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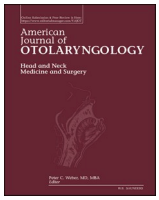

MAUDE database and Eustachian tube balloon dilation: Evaluation of adverse events and sales data

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ABSTRACT

Study design: Review of database.
Setting: Tertiary care neurotology center.
Patients: Patients undergoing adverse events.
Intervention: MAUDE database evaluation of Eustachian tube balloon dilation (ETBD) for the treatment of Eustachian tube dysfunction.
Main outcome measures: Medical device reports (MDRs) from the MAUDE database were analyzed for adverse patient events (AE) and device malfunctions (DM) among different devices for ETBD. The objective of this analysis is to assess AE rates and compare them across different devices. Sales data was also used to calculate AE rates.
Results: There were 18 MDRs noted in the MAUDE database for patients undergoing ETBD out of an initial 23 results. When separated into devices, the Aera had 9 total MDRs (50 %), Xpress had 8 (44.4 %) and Audion had 1 (5.6 %). There were 10 AE and 8 DM. When separated by device, Aera had 4 AEs and 5 DMs, Xpress had 5 AEs and 3 DMs, and Audion had 1 AE. The most common AE was subcutaneous emphysema ($n = 4$), in the head and neck region with one report of mediastinal involvement. Using this sales data, the Aera balloon has an MDR rate of 0.0128 % is established, with a rate of AE at 0.0058 %. The Audion balloon had an MDR and AE rate of 0.0164 %.
Conclusions: ETBD is a safe procedure with minimal complications, with subcutaneous emphysema being the most commonly reported adverse event, consistent with literature findings. A comprehensive analysis of AE, coupled with sales data, indicates a commendably low MDR rate of 0.0128 % for the Aera balloon while the Audion balloon had an MDR rate of 0.0164 %. These findings offer valuable insights on post-procedure expectations and engaging in informed consent discussions with patients, highlighting the overall safety of ETBD as an intervention.

1. Introduction

The Eustachian tube (ET) connects the nasal airway to the middle ear space, allowing ventilation and equalization of pressure. Equalization of pressure is necessary in the middle ear space as resorption of gases creates a vacuum in relation to atmospheric pressures [1]. In cases of Eustachian tube dysfunction (ETD), this equalization of pressure does not occur, leading to symptoms of muffled hearing and aural fullness, with potential sequalae including otitis media with effusion, atelectasis, and chronic otitis media (COM) with or without cholesteatoma. ETD occurs in approximately 4.6 % of adults and is even higher in children owing to their shorter and more horizontal ET [2–4].

Treatment of ETD includes a mix of observational, medical, and procedural therapy. Historically, medical therapy, particularly intranasal steroids have been prescribed for theoretical nasal mucosal swelling, however there is limited evidence demonstrating benefit [5]. Procedural therapy, including myringotomy, and more recently balloon tuboplasty have been demonstrated to have improved outcomes [6]. ET balloon dilation was recently pioneered as an efficacious treatment outcomes which has been shown to reduce inflammatory changes in the cartilaginous portion of the ET [7,8].

ET balloon dilation can be performed either alone or in adjunct with

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other procedures, such as myringotomy or tympanoplasty [9]. Additionally, balloon dilation can be performed both under general anesthesia in the operating room or in the office under local anesthesia [10]. While typically well tolerated, complications of ET balloon dilation can be serious and their risk profile is still being evaluated [11]. The manufacturer and user facility device experience (MAUDE) database through the Food and Drug Administration (FDA) is a database for adverse event reporting involving medical devices, including balloon dilation systems. The purpose of this study is to further evaluate the complication and risk profile of Eustachian tube balloon dilation systems utilizing the MAUDE database and sales data from medical device companies.

2. Methods

The MAUDE database contains medical device reporting (MDR) data from the past 10 years. There are both mandatory and voluntary reporters for this database. The primary purpose of this database is to evaluate rates of adverse events or to compare adverse event occurrence across devices.

The MAUDE database was searched for the term "Eustachian tube balloon" and relevant reports were identified. Reports were excluded if solely involved in balloon sinus surgery. MDRs were separated into different manufacturers and devices, including Acclarent Aera (Johnson & Johnson, New Brunswick, NJ), Entellus Xpress and the Entellus Audion (Stryker, Kalamazoo, MI). They were also separated into device only malfunctions and patient adverse events (AE) based on whether there were any poor outcomes to the patient.

Sales data from Acclarent up until May 2023 was then utilized to form a rate of adverse effects.

3. Results

There were 18 MDRs noted in the MAUDE database for patients undergoing Eustachian tube balloon dilation out of an initial 23 results reported with the previously reported search terms. When separated into devices, the Aera had 9 total MDRs (50 %), the Xpress had 8 MDRs (44.4 %) and the Audion had 1 MDR (5.6 %). In total, there were 10 adverse patient events (AE) and 8 device malfunctions (DM). When separated by device, the Aera had 4 AEs and 5 DMs, the Xpress had 5 AEs and 3 DMs, and the Audion had 1 AE. The most common AE was subcutaneous emphysema ($n = 4$), specifically in the head and neck region with one reported patient having mediastinal involvement.

