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Adverse Events Associated with Balloon Sinuplasty: A MAUDE Database Analysis

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Abstract

Objective. Balloon sinuplasty utilization has increased significantly since its introduction over a decade ago. However, the most common associated complications are still unknown. The objective of this study was to analyze adverse events related to balloon sinuplasty.

Study Design. Retrospective cross-sectional analysis.

Setting. Food and Drug Administration's MAUDE database (Manufacturer and User Facility Device Experience; 2008-2018).

Subjects and Methods. The MAUDE database was searched for all reports on adverse events involving balloon sinuplasty devices from the 3 leading manufacturers: Acclarent, Entellus, and Medtronic. Reported events were reviewed and categorized.

Results. During the study period, there were 211 adverse events from 208 reports divided into the following categories: patient related (n = 102, 48.3%), device related (n = 101, 47.9%), and packaging related (n = 8, 3.8%). Four periprocedural deaths were reported but were not clearly associated with technical complications. The most common device-related complications were guide catheter malfunction (39.6%), balloon malfunction (38.6%), and imprecise navigation (17.8%). The most common patient-related complications were cerebrospinal fluid leak (36.3%), eye swelling (29.4%), and epistaxis (11.8%). A lateral canthotomy was performed in 30.0% of eye-swelling complications. Sixty percent of eye complications occurred during balloon dilation of the maxillary sinus. The years 2014 (n = 48) and 2012 (n = 32) had the highest number of adverse events reported as compared with all other years.

Conclusion. The most common adverse events associated with balloon sinuplasty include balloon malfunction, guide catheter malfunction, cerebrospinal fluid leak, and significant eye swelling. Health care providers should discuss these possible complications when consenting patients for balloon sinuplasty.

Keywords

balloon sinuplasty, complications, MAUDE, sinus surgery, rhinology, paranasal sinuses

Chronic rhinosinusitis is a common disease affecting >31 million people in the United States. The treatment for chronic rhinosinusitis has long followed the principle of topical therapy assisted by surgical optimization of paranasal sinus ventilation and drainage pathways. The correction of impaired sinus outflow tracts improves mucociliary function and allows for better penetration of topical medications and nasal irrigation in the treatment of this chronic disease.[1]

While functional endoscopic sinus surgery largely replaced open procedures, due to the benefits from limiting the disruption of sinonasal mucosa, it still requires resection of bone and mucosa. More common sequelae include scar band formation and mucociliary stunning, causing reobstruction of the targeted sinus. Severe complications can also occur due to unintentional damage of critical structures. This has led to research in techniques further minimizing the resection of tissue while maintaining the same basic principles of sinus surgery.

Balloon sinuplasty (BSP) obtained US Food and Drug Administration approval in 2005 and has since exploded in procedural volume. Medicare data from 2012 to 2016 demonstrate a steady increase in BSP utilization, growing from 26.5% to 58.5% of all sinus procedures performed.[2] Surgeons have found BSP particularly advantageous given its relative ease in targeting the frontal sinus and lack of tissue resection.[3,4] The avoidance of tissue resection required in BSP led to its increased use in pediatrics and as an in-office procedure, 2 unique situations where it stands

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to further its growth.[2,5,6] By 2016, 99.2% of BSP in Medicare patients were performed in office.[2]

Additionally, more than in any previous advancement in sinus surgery, the direct-to-patient marketing campaign surrounding catheter dilations is likely contributing to the interest and frequency of BSP. This patient demand is not without reason, as there are data to support positive outcomes in patients undergoing BSP. Recently published long-term outcomes of BSP showed similar patient satisfaction and symptomatic relief as compared with a matched group of patients who underwent endoscopic maxillary antrostomy.[7]

As more BSPs are performed, more adverse events are being documented.[8] The first individual cases of BSP complications were reported in 2010, with a large study on complications in a private health plan cohort being published in 2018.[9] Building on previous findings, our project aims to describe the types of patient complications related to BSP, as well as device-related failures, on a nationwide basis by using the Manufacturer and User Facility Device Experience (MAUDE) database.

