



# The Value of Multiple Medication Trials Prior to Balloon Sinuplasty in the Management of Chronic Sinonasal Disease

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## Abstract

**Introduction** In patients with chronic rhinosinusitis, conservative interventions with extended medical trials are often attempted prior to procedural treatment. Balloon sinuplasty (BSP) is an established procedure for symptomatic relief from chronic rhinosinusitis. However, data suggesting the suboptimal efficacy of prolonged medication management trials, prior to BSP, is lacking.

**Objectives** The purpose of this study was to evaluate the efficacy of prolonged medication management trials, prior to BSP, for patients with chronic rhinosinusitis.

**Methods** A retrospective review was performed for all adults with chronic rhinosinusitis who received extended medical management prior to their BSP at two outpatient clinics, from November 1, 2013, to June 31, 2018. The patients' Sino-Nasal Outcome Test (SNOT) scores were compared between baseline, post-medication trials, and post-BSP.

**Results** The SNOT scores of a total of 64 patients were collected. Overall, patients showed a significant worsening of symptoms during the medication management trials from baseline ( $p = 0.002126$ ) but significant improvement of symptoms after undergoing BSP ( $p < 0.0001$ ).

**Conclusion** The patient symptom burden worsened and prolonged during medication management trials. The BSP procedure alone showed significant improvement in the quality of life for chronic rhinosinusitis patients, when considering their SNOT scores. The worsening of patients' symptoms during medication management may invalidate the necessity of prolonged medication management trials.

## Keywords

- ▶ rhinology
- ▶ allergy
- ▶ chronic rhinosinusitis
- ▶ upper airway inflammation
- ▶ otolaryngology
- ▶ sinus surgery

## Introduction

Chronic rhinosinusitis is defined as the inflammation of the paranasal sinus and nasal mucosa lasting longer than

12 weeks. Individuals with chronic rhinosinusitis experience symptoms such as nasal obstruction, facial tenderness, mucopurulent nasal drainage, decreased sense of smell, and headaches.<sup>1</sup> The diagnosis is usually confirmed via CT

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or nasal endoscopy demonstrating evidence of mucosal inflammation, edema, or multiple air fluid levels. There are currently two treatment paradigms for patients with chronic rhinosinusitis: long-term medication management, and a surgical approach.

Balloon sinuplasty (BSP) has been accepted in the literature as an effective intervention for chronic rhinosinusitis.<sup>2</sup> The BSP procedure can be performed in the operating room or in-office. A lighted guidewire balloon is atraumatically cannulated through the natural sinus ostium. After guidewire placement is confirmed, a high pressure, low volume balloon catheter is advanced and inflated to expand the natural opening. The balloon device is designed to microfracture and modify the sinus ostium, which effectively increases its diameter and restores patency without precipitating secondary trauma to the sinuses.<sup>3,4</sup>

An estimated 31 million Americans suffer from chronic rhinosinusitis.<sup>5</sup> The socioeconomic burden of the disease is high and leads to 18 to 22 million office visits annually.<sup>6</sup> Physician office visits and prescription expenditures for chronic rhinosinusitis add up to nearly \$8.6 billion in health care costs annually.<sup>7,8</sup> In addition to the substantial socioeconomic burden, individuals with chronic rhinosinusitis report increased absences from work and decreased work productivity.<sup>9</sup>

Many patients with chronic rhinosinusitis are required to go through extensive unsuccessful medical management of their symptoms before receiving insurance authorization for BSP. The pre-authorization period for BSP often requires multiple ongoing specialist clinic visits that consume the resources of both patients and providers. Over the long-term, sinus surgery has been suggested to be more cost-effective than long-term medication management.<sup>10</sup> Perhaps, the economic burden created by chronic rhinosinusitis may be blunted by earlier coverage of BSP, which has the added advantage of being minimally invasive and office based. Studies have previously supported the ineffectiveness of medical treatment in patients with chronic rhinosinusitis and validated the effectiveness of BSP. The purpose of this study is to evaluate the efficacy of prolonged medical management, prior to BSP, for patients with chronic rhinosinusitis.

## Materials and Methods

A retrospective chart analysis was performed on all patients with chronic rhinosinusitis who underwent medical management prior to surgical intervention with BSP at two outpatient clinics from November 1, 2013, to June 31, 2018. All patients signed a consent form to research participation prior to demographic and clinical data collection. Individuals who met the following criteria were excluded from the analysis: (1) loss of follow-up; (2) did not pursue medical management; (3) did not elect to undergo BSP. The average patient was male, 54-years-old, identified as non-Hispanic Caucasian, and never smoked.

