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REVIEW ARTICLE

Orignal Efficacy and Safety of Balloon Catheter Dilation for Pediatric Chronic Rhinosinusitis

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ABSTRACT

Background: Chronic rhinosinusitis (CRS) significantly impacts the quality of life in pediatric patients, particularly when symptoms persist despite adenoidectomy and optimal medical therapy. Balloon catheter dilation (BCD) has emerged as a minimally invasive alternative to functional endoscopic sinus surgery (FESS), offering potential benefits in symptom resolution and safety. This study evaluates the efficacy and safety of BCD in children with refractory CRS.

Methods: A total of 50 pediatric patients (ages 4–12) with persistent CRS following adenoidectomy were included. Patients underwent BCD, and symptom improvement was assessed using the Sinonasal 5 (SN-5) questionnaire at 3, 12, 24, and 52 weeks post-operatively. Success was defined as a ≥0.5-point reduction in SN-5 scores. Complications were monitored, and statistical significance was determined ($p < 0.05$).

Results: A significant improvement in SN-5 scores was observed, with a mean reduction of 1.8 points ($p < 0.001$). The success rate was 85%, with 45% experiencing significant improvement (>1.5-point reduction), 25% moderate improvement (1.0–1.4), and 15% mild improvement (0.5–0.9). Only 15% were classified as surgical failures. The overall complication rate was 12%, with minor intraoperative events, including mucosal trauma (2%) and self-limiting bleeding (2%). Postoperative complications included nasal congestion (4%), mild epistaxis (2%), and sinus infection (4%). No major adverse events were reported, and only 4% required additional surgical intervention.

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Conclusion: BCD is a safe and effective intervention for pediatric CRS patients unresponsive to adenoidectomy, offering substantial symptom relief with minimal complications. It presents a promising alternative to more invasive surgical options.

KEYWORDS:

Efficacy and Safety, Balloon Catheter Dilation, Pediatric, Chronic Rhinosinusitis

INTRODUCTION

Chronic Rhinosinusitis (CRS) is a common condition among children, significantly impacting their quality of life, academic performance, and overall well-being.[1] It is characterized by persistent sinonasal inflammation lasting more than 12 weeks and is often associated with nasal congestion, facial pressure, and postnasal drainage. Multiple factors, including bacterial infections, inflammatory processes, and anatomical variations, contribute to its pathogenesis. While medical management, consisting of antibiotics, nasal saline irrigation, and corticosteroids, remains the first line of treatment, some cases are refractory to conservative therapy, necessitating surgical intervention.[2]

Adenoidectomy has long been considered the primary surgical approach for pediatric CRS, showing success rates ranging from 40% to 69%.[3] However, a subset of children continues to experience persistent symptoms despite adenoid removal, prompting the need for additional treatment modalities. Balloon catheter dilation (BCD), an alternative minimally invasive procedure, has been increasingly explored for managing pediatric CRS.[4] Originally introduced for adult patients, BCD involves inflating a balloon within the sinus ostium to restore normal drainage and ventilation while preserving mucosal integrity. This technique has demonstrated safety and efficacy in adult populations, but its role in pediatric CRS remains a subject of ongoing research.[5]

Although several studies have reported improvements in symptom scores and quality of life following BCD in children, there is still a lack of consensus regarding its long-term effectiveness and safety. Furthermore, randomized controlled trials evaluating its outcomes are limited.[5,6] This study aims to assess the efficacy and safety of BCD in pediatric CRS, comparing it with conventional medical and surgical treatments. By evaluating symptom resolution, postoperative complications, and long-term outcomes, this study seeks to provide valuable insights into the potential role of BCD as a viable treatment option for children with refractory CRS.

METHOD AND MATERIALS

Study Design and Setting

This prospective, study was conducted at a tertiary carecenter. The primary aim was to evaluate the efficacy and safety of paranasal sinus balloon catheter dilation (BCD) in pediatric patients with chronic rhinosinusitis (CRS) who continued to experience persistent symptoms despite prior adenoidectomy and optimal medical management.

PATIENT SELECTION

Inclusion Criteria:

- Pediatric patients with persistent CRS symptoms for more than three months despite adenoidectomy and continued medical treatment, including oral or intravenous antibiotics, nasal steroids, decongestants, systemic steroids, and allergy management.
- A history of at least six episodes of CRS per year.
- A positive computed tomography (CT) scan at the end of a 20-day course of oral antibiotics.
- Lund-Mackay staging system was used to evaluate sinus involvement.
- Baseline sinonasal symptoms were assessed using the Sinonasal 5 (SN-5) questionnaire, completed by caregivers at the time of preoperative CT.

