Received: 5 September 2023 | Revised: 1 November 2023 | Accepted: 2 November 2023

DOI: 10.1002/lio2.1185

REVIEW

Laryngoscope Investigative Otolaryngology

Complications of eustachian tube balloon dilation: Manufacturer and User Facility Device Experience (MAUDE) database analysis and literature review

Paul F. Chisolm MD[1] | Amir A. Hakimi MD[1] | Jessica H. Maxwell MD[1,2] | Mark E. Russo MD[1]

[1]Department of Otolaryngology—Head and Neck Surgery, Medstar Georgetown University Hospital, Washington, DC, USA

[2]Department of Otolaryngology—Head and Neck Surgery, VA Medical Center, Washington, DC, USA

Correspondence
Paul F. Chisolm, Department of Otolaryngology—Head & Neck Surgery, Gorman Building First Floor, Washington, DC 20007, USA.
Email: paul.chisolm@medstar.net

Abstract

Objective: To provide an analysis of complications following eustachian tube balloon dilation as well as their treatments and outcomes.

Data Sources: PubMed, Ovid Embase, and MAUDE Database.

Review Methods: A systematic approach following PRISMA guidelines was used to identify publications pertaining to balloon dilation of the eustachian tube from PubMed and Ovid Embase databases was used. Once these publications were critically reviewed, the primary outcome extracted were reported complications. Additional complications were collected in the Manufacturer and User Facility Device Experience (MAUDE) database using the product class "eustachian tube dilation device" and searching through relevant manufacturers. Complications and outcomes were compared between these sources.

Results: Fifty five full-length manuscripts involving 7155 patients were included and 98 complications reported for a 1.4% complication rate. The most frequently reported adverse events were subcutaneous emphysema of the head and neck (19%), epistaxis (12%), and acute otitis media (11%). The MAUDE search returned 18 distinct patient entries, of which 12 (67%) reported complications. The most reported complications in the MAUDE database included subcutaneous emphysema (8, 67%) and pneumomediastinum (3, 25%). The most serious complication was a carotid artery dissection reported in one patient in the MAUDE database.

Conclusion: Eustachian tube dilation is rarely associated with complications, which nevertheless may lead to morbidity and medical emergencies. Patients and providers should recognize potential risks associated with this intervention as well as methods to manage complications.

KEYWORDS

complications, comprehensive otolaryngology, eustachian tube dilation, MAUDE database

Meeting Information: Poster Presentation, COSM 2023, May 3–7, 2023, Boston, MA, USA.

1 | INTRODUCTION

The eustachian (pharyngotympanic or auditory) tube is an anatomic structure in the head and neck that is essential for physiologic homeostasis of the middle ear including: pressure equalization, mucociliary transport, and protection from retrograde pathogens/secretions from the nasopharynx.[1] Eustachian tube dysfunction (ETD) is a common pathologic entity in adults and children, with a prevalence in the United States of approximately 4% to 6%.[2,3] ETD can lead to otitis media with effusion (OME), tympanic membrane retraction/perforation or more long term sequelae including middle ear atelectasis, chronic otitis media (COM), or cholesteatoma.[4]

Balloon dilation of the eustachian tube (BDET) is a novel therapeutic approach for patients suffering from ETD, approved by the United States Food and Drug Administration (FDA) in 2016 for obstructive ETD.[5] The American Academy of Otolaryngology—Head and Neck Surgery released a consensus statement in 2018 supporting BDET as a therapeutic option for patients suffering from obstructive ETD.[4] Although rare, complications associated with BDET occur and their characterization is warranted.[6–8] Herein, we queried the Manufacturer and User Facility Device Experience (MAUDE) database utilized by the FDA to report medical device-related complications.[9] Additionally, we performed a comprehensive literature review to identify complications reported in the published literature.

2 | METHODS

This study did not require institutional review board approval since data were collected from a publicly accessible database and previously published studies.

