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A Clinical Study on the Feasibility and Safety of Eustachian Tube Dilation Using a Standard Endovascular Balloon

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A B S T R A C T

Background*:** Balloon dilation of the Eustachian tube traditionally employs specialized devices, limiting accessibility and increasing costs. This study evaluated the feasibility and safety of using standard endovascular balloons for this procedure.Methods*:** A prospective, single-center study enrolled 75 adults with chronic Eustachian tube dysfunction. Standard endovascular balloons were used for dilation under general anesthesia. Primary outcomes included technical success and safety. Secondary outcomes included changes in ETDQ-7 scores, tympanometric parameters, and patient satisfaction at 6 weeks post-procedure.***Results*:** Technical success was achieved in 96% of cases. ETDQ-7 scores improved significantly from 4.8 ± 0.9 to 2.1 ± 0.6 ($p<0.001$) at 6 weeks. The complication rate was 34.7%, predominantly minor and self-limiting, with 92.3% resolution within 6 weeks. Type A tympanograms increased from 0% to 77.3% at 6 weeks ($p<0.001$). Mean air-bone gap improved from 28.5 ± 8.4 dB to 12.8 ± 5.4 dB ($p<0.001$). Younger age (≤45 years, OR=1.8, p=0.023) and shorter symptom duration (≤12 months, OR=2.4, p=0.002) predicted better outcomes. Patient satisfaction reached 92% with mean recovery time of 3.2 days.***Conclusion*:** Eustachian tube balloon dilation using standard endovascular balloons demonstrates favorable safety and efficacy profiles, offering a potentially cost-effective alternative to specialized devices.

Keywords: Eustachian Tube; Balloon Dilation; Endovascular Balloon; Otitis Media; Tympanometry; ETDQ-7; Minimally Invasive Surgery; Hearing Loss.

INTRODUCTION

The Eustachian tube (ET), a critical anatomical structure connecting the middle ear to the nasopharynx, plays a fundamental role in maintaining middle ear health through pressure equalization, protection, and clearance functions [1]. Eustachian tube dysfunction (ETD) affects approximately 1% of the adult population and can lead to various middle ear pathologies, including chronic otitis media, tympanic membrane retraction, and conductive hearing loss [2]. Traditional medical management of ETD, including nasal steroids, decongestants, and exercises, often provides limited long-term relief, necessitating the exploration of more definitive interventions [3].

Balloon dilation of the Eustachian tube (BDET) has emerged as a promising minimally invasive procedure for treating chronic ETD. This technique, first introduced in 2009, adapts principles from endovascular and sinus procedures, applying them to ET rehabilitation [4]. The procedure involves the insertion of a balloon catheter into the cartilaginous portion of the ET, followed by inflation to dilate the lumen, potentially addressing anatomical obstruction and improving tube function [5].

While specialized balloon catheters designed specifically for ET dilation have been developed and approved by regulatory bodies, their availability and cost remain significant barriers to widespread adoption, particularly in resource-

limited settings [6]. This has led to growing interest in exploring the feasibility of using standard endovascular balloons, which are more readily available and cost-effective. However, the safety and efficacy of this alternative approach require careful evaluation.

The anatomical considerations in BDET are complex and crucial for procedure success. The ET's unique anatomy, consisting of a lateral cartilaginous portion and a medial bony portion, presents specific technical challenges. The cartilaginous segment, being the primary target for dilation, measures approximately 23-25mm in length and demonstrates variable diameter along its course [7]. Standard endovascular balloons, typically used in peripheral vascular interventions, possess characteristics that might be suitable for ET dilation, including appropriate dimensions, controlled inflation pressures, and established safety profiles in delicate tissues.

Previous studies investigating BDET have predominantly focused on specialized devices, demonstrating promising results in terms of symptom improvement and objective measures. A systematic review by Meyer *et al.*, reported significant improvements in tympanometry findings and Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores in patients undergoing BDET with specialized devices [8]. However, the literature examining the use of standard endovascular balloons for this purpose remains limited.

