Contemporary Trends in Frontal Sinus Balloon Sinuplasty, A Pilot Study

Daniel H. Lofgren DO[1]; Brandon B. Knight DO[1] ; Carl B. Shermetaro DO[2]

[1]Otolaryngology & Facial Plastic Surgery Resident, McLaren Oakland Hospital, Pontiac, MI, USA
[2]Otolaryngology & Facial Plastic Surgery Program Director, McLaren Oakland Hospital, Pontiac, MI, USA

Abstract

- **Background:** Balloon sinuplasty (BSP) is a common treatment modality used in the management of chronic rhinosinusitis (CRS) with (CRSwNP) and without nasal polyposis (CRSsNP) of the frontal sinus. Although, it's gained popularity in recent years, minimal self-reported data on its utilization and complications have been reported. The goal of this study was to describe current practices and complications experienced during frontal sinus BSP among an American otolaryngologic community.
- **Methods:** An anonymous 20-question online survey was distributed to members of the American Osteopathic Colleges of Ophthalmology and Otolaryngology-Head and Neck Surgery (AOCOO-HNS) from August 1, 2022, to August 30, 2022.
- **Results:** Forty-two respondents participated in the survey, with the majority practicing in the following hospital settings: community (80.95%), hybrid (11.90%), and academic (7.14%). The southeast had the largest proportion of respondents (30.95%), versus the midwest (28.57%), southwest (23.81%), northeast (11.90%), and northwest (4.76%). On average, 50.52% of cases were performed in the hospital setting, versus 48.50% in-office, and 42.40% in surgery centers. Respondents who used BSP primarily, reported a yearly average of 35.72 cases, a median of 12 cases, and a range of 0-361 cases. Respondents who used BSP secondary to functional endoscopic sinus surgery (FESS), reported a yearly average of 48.62 cases, a median of 31 cases, and a range of 0-189 cases. Overall, perioperative nasal packing was used in 15.3% of cases; intraoperative (11.72%) vs. postoperative (3.62%). Early complications included postoperative headaches (9.86%), acute bacterial sinusitis (ABRS) (3.52%), and tooth/facial numbness (0.86%). Reported long-term complications included postoperative synechiae (5.10%), orbital complications (0.14%), and skull base complications (0.10%). A previously unreported complication was identified through this study - accidental sphenopalatine fossa dilation.
- **Conclusions:** Although further investigation is needed, this pilot study contributes to the growing body of literature on frontal sinus BSP by characterizing utilization and complications from a large otolaryngologic academy. We hope to continue this study by surveying a larger number of respondents within other otolaryngologic academies across the world.

Introduction

- CRS has been reported to affect over 10% of the population in the United States (US) and Europe and remains a significant healthcare burden, with estimates of 14.4 billion dollars in direct healthcare costs. It also affects approximately 1.7 million school-aged children in the US resulting in over $1.8 billion dollars of pediatric healthcare-related expenses per year.[1,2]
- Balloon sinuplasty (BSP) has been FDA-approved since 2005 and is used with increasing frequency over the last 10 years as a treatment option for CRS. It provides mucosal-sparing treatment, without disturbing the physiologic function of the sinuses by microfracturing and dilating the sinus ostia to improve patency and decrease symptomatology, which has been shown to last up to two years.[3-6]
- Currently, there is a limited discussion regarding where BSP fits in the treatment algorithm for patients diagnosed with CRSwNP & CRSsNP, as there are only a handful of studies evaluating complications.[3,5,7-9]
- The overall complication rate of BSP has been reported as 5.26% in the literature. Specific complications include device failure, epistaxis, hematoma, synechiae, orbital pain, orbit or facial swelling, vision loss, ophthalmoplegia, orbital ptosis, orbital fractures, acute sinusitis, cerebrospinal fluid leak (CSF), pneumocephalus, dural exposure, intracranial bleeds, meningitis, and headache among others. Reported complication and two-year restenosis rates of BSP across all sinuses were noted to be 5.26% and 7.89% respectively. The re-operation rate at six months has been reported as 3.5%.[3,5,8,9]
- The frontal sinuses have been shown to have the highest complication rates and are associated primarily with CSF leaks. Only one publication reported data on the causes of adverse events, showing complicated anatomy in 14.1% of cases and surgeon error in 9.0% of cases.[3,5,8]
- With the frontal sinuses being one of the most common sites of complications, we aimed to further characterize current trends, utilization, and complications of frontal sinus BSP. To the authors' knowledge, no studies have provided self-reported physician data on frontal sinus BSP.