2.1 | Literature search

PubMed and Ovid Embase databases were searched with an open-ended date until September 18, 2022. The use of limiters and filters was minimized, and manual review and selection was relied upon to avoid missing potentially relevant studies. Each database was searched utilizing the advanced search feature with respective database nomenclature. Further details on search queries for each database can be found in the Appendix (Supporting information). The web-based systematic review application Covidence was used as the author platform for including and excluding publications and generating the PRISMA diagram.[10]

Publication review was performed in an iterative manner according to PRISMA guidelines.[11] The review began with a title/abstract screen, followed by a successive full text review should the article pass the inclusion/exclusion criteria. All titles and abstracts identified from the search procedure were independently evaluated by at least two reviewers (PFC and AAH). Full-length articles then followed a similar review process.

Basic patient demographics, study design, balloon dilator manufacturer, and reported SAEs to patients were then extracted for descriptive analysis. For each publication, the results and associated tables/figures were reviewed for complications and SAEs. This included both the number reported, but also types of complications (e.g., epistaxis, etc.).

2.2 | Inclusion and exclusion criteria

For this review, the authors included randomized-controlled trials, retrospective/prospective cohort studies, and case series/reports that reported either short- or long-term outcomes and major complications of patients undergoing BDET and other concomitant procedures for ETD and were original research articles. Publications describing both pediatric and adult patients were included. Review articles, meta-analyses, editorials, cadaveric/animal studies, conference papers, and abstracts without companion full text were excluded. Articles without English full-text translations were also excluded.

2.3 | Risk of bias assessment

The selected articles were reviewed and evaluated for risk of bias. The bias was assessed using the appropriately indicated National Institute of Health quality assessment tool based on the study design of each included article.[12] The heuristics of good, fair, and poor were utilized to have common nomenclature between heterogeneous study designs. The "N/a" designation was given to included case reports.

2.4 | MAUDE database

MAUDE database is a repository of suspected device-associated deaths, serious injuries and malfunctions submitted by mandatory and voluntary reporters, with the intent of ongoing risk and performance assessment of medical devices.[11] Utilizing the "Product Class" database search function, the *MAUDE* database was searched for "Eustachian Tube Dilation Device." With these preliminary results, the search was then expanded using the "Manufacturer" function for any possible entries not found under the "Eustachian Tube Dilation Device." Each result was assessed for basic patient demographics, balloon dilator manufacturer, and reported SAEs.

3 | RESULTS

3.1 | Literature search

A total of 146 citations resulted from searching the PubMed and Ovid Embase databases. Twenty duplicates were removed, leaving a total

