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American Head and Neck Society
The American Academy of Facial Plastic and Reconstructive Sur



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PUBLICATION

Original Investigation

Sinus Balloon Catheter Dilation in Pediatric Chronic Rhinosinusitis Resistant to Medical Therapy

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IMPORTANCE Sinus balloon catheter dilation (SBCD) has been used for chronic rhinosinusitis (CRS). It is necessary to evaluate its effect on children with CRS.

OBJECTIVE To evaluate the efficacy of SBCD on pediatric CRS in China.

DESIGN, SETTING, AND PARTICIPANTS A prospective case-control study was conducted from October 1, 2012, to May 31, 2013, in an academic tertiary referral hospital. Participants included a total of 79 patients, aged 7 to 12 years, with CRS resistant to medical therapy.

INTERVENTIONS Medical or SBCD treatment of pediatric CRS.

MAIN OUTCOMES AND MEASURES Age, sex, and results of computed tomographic scan, SBCD (case group) or conservative treatment (control group), sinonasal-5 questionnaire (SN-5), and visual analog scale (VAS) were analyzed and compared.

RESULTS Data from 79 of 96 patients who had complete follow-up documents were statistically analyzed (42 boys; 37 girls; mean [SD] age, 9.3 [1.7] years). Compared with the preoperative scores, the SN-5 and VAS scores in children with CRS who underwent SBCD with or without adenoidectomy were significantly lower at 3 months (2.5 vs 4.3 for SN-5; $P < .001$; 3.1 vs 5.2 for VAS; $P < .001$) and at 1 year (2.9 vs 4.3 for SN-5; $P = .001$; 3.1 vs 5.2 for VAS; $P < .001$). Both SN-5 and VAS scores in the control group were significantly decreased at 3 months (3.1 vs 4.2 for SN-5; $P = .001$; 3.9 vs 5.1 for VAS; $P < .001$) but not significantly changed at 12 months (3.8 vs 4.2 for SN-5; $P = .01$; 4.9 vs 5.1 for VAS; $P = .54$). The SN-5 and VAS scores in the SBCD group were significantly lower than those for controls at 3 months (2.5 vs 3.1 for SN-5; $P = .003$; 3.1 vs 3.9 for VAS; $P = .01$) and at 1 year after surgery (2.9 vs 3.8 for SN-5; $P < .001$; 3.1 vs 4.9 for VAS; $P < .001$). By the 12-month SN-5 score evaluation, the rates of marked, moderate, and mild improvement were significantly better in the SBCD group (52% [22 of 42], 26% [11 of 42], and 14% [6 of 42], respectively) than in the control group (14% [5 of 37], 19% [7 of 37], and 11% [4 of 37], respectively) ($P < .05$ for all comparisons).

CONCLUSIONS AND RELEVANCE The SBCD procedure is a safe and effective technique for pediatric CRS resistant to medical therapy.

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Chronic rhinosinusitis (CRS) in children is very commonly seen in clinic and negatively affects the child's quality of life and learning ability. Multiple factors contribute to the disease, including bacteriologic and inflammatory factors. The adenoids are a prominent contributor to this entity in the pediatric age group. The mainstay of treatment for CRS has been antibiotic therapy coupled with topical or systemic corticosteroid therapy and saline irrigation.¹ Symptoms or outcomes of CRS in children were improved in half of patients or more after adenoidectomy.² Some patients, however, have persistent symptoms despite maximum medical management and adenoidectomy, and further surgical intervention may be indicated.

Sinus balloon catheter dilation (SBCD) of the maxillary, frontal, and sphenoid sinuses to treat CRS was introduced in 2006 and has been shown to be safe and effective in recent multiple-center studies in adults.³ It has also been used for CRS in children⁴ and has increased the effectiveness of surgery from 50% with adenoidectomy alone to 80% when balloon dilation was performed.⁵ Herein, we report a case-control study of Chinese children with CRS who underwent SBCD (case) or conservative therapy (control).

Methods

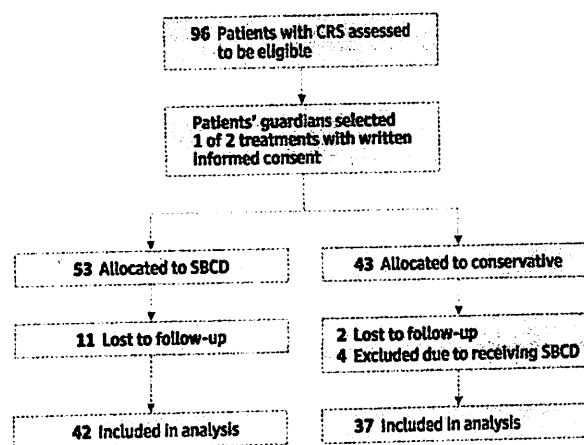
Patients

A total of 96 children with CRS, diagnosed according to the criteria described in the European Position Paper on Rhinosinusitis and Nasal Polyps 2012,⁶ were enrolled in this study from October 1, 2012, through May 31, 2013. The patients' ages ranged from 7 to 12 years. This study was approved by the institutional ethics committee of the Third Xiangya Hospital, Central South University, Changsha, China, and patient written informed consent was obtained from all patients' parents or guardians.

