Safety and Feasibility of Balloon Catheter Dilation of Paranasal Sinus Ostia: A Preliminary Investigation

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Objectives: Endoscopic sinus surgery (ESS) is an effective option for managing patients in whom medical therapy for rhinosinusitis fails. However, ESS is not always successful, and serious complications can occur. New techniques and instrumentation that improve outcomes and reduce complications would be seriously welcomed. Innovative catheter-based technology has improved treatment of several conditions such as coronary artery disease, peripheral vascular disease, and stroke. Recently, catheter devices have been developed for the paranasal sinuses. Cadaver studies confirm the potential use of these devices in rhinosinusitis. The objective of this investigation was to ascertain the feasibility and safety of these newly developed devices in performing catheter-based dilation of sinus ostia and recesses in patients with rhinosinusitis.

Methods: A nonrandomized prospective cohort of 10 ESS candidates was offered treatment with a new technique of balloon catheter dilation of targeted sinus ostia. The frontal, maxillary, and sphenoid sinuses were considered appropriate for this innovative catheter-based technology. The primary study end points were intraoperative procedural success and absence of adverse events.

Results: A total of 18 sinus ostial regions were successfully catheterized and dilated, including 10 maxillary, 5 sphenoid, and 3 frontal recesses. No adverse events occurred. Mucosal trauma and bleeding appeared to be less with catheter dilation than is typically observed with ESS techniques.

Conclusions: Dilation of sinus ostial regions via balloon catheter-based technology appears to be relatively safe and feasible. Larger multicenter clinical trials are now warranted to further establish safety and to determine the role of this new technique.

Key Words: balloon catheter, dilation, rhinosinusitis, sinus.

INTRODUCTION

Sinus surgery has evolved significantly in the past 20 years. Headlights have given way to endoscopes that provide superior illumination and magnification. Forceps that pull and tear tissue have given way to new through-cutting forceps and tissue microdebriders that spare sinus mucosa and improve healing. Endoscopic sinus surgery (ESS) is widely accepted as an efficacious method to relieve sinus ostial obstruction and treat the vexing problem of rhinosinusitis. However, problems still occur with ESS. Circumferential scarring and adhesions can limit the ability of sinus ostial openings to remain patent. Bleeding can obscure intraoperative visualization. Orbital injury and accidental penetration of the brain are possible. Furthermore, powered instrumentation can rapidly escalate the significance of complications with disastrous outcomes. Given all this, new developments that improve outcomes and reduce complications would still be seriously welcomed.

Technological advancements made in other medical subspecialties may have a role in sinus surgery. Catheter-based devices have been effectively used to relieve stenosis in gastrointestinal, cardiac, vascular, and urological conditions.1–4 Recently, catheter-based devices were proposed for relieving sinus ostial obstruction (Fig 1). Preliminary cadaver studies indicate that catheter-based dilation of the sinus ostia is feasible and appears safe.5 By means of a combination of guiding catheters, guidewires, and balloon catheters, 31 sinuses in 6 cadaver specimens were successfully cannulated and dilated. Endoscopic examinations revealed patent sinus ostial openings, and importantly, minimal mucosal damage. Computed tomographic (CT) imaging of cadaver heads revealed microfractures of ethmoid septations and cellular elements around sinus ostial regions but no evidence of
damage to surrounding structures, such as the orbit and the base of the skull. With this in mind, the purpose of this investigation was to assess the safety and feasibility of catheter-based dilation of sinus ostia in patients with rhinosinusitis.

