Retained drug-eluting stents and recalcitrant chronic rhinosinusitis: A case report

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ABSTRACT

Corticosteroids are the mainstay of treatment for refractory chronic rhinosinusitis. The off-label use of steroid-eluting stents has increasingly gained popularity in functional endoscopic sinus surgery for decreasing postoperative inflammation and synechiae formation. However, there is a paucity of data outlining the safety profile of this device despite its widespread use. This study was designed to report a newly described complication of retained drug-eluting stents from endoscopic sinus surgery for refractory rhinosinusitis. This report highlights a potential risk of the drug-eluting stent in the treatment of recalcitrant rhinosinusitis and the need for further clinical investigations whenever a novel medical device becomes available on the market.

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The treatment of refractory chronic rhinosinusitis (CRS) has posed a long-standing challenge for health care providers. An estimated 14–16% of the population in the United States is affected by CRS. The socioeconomic impact is considerable given that patients with CRS seek health care visits twice as often as those without the disease.[1] Patients with CRS who are referred to otolaryngologists score worse on measures of bodily pain and social functioning when compared with patients with angina, congestive heart failure, chronic obstructive pulmonary disease, and back pain.[2] Recalcitrant CRS is a prevalent disease that has prompted numerous forms of treatment over the past few decades. A recently described innovation is the placement of drug-eluting stents into the paranasal sinuses. Surprisingly, there is a paucity of published data surrounding this technology despite its widespread use. To our knowledge, only one complication regarding this device has been described in the literature.[3] In this report, we present a complication involving retained drug-eluting ethmoid stents discovered on revision endoscopic sinus surgery for recalcitrant disease.

CASE REPORT

A 45-year-old man was referred from an outside facility for CRS with nasal polyposis with symptoms of chronic nasal congestion and headaches for many years. Seven months before presentation, the patient had undergone functional endoscopic sinus surgery (FESS) at an outside institution for the same symptoms. Before surgery, the placement of Relieva Stratus Microflow Spacer (Acclarent, Menlo Park, CA) was discussed with the patient, with mention of use of steroids (off label) in conjunction with the stents. After the surgery, the family of the patient was told that drug-eluting, nonabsorbable stents were not used during the procedure. A different provider performed the patient's postoperative visit and the presence of the stents was not noted or communicated to the patient. Within 2 months of surgery, there was regrowth of polyps and return of symptoms. He was treated with multiple combinations of oral and topical therapies without resolution of symptoms and was referred for further evaluation.

His medical history was otherwise notable for severe persistent asthma, seasonal allergies, hypertension, and gastroesophageal reflux disease. At presentation he was on 20 mg of prednisone daily as well as nasal antihistamine spray. On anterior rhinoscopy, there was total nasal obstruction caused by bilateral nasal polyposis. Abundant clear mucoid rhinorrhea was also noted throughout both nasal passages. Available imaging included a computed tomography (CT) scan from several years ago, which showed pansinusitis. No further imaging had been obtained since his previous sinus surgery.

Because of the patient's symptoms and physical examination findings, he was scheduled for FESS with image guidance and was started on a 5-day pre- and postoperative course of 60 mg of prednisone. The CT was obtained and reviewed on the day of the procedure and was remarkable for bilateral ethmoid and frontal opacification; in addition, hyperdense structures within the ethmoid cavities traversing into the frontal sinuses were noted bilaterally (Fig. 1). These preoperative images raised suspicion of possible re-