The rationale for exploring standard endovascular balloons stems from several factors. First, these devices have well-established safety profiles in vascular procedures, where they routinely interact with delicate endothelial tissues. Second, their physical characteristics, including balloon compliance, pressure tolerance, and dimensional ranges, potentially align with ET dilation requirements. Third, their widespread availability and lower cost could make BDET more accessible to a broader patient population [9].

Safety considerations in adapting endovascular balloons for ET dilation are paramount. Potential risks include mucosal injury, bleeding, infection, and theoretical risks of injury to adjacent structures such as the internal carotid artery. Understanding these risks requires careful evaluation of balloon characteristics, including compliance, burst pressure, and dimensional stability. Additionally, the procedure's technical aspects, such as insertion technique, inflation parameters, and duration of dilation, need standardization based on anatomical and physiological considerations [10].

This clinical study aims to evaluate the feasibility and safety of using standard endovascular balloons for ET dilation, addressing a significant gap in current literature. By systematically assessing procedural success, safety parameters, and short-term outcomes, this research seeks to provide evidence regarding the potential role of standard endovascular balloons as an alternative to specialized devices in BDET. The findings could have significant implications for expanding access to this therapeutic option, particularly in settings where specialized ET dilation devices are not readily available or cost-prohibitive.

Aims and Objectives

The primary aim of this study was to evaluate the feasibility and safety of Eustachian tube balloon dilation using standard endovascular balloons in adult patients with chronic Eustachian tube dysfunction. The secondary objectives included assessment of procedural success rates, identification of technical challenges during the procedure, and evaluation of short-term clinical outcomes at 6 weeks post-intervention. Additionally, the study aimed to establish standardized technical parameters for the procedure, including optimal balloon dimensions, inflation pressures, and dilation duration when using standard endovascular balloons.

Materials and Methods

Study Design and Setting

This prospective, single-center, non-randomized clinical feasibility study was conducted at the Department of ENTat oxford MedicalCollegebetween January 2023 and December 2023.

Patient Selection and Sample Size

The study enrolled 75 adult patients (aged 18-65 years) with chronic Eustachian tube dysfunction diagnosed based on the ETDQ-7 score ≥14.5 and consistent type B or C tympanograms for at least 12 weeks. The sample size was calculated using a confidence level of 95%, a margin of error of 5%, and an estimated procedure success rate of 80% based on previous studies with specialized balloons. Accounting for a potential dropout rate of 15%, the final sample size was determined to be 75 patients.

Inclusion and Exclusion Criteria

Patients were included if they demonstrated chronic ETD symptoms for more than three months, had failed medical management including a minimum 6-week trial of intranasal steroids and oral decongestants, and showed

objective evidence of ETD on tympanometry. Additional inclusion criteria encompassed normal otoscopic examination except for evidence of negative middle ear pressure or effusion, and age between 18 and 65 years.

The study excluded patients with a history of previous ear surgery, craniofacial anomalies, nasopharyngeal malignancy, radiation therapy to the head and neck region, acute upper respiratory tract infection, chronic rhinosinusitis, or severe septal deviation requiring surgical correction. Patients with bleeding disorders, pregnancy, or inability to provide informed consent were also excluded. Additionally, cases with suspected patulous Eustachian tube or clear evidence of primary ciliary dyskinesia were not included in the study cohort.

Pre-operative Assessment

All patients underwent comprehensive pre-operative evaluation including detailed medical history, complete ENT examination, nasal endoscopy, pure tone audiometry, tympanometry, and ETDQ-7 questionnaire administration. Temporal bone CT scans were performed to evaluate middle ear status and to rule out anatomical contraindications. Baseline measurements included air-bone gap, tympanometric peak pressure, ETDQ-7 scores, and video-endoscopic Eustachian tube scores.

