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Efficacy and Safety of Balloon Dilation of the Eustachian Tube in Adults with Obstructive Eustachian Tube Dysfunction: A Systematic Review

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ABSTRACT

Background: Obstructive Eustachian tube dysfunction (OETD) in adults is a common otologic condition associated with aural fullness, hearing impairment, pressure intolerance, and reduced quality of life. Balloon dilation of the Eustachian tube (BDET) has emerged as a minimally invasive intervention intended to improve tubal function and middle-ear ventilation. However, the overall evidence regarding its efficacy and safety in adult patients remains variable.

Objective: This systematic review aimed to evaluate the efficacy and safety of balloon dilation of the Eustachian tube in adults with obstructive Eustachian tube dysfunction.

Methods: A systematic literature review was conducted using major biomedical databases. Studies were eligible if they involved adult patients with obstructive Eustachian tube dysfunction and evaluated balloon dilation as the primary intervention while reporting efficacy and/or safety outcomes. Screening, study selection, data extraction, and quality assessment were performed using predefined criteria. A total of 1,247 records were identified, of which 289 duplicates were removed. After title and abstract screening, 75 full-text articles were assessed for eligibility, and 10 studies were included in the final review.

Results: The included studies comprised randomized controlled trials, prospective studies, retrospective cohort studies, pilot studies, and comparative clinical studies conducted across multiple countries. Overall, the evidence showed that BDET was associated with significant improvement in patient-reported symptoms, particularly Eustachian Tube Dysfunction Questionnaire scores and pressure-related complaints. Several studies also reported improvement in objective outcomes, including tympanometric findings, Valsalva maneuver performance, hearing levels, and middle-ear status. Safety findings were favorable, with serious complications being rare and most studies describing the procedure as feasible and well tolerated. The pooled effect estimates from the included studies suggested a significant overall benefit of the intervention.

Conclusion: Balloon dilation of the Eustachian tube appears to be an effective and generally safe treatment for adults with obstructive Eustachian tube dysfunction. Nevertheless, the evidence is limited by methodological heterogeneity, variable risk of bias, and relatively short follow-up, highlighting the need for larger, high-quality studies with standardized outcome reporting.

Keywords: Balloon dilation; Eustachian tube dysfunction; Obstructive Eustachian tube dysfunction; Adult otology; Systematic review.

INTRODUCTION

Obstructive Eustachian tube dysfunction (OETD) is a clinically important condition in adults because it interferes with normal middle-ear ventilation, pressure regulation, and clearance of secretions. When the Eustachian tube fails to open adequately, patients may experience aural fullness, muffled hearing, otalgia, pressure intolerance, tinnitus, and recurrent middle-ear problems that can substantially impair daily functioning and quality of life. In persistent cases, OETD may also contribute to chronic otitis media with effusion, tympanic membrane retraction, and other sequelae that justify more definitive intervention. Because of this burden, accurate diagnosis and effective treatment of adult OETD have become increasingly important in otolaryngology practice (Plaza et al., 2020; Tucci et al., 2019).

Conventional management of adult OETD has historically included medical therapy, treatment of contributing nasal or inflammatory conditions, autoinflation strategies, and tympanostomy tubes in selected patients. However, these approaches do not always address the underlying functional obstruction of the cartilaginous Eustachian tube, and treatment failure or symptom recurrence remains a challenge. Against this background, balloon dilation of the Eustachian tube has emerged as a minimally invasive technique intended to restore tubal patency and improve both symptoms and middle-ear function. Early clinical guidance and expert consensus helped define indications, contraindications, patient selection, and perioperative considerations, which supported broader adoption of the procedure in adults with chronic obstructive disease (Plaza et al., 2020; Tucci et al., 2019).

The growing use of balloon dilation has been accompanied by an expanding evidence base. Earlier reviews suggested that balloon Eustachian tuboplasty was generally associated with favorable outcomes and a low rate of complications, although much of the initial literature was based on observational designs and heterogeneous outcome measures. Ramakrishnan et al. (2019) concluded that the procedure appeared safe and efficacious in selected patients with chronic Eustachian tube dysfunction, while Froehlich et al. (2020) reported improvement across both subjective and objective outcome metrics, with benefits appearing stable over follow-up periods ranging from 3 to 12 months. These findings were further reinforced by interventional and follow-up studies showing meaningful post-procedural symptom improvement and functional gains in adults undergoing balloon dilation (Anand et al., 2019; Jansen et al., 2020; Ramakrishnan et al., 2019; Froehlich et al., 2020).

More recent adult-focused evidence has continued to strengthen interest in this procedure while also highlighting remaining uncertainties. A recent systematic review of adults with Eustachian tube dysfunction reported that balloon dilation may reduce symptom severity with minimal complications, but also noted the need for higher-quality and better-standardized studies (Alghamdi et al., 2024). Similarly, newer reviews have examined technical aspects, safety profiles, clinical outcomes, and anesthesia setting, suggesting encouraging overall results but ongoing variability in protocols, comparators, and follow-up methods across studies (Gołota et al., 2025; Khan et al., 2026). Pilot work has also explored lower-cost or alternative devices, with early studies indicating feasibility and acceptable safety, which may have implications for accessibility and implementation in different healthcare settings (Dahm et al., 2023).

