

Real-World Safety and Performance of The Mesire Sinus Balloon Catheter: A Retrospective Multicenter Study

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Abstract

Background Chronic rhinosinusitis (CRS) is a common, persistent inflammatory disease of the sinonasal mucosa with a profound effect on patients' quality of life. Although endoscopic sinus surgery (ESS) is an effective standard method of treatment, complications such as postoperative bleeding, mucosal damage and scarring may result. Balloon catheter dilation (BCD) has been developed as a less invasive procedure to recover sinus ventilation and, more importantly, to preserve the mucosal integrity.

Aim The aim of the study was to assess the safety and performance of the Mesire™ Sinus Balloon Catheter in patients with sinonasal ostial obstruction.

Methods This retrospective, multicentre post-marketing clinical follow-up study enrolled 111 patients who had undergone sinus ostial dilation with the Mesire™ Sinus Balloon Catheter in 12 clinical centres in India. The primary endpoint of the study was a composite of postoperative complication rate and revision surgery frequency during a 6-month follow-up. Secondary endpoints were adverse events, revision surgery rate, nasal bleeding, and hospital stay.

Results All 111 enrolled patients (71 males and 40 females; mean age = 39.73 ± 10.74) completed the 6-month follow-up, with no dropouts or deviations from protocol supervision. Chronic sinusitis was the main diagnosis in 87.39% of instances. The frontal (66.67%) and maxillary (47.75%) sinuses were the most involved. All procedures were performed with technical success (100%) and without device-related complications. No intra- or postoperative complications, adverse events, or revision surgery occurred during the study period.

Conclusions The Mesire™ Sinus Balloon Catheter achieved a 100% success rate at 6 months of follow-up, with no complications or need for revision. These results demonstrate its safety and effectiveness as a feasible, minimally invasive option that preserves sinus mucosa compared to standard ESS.

Keywords Balloon sinuplasty; Chronic sinusitis; Paranasal Sinus Diseases; Pediatrics; Sinusitis.

Introduction

Chronic rhinosinusitis (CRS) is a prevalent form of chronic nasal inflammation resulting from infection of the sinuses' mucous membranes and is characterized by symptoms of both sinus and extrasinus origin. It is a common, diverse disease of the upper airways, characterized by a prolonged inflammatory reaction in the sinuses or nasal cavity lasting at least 3 months. The duration of the condition is directly related to a significant deterioration in health-related quality of life [1,2]. The clinical symptoms usually expected are nasal obstruction, anosmia, facial pain, and nasal discharge (rhinorrhea). CRS is classified into two primary phenotypes in either nasal polyps present or not present: CRS without nasal polyps (CRSsNP) or CRS with nasal polyps (CRSwNP). The CRSwNP phenotype accounts for approximately 20-33% of patients with CRS. Fresh data are beginning to emerge that point to the CRSwNP phenotype being principally due to a Type 2 cytokine inflammatory response, but the precise mechanism on the molecular and immunological levels is still not well understood [1]. The etiology of CRS is extremely complex, involving interactions between environmental stimuli and host-specific responses. Environmental stimuli, such as microbial agents

(bacteria, fungi, and biofilm-forming communities) and airborne allergens, are responsible for the pro-inflammatory state in the paranasal sinuses. At the same time, the biological factors specific to the individual, namely aberrant immune system responses, disturbed integrity of the mucous membranes, and impaired regulation of eicosanoid synthesis, together result in reduced resistance of the host's connective tissue to chronic inflammatory/infectious stimuli [3].

The management of CRS utilizes a multimodal strategy targeting the key elements of this disease inflammation, drainage, and infection. Initial pharmacotherapy centers on corticosteroid therapy (both topical and systemic), nasal saline douching, and culture-directed antibiotics. In pediatric CRS that is unresponsive to medical therapy, adenoidectomy represents a fundamental surgical procedure to improve sinus ventilation and lessen the available bacterial pool [4]. During the past several decades, a gradual evolution in sinus surgery has occurred from the open surgical techniques to functional endoscopic sinus surgery (FESS). At that time, exposure and mucosal preservation had improved. This improvement has occurred with the introduction of technologies such as thru-cutting forceps and “powered” microdebridors, which improve precision in surgical technique and reduce disease recurrence. The risks inherent in endoscopic sinus surgery (ESS) are the same as those of other surgeries, including bleeding, adhesions, and injury to orbital or intracranial structures [5,6].

