosa by endoscopic intranasal approach, a balloon catheter (Spiggle & Theis Medizintechnik GmbH, Overath, Germany) was inserted into the orifice of

ET pushed through the cartilaginous part up to 2 cm. After the balloon positioned correctly, it was inflated by saline solution with a pressure up to 10 bars for 2 minutes, and then was deflated. The BET was performed by a surgeon during the study. For two patients, the procedure failed to be completed due to inability to insert the catheter into the orifice of ET probably because of anatomical variations or defects such as osseous web or orifice constriction. Therefore, BET was finally conducted on 13 patients. The procedure was performed bilaterally on 5 patients and unilaterally on 8 patients. Three to six months later, all post-BET evaluations were repeated.

Statistical analysis

Data were described as mean \pm standard deviation (SD). Using Shapiro-Wilk test for examining their normality of distribution, paired t-test was carried out for comparing pre- and post-test scores. All data were analyzed in SPSS 20 software and $p < 0.05$ was set as the significance level.

Results

Demographic, clinical, and paraclinical characteristics of patients in pre- and post-test phases are shown in Table 1. Out of 13 patients, 8 (61.5%) were male and 5 (38.5%) were female with a mean age of 34.61 ± 6.05 years. Five patients (38.5%) underwent the BET bilaterally and eight patients (61.5%) received the BET unilaterally. All patients tolerated the BET and discharged from the hospital without any complication. We found a significant reduction in the mean ETDQ-7 scores comparing pre- and post-test scores (35.72 vs. 13.62; $p < 0.0001$). There was also a statistically significant decrease in the average air-bone gap evaluated by PTA after treatment (40.55 vs. 27.22; $p < 0.001$). Under the Valsalva test, 17 out of 18 study ears (92.3%) had a positive result after the surgery. In tympanometric evaluation, 9 ears (50%) reported a conversion from type B to type A after treatment, 2 ears (11%) had a conversion from type B to C, and 7 ears (39%) showed no any change in tympanogram and stayed in type B after BET. After six months, there was no sign of retraction

pocket or cholesteatoma in patients.

Discussion

We performed a prospective case-series study on BET to evaluate its feasibility, safety, and efficacy in patients with chronic ETD. The patients tolerated the procedure fairly without any reported complication. Two evaluation methods used in this study were subjective in nature including Valsalva maneuver and ETDQ-7 whose results showed improvement after BET in comparison with the baseline scores. There was a significant improvement in the air-bone gap after BET from type B to type A tympanogram which can indicate the objective improvement in tested scales in the present study. It seems that our study provides both subjective and objective evidence supporting the efficacy of BET for treating chronic ETD, contrary to the study by Singh et al. which did not show significant changes in the PTA and tympanogram after treatment [4]. This potential of BET that caused both objective and subjective improvement in the outcome should be re-evaluated in the future studies using a larger sample size and with placebo-controlled design.

Since five out of seven patients with negative test results in terms of tympanogram and air-bone gap, had ETD for a longer period and a history of ventilation tube insertion during childhood, it can be claimed that the history of chronic otitis media and grommet insertion in childhood can be a possible negative prognostic factor for the chronic ETD treatment by BET in adulthood, which should be validated in further studies. There are some studies reported that BET is safe, feasible, and an effective treatment method for chronic ETD in children [20,21]. In this regard, it seems that the use of BET in children with chronic and refractory ETD should be done as early as possible in these children to reach a better outcome. However, early treatment with BET in children with chronic ETD should be avoided until this claim is confirmed by further studies. Two patients of those with positive test results had septal deviation which made the BET catheter impossible to be inserted. We, therefore, performed septoplasty during and before the BET in these

Table 1. Demographic, clinical, and para-clinical characteristics of the patients, pre- and post-operation