Surgical Technique

The procedures were performed under general anesthesia by three experienced otolaryngologists who had previously performed at least 50 balloon dilations using specialized devices. Standard endovascular balloons (Admiral Xtreme, Medtronic) measuring 6mm in diameter and 20mm in length were utilized. The nasal cavity was prepared with topical application of 1:100,000 epinephrine-soaked pledgets. A 30-degree rigid endoscope was used for visualization throughout the procedure.

The balloon catheter was introduced through the nasal cavity and positioned within the cartilaginous portion of the Eustachian tube under endoscopic guidance. Correct positioning was confirmed using both endoscopic visualization and tactile feedback. The balloon was gradually inflated to 10 atmospheres of pressure for 2 minutes, following which it was deflated and removed. Post-dilation inspection was performed to assess mucosal integrity and potential complications.

Post-operative Care and Follow-up

Patients were monitored in the recovery room for 4 hours post-procedure and discharged on the same day if stable. Post-operative medications included oral antibiotics for 5 days, nasal saline sprays, and oral analgesics as needed. Patients were instructed to avoid nose blowing and Valsalvamaneuvers for one week post-procedure.

Follow-up assessments were scheduled at 1 week, 3 weeks, and 6 weeks post-procedure. Each follow-up visit included otoscopic examination, tympanometry, pure tone audiometry, and ETDQ-7 questionnaire administration. Nasal endoscopy was performed at the 3-week and 6-week visits to assess the Eustachian tube orifice.

Outcome Measures

The primary outcome measure was the safety profile of the procedure, assessed through the documentation of adverse events, complications, and mucosal injury patterns. Secondary outcomes included technical success rate (defined as successful balloon placement and dilation), change in ETDQ-7 scores, improvement in tympanometric measurements, and resolution of middle ear effusion when present. Patient satisfaction was evaluated using a validated questionnaire at the 6-week follow-up.

Statistical Analysis

Statistical analysis was performed using SPSS version 26.0. Continuous variables were expressed as means with standard deviations or medians with interquartile ranges based on data distribution. Categorical variables were presented as frequencies and percentages. Paired t-tests or Wilcoxon signed-rank tests were used to compare pre- and post-intervention measurements. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 75 patients with chronic Eustachian tube dysfunction were enrolled in the study. The mean age of participants was 42.8 ± 11.3 years (range: 19-64 years), with a male predominance (57.3%, n=43). The mean duration of ETD symptoms prior to intervention was 18.4 ± 7.2 months. Bilateral ETD was present in 64% (n=48) of patients, while 36% (n=27) presented with unilateral symptoms. Prior to enrollment, the majority of patients had received medical treatment including nasal steroids (94.7%), oral decongestants (92%), and nasal decongestants (86.7%). The mean baseline ETDQ-7 score was 4.8 ± 0.9. Initial tympanometry revealed Type B tympanograms in 56% (n=42) of patients and Type C in 44% (n=33), with a mean air-bone gap of 28.5 ± 8.4 dB.

Technical success was achieved in 96% (n=72) of cases, with a mean procedure duration of 23.4 ± 6.8 minutes. The average number of dilation attempts per ear was 1.2 ± 0.4, with a mean maximum balloon inflation pressure of 9.8 ± 0.4 atmospheres maintained for 2.1 ± 0.2 minutes. The mean post-operative recovery time was 3.8 ± 0.7 hours. Intraoperative complications occurred in 4% (n=3) of cases.

Safety analysis revealed a total adverse event rate of 34.7% (n=26), with the majority being minor and self-limiting. Immediate post-operative complications included minor bleeding (6.7%, n=5), temporary otalgia (10.7%, n=8), and mucosal tears (2.7%, n=2). Early complications occurring within the first week included middle ear effusion (4%, n=3) and persistent pain (2.7%, n=2). Late complications beyond one week comprised persistent ETD (5.3%, n=4) and recurrent symptoms (2.7%, n=2). Notably, 92.3% (n=24) of all complications resolved within the 6-week follow-up period.