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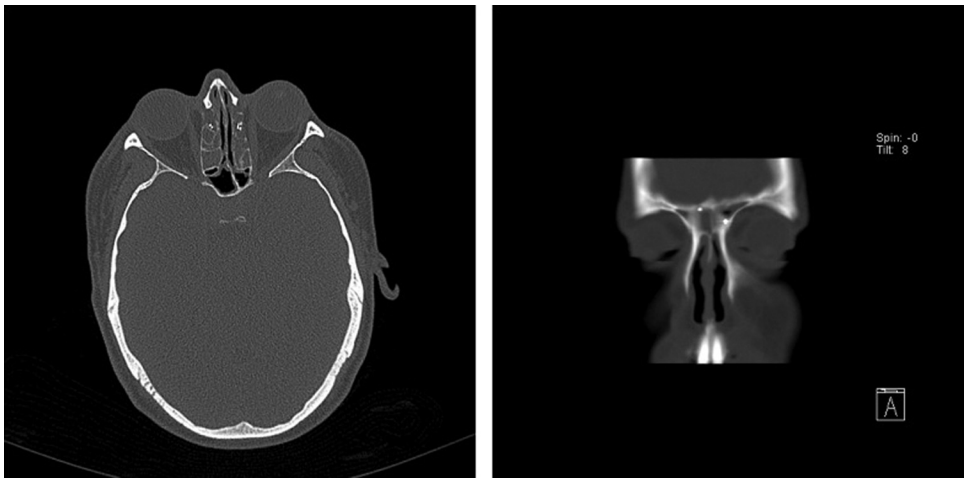

Figure 1. *Axial and coronal CT scans showing radio-opaque objects in frontal and ethmoid recesses bilaterally.*

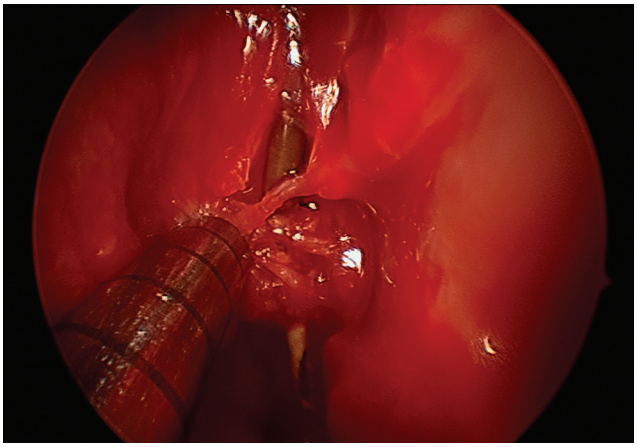

Figure 2. *Intraoperative photograph of foreign body found in sphenoethmoidal recess.*

tained stents from his surgery performed 7 months earlier. After discussing the unknown but potential risks related to removing the retained stents, the patient elected to proceed as planned.

During the initial suctioning and injection portion of the case, it became evident that there was indeed a foreign body consistent with a retained stent imbedded in the tissues of the sphenoethmoidal recess on the left side (Fig. 2). There was extensive chronically inflamed mucosal tissue diffusely, with more focal granulation tissue surrounding the device. Careful dissection was performed to identify the entire length of the stent, which required gentle retraction, tissue cutting instruments, and a sickle knife. An attempt to grasp the string was made, but this was brittle and broke. Ultimately, the stent was removed in its entirety, including the nitinol wings. A similar approach was used to remove an identical stent on the right. Injury to the orbits or skull base was avoided. Performance of the planned operation to remove polyps and ventilate the ethmoid, frontal, and sphenoid sinus was somewhat encumbered by bleeding, potentially worsened by granulation tissue and infection. At the end of the procedure, Gelfilm (Pfizer, New York, NY) was wrapped around MeroGel (Medtronic Xomed Surgical Products, Jacksonville, FL) and placed in the middle meatus to act as a spacer between the middle turbinate and lateral nasal wall because of the risk of synechia at the site of opposing granulation tissue.

Cultures of specimens taken from both left and right stents showed heavy growth of *Stenotrophomonas maltophilia* and moderate growth of *Klebsiella oxytoca*, coagulase negative *Staphylococcus*, and β-hemolytic *Streptococcus anginosus*. Fungal cultures were negative.

Postoperatively, the patient underwent nebulizer treatments with antibiotics, antifungals, and steroid solution twice daily. He was started on a 28-day course of Levofloxacin because of the multiple bacteria that were isolated from his retained stents. At follow-up 10 days after the surgery, the patient had minimal postoperative pain or drainage. There was a moderate amount of crusting that was debrided and an adhesion on the left side that was lysed with a suction catheter. Debridement was repeated the following week and then again at 6 weeks with appropriately healing tissues and no evidence of polypoid regrowth.

