World Journal of Otorhinolaryngology-Head and Neck Surgery (2019) 5, 143–147

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.keaipublishing.com/WJOHNS; www.wjent.org

Research Paper

In-office balloon dilation of the Eustachian tube under local anesthesia: A retrospective review

Marc Dean

Texas Tech University Health Science Center, Lubbock, TX, USA
Vitruvio Institute of Medical Advancement, Dallas, TX, USA

Received 19 May 2019; accepted 22 August 2019
Available online 12 October 2019

KEYWORDS
Balloon dilatation;
Eustachian tube;
Local anesthesia;
In office;
Topical

Abstract *Objective:* To study the effectiveness and feasibility of in office balloon dilation of the Eustachian tube (BDET) utilizing a novel anesthetic protocol. Study design: retrospective review.
Methods: Retrospective chart review looking at the tolerability and effectiveness of stand-alone BDET in an office setting utilizing a novel topical anesthesia protocol in 33 patients with Eustachian tube dysfunction as defined by an ETDQ-7 score greater than 2.2 and type B or C tympanograms for greater than 3 months despite maximal medical management, including at least 4 weeks of nasal steroids.
Results: BDET in the office was well tolerated with 94% (31/33) of patients completing the procedure as planned. No adverse effects or complications were reported; however, the planned dilation time was cut short in one case due to significant discomfort and aborted prior to dilation in another due significant coughing. Tympanograms normalized at six weeks in 87.1% (27/31) of patients who underwent dilation.
Conclusion: This study demonstrates that performing BDET in an office setting utilizing a local anesthesia protocol is feasible and effective when the unique barometric considerations of BDET are addressed.
Copyright © 2019 Chinese Medical Association. Production and hosting by Elsevier B.V. on behalf of KeAi Communications Co., Ltd. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

E-mail address: marc.dean@gmail.com.
Peer review under responsibility of Chinese Medical Association.

Production and Hosting by Elsevier on behalf of KeAi

https://doi.org/10.1016/j.wjorl.2019.08.001
2095-8811/Copyright © 2019 Chinese Medical Association. Production and hosting by Elsevier B.V. on behalf of KeAi Communications Co., Ltd. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Introduction

Balloon dilation of the cartilaginous Eustachian tube has been emerging as a readily performed procedure that has demonstrated both safety and efficacy, with success rates ranging between 64% and 87% and complication rates less than 1%. However, the true advantage of BDET is the ability to address the entire cartilaginous Eustachian tube with relative simplicity.[1] Currently, BDET is mainly performed under general anesthesia, previous studies have looked at the feasibility of performing BDET in an office setting under local anesthesia using various local anesthetic protocols, but felt there was still significant pain and discomfort during the procedure, as well as potential for vagal reactions.[2] The ability to perform BDET under local anesthesia in an office setting would offer obvious advantages, including improved patient safety, faster patient recovery, and reduced treatment costs.

The anatomical structures of Eustachian Tube (ET) were first described by Bartolomeus Eustachius in 1562, but actual function of the ET wasn't really understood until Duverney proposed that the ET served as the channel through which the air of the middle ear was renewed, rather than an avenue for hearing or respiration in 1683. In 1724, Guyot performed the first procedures aimed at improving function of the ET.[3] Since that time, many different procedures have been attempted to restore function to the Eustachian tube, unfortunately the majority have been shown to be ineffective. In 2009 Ockermann et al,[4] first described the clinical use of a noncompliant balloon to dilate the eustachian tube to treat Eustachian tube Dysfunction (ETD). Since then, multiple studies have demonstrated symptomatic as well as objective clinical improvement in patients undergoing balloon dilation of the cartilaginous Eustachian tube for ETD.[5]

In one of the first studies looking at the effectiveness of BDET, Catalano et al[6] retrospectively reviewed 100 BDET and reported, 71% of patients experienced improvement in ear fullness and pressure with 87% of those reporting persistent improvement. Importantly, 37% of these procedures where performed under local anesthesia in the office, but many of these procedures only achieved 6—8 ATM and were discontinued after 10 seconds due to pain. Luukkainen et al[2] prospectively evaluated the effectiveness of topical anesthetic ointment applied directly into the lumen of the eustachian tube in conjunction with monitored anesthesia care (MAC). Their study demonstrated significantly more discomfort occurs in patients undergoing BDET compared to patients undergoing FESS.

