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Balloon sinus dilation

Summary of clinical evidence for balloon sinus dilation **for the treatment of chronic rhinosinusitis**

April 2017

Clinical evidence supporting balloon sinus dilation in **patients with chronic rhinosinusitis**

Disease clinical and economic burden

Chronic rhinosinusitis (CRS) is one of the most common diseases in the United States, estimated to affect approximately 30 million adults.[1] In 2000, approximately 1.2 million annual visits to hospital outpatient departments, emergency rooms, and walk-in clinics were attributed to CRS.[2] It is characterized by prolonged or recurrent symptoms of nasal blockage, obstruction, congestion, and/or nasal discharge. CRS has a significant negative impact on quality of life and it ranks as one of the 10 costliest physical health conditions.[3] A recent systematic review estimated overall CRS costs to be as high as $9.9 billion annually in the United States with the costs of medications alone averaging from $1,537 to $2,700 per patient per year.[4]

A 2012 investigation into the cost burden of recurrent acute rhinosinusitis (RARS) concluded that the total direct health care costs related to this form of CRS averaged $1,091 per patient per year, with oral antibiotic and nasal prescription costs averaging $210 and $452 per year, respectively.[5]

According to the National Health Interview Survey (NHIS), approximately 12.5 million lost workdays and 58.7 million restricted activity days were attributed to CRS between 1990 and 1992.[6] For an affected individual, in 2003, it was estimated that CRS accounted for 4.8 to 5.7 days of missed work per year compared with 3.74 days of missed work per year for individuals who were not affected by CRS.[7]

From a systematic review, Smith et al. estimated the overall economic burden (direct and indirect costs) of CRS at $22 billion in 2014-adjusted U.S. dollars.[4] Productivity costs have been estimated to be over $10,000 annually per patient with refractory CRS and a direct correlation was found between increased costs and worse sinus-related quality of life.[8] Two recent cost-effectiveness studies determined that there is 74% to 85% certainty that surgical therapy is more cost effective than medical management with incremental cost effective ratios of $5,901.90 to $13,851.26 per quality of adjusted life year at a willingness to pay threshold of $25,000.[9,10] Acclarent developed a budget impact model using 2012 payment data that showed favorability towards in-office balloon dilation over FESS within a 2-year time-frame.[11]

Medical management is the first-line therapy; however, if medical management fails and symptoms persist, functional endoscopic sinus surgery (FESS) is commonly performed. In 2005, sinus ostial balloon dilation was added as a treatment option to open sinus outflow tracts. Sinus balloon dilation is sometimes performed adjunctively with FESS as a hybrid procedure but it can also be performed as a standalone procedure. The procedures are commonly performed on an outpatient basis with the hybrid procedures frequently taking place in an operating room (OR) or ambulatory surgical center (ASC) under general anesthesia or intravenous sedation. Standalone balloon sinus dilation procedures can be performed in the OR, ASC, or physician's office under general or local (topical and local injections) anesthesia.

Based on the 2017 Medicare Fee Schedule, the cost of FESS procedures in the operating room (OR) range from 8% to 74% more than standalone office balloon sinus dilation, depending on the number of sinuses treated and the location of the FESS procedure (OR ASC).

Intended indication and use

Entellus Medical, now a part of Stryker, manufactures the XprESS multi-sinus dilation system. An earlier FDA-cleared device, the FinESS sinus treatment, is no longer manufactured.

The XprESS device was first cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process in February 2010. The current indication for use is to access and treat the maxillary ostia/ethmoid infundibula in patients 2 years and older, and frontal ostia/recesses and sphenoid sinus ostia in patients 12 years and older, using a transnasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

The XprESS device received CE mark in October 2010 and Health Canada Device License was obtained in April 2012.

Professional organization policy statements

Balloon sinus dilation has the support of the medical community when used during FESS (hybrid) or as a standalone procedure for CRS. The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) and American Rhinologic Society (ARS) have published policy statements supporting the appropriateness of standalone and hybrid balloon sinus dilation procedures for the treatment of patients suffering from CRS and recurrent acute rhinosinusitis (RARS).[12,13] The American Medical Association (AMA) and the AAO-HNS developed coding guidance surrounding the use of balloons and the AMA approved Level I CPT codes for standalone balloon procedures. The codes became effective in January 2011.