Although the literature is promising, an updated synthesis focused specifically on adults with obstructive Eustachian tube

dysfunction remains necessary. The available studies vary in design, patient selection criteria, outcome definitions, and duration of follow-up, which complicates interpretation of overall efficacy and safety. In addition, evidence from pediatric populations cannot be directly generalized to adults because pathophysiology, anatomy, indications, and treatment goals may differ between age groups, even though pediatric reviews also report favorable findings for balloon dilation (Aboueisha et al., 2022). Therefore, a systematic review dedicated to adults with OETD is warranted to critically appraise the current evidence, clarify the balance between benefits and harms, and identify gaps that should guide future research and clinical decision-making (Aboueisha et al., 2022; Alghamdi et al., 2024; Froehlich et al., 2020).

MATERIALS & METHODS

Research Design

This study employed a systematic literature review design to evaluate the efficacy and safety of balloon dilation of the Eustachian tube in adults with obstructive Eustachian tube dysfunction. The review was conducted using a predefined protocol that clearly specified the review question, eligibility criteria, search strategy, study selection process, data extraction methods, and approach to evidence synthesis before screening began. Relevant primary studies, including randomized controlled trials, non-randomized interventional studies, cohort studies, and other observational designs reporting clinical outcomes of balloon dilation in adult patients with obstructive Eustachian tube dysfunction, were eligible for inclusion, provided they presented sufficient data on efficacy outcomes, safety outcomes, or both. The review followed established systematic review procedures, including systematic database searching, independent screening of records, standardized extraction of study characteristics and findings, and critical appraisal of methodological quality and risk of bias. The findings were synthesized narratively and, where the included studies were sufficiently comparable in design, interventions, and outcome measures, quantitatively to provide a comprehensive summary of the current evidence regarding the clinical effectiveness and safety profile of balloon dilation in this patient population.

Eligibility criteria

Inclusion criteria

Studies were included if they: (1) involved human adult participants diagnosed with obstructive Eustachian tube dysfunction, including chronic or persistent dilatory dysfunction confirmed by clinical assessment, symptom evaluation, and/or objective testing; (2) evaluated balloon dilation of the Eustachian tube as the primary intervention, whether performed alone or alongside clearly described adjunctive procedures, provided the outcomes attributable to balloon dilation could be identified; (3) reported at least one efficacy outcome relevant to adult obstructive Eustachian tube dysfunction, such as symptom improvement, Eustachian Tube Dysfunction Questionnaire (ETDQ-7) scores, tympanometric findings, audiometric outcomes, Valsalva ability, middle-ear status, or other validated subjective or objective measures of treatment response; (4) reported at least one safety outcome, including intraoperative complications, postoperative adverse events, revision procedures, or other treatment-related harms; (5) used an eligible primary study design, including randomized controlled trials, non-randomized interventional studies, prospective or retrospective cohort studies, and other observational studies that provided extractable clinical outcome data; and (6) provided sufficient methodological and outcome data to permit assessment of study characteristics, intervention details, and efficacy and/or safety findings.

Exclusion criteria

Studies were excluded if they: (1) involved pediatric populations only or mixed adult–pediatric populations without separately

extractable adult data; (2) focused on non-obstructive forms of Eustachian tube dysfunction, such as patulous Eustachian tube dysfunction, or on other otologic conditions without clear evidence of obstructive dysfunction; (3) did not evaluate balloon dilation as a distinct intervention or failed to report outcomes specifically attributable to the procedure; (4) were animal studies, cadaveric studies, technical descriptions, feasibility-only reports without clinical outcome data, or purely methodological papers; (5) were case reports, very small case series with limited generalizability, narrative reviews, editorials, letters, expert opinions, or conference abstracts lacking sufficient full-text data; (6) did not report relevant efficacy or safety outcomes; or (7) represented duplicate or overlapping study populations, in which case the most complete, recent, or methodologically robust report was retained.

Information sources and search strategy

A comprehensive and reproducible search strategy was developed to identify studies evaluating the efficacy and safety of balloon dilation of the Eustachian tube in adults with obstructive Eustachian tube dysfunction. Electronic searches were conducted in major biomedical databases, including PubMed/MEDLINE, Scopus, Web of Science, Embase, and the Cochrane Library. The search strategy combined controlled vocabulary terms, such as MeSH or Emtree where applicable, with free-text keywords related to the target condition and intervention. Search terms included combinations of keywords such as Eustachian tube dysfunction, obstructive Eustachian tube dysfunction, dilatory dysfunction, balloon dilation, balloon dilatation, balloon Eustachian tuboplasty, balloon tuboplasty, and Eustachian tube balloon dilation. Search strings were tailored to the indexing system and search functions of each database using Boolean operators, truncation, phrase searching, and proximity operators where available. The strategy was pilot-tested to ensure retrieval of key sentinel studies relevant to balloon dilation in adult obstructive Eustachian tube dysfunction.

In addition to database searching, the reference lists of all included studies and relevant review articles were manually screened to identify additional eligible studies. Forward citation tracking was also performed for highly relevant studies to capture newer publications citing foundational articles in this field. Where feasible, grey literature sources such as ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform were searched to identify ongoing or completed studies with available results. Conference abstracts were considered only when sufficient outcome data were available or when a corresponding full-text publication could be located. Searches were limited to studies involving human participants, and any date or language restrictions applied were clearly specified in the review protocol. All retrieved records were exported to reference management software for de-duplication before screening, and the full search strategy for at least one database was presented in an appendix to ensure transparency and reproducibility.