A unique catheter-delivery system has been devised to reduce the complications of excessive mucosal growth, injury, scar tissue, bleeding, and other issues. The technical rationale is based on mimicking the clinical advantages of a minimally invasive catheterization procedure, so much a part of the diagnostic and therapeutic armamentarium of almost every organ system in the world of interventional medicine, ranging from vascular access to endoscopic techniques [5].

The newly developed surgical technique of balloon catheter dilation (BCD) now presents a new treatment option for CRS. This treatment is currently approved for adults and is unique for its minimally invasive application. This therapeutic approach produces controlled microfractures at the sinus ostia, re-establishing physiological drainage patterns. It also reduces the likelihood of developing scar tissue, which is so prevalent with traditional surgical techniques for the sinus ostia, in which the mucosa is completely removed [7].

The Mesire™ Sinus Balloon Dilation System (Meril Life Sciences Pvt. Ltd., India) is intended to treat patients with medically refractory CRS or chronic sinusitis in a minimally invasive manner. Its intended purpose is to regain patency of obstructed paranasal sinus ostia mechanically. The underlying method involves preserving and maintaining mucosal and structural integrity, as this directly reduces postoperative complications and shortens total healing time for patients. The present study evaluated the safety and performance of the Mesire™ Sinus Balloon Catheter under application for diagnostic and therapeutic dilation of sinus ostia.

Methods

Study design

This study was designed as a retrospective, observational, multicenter, and post-market follow-up. The study population involved all consecutive cases of sinus ostial dilation performed with the test device at 12 clinical sites in India. Participants with obstruction of the sinonasal ostia and associated paranasal sinus cavities, and pediatric patients (aged ≤17 years) with maxillary sinus ostial and cavity involvement were included in this study (Figure 1). Participants were excluded if they possessed any of the following: severe structural/anatomical abnormalities (major trauma, past surgery, new bone growth), significant pre-existing pathology (extensive polyps, tumors), underlying systemic diseases (cystic fibrosis, ciliary dyskinesia), or pregnancy. The study enrolled 111 patients who fulfilled the inclusion criteria. Baseline demographics, intraoperative parameters, and postoperative outcomes were collected from the existing medical records and documented in a Case Report Form (CRF). The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and fully conformed to international standards, including ICH GCP guidelines and ISO 14155:2020 for Good Clinical Practice. Prior to study initiation, the research protocol was approved by the Ethics Committee (EC).

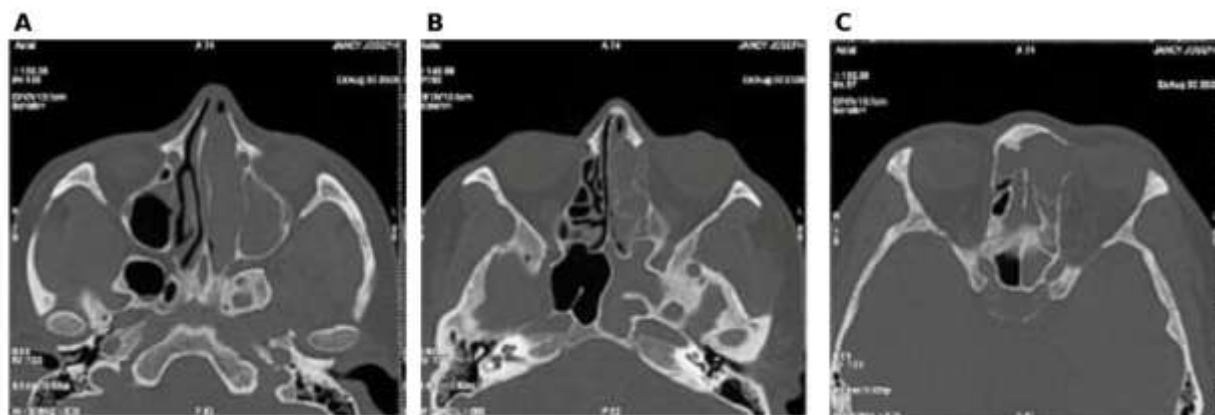


Figure 1: Preoperative CT of the paranasal sinuses. Representative axial CT images (A–C) demonstrating left-sided sinonasal disease with marked maxillary sinus opacification and involvement of adjacent paranasal sinuses.