Clinical evidence

The clinical evidence in this dossier concentrates on 26 published articles from 2 meta-analyses; 7 prospective, randomized, controlled trials (RCTs); 1 prospective, multicenter, nonrandomized, comparative study; and 8 prospective, multicenter, single-arm clinical studies. Follow-up in these studies ranged from 1 month to 2 years. The 2 meta-analyses and the REMODEL RCT provide the highest level of evidence for balloon sinus dilation compared with traditional sinus surgery (FESS).

Meta-analyses

In 2016, Levy et al. published a systematic review and meta-analysis of clinical studies evaluating postoperative performance outcomes after transnasal balloon sinus dilation.[14] Their review identified 17 articles for qualitative analysis and 11 articles for inclusion in the quantitative meta-analysis (including the REMODEL 1-year data). Results of the meta-analysis by Levy et al. show a statistically significant mean change from baseline in the 20-item Sino-Nasal Outcome Test (SNOT-20) score of -1.52 ($p<0.0001$) at a median follow-up of 12 months in 454 balloon dilation participants.

Also in 2016, Chandra et al. published a meta-analysis of patient-level data performed on data from the final REMODEL balloon arm cohort and 5 prospective, multicenter single-arm studies of standalone balloon dilation using Stryker devices.[15] The meta-analysis population included 358 treated patients (846 sinuses) with follow-up ranging from 6 months to 2 years, depending on the individual study protocols. Inclusion and exclusion criteria were very similar between studies as were the outcomes evaluated. Changes from baseline were evaluated for mean SNOT-20 scores. Other outcomes included technical success rate, debridement rate, revision rate, recovery outcomes, postoperative pain, health care utilization, and work productivity/limitations. Table 1 summarizes the results of the Chandra meta-analysis.

The patient-level meta-analysis included a comparison of the outcomes of the balloon dilation studies to those of the FESS arm of the REMODEL trial. There were no significant differences at any time period in mean change in SNOT-20 scores between the REMODEL FESS arm, REMODEL balloon dilation arm, and the other 5 standalone balloon dilation studies. All 3 groups demonstrated significant ($p<0.0001$), clinically meaningful changes in mean SNOT-20 scores from baseline to follow-up of up to 2 years. Revision rates at 1 year were also comparable between the groups (REMODEL FESS, 1.7%; REMODEL balloon dilation, 1.4%, other balloon dilation studies, 3.2%; $p=0.628$). The outcomes were the same when the REMODEL balloon dilation arm was combined with the other standalone balloon dilation studies and compared with the REMODEL FESS arm.

Subgroup analyses of the meta-analysis data also demonstrated both clinically meaningful and statistically significant ($p<0.0001$) symptom improvement from baseline in CRS and RARS patients. There were no statistical differences between these patient subgroups in the meta-analysis or in any of the other studies that included both CRS and RARS patients. Additional subgroup analyses of the meta-analysis demonstrated both clinically meaningful and statistically significant ($p<0.0001$) symptom improvement in patients with maxillary-only disease and maxillary and anterior ethmoid disease with no difference between groups.

Table 1 - Summary of balloon sinus dilation meta-analysis outcomes

Meta-analysis outcomes	Subjects evaluated	Mean or %
Change in SNOT-20, 1-year	310	-1.59
Change in SNOT-20, 2-year	74	-1.82
Number of debridements/patient	145	0.2
Technical success	846 (sinuses)	97.5%
Patients discharged with nasal bleeding	232	13.8%
Recovery time (days)	94	1.4
Revision surgery rate (1-year, pooled 5 single arm studies)	250	3.2%
Duration of prescription pain medications (days)	94	0.8
Duration of OTC pain medications (days)	94	1.5
Procedural pain score (0=no pain, 10=severe pain)	241	2.6
Change in number of work/school days missed	161	-5.0
Change in number of homebound days	167	-6.3
Change in number of MD/nurse visits	172	-4.5
Change in number of acute infection episodes per patient	167	-3.9
Change in number of antibiotic courses	165	-2.9

Clinical evidence (continued)

Randomized controlled trials

REMODEL was a prospective, multicenter RCT that compared standalone in-office balloon sinus dilation to FESS for the treatment of medically refractory CRS or RARS.[15-17] REMODEL was a well-designed, adequately powered RCT that evaluated differences in appropriate health outcomes between the 2 treatments. Adults with uncomplicated CRS of the maxillary sinuses with or without anterior ethmoid disease who met criteria for medically necessary FESS were randomized 1:1 to office balloon dilation or FESS and followed for a minimum of 1-year post treatment. Primary endpoints included symptom improvement using the validated SNOT-20 survey and the postprocedure debridement rate. A sample size calculation indicated that a minimum of 36 patients per arm were required for 90% power at a 1-sided α level of 0.025.