Methods

- Cross-sectional observational study (Survey) from August 1, 2022 to August 30, 2022
  - Anonymous and voluntary 20-item survey. Questions were listed as multiple choice or a percentage sliding bar. Expert peers reviewed the survey for content validity.
  - Results reported as frequencies, means, median numbers, and percentages.
  - Response alternatives for some questions were not mutually exclusive, participants could choose more than one choice, and for this reason, the aggregate total could exceed 100%
- Study population:
  - Inclusion: board-certified, active otolaryngologic members of the American Osteopathic Colleges of Ophthalmology and Otolaryngology-Head and Neck Surgery (AOCOO-HNS).
  - Exclusion: inactive otolaryngologic members, active/inactive ophthalmologic members, current fellows, residents, and medical students.

Results

- ***Characteristics of the study sample (Table 1)***
  - Forty-two respondents participated, with 29 respondents fully completing the survey (67.4%).
  - Thirty-three respondents were general otolaryngologists (78.57%) and the remaining (9) were fellowship trained: Allergy-Immunology (4.76%), Pediatric (4.76%), Rhinology (4.76%), Otology/Neurotology (4.76%), and Head and Neck Oncology (2.38%).
  - Most respondents practiced in a community setting (80.95%), while 11.90% practiced within a hybrid model, and 7.14% in an academic setting. In regards to location, 30.95% of respondents performed balloon sinuplasty in the southeast, compared with the Midwest (28.57%), the Southwest (23.81%), the Northeast (11.90%), and the Northwest (4.76%).
- ***Location of performing BSP (Table 2)***
  - Utilization of BSP varied by surgical location. On average 50.52% were performed in the hospital setting followed by in-office (48.50%) and within a surgery center (42.40%).
  - The average percent usage of BSP as a supplement to functional endoscopic sinus surgery (FESS) for CRSsNP was 55.27% vs. 52.29% in CRSwNP.

Table 1. Distribution of Participants Characteristics (N=42)

Characteristic	Number	Percent
Training Background		
Allergy and Immunology	2	4.76
General Otolaryngology	33	78.57
Head and Neck Oncology and Microvascular Surgery	1	2.38
Pediatric Otolaryngology-Head and Neck Surgery	2	4.76
Otology/Neurotology and Lateral Skull Base Surgery	2	4.76
Rhinology and Anterior Skull Base Surgery	2	4.76
Practice Type		
Academic	3	7.14
Academic/Community Hybrid	5	11.90
Community	34	80.95
Location		
Midwest	12	28.57
Northeast	5	11.90
Northwest	2	4.76
Southeast	13	30.95
Southwest	10	23.81

Table 2. Distribution of Location of Use of Frontal Sinus Balloon Sinuplasty

Location	Percent (N=42)
Locations	
BSP Performed - In-office	48.50
BSP Performed - Surgery Center	42.14
BSP Performed - Hospital	50.52
Percent of cases BSP Supplement to FESS	
in Chronic rhinosinusitis without nasal polyposis	55.27
In Chronic Rhinosinusitis with nasal polyposis	52.29

BSP = Balloon sinuplasty; FESS = functional endoscopic sinus surgery

- ***Frequencies of Cases Reported (Table 3)***
  - BSP was reported as a primary procedure for an average of four cases per month (range of 0-31), and an average of 36 cases per year (range 0-361).
  - BSP was reported as a hybrid procedure (FESS primarily and BSP secondarily), on average five cases per month (range of 0-20), and 48.62 cases per year (range of 0-189).
- ***Complications (Table 4)***
  - Overall, respondents reported the use of absorbable or non-absorbable nasal packing in 15.34% of cases; intraoperative (11.72%) versus postoperative (3.62%).
  - Reported short-term complications included: headaches lasting greater than 24 hours (9.86%), postoperative acute bacterial sinusitis (3.52%), and tooth/facial numbness (0.86%).
  - Reported long-term complications included: postoperative synechiae (5.10%), orbital complications (0.14%) [orbital wall fracture, ophthalmoplegia, ophthalmology, diplopia, vision loss, globe rupture, preseptal cellulitis, orbital cellulitis, subperiosteal abscess, orbital abscess, cavernous sinus thrombosis], and skull base complications (0.10%) [pneumocephalus, CSF leak, skull base injury, dural exposure, central nervous system complication, cranial complication].