Study device and procedure

The Mesire™ Sinus Balloon Catheter is a non-compliant balloon catheter, indicated for the dilation of the sinus ostia. It offers distal tip responsiveness for delicate manipulation, a smooth balloon insertion stylet, and single-handed flange actuation, providing the ultimate procedural control. Endoscopic markers and color-coded balloon shafts enable precise placement in low-light conditions (Figure 2).

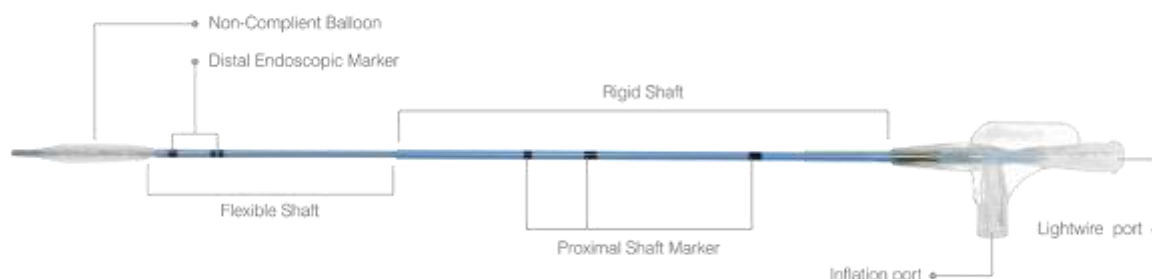


Fig. 2 MESIRE balloon catheter

The Sinus Balloon Dilation System offers three distinct balloon catheter dimensions: 5mm × 17 mm, 6mm × 17 mm, and 7mm × 17 mm, for different sinus anatomies and procedural needs. The sheath fits guide catheters at angles of 0°, 30°, 70°, or 90°, depending on the size of the targeted sinus, and this permits accurate access to multiple sinus regions under endoscopic visualization (Figure 3). It is made with a small-diameter light wire.



Fig. 3 MESIRE guide catheter

The Mesire™ Sinus Balloon Catheter is a minimally invasive technique that can be performed under local or general anaesthesia; it involves using a flexible guide catheter to dilate the obstructed sinus ostium under endoscopic control.

A balloon catheter is then inserted and inflated to elevate the sinus lining, creating tiny fractures in the surrounding bone through which the packed cavity of the maxillary sinus drains. After dilatation, the sinus cavity is irrigated with saline, and any remaining secretions are evacuated; the system is then removed, and the newly formed ostium is allowed to remain open for spontaneous drainage (Figure 4).

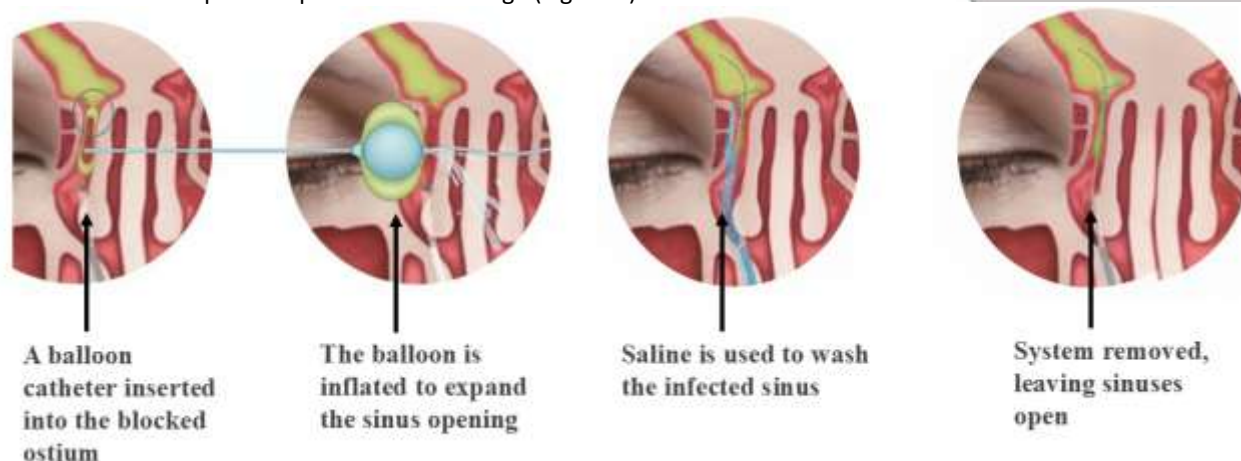


Fig. 4 Schematic illustration of balloon sinus dilation procedure

Outcome measure

The primary endpoint of this study was to assess the composite of post-operative complication rate with the frequency of revision surgical procedures in a six-month post-operative period. Secondary endpoints include incidence of complications such as orbital injuries, bleeding, or skull base/central nervous system involvement over the six-month follow-up. The length of hospital stay was measured as the number of days between the initial procedure and patient discharge, and the prevalence of nasal bleeding at discharge was documented as the number of patients presenting with this complication.