All patients were dissatisfied with previous repeated medical therapy they had undergone for at least 2 years, which included nasal steroid spray, oral and sometimes intravenous antibiotics, decongestants, and saline irrigation, and their symptoms significantly degraded their quality of life (QOL). The guardians of all these patients consulted physicians to learn whether surgical treatment might be beneficial for their children. Computed tomographic (CT) scans were performed, and Lund-Mackay scores were recorded for all patients. The children's guardians also completed a sinonasal-5 questionnaire (SN-5)⁷ and visual analog scale (VAS)⁷ in the clinic to evaluate the child's QOL of the last month. All patients underwent a skin-prick test of allergens, an immunoglobulin deficiency workup, and a sweat chloride test, if indicated. Patients were excluded if they had cystic fibrosis, syndromic diseases, rhinitis and/or asthma, or a history of prenasal surgery.

Ninety-six eligible patients were divided into 2 treatment groups as follows: first, the physicians explained the 2 therapeutic methods in detail to the patients' guardians: SBCD (case group) and conservative treatment (control group) (including oral antibiotics, local nasal steroid spray, and nasal saline ir-

Figure. Flowchart of Patient Recruitment and Allocation to the 2 Study Arms



CRS indicates chronic rhinosinusitis; SBCD, sinus balloon catheter dilation.

rigation). Second, the patient's guardians selected 1 of the 2 treatments. Of the 96 patients, 53 chose SBCD, and 43 chose conservative treatment (Figure). Follow-up ended on May 31, 2014, and at that time a total of 79 patients had been enrolled in the study for longer than 1 year: 42 SBCD patients and 37 control patients. Thirteen patients were lost to follow-up because of changes in telephone numbers and residences. Four control patients were excluded because they underwent SBCD after 6 months of conservative therapy. The patient characteristics are summarized in Table 1. No significant differences were noted in sex, age, or medical history between the 2 groups.

Treatments

SBCD Group

The SBCD procedure was performed as described elsewhere.³⁻⁵ Briefly, all patients were placed under general anesthesia in the supine position on the operating table with the head slightly lowered. The nose was appropriately decongested with epinephrine pledgets. The procedure was conducted using guided imaging through a wide-angle endoscope (0°, 4 mm) and proceeded from maxillary sinus followed by frontal sinus. The uncinate process and ethmoid bulla were first identified, and polyps removed if present on the uncinate process.

The sinus guide catheter was inserted posteriorly and inferiorly within the middle meatus between the uncinate process and ethmoid bulla, and the tip of sinus guide was kept in line with the natural maxillary ostium. The lighted guide wire was then passed through the catheter into the sinus. Transillumination of the lateral and inferior maxilla confirmed that the guide wire was within the maxillary sinus. Once the guide wire was in place, the sinus balloon catheter was passed over the guide wire into the sinus and placed across the ostium. After positioning was confirmed, the balloon was inflated to 10 Pascal for 10 seconds. Inflation was repeated 3 times; dilation of the ostium was verified; and then the sinus was irrigated through the catheter with 100 mL of saline containing 0.1 mg/mL of dexamethasone and 1.6 mg/mL of gentamicin.

Table 1. Characteristics of the Participants by Study Treatment Group^a

Characteristic	Total, No.	Treatment		t Value	P Value
		SBCD (n = 42)	Medication (n = 37)		
Sex					
Boys	42	23	19	0.301	.76
Girls	37	19	18		
Age, mean (SD), y	NA	9.4 (1.9)	9.1 (1.8)	0.625	.53
Adenoid hypertrophy					
Yes	14	8	6	0.471	.64
No	65	34	31		
Polyps					
Yes	9	5	4	0.327	.74
No	70	37	33		
CT score, mean (SD) ^b	NA	13.3 (3.3)	12.8 (3.5)	0.618	.54

Abbreviations: CT, computed tomography; NA, not applicable; SBCD, sinus balloon catheter dilation.

^a Unless otherwise noted, data are number of patients.

^b Lund-Mackay score from CT scan of nasal sinus.