**METHODS**

**Patient Selection and Recruitment.** Patients in whom medical therapy for chronic rhinosinusitis had failed and who were considered surgical candidates were considered for catheter-based therapy. Patients were excluded from the trial if they were less than 18 years of age, were pregnant or at risk of pregnancy, or had cystic fibrosis, significant nasal polyposis, sinus osteoneogenesis, or significant previous sinus surgery. Patients who met the selection criteria were then offered an opportunity to participate in the evaluation. Initially, the patients were informed of current ESS techniques and the risks, benefits, options, and possible complications associated with it. Thereafter, the concept of balloon catheter ostial dilation was introduced. The patients were informed that instead of using tissue-cutting forceps and other instruments to dilate and enlarge their sinus ostia, a specially designed catheter and balloon would be used to dilate and open targeted sinuses. Fluoroscopy would be used to aid placement of these devices across sinus ostial regions. A frank discussion followed regarding the role of balloon-based technologies in other disciplines, the cadaver studies undertaken to assess the safety and feasibility of catheters in the sinuses, radiation exposure, and possible outcomes with this new technique. If initial balloon dilation of a sinus ostium was deemed successful, no further intervention would be performed. If, however, balloon dilation was deemed unsuccessful, standard ESS techniques would be used. As this was an entirely new technique, catheter-based treatment was limited to a maximum of two sinuses. Additional sinuses would then be addressed by standard ESS, with the result of an overall “hybrid”-type treatment. Furthermore, if any complication occurred as a result of the trial of the new intervention, catheter application would be abandoned, and standard ESS would be performed as appropriate. An independent otolaryngologist, acting as a safety officer, was appointed to review any complications. The principal investigator (C.L.B.) in all cases conducted patient recruitment and consent. The patients were seen in a tertiary referral center in a subspecialty clinic for nasal and sinus disorders. The principal investigator performed the preoperative, intraoperative, and postoperative care. Before commencing the study, we obtained Ethics Committee approval from the

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*Fig 1. Catheter-based dilation of sinus ostium is illustrated in obstructed sinus. A) Obstructed sinus ostium with mucous obstruction. B) Guidewire is passed through obstructed ostium. C) Balloon catheter is advanced over guidewire and positioned across ostium. D) Balloon catheter is inflated. E) Balloon catheter and guidewire are removed, ostial obstruction is relieved, and secretions can be cleared from sinus.*
Brown & Bolger. Dilation of Paranasal Sinus Ostia

Fig 2. Preoperative computed tomogram of an atelectatic infundibulum and obstructed maxillary ostium with maxillary sinus opacification.

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Device Application. All patients had a general anesthetic. To limit radiation exposure during fluoroscopy, we placed a lead apron over the patient's chest and placed a protective collar around the patient's neck. A mobile fluoroscopy unit with a C arm was placed to the left of the patient's neck. The C arm was then mobilized into position when necessary. The fluoroscopy monitor and a standard endoscopic tower were placed at the head of the bed. All personnel in the theatre wore appropriate lead aprons. Standard nasal preparation included Cophenylcaine spray (phenylephrine and lidocaine) and placement of neuropatties (soaked in a solution of cocaine, epinephrine, and normal saline) within the nasal cavity. Lidocaine and epinephrine were used for local mucosal infiltration.

Sinuses deemed appropriate for balloon dilations were addressed first (Fig 2). Under endoscopic visualization, a guiding catheter (Acclarent, Inc, Menlo Park, California) was placed in the region of the sinus ostia. A guidewire was then introduced through the guiding catheter. Under fluoroscopic guidance, the guidewire (Acclarent, Inc) was advanced through the sinus ostia into the sinus. If any resistance was met, gentle manipulation of the guiding catheter and guidewire was performed until the guidewire successfully cannulated the sinus. The guidewire was then further advanced into the sinus in such a way that it curled upon itself and formed a loop within the sinus (Fig 3). This configuration improved guidewire stability and minimized the potential for inadvertent dislodgement of the guidewire with subsequent manipulation.

After successful cannulation of the sinus with the guidewire, an uninflated balloon catheter (Acclarent, Inc) was threaded over the guidewire and through the guiding catheter. Under fluoroscopy, the uninflated balloon was advanced into position until it straddled the sinus ostium. The balloon was then inflated with contrast medium to a maximum of 16 atmospheric pressure (atm; Fig 4). A pressure gauge attached to the end of the balloon catheter recorded the incremental rise in balloon pressure. The balloon was

Fig 3. Fluoroscopic image of guide catheter in middle meatus and guidewire with undilated balloon catheter passed beyond obstructed ostium and looping within maxillary sinus.

Fig 4. Fluoroscopic image of balloon catheter dilated across ostium.
then deflated and removed. The dilated sinus ostial region was examined with sinonasal endoscopy. If it was deemed acceptable, no further manipulation of the ostium occurred. Where appropriate, further dilations were performed with balloons of larger sizes. In some cases a subselective catheterization of the sinus ostial region was performed for irrigation of the sinus.