Recently a multi-institutional prospective randomized controlled trial of patients with chronic ETD, Poe et al.[5] demonstrated that at 6-weeks post procedure, patients undergoing BDET experienced normalization of tympanograms (51.8% versus 13.9%) and ETDQ-7 scores (56.2% versus 8.5%) and these results were durable for 24 weeks. In a follow up study, Annad et al.[7] demonstrated these results to be durable for 52 weeks In another recent randomized controlled trial where 72% of the procedures were performed under local anesthesia, BDET showed significant improvement in ETDQ-7 scores that were durable through 12 months of follow up.[8]

With increased utilization of BDET to treat ETD, as well as mounting evidence indicating efficaciousness of BDET, there is a renewed interest in performing this procedure in an office setting under local anesthesia. The purpose of this work was to determine if a novel topical local anesthetic protocol can enable BDET to be performed safely and effectively in an office setting.

Materials and methods

Approval was obtained from Western institutional review board and the medical records at a single office facility where reviewed and 117 patients where identified who had undergone in office BETD for Eustachian tube dysfunction as defined by an ETDQ-7 score greater than 2.2 and type B or C tympanograms for greater than 3 months despite medical management, including at least 4 weeks of nasal steroids. Of these 117 patients, 33 underwent in office BDET under local anesthesia without any concomitant procedures, and had undergone objective evaluation with tympanograms both preoperatively as well 6 weeks postoperatively.

Prior to the procedure, patients had been premedicated with diazepam to suppress any significant vestibular events during the procedure. Upon arrival to the office Oxymetazoline was administered into each nostril, followed by 5 drops of 7% tetracaine/7% lidocaine compounded into an otic solution placed onto the ipsilateral intact tympanic membrane via the external auditory canal. Cottonoids soaked in 2% tetracaine where placed along the nasal floor bilaterally and left to sit for approximately 10 min. The cottonoids where then removed and approximately 0.5 cc of compounded 7% Tetracaine/7% Lidocaine cream was applied to the ET orifice via a Weiss catheter (Grace Medical, Memphis, TN, USA) (Fig. 1). The tetracaine soaked cottonoids where then replaced. After approximately 10—15 min, the cottonoids were removed and the procedure initiated. The BDET local anesthesia protocol see Fig. 2.

All procedures were performed utilizing a 45-degree rigid endoscope with a diameter of 2 mm. The balloon dilatation itself was carried out with an Acclarent Aera balloon catheter (Acclarent, Irvine CA). The balloon was inserted into the Eustachian tube orifice under direct endoscopic view to avoid creation of a false passage, and inflated at approximately 1 ATM per second until the pressure reaches 12 ATM. The balloon was then held in the inflated position for 2 min then deflated and slowly retracted into the guide to avoid creating a vacuum upon removal.

Results

A total of 33 patients where included in the study, ranging from 18 to 86 years old. No adverse effects, vagal reactions or complications were reported; however only 94% (31/33) of patients were able to complete the procedure as planned. In one instance, the planned dilation time was cut short due to significant discomfort. In the other, the procedure was aborted prior to dilation due to significant coughing. Of the patients who completed the procedure,