Statistical analysis

All statistical analyses were conducted on participants meeting the inclusion criteria. Categorical variables were summarized and presented as frequencies and percentages (n, %), while continuous variables were expressed as mean $\pm$ standard deviation. All analyses were performed using Statistical Package for the Social Sciences (SPSS), Version 20.

Results

Patient characteristics

A total of 111 patients were included, with a mean age of 39.73 ± 10.74 years, and 71 (63.96%) were male. The majority of patients presented with chronic sinusitis 97(87.39%), while 31(27.93%) had recurrent acute sinusitis. Almost half of patients (44.14%) experienced four or more episodes of acute rhinosinusitis in the previous year, while a majority (89.19%) had chronic sinusitis lasting longer than 12 weeks. Additional diagnoses included rare cases of nasal polyps, recurrent sinonasal polyposis, allergic fungal sinusitis, asthma, and severe frontal headache, each representing about 0.9% of cases. Preoperative evaluations showed that all patients underwent nasal endoscopy, and 94.59% received CT scans (Table 1).

Table 1 Patients data

Demographic	n(%)
Gender	
Male	71 (63.96)
Female	40 (36.04)
Age (years)	39.73 $\pm$ 10.74

Age Bifurcation	n(%)
17-34	33 (29.73)
35-51	61 (54.95)
52-65	15 (13.51)
>65	2 (1.80)
Medical History	n(%)
Hypertension	8 (7.21)
Diabetes	6 (5.41)
Acute Bacterial Sinusitis	6 (5.41)
Chronic Sinusitis	97 (87.39)
Subacute Sinusitis	8 (7.21)
Recurrent Acute Sinusitis	31 (27.93)
Chronic Obstructive Pulmonary Disease	0 (0.00)
Asthma	3 (2.70)
Allergy	11 (9.91)
History of any other illness	n(%)
Cleft lip+Nose	1 (0.90)
Community Acquired Pneumonia – Pseudomonas	1 (0.90)
Angioplasty	1 (0.90)
Endoscopic surgery	1 (0.90)
Hyperthyroidism	1 (0.90)
Hypothyroidism	1 (0.90)
Tuberculosis (Pulmonary)	1 (0.90)
Migraine	1 (0.90)
Nasal surgery polypectomy(1998) Vocal cord Poly surgery (2008)	1 (0.90)
Single Kidney	1 (0.90)
Sinonasal Sx	1 (0.90)
Baseline Physical Examination	Mean $\pm$ SD
Heart Rate (bpm)	81.09 $\pm$ 9.14
Height (cm)	165.11 $\pm$ 11.89
Weight (Kg)	68.94 $\pm$ 10.02
Pre-opert Systolic BP (mm/Hg)	124.98 $\pm$ 10.96
Pre-opert Diastolic BP (mm/Hg)	79.68 $\pm$ 7.94
Disease History	n(%)
Four or more documented episodes of Acute Rhinosinusitis in the past one year	49 (44.14)
Chronic Sinusitis (greater than 12 weeks duration)	99 (89.19)
Any Other	
Nasal Polyp	1 (0.90)
Recurrent Sinonasal polyposis	1 (0.90)
Recurrent extensive sinonasal polyposis/ Recurrent Vocal cord Polyp	1 (0.90)
Cleft lip+ nose	1 (0.90)
Recurrent allergic fungal sinusitis	1 (0.90)
Recurrent acute sinusitis - fungal P/H/O endoscopic sinus Sx	1 (0.90)
Severe right frontal headache (1 week)	1 (0.90)
Asthma	1 (0.90)

