WHITE PAPER

PATIENT SELECTION AND MANAGEMENT OF IN-OFFICE BALLOON SINUS DILATION UNDER LOCAL ANESTHESIA IN ADOLESCENT PATIENTS

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INTRODUCTION

In-office balloon sinus dilation has become a recognized method for treating adults with chronic rhinosinusitis, but few published studies exist on the use of balloon sinus dilation in children, especially adolescent patients. The few studies demonstrating the safety and effectiveness of balloon dilation in children have focused on children less than 12 years old.[1-4]

Recently, Soler et al. published the results of a multicenter balloon sinus dilation study in 50 pediatric patients (2 to 21 years old).[5] Seventeen of these patients were in the age range of 12 to 21 years; eight of whom were treated in the office under local anesthesia by the lead author (JSR). Here, we focus on our experience selecting and managing these eight adolescent patients.

KEY POINTS

- In-office balloon sinus dilation under local anesthesia is well tolerated in adolescent patients.
- Appropriate patient selection for in-office procedures is critical.
- Good communication and setting expectations with patients and their parents helps to reduce anxiety.
- Most adolescent patients can return to their usual daily activities within one day after standalone balloon dilation, which may lead to patient preference for these procedures.
- At this time, if concomitant procedures are needed, the patient may be more appropriate for procedures in the surgical center.

METHODS

Ethical Considerations

Western Institutional Review Board (WIRB) reviewed and approved the study. Informed consent and assent was obtained from all patients/parents. The study was conducted in accordance with national and local regulations and Good Clinical Practices (GCP).

Study Design

The study design, methods, and patients have previously been described in detail.[5] Briefly, a prospective, multicenter, single-arm study was conducted at four centers in the US from October 2014 to June 2015. Medically refractory patients with chronic rhinosinusitis were treated with the XprESS™ Multi-Sinus Dilation System (Entellus Medical, Inc., Plymouth, MN, USA). The site of service (in-office or ambulatory surgical center [ASC]) and type of anesthesia used (local or general) were at the discretion of the surgeon and patient/parent. Concomitant procedures, such as adenoidectomies and turbinate reductions, were permitted when deemed necessary by the treating surgeon.

Selection Process for In-office Procedures

Selecting children and young adults for in-office balloon sinus dilation is based on the individual candidate. My experience is that children over the age of 12 are the best candidates, though age alone is not the only factor.

When I discuss balloon sinus dilation with a family, I first discuss and document information about the adolescent regarding their activities and hobbies that may impact their desire for a quick recovery. I educate the parents and adolescent about local versus general anesthesia and answer questions that they might have regarding which anesthetic is best for them. I clearly describe the entire in-office balloon sinus dilation procedure, risks of the procedure, and postoperative care and recovery with the adolescent and their parents. I reassure them that adolescents tolerate balloon dilation procedures very well in the office.

During the evaluation visit, I decongest and anesthetize the child's nose to let them experience the sensation of the numbing effect, a key and time-consuming portion of the procedure. I anesthetize the nose using a 50/50 mixture of 4% topical lidocaine and 1% oxymetazoline on nasal pledgets. I specifically describe what they may feel from the local anesthesia such as numbness in their throat with possible sensations of difficulty

swallowing or breathing. I offer assurance that, despite these sensations, they are able to breathe and swallow normally. Describing the sensation ahead of time and preventing any surprise sensation is important to anticipate. The patient's reaction to the local anesthetic is an important indication whether they are a good candidate for an in-office procedure.

In addition to discussing the risks of balloon sinus dilation in the office under local anesthesia, I also discuss and compare the risks of the procedure in the ASC under general anesthesia. General anesthesia side effects are typically mild but can include postoperative nausea and longer duration of postoperative bleeding. Recovery also takes longer after general anesthesia.

In summary, I review the procedure options and risks, decongest and anesthetize the patient's nose, and answer questions and concerns of the parent and child, before they decide what procedure setting is best for them. The patient will know after the evaluation if they are comfortable consenting for the in-office balloon sinus dilation. I send postoperative instructions home with them after the evaluation visit.

In-office Procedure

On the day of the procedure, the adolescent is encouraged to bring music of their choice or any activity, such as knitting, video games, or puzzles, that enhances their ability to feel comfortable, entertained, and relaxed during the procedure. Premedication with oral antianxiety or pain medication is not prescribed or recommended. The adolescent should be accompanied by their parent(s). Additional support persons, such as a sibling or friend, may also attend.

Upon the patient's arrival to the clinic, I start by decongesting the patient's nose with Afrin (oxymetazoline hydrochloride 0.05%) spray. I leave the room with the patient listening to their music or visiting with family members to give the medication time to take effect. After five minutes, I spray a 50/50 mixture of Afrin and 4% topical lidocaine and stay in the room to talk with the patient and family to let them know what to expect. I review the CT scan in the room and explain the procedure using the films. I place 2 pledgets, soaked in the 50/50 mixture of Afrin and 4% topical lidocaine, in the nose and then leave the room for several minutes for the medication to take effect.