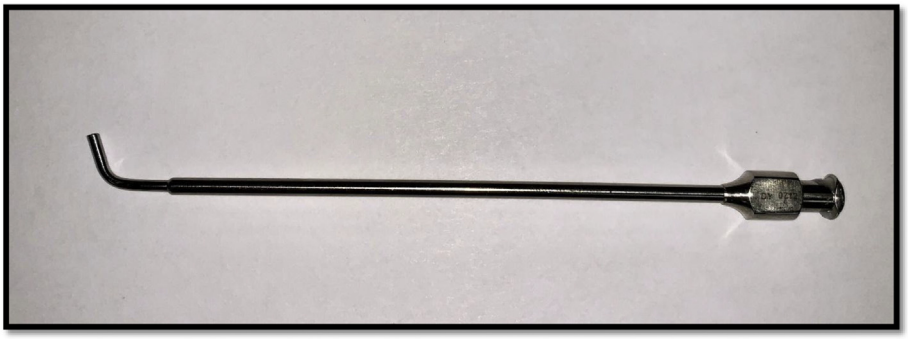

Fig. 1 Weiss catheter (Grace Medical, Memphis, TN, USA).

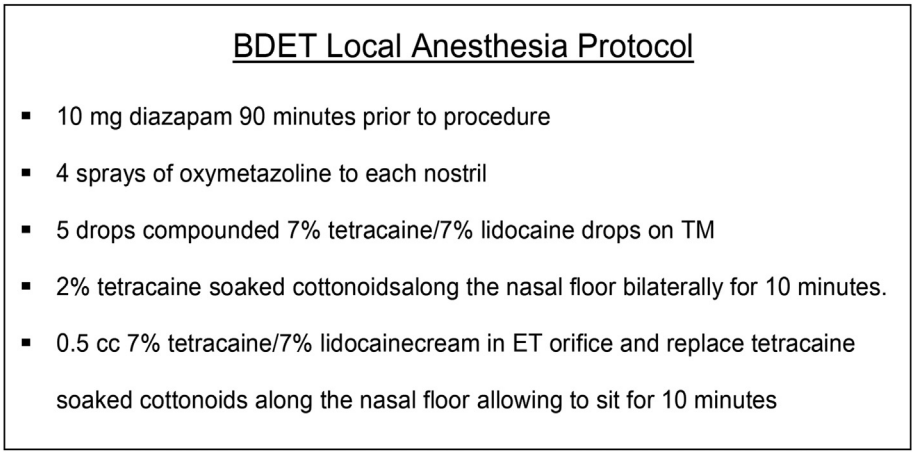

Fig. 2 BDET local anesthesia protocol.

87.1% (27/31) demonstrated normalization of their 6 weeks post-operative tympanograms (Fig. 3). A total of 43 Eustachian tubes where dilated and 90.1% (39/43) normalized, of those the 4 that failed to normalize, 2 remained type C and 2 switched from a type B to a type C (Fig. 4).

Discussion

Dilatory Eustachian tube dysfunction has been estimated to effect up to 30%—80% of children, at some point during their childhood.[9] Despite the maturation of the eustachian tube, and aggressive medical and surgical management of underlying pathologies, ETD continues to plague as much as 5% of the population throughout their adult lives.[5]

Work by Poe et al,[10] has shown that the most common cause of dilatory dysfunction is mucosal inflammation within the cartilaginous Eustachian tube, most often due to allergic rhinitis, chronic rhinosinusitis, laryngopharyngeal reflux, ortobacco smoke exposure. This mucosal inflammation directly effects a dynamic valve-like region within the cartilaginous Eustachian tube created by the insertion of the tensor veli palatine muscle located 12—20 mm distal to the nasopharyngeal orifice. It is the abnormal opening of this valve that is believed to be the underlying factor in Eustachian tube dysfunction.[11]

Kujawaski[3] ushered in the modern era of surgical treatment of the Eustachian tube in 1997 by describing the first eustachian tuboplasty. He approached the eustachian tube both transorally and transnasally to obliterate mucosa and cartilage from the posterior cushion using a laser. Ten years later Metson[12] described an exclusively transnasal approach that utilized a powered shaver such as is commonly used in endoscopic sinus surgery. In 2009 Ockerman[4] published his study exploring the use of sinus balloons as a device to treat dilatory Eustachian Tube Dysfunction. Since then BDET has emerged as the treatment of choice mainly due to its high reported success rates ranging anywhere from 64% to 87%, and low complication rate of approximately 1%.[1]

Today many sinonasal procedures are routinely performed in the office under local anesthesia, including balloon dilation of the sinus ostium. However, both Catalano et al[6] and Luukkainen et al[2] demonstrated that typical in office protocols did not provide sufficient pain control to perform BDET reliably. One reason for this, may be that compared to commonly performed office procedures, BDET presents specific barometric challenges that if not addressed can lead to undesirable results in an office setting.