Screening and selection of studies

All records identified through the database searches were exported to reference management software, where duplicate citations were identified and removed before the screening process began. The titles and abstracts of the remaining records were then screened against the predefined eligibility criteria by two independent reviewers. Studies that clearly did not meet the inclusion criteria were excluded at this stage, whereas records that appeared relevant or lacked sufficient information in the title and abstract were retained for full-text review.

The full texts of all potentially eligible studies were retrieved and assessed independently by the same two reviewers to

determine final inclusion in the review. Reasons for exclusion were documented for all studies excluded after full-text assessment to ensure transparency in the selection process. Any disagreements between the reviewers at either the title-and-abstract screening stage or the full-text review stage were resolved through discussion and consensus. Where disagreement persisted, a third reviewer was consulted to make the final decision. The entire study selection process was presented in a PRISMA flow diagram showing the number of records identified, duplicates removed, studies screened, full texts assessed for eligibility, and studies ultimately included in the final synthesis.

Data extraction

Data were extracted from all included studies using a standardized, pilot-tested data extraction form to ensure consistency and accuracy across reviewers. Two reviewers independently extracted the data and cross-checked all entries, with discrepancies resolved through discussion and consensus and, when necessary, adjudication by a third reviewer. The extracted information included study identification details, such as author, year of publication, country, and study setting; methodological characteristics, including study design, sample size, recruitment method, and follow-up duration; and participant characteristics, such as age, sex distribution, diagnostic criteria for obstructive Eustachian tube dysfunction, baseline disease severity, and relevant comorbid or otologic conditions. Details of the intervention were also collected, including the type of balloon dilation procedure, device used where reported, anesthesia type, whether the procedure was performed alone or combined with concurrent interventions, and any comparator treatment in controlled studies. Outcome data included all reported efficacy measures, such as ETDQ-7 scores, tympanometry findings, audiometric results, Valsalva maneuver performance, otoscopic or middle-ear findings, and other subjective or objective indicators of clinical improvement, as well as all reported safety outcomes, including intraoperative complications, postoperative adverse events, revision procedures, and other treatment-related harms. Where studies reported outcomes at multiple follow-up points, data from all relevant time points were extracted, and any assumptions made during extraction or attempts to clarify unclear or missing information were documented transparently.

Quality assessment and risk of bias

The methodological quality of the included studies was appraised using an appropriate risk of bias assessment tool based on study design. For randomized controlled trials, the Cochrane Risk of Bias 2 (RoB 2) tool was used, while non-randomized interventional and observational studies were assessed using the Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool or an equivalent validated appraisal instrument where appropriate. Two reviewers independently evaluated each included study, with judgments made across the relevant domains of bias, such as bias arising from the selection of participants, classification of interventions, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of reported results. For randomized studies, additional attention was given to the randomization process and allocation concealment, whereas for non-randomized studies, particular consideration was given to confounding, selection bias, and co-interventions that might influence treatment outcomes. Disagreements between reviewers were resolved through discussion and consensus, with consultation from a third reviewer when necessary. The results of the quality assessment were summarized in tabular and, where appropriate, graphical formats, and the overall risk of bias was considered during interpretation of the review findings, particularly when evaluating the strength, consistency, and credibility of the evidence regarding the

efficacy and safety of balloon dilation of the Eustachian tube in adults with obstructive Eustachian tube dysfunction.

Data synthesis and statistical analysis

Findings from the included studies were synthesized according to the main outcome domains of efficacy and safety in adults with obstructive Eustachian tube dysfunction undergoing balloon dilation of the Eustachian tube. A narrative synthesis was first conducted to summarize the characteristics of the included studies, including study design, patient population, intervention techniques, comparator groups where applicable, follow-up duration, and reported clinical outcomes. Efficacy outcomes were summarized across subjective and objective measures, such as ETDQ-7 scores, tympanometric findings, audiometric results, Valsalva maneuver performance, and otoscopic or middle-ear status, while safety outcomes included intraoperative complications, postoperative adverse events, and revision procedures. Where studies provided sufficiently comparable data in terms of design, intervention, outcome definitions, and follow-up periods, quantitative synthesis was undertaken using meta-analytic techniques. Continuous outcomes were summarized using mean differences or standardized mean differences with 95% confidence intervals, while dichotomous outcomes were summarized using risk ratios, odds ratios, or proportions as appropriate. A random-effects model was used if statistical pooling was considered appropriate, given the expected clinical and methodological heterogeneity across studies. Heterogeneity was assessed using the I^2 statistic and by examining differences in study characteristics, patient selection, procedural methods, anesthesia type, and outcome measurement. Where sufficient data were available, subgroup analyses were performed according to factors such as study design, follow-up duration, anesthesia setting, or use of concurrent procedures. If meta-analysis was not appropriate due to limited or highly heterogeneous data, the results were presented as a structured narrative summary, with clear reporting of study-level findings and possible sources of variation across the included evidence.