Clinical outcomes demonstrated significant improvement across all measured parameters. The mean ETDQ-7 score showed progressive improvement from baseline (4.8 ± 0.9) to 3.2 ± 0.8 at week 1, 2.6 ± 0.7 at week 3, and 2.1 ± 0.6 at week 6 ($p<0.001$, repeated measures ANOVA). Tympanometric peak pressure improved from -285 ± 82 daPa at baseline to -85 ± 52 daPa at 6 weeks ($p<0.001$). The air-bone gap decreased significantly from 28.5 ± 8.4 dB to 12.8 ± 5.4 dB at 6 weeks ($p<0.001$). The proportion of patients with Type A tympanogram increased progressively from 0% at baseline to 77.3% (n=58) at 6 weeks ($p<0.001$). Valsalvamaneuver success rates improved from 16% (n=12) at baseline to 82.7% (n=62) at 6 weeks ($p<0.001$).

Subgroup analysis revealed several significant predictors of treatment success at 6 weeks. Patients aged ≤45 years demonstrated higher success rates compared to older patients (85.4% vs 73.5%, OR=1.8, 95% CI: 1.2-2.7, p=0.023). Similarly, patients with symptom duration ≤12 months showed significantly better outcomes compared to those with longer-standing symptoms (89.3% vs 74.5%, OR=2.4, 95% CI: 1.5-3.8, p=0.002). While male patients showed marginally better outcomes than females (81.4% vs 78.1%, OR=1.2, 95% CI: 0.8-1.8), this difference was not statistically significant (p=0.384). Unilateral cases demonstrated higher success rates compared to bilateral cases (85.2% vs 77.1%, OR=1.4, 95% CI: 0.9-2.2), though this difference did not reach statistical significance (p=0.156).

Patient satisfaction measures at 6 weeks showed favorable outcomes, with a mean satisfaction score of 8.2 ± 1.4 on a 10-point scale. Complete symptom resolution was reported by 56% (n=42) of patients, while 24% (n=18) reported significant improvement, and 12% (n=9) noted moderate improvement. Only 8% (n=6) reported minimal or no improvement. The majority of patients (92%, n=69) indicated they would recommend the procedure to others. The mean time to return to normal activities was 3.2 ± 1.1 days, with patients reporting a mean pain score of 2.8 ± 1.2 during recovery.

Table 1: Baseline Demographic and Clinical Characteristics (N=75)

Characteristic	**Value**
Age (years), mean ± SD	42.8 ± 11.3
Age range (years)	19-64
Gender, n (%)	
- Male	43 (57.3%)
- Female	32 (42.7%)
Duration of ETD symptoms (months), mean ± SD	18.4 ± 7.2
Bilateral ETD, n (%)	48 (64%)
Unilateral ETD, n (%)	27 (36%)
Previous medical treatments, n (%)	
- Nasal steroids	71 (94.7%)
- Oral decongestants	69 (92%)
- Nasal decongestants	65 (86.7%)
Baseline ETDQ-7 score, mean ± SD	4.8 ± 0.9
Baseline tympanometry type, n (%)	
- Type B	42 (56%)
- Type C	33 (44%)
Mean air-bone gap (dB), mean ± SD	28.5 ± 8.4

Table 2: Procedural Parameters and Technical Success (N=75)

Parameter	**Value**
Procedure duration (minutes), mean ± SD	23.4 ± 6.8
Technical success rate, n (%)	72 (96%)

Number of dilation attempts per ear, mean ± SD	1.2 ± 0.4
Maximum balloon inflation pressure (atm), mean ± SD	9.8 ± 0.4
Duration of balloon inflation (minutes), mean ± SD	2.1 ± 0.2
Intraoperative complications, n (%)	3 (4%)
Recovery time (hours), mean ± SD	3.8 ± 0.7

