

# Balloon Catheter Sinuplasty and Adenoidectomy in Children With Chronic Rhinosinusitis

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**Objectives:** Adenoidectomy is the first step in the surgical management of children with chronic rhinosinusitis (CRS). Adenoidectomy, however, is only effective in half of these children. Although endoscopic sinus surgery is effective for CRS, there is concern for facial growth retardation and major complications. We propose that balloon catheter sinuplasty (BCS) is a minimally invasive, effective procedure in the treatment of pediatric CRS.

**Methods:** We undertook a nonrandomized, controlled, prospective review of children with failed medical management of CRS who underwent BCS or adenoidectomy. Outcomes were assessed at 1 year of follow-up and were based on SN-5 scores and the need for revision surgery.

**Results:** Forty-nine children who satisfied the inclusion criteria were reviewed. Thirty of the children had BCS. The age range was 4 to 11 years (mean, 7.7 years), and the mean computed tomography score (Lund-Mackay system) was 7.5. Twenty-four of the 30 patients (80%) who underwent BCS showed improvement of their symptoms after 12 months of follow-up, compared with 10 of the 19 patients (52.6%) who underwent adenoidectomy ( $p < 0.05$ ). A multivariate analysis using logistic regression analysis with age, sex, asthma, and computed tomography score as covariables showed that BCS was also more effective than adenoidectomy in older children. None of the other variables showed statistical significance.

**Conclusions:** Balloon catheter sinuplasty offers a procedure that is more effective than adenoidectomy and less invasive than endoscopic sinus surgery in the treatment of pediatric CRS.

**Key Words:** balloon, pediatrics, sinuplasty, sinusitis.

## INTRODUCTION

Chronic rhinosinusitis (CRS) affects approximately 30 million Americans annually.<sup>1</sup> In 1996, the costs of CRS amounted to US \$5.8 billion, of which \$1.8 billion was spent on children less than 12 years of age.<sup>2</sup> The vast majority of children with CRS will improve with medical management, including antibiotics, saline irrigation, nasal steroids, antihistamines, allergy therapy, and asthma control. Some children, however, have persistent symptoms despite maximal medical management, and surgical intervention may be indicated.

Surgery for children with CRS continues to evolve. Adenoidectomy is currently the mainstay of treatment for pediatric CRS, but is effective in only 50% of cases.<sup>3,4</sup> It has even less success in children with asthma or children 6 years old and younger. Also, 25% of children who undergo adenoidectomy may need revision surgery.<sup>4</sup> Endoscopic sinus surgery (ESS) has been shown to be more effective

than adenoidectomy alone,<sup>4-6</sup> although revision may still be required in 12% of children.<sup>4</sup> The complication rate is low, but serious complications can occur, including hemorrhage, meningitis, and orbital complications.<sup>6</sup>

Balloon catheter sinuplasty (BCS) has been shown to be an effective treatment for CRS in adults.<sup>7,8</sup> Results from adult studies demonstrate an excellent safety profile with a major complication rate of 0.0035% per sinus or 0.01% per patient.<sup>9</sup> More recently, it has been shown that BCS can be performed relatively safely and effectively in children.<sup>10</sup> The goal of the current study was to determine whether BCS was more effective than adenoidectomy in the treatment of pediatric CRS and could be offered before ESS.

## MATERIALS AND METHODS

A nonrandomized prospective evaluation was performed of patients referred to the pediatric otolaryn-

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gology service at a tertiary referral hospital setting between February 2006 and May 2008. Institutional Review Board approval was obtained from West Virginia University. All patients were referred to the senior author (H.H.R.) for an opinion regarding surgery because of refractory CRS that had been treated medically for at least 3 to 6 months. Medical treatment included oral and sometimes intravenous antibiotics, nasal steroids, decongestants, systemic steroids, and allergy management. Children had an allergy evaluation, an immunoglobulin deficiency workup, and a sweat chloride test. Certain selected patients in whom ciliary abnormalities were strongly suspected had cilia biopsy performed. Those who had a positive biopsy were excluded from this study. The children ranged in age from 2 to 11 years. Those who met all of the following criteria were included in this study: 1) age between 2 and 12 years; 2) planned surgical intervention (ie, ESS, adenoidectomy, sinus irrigation for obtaining a culture) recommended by the primary investigator and consented to by the patient's legal guardian; and 3) long-standing sinusitis (more than 3 months of symptoms or 6 episodes per year) and 2 failed courses of antibiotics followed by a positive computed tomography (CT) scan. Both male and female patients were eligible. Staging was reported according to the Lund-Mackay system.<sup>11</sup> An SN-5 questionnaire was also filled out by the child's guardian at the time of the preoperative CT scan.<sup>12</sup>