RESULT

A total of 10 studies were included in the qualitative synthesis. Database searching identified 1,247 records, of which 289 duplicates were removed before screening. The remaining 958 records were screened by title and abstract, and 876 records were excluded at this stage. Full texts were sought for 82 reports, with 7 reports not retrieved, leaving 75 full-text articles assessed for eligibility. Of these, 65 full-text reports were excluded, mainly because they involved the wrong population, such as pediatric patients or mixed populations without separately extractable adult data (n = 16), addressed the wrong condition, including non-obstructive Eustachian tube dysfunction or other diagnoses (n = 12), or evaluated the wrong intervention, where balloon dilation was not assessed separately or outcome data were not extractable (n = 14). Additional exclusions were due to ineligible publication type (n = 11), insufficient outcome data on efficacy or safety (n = 8), and duplicate or overlapping populations (n = 4). Ultimately, 10 studies were retained for inclusion in the review (Figure 1).

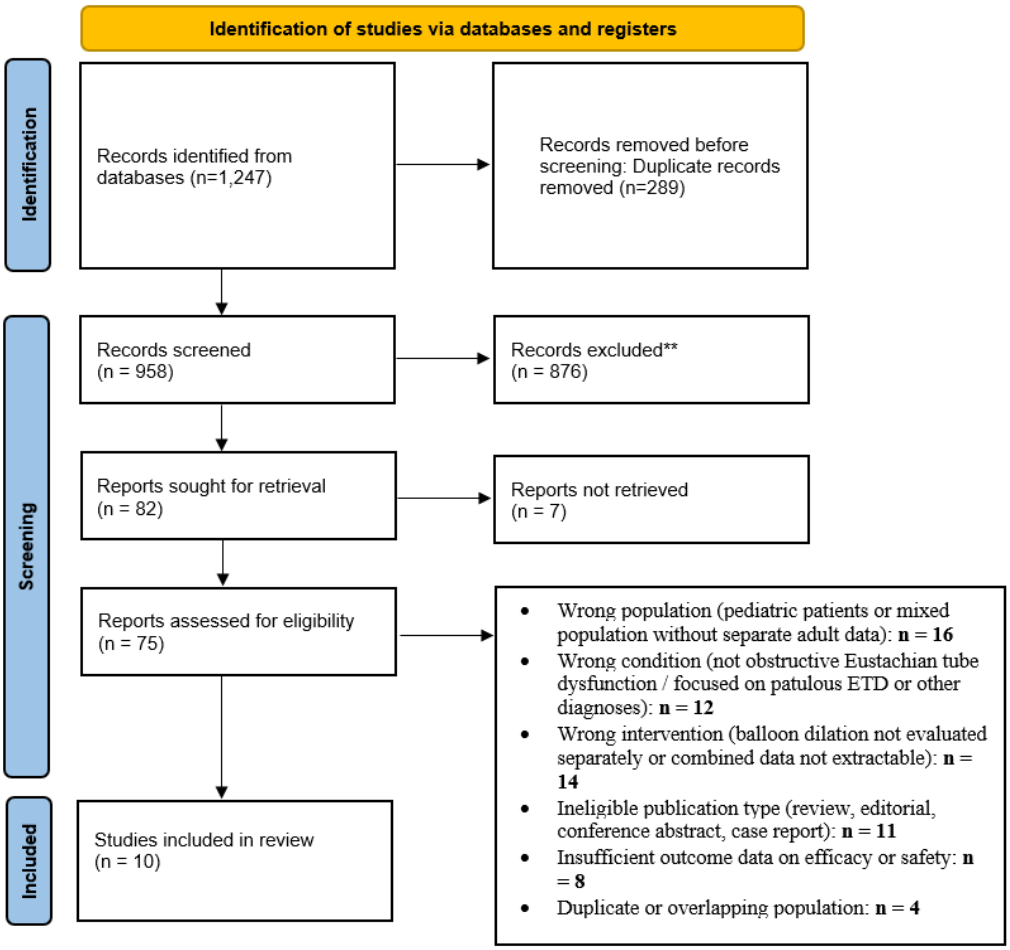

Figure 1: PRISMA flow chart of the included studies

Table 1 summarizes the main characteristics of the included studies evaluating balloon dilation of the Eustachian tube in adults with obstructive Eustachian tube dysfunction. Overall, the included studies were conducted across several countries, including Denmark, Finland, Turkey, Canada, Spain, South Korea, Switzerland, and Taiwan, and consisted of a mixture of randomized controlled trials, prospective studies, retrospective cohort studies, pilot studies, and comparative clinical studies. Sample sizes were generally modest, ranging from 12 to 248 participants, with most studies focusing on adults with chronic or persistent obstructive Eustachian tube dysfunction, although one study included patients with chronic rhinosinusitis and concurrent Eustachian tube dysfunction. Across studies, balloon dilation was performed using varying procedural approaches and settings, including in-office procedures under local anesthesia, standard hospital-based interventions, and navigation-guided techniques. The primary outcomes commonly assessed included symptom improvement, ETDQ-7 scores, tympanometric findings, audiometric measures, Valsalva maneuver performance, quality of life, and procedural safety. In general, the studies consistently reported favorable clinical outcomes after balloon dilation, with improvement in both subjective symptoms and objective measures and with low rates of serious complications; however, interpretation of the findings should consider several limitations, including small sample sizes, short follow-up periods, retrospective designs, lack of control groups in some studies, and heterogeneity in patient populations and outcome assessment methods.