Previously reported local anesthetic protocols have mainly focused on anesthetizing the cartilaginous Eustachian tube via the nasopharynx, and have not addressed the significant variations of middle ear pressure that occur during BDET, and the effect it has on the tympanic membrane (TM). Sudhoff et al[13] studied middle ear pressures generated during in BDET in patients with normal middle

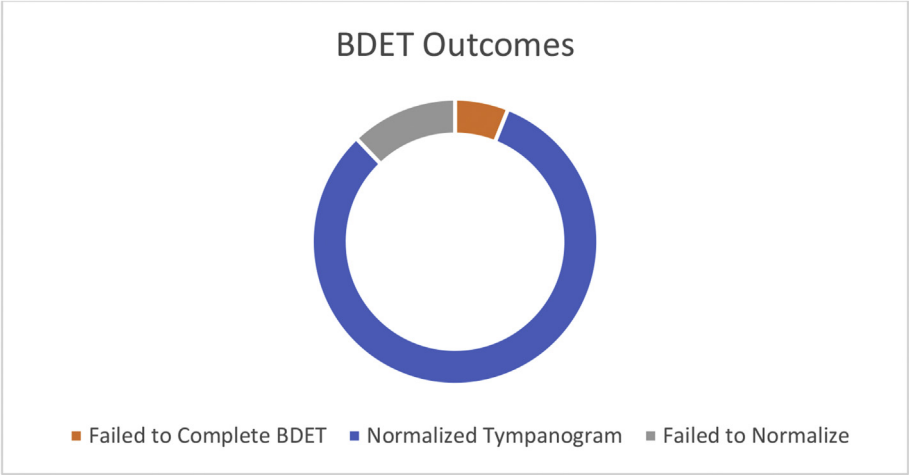

Fig. 3 BDET outcomes.

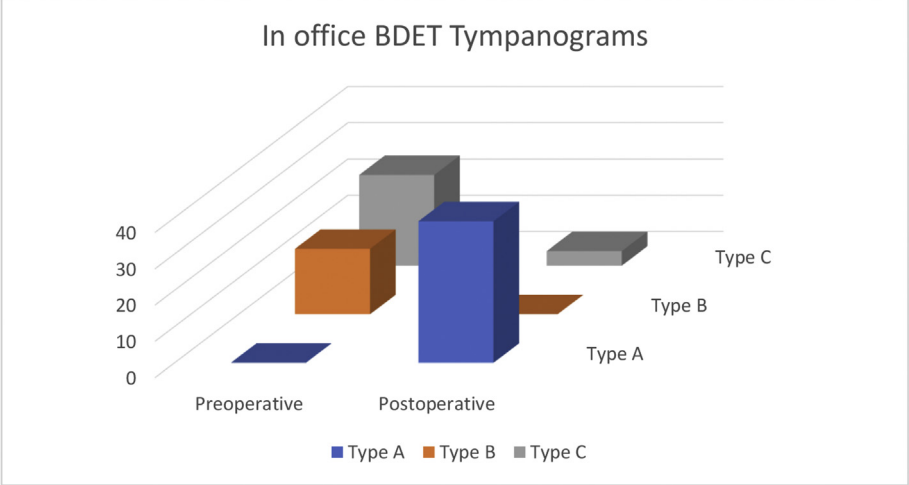

Fig. 4 In office BDET tympanograms.

ears and ET function, as defined by a type A tympanogram with a middle ear pressure of 0 daPa prior to the procedure and demonstrated that during BDET, middle ear pressures increased an average + 58 daPa on insertion and inflation, and decreased an average −90 daPa on deflation and withdrawal, but were noted to be as high as 206 daPa and as low as −253 daPa.