Patient	Side	Age (years)	Sex	ETDQ-7		Air-bone gap (dB)		Valsalva		Tympanometry type	
				Pre-Op	Post-Op	Pre-Op	Post-Op	Pre-Op	Post-Op	Pre-Op	Post-Op
1	Left	26	M	28	10	30	25	Negative	Positive	B	C
2	Right	32	F	20	15	40	35	Negative	Positive	B	B
2	Left	32		18	15	50	50	Negative	Positive	B	B
3	Left	34	F	40	10	40	20	Negative	Positive	B	A
4	Left	36	F	44	20	50	50	Negative	Positive	B	A
5	Left	50	M	45	7	30	5	Negative	Positive	B	A
6	Left	35	M	29	20	20	20	Negative	Positive	B	A
7	Right	28	F	33	7	30	5	Negative	Positive	B	A
7	Left	28		36	7	35	10	Negative	Positive	B	A
8	Right	42	M	42	30	45	40	Negative	Positive	B	B
9	Right	27	M	47	20	70	70	Negative	Negative	B	B
10	Right	32	F	35	10	50	10	Negative	Positive	B	A
10	Left	32		32	10	50	10	Negative	Positive	B	A
11	Right	38	M	28	15	40	40	Negative	Positive	B	B
11	left	38		30	16	30	30	Negative	Positive	B	C
12	left	33	M	44	8	60	50	Negative	Positive	B	B
13	Right	40	M	47	15	40	25	Negative	Positive	B	B
13	left	40		45	10	30	5	Negative	Positive	B	A
Mean ±		34.61 ±		35.72 ±	13.61 ±	40.55 ±	27.22 ±				
SD		6.05		9.08	6.09	13.60	19.57				

ETDQ-7; eustachian tube dysfunction questionnaire-7, pre-op; pre-operation, post-op; post-operation

patients. It seems that we should inform the BET candidates about the possibility of undergoing septoplasty during the BET at baseline. Moreover, performing septoplasty for these patients can be a confounding factor for the efficacy of BET and as a limitation for the present study. Other limitations of our study were the small sample size and the study design.

Conclusion

The Balloon Eustachian tuboplasty (BET) is a safe and technically feasible method; however, in the future studies, the patients with anatomical

variations or defects such as septal deviation should be excluded from receiving BET. Our study revealed improvement in both subjective and objective measures in patients with chronic Eustachian tube dysfunction (ETD) after BET. We recommend further studies with larger sample size, better study designs (such a placebo-controlled), different types of patients, and longer duration using multiple post-test measures.

Acknowledgments

We would like to thank otorhinolaryngology research center, Tehran University of Medical

Sciences (project number, 29610-48-02-94) and Spiggle & Theis Medizintechnik GmbH, Overath, Germany for their support in performing this study.

Conflict of interest

The authors declared no conflicts of interest.