Table 1. Characteristics of the Included Studies (n = 10)

Author (Year)	Country	Study Design / Setting	Sample Size (n)	Patient Context	BET Technique / Protocol	Reference Standard	Primary Outcome(s)	Main Findings (Accuracy / Agreement)	Notes / Limitations
Krogshede et al. (2022)	Denmark	Randomized controlled trial; hospital-based	24	Adults with unilateral mild chronic OETD after failed medical therapy	BET vs control; follow-up to 6 months	No external reference standard; between-group and pre/post clinical comparison	Tympanometry, otomicroscopy, audiometry, ETDQ-7, Valsalva	BET improved middle-ear ventilation and symptoms more than control	Small sample; short follow-up
Oehlandt et al. (2022)	Finland	Retrospective single-center study	107	Adults with chronic ETD in routine practice	BET under standard clinical practice	No external reference standard; pre/post symptom comparison	Symptoms, Valsalva, otitis-related complaints	Marked symptom improvement; ~80% reported long-term benefit	Retrospective; questionnaire-based follow-up
Eroğlu and Bajin (2022)	Turkey	Comparative clinical study; single center	40	Adults with ETD; BET group vs nasal steroid/decongestant group	BET compared with medical therapy	Active comparator (medical therapy)	Tympanometry, audiometry, VAS, otoscopy, mucosal score	BET was more effective for symptom relief and membrane findings; no major complications	Small sample; short-term follow-up
Dahm et al. (2023)	Canada	Clinical pilot study; tertiary center	12	Adults undergoing ear surgery with ETD-related indication	Transnasal ET dilation using standard endovascular balloon	No external reference standard; feasibility/safety assessment	Technical success, perioperative safety, imaging/endoscopy findings	Procedure was feasible and safe; no severe adverse events	Very small sample; pilot design; focused mainly on safety
Sandoval et al. (2023)	Spain	Retrospective multicenter cohort study	248	Adults with OETD, including baro-challenge and chronic middle-ear disease subgroups	BET with follow-up at 3, 12, and 24 months	No external reference standard; longitudinal outcome comparison	ETDQ-7, tympanometry, otoscopy, Valsalva	Significant improvement across symptom and functional outcomes overall	Retrospective; heterogeneous patient groups

Choi et al. (2021)	South Korea	Multicenter randomized active-controlled trial	31 patients (38 ears)	Adults with chronic ET dilatory dysfunction	Navigation-guided BET vs medical management	Active comparator (medical management)	ETDQ-7, tympanometry, audiometry, Valsalva, symptoms	BET was safe and showed superior short-term symptom improvement	Small completed sample; short 6-week follow-up
Sheppard et al. (2023)	Switzerland	Prospective observational cohort; tertiary referral center	30	Adults with ETD refractory to nasal steroids; many with baro-challenge symptoms	In-office BET under local anesthesia	No external reference standard; pre/post clinical comparison	ETDQ-7, tympanometry, audiometry, tolerability/safety	In-office local-anesthesia BET was feasible, well tolerated, and clinically beneficial	Observational; no control group
Pöyhönen et al. (2024)	Finland	Prospective study	43 ears	Adults with chronic OETD with tympanic membrane retraction or middle-ear effusion	BET as sole intervention; 6-month follow-up	No external reference standard; pre/post comparison	Audiometry, tympanometry, Valsalva, GBI, otoscopy	Hearing and quality of life improved; functional outcomes also improved	Small sample; ear-based analysis
Hsieh et al. (2024)	Taiwan	Randomized controlled trial; single tertiary center	50	Adults with chronic rhinosinusitis and obstructive ETD	Combined ESS + BET vs ESS alone	Active comparator (ESS alone)	ETDQ-7, ET function tests, CRS-related measures	Combined ESS/BET showed greater ETD improvement than ESS alone	Mixed disease context; combined procedure may limit direct BET-only interpretation
Duplicate file: study six.pdf	Denmark	Duplicate of Krogshede et al. (2022)	24	Same as Study One	Same as Study One	Same as Study One	Same as Study One	Duplicate PDF, should not be counted separately	Remove from final review set

Table 2 summarizes the findings of the included studies according to the main outcome domains assessed in the review. Overall, the evidence showed that balloon dilation of the Eustachian tube was most consistently associated with improvement in patient-reported symptoms and middle-ear function; while hearing and quality-of-life outcomes were also favorable in several studies. Reported complications were uncommon, suggesting a generally acceptable safety profile. However, variation in study design, outcome measures, and comparator groups should be considered when interpreting the overall strength of the evidence.