The adverse outcomes were broken down into adverse events that potentially lead to patient harm or the actual device malfunctioning. As previously stated, the Aera had 4 AEs consisting of material fragmentation leading to an itching and discomfort feeling, bradycardia during the procedure, swelling postoperatively, and one case in which an adverse event was reported but specifics were not reported. There were 5 reported DM's issues with the Aera balloon consisting of 2 burst balloon or vessel issue, bent device, unsealed device packaging and one reporting contamination of device ingredient or reagent.

The Xpress balloon had 5 AEs consisting of 3 patients that developed postoperative subcutaneous emphysema of the head and neck, one report of stroke secondary to carotid artery dissection one week following the procedure, and one report of patulous ET postoperatively. There were 3 reported DMs with the Xpress balloon consisting of all 3 being issues related to the light associated with the balloon, 2 cases of the light not illuminating correctly, and one where the light did not turn off and the device was reported to overheat at the end of the case. The Audion balloon had 1 AE that consisted of the patient developing subcutaneous emphysema postoperatively.

Acclarent sales data was then utilized with 70,484 devices being sold up until May 2023. Using this sales data, a MDR rate of 0.0128 % is established, with a rate of AE at 0.0058 %. Given that the Audion balloon launched in 2023, there has been 6116 devices sold up until February 2024. The reported MDR and AE rate for the Audion balloon was 0.0164 %.

4. Discussion

ET balloon dilation is an efficacious treatment of ETD and appears to have benefit in patients with sequalae of ETD, including COM [12]. While its efficacy has been documented, the risk profile has been difficult to report given the low incidence of complications. There are many studies evaluating the efficacy of the ET balloon dilation, without any mention of significant adverse side effects [6,13]. Given this low incidence, the MAUDE database allows a combined central system of adverse events to be evaluated.

There was a relatively equal absolute number of MDRs between The Aera and Xpress/Audion balloon systems. The most common adverse event as previously stated was subcutaneous emphysema, which is consistent with other studies that looked complications with ETD [14]. All cases of emphysema were self-resolving and patients did well thereafter. Other adverse events included material fragmentation, bradycardia during the procedure, swelling postoperatively, patulous Eustachian tube and one reports of case of a carotid artery dissection leading to a stroke.

Of note, one major adverse event that was previously states was the incidence of a stroke secondary to a carotid artery dissection. The patient had an uneventful procedure and underwent bilateral Eustachian tube dilation using the XPRESS balloon. One week after surgery the patient presented to the emergency department and was diagnosed with a stroke and was stented by the interventional radiologists which he attributed it to be due to a right sided carotid artery dissection. The patient had a full recovery but there are differences between the AERA and the XPRESS balloon that may have prevented this outcome. The distal tip of the XPRESS balloon has a 1.5 mm ball and the distal shaft and tip is rigid and metal. The AERA has a 2.2 mm bulb tip and soft and compliant distal shaft. There is some thought that this larger bulb and lack of rigidity prevents advancement pass the bony isthmus, preventing potential carotid artery involvement.

This study allows for the potential risks to be discussed with patients in the preoperative setting before proceeding with surgery. Given the case reports that were under review it is known that all patients made a full recovery with the given adverse events. Previous studies have also looked at the MAUDE database in relation to Eustachian tube balloon dilation with similar reports of MDRs and AEs [15,16]. This study sheds light on the number of actual balloons sold as of May 2023 and further reinforcing the very low percentage of adverse events that may happen with the procedure eluting to the safety of the procedure itself. Since there were 70,484 balloons sold, the MDR and AE rate were 0.0128 % and 0.0058 % respectively. The uniqueness to this study, with actual number of balloons sold, further reinforces the safety of the procedure. When educating patients in the preoperative setting, these numbers may be a strong supportive factor if patients are apprehensive about the risks of the surgery.

The MAUDE database is a collective way to review complications associated with this but are a few limitations associated with the study. First, there may be inaccuracies from the data reported on the MAUDE database. That may be inaccuracies in data collection or data that was not reported. Another limitation of this study was that it was uncontrollable to determine the number of items sold but not actually used. Even though the numbers appear significantly low there is no way in determining the number of balloons sold but not actually used. Finally, the total devices sold from XPRESS could not be accurately determined given the varying utilization between sinuses and Eustachian tubes. Despite these limitations, this study still highlights the MDR and AE of commonly used devices for ETBD.

5. Conclusion

ETBD is a safe and well-tolerated procedure, characterized by a minimal incidence of complications. Notably, subcutaneous emphysema emerged as the most frequently reported adverse event in the existing literature. A comprehensive analysis of reported events across the three devices revealed a total of 18 Medical Device Reports (MDRs). Sales data for Acclarent indicates a commendably low MDR rate of 0.0128 % while Audion's was 0.0164 %. These findings provide valuable insights that contribute to establishing more accurate post-procedure expectations and facilitating informed consent discussions with patients. Overall, the documented safety profile underscores the safety of ETBD as a medical intervention.

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CRediT authorship contribution statement

Zaid Shareef: Conceptualization, Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. **Robert M. Conway:** Writing – review & editing. **Trevor Creaman:** Data curation, Investigation. **Seilesh C. Babu:** Supervision, Writing – review & editing.

Declaration of competing interest

No relationship to paper.

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