Nasal Epistaxis Balloons: A Comprehensive Analysis of the MAUDE Database

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Abstract

Background: While nasal epistaxis balloons are generally seen as safe and routinely utilized by both surgical and nonsurgical providers, the complication profile related to this type of device 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 use of nasal epistaxis balloons.
Methods: The FDA MAUDE database was queried for all medical device reports (MDR) related to nasal epistaxis balloon devices from January 2012 to November 2022.
Results: 19 MDRs met inclusion criteria. 14 MDRs (73.7%) were classified as patient related. Two documented MDRs were patient deaths due to exsanguination. Additional serious AEs included balloon ingestion and subsequent small bowel perforation (n=1), cerebrospinal fluid leak (n=1), skull base violation and intracranial placement of the device (n=1), and respiratory distress (n=3).
Conclusion: Though epistaxis control with nasal balloons is generally seen as a safe procedure, there have been several concerning AEs reported. Increased awareness of associated complications can be used to better counsel patients during the informed consent process as well as providers in their clinical decision making.

Introduction

Epistaxis is a common problem managed by multiple different groups of healthcare providers. Reports estimate that epistaxis accounts for roughly one in every 200 emergency department visits.

Epistaxis is often self-resolving, and it is uncommon to require emergent medical attention. However, when epistaxis is persistent, immediate management is required. When conservative treatment fails, recent AAO HNS guidelines have recommended consideration of nasal packing. While nasal epistaxis balloons are generally seen as safe and routinely used by both surgical and nonsurgical providers, the complication profile has not been completely described.

Most data regarding complications of nasal balloon packing exists in case series and reports. This study sought to utilize the Manufacturer and User Facility Device Experience (MAUDE) database maintained by the United States Food and Drug Administration (FDA) to provide insight into complications associated with nasal epistaxis balloons.

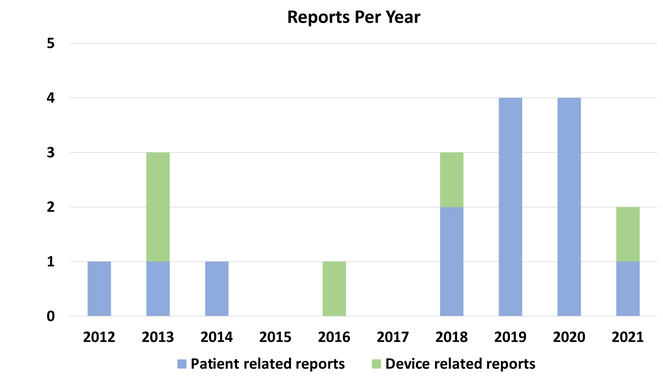

Figure 1. Timeline of events reported

Methods and Materials

The 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 (AEs) in which a device may have played a role.

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 MDRs related to epistaxis balloon devices from January 2012 to November 2022. The product class “Balloon, Epistaxis” was used to identify all relevant results. 28 MDR were initially identified by searching MAUDE, 19 of which were specific to nasal balloons. All reports were thoroughly reviewed and classified as either a device or patient related event. All AEs were reviewed in-depth and details regarding the nature of the event, severity, readmission, complication management, and outcome were collected and tabulated. Given the nature of the MAUDE database, this study is retrospective and descriptive in nature.

Results

Between January 2012 and November 2022, 19 MDRs in the FDA maintained MAUDE database met inclusion criteria. Fourteen (73.7%) MDRs were classified as patient related and 5 (26.3%) were classified as device related (Table 1).

Of the 14 MDRs classified as patient related, 2 were associated with patient deaths. Very little information is available about these two specific cases in the MAUDE database, other than the fact that despite nasal epistaxis balloon deployment, both patients expired due to hemorrhagic shock and exsanguination.

One patient ingested the nasal balloon and suffered a small bowel perforation requiring exploratory laparotomy. This report notes that the balloon was inflated but not secured before the agitated patient reported that he had swallowed the device.

Two patients suffered skull base iatrogenic injuries. One of these patients developed cerebrospinal fluid rhinorrhea (confirmed by beta two transferrin testing). This was managed conservatively and resolved within 6 days. The second patient with a skull base injury occurred in a craniomaxillofacial trauma patient who developed epistaxis. A nasal balloon was placed during transit to the hospital. Imaging upon arrival showed that the balloon had been placed through the fractured cribriform plate into the frontal lobe. The patient eventually required craniotomy.

Airway obstruction secondary to nasal balloon was seen in three reports. In one case, the balloon displaced posteriorly into the oropharynx. The second case resulting in respiratory distress was due to device breakage into two parts with one piece obstructing the larynx. Both cases resolved with removal of the device. The third case lacked specific details.

Adverse Event		n (19)
Patient Related		**14**
	Fever	1
	CSF leak/skull base violation	2
	Small bowel peroforation	1
	Respiratory distress	3
	Local tissue damage	3
	Rupture	2
	Death	2
Device Related		**5**
	Device breakage	2
	Balloon leak	2
	Unknown	1

Table 1. Adverse events reported

Discussion

Nasal epistaxis balloons have been used for years and have played a valuable role in the armamentarium for providers who manage acute epistaxis. Complications are rare but given the prevalence of problematic epistaxis, a solid understanding of possible AEs is imperative for any provider managing epistaxis.

The most concerning events reported in the MAUDE database were two patient deaths. Little information was provided other than the fact that the patients passed away because of bleeding after balloon packs were placed. In cases where the balloon device is failing to control bleeding, appropriate escalation is necessary.

Two AEs with skull base violation were also reported. This is a known risk of instrumentation of the nose and has even been seen with instrumentation as seemingly minor as nasal swabs for viral testing. The most important factors in avoiding skull base violation when placing nasal balloons are understanding sinonasal anatomy and proper placement techniques for packing placement as well as considering imaging in any case concerning for prior skull base surgery or injury.

Conclusions

Epistaxis is common and treated by many different groups of providers. Though epistaxis control with nasal balloons is generally seen as a safe procedure, there have been several concerning AEs reported over the past decade. While two reports of death due to exsanguination were the most severe AEs, multiple other life-threatening AEs were also documented. Use of nasal balloons to control acute epistaxis is widespread across multiple practice settings, so an increased awareness of associated complications can be used to better counsel patients during the informed consent process as well as providers in their clinical decision making in the management of acute epistaxis. Future studies with standardized reporting protocols are warranted to create a central registry for nasal balloon utilization to further investigate root causes of associated complications.

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