For SBCD of the frontal sinus, the tip of the sinus guide was insinuated between the uncinate process and the face of ethmoid bulla in the para-sagittal plane. Once the lighted wire was confirmed to be inside the frontal sinus, balloon advancement and dilation were performed and repeated more proximally or distally within the frontal sinus outflow tract. Sinus irrigation of the frontal sinus was carried out as with the maxillary sinus.

All SBCD patients were treated with oral antibiotics (amoxicillin-clavulanate, 750 mg, twice a day) for 2 weeks, and a steroid nasal spray (mometasone furoate, 50 µg/nostril) and saline rinse for 3 months after the operation.

Endoscopic adenoidectomy was also carried out through a 70 endoscope via the mouth approach in patients with CRS if the following criteria were satisfied: adenoids occupied more than 1/3 of the posterior choana as visualized by endoscopy; presence of snoring; and repeated episodes of otitis media.

Conservative Treatment Group

The control patients were treated with antibiotics for 2 weeks (amoxicillin-clavulanate, 750 mg, twice a day) and a combination of a steroidal nasal spray (mometasone furoate, 50 µg/nostril) and saline rinse for 3 months.

Follow-up

All the patients were asked to return to the clinic for examination at 3 months, 6 months, and 1 year after undergoing the initial treatment. To improve patient follow-up rates, specialty nurses regularly conducted telephone interviews with all the patients. During each clinical follow-up, in addition to undergoing conventional examination of the nasal cavity, each patient was required to complete the SN-5 and VAS to evaluate his or her QOL of the last month as a result of nose and sinus problems.⁷ The use of antibiotics and steroids was recorded.

The overall effects were measured by comparing the 12-month SN-5 score with the preoperative SN-5 score. As originally described by Kay and Rosenfeld,⁷ a decrease of 0.5 to 1.0 in SN-5 score is a mild improvement; 1.0 to 1.5 is a moderate improvement; and a greater than 1.5 decrease is a marked im-

provement. Any case with SN-5 scores that decreased less than 0.5 were considered treatment failures.⁷ All follow-up data were obtained by a technician who was blinded to study group.

A postoperative CT scan was not performed because this represented added radiation exposure, and previous reports have shown that SN-5 scores correlate with CT scores.⁸

Statistical Analysis

Data were analyzed using the SPSS statistical package, version 13.0 (SPSS Inc). One-way analysis of variance and the Mann-Whitney test were used for comparative analysis of the QOL scores and the overall efficacy of treatments. Statistical significance was set at $P < .05$.

Results

Operative Outcomes

A total of 96 children with CRS were enrolled in this study: 53 patients in SBCD group and 43 patients in the control group. The mean (SD) sinus CT scores were 13.3 (3.3) in SBCD group and 12.8 (3.5) among controls. A total of 104 maxillary sinuses in 53 patients and 69 frontal sinuses in 41 patients were targeted for balloon dilation after evaluation of the sinus CT scans in the SBCD group. Technique success rates for frontal and maxillary sinuses were 99% (68 of 69) and 99% (103 of 104), respectively. One planned bilateral frontal and maxillary sinus dilation could not be completed in the right side because severe septum deviation prevented access to the right side ostia planned for treatment.

Comparison of the SN-5 and VAS Scores

Between the 2 Groups

A total of 79 of 96 patients completed 12 months of follow-up and the SN-5 and VAS questionnaires at each of the visits at 3 months, 6 months, and 1 year (42 boys; 37 girls; mean [SD] age, 9.3 [1.7] years). Table 2 summarizes the dynamic changes of SN-5 and VAS scores in patients in the 2 SBCD and control groups. Compared with the preoperative scores, the SN-5 and VAS scores in children with CRS were significantly lower at 3

to eradicate the reservoir of pathogenic microorganisms in ad-
be effective in more than 50% of children with CRS.¹¹ It serves
Adenoidectomy is a first-line surgical therapy for pediatric
surgical intervention.