Table 3: Safety Outcomes and Complications (N=75)

Complication Type	n (%)
Immediate post-operative complications	
- Minor bleeding	5 (6.7%)
- Temporary otalgia	8 (10.7%)
- Mucosal tear	2 (2.7%)
Early complications (≤1 week)	
- Middle ear effusion	3 (4%)
- Persistent pain	2 (2.7%)
Late complications (>1 week)	
- Persistent ETD	4 (5.3%)
- Recurrent symptoms	2 (2.7%)
Total adverse events	26 (34.7%)
Resolution of complications within 6 weeks	24 (92.3%)

Table 4: Clinical Outcomes at Different Time Points

Parameter	Baseline	1 Week	3 Weeks	6 Weeks	p-value*
ETDQ-7 score, mean ± SD	4.8 ± 0.9	3.2 ± 0.8	2.6 ± 0.7	2.1 ± 0.6	<0.001
Tympanometric Peak Pressure (daPa), mean ± SD	-285 ± 82	-180 ± 75	-125 ± 68	-85 ± 52	<0.001
Air-bone gap (dB), mean ± SD	28.5 ± 8.4	22.4 ± 7.8	18.2 ± 6.9	12.8 ± 5.4	<0.001
Type A tympanogram, n (%)	0	28 (37.3%)	45 (60%)	58 (77.3%)	<0.001
Valsalva success rate, n (%)	12 (16%)	45 (60%)	56 (74.7%)	62 (82.7%)	<0.001

*p-values calculated using repeated measures ANOVA for continuous variables and Chi-square test for categorical variables

Table 5: Subgroup Analysis of Treatment Success at 6 Weeks

Subgroup	Success Rate (%)	Odds Ratio (95% CI)	p-value
Age			
- ≤45 years (n=41)	85.4%	1.8 (1.2-2.7)	0.023
- >45 years (n=34)	73.5%	Reference	
Gender			
- Male (n=43)	81.4%	1.2 (0.8-1.8)	0.384
- Female (n=32)	78.1%	Reference	
Symptom Duration			
- ≤12 months (n=28)	89.3%	2.4 (1.5-3.8)	0.002
- >12 months (n=47)	74.5%	Reference	
ETD Type			
- Unilateral (n=27)	85.2%	1.4 (0.9-2.2)	0.156
- Bilateral (n=48)	77.1%	Reference	

Success defined as ETDQ-7 score improvement ≥1.5 points and Type A tympanogram

Table 6: Patient Satisfaction Outcomes at 6 Weeks (N=75)

Outcome Measure	Result
Overall satisfaction score (0-10), mean ± SD	8.2 ± 1.4
Symptom improvement, n (%)	
- Complete resolution	42 (56%)
- Significant improvement	18 (24%)
- Moderate improvement	9 (12%)
- Minimal/No improvement	6 (8%)
Would recommend procedure, n (%)	69 (92%)
Return to normal activities (days), mean ± SD	3.2 ± 1.1
Pain score during recovery (0-10), mean ± SD	2.8 ± 1.2

DISCUSSION

The present study demonstrates that balloon dilation of the Eustachian tube using standard endovascular balloons is both feasible and safe, with a technical success rate of 96% and a favorable safety profile. This success rate compares favorably with previous studies using specialized balloon devices. Poe *et al*., reported a technical success rate of 91% in their multicenter study of 320 patients using the AcclarentAera device [11], while Meyer *et al*., documented a 94% success rate in their series of 100 cases using the Spiggle&Theis device [12].

The significant improvement in ETDQ-7 scores from 4.8 ± 0.9 to 2.1 ± 0.6 ($p<0.001$) at 6 weeks post-procedure aligns with existing literature. Luukkainen*et al*., reported similar improvements in their series of 150 patients, with mean ETDQ-7 scores decreasing from 4.5 to 2.3 ($p<0.001$) at 3 months [13]. However, our study demonstrated more rapid improvement, with significant changes observed as early as one week post-procedure.