A total of 135 patients (74 balloon dilation; 61 FESS) were randomized and treated; 130 patients (96.3%) completed 1-year follow-up. In addition, 66 patients completed an 18-month visit and 25 patients completed a 24-month visit (100% of expected visits for each time point). Table 2 presents the REMODEL RCT outcomes by treatment arm through 1-year follow-up.

The REMODEL results show that standalone balloon dilation performed in the physician's office is safe, effective, and a beneficial alternative to FESS in patients with maxillary sinus disease, with or without anterior ethmoid disease, who fail medical management and meet the surgical criteria for uncomplicated CRS. The efficacy of balloon dilation is comparable to that of FESS for symptom improvement, ostial patency, reduction of rhinosinusitis, and very low surgical revision rates at 1-year follow-up. Advantages of balloon dilation over FESS include faster patient recovery, fewer debridements, less bleeding, and reduced use of postoperative pain medication.

Six other single-center RCTs have been reported.[18-23] Although these studies did not have sufficient sample sizes to provide adequate statistical power, their results are consistent with the REMODEL results and supplement the findings of the larger study.

Table 2 - REMODEL RCT outcomes by treatment arm

Overall outcomes	Balloon dilation mean or %	FESS mean or %	P value[a]	Balloon dilation versus FESS
Primary endpoints				
1-year change in SNOT-20	-1.59	-1.60	<0.001	Balloon dilation noninferior to FESS
Number of debridements/patient	0.2	1.0	<0.0001	Balloon dilation superior to FESS
Secondary outcomes (recovery and short-term)				
Technical success	99.3%	99.4%	NS	No significant difference between study arms
Patients discharged with nasal bleeding	32%	56%	0.009	Balloon dilation significantly better than FESS
Recovery time (days)	1.7	5.0	<0.0001	Balloon dilation significantly better than FESS
Duration of prescription pain medications (days)	1.0	2.8	<0.0001	Balloon dilation significantly better than FESS
Secondary outcomes (1 year)				
Change in number of rhinosinusitis episodes per patient	-4.2	-3.7	NS	No significant difference between study arms
Ostial patency	92%	97%	NS	No significant difference between study arms
Mean reduction of activity impairment due to CRS	68%	76%	NS	No significant difference between study arms
Mean reduction in overall work impairment due to CRS	72%	80%	NS	No significant difference between study arms
Complications	0%	0%	NS	No significant difference between study arms
Revision surgery rate	1.4%	1.6%	NS	No significant difference between study arms

SNOT-20 = 20-item Sino-Nasal Outcome Test; NS = not significant.
[a]Comparison of difference between study arms.

Prospective, multicenter, nonrandomized comparative study

The MERLOT study is a prospective, multicenter, nonrandomized study comparing balloon sinus dilation with medical management for treatment of medically recalcitrant CRS.[24] The study enrolled a total of 198 participants at 24 U.S. centers. Three-quarters of the study participants (146/198) chose balloon sinus dilation as their treatment choice compared with 26% (52/198) who chose to continue with medical management. Seventy-two percent of the patients were treated in-office under local anesthesia only. Adjunctive procedures such as polypectomy, septoplasty, ethmoidectomy, and turbinate reduction were permitted, as indicated. Balloon sinus dilation patients experienced statistically and clinically significant improvements from baseline in the CSS, RSDI, and SNOT-20 questionnaires at 6 months post procedure. The results were unchanged when limited to those patients undergoing standalone balloon dilation.

Prospective, multicenter, single-arm clinical studies

The 8 prospective, multicenter, single-arm clinical studies were well designed and were conducted in a well-controlled environment with follow-up ranging from 6 months to 2 years. Although these studies did not contain direct comparator groups, they all demonstrated significant within patient changes from baseline. Most importantly, these studies all had consistent safety and effectiveness results between one another and to those of the meta-analyses and the randomized trials. These studies demonstrated the following:

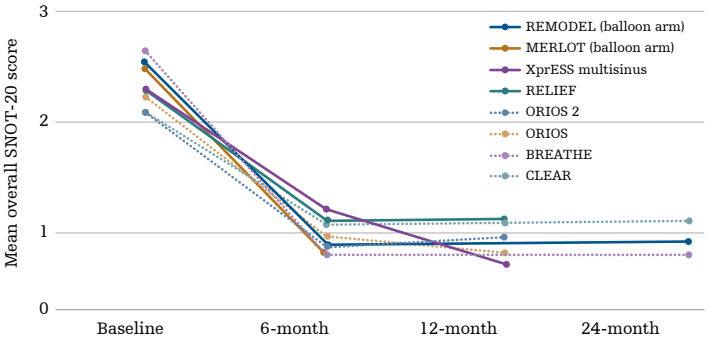
- Clinically meaningful, statistically significant, and durable improvement in sinus symptoms up to 2 years post procedure
- Low incidence of postoperative debridement
- Quick postoperative recovery
- High patency rates
- Low rates of subsequent revision surgery
- Very low complication rates
- Reduced health care utilization

As seen in Figure 1, standalone balloon sinus dilation studies show consistent SNOT-20 scores at baseline and follow-up of 1-year or more for over 650 patients. In addition, the studies consistently demonstrate that SNOT-20 scores stabilize by 6 months post treatment, establishing clinically meaningful and durable symptom improvement out to 2 years post balloon dilation. This finding is consistent with other studies that have demonstrated stable SNOT-20 scores out to 2 years follow-up after FESS[25,26] and supports the recommendation that symptom assessment at 6 months establishes an acceptable long-term primary endpoint for use in rhinosinusitis clinical trials.[26] Therefore, the results of balloon dilation studies carried out to 1 and 2 years exceed this standard and are sufficient to confirm that the durability of balloon dilation is similar to FESS.

More recent studies have used the SNOT-22 instead of the SNOT-20.[19,20,23,26] In these studies, there was statistically significant improvement from baseline in total SNOT-22 scores after balloon sinus dilation ($p<0.001$).

In the XprESS pediatric study, Soler et al. used the 5-item Sinus and Nasal Quality of Life Survey (SN-5), a validated, standardized assessment for reporting of sinusitis symptoms in children.[26] The mean change from baseline to 6-month follow-up in the overall SN-5 score

Figure 1 - SNOT-20 symptom scores in standalone balloon dilation studies



was statistically significant (-2.9; $p<0.0001$) with 92% of the children showing improvement of ≥1.0, the minimal clinically important difference.

The low debridement rate observed in the REMODEL trial is consistent with other single-arm studies that reported debridement rates ranging from 0% to 0.43% for standalone balloon dilation.[25,27-30] The meta-analysis by Chandra et al. reported a postoperative debridement rate of 0.16 per patient.[15]

The meta-analysis of standalone balloon dilation patients by Chandra et al. showed a mean recovery time of 1.4 days in 94 patients (including 73 patients from the REMODEL RCT balloon arm). This recovery time was significantly shorter than that of the REMODEL RCT FESS arm: 5.0 days ($p<0.001$).[15] Similarly, the meta-analysis by Levy et al. reported a mean recovery time of 1.72 days after balloon dilation compared with 4.84 days after FESS ($p<0.001$).[14] In the XprESS system pediatric study, recovery time was 1.1 days after standalone balloon dilation and 3.3 days after balloon dilation with concomitant procedures.[26] Recovery time of 2.2 days was reported in both the Achar RCT[21] and the single-arm ORIOS 2 study.[29] In the MERLOT study, the mean recovery time for balloon dilation patients was 2.0 days.[24] Additionally, in the BREATHE study, 88% of patients returned to normal activities within 2 days.[32] The mean recovery time of the balloon dilation arm of the REMODEL trial was 1.7 days.[15] These studies all consistently show a recovery time of 1 to 2 days that is significantly faster than typically seen for FESS.

Two of the prospective, single-arm balloon dilation studies[30,31] and 3 RCTs[16,18,22] determined ostial patency at 1 year post procedure; the BREATHE study reported patency at 3 months post procedure.[32] The overall patency rate for 285 patients treated with balloon dilation was 91.2% (534/585 sinuses).

Revision surgery rates from 11 studies range from 1.3% to 9.2% for follow-up periods from 6 months to 2 years post balloon dilation.[16,22-29,31,33,34] The study with the highest revision surgery rate (9.2%) was from the first 65 patients treated with balloon sinus dilation in 2005.[34] Subsequent studies show continuing improvement of this outcome measure. Review of the FESS literature demonstrates revision rates are typically in the range of 7% to 12%, suggesting that balloon dilation provides a durable patient outcome with revision surgery rates that are similar to or less than that of FESS.