Children were excluded from this analysis if they had extensive previous sinonasal surgery in target ostia, cystic fibrosis, extensive sinonasal osteoneogenesis, sinonasal tumors or obstructive lesions, a history of facial trauma that distorted the sinus anatomy and precluded access to the sinus ostium, or ciliary dysfunction.

After preoperative evaluation, children who needed surgery were offered BCS at the time of adenoidectomy.

Balloon catheter sinuplasty has been described elsewhere.<sup>10</sup> In brief, it was performed in the following manner. All procedures were performed under general anesthesia. The nose was appropriately decongested with pledgets and local anesthetic. The sinus guide catheter was inserted behind the uncinate process by use of a rigid endoscope for visualization, and then the flexible guidewire was passed through the catheter. Confirmation that the guide wire was in the sinus was made with fluoroscopy or transillumination. Once the guidewire was in place, the sinus balloon catheter was passed over the guidewire into the sinus and placed across the ostium. After positioning was confirmed, the balloon

was inflated. After inflation, the balloon dilating system was removed. Sinus wash and culture were then performed as deemed necessary. Nasal packing was used as necessary. Adenoidectomy was performed with suction cautery.

After the procedure, all children were evaluated at 1, 12, 24, and 52 weeks. An SN-5 questionnaire was administered at baseline for all children to assess the status of the preoperative symptoms of each child, and at each follow-up date, the validated questionnaire was administered to assess the degree to which these symptoms had changed since surgery. A nurse or medical doctor administered the questionnaire.

Outcomes were based on 12-month SN-5 scores compared to the preoperative SN-5 score. As originally described by Kay and Rosenfeld,<sup>12</sup> a decrease of 0.5 to 0.9 is a mild change, one of 1.0 to 1.4 is a moderate change, and one of more than 1.5 is a large change. Any child with a decrease in SN-5 score of at least 0.5 was considered a success. Scores with a decrease of less than 0.5 were considered to indicate failure. Any child with a worse score or any child who needed revision surgery was considered to have undergone a surgical failure. Univariate statistical analysis was performed with a  $\chi^2$  analysis and a *t*-test of SN-5 scores. Multivariate analysis was performed with SAS software (Cary, North Carolina).

## RESULTS

Forty-nine children satisfied the inclusion criteria and completed 12 months of follow-up. Thirty children (61%) underwent BCS, and 19 children (39%) underwent adenoidectomy alone. The age range was 2 to 11 years (mean, 6.6 years). The preoperative CT scores ranged from 2 to 20 (mean, 7.3), and the preoperative SN-5 scores ranged from 3.0 to 6.2 (mean, 4.1). All patients had postoperative follow-up for 1 year ( $\pm 2$  months). Patient characteristics are summarized in Table 1. The two groups were very similar except for age; the adenoidectomy-alone group was statistically younger than the balloon group.

TABLE 1. PATIENT CHARACTERISTICS BY SURGERY GROUP (N = 49)

Variable	BCS	Adenoidectomy	<i>p</i>
Number of patients	30 (61%)	19 (39%)	
Male sex	16 (53%)	11 (58%)	0.75
Mean age	7.7 y	4.8 y	0.001
Allergy	11 (38%)	5 (28%)	0.48
Asthma	10 (33%)	9 (47%)	0.33
Mean CT score (Lund-Mackay system)	7.5	6.9	0.68
Mean SN-5 score	4.2	3.8	0.06

BCS — balloon catheter sinuplasty; CT — computed tomography.