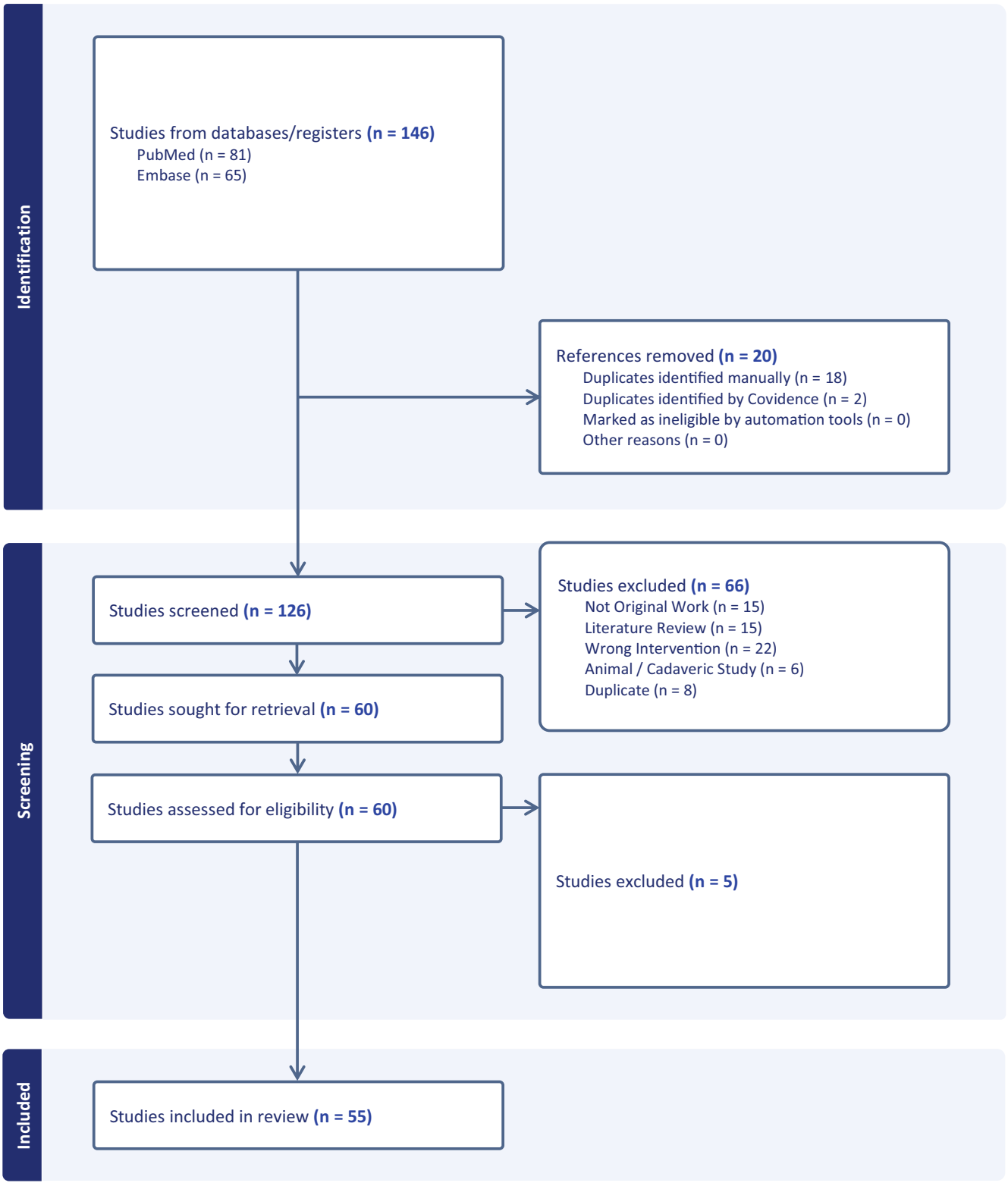

FIGURE 1 PRISMA diagram.

of 126 unique citations. Sixty potential full texts were reviewed for inclusion after a title and abstract screen was performed. After completion of the full-text reviews, 55 manuscripts were selected to proceed for data abstraction (Figure 1).

3.2 | General study characteristics

Table 1 displays study characteristics for the 55 publications, including basic patient demographics, study design, balloon dilator manufacturer,

TABLE 1 Summary of included publications from PubMed and Ovid Embase literature search with adverse events reported.

	Authors	No. of patients	No. of ears	Patient age, in y (mean)	Study design	Risk of bias	Balloon manufacturer	Average follow-up (in months)	No. of complications (%)	Complications (*n*)
1	Abdel-Aziz et al. (2014)	284	510	Unknown	Retrospective case series	Good	Spiggle and theiss	2.00	3 (1%)	Hypoglossal Paresis (1), Subcutaneous emphysema (2)
2	Ashry et al. (2017)	48	67	50	Retrospective cohort study	Good	Acclarent	15.60	1 (2%)	Patulous ET (1)
3	Bowles et al. (2017)	39	55	45.5	Prospective cohort study	Good	Acclarent	6.00	0	NRAE
4	Catalano, Peter et al. (2012)	70	100	45	Retrospective cohort study	Good	Acclarent	7.58	1 (1%)	Subcutaneous Emphysema (1)
5	Chen, Nina et al. (2022)	35	49	38.4	Retrospective cohort study	Poor	Unknown	36.00	0	NRAE
6	Chen et al. (2020)	49	25	10.2	Retrospective cohort study	Good	Spiggle and theiss	18.00	3 (6%)	Epistaxis (3)
7	Cheng et al. (2021)	62	96	47.3	Retrospective cohort study	Good	Spiggle and theiss	10.00	0	NRAE
8	Choi et al. (2021)	31	38	44.7	Randomized controlled trial	Good	Mega medical	1.50	0	NRAE
9	Cutler et al. (2019)	47	83	52.5	Randomized controlled trial	Good	Entellus	29.40	0	NRAE
10	Dai et al. (2016)	8	12	53.1	Retrospective case series	Fair	Spiggle and theiss	6.40	0	NRAE
11	Dalchow et al. (2016)	217	342	45.58	Prospective cohort study	Good	Spiggle and theiss	7.50	0	NRAE
12	Dean (2019)	33	43	Unknown	Retrospective cohort study	Fair	Acclarent	1.50	0	NRAE
13	Demir and Batman (2020)	62	55	7	Retrospective cohort study	Good	Spiggle and theiss	12.00	4 (6%)	Hemotympanum (2), OME (2)
14	Giunta et al. (2019)	20	21	Unknown	Retrospective cohort study	Good	Spiggle and theiss	34.80	4 (20%)	AOM (1), Tinnitus (1), SNHL (1), Subcutaneous Emphysema (1)
15	Gürtler et al. (2015)	21	21	37.5	Retrospective cohort study	Good	Spiggle and theiss	26.00	1 (5%)	Epistaxis (1)
16	Howard et al. (2021)	43	81	12.4	Retrospective cohort study	Good	Acclarent	0.96	2 (5%)	Epistaxis (1), Vertigo (1)
17	Jenckel et al. (2015)	33	56	11	Retrospective cohort study	Fair	Spiggle and theiss	6.00	0	NRAE
18	Jurkiewicz et al. (2013)	4	7	45.75	Prospective case series	Fair	Spiggle and theiss	1.50	0	NRAE