Study End Points. The primary end points were safety and procedural success. Procedural success was defined as the ability to catheterize the targeted sinus and complete balloon dilation. Safety was defined as the absence of significant adverse results. The nasal endoscope was used to inspect the dilation site for any signs of excessive tissue trauma or trauma to neighboring structures. Fluoroscopy time, balloon inflation time, and balloon pressure were also recorded during the dilation.

Postoperative Care. The patients underwent standard postoperative care for ESS. This typically involved examining patients in the clinic with sinonasal endoscopy within the first 1 to 2 weeks after surgery and several more times during the first 2 months after the procedure (approximately 3 to 4 times). Special attention was given in postoperative examinations to balloon-dilated ostia and surrounding tissue for any signs of adverse event. If a CT scan was performed as part of the patient’s postoperative management, it was examined for any signs of adverse effect to the structures neighboring the balloon dilation site (Figs 5 and 6).

RESULTS

Ten patients were enrolled in the trial. A total of 18 individual sinuses in 10 patients were approached: 10 maxillary, 5 sphenoid, and 3 frontal. All 18 sinuses were successfully catheterized and dilated. Eight of the 10 patients had other sinus regions treated concurrently by standard ESS. The sphenoid and maxillary sinus ostia were dilated with 5- or 7-mm balloon catheters, and the frontal sinus region was dilated with 5-mm balloon catheters. The balloon catheters were inflated to a mean maximum pressure of 13 atm (range of maximum inflation, 10 to 16 atm). The inflation time typically occurred over 10 seconds, and the final pressure was maintained for 5 seconds. The subsequent deflation time typically took 10 seconds. The total patient fluoroscopy times ranged from 3.25 to 17.5 minutes (mean, 9.3 minutes). Bleeding and tissue trauma appeared to be minimal, and no adverse events occurred.

Several important observations were made during the investigation. First, the easiest sinus to cannulate was the sphenoid sinus. The sphenoid sinus was cannulated by placing the guiding catheter, under endoscopic guidance, into the sphenoethmoid recess. On some occasions the guidewire would “track” into the nasopharynx. Sagittal fluoroscopic images helped confirm the guidewire position and aided in repositioning the guidewire. During inflation, the sphenoid ostium created a kink in the balloon, which fluoroscopically disappeared upon completion of balloon dilation. Subsequent endoscopic examination revealed an ostium resembling the shape of the balloon. Circumferential trauma to the mucosa in the region of the ostium was not evident.

The next-easiest sinus to cannulate was the frontal sinus. After the guiding catheter was positioned in the middle meatus, the guidewire would be advanced in the direction of the frontal sinus outflow tract according to preoperative analysis of the CT scan. Correct positioning of the guiding catheter and guidewire resulted in the guidewire’s promptly passing into the sinus without resistance. If the guidewire
encountered resistance, the guide catheter and wire were repositioned under fluoroscopy and the guidewire was redirected into the sinus. Tactile feedback through the guidewire readily revealed whether the guidewire was abutting tissue. Coronal fluoroscopic images and sagittal images were used to confirm successful cannulation of the frontal sinus. Balloon dilation was performed over several contiguous areas in an attempt to address the longer path of the frontal sinus outflow tract. Mucosal trauma and bleeding were minimal.

The maxillary sinus was the hardest to cannulate because of the relative position of the natural ostium and the uncinate process. Ultimately, the guiding catheter and wire must make an acute bend around the posterior margin of the uncinate process and then track anteriorly, laterally, and inferiorly to encounter and traverse the ostium. On some occasions the guiding catheter did not provide the appropriate angle for the guidewire to approach the maxillary sinus ostium. This tendency prompted subsequent modifications of the guiding catheter. After balloon dilation, the uncinate process was displaced anteriorly and the infundibulum was widened. The displaced uncinate process often shielded the ostium from anterior visualization with a 0° or 30° endoscope. When this shielding occurred, a small portion of the inferior aspect of the uncinate process was removed with the microdebrider or back-biter to confirm that the natural ostium, rather than an accessory ostium, had been dilated. During removal of this portion of the uncinate process, the mucosa of the dilated ostium was not touched with the instrument. A portion of the uncinate process was removed for visualization in approximately half of the maxillary dilations.