TABLE 2. PERCENTAGES OF CHILDREN IN CATEGORIES OF SN-5 SCORE CHANGE

<i>SN-5 Change</i>	<i>BCS</i>	<i>Adenoidectomy</i>
Total success	80	52.6
Marked improvement (at least -1.5)	43.3	36.8
Moderate improvement (-1 to -1.4)	20	10.5
Mild improvement (-0.5 to -0.9)	16.7	5.3
Same (0 to -0.4)	16.7	36.8
Worse (at least +0.1)	3.3	10.5
Total failure	20	47.4

A total of 57 sinuses were targeted for surgery. Fifty-five sinuses (96%) were successfully dilated in 30 children. Of the 55 sinuses dilated, 48 were maxillary sinuses, 2 were frontal sinuses, and 5 were sphenoid sinuses. The 2 sinuses that could not be dilated with the balloon were hypoplastic maxillary sinuses. Seventeen of the 30 children underwent adenoidectomy at the same time as BCS, whereas 9 had previously undergone adenoidectomy. Four children in the BCS group did not have adenoidectomy because it was felt at the time of surgery that insufficient adenoid tissue was present to warrant it.

Twenty-four of the children (80%) who underwent BCS had improvement of their symptoms (0.5 decrease or more in SN-5 score), compared to 10 (52.6%) of those who had adenoidectomy ( $p = 0.04$ ; Table 2). Two of the patients (6%) in the BCS group had BCS failures and subsequently required ESS. One was lost to follow-up, and the second still has symptoms a year after surgery (SN-5 score did not change). Three children (15%) in whom adenoidectomy failed went on to have BCS (Table 3). Four of the 6 patients in whom BCS failed had BCS with adenoidectomy, whereas the other 2 were in the BCS-only group.

The mean change in SN-5 score (from before to after operation) for all 49 children was from 4.1 to 2.9 ( $p < 0.0001$ ). The mean change in SN-5 score in children who underwent BCS was from 4.2 to 3.0 ( $p < 0.0001$ ). For the adenoidectomy group, the preoperative SN-5 score of 3.8 improved to 2.9 after operation ( $p < 0.01$ ).

Multivariate logistic regression analysis was then performed with use of age, gender, CT score, prior

TABLE 3. SN-5 AND CT SCORES OF THREE PATIENTS WHO UNDERWENT FAILED ADENOIDECTIONY AND HAD BCS

<i>Patient</i>	<i>SN-5 Score Before Adenoidectomy</i>	<i>SN-5 Score After Adenoidectomy</i>	<i>CT Score After Adenoidectomy</i>	<i>SN-5 Score After BCS</i>
1	4.4	4.2	7	3.0
2		5.6	12	2.4
3	3.8	4.2	5	1.6

TABLE 4. MULTIVARIATE ANALYSIS OF ALL COVARIABLES WITH SURGERY AS OUTCOME

<i>Variable</i>	<i>p</i>
Surgery	0.038
Age	0.10
CT score	0.70
Prior adenoidectomy	0.18
Asthma	0.92
Allergy	0.19
Gender	0.08

adenoidectomy, asthma, and allergy as covariables. The analysis showed that the effect of surgery was still significant (Table 4). Age was not a confounder, despite the fact that the two groups were statistically different by age. Analysis of subgroups was not performed because of small numbers in each group.

## DISCUSSION

Adenoidectomy has long been advocated as the primary surgical treatment of choice for children with CRS because of its excellent safety profile and its technical ease. Adenoidectomy serves to eradicate a reservoir for bacteria<sup>13</sup> and open the nose to enhance drainage.<sup>14</sup> Past studies have demonstrated that adenoidectomy is effective in only about half of children with CRS.<sup>3,4</sup> The current study also demonstrates a similar rate of success (52.6%). In particular, children with asthma and children less than 7 years old require revision surgery sooner after adenoidectomy.<sup>15</sup>

Children who still have CRS after adenoidectomy often undergo ESS. Endoscopic sinus surgery is effective in 80% to 90% of children with CRS.<sup>6,16</sup> A meta-analysis reported an effectiveness rate of 88%, with an incidence of major complications of 0.6%. In the past, there has been concern that surgical intervention could affect facial growth in children. Although an effect on facial growth was demonstrated in animal models,<sup>17</sup> ESS does not seem to significantly affect pediatric facial growth.<sup>18</sup> Although they are infrequent, potential major complications include orbital hematoma, blindness, epiphora, cerebrospinal fluid leak, and meningitis. Although ESS offers an effective alternative to adenoidectomy, its potential for serious complications limits its widespread use.