Prior to the start of medical management, the Sino-Nasal Outcome Test-22 (SNOT-22) was utilized throughout the course of treatment, to determine the effectiveness of BSP and assess the quality of life in patients suffering from chronic rhinosinusitis. The SNOT-22 questionnaire consisted of 22 questions and allowed patients to rate their symptoms from 0 to 5, with higher scores correlating to more severe symptoms and a worse quality of life.<sup>11</sup> Each patient completed the SNOT-22 evaluation surveys alone, without a physician or staff member present, to reduce risk of bias. The SNOT-22 scores collected per patient include one before medication management, one post-medication management, one just prior to the operation, and one after the BSP operation.

Medical management consisted of saline nasal rinses, antihistamines, corticosteroids, and antibiotics. All of the patients included had at least one follow-up appointment to assess their progress on medication management. New SNOT-22 scores were collected at these follow-up appointments. Several patients had subsequent follow-up visits during medical management, where additional SNOT-22 scores were recorded. All patients included had at least one BSP follow-up appointment, where a post-BSP SNOT-22 score was collected. Additional SNOT-22 scores were collected from patients who had more than one BSP follow-up appointment.

## Statistical Analysis

The standard *t*-test was used to compare SNOT-22 scores at different points in the chronic rhinosinusitis treatment course. *P*-values less than 0.05 were considered statistically significant.

## Funding

No external funding was used for this study.

## Results

A total of 64 patients met the inclusion criteria from November 1, 2013, to June 31, 2018, and were included in the analysis. The *t*-test comparing pre-medication management and post-medication management SNOT-22 scores revealed a significant worsening in scores ( $p < 0.0021$ ). This represents the worsening in symptom burden for patients while continuing medication management; thus, medication management for chronic rhinosinusitis can aggravate and prolong the patient's suffering.

The second *t*-test compared the post-medication management SNOT-22 score (or pre-BSP SNOT-22 score) to the initial SNOT-22 score collected after the procedure was performed (1<sup>st</sup> post-BSP SNOT-22 score). There was a significant improvement in scores after the procedure ( $p < 0.0001$ ). The same *t*-test was performed again but this time comparing post-medication management to the second SNOT-22 score collected post-BSP (2<sup>nd</sup> post-BSP SNOT-22 score). The SNOT-22 score remained significantly improved after the procedure compared with before ( $p < 0.0001$ ). The *t*-tests comparing post-medication management to post-BSP emphasize the

superiority of BSP over medication management for chronic rhinosinusitis symptom burden reduction. A final *t*-test was performed to further underscore the effectiveness of BSP. The pre-medication management SNOT-22 scores were compared with post-BSP scores, showing a significant improvement in symptoms once BSP was performed ( $p < 0.0001$ ). (— Fig. 1)

## Discussion

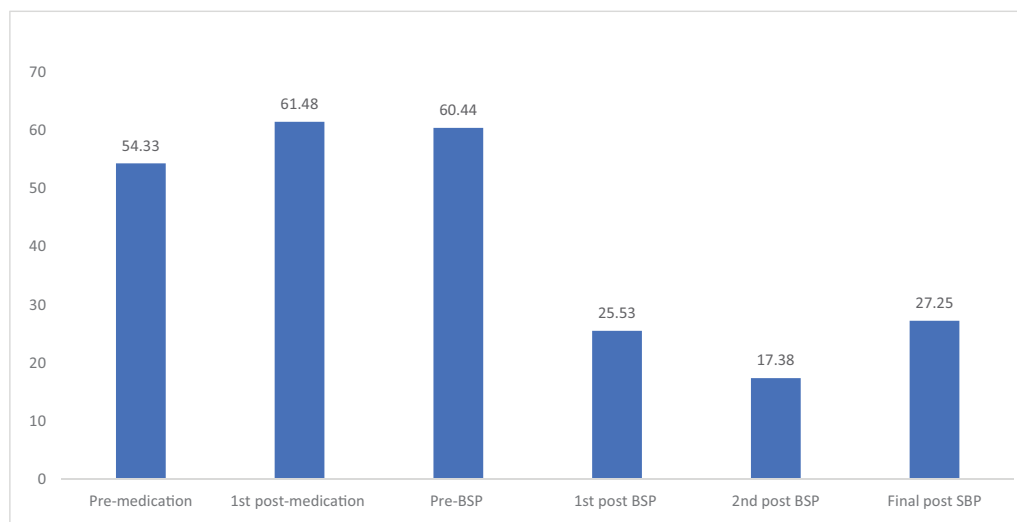
This study sought to investigate the value and medical necessity of requiring patients to undergo extensive medication management prior to BSP. Primarily, the defining goal and results of our study potentially devalue the need for insurance-mandated, prolonged medical management. A comparison of patients' reported SNOT-22 scores demonstrated no improvement in patient symptoms with medication management during the pre-authorization phase. However, a dramatic improvement in our patients' SNOT-22 score was observed after BSP. Therefore, the step of multiple medication treatments before the procedure may be unnecessary. The results of this study suggest that exhaustive medication trials before BSP in certain patients are economically wasteful and only prolong patient suffering. The significant results should perhaps motivate health insurance companies to revoke the requirement of multiple medical trials for patients pursuing BSP before surgery authorization. Additionally, this study further validates the effectiveness of BSP, as has been done in previous studies such as Smith et al,<sup>10</sup> and Payne et al.<sup>12</sup>

