Eustachian Tube Balloon Dilation: A Comprehensive Analysis of Adverse Events

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Abstract

Background: While Eustachian tube balloon dilation (ETBD) is generally seen as safe, the complication profile has not been well defined.
Objective: The objective of this study was to utilize the FDA MAUDE (Manufacturer and User Facility Device Experience) database to better assess adverse events (AE) related to ETBD.
Methods: This is a study of a multi-institutional database maintained by the US FDA. A database analysis was performed via collaboration of multiple clinicians at tertiary referral centers.
Results: The most common adverse event was postoperative subcutaneous emphysema (n=6, 46.2%).
Conclusion: Though ETBD is generally seen as a safe procedure, there have been several concerning AEs reported to date.

Introduction

The eustachian tube (ET) serves three main functions: protecting the middle ear from pathogens from the nasopharynx, maintaining appropriate ventilation of the middle ear space, and serving as a conduit for drainage of secretions from the middle ear. Eustachian tube dysfunction (ETD) refers to failure of the ventilatory function of the ET and may lead to symptoms such as aural fullness, pain, ear pressure, and chronic otitis media with effusion. This condition has an estimated prevalence of 0.9% of adults suffering from ETD.

Treatment options for ETD are numerous, however data is lacking for many interventions with few high-quality studies available. A Clinical Consensus Statement released by the American Academy of Otolaryngology – Head and Neck Surgery stated that there is no standard therapy for ETD

ETBD has recently become more widely studied since first described in 2010. This device comprises of an inflatable balloon that is advanced under direct endoscopic visualization to guide the catheter transnasally to the ET orifice. It is advanced into the ET and then inflated for a predetermined period of time with the primary goal of increasing patency and thereby improving long-term ET function. Several ETBD devices specifically designed for this use have since gained FDA approval. ETBD is generally seen as less invasive than surgical tuboplasty, but data assessing the risk profile of this procedure is still in its early phases. This study sought to utilize the FDA MAUDE database to provide insight into complications associated with ETBD.

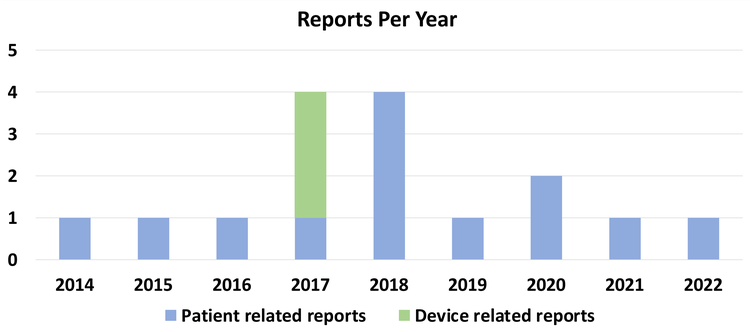

Figure 1. Timeline of events reported

Methods and Materials

The US Food and Drug Administration (FDA) created the MAUDE database in 1991 as a repository of all Medical Device Reports (MDR) filed with the agency. MDRs can be due to product problems or adverse events in which a device may have played a role. In total, over 4 million reports have been amassed by this system from multiple sources. The past 10 years of reports are readily available to the public online. Among other strengths, MAUDE offers a valuable source of information on medical device failures and AEs to better inform providers and allow for more accurate patient counseling.

The FDA MAUDE database was queried for all MDR related to ETBD devices from January 2012 to November 2022. 88 MDR were identified by searching MAUDE for any report related to the ET, 16 of which were relevant to ETBD. All reports were thoroughly reviewed and classified as either a device or patient issue. Timing of the event was also assessed (intraoperative vs postoperative). All adverse events were reviewed in-depth and details regarding the nature of the event, severity, need for readmission, and methods of complication management were collected and tabulated. Given the nature of the MAUDE database, this study is retrospective and descriptive in nature.

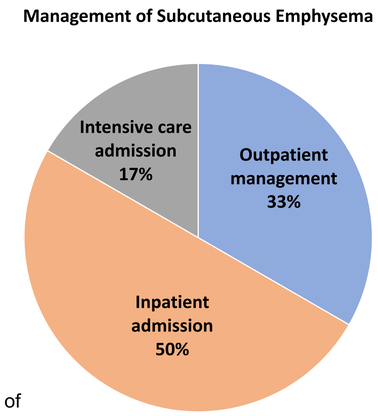

Figure 2. Management of subcutaneous emphysema

Results

From January 2012 to November 2022, a total of 16 MDRs in the MAUDE database met inclusion criteria and were evaluated. All reports were filed in 2014 or later. A timeline of these reports is outlined in figure 1. 3 MDRs were classified as device related (18.8%), none of which resulted in an AE. 13 MDRs (81.3%) were patient related, all of which were classified as AEs. These are outlined in table 1.

The most common AE was postoperative subcutaneous emphysema (n=6, 46.2%). All patients with subcutaneous emphysema had some degree of cervicofacial involvement. More concerningly, three patients suffered chest involvement, with one patient developing pneumomediastinum and one patient requiring a chest tube. Management of subcutaneous emphysema was variable: two patients were managed conservatively on an outpatient basis, three patients required admission to a general hospital bed, and one patient required ICU admission, and chest tube placement. Admission duration lasted between one and four days. The most severe AE was carotid artery dissection.

Adverse Event		n (16)
Patient Related		**13**
	Subcutaneous Emphysema	6
	Carotid artery dissection, stroke	1
	Patulous Eustachian tube	2
	Intraoperative bradycardia	1
	Mucocele	1
	Tinnitus	1
	Hearing loss	1
Device Related		**3**
	Balloon rupture	1
	Packaging issue	1
	Provider concern over design	1

Table 1. Adverse events reported

Discussion

ETBD is a relatively new procedure and has become increasingly popular over the past few years as favorable outcomes continue to be reported. To better understand possible complications associated with ETBD, MDRs from the MAUDE database were thoroughly examined.

A meta-analysis from 2018 that included 1155 patients found a~2% rate of adverse events. Mucosal bleeding was reported as the most common adverse event. Other complications described included rhinitis, acute otitis media, hemotympanum, and preauricular emphysema. Overall, they classify adverse events as rare and even when suffered, events were mild. Severe adverse events have been mostly relegated to case reports up to this point. This study is the first comprehensive analysis of ETBD complications using an FDA maintained national database. The data here caution of a previously underappreciated risk of rare, albeit severe, adverse events. A better understanding of the risk profile of ETBD is imperative for proper patient counseling and shared decision making.
The vast majority (12 of 13) of the reported adverse events were not appreciated intraoperatively. This delayed presentation is another reason patients need to be aware of possible complications to be mindful of during convalescence.

Conclusions

Though ETBD is generally seen as a safe procedure, there have been several rare but concerning AEs reported to date. Only one of the 13 patient related AEs was identified intraoperatively, indicating that adverse events may precipitate anytime in the postoperative period. An increased awareness of ETBD complications will provide improved patient education and counseling during the informed consent process and aid surgeons in clinical decision making. Future studies with standardized reporting protocols are warranted to create a central registry for ETBD which captures adverse events to further investigate root causes of surgical complications.

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