Subacute>4 weeks	1 (0.90)
Pre Operative Laboratory Tests	n(%)
Endoscopy (Y/N)	111 (100.0)
CT Scan (Y/N)	105 (94.59)
If any other, specify	n(%)
Intact bulla used as a guide, adrenaline-soaked mucocel used to clear the field	6 (5.41)
KerosII	1 (0.90)
KOH aseptate fungal hyphae seen	1 (0.90)
Left nasal mucosa pale	1 (0.90)
Middle meatus-widened. By pushing middle turbinate (microfracture)medially	16 (14.41)
Right ethmoid sinusitis and Right OMU blocked/Right ethmoid sinusitis	2 (1.80)

n: number of subjects; SD: standard deviation; bpm: beats per minute; cm: centimeter; Kg: kilogram; BP: blood pressure; mm/Hg: millimeters of mercury; Pre-opert: pre-operative; CT: computed tomography; Y/N: yes/no; OMU: osteomeatal unit; Sx: surgery; P/H/O: past history of; KOH: potassium hydroxide.

Procedure and device performance

The most frequently treated sinuses were the frontal (66.67%) and maxillary sinuses (47.75%), with a smaller number involving the ethmoid and sphenoid regions (each 3.60%). The primary indication for device use was CRS (73.87%), followed by recurrent acute rhinosinusitis (17.12%) and revision surgeries (11.71%). Indications for device use included CRS (73.87%), recurrent acute rhinosinusitis (17.12%), and revision surgeries (11.71%). Regarding device specifications, 196 Mesire sinus balloon catheters were used, all measuring 17 mm in length, with an initial preferred diameter of 7 mm and guide catheter angles mainly at 70° (66.67%), followed by 110° (31.53%), and rarely 30° (1.8%). The accessory light wire was 0.83 mm in diameter and 100 cm long, with consistent dimensions across all procedures (Table 2).

Table 2 Procedure and device performance data

Procedure Details	
Location of Sinus	n(%)
Side of the nose, near the cheekbones (Maxillary sinuses)	53 (47.75)
Above the eyes, near the forehead (Frontal sinuses)	74 (66.67)
Bridge of nose, near your eyes (Ethmoid sinuses)	4 (3.60)
Behind the eyes, deeper into the skull (Sphenoid sinuses)	4 (3.60)
Indication for which study device used	n(%)
Chronic Rhinosinusitis	82 (73.87)
Recurrent Acute Rhinosinusitis	19 (17.12)
Revision Surgery	13 (11.71)
For dilatation of Sinus ostia	29 (26.13)
Spaces within the paranasal sinus cavities	6 (5.41)
Spaces associated with the maxillary sinus	3 (2.70)
Additional Comments related to procedure	n(%)
Allergic fungal rhinosinusitis/ Allergic fungal rhinosinusitis with polyposis with DNS	2 (1.80)
Changes of Allergic fungal rhinosinusitis	1 (0.90)
Ballon got burst on the third attempt	1 (0.90)

Anterior ethmoid sinuses cleared by microdebrider	1 (0.90)
Eustachian tuboplasty	1 (0.90)
Eustachian tube dysfunction	1 (0.90)
FESS with Balloon dilation with septoplasty under GA	4 (3.60)
Maxillary Fungal Ball (Left) Maxillary polyp (Right)	1 (0.90)
Right anterior and posterior ethmoid sinus opened	1 (0.90)
The sinuses were flushed and cleaned with saline	1 (0.90)
Device Specifications	
No. of study devices used	
Mesire Sinus Balloon Catheter	196*
Length of Sinus Balloon Catheter (mm)	
17	196*
1st Location of Sinus	n(%)
Maxillary sinusitis	41 (36.94)
Frontal Sinus	69 (62.16)
Sphenoid	1 (0.90)
1st Sinus Balloon Catheter Diameter (mm)	n(%)
7	111 (100.0)
1st Sinus Guide Catheter Angle (Degree)	n(%)
30	2 (1.80)
70	74 (66.67)
110	35 (31.53)
2nd Location of Sinus	n(%)
Maxillary sinusitis	14 (12.61)
Frontal Sinus	50 (45.05)
Sinus ostia	6 (5.41)
Sphenoid	2 (1.80)
Ethmoid	1 (0.90)
2nd Sinus Balloon Catheter Diameter (mm)	n(%)
7	73 (65.77)
2nd Sinus Guide Catheter Angle (Degree)	n(%)
30	3 (2.70)
70	56 (50.45)
110	14 (12.61)
3rd Location of Sinus	n(%)
Maxillary sinusitis	1 (0.90)
Frontal Sinus	2 (1.80)
Sinus ostia	8 (7.21)
Sphenoid	1 (0.90)
3rd Sinus Balloon Catheter Diameter (mm)	n(%)
7	12 (10.81)
3rd Sinus Guide Catheter Angle (Degree)	n(%)
30	1 (0.90)
70	5 (4.50)
110	6 (5.41)
Diameter of Light Wire (mm)	n(%)