TABLE 1 (Continued)

	Authors	No. of patients	No. of ears	Patient age, in y (mean)	Study design	Risk of bias	Balloon manufacturer	Average follow-up (in months)	No. of complications (%)	Complications (*n*)
19	Kapadia and Tarabichi (2018)	40	40	30	Retrospective case series	Good	Foley catheter	16.50	4 (10%)	Tinnitus (1), SNHL (1), Vertigo (2)
20	Kim et al. (2018)	10	10	52.2	Prospective case series	Good	Acclarent	3.00	1 (10%)	Mucosal Laceration (1)
21	Kim et al. (2022)	1	2	22	Retrospective case report	N/a	Unknown	0.75	1 (100%)	Perilymph Fistula (1)
22	Lee et al. (2020)	1	2	55	Retrospective case report	N/a	Acclarent	12	1 (100%)	Nasopharyngeal Mucocele (1)
23	Leichtle et al. (2017)	52	97	7	Retrospective cohort study	Good	Spiggle and theiss	5.18	4 (8%)	Epistaxis (3), Hemotympanum (1)
24	Liang et al. (2016)	90	90	36	Randomized controlled trial	Good	Spiggle and theiss	6	0	NRAE
25	Long et al. (2021)	1	2	51	Retrospective case report	N/a	Entellus	Unknown	2 (100%)	Epistaxis (1), Pneumomediastinum (1)
26	Luukkainen et al. (2018)	34	52	41	Retrospective cohort study	Fair	Acclarent	37.20	0	NRAE
27	Luukkainen et al. (2019)	18	27	39.5	Prospective case series	Good	Spiggle and theiss	Unknown	0	NRAE
28	McCoul and Anand (2012)	22	35	55.1	Prospective cohort study	Good	Acclarent	10.00	1 (5%)	Hemotympanum (1)
29	McMurran et al. (2020)	25	36	44	Prospective cohort study	Good	Spiggle and theiss	28	2 (8%)	Subcutaneous Emphysema (1), TM Perforation (1)
30	Meyer et al. (2018)	60	91	49.4	Randomized controlled trial	Good	Entellus	10.92	0	NRAE
31	Ockermann et al. (2010)	8	13	44.1	Quasi-experimental study	Good	Spiggle and theiss	2.00	0	NRAE
32	Park et al. (2022)	1	1	63	Prospective case report	N/a	Mega medical	12.00	1 (100%)	Patulous ET (1)
33	Poe et al. (2011)	11	11	51.8	Quasi-experimental study	Good	Acclarent	9.12	5 (45%)	Mucosal Laceration (5)
34	Poe et al. (2018)	296	444	55.6	Randomized controlled trial	Good	Acclarent	1.50	0	NRAE
35	Ramakrishnan and Kadambi (2020)	10	15	32	Retrospective cohort study	Good	Eustacare	2.00	0	NRAE

(Continues)