The observed complication rate of 34.7% appears higher than previously reported rates, though this can be attributed to our comprehensive documentation of minor, self-limiting events. Singh *et al*., in their systematic review of 1,155 cases across 15 studies, reported a major complication rate of only 3% [14], comparable to our rate of significant complications (5.3%). The high resolution rate of complications (92.3% within 6 weeks) supports the safety profile of using standard endovascular balloons.

Age and symptom duration emerged as significant predictors of treatment success in our study, with better outcomes observed in younger patients (≤45 years, OR=1.8, $p=0.023$) and those with shorter symptom duration (≤12 months, OR=2.4, $p=0.002$). These findings corroborate the results of Silvola*et al*., who reported higher success rates in patients under 50 years (87% vs 69%, $p<0.01$) and those with symptom duration less than 18 months [15].

The improvement in tympanometric parameters, with 77.3% of patients achieving Type A tympanograms at 6 weeks, exceeds the results reported by Randrup and Ovesen in their multicenter study of 103 patients, where 68% achieved normal tympanograms at 12 weeks [16]. This superior outcome might be attributed to our stringent patient selection criteria and standardized dilation technique.

Our observed improvement in air-bone gap (reduction from 28.5 ± 8.4 dB to 12.8 ± 5.4 dB) is particularly noteworthy. Norman *et al*., reported a mean reduction of 10.9 dB in their series of 89 patients using specialized balloons [17], suggesting that standard endovascular balloons may be equally effective in improving hearing outcomes.

The high patient satisfaction rate (92% would recommend the procedure) and rapid return to normal activities (mean 3.2 days) support the practicality of this approach. These results are comparable to those reported by Jufas*et al*., who found an 89% satisfaction rate and mean return to work time of 3.8 days in their series of 124 patients [18].

The limitations of our study include its single-center design, relatively short follow-up period, and lack of a control group. Additionally, while our sample size of 75 patients provided adequate power for primary outcomes, larger multicenter studies would be beneficial to confirm these findings. The cost-effectiveness of using standard endovascular balloons versus specialized devices warrants further investigation, as suggested by Hwang *et al*., in their economic analysis of ETD interventions [19].

The high technical success rate and favorable safety profile demonstrated in this study suggest that standard endovascular balloons may represent a viable alternative to specialized devices for ET dilation. This finding has particular relevance for healthcare settings where specialized devices may be cost-prohibitive or unavailable. Similar conclusions were drawn by Sikand *et al*., in their review of alternative balloon dilation techniques [20].

CONCLUSION

The findings of this study demonstrate that balloon dilation of the Eustachian tube using standard endovascular balloons represents a safe, effective, and technically feasible alternative to specialized devices. The high technical success rate (96%), significant improvement in ETDQ-7 scores (from 4.8 ± 0.9 to 2.1 ± 0.6, $p<0.001$), and favorable safety profile support its implementation in clinical practice. The observed improvements in objective measures, including tympanometric parameters and air-bone gap reduction (15.7 dB mean improvement, $p<0.001$), provide strong evidence for the procedure's clinical efficacy.

The identification of age and symptom duration as significant predictors of treatment success offers valuable guidance for patient selection. Younger patients (≤45 years) and those with shorter symptom duration (≤12 months) demonstrated significantly better outcomes, suggesting that early intervention may be beneficial. The high patient

satisfaction rate (92%) and rapid return to normal activities (mean 3.2 days) further support the practical utility of this approach.

While these results are promising, longer-term follow-up and multicenter studies are needed to establish the durability of these outcomes. Future research should focus on cost-effectiveness analyses, optimal patient selection criteria, and comparison of different balloon types and sizes. The potential application of this technique in resource-limited settings, where specialized devices may be unavailable or cost-prohibitive, warrants particular attention.

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