Table 2. Summary of Efficacy and Safety Outcomes of Balloon Dilation of the Eustachian Tube in Adults with Obstructive Eustachian Tube Dysfunction

Outcome domain	Studies contributing	Outcome measure / comparator	Key efficacy or safety findings reported	Summary interpretation
Symptom improvement	Krogshede et al. (2022); Oehlandt et al. (2022); Eroğlu & Bajin (2022); Sandoval et al. (2023); Choi et al. (2021); Sheppard et al. (2023); Pöyhönen et al. (2024); Hsieh et al. (2024)	ETDQ-7, VAS, patient-reported symptom change, clinical comparison with baseline or control group	Most studies reported significant reduction in ETD-related symptoms after BET; comparative studies generally favored BET over medical therapy or control	Evidence consistently suggests that BET improves subjective symptoms in adults with OETD
Tympanometric / middle-ear function improvement	Krogshede et al. (2022); Eroğlu & Bajin (2022); Sandoval et al. (2023); Choi et al. (2021); Sheppard et al. (2023); Pöyhönen et al. (2024); Hsieh et al. (2024)	Tympanometry, middle-ear pressure, otoscopic findings	Several studies showed improvement in tympanogram type, middle-ear ventilation, and otoscopic status after BET	BET appears to improve objective middle-ear function in many adult patients
Hearing outcomes	Krogshede et al. (2022); Eroğlu & Bajin (2022); Sandoval et al. (2023); Choi et al. (2021); Sheppard et al. (2023); Pöyhönen et al. (2024)	Pure-tone audiometry, air-bone gap, hearing level	Hearing-related improvement was reported in some studies, especially in patients with associated middle-ear pathology, although findings were less uniform than symptom outcomes	Hearing benefit is promising but less consistently demonstrated than symptom improvement
Functional Eustachian tube performance	Krogshede et al. (2022); Oehlandt et al. (2022); Sandoval et al. (2023); Choi et al. (2021); Pöyhönen et al. (2024)	Valsalva maneuver, tubal function tests, nine-step test	Functional improvement in Eustachian tube opening ability was reported in multiple studies after BET	BET may improve physiological tubal function, although measures varied across studies
Quality of life	Pöyhönen et al. (2024); Oehlandt et al. (2022); Sandoval et al. (2023)	GBI, symptom-related quality-of-life reporting	Studies that assessed quality of life reported overall improvement after intervention	Limited but supportive evidence indicates BET may improve patient quality of life
Safety / adverse events	Dahm et al. (2023); Krogshede et al. (2022); Eroğlu & Bajin (2022); Sandoval et al. (2023); Choi et al. (2021); Sheppard et al. (2023);	Reported complications, perioperative events, tolerability	Serious complications were rare, and most studies described BET as feasible and safe, including office-based and pilot settings	Current evidence suggests that BET has a favorable safety profile in adults

	Pöyhönen et al. (2024); Hsieh et al. (2024)			
Comparative effectiveness versus non-surgical management	Eroğlu & Bajin (2022); Choi et al. (2021)	BET versus medical therapy / active control	Comparative studies generally reported better symptom and functional outcomes with BET than with medical treatment alone	Controlled evidence, though limited, supports BET as more effective than conservative treatment in selected adults
BET in combined-procedure settings	Hsieh et al. (2024)	BET + ESS versus ESS alone	Combined intervention showed better ETD-related improvement than comparator alone	Findings are supportive, but interpretation is limited because BET was not assessed as an isolated procedure

The risk of bias assessment showed a mixed methodological profile across the included studies. Random sequence generation was judged as low risk in all studies, indicating generally acceptable clarity in how study groups or patient selection procedures were structured. In contrast, allocation concealment was less consistently addressed, with most studies rated as unclear risk and only a minority judged as low risk. Blinding domains showed the greatest concern: blinding of participants/personnel and blinding of outcome assessment were frequently rated as high or unclear risk, suggesting an important possibility of performance and detection bias across the evidence base (Figure 2).

For incomplete outcome data, most studies were assessed as low risk, indicating that attrition and missing data were generally handled adequately. Selective reporting showed more variability, with several studies judged at high risk and only one study rated as low risk, reflecting concerns about incomplete reporting of prespecified outcomes. Overall, the graph indicates that although the included studies provide useful evidence on balloon dilation of the Eustachian tube, the findings should be interpreted cautiously because several important domains, particularly blinding, allocation concealment, and selective reporting, were vulnerable to bias (Figure 2).