When I return, I use a 30° pediatric endoscope to evaluate the nasal cavity. If the decongestion is adequate, I place 0.25% topical tetracaine gel on the middle turbinate and uncinate area. This gel provides additional anesthesia. I reapply or replace the 50/50 mixture of Afrin and topical lidocaine pledgets in the nose and wait another 5 minutes for the medication to take effect. Again, communication is key and asking the family if they have any questions at this point will go a long way to improve the success of the procedure. If the patient and family appear comfortable and relaxed, I leave the room.

Approximately 5 minutes later, I return to remove the pledgets and inject 1% lidocaine with 1:200,000 epinephrine at the insertion of the middle turbinate and uncinate area, typically using a volume of less than 0.5 mL on each side. It is important to let the patient know that the "medicine" may drip down the back of their throat and not only taste bad but further numb the back of their throat. It is important to reassure them that they can still swallow even if they sense that they can't. Avoiding any concern or surprise will lead to trust and a successful procedure. Again, I leave the room for a few minutes to give the anesthetic time to take effect. At this point, the patient should be comfortable, relaxed, and trusting and the procedure should be well tolerated.

During the procedure, I maintain constant communication with the patient as well as the parent(s). I use the video monitor showing the endoscopic procedure to explain what I am doing surgically. The use of the video monitor reassures the parents and helps them feel more comfortable since they are visually participating in the procedure. It is important to tell the patient what to expect before doing anything. For example, I inform the patient about feelings, sensations, noises, and tastes they may have at each step of the procedure. The parents and patients appreciate the explanations and it creates a more relaxed atmosphere.

Postoperative Care

Postoperatively, I explain what the patient should anticipate regarding bleeding and recovery. A small amount of bleeding for a day or two after the procedure is normal as well as a headache that evening. Over-the-counter medication such as acetaminophen can be used for pain, and hypertonic nasal irrigations should be done morning and evening. In general, I let them know they can resume their full activities the following day without restrictions.

RESULTS

Study Population

Eight of the adolescents enrolled in the study were treated in the office setting under local anesthesia only. Table 1 shows the baseline characteristics, procedural characteristics, and outcomes for these eight patients. All eight underwent standalone balloon dilation (no concomitant procedures).

Table 1

Baseline and Procedure Characteristics and Outcomes of 8 Adolescent Patients Treated with In-office Balloon Dilation

STUDY ID	AGE	SEX	RACE	SINUSES TREATED	PREVIOUS SURGICAL PROCEDURES	SEPTAL DEVIATION GRADE †	POLYPOSIS	PAIN SCORE‡	SNOT-22 CHANGE FROM BASELINE§	RECOVERY TIME (DAYS)¶
1	16	F	Caucasian	2 Max, 2 Fr	None	1+	None	2	-18	0.2
2	16	F	Caucasian	2 Max, 2 Fr	Septoplasty, bone spur	None	None	1	-24	1.5
3	20	F	Caucasian	2 Max, 2 Fr	Tonsillectomy, adenoidectomy, ear tubes	2+	None	2	-21	2.0
4	15	M	Caucasian/ Hispanic	2 Max, 1 Sph	None	3+	None	0	-19	1.0
5	21	M	Caucasian	2 Max, 2 Fr	None	2+	None	1	-24	2.0
6	14	M	Caucasian	2 Max, 2 Fr	None	None	None	4	-20	0.4
7	14	M	Caucasian	2 Max	None	1+	None	1	-44	1.0
8	15	M	Caucasian	2 Max, 2 Fr	Adenoidectomy	None	None	1	4	0.3

ABBREVIATIONS: Max = maxillary sinus; Fr = frontal sinus; Sph = sphenoid sinus.

† Septal deviations were graded on the degree of air flow obstruction as follows: 1+ = 25% or less, 2+ = 26% to 50%, 3+ = 51% to 75%, 4+ = greater than 75%.

‡ Pain scores are based on a FACE score that ranges from 0 (no hurt) to 5 (hurts worst).

§ A change of ≥8.9 in the overall SNOT-22 score is considered the minimal clinically meaningful difference.