While the pressures generated during BDET are not enough to damage middle ear structures, speed and degree of pressure changes may be significant enough to induce discomfort. Schwanitz et al[14] investigated the influence of pressure changes on the level of comfort and found that 14% of people reported a significant level of discomfort at a pressure change rate of 50 daPa/s. This is well within the range of pressure changes reported by Sudhoff et al. More importantly, a pressure differential greater than 500 daPa between the left and right middle ears, can result in Alternobaric vertigo (AV) which is characterized by vertigo, nystagmus, nausea, visual disturbances. This is an important consideration, as it is possible for patients with significant negative middle ear pressure secondary to bilateral ETD undergoing BDET to generate a greater than 500 daPa difference between ears when the balloon is inserted and inflated into the first eustachian tube.[15,16] Vestibular suppressants, such as those described in this study, can minimize this phenomenon.[17]

In addition to utilizing vestibular suppressants to blunt the effects of rapid barometric changes, the topical anesthetic protocol described in this study employs a 7% tetracaine/7% Lidocaine otic solution to anesthetize the TM as it stimulated during BDET, reducing pain and discomfort as well as helping to prevent the vasovagal reactions that have been reported in the other series.[2]

The sensory innervation of the tympanic membrane is derived from multiple sources. The external surface is supplied primarily by the auriculotemporal nerve, a branch of the mandibular nerve, with contributions from the auricular branch of the Vagus nerve (ABVN), the facial nerve, and occasionally the glossopharyngeal nerve. The inner surface of the TM is innervated mainly by the glossopharyngeal nerve.[18] In addition, there are also mechanical receptors located on the TM, which in combination with mechanical receptors on the promontory and nasopharynx create a neuronal reflex arc that is uniquely sensitive to the barometric changes.[19]

Because of this complex innervation, physical distortion of the TM, not only induces pain and discomfort via stimulation of the sensory afferent innervation located on the membrane, but has the potential to trigger vasovagal responses through direct stimulation of the ABVN or indirectly through stimulation of the trigeminal nerve. Functional MRI scans have shown that stimulation of the ABVN within the ear produces significant activation of classical central vagal projections within the brain, and while this direct vasovagal response is relatively uncommon, it has been demonstrated to occur in 1.7%—4.2% of the population and is believed be due to hypersensitivity of the ABVN.[20]

Stimulation of the auriculotemporal nerve, a branch of the trigeminal nerve has also been observed to trigger vagal responses via the Trigeminal Cardiac Reflex (TCR) which is a clinical phenomenon consisting of sudden onset of hemodynamic, respiratory and gastric changes resulting from stimulation of any branch of the fifth cranial nerve along its course. This stimulation triggers the nerve to send neuronal signals via the Trigeminal ganglion to the sensory nucleus, and then through short internuncial fibers, to the reticular formation and finally onto motor nucleus of the Vagus nerve. This activation of the Vagus nerve is responsible for bradycardia and occasional hypotension as well as other manifestations including predominantly apnea and gastric hypermotility seen in TCR, however direct sympathetic stimulation can also occur, causing peripheral vasoconstriction explaining the lack of hypotension seen in many of these cases.[21]

The topical local anesthetic protocol described in this study addresses the unique barometric considerations of BDET allowing for 94% of patients to undergo BDET in the office at the recommended 12 ATM for two minutes.[2] In addition, 87.1% of these patients normalized their tympanograms at 6 weeks post op, indicating that utilizing a topical local anesthesia protocol in an office setting does not inhibit the effectiveness of BDET.

Conclusion

This study demonstrates that by utilizing a local anesthetic protocol that employs both a vestibular suppressant prior to the procedure to minimize the risk of alternobaric vertigo and topically anesthetizing the tympanic membrane to block the vagal responses, BDET can be performed safely and effectively in an office setting.