Mucosal preservation and restoration of sinus ventilation by opening natural ostia are tenets of ESS. Balloon catheter sinuplasty is a tool in the surgeon's armamentarium to accomplish these goals. Evidence that supports its effectiveness is increasing. A multicenter trial of 1,036 adult patients who underwent BCS demonstrated improvement in 95%

of patients, with only 2.4% requiring revision surgery. There were no major adverse events associated with BCS in this study.<sup>7</sup> For comparison, the incidences of cerebrospinal fluid leak and periorbital injury during ESS among experienced, high-volume surgeons were 0.5% and 2.6%, respectively.<sup>19</sup> A separate study of 65 BCS patients with 2-year follow-up reported symptom improvement in 85% of adult patients, with a revision rate of 9.2%, with no major adverse events.<sup>8</sup> In adults, BCS is a relatively safe and effective treatment for CRS in selected patients.

Balloon catheter sinuplasty may also be relatively safe and effective in the treatment of CRS in the pediatric population. At our institution, we recently investigated the safety and feasibility of BCS in children. We demonstrated successful cannulation and dilation in 51 of 56 sinuses (91%) in 30 children.<sup>10</sup> Four of the 5 sinuses that were unable to be dilated were hypoplastic, and the other was a frontal sinus. In our present study, there were 5 hypoplastic sinuses. Two of the 5 were unable to be dilated. Therefore, BCS may not be feasible for hypoplastic sinuses. In a prospective, multicenter trial, 32 patients were enrolled at 5 sites, of whom 24 completed follow-up. Their symptoms improved from a mean baseline SN-5 score of 4.9 to a 12-month postoperative score of 2.95 ( $p < 0.0001$ ). Eighty-eight percent of the patients had improvement in their symptoms according to their SN-5 scores.<sup>20</sup> No complications or adverse events were reported in that study, as in our current study.

The present study is the first study of BCS in children with CRS to compare this procedure to adenoidectomy alone. Eighty percent of the children who underwent BCS had a significant improvement in their SN-5 score 12 months after operation, compared to 52.6% of children who underwent adenoidectomy. No adverse events or complications occurred in either group. This study showed that BCS was relatively safe, was feasible, and had a better outcome than adenoidectomy alone. The intent of this study was not to compare it to ESS, but to find out whether adding BCS at the time of adenoidectomy improved the outcome.

tomy improved the outcome.

Although there were significant differences in the outcomes between the BCS group and the adenoidectomy group, there are weaknesses and limitations in this study. Even though this study was a prospective trial, children were assigned to the BCS or adenoidectomy arm in a nonrandomized manner. A prospective, randomized trial would eliminate this selection bias. Another weakness is the low number of subjects, but this was intended to be a pilot study. Children rarely need surgical management for CRS; therefore, collecting large numbers is difficult. Although this study has limitations, it does provide useful information regarding the outcomes of BCS and adenoidectomy in pediatric CRS.

Balloon catheter sinuplasty is a relatively new procedure in adults, and only recently has it been used in children. More studies are needed to determine the appropriate indications for using BCS as opposed to adenoidectomy or ESS. For example, BCS is more difficult in hypoplastic sinuses and has a high rate of intraoperative failure to dilate these sinuses. These children may be better candidates for traditional ESS. Our experience is that BCS does not open up Haller cells. If Haller cells are playing a significant role in ostiomeatal obstruction, BCS might not be effective. Further study is also needed to determine the effectiveness of BCS as a revision surgery after adenoidectomy failure. Studying BCS failures will also help us to determine which children will benefit most from BCS. Much more work is required to appropriately assess BCS in children with CRS.

#### CONCLUSIONS

Balloon catheter sinuplasty is a relatively safe and effective treatment for children with CRS that is refractory to maximal medical management. A higher percentage of children were improved at 12 months after operation in the BCS group than in the group that underwent adenoidectomy alone. There were no complications or adverse events in either group in this study. Further work still needs done to determine which children will benefit most from surgical treatment with BCS.

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