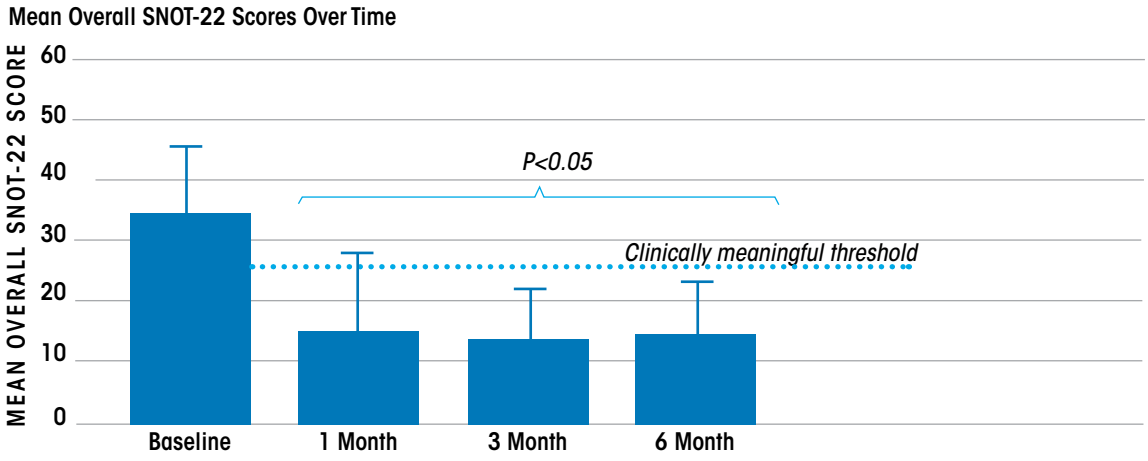
¶ Recovery time is defined as the time needed to return to normal daily activities.

Outcomes

A total of 29 sinuses were successfully dilated in the office setting under local anesthesia. Although five of the eight adolescents had mild to moderate septal deviations, these did not require treatment and did not compromise the ability to access the sinuses with the XprESS device. The mean procedural pain score was 1.5 (on a scale of 0 to 5) and the mean (SD) recovery time was 1.0 (0.7) day. In contrast, the mean (SD) recovery time for adolescent patients undergoing balloon dilation with concomitant procedures in the ASC under general anesthesia (n = 8) was 5.0 (3.9) days.

The disease-specific quality of life, as measured by the mean overall SNOT-22 score (see Fig. 1), was significantly improved from baseline in the in-office balloon dilation patients (35.0 at baseline vs. 14.3 at 6 months, change –20.8; $p < 0.01$). Seven of the eight patients had a change from baseline of more than 8.9 (the minimal clinically meaningful difference[6]) in the overall SNOT-22 score at 6 months follow-up.

Figure 1



Each of the 22 items are scored 0 (no problem) to 5 (problem as bad as can be). The 22 item scores are summed to provide the overall SNOT-22 score that can range from 0 to 110. The minimum clinically meaningful difference is a change from baseline of –8.9.[6] The change from baseline was statistically significant (p<0.05) at 1, 3, and 6 months post procedure. Error bars indicate the standard deviation of the mean at each follow-up period.

DISCUSSION

Synopsis of Key/New Findings

This paper reports patient selection and management of balloon sinus dilation in eight adolescent patients treated in the office under local anesthesia. To our knowledge this is the first study reporting on balloon dilation in adolescent patients as well as the first study reporting on patient selection for adolescent patients treated under local anesthesia in the office setting. We found that the procedures were well tolerated in this age group with clinically and statistically significant symptom improvement through 6 months. Standalone balloon dilation in the office results in more rapid recovery time, which may be an important factor for some adolescent patients.

Concomitant sinonasal procedures are common in pediatric studies, especially adenoidectomies.[1-5] Although our study allowed concomitant procedures, this group of eight adolescents did not undergo concomitant procedures. This study provides a glimpse of the efficacy and tolerability of standalone, in-office balloon dilation in this age group.

Clinical Applicability of the Study

Selecting adolescents for in-office balloon sinus dilation is based on the individual candidate. The selection process requires time and excellent communication on the part of the physician to adequately evaluate the patient, but the effort can result in a rewarding experience for patients and their families. Many adolescents have busy lives with rigorous academic schedules, competitive sports, and/or extracurricular activities and want to return to their activities as soon as possible. Four of the eight adolescents, three boys and one girl, were active in sports (baseball, football, golf) and camping. They all returned to their athletic activities within 2–3 days. The girl played a three-day golf tournament successfully. All reported they felt better postoperatively and thought the procedure improved their performance.

Additionally, parents often want to avoid general anesthesia for their child for safety concerns. In this study, avoiding anesthesia and offering a quick recovery was the deciding factor for every family selecting the in-office procedure. Balloon sinus dilation in the office often meets both the patient's

and parent's needs. In-office balloon sinus dilation is a procedure that offers considerable benefits to adolescents with chronic rhinosinusitis who do not require additional concomitant procedures.

The key to successful in-office balloon dilation in adolescents is careful patient selection, good communication, and creating a comfortable setting.

CONCLUSION

Balloon sinus dilation is a safe and effective treatment for adolescents with medically refractory chronic rhinosinusitis. With proper patient selection, in-office balloon sinus dilation under local anesthesia is well tolerated in this age group. Recovery times are rapid with most patients back to normal activities within one day.

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