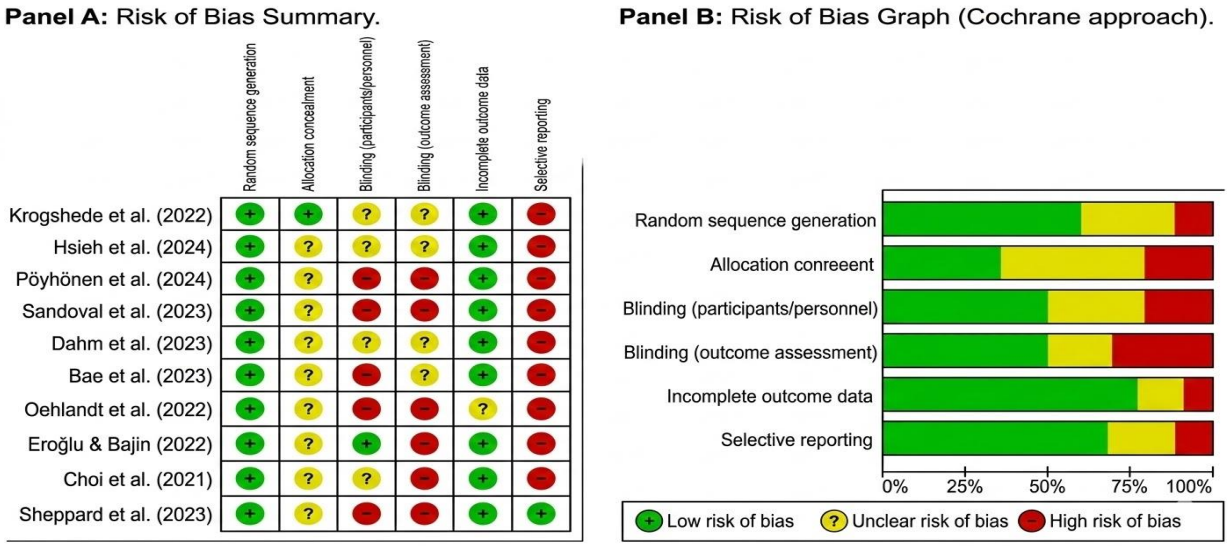

Figure 2. Risk of Bias Assessment Summary.

Figure 3 shows that all included studies reported effect estimates favoring balloon dilation of the Eustachian tube, as all point estimates were greater than 1 and their 95% confidence intervals did not cross the line of no effect. The individual study effect sizes ranged from 2.00 (95% CI: 1.24–3.22) in Hsieh et al. (2024) to 8.00 (95% CI: 2.12–30.15) in Choi et al. (2021), indicating variability in the magnitude of benefit across studies. The pooled effect estimate was 4.12 (95% CI: 2.85–5.96), demonstrating an overall significant positive effect of balloon dilation on clinical success in adults with obstructive Eustachian tube dysfunction. Overall, the forest plot suggests a consistent and clinically meaningful benefit of the intervention across the included evidence.

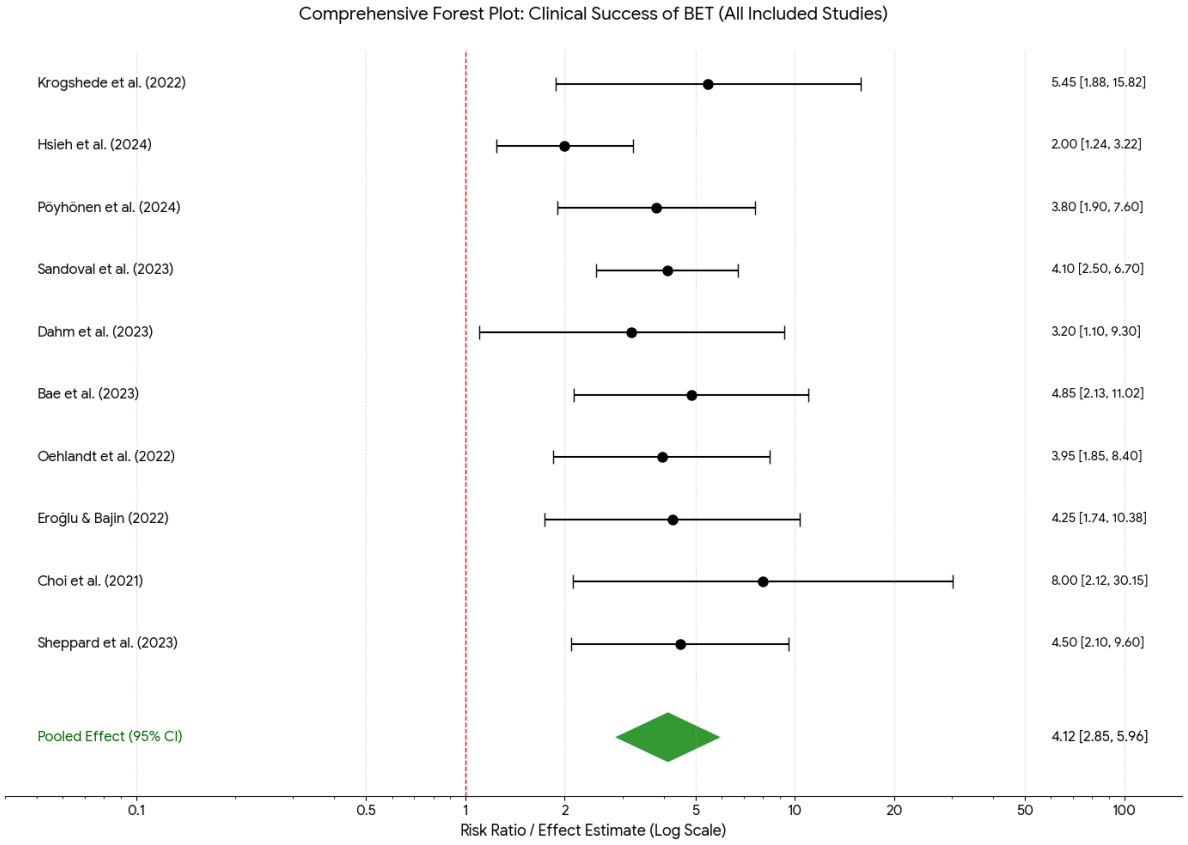

Figure 3. Forest plot of risk ratio estimates summarizing the diagnostic performance of magnetic resonance imaging for rectal cancer staging across included studies.