Table 3. Frequencies of Cases Reported by Study Participants (N=29).

	Mean	Median	Mode	Range
Number of hybrid (FESS and BSP) frontal sinus cases perform *per month*	5.03	3	2	0 - 20
Number of hybrid (FESS and BSP) frontal sinus cases perform *per year*	48.62	31	100	0 - 189
Primary (BSP Only) frontal sinus balloon sinuplasty procedures *per month*	4.03	1	0	0 - 31
Primary (BSP Only) frontal sinus balloon sinuplasty procedures *per year*	35.72	12	2	0 - 361

BSP = Balloon sinuplasty; FESS = functional endoscopic sinus surgery

Table 4. Frequency of Complications Reported by Study Participants (N=29)

Complication	Mean (%)	Range (%)
Intraoperative Complications		
Required Intra-Op Packing	11.72	0 - 80
Postoperative Complications		
Required Post-Op Packing	3.62	0 - 50
Post-Op Acute Bacterial Sinusitis (within 1 week)	3.52	0 - 25
Post-Op Headache Longer than 24 hours	9.86	0 - 50
Orbital Complications	0.14	0 - 2
Skull Base Complications	0.10	0 - 2
Post-Op Synechia	5.10	0 - 30
Tooth & Facial Numbness	0.86	0 - 15

Notes Orbital complications included: orbital wall fractures, ophthalmalgia, ophthalmoplegia, diplopia, vision loss, globe rupture, preseptal cellulitis, orbital cellulitis, subperiosteal abscess, orbital abscess, cavernous sinus thrombosis. Skull base complications included: CSF leak, pneumocephalus, skull base injury, dural exposure, central nervous system complications, and intracranial complications.

Discussion

- The majority of respondents, who performed BSP, were general otolaryngologists (78.57%)
- The majority of respondents practiced in a community hospital settings (80.95%).
- There was a slight geographic prevalence for performing BSP in descending order: the southeast (30.95%), midwest (28.57%), southwest (23.81%), northwest (11.90%), and northeast (4.76%).
- Frontal balloon sinuplasty was used slightly more for CRSsNP (55.27 %) versus CRSwNP (52.29%).
- Otolaryngologists surveyed performed on average more monthly (5.03) and yearly (48.62) hybrid procedures for frontal sinus CRS than BSP-only procedures (4.03 monthly and 35.72 yearly)
  - Hybrid monthly range (0-20) and yearly range (0-189) versus BSP-only monthly range (0-31) and yearly range (0-361)
- Most BSP-only cases were performed in the hospital setting (50.52%) compared with in-office (48.50%), or in a surgical center (42.14%)
- Complications
  - Overall, respondents reported the use of absorbable or non-absorbable nasal packing in 15.34% of cases; intraoperative (11.72%) versus postoperative (3.62%).
  - Reported short-term complications included: headaches lasting greater than 24 hours (9.86%), postoperative acute bacterial sinusitis (3.52%), and tooth/facial numbness (0.86%).
  - Reported long-term complications included: postoperative synechiae (5.10%), orbital complications (0.14%) [orbital wall fracture, ophthalmoplegia, ophthalmology, diplopia, vision loss, globe rupture, preseptal cellulitis, orbital cellulitis, subperiosteal abscess, orbital abscess, cavernous sinus thrombosis], and skull base complications (0.10%) [pneumocephalus, CSF leak, skull base injury, dural exposure, central nervous system complication, cranial complication].
  - One respondent did note a complication of "accidental sphenopalatine fossa dilation" which had not been reported prior in the literature.
- We do acknowledge some notable limitations to this study including a low number of respondents who fully participated in the survey, polling respondents from a single American ENT academy, physician preferences, heterogeneity of operative and post-operative protocols, and recall bias from the respondents. We hope to build on this study by surveying a larger number of respondents within other otolaryngologic academies around the world.
- Future goals of this project include evaluation of frontal BSP revision rates, other complications (device malfunction/ostial restenosis), image guidance use, and physicians' reasoning for their chosen operative setting with a larger survey population.

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