0.83	111 (100.0)
Length of Light Wire (cm)	n(%)
100	111 (100.0)

*Total Balloon Catheter with 17 mm length and 7mm Diameter 111+73+12=196

n: number of subjects; mm: millimeter; cm: centimeter; DNS: deviated nasal septum; FESS: functional endoscopic sinus surgery; GA: general anesthesia; Sx: surgery.

Performance outcomes

In this study, the Mesire Sinus Balloon Catheter demonstrated complete technical achievement in dilating the designated sinus drainage pathways. No patients had nasal bleeding (epistaxis) at discharge. Furthermore, the observation period through six months post-intervention documented a 0% rate of complication; no events of orbital trauma, bleeding, skull base, or central nervous system complications were recorded. Over the six-month observation period, no reports of revision surgery or secondary procedures indicated a 0% rate of postoperative complications. These findings validate the device's consistent reliability and clinical endurance (Table 3).

Safety outcomes

All treated patients (111, 100%) were subjected to safety evaluation. No patients experienced adverse or serious adverse events (AEs or SAEs), and all were discharged safely. There were no delayed complications, infections, or revisions throughout the six-month post-procedure follow-up. The absence of revision surgeries and 0% postoperative complications demonstrates the device's favorable safety profile (Table 3).

Table 3 Outcome details (n= 111).

Detail	n(%)
Discharged	111 (100.0)
In-Hospital AE/SAE	0 (0.00)
Nasal Bleeding	0 (0.00)
Follow-Up Visit [Time Frame: Through Six Months]	
Post-operative Complication rate	n(%)
Orbital complications Fracture, Hemorrhage, Orbital cellulitis, Pain/ redness around the eye, Ophthalmoplegia, Diplopia, Orbital disorder	0 (0.00)
Severe bleeding	0 (0.00)
Skull Base Complication Pneumocephalus, CSF leaks, Skull base injury	0 (0.00)
CNS complication	0 (0.00)
Rate of revision surgery	0 (0.00)
Composite of post-operative complication rate and rate of revision surgery	0 (0.00)
Adverse event (AE)/Serious adverse event (SAE) through 6 Months	0 (0.00)

n: number of subjects; AE: adverse event; SAE: serious adverse event; CSF: cerebrospinal fluid; CNS: central nervous system.

Discussion

The Mesire Sinus Balloon Catheter, a surgical device for minimally invasive dilation of the sinus ostia, was the subject of a retrospective, multicenter, post-market surveillance study to determine its safety and performance characteristics. The procedure is associated with enhanced patient recovery, including minimal blood loss, shorter recovery time, and a prompt return to normal function, compared with more invasive modalities. Furthermore, the study recorded no incidence of device-related AEs or SAEs. These findings constitute compelling evidence that the Sinus Balloon Catheter is a safe and effective technique for achieving ostium dilation and treating CRS.

The current study achieved a 100% completion rate for the six-month follow-up across all enrolled patients. The high prevalence of CRS (89.19%) indicates the real-world prevalence of resistant disease that requires surgery, thereby establishing a clinical justification for minimally invasive procedures such as balloon dilation. All cases achieved complete technical success, or dilation of the required sinus ostia during the follow-up period. The frontal (66.7%) and maxillary (47.7%) sinuses represented were most frequently treated, consistent with the anatomical predilection of CRS. There were no device malfunctions, and the absence of revision procedures demonstrates both the mechanical soundness of the device and the long-term stability of its clinical effect. These results are consistent with previous reports on the success rates of balloon catheter sinus procedures [6,8].

Zalzal et al. (2019) studied the use of balloon catheter sinus plastic (BCS) in refractory CRS in 38 patients who had not responded to childhood adenoidectomy. It was noted in this study that there was also a low therapeutic failure, as 21.1% of these children had persistent symptoms. The number of cases that finally required FESS was 13.1%. This suggests that BCS represents a practical and durable therapeutic option for children with complex CRS, offering a high likelihood of avoiding more invasive procedures and disease recurrence [5].