The primary measured quantitative aspect of this study was the collection of patients' -reported SNOT-22 scores. The purpose of filling out the questionnaire is for the patient to assess their symptom burden, or quality of life impairment, in terms of their suffering with chronic rhinosinusitis. All 22 questions are possible symptoms and consequences of chronic rhinosinusitis, ranging from the need to blow one's nose, difficulty smelling and tasting, to psychological components

such as shame and sadness. All of the questionnaire points can be answered based on a given rank scale from 0 to 5, with 5 being the most severe indicator of patient symptom burden.

Limitations of the study include the subjective nature of the SNOT-22 scores, varying patient timelines, and varying medications used or prescribed for patients. Not every patient received the same medication management, thus treatment options for each patient were tailored to best address their specific needs during the pre-authorization period. Some patients received antibiotics, if they were having an acute infection along with their chronic symptoms, while some also used additional antihistamines, and medicated or saline nasal sprays. Regardless of the medications used and their duration of use, the SNOT-22 scores reported after medication management did not result in a reduction of symptom burden. Indeed, prolonging the time before BSP procedure resulted in the worsening of symptom burden, according to increasing SNOT-22 scores.

In terms of SNOT-22 scoring, each patient has their unique symptom threshold. A consequence of chronic rhinosinusitis to one patient may seem relatively manageable, but extremely burdensome to another patient. Quality of life with or without a chronic illness is challenging to define, as each component can be perceived differently across populations. Regardless of the SNOT-22 score breakdown of the 64 included patients, there were significant decreases in scores once BSP was performed. This means that irrespective of an individual's threshold for symptom burden, their symptom burden will decline with BSP. There was no strict timeline required for the patients included, so there are variations in terms of length of time between the recording of SNOT-22 scores and the duration of medication management. Due to SNOT-22 scores being subjective, each patient is followed and managed according to their concerns and the state of their chronic rhinosinusitis, but there are common trends in improvement once BSP is performed. Although the degree of improvement may vary from patient to patient,



**Fig. 1** Average SNOT scores.

we noted a statistically significant improvement once BSP was performed, versus a statistically worsening of symptoms during the medication management period.

The results of the study can also support better allocation of resources within the management of chronic rhinosinusitis, as medication management is often wasteful in many regards. The implications of medication management include, but are not limited to, a lack of effectiveness, economic burden, and a strain on patients and physicians' time. With fewer appointments for medication management, providers can allocate more time and resources for counseling patients on BSP and performing the procedure. Sharing the results of this study with patients may also help them make a better-informed decision about how they wish to manage their chronic rhinosinusitis. These results serve to provide both physicians and patients with a greater understanding of the implications of long-term medication management for chronic rhinosinusitis.

## Conclusion

Chronic rhinosinusitis is a debilitating disease affecting more than 100 million people worldwide. The current treatment paradigm for the management of chronic rhinosinusitis includes medical management for symptomatic relief and surgical intervention. As a minimally invasive endoscopic technique, BSP is clinically proven to be an effective solution to decreasing disease burden in patients suffering from chronic rhinosinusitis. Since approval by the Food and Drug Administration (FDA) in 2005, BSP has gained increasing popularity among patients with chronic rhinosinusitis refractory to medical management. Our study sought to investigate the efficacy of BSP in patients with chronic rhinosinusitis who had received prolonged medical management. Using self-reported SNOT-22 scores, our study was able to demonstrate that patients assigned to receive BSP reported improved quality of life after the procedure. We found the patient symptom burden to be exacerbated by lengthy medication management trials, which may invalidate the necessity of such trials prior to the BSP procedure.

## Conflict of Interests

The authors have no conflict of interests to declare.

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