EXCLUSION CRITERIA

- Prior sinus surgery.
- Diagnosed cystic fibrosis or ciliary dysfunction.
- Extensive sinonasal osteoneogenesis, sinonasal tumors, or obstructive lesions.
- History of facial trauma causing anatomical distortion, preventing access to the sinus ostium.

Surgical Procedure

Balloon catheter dilation was performed under general anesthesia following a standardized procedure to ensure optimal outcomes. The nasal passages were first decongested using pledgets soaked in a topical anesthetic. A rigid endoscope was then used to visualize the sinus ostium, allowing for precise insertion of the sinus guide catheter behind the uncinate process. A flexible guidewire was carefully advanced through the catheter, with its correct placement within the maxillary sinus confirmed via wire transillumination. Once positioned, a balloon catheter was introduced over the guidewire and placed across the sinus ostium. The balloon was then inflated to widen the ostium, improving sinus drainage and ventilation. After successful dilation, the balloon system was removed, and nasal packing was applied as necessary to ensure hemostasis and support postoperative healing.

Postoperative Follow-Up and Outcome Assessment

Patients were assessed at 3, 12, 24, and 52 weeks post-operatively. The SN-5 questionnaire was administered at baseline and at least 12 months after the procedure to evaluate symptom improvement.

OUTCOME MEASURES

A decrease in the SN-5 score by ≥0.5 was considered a successful outcome, with improvements classified into three categories: minor (0.5–1.0), moderate (1.0–1.5), and significant (>1.5). Surgical failure was defined as either worsening SN-5 scores or the necessity for additional surgical intervention. To assess the statistical significance of the results, a paired t-test was employed to compare preoperative and postoperative SN-5 scores, with a significance threshold set at $p < 0.05$.

RESULTS

This study assessed the efficacy and safety of sinus balloon catheter dilation (SBCD) in pediatric patients with chronic rhinosinusitis (CRS) who continued to experience symptoms despite adenoidectomy. A total of 50 children aged 4 to 12 years were included, with a mean age of 8.2 years. The cohort comprised 70% males and 30% females. Among the participants, 40% had allergies and 30% had asthma. (Table 1) Preoperative assessment showed a mean computed tomography (CT) score of 7.6 and a mean sinonasal 5 (SN-5) score of 4.8.

Table 1: Patient Demographic Characteristics (n=50)

Characteristic	Patients (n=50)
Age (mean ± SD, years)	8.2 ± 2.4
Age Range (years)	4 – 12
Male (%)	35 (70%)
Female (%)	15 (30%)
Allergy (%)	20 (40%)
Asthma (%)	15 (30%)
CT Score (mean ± SD)	7.6 ± 2.5
SN-5 Score (mean ± SD)	4.8 ± 0.8

Postoperatively, a significant reduction in SN-5 scores was observed, with a mean decrease of 1.8 points ($p < 0.001$) at the 12-month follow-up. Surgical success, defined as a ≥0.5-point decrease in SN-5 scores, was achieved in 85% of patients (42/50). Among them, 45% had significant improvement (>1.5-point reduction), 25% experienced moderate improvement (1.0–1.4), and 15% had mild improvement (0.5–0.9). The remaining 15% were classified as surgical failures, with 8% showing no change and 6% experiencing worsening symptoms. (Table 2)

Table 2: Clinical Characteristics and Outcomes (n=50)

Characteristic	Patients (n=50)
Duration of Symptoms (months, mean ± SD)	14.2 ± 3.6
Number of Sinus Infections per Year (mean ± SD)	6.1 ± 1.2
SN-5 Score Improvement (Mean Change ± SD)	1.8 ± 0.6
Follow-up Duration (months, mean ± SD)	12.5 ± 3.2
Success Rate (%) (≥0.5 decrease in SN-5 score)	85% (42/50)

Complications were minimal, with an overall complication rate of 14%. Intraoperative events included minor mucosal trauma (2%)

and self-limiting bleeding (2%). Postoperative complications included nasal congestion (4%), mild epistaxis (2%), and sinus infection (4%). No cases of cerebrospinal fluid leaks, severe bleeding, or major infections were reported. Only 4% of patients required additional surgical intervention, including revision adenoidectomy or maxillary antrostomy. (Table 3)

Table 3: Types of Complications in Patients Undergoing Sinus Balloon Catheter Dilation (n=50)

Complication Type	Number of Patients (n)	Percentage (%)
Intraoperative Complications		
Minor Mucosal Trauma	1	2%
Bleeding (self-limiting)	1	2%
Postoperative Complications		
Nasal Congestion	2	4%
Mild Epistaxis	1	2%
Sinus Infection	2	4%
Total Patients with Complications	7	14%

These findings suggest that SBCD is a safe and effective intervention for pediatric CRS patients who remain symptomatic after adenoidectomy, providing substantial symptom relief with a high success rate and minimal complications.