Methods

The MAUDE database was accessed on January 1, 2019, at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. The MAUDE database was developed by the Food and Drug Administration as a way of systematically collecting data on adverse outcomes related to medical devices, with >4 million recorded events and approximately 2000 new entries submitted daily.[10] Device manufacturers and providers are required to submit reports to MAUDE whenever an adverse event is encountered. This includes device failures and patient complications. The result is a rich database of experiences for providers and device manufacturers to improve product development, patient counseling, and surgical technique. The database has been used to examine a range of devices, including robot-assisted surgical systems, endometrial ablation devices, catheters, bone-anchored hearing aids, cochlear implants, among others.[11-15] We searched for all medical device reports between January 1, 2008, and January 1, 2019. Only 3 companies have sinus balloons that have been approved by the Food and Drug Administration: Entellus, Acclarent, and Medtronic. To identify all reports on BSP, those 3 manufacturers were used as search criteria. All reports that involved using a device to balloon any paranasal sinus were included in this study. Each report was reviewed by 2 authors (K.H. and M.G.) to collect the following information: date of report, date of incident, manufacturer, brand name of product, complication, and category of complication. Complications were categorized into 1 of 4 categories: patient related, device malfunction, packing malfunctions, and patient death. If the adverse event occurred during the dilation of a paranasal sinus or sinuses, the sinuses involved were recorded as well. This study was exempt from review by the University of Southern California Institutional Review Board.

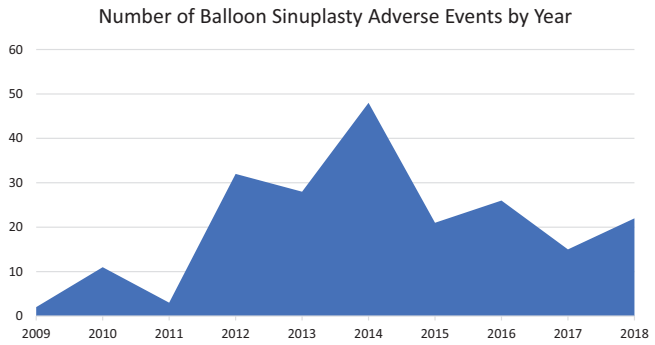

Figure 1. Number of balloon sinuplasty adverse events by year.

Results

From 2008 to 2018, there were 211 adverse events reported from 208 reports. **Figure 1** demonstrates the number of adverse events reported by year. The years 2014 (n = 48) and 2012 (n = 32) had the highest number of adverse events reported as compared with all other years. When stratified by category, 48.3% of adverse events were patient complications, 47.9% were device-related complications, and 3.8% were package related (**Table 1**). The most common patient-related complications were cerebrospinal fluid (CSF) leak (n = 37, 36.3%), eye swelling (n = 30, 29.4%), and epistaxis (n = 12, 11.8%). The most common dilated paranasal sinus where a CSF leak occurred was the frontal sinus (67.6%), followed by the sphenoid sinus (10.8%). The most common dilated sinus where perioperative eye swelling occurred was the maxillary sinus (56.7%), followed by the frontal sinus (20.0%). Of the 30 patients who had eye swelling after BSP, 9 (26.7%) required a lateral canthotomy. The most common dilated sinuses where epistaxis occurred were the frontal (25.0%) and sphenoid (16.7%) sinuses, respectively (**Table 2**).

The most common device-related adverse events were balloon and catheter malfunctions, which are described in **Table 1**. Balloon malfunctions included rupture of the balloon during inflation (n = 34, 33.7%), detachment of the balloon from the device (n = 4, 4.0%), and the balloon not inflating at all (n = 8, 7.9%). Catheter malfunctions most commonly involved detachment of the catheter guide wire tip from the device (n = 34, 33.7%).

When stratified by year (**Figure 2**), device malfunctions were highest in 2014, with 27 adverse events. Patient complications peaked in 2012, with 21 adverse events, and steadily declined to 6 reported events in 2018. There have not been any patient deaths reportedly associated with BSP since 2014.