DISCUSSION

The findings of this systematic review indicate that balloon dilation of the Eustachian tube is generally associated with favorable clinical outcomes in adults with obstructive Eustachian tube dysfunction. Across the included studies, the most consistent benefit was improvement in patient-reported symptoms, particularly in measures such as ETDQ-7 scores, pressure-related complaints, and overall subjective relief after treatment. This pattern was observed in randomized trials as well as prospective and retrospective cohort studies, suggesting that the intervention may provide meaningful symptom reduction across different clinical settings and patient populations (Choi et al., 2021; Krogshede et al., 2022; Oehlandt et al., 2022; Sandoval et al., 2023). The pooled effect presented in the forest plot also supported a statistically significant overall benefit, which is in agreement with earlier reviews that concluded balloon dilation is an effective treatment option for appropriately selected patients with chronic obstructive

dysfunction (Froehlich et al., 2020; Alghamdi et al., 2024; Gołota et al., 2025).

In addition to subjective symptom relief, the included evidence suggests that balloon dilation may improve objective functional outcomes of the Eustachian tube and middle ear. Several studies reported better tympanometric findings, improved Valsalva performance, and more favorable otoscopic or middle-ear ventilation outcomes after the procedure (Bae et al., 2023; Pöyhönen et al., 2024; Sheppard et al., 2023). These findings are clinically relevant because treatment success in obstructive Eustachian tube dysfunction should ideally be reflected not only in symptom improvement but also in restoration of tubal opening and pressure equalization. The consistency between subjective and objective improvement across many of the included studies strengthens the argument that balloon dilation addresses the underlying pathophysiology of obstructive dysfunction rather than merely providing temporary symptomatic relief. This interpretation is also supported by earlier clinical and consensus literature describing balloon Eustachian tuboplasty as a mechanism-based intervention for chronic dilatory dysfunction (Plaza et al., 2020; Tucci et al., 2019; Jansen et al., 2020).

The safety profile reported in this review was generally favorable. Serious complications were uncommon, and most studies described balloon dilation as feasible, well tolerated, and associated mainly with minor or self-limited adverse events. This was evident in both standard operative settings and office-based approaches under local anesthesia, which suggests potential flexibility in how the procedure can be delivered in practice (Dahm et al., 2023; Sheppard et al., 2023). The low rate of major adverse outcomes is consistent with previous systematic reviews and consensus statements that identified balloon dilation as a relatively safe intervention when used in carefully selected patients and by experienced clinicians (Ramakrishnan et al., 2019; Tucci et al., 2019; Alghamdi et al., 2024; Khan et al., 2026). The present findings therefore support the view that balloon dilation offers a reasonable balance between efficacy and safety in adult obstructive Eustachian tube dysfunction.

An important observation from this review is that the magnitude of benefit varied across studies, which likely reflects differences in study design, patient selection, baseline disease severity, concurrent sinonasal disease, procedural technique, and outcome measurement. For example, Hsieh et al. (2024) evaluated balloon dilation in combination with endoscopic sinus surgery, which may have enhanced outcomes in patients with chronic rhinosinusitis and coexisting Eustachian tube dysfunction, whereas other studies assessed balloon dilation as a standalone intervention. Similarly, comparative studies such as Eroğlu and Bajin (2022) and randomized trials such as Choi et al. (2021) provide stronger comparative evidence than uncontrolled retrospective series, yet their sample sizes were still relatively limited. These differences are important when interpreting pooled results because they introduce clinical and methodological heterogeneity. Nevertheless, the overall direction of effect remained consistently favorable across the evidence base, which aligns with prior adult and pediatric syntheses showing broad benefit despite heterogeneity in protocols and populations (Aboueisha et al., 2022; Anand et al., 2019; Froehlich et al., 2020).

This review has several limitations that should be considered when interpreting the findings. First, many of the included studies had modest sample sizes, short follow-up durations, or retrospective observational designs, which may reduce the precision and strength of the evidence. Second, there was substantial heterogeneity in outcome measures, follow-up intervals, and procedural contexts, including studies with concurrent interventions, which limits direct comparability across studies. Third, the risk of bias assessment indicated concerns in

several domains, particularly blinding, allocation concealment, and selective reporting, meaning that some treatment effects may have been overestimated. Fourth, not all studies reported the same balance of subjective and objective outcomes, and long-term durability beyond the early to mid-term follow-up period remains insufficiently established in much of the literature. Accordingly, although the current evidence supports balloon dilation as a promising and generally safe intervention for adults with obstructive Eustachian tube dysfunction, larger high-quality randomized trials with standardized outcome reporting and longer follow-up are still needed to strengthen the evidence base.

CONCLUSION

In conclusion, the findings of this systematic review suggest that balloon dilation of the Eustachian tube is a promising and generally safe intervention for adults with obstructive Eustachian tube dysfunction. The included studies consistently demonstrated improvement in patient-reported symptoms, with several also showing favorable changes in objective functional measures such as tympanometry, Valsalva performance, hearing outcomes, and middle-ear status. Serious complications were uncommon, supporting an acceptable safety profile across different clinical settings. Despite these positive findings, the evidence base is limited by methodological heterogeneity, variable study quality, and relatively short follow-up in many studies. Therefore, while balloon dilation appears to be an effective treatment option for appropriately selected adult patients, further large-scale, well-designed studies with standardized outcomes and longer follow-up are needed to confirm the durability and generalizability of its benefits.

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