The present study extends this knowledge by reporting multicentric post-market data without complication and revision rates. This data shows a good surgical advantage compared to past results for ESS with postoperative bleeding and adhesion formation in up to 10-15% of patients. The results are overall consistent with the literature in that BCD has outcomes similar to ESS but markedly reduced perioperative morbidity [9]. The present evidence aligns with the findings of the retrospective comparative study by Chaaban et al. (2018), which examined surgical efficiency in pediatric and adult CRS patients. This study directly compared the results of BSP, FESS, and a hybrid surgical technique using the important clinical variables of complication rate and 6-month reoperation rate. The data established that BSP was the safest procedure with a lower complication rate (5.26%) than FESS (7.35%). The study further established that BSP showed significantly greater resistance to recurrence, with a revision rate of 7.89%, approximately one-half that of FESS (16.85%) and less than that of the hybrid technique (15.15%) [10].

In a study by Minni et al. (2018), a comparative effectiveness and safety assessment was conducted between BCD, used either as monotherapy or in combination with a nonabsorbable drug-eluting stent (Relieva Stratus), in the clinical management of non-polypoid CRS in the frontal sinus. The study identified 76 frontal sinuses (41 BCD-only and 35 BCD + Spacer) and concluded that BCD had a good safety profile and therapeutic effectiveness. However, the addition of Relieva Stratus, while providing a good safety profile, did not provide statistically significant additional benefit in the treatment of mild to severe frontal CRS [8]. In the present study, no AEs or SAEs occurred during or after surgery, and no patient experienced bleeding, orbital, skull base, or cerebrospinal fluid complications. The revision rate in this trial was zero over the 6-month observation period. Such a finding suggests the favorable safety characteristic of the Mesire system. Prior investigations suggest that endoscopic dilation type surgery (EBD) provided good operative performance and a safety profile in the treatment of CRS. Successful dilation was accomplished in better than 96% of the 497 sinus procedures attempted; only 18 needed to be converted to conventional surgical-type dissection, usually due to anatomical limitations or technical difficulties. The AE rate was extremely low at 1.1% (n = 2), was classified as non-serious, and was independent of the device or the procedure. This data supports the minimal invasiveness of the technique [11]. In another retrospective cross-sectional study, 211 AEs were identified from 208 balloon sinuplasty reports. The distribution of causation was nearly equal, with 48.3% reported as patient-related and 47.9% as device-related. The major categories of serious AEs reported were balloon or guide catheter malfunction, cerebrospinal fluid leakage, and clinically significant periorbital edema. These findings illustrate the need to discuss these potentially serious AEs with patients during pre-operative counseling and the informed consent process for patients who are candidates for balloon sinuplasty [12].

Balloon sinus dilation is clinically valuable as a minimally invasive means of correcting sinus ostial obstruction. The procedure effectively relieves the obstruction while maintaining native sinonasal anatomy and mucosal integrity, with a corresponding reduction in procedural morbidity. Its ability to restore physiologic ventilation and sinus drainage supports the idea that it has a durable role as a therapeutic option. This approach aids in restoring normal sinus function and supports its continued integration into modern rhinologic practice.

Study Limitations

The retrospective design limits causal inference and depends on the comprehensiveness of existing records. The relative effectiveness of therapeutic alternatives cannot be directly evaluated without comparison or control groups. Additionally, patients symptom relief and quality-of-life assessments were not included, which would potentially

affect clinical interpretation. The study cohort, defined by consecutive enrollment, is small, and the lack of extended follow-up limits understanding of long-term outcomes.

Clinical Implications

The Mesire™ Sinus Balloon Catheter provides compelling evidence for its inclusion in recommended protocols for the management of CRS. Clinical observation indicates that its minimally invasive design, enhanced by standardized procedure and reproducible operative outcomes, allows its use in both inpatient and outpatient settings. The absence of complications and revision requirements can translate into shorter hospital stays, reduced healthcare costs, and improved patient satisfaction, key priorities in modern surgical practice.

Conclusion

This multicenter, real-world assessment demonstrated that the Mesire™ Sinus Balloon Catheter offers a safe, effective, and reproducible method for sinus ostial dilation. The device achieved 100% technical success with no postoperative complications or revisions, underscoring its reliability in diverse clinical environments. The reproducibility of these results in various practice settings points to this catheter's versatility and clinical viability. These findings support the clinical usefulness of balloon catheter technology as a revolutionary alternative to conventional ESS, enhancing outcomes while reducing patient risk.

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