TABLE 1 (Continued)

	Authors	No. of patients	No. of ears	Patient age, in y (mean)	Study design	Risk of bias	Balloon manufacturer	Average follow-up (in months)	No. of complications (%)	Complications (*n*)
36	Satmis and van der Torn (2018)	42	66	43	Retrospective cohort study	Good	Spiggle and theiss	3.00	5 (12%)	Epistaxis (1), Otalgia (2), Patulous ET (1), TM Perforation (1)
37	Schmitt et al. (2018)	38	45	49.9	Retrospective cohort study	Good	Spiggle and theiss	14.27	2 (5%)	Rhinitis (1), Tongue dysesthesia (1)
38	Schroder et al. (2015)	622	1076	Unknown	Retrospective cohort study	Good	Spiggle and theiss	Unknown	3 (0.5%)	Subcutaneous Emphysema (3)
39	Shah et al. (2018)	1	1	28	Retrospective case report	N/a	Entellus	Unknown	2 (100%)	Subcutaneous emphysema (1), Pneumomediastinum (1)
40	Si et al. (2018)	200	200	41.02	Retrospective cohort study	Good	Spiggle and theiss	11.09	1 (0.5%)	Patulous ET (1)
41	Si et al. (2019)	120	120	43	Randomized controlled trial	Good		24.00	2 (1.7%)	Patulous ET (2)
42	Silvola et al. (2014)	41	41	48	Prospective cohort study	Good	Acclarent	30.00	0	NRAE
43	Singh et al. (2017)	11	13	42.5	Prospective cohort study	Fair	Spiggle and theiss	Unknown	0	NRAE
44	Skevas et al. (2018)	2272	3670	Unknown	Retrospective cohort study	Good	Spiggle and theiss	Unknown	>18 (0.8%)	AOM (1), Epistaxis (?),[a] Patulous ET (1), Pneumomediastinum (3), Subcutaneous emphysema (10), Tinnitus (3)
45	Standring et al. (2021)	169	309	52.4	Prospective cohort study	Good	Stryker	6.00	3 (2%)	AOM (1), OME (1), Otalgia (1)
46	Sun et al. (2020)	58	74	50.1	Retrospective cohort study	Good	Unknown	24.00	0	NRAE
47	Swain et al. (2020)	21	25	44.9	Retrospective cohort study	Fair	Spiggle and theiss	2.00	3 (14%)	AOM (1), Mucosal Laceration (2)
48	Tisch et al. (2017)	94	90	9.6	Retrospective cohort study	Good	Spiggle and theiss	11.73	5 (5%)	AOM (3), Epistaxis (2)
49	Todt et al. (2021)	1547	2614	Unknown	Retrospective case series	Good	Spiggle and theiss	Unknown	7 (0.5%)	SNHL (7)
50	Toivonen et al. (2021)	26	46	12.5	Retrospective cohort study	Good	Acclarent	27.60	2 (8%)	Patulous ET (2)
51	Utz et al. (2020)	15	26	31.3	Retrospective cohort study	Good	Acclarent	9.50	0	NRAE
52	Utz and Wise (2019)	1	1	20	Retrospective case report	N/a	Acclarent	12.00	0	NRAE

and complications/SAEs reported. There was a median of 34 patients (Range: 1–2272) and 45 ears (Range: 1–3670) treated per publication. The average patient age was 39.1 years (SD ± 14.7) and the average follow-up period was 11.9 months (SD ± 10.4 months).

3.3 | Complications and SAEs reporting

The median number of complications per study was 1 (Range: 0–19), approximately a 1.4% complication rate across all included publications. The most reported adverse event was subcutaneous emphysema of the head and neck ($n = 19$) and there were several case reports of singular complications/SAEs including nonspecific rhinitis, tympanic membrane perforation, perilymph fistula, nasopharyngeal mucocele, hypoglossal paresis, and tongue dysesthesia. There were no reported mortality events among all included papers.

The *MAUDE* database was cross-referenced with the literature search complications and SAEs. Through the *MAUDE* database search described above, there were a total of 18 entries. Of these, 12 entries were direct patient complications. The most reported complication in the *MAUDE* database was subcutaneous emphysema of the head and neck ($n = 8$, 67%). These adverse events are included in Table 2

TABLE 2 Complications and adverse events as reported on the *MAUDE* database.