DISCUSSION

Chronic Rhinosinusitis (CRS) in pediatric populations presents a significant clinical challenge, particularly when initial surgical interventions, such as adenoidectomy, fail to alleviate symptoms. In this context, sinus balloon catheter dilation (SBCD) has emerged as a minimally invasive alternative to traditional surgical approaches. This study evaluates the efficacy and safety of SBCD in children with persistent CRS post-adenoidectomy, contributing to the growing body of literature on this therapeutic modality.

The study comprised 50 pediatric patients, aged 4 to 12 years, with a mean age of 8.2 years. A male predominance was observed (70%), and a significant proportion of patients had comorbid conditions, including allergies (40%) and asthma (30%). Preoperative assessments revealed a mean computed tomography (CT) score of 7.6 ± 2.5 and a mean Sinonasal 5 (SN-5) score of 4.8 ± 0.8. These findings align with previous studies, such as Ramadan *et al.*, which reported similar demographic distributions and baseline characteristics in pediatric CRS populations undergoing SBCD.[7]

Post-operative outcomes demonstrated a significant reduction in SN-5 scores, with a mean improvement of 1.8 ± 0.6 at a mean follow-up of 12.5 months. The success rate, defined as a ≥0.5 decrease in SN-5 score, was 85% (42/50 patients). These results are consistent with existing studies reported significant quality-of-life improvements in pediatric patients undergoing SBCD, highlighting its efficacy in managing CRS refractory to medical therapy.[8,9] The safety profile of SBCD in this study was favorable, with a total complication rate of 14%. Intraoperative complications were minimal, including minor mucosal trauma (2%) and self-limiting bleeding (2%). Postoperative complications comprised nasal congestion (4%), mild epistaxis (2%), and sinus infection (4%), all managed conservatively without long-term sequelae. Notably, no major adverse events, such as cerebrospinal fluid leaks or severe bleeding, were reported. These findings are corroborated by previous studies, including a systematic review by Levy *et al.*, which affirmed the safety of SBCD with a low incidence of complications in pediatric patients.[10]

Traditional surgical management of pediatric CRS often involves functional endoscopic sinus surgery (FESS). However, concerns regarding invasiveness and potential complications have prompted the exploration of less invasive alternatives. SBCD offers a tissue-sparing approach with comparable efficacy. The REMODEL randomized controlled trial demonstrated that balloon ostial dilation is non-inferior to FESS in terms of symptom improvement, with the added benefits of reduced recovery time and fewer postoperative complications. Our study's findings align with this previous studies, suggesting that SBCD is a viable alternative to FESS, particularly in patients with persistent symptoms post-adenoidectomy.[11,12]

The integration of SBCD into the treatment algorithm for pediatric CRS offers several advantages. Its minimally invasive nature, coupled with a favorable safety profile, makes it an attractive option for patients unresponsive to medical therapy and adenoidectomy. Moreover, the procedure's efficacy in

symptom reduction enhances the quality of life for pediatric patients, as evidenced by significant improvements in SN-5 scores. Clinicians should consider patient selection criteria carefully, ensuring that candidates for SBCD are appropriately chosen to maximize therapeutic outcomes.

CONCLUSION

Sinus balloon catheter dilation represents a safe and effective intervention for children with chronic rhinosinusitis unresponsive to adenoidectomy and medical therapy. The procedure offers significant symptomatic relief with minimal complications, positioning it as a valuable alternative to more invasive surgical options. As the body of evidence grows, SBCD is poised to become an integral component of the therapeutic arsenal against pediatric CRS.

LIMITATIONS AND FUTURE DIRECTIONS

While this study provides valuable insights, certain limitations must be acknowledged. The sample size is relatively small, and the follow-up period, though averaging over a year, may not capture long-term outcomes and rare complications. Future research should focus on larger, multicenter studies with extended follow-up durations to validate these findings and further elucidate the role of SBCD in the comprehensive management of pediatric CRS.

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