DISCUSSION

FESS has gained wide acceptance as a treatment modality for medically recalcitrant CRS.[4] Although this procedure aims to reestablish the physiological pattern of ventilation and mucociliary clearance, it does not address the diffuse inflammatory component of CRS. The concept of drug-eluting sinus stents combines the space-occupying function of the device with the benefits of local pharmacotherapy.

The use of drug-eluting devices in other areas of medicine is well established, such as coated cardiovascular stents. The technology is progressively being explored in sinus surgery. For example, paclitaxel-impregnated stents in sheep are hypothesized to reduce

postoperative scarring after sinus surgery.[5] Preliminary research on antimicrobial- and antifungal-containing instruments has also been described, but no substantial data currently support their routine use.[6] In contrast to the Microflow Spacer, a slightly different method of providing postoperative topical steroid therapy is through the Propel sinus implant (Intersect ENT, Palo Alto, CA). This bioabsorbable device is capable of controlled release of mometasone furoate from an embedded polymer matrix over a period of 30 days and has gained Food and Drug Administration approval. A randomized controlled trial has shown promising results in reducing synechiae formation, polyposis, and the need for postoperative interventions.[7]

The anti-inflammatory properties of a steroid-eluting stent seem to hold great potential for noninvasive treatment of recalcitrant CRS. In a study investigating allergic patients with CRS by Lavigne *et al.*, it was shown that topical budesonide released into the maxillary sinus decreased inflammation by altering cytokine expression. They observed a reduction in eosinophilia and expression of the Th2 cytokines IL-4 and IL-5, as well as prolonged improvement in clinical symptoms.[8] In a rabbit model, it was shown that dexamethasone drug-releasing stents resulted in thinner stroma thickness and reduced granulations without hindering epithelial differentiation in comparison with conventional stenting.[9] Targeted local corticosteroid therapy would also minimize exposure to systemic steroids, which carry side effects of hyperglycemia, immunosuppression, lethargy, and mood disturbances. Novel methods to provide continuous delivery of steroids into the paranasal sinus tissues are promising.

Despite evidence that corticosteroids are an important player in the management of CRS, research dedicated to the safety the Relieva Stratus Microflow Spacer is nominal. The device was introduced into clinical practice in 2009 as a catheter-based, self-retaining implantable device with a microporous reservoir for moistening the ethmoid and frontal sinuses. It is currently Food and Drug Administration approved for use with saline only and was designed for removal in the office setting.[10] The catheter is capable of releasing an instilled therapeutic agent over a 14- to 28-day period, but its application with an active drug substance is considered off-label. An initial report by Catalano *et al.* investigated the short-term outcomes and safety of the Stratus Spacer infused with triamcinolone in 23 patients. No complications were encountered and it was recommended that insertion of the Stratus Spacer into the ethmoid sinuses should be used with C-arm fluoroscopy for novice users.[11]

In a study supported by Acclarent, this instrument was evaluated in a dozen cadaveric models using a trocar insertion system into diseased ethmoid sinuses. Their results endorsed the relatively safe implantation of the device into the ethmoid sinuses without injury to the skull base, lamina papyracea, or sphenoid face.[12] Nevertheless, the only other published complication in the literature to involve the Stratus catheter described the violation of the lamina papyracea and orbit. A postoperative CT scan showed the stent abutting the lateral orbital wall. Despite the eventual removal of the device, the patient's pupil remained dilated in the affected eye.[3]

CONCLUSION

Considerable progress has been made in the treatment of paranasal sinus disease with promising innovations on the horizon. Corticosteroids are a mainstay of therapy for medically refractive CRS and are now being combined with FESS in the form of drug-eluting stents. These exciting innovations, however, do not obviate the need for extensive trials that better outline risks and benefits of the new technology. This is the first case to describe steroid-eluting catheters that were inadvertently left in the ethmoid and frontal sinuses. The retained catheters led to persistent mucosal inflammation and granulation tissue formation in our patient and likely contributed to symptom recurrence. The stents necessitated meticulous removal from inflamed tissues of the frontal, ethmoidal, and sphenoethmoidal recesses in which they were completely imbedded. Ultimately, we are fortunate that no further complications arose due to the retainment of the stents or during the process of their removal. One goal of this report was to highlight the importance of diligent postoperative monitoring should this stent be used in the treatment of