Clinical evidence (continued)

Complications are very rare after balloon dilation procedures. In the BREATHE study, 1 patient experienced subcutaneous emphysema after resuming continuous positive airway pressure (CPAP) the same evening as the procedure. This event spontaneously resolved within 1 week.[32] The MERLOT study reported 2 procedure-related complications that were not related to the balloon dilation: 1 patient had a transient ischemic attack 3 days post procedure after discontinuing anticoagulation medication and a second patient had a dental crown broken during extubation.[24] Out of a combined population of 1,145 patients treated with balloon dilation in the studies summarized in this report, the combined complication rate is 0.3%. This compares favorably with FESS complication rates that are estimated to be approximately 1%.[35,36]Balloon dilation procedures have been performed in hospitals, ASCs, and in physician offices. These results demonstrate that balloon dilation is safe when performed in any of these settings.

RSI results were assessed at baseline and at 1 year post balloon procedure in 3 of the prospective, multicenter, single-arm studies.[27,31,33] All 3 studies showed significant decreases of 2 to 3.8 antibiotic courses in the year after the procedure. The number of sinus-related physician visits in the year after balloon dilation were also significantly decreased by 1.7 to 4.7 visits. Additionally, both the XprESS multisinus[33] and RELIEF[27] studies found significant decreases in the number of acute sinus infections of 2.3 to 4.4 in the year after balloon dilation while the XprESS system registry[31] showed a near significant ($p=0.06$) decrease of 2.6 infections. These findings suggest significant savings in health care utilization after balloon dilation procedures.

Analyses from the meta-analyses, the final REMODEL data, and other studies have further demonstrated that there are no statistically significant differences in the outcomes of balloon dilation in patients with CRS versus RARS; with versus without ethmoid disease; with versus without mild to moderate septal deviation; and among any combination of sinus disease locations.

Clinical-based health economics

In December 2016, after an extensive independent review, the National Institute for Health and Clinical Excellence (NICE) in the UK published a positive guidance for the XprESS balloon dilation system.[37] Their review concluded that adoption of balloon sinus dilation with XprESS system for treatment of uncomplicated CRS after medical therapy failed was supported by the clinical evidence. In their recommendation they state: "Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS)." Furthermore, regarding the economics of balloon dilation, their recommendation stated that "XprESS is cost-saving compared with FESS when treatment is done using local anesthetic in an outpatient setting."

Patient selection

A number of the clinical studies, including REMODEL, used the definitions of CRS as outlined by the AAO Clinical Practice Guideline (2007) or the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS) as inclusion criteria. Further support of the applicability of balloon dilation to general clinical practice is supported by the similar outcomes in 1,036 patients treated with balloon dilation and reported in the PatiENT Registry.[38] Based on the similarity in patient selection criteria and improvements achieved between studies, there is sufficient clinical evidence to demonstrate that this improvement is attainable outside the investigational setting for the following general populations:

- **General population for standalone balloon dilation**
  Patients with uncomplicated chronic or recurrent acute rhinosinusitis who meet the criteria for medically necessary FESS

- **General population for hybrid balloon dilation**
  Patients with chronic or recurrent acute rhinosinusitis who meet the criteria for medically necessary FESS

Conclusion

Clinical evidence and a clinically based health economic assessment support the use of standalone or hybrid balloon sinus dilation for the treatment of medically refractory CRS or RARS as a cost-effective alternative to FESS. Balloon sinus dilation devices have been studied in meta-analyses, prospective RCTs, a prospective, nonrandomized, comparative study, and numerous prospective, multicenter, single-arm studies. The clinical evidence from these studies has been published in peer-reviewed literature and includes adequately selected outcomes. Multiple studies provide consistent data documenting that sinus balloon dilation is safe and results in significant, sustained sinus symptom improvement, low debridement rates, high patency, quick recovery, a low surgical revision rate, and improved health care utilization. Most significantly, the meta-analyses and the final long-term (1-2 year) results from the REMODEL RCT demonstrate that balloon sinus dilation improves net health outcomes long-term and is as beneficial as, or better than, the established alternative of FESS. The final REMODEL results are consistent with results of previously published studies, thus validating the body of clinical evidence of studies on balloon dilation for the treatment of CRS.

Based on the evidence provided in this report, balloon sinus dilation should be considered medically necessary as a covered payable procedure to adequately treat patients with rhinosinusitis when medical management has failed.

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