Conflict of interest

The author declare no conflict of interest relevant to this paper.

References

1. Miller BJ, Elhassan HA. Balloon dilatation of the Eustachian tube: an evidence-based review of case series for those considering its use. *Clin Otolaryngol*. 2013;38:525—532.
2. Luukkainen V, Kivekäs I, Hammarén-Malmi S, et al. Balloon Eustachian tuboplasty under local anesthesia: is it feasible? *The Laryngoscope*. 2017;127:1021—1025.
3. McCoul ED, Lucente FE, Anand VK. Evolution of Eustachian tube surgery. *The Laryngoscope*. 2011;121:661—666.
4. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilatation eustachian tuboplasty: a clinical study. *The Laryngoscope*. 2010;120:1411—1416.
5. Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: a randomized controlled trial. *The Laryngoscope*. 2018;128:1200—1206.
6. Catalano PJ, Jonnalagadda S, Yu VM. Balloon catheter dilatation of Eustachian tube: a preliminary study. *Otol Neurotol*. 2012;33:1549—1552.
7. Anand V, Poe D, Dean M, et al. Balloon dilation of the Eustachian tube: 12-month follow-up of the randomized controlled trial treatment group. *Otolaryngol Head Neck Surg*. 2019;160:687—694.
8. Meyer TA, O'Malley EM, Schlosser RJ, 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;39:894—902.
9. Bluestone CD. *Eustachian Tube: Structure, Function, Role in Otitis Media*vols. 1—9. New York: BC Decker; 2005.
10. Adil E, Poe D. What is the full range of medical and surgical treatments available for patients with Eustachian tube dysfunction? *Curr Opin Otolaryngol Head Neck Surg*. 2014;22:8—15.
11. Poe DS, Pyykkö I, Valtonen H, Silvola J. Analysis of eustachian tube function by video endoscopy. *Am J Otol*. 2000;21:602—607.
12. Metson R, Pletcher SD, Poe DS. Microdebrider eustachian tuboplasty: a preliminary report. *Otolaryngol Head Neck Surg*. 2007;136:422—427.
13. Sudhoff H, Mittmann P, Todt I. In vivo measurement of middle ear pressure changes during balloon eustachian tuboplasty. *Biomed Res Int*. 2018;2018:9519204.
14. Schwanitz S, Wittkowski M, Rolny V, Basner M. Pressure variations on a train - where is the threshold to railway passenger discomfort? *Appl Ergon*. 2013;44:200—209.
15. Kitajima N, Sugita-Kitajima A, Kitajima S. Altered eustachian tube function in SCUBA divers with alternobaric vertigo. *Otol Neurotol*. 2014;35:850—856.
16. Klingmann C, Knauth M, Praetorius M, Plinkert PK. Alternobaric vertigo-really a hazard? *Otol Neurotol*. 2006;27:1120—1125.
17. Hain TC, Yacovino D. Pharmacologic treatment of persons with dizziness. *Neurol Clin*. 2005;23:831—853.
18. O'Rahilly R, Müller F, Carpenter S, Swenson R. *Basic Human Anatomy: A Regional Study of Human Structure*; 2008. http://www.dartmouth.edu/~humananatomy/.
19. Songu M, Aslan A, Unlu HH, Celik O. Neural control of eustachian tube function. *The Laryngoscope*. 2009;119:1198—1202.
20. Murray AR, Atkinson L, Mahadi MK, Deuchars SA, Deuchars J. The strange case of the ear and the heart: the auricular vagus nerve and its influence on cardiac control. *Auton Neurosci*. 2016;199:48—53.
21. Meuwly C, Golanov E, Chowdhury T, Erne P, Schaller B. Trigeminal cardiac reflex: new thinking model about the definition based on a literature review. *Medicine (Baltimore)*. 2015;94:e484.

Edited by Xin Jin