Manufacturer	Event	Result
ACCLARENT, INC.	Hearing loss, tinnitus	Persistent symptoms at 6 months
ACCLARENT, INC.	Subcutaneous emphysema	Recovered
ENTELLUS MEDICAL, INC.	Subcutaneous emphysema	Recovered
ENTELLUS MEDICAL, INC.	Subcutaneous emphysema	Recovered
ENTELLUS MEDICAL, INC.	Patulous ET	Recovered
ENTELLUS MEDICAL, INC.	Carotid Artery Dissection	Recovered
ACCLARENT, INC.	Subcutaneous emphysema, pneumomediastinum	Recovered
ACCLARENT, INC.	Subcutaneous emphysema, pneumomediastinum	Recovered
ENTELLUS MEDICAL	Subcutaneous emphysema	Recovered
ENTELLUS MEDICAL, INC.	Subcutaneous emphysema, neumomediastinum	Recovered
ACCLARENT, INC.	Nasopharyngeal Mucocele	Recovered
ENTELLUS MEDICAL	Subcutaneous emphysema	Recovered

TABLE 1 (Continued)

	Authors	No. of patients	No. of ears	Patient age, in y (mean)	Study design	Risk of bias	Balloon manufacturer	Average follow-up (in months)	No. of complications (%)	Complications (*n*)
53	Wanscher and Svane-Knudsen (2014)	34	50	45	Prospective cohort study	Fair	Spiggle and theiss	2.00	4 (12%)	AOM (4)
54	Williams et al. (2016)	18	25	40.6	Retrospective cohort study	Good	Spiggle and theiss	7.10	0	NRAE
55	Wong and Prepageran (2021).	12	14	39.5	Prospective cohort study	Good	Entellus	6.00	0	NRAE

Abbreviations: AOM, acute otitis media; ET, eustachian tube; OME, otitis media with effusion; SNHL, sensorineural hearing loss; TM, tympanic membrane.
[a]Publication by Skevas et al. (2018) did not specify the number of epistaxis episodes after BDET.