**DISCUSSION**

The results of this investigation indicate that catheter-based dilation of the sinus ostial regions is feasible and appears safe. All targeted sinuses were successfully catheterized and dilated, and no complications occurred.

One of the surprising results of this trial was the relative ease of using the devices to successfully cannulate the sphenoid and frontal sinuses. In ESS, the posteriorly located sphenoid sinus can be challenging to locate in patients with extensive disease or intraoperative bleeding. Similarly, the frontal sinus and recess present a challenge to surgeons due to the variable nature of the recess and the difficulty with instrumentation in this area. Additionally, the risk of skull base penetration or inadvertent mucosal stripping with subsequent stenosis adds to the challenge of operating in this area. Catheter-based treatment appears to meet these challenges well and provides the practicing sinus surgeon with a new tool to consider using in treating these sinus regions.

With new techniques there is always a “learning curve,” and training is an important consideration. We noted that just as in ESS, cadaver training helped prepare the surgeon to handle the new balloon catheter devices in surgery. Otolaryngologists are very experienced with endoscopes, microscopes, and an array of rigid instruments such as forceps, knives, and scissors that are needed to handle ear, sinus, neck, and larynx surgery. However, manipulating catheters and working from a fluoroscopy monitor is a different matter for most otolaryngologists, and cadaver training is very helpful in preparing one for actual patient care with the new devices.

In this investigation, a high degree of mucosal preservation was associated with catheter-based dilation of the sinus ostium. Only small, occasional, radially oriented mucosal “releasing tears” were noted, which appeared to accommodate the dilating balloon. The circumferential mucosal stripping that can sometimes be seen in ESS was not observed. Another important observation was the low degree of bleeding associated with the devices, both during their application and in the immediate postoperative period. This feature may be especially beneficial to patients who are at a particular risk of bleeding.

Although initial safety testing in cadaver specimens did not reveal any damage to the lamina papyracea or the lateral lamella of the cribriform plate, and adverse effects were not encountered in patients during this study, our findings should not necessarily be extrapolated to all patients. The anatomy of the paranasal sinuses is highly variable between patients, and disease processes can further distort the sinus anatomy. Careful case selection is indicated until more experience is gained in patients with anatomic variations such as a thin lamina papyracea or a Keros type III skull base. Additional safety analysis in these patient groups, as well as replication of our study by other investigators at other centers, is needed.

The final ostial size with balloon catheter ostial dilation is another important consideration to discuss. As expected, dilated ostia appeared to be slightly smaller than the maximal balloon diameter used. However, the size compares favorably with the openings after ESS. It is important to note that the optimal ostial size to achieve with surgery has never been scientifically established. Recently, concerns have arisen that the mega-antrostomy and mega-sphenoidotomy that some practitioners elect to perform may not be necessary and might adversely alter the
microenvironment within the sinus. Although balloon catheter ostial dilation achieves a smaller final ostial size than that achieved with ESS, the reduced mucosal trauma and improved mucosal preservation may prove advantageous.

New devices and techniques can offer advantages, but they can also present their own set of challenges and limitations. Postoperative examination of ostia dilated with the balloon catheter devices can be difficult to perform with our current endoscopes. The retained and anteriorly deflected uncinate process impairs visualization. After sphenoethmoid balloon catheter dilation, the narrow confines of the sphenoid recess render endoscopic evaluation difficult. This is a change from the visualization possible after transethmoid sphenoidotomy. A greater range of instruments may be required for postoperative visualization. Another challenge may lie in the effect of dilation on neighboring sinus outflow tracts. In dilating one ostium, recess, or sinus outflow tract, an adjacent outflow tract could be reduced or possibly even obstructed. This is most relevant to the frontal recess, in which an ethmoid partition could be displaced posteriorly to obstruct the suprabullar recess. Additional instrumentation that can maintain one outflow tract while dilating another may also have to be developed. Another area that warrants future attention is the effect of the balloon pressure on the ostial mucosa. Although the mucosa is preserved and appears to sustain relatively little trauma, the pressure needed for balloon dilation could disrupt the cellular architecture and cause microscopic injury or an inflammatory response. A final concern is that unless directly visualized, it may be difficult to determine whether the natural ostium rather than the accessory ostium is dilated with the balloon catheter. Direct endoscopic visualization of the maxillary ostium appears to offer an advantage over fluoroscopy in this regard.