A minority of children will have continued symptoms and need
sider conservative medical treatments for pediatric CRS; only
treatment-resistant CRS. Therefore, it is necessary to con-
otics, and nasal saline irrigation in about 44% of children with
medical treatments including steroid nasal spray, oral anti-
study shows that SN-5 score is also improved by a series of
long-term treatment with nasal saline lavage. Treatment of co-
sinusitis.¹⁰ In addition, some patients have a good response to
atrophic CRS.⁶ Antibiotics can be used at the acute stage of chronic
treatment in China, and it has a good curative effect on pedi-
resistance in China. Intranasal corticosteroid is a mainstay of
treatment because of the potential for developing bacterial drug-
biotic therapy has been limited by the China Health Adminis-
and effective.⁹ However, for chronic disease, long-term anti-
ease. Long-term appropriate antibiotic therapy is necessary
(FESS). Medical treatment is usually a first choice for this dis-
adenoidectomy, and functional endoscopic sinus surgery
agement of pediatric CRS, and it includes medication,
A stepwise approach has been conventionally used for man-

Discussion

used for comparison analysis. The results demonstrated that
the efficacy of SBCD with or without adenoidectomy was sig-
nificantly better than that of conservative treatment ($P < .05$
for all comparisons; see Table 3).
In a separate analysis of CRS with adenoid hypertrophy, 8
patients undergoing SBCD with adenoidectomy had an im-
provement rate of 100% (8 of 8) 12 months after the opera-
tion, whereas 6 patients treated with medication had an im-
provement rate of only 33% (2 of 6).
Surgical Complications
One of 53 patients (2%) who underwent SBCD experienced peri-
orbital swelling without hematoma, and it was resolved within
1 week with no special treatment.

The Overall Efficacy of Treatments
The overall treatment efficacy was evaluated by comparing the
12-month SN-5 score with the pretreatment SN-5 score accord-
ing to the criteria established by Kay and Rosenfeld.⁷ The rates
of marked, moderate, and mild improvement were 52% (22 of
42), 26% (11 of 42), and 14% (6 of 42), respectively, in the SBCD
group, and 14% (5 of 37), 19% (7 of 37), and 11% (4 of 37), re-
spectively, in the control group. The Mann-Whitney test was

patients.
ment with medications has a shorter-term efficacy for these
longer-term efficacy for children with CRS; whereas treat-
ing indicates that SBCD with or without adenoidectomy has a
1-year follow-up compared with the 3-month scores. This find-
the control group ($P < .05$ for all comparisons; see Table 2) at
for all comparisons; see Table 2) and significantly increased in
and VAS scores slightly increased in the SBCD group ($P < .05$
Dynamic observation of QOL demonstrated that both SN-5
QOL for children with CRS.

enoidectomy could significantly improve the symptoms and
Table 2). This finding indicated that SBCD with or without ad-
those for the control group ($P < .05$ for all comparisons; see
after surgery in the SBCD group were significantly lower than
The SN-5 and VAS scores at 3 months, 6 months, and 1 year
12 months of follow-up ($P < .05$; see Table 2).
all comparisons; see Table 2), but not significantly changed at
significantly decreased at 3 months and 6 months ($P < .05$ for
Table 2). Both SN-5 and VAS scores in the control group were
without adenoidectomy ($P < .05$ for all comparisons; see
months, 6 months, and 1 year after undergoing SBCD with or

Table 3. The Overall CRS Improvement in Study Participants by SN-5 Score Change After Treatments^a

SN-5 Score	Medication (n = 37)	Z Value	P Value ^b	SBCD		
				(n = 42)	(n = 37)	(n = 37)
Marked	22 (52.4)	5 (13.5)		11 (26.2)	7 (18.9)	4 (10.8)
Moderate	11 (26.2)	7 (18.9)	4.049	6 (14.3)	4 (10.8)	3 (7.1)
Mild	6 (14.3)	4 (10.8)		3 (7.1)	2 (5.6)	2 (5.6)
Failure	3 (7.1)	2 (5.6)				

Abbreviations: CRS, chronic rhinosinusitis; SBCD, sinus balloon catheter
dilation; SN-5, sinonasal-5 questionnaire.
^a Unless otherwise noted, data are number (percentage) of patients.
^b P value is for comparison between SBCD and medication groups and
represents all improvement (marked, moderate, and mild) taken together.

Table 2. Dynamic Changes of SN-5 and VAS Scores in Children With CRS Treated With SBCD or Medication^a

SN-5 Score	Medication (n = 42)	t Value	P Value	VAS Score		
	(n = 37)	(n = 42)	(n = 37)	t Value	P Value	P Value
Baseline	4.3 (0.9)	4.2 (1.0)	0.324	5.2 (1.4)	5.1 (1.6)	0.164
Follow-up, mo						
3	2.5 (0.7) ^b	3.1 (0.9) ^b	3.088	3.1 (1.3) ^b	3.9 (1.4) ^b	2.636
6	2.7 (0.9) ^b	3.3 (1.0) ^b	2.813	3.2 (1.5) ^b	4.3 (1.2) ^b	3.755
12	2.9 (0.8) ^b	3.8 (1.1) ^c	3.506	3.1 (1.6) ^b	4.9 (1.5) ^c	5.235