There were 4 reported periprocedural deaths—1 each from bacterial meningitis (with no associated CSF leak), cardiopulmonary arrest, intracranial bleed, and seizure. However, these events were not clearly associated with technical complications from the surgeon or device.

Table 1. Adverse Events by Category.

Category	n (%)
Patient	102 (48.3)
Cerebrospinal fluid leak	37
Eye swelling	30
Epistaxis	12
Orbital fracture	2
Seizures[a]	2
Acute sinus infection	1
Cheek swelling	1
Ptosis	1
Dura exposed	1
Lightheaded	1
Pneumocephalus	1
Frontal sinus hematoma	1
Restrictive extraocular movement	1
Subperiosteal hematoma	1
Orbital fat herniation	1
Pneumonia	1
Eye pain	1
Frontal lobe abscess	1
Toxic shock syndrome	1
Stroke	1
Cardiac arrest	1
Bacterial meningitis[a]	1
Intracranial bleed[a]	1
Cardiopulmonary arrest[a]	1
Device	101 (47.9)
Balloon malfunction	
Balloon rupture	27
Balloon detached	4
Balloon did not inflate	8
Catheter malfunction	
Catheter tip detached	34
Catheter would not advance	3
Catheter light malfunction	3
Imprecise navigation	18
Locking lever stuck	1
Detached plastic sheath	1
Piece of device became detached	1
Device hot after use	1
Packaging	8 (3.8)
Hole in packaging	8

[a]Resulted in patient death.

Discussion

BSP is increasingly utilized as an adjunct to functional endoscopic sinus surgery in the management of chronic rhinosinusitis.[16] Although it is considered less invasive than endoscopic sinus surgery and believed to be safe, the most common associated complications are still unknown. Our study is the first series to report adverse events related to BSP for patient- and device-related complications with a nationwide database.

The theoretical possible complications of BSP are similar to those of endoscopic sinus surgery. A few studies to date have reported variable complications from BSP. Siller et al in 2015, using an administrative claim database, reported hemorrhage (1.1%, 7 of 628) and orbital (0.3%, 2 of 628) complications in 628 in-office balloon catheter dilation cases.[17] A higher rate of complications (7.8%, 17 of 217) was reported by Laury et al[18] for data including concurrent operative procedures (ie, functional endoscopic sinus surgery and septoplasty)—specifically, bleeding (8 of 217), pain greater than expectation (6 of 217), infection (1 of 217), orbital chemosis and proptosis (1 of 217), and facial subcutaneous emphysema (1 of 217). Two separate case reports reported CSF leak from the ethmoid roof.[19,20] The largest study evaluating complications of BSP was published by Chaaban et al in 2018. Using a commercial insurance database, they reported a 2.95% rate of orbital complications and 3.46% rate of skull base complications out of 2851 BSP procedures studied. The higher percentage of skull base complications in Chaaban's study as compared with orbital complications is consistent with our study's findings.[9]

It should be noted that in our study frontal sinus balloon dilation accounted for the majority (67.6%) of CSF leak complications, while maxillary sinus balloon dilation accounted for the majority (56.7%) of eye-swelling complications. These complications were likely due to the creation of false passages submucosally or the fracturing of the ethmoid or orbital wall during the procedure.[21] It is imperative that surgeons review relevant anatomy, specifically frontal sinus outflow tract anatomy and any area of bony dehiscence or thinning of the skull base, preoperatively to avoid major intracranial or orbital complications.[4] Delayed recognition of these complications may result in severe morbidity and mortality. In comparison, major complications in

Table 2. Patient Adverse Events by Paranasal Sinus.[a]

Type	Maxillary	Frontal	Sphenoid	Maxillary and Frontal	Not Available
CSF leak (n = 37)	0 (0)	24 (67.6)	4 (10.8)	3 (8.1)	6 (16.2)
Eye swelling (n = 30)	17 (56.7)	6 (20.0)	1 (3.3)	2 (6.7)	4 (13.3)
Epistaxis (n = 12)	1 (8.3)	3 (25.0)	2 (16.7)	1 (8.3)	5 (41.7)

Abbreviation: CSF, cerebrospinal fluid.
[a]Values are presented as n (%). Sinus dilated was either not specified or not reported.