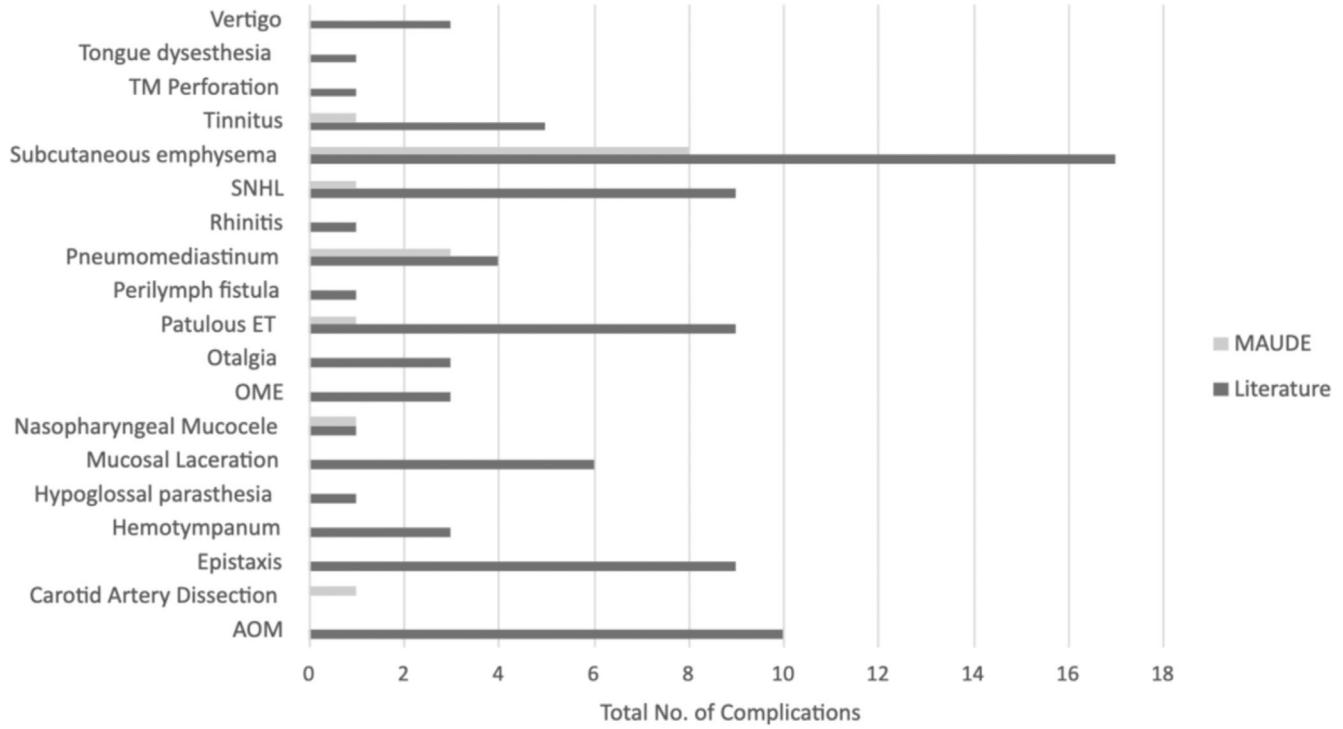

FIGURE 2 Absolute number of complications, comparing the Literature Search results to the *MAUDE* database. AOM, acute otitis media; ET, eustachian tube; OME, otitis media with effusion; TM, tympanic membrane.

and their relative rates are compared with the Literature Search results in Figure 2. There were no mortality events related to BDET in the *MAUDE* database.

4 | DISCUSSION

Since the initial publications of clinical feasibility of BDET for ETD by Ockermann et al. in 2010 and Poe et al. in 2011, complication rates have been reported around 2%.[13,14] BDET was officially endorsed by AAO-HNS in 2019 for ETD given its efficacy and generally benign, self-limited complications.[4,15] Our present study reflects this low complication rate and, indeed, a large majority of the complications reported were minor. Even still, SAEs such as subcutaneous emphysema of the head and neck, pneumomediastinum, and trauma to the carotid artery carries a nonzero risk and is important during preoperative consultation with patients. Therefore, by cross-referencing the *MAUDE* database with regards to complications, this work adds to the current literature on BDET by further characterizing the extent and occurrence of possible complications.

The *MAUDE* database is a domestic repository for the United States. In this present study, the ET balloon dilating system manufactured by the German company, Spiggle and Theiss, was the most used system reported in the literature (16/41 studies). Given that some of the included studies were performed in an international setting and the product was approved internationally before it was approved in the United States, there is not as much robust data in our MAUDE database. Germany does have a similar SAE reporting system available under the Federal Institute for Drugs and Medical Devices (BfArM), but the results were unavailable in an English translation and was deemed outside the scope of the current project. The proprietary nature and respective geographies of these medical device manufacturers could thusly be a contributing factor to the rates seen in the *MAUDE* database and represents a limitation of the present work.

First, there were much fewer complications and SAEs registered in the *MAUDE* database compared with the literature search. The authors hypothesize several plausible reasons for this. Second, the AEs reported to the *MAUDE* database were of greater severity on average when compared to the results from the literature review. Two-thirds of the reported complications in the *MAUDE* database were subcutaneous emphysema (several with tracking pneumomediastinum as well) versus approximately 20% in the literature search. Subcutaneous emphysema is generally a benign, self-limited pathology, but does portend a life-threatening risk should the gaseous expansion cause compression of vascular or aerodigestive structures in the head and neck.[16] In the setting of recent BDET, the underlying pathophysiology for subcutaneous emphysema is thought to be from mucosal microtrauma allowing baro-dissection into the adjacent soft tissue during episodes of increased upper airway pressure (e.g., Valsalva, sneezing, etc.). Further, the *MAUDE* database did have the only report of a cerebrovascular accident attributed to a carotid artery dissection 1 week after a patient had bilateral BDET. Hence, in accordance with the mission behind the *MAUDE* database, it does

make plausible sense that, while fewer in number, the reporting of SAEs be relatively higher in severity than that of the literature search.