Abbreviations: CRS, chronic rhinosinusitis; SBCD, sinus balloon catheter
dilation; SN-5, sinonasal-5 questionnaire; VAS, visual analog scale.
^a Unless otherwise indicated, data are mean (SD) scores.
^b $P < .05$, different time points compared with baseline.
^c $P < .05$, scores in 1 compared with 3 mo.

enoids and reduces the bacteria in the middle meatus: a high correlation has been shown between the bacteria present within the adenoids and the middle meatus in children with CRS.¹² However, minorities of children who have persistent CRS after adenoidectomy are often treated with FESS. Balloon catheter dilation has been reported to be effective in some refractory cases of chronic sinusitis and has a similar success rate to that of FESS.^{4,5} A multicenter randomized study comparing balloon dilation with FESS showed similar symptom relief between groups in patients with adult CRS and disease limited to the maxillary and anterior ethmoid sinuses.¹³ In the present study, our data demonstrate that both SN-5 and VAS scores are significantly decreased in patients with treatment-resistant pediatric CRS 12 months after SBCD, and symptoms are significantly improved. It indicates that SBCD is an appropriate therapy for CRS in children.

Sinus balloon catheter dilation has been shown to be safe and effective in children.⁴ Ramadan et al¹⁴ found the improvement rate of symptoms to be 81% to 92% in pediatric CRS, and the SN-5 improvement rates to be 50% marked, 29% moderate, and 8% mild. In the present study, the overall efficacy of SBCD shows that the rates of marked, moderate, and mild improvement are 52%, 26%, and 14%, respectively, and significantly better than controls. We found outcomes similar to those previously reported.

Balloon dilation alone is considered to be ineffective for children with a hypoplastic sinus or older children with significant ethmoid disease.¹⁵ However, it is effective for maxillary atelectasis¹⁶ and was performed in the ethmoidal air cell area by Kutluhan et al.¹⁷ Our results show that balloon dilation of the frontal and maxillary sinuses, combined with medical therapy, is effective for children with pan-rhinosinusitis associated with mucosal thickening in the frontal, ethmoid, maxillary, and sphenoid sinuses seen on preoperative CT scan. Dilation of the drainage pathway around the ostiomeatal complex is beneficial to control the inflammation of pan-sinusitis by a series of intraoperative and postoperative medical therapy regimens. Therefore, we suggest that balloon dilation of the

frontal and maxillary sinuses is sufficient treatment for pediatric CRS, even though the ethmoid and sphenoid sinuses might also be invaded by inflammation.

There are data showing that irrigation added to adenoidectomy increases the success rate from 60% with adenoidectomy alone to 88% when maxillary sinus wash is added in children with CRS that previously failed to respond to medical therapy.¹⁸ Our data demonstrate that the overall improvement rate (marked, moderate, and mild) as measured by the SN-5 is 93% in children with CRS resistant to medical management after SBCD with sinus irrigation of dexamethasone and gentamicin. Therefore, irrigation alone, and not necessarily balloon dilation, might account for the positive results reported herein. Furthermore, an anti-inflammatory agent was used for irrigation in our patients, which might have enhanced the effect. The role of the SBCD procedure may be only to provide a good channel for sinus irrigation and improve sinus drainage.

The SBCD is quite safe for treating CRS, and complications are very rare. Sillers and Melroy¹⁹ recently reviewed complications of SBCD from 7 clinical studies and found only 3 adverse events reported. In the present study, only 1 patient experienced periorbital swelling, and that resolved without any sequelae within 7 days after the procedure. Our findings indicate that SBCD is a safe procedure for children with CRS.

The limitation of this study is that we did not carry out the randomization as initially designed because it was quite difficult to obtain informed consent from patients' guardians for such a randomization. However, the technician responsible for obtaining the follow-up data was blinded to study group.

Conclusions

Our findings indicate that SBCD is a safe and effective method for treating pediatric CRS proven resistant to medical treatments. Dilation of the maxillary ostium and nasal frontal duct is sufficient to treat pan-rhinosinusitis in children.

ARTICLE INFORMATION

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Study concept and design: Tan.

Acquisition, analysis, or interpretation of data: Wang, Song, Zhang, Tan.

Drafting of the manuscript: Wang, Song, Tan.
Critical revision of the manuscript for important intellectual content: Zhang, Tan.

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CORRECTION

Error in Byline: In the Case Report titled "Progressive Left Periorbital Swelling," published online March 12, 2015 (doi:10.1001/jamaoto.2015.0205), the byline should have read "Kaete A. Archer, MD; Ryan Winters, MD; and Sherard A. Tatum, MD." (Dr Archer's middle initial was added.) The article has been corrected online.