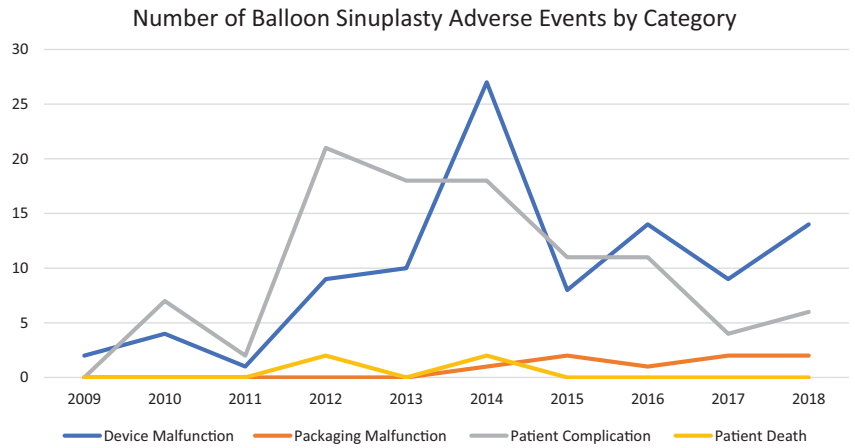

Figure 2. Number of balloon sinuplasty adverse events by category and year.

functional endoscopic sinus surgery have been reported to range from 0.36% to 7.35%.[9,22,23] Skull base complications range from 0.17% to 0.39% and orbital injury rates from 0.07% to 3.46% in nationwide databases of patients who underwent endoscopic sinus surgery.[22]

Our study also described device-related adverse events associated with BSP (**Table 2**), which have not been reported in the literature to the best of our knowledge. Forty cases of intraoperative detachment of parts from the devices were reported, which has the potential to lead to patient complications such as infection, especially if the foreign body is not removed properly. Similarly, when there is rupture of the balloon during inflation (27 cases), the provider must ensure that there is no remnant foreign body left behind. Interestingly, the proportion of device complications (47.9%) were similar to the proportion of patient complications (48.3%). Based on these findings, the provider should discuss the possibility of device complications in addition to possible patient complications during the consent process.

When we analyzed the number of adverse events reported each year (**Figures 1 and 2**), there was a peak between 2012 and 2014 that has since declined. This observation suggests that, as expected with the introduction of a new device in 2005, adverse events steadily increased as more new providers began incorporating BSP into their practice. The eventual decline may be a sign that most providers have attained enough hours of experience performing BSP that they are able to minimize possible complications. However, further research analyzing this interesting trend is needed.

The limitations of our study should be noted. First, the MAUDE database relies on mandatory and voluntary reporters to submit adverse event reports. Therefore, there may be an underreporting of adverse events if no reporter is available to document an adverse event when it occurs. Second, actual complication rates cannot be calculated with the MAUDE database, since the total number of BSP devices used without complications is not available. Third, no patient information, such as age, sex, race, comorbidities, or operative reports, is available to better understand the context of the adverse event.

Conclusion

The most commonly reported patient- or device-related adverse events associated with BSP were balloon malfunction, guide catheter malfunction, CSF leak, and significant eye swelling. Health care providers should discuss these possible complications when consenting patients for BSP. Continued research in analyzing the possible complications of BSP as compared with the rates of complications in endoscopic sinus surgery over time is warranted, as this procedure becomes further incorporated into otolaryngology practices.

Author Contributions

Kevin Hur, conception and design of work, data acquisition and analysis, interpretation of data, drafting of manuscript, critical revision; **Marshall Ge**, conception and design of work, data acquisition, interpretation of data, drafting of manuscript; **Jeehong Kim**, interpretation of data, drafting of manuscript; **Elisabeth H. Ference**, conception and design of work, interpretation of data, critical revision.

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