References

1. Bluestone CD, Doyle WJ. Anatomy and physiology of eustachian tube and middle ear related to otitis media. *J Allergy Clin Immunol.* 1988;81(5 Pt 2):997-1003. doi: [10.1016/0091-6749\(88\)90168-6](https://doi.org/10.1016/0091-6749(88)90168-6)
2. Schilder AGM, Bhutta MF, Butler CC, Holy C, Levine LH, Kvaerner KJ, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical presentation and diagnosis. *Clin Otolaryngol.* 2015;40(5):407-11. doi: [10.1111/coa.12475](https://doi.org/10.1111/coa.12475)
3. Teschner M. [Evidence and evidence gaps in the treatment of eustachian tube dysfunction and otitis media]. *Laryngorhinootologie.* 2016;95 Suppl 1:S136-54. German. doi: [10.1055/s-0041-108952](https://doi.org/10.1055/s-0041-108952)
4. 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):614-9. doi: [10.1017/S0022215117000974](https://doi.org/10.1017/S0022215117000974)
5. Randrup TS, Ovesen T. Balloon eustachian tuboplasty: a systematic review. *Otolaryngol Head Neck Surg.* 2015;152(3):383-92. doi: [10.1177/0194599814567105](https://doi.org/10.1177/0194599814567105)
6. Hwang SY, Kok S, Walton J. Balloon dilation for eustachian tube dysfunction: systematic review. *J Laryngol Otol.* 2016;130 Suppl 4:S2-6. doi: [10.1017/S0022215116008252](https://doi.org/10.1017/S0022215116008252)
7. Poe DS, Grimmer JF, Metson R. Laser eustachian tuboplasty: two-year results. *Laryngoscope.* 2007;117(2):231-7. doi: [10.1097/01.mlg.0000246227.65877.1f](https://doi.org/10.1097/01.mlg.0000246227.65877.1f)
8. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilatation eustachian tuboplasty: a clinical study. *Laryngoscope.* 2010;120(7):1411-6. doi: [10.1002/lary.20950](https://doi.org/10.1002/lary.20950)
9. Smith ME, Tysome JR. Middle ear pressure changes during balloon eustachian tuboplasty. *Otolaryngol Head Neck Surg.* 2017;156(1):161-5. doi: [10.1177/0194599816672842](https://doi.org/10.1177/0194599816672842)
10. Huisman JML, Verdham FJ, Stegeman I, de Ru JA. Treatment of Eustachian tube dysfunction with balloon dilation: A systematic review. *Laryngoscope.* 2018;128(1):237-47. doi: [10.1002/lary.26800](https://doi.org/10.1002/lary.26800)
11. McMurran AEL, Hogg GE, Gordon S, Spielmann PM, Jones SE. Balloon Eustachian tuboplasty for Eustachian tube dysfunction: report of long-term outcomes in a UK population. *J Laryngol Otol.* 2020;134(1):34-40. doi: [10.1017/S0022215119002548](https://doi.org/10.1017/S0022215119002548)
12. Anand V, Poe D, Dean M, Roberts W, Stolovitzky P, Hoffmann K, et al. Balloon dilation of the eustachian tube: 12-month follow-up of the randomized controlled trial treatment group. *Otolaryngol Head Neck Surg.* 2019;160(4):687-94. doi: [10.1177/0194599818821938](https://doi.org/10.1177/0194599818821938)
13. Silvola J, Kivekäs I, Poe D. Balloon dilation of the cartilaginous portion of the eustachian tube. *Otolaryngol Head Neck Surg.* 2014;151(1):125-30. doi: [10.1177/0194599814529538](https://doi.org/10.1177/0194599814529538)
14. Schröder S, Lehmann M, Ebmeyer J, Upile T, Sudhoff H. Balloon Eustachian tuboplasty: a retrospective cohort study. *Clin Otolaryngol.* 2015;40(6):629-38. doi: [10.1111/coa.12429](https://doi.org/10.1111/coa.12429)
15. Luukkainen V, Vnencak M, Aarnisalo AA, Jero J, Sinkkonen ST. Patient satisfaction in the long-term effects of Eustachian tube balloon dilation is encouraging. *Acta Otolaryngol.* 2018;138(2):122-7. doi: [10.1080/00016489.2017.1384568](https://doi.org/10.1080/00016489.2017.1384568)
16. Poe D, Anand V, Dean M, Roberts WH, Stolovitzky JP, Hoffmann K, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: A randomized controlled trial. *Laryngoscope.* 2018;128(5):1200-6. doi: [10.1002/lary.26827](https://doi.org/10.1002/lary.26827)
17. Meyer TA, O'Malley EM, Schlosser RJ, Soler ZM, Cai J, Hoy MJ, et al. A randomized controlled trial of balloon dilation as a treatment for persistent eustachian tube dysfunction with 1-year follow-up. *Otol Neurotol.* 2018;39(7):894-902. doi: [10.1097/MAO.0000000000001853](https://doi.org/10.1097/MAO.0000000000001853)
18. Sudhoff HH, Mueller S. Treatment of pharyngotympanic tube dysfunction. *Auris Nasus Larynx.* 2018;45(2):207-14. doi: [10.1016/j.anl.2017.07.001](https://doi.org/10.1016/j.anl.2017.07.001)
19. McCoul ED, Anand VK, Christos PJ. Validating the clinical assessment of eustachian tube dysfunction: The eustachian tube dysfunction questionnaire (ETDQ-7). *Laryngoscope.* 2012;122(5):1137-41. doi: [10.1002/lary.23223](https://doi.org/10.1002/lary.23223)
20. Leichtle A, Hollfelder D, Wollenberg B, Bruchhage K. Balloon Eustachian Tuboplasty in children. *Eur Arch Otorhinolaryngol.* 2017;274(6):2411-9. doi: [10.1007/s00405-017-4517-8](https://doi.org/10.1007/s00405-017-4517-8)
21. Tisch M, Maier H, Sudhoff H. Balloon dilation of the Eustachian tube: clinical experience in the management of 126 children. *Acta Otorhinolaryngol Ital.* 2017;37(6):509-12. doi: [10.14639/0392-100X-1690](https://doi.org/10.14639/0392-100X-1690)