The role of balloon catheter devices cannot be ascertained from this feasibility and safety study alone. Additional multicenter trials are needed to more clearly determine the role of balloon catheter dilation and to determine long-term treatment results and patient outcomes. However, on the basis of this initial experience, we do have some observations. The technique appears to provide another tool for the otolaryngologist performing sinus surgery, especially in cases in which sinus disease is due to ostial obstruction. Cases of maxillary sinus hypoplasia, atelectatic infundibulum, or silent sinus syndrome appear particularly well suited for balloon catheter therapy. In these cases the guidewire can seek the laterally displaced maxillary ostium rather easily, whereas standard instrumentation may fail to engage the lateralized uncinate process. Alternatively, standard instruments that incise the thin uncinate process risk orbital penetration. In contrast, the balloon lifts the uncinate process away from the orbit, providing a much safer dissection vector. Balloon catheter devices might also have a role in cases of isolated sphenoid sinusitis in ill patients in an intensive care unit on anticoagulant therapy. Anesthesia time might be reduced, and the need to adjust anticoagulation therapy lessened. A role for balloon catheter dilation also becomes quickly apparent when the device is used in the frontal recess region. Otolaryngologists are presented with a difficult challenge in trying to determine and follow the course of this pneumatization pathway during ESS. Catheter-based treatment appears to allow rapid identification of the frontal sinus outflow tract, a welcome contribution.

According to our initial experience, this technology may have important applications as a minimally invasive alternative to widen the sinus ostia currently targeted by ESS. However, it is clear that there are disease states that are not addressed with this technology in its current form. Sinonasal polyposis and eosinophilic mucosal membrane disease will not respond to simple dilation by a balloon catheter. We must await other innovations to improve these important clinical conditions for our patients. Cases of extensive chronic sinus disease with osteoneogenesis may not be suitable for treatment by balloon catheters, as the devices cannot remove thick bone if the clinician believes this is indicated. Balloon catheter ostial dilation appears to be safe in part because the ethmoid septations are thinner than the skull base bone and orbital bone to which the septations attach. If, however, the ethmoid cellular elements are thickened by osteoneogenesis, they might resist being molded by the balloon, and the dilation force could be transmitted through them into surrounding structures such as the skull base or orbit. Although this problem has not been observed clinically or in prior cadaver testing, we recommend careful case selection when osteoneogenesis is suspected. It is also important to point out that currently, balloon technology does not address the entire ethmoid complex, but rather just the elements leading to the sphenoid, maxillary, and frontal sinuses. Because of the importance placed on the ethmoid sinus in treating patients with chronic rhinosinusitis, this is an area of active research and device development.

Balloon catheter ostial dilation in its present form requires fluoroscopy, and this deserves special comment. Fluoroscopy is still used today in transsphenoidal hypophysectomy, and it was not long ago that it was also used in transnasal sphenoidotomy. Although appropriate steps can be taken to reduce radi-
ation exposure, the risks of radiation remain. Wearing lead aprons during sinus surgery is also a slight inconvenience for surgeons and operating room staff. The fluoroscopy unit is a large piece of equipment that needs to be positioned in an operating room with an endoscopy tower, an anesthesia cart, and sometimes an image guidance unit. Positioning all of these large pieces of equipment in a small operating room can be difficult. These inconveniences may be offset by the ability of fluoroscopy to help identify ostia and recesses quickly and reduce surgery and anesthesia time.

Although the primary purpose of this study involved safety and feasibility, the patients were followed closely and some conclusions about outcomes can be made. Generally speaking, the patients improved symptomatically and were surprised by the minimal amount of discomfort from the balloon dilation. When questioned, the patients were pleased overall with the treatment experience. Furthermore, from the clinician’s perspective, there appeared to be less mucosal edema and patients required less postoperative debridement than typically is seen with ESS.

CONCLUSIONS

Dilation of sinus ostia and recesses via balloon catheter-based technology is feasible and appears to be safe. Mucosal preservation appears to be a major advantage of this new technique. The technique is relatively easy to learn and can be applied in most surgical settings in which fluoroscopy is available. The potential applications of this new device are exciting and warrant additional testing via larger multicenter trials.

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REFERENCES


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