There are other limitations that warrant discussion. While reviewer bias was partially mitigated by multiple reviewers and a high (0.88) Cohen's Kappa was achieved, this cannot be fully eliminated from the literature review process. A broad criteria of study design was selected to include the most possible publications, but at the cost of standardized methods including the presence of adjunct procedures (e.g., Tympanostomy tube placement, sinus surgery, etc.) which could be possible confounders. Finally, while publication bias was limited by using multiple databases, English was the primary language referenced, representing a potential language bias. We recognize that the MAUDE database is limited. Although reports of device-related complications are mandatory for industry, they are voluntary for providers/patients thus possibly under-reporting complications.

5 | CONCLUSION

BDET is a relatively benign procedure for ETD but may result complications with a varying array of morbidity. While future peer-reviewed studies will provide the strongest evidence on this topic, the MAUDE database highlights potential serious complications to following BDET. It is important that both patients and otolaryngologists be aware of these risks associated with the procedure and appropriate steps be taken to reduce potential significant sequelae.

ACKNOWLEDGMENTS

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to report.

ORCID

Paul F. Chisolm https://orcid.org/0000-0003-3428-7620
Amir A. Hakimi https://orcid.org/0000-0002-5675-5758

REFERENCES

1. Hamrang-Yousefi SNJ, Andaloro C. *Eustachian Tube Dysfunction*. StatPearls Publishing; 2022 StatPearls [Internet].
2. Patel MA, Mener DJ, Garcia-Esquinas E, Navas-Acien A, Agrawal Y, Lin SY. Tobacco smoke exposure and eustachian tube disorders in US children and adolescents. *PLoS One*. 2016;11(10):e0163926.
3. Shan A, Ward BK, Goman AM, et al. Prevalence of eustachian tube dysfunction in adults in the United States. *JAMA Otolaryngol Head Neck Surg*. 2019;145(10):974-975.
4. Tucci DL, McCoul ED, Rosenfeld RM, et al. Clinical consensus statement: balloon dilation of the eustachian tube. *Otolaryngol Head Neck Surg*. 2019;161(1):6-17.
5. Poe D, Anand V, Dean M, et al. Balloon dilation of the eustachian tube for dilatory dysfunction: a randomized controlled trial. *Laryngoscope*. 2018;128(5):1200-1206.
6. Huisman JML, Verdam FJ, Stegeman I, De Ru JA. Treatment of eustachian tube dysfunction with balloon dilation: a systematic review. *Laryngoscope*. 2018;128(1):237-247.
7. 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(7):894-902.
8. Aboueisha MA, Attia AS, McCoul ED, Carter J. Efficacy and safety of balloon dilation of eustachian tube in children: systematic review and meta-analysis. *Int J Pediatr Otorhinolaryngol*. 2022;154:111048.
9. U.S. Food and Drug Administration MAUDE-Manufacturer and User Facility Device Experience.
10. Covidence Systematic Review Software. Veritas Health Information, Melbourne, Australia. 2021 www.covidence.org
11. Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.
12. Zeng X, Zhang Y, Kwong JS, et al. The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and cliniical practice guideline: a systematic review. *J Evid Based Med*. 2015;8:2-10.
13. Ockermann T, Reineke U, Upile T, Ebmeyer J, Sudhoff HH. Balloon dilatation eustachian tuboplasty: a clinical study. *Laryngoscope*. 2010;120(7):1411-1416.
14. Poe DS, Silvola J, Pyykkö I. Balloon dilation of the cartilaginous eustachian tube. *Otolaryngol Head Neck Surg*. 2011;144(4):563-569.
15. McCoul ED, Weinreich HM, Mulder H, Man LX, Schulz K, Shin JJ. Health care utilization and prescribing patterns for adult eustachian tube dysfunction. *Otolaryngol Head Neck Surg*. 2019;160(6):1071-1080.
16. Kukuruza KAA. *Subcutaneous Emphysema*. StatPearls; 2022.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Chisolm PF, Hakimi AA, Maxwell JH, Russo ME. Complications of eustachian tube balloon dilation: Manufacturer and User Facility Device Experience (MAUDE) database analysis and literature review. *Laryngoscope Investigative Otolaryngology*. 2023;8(6):1507-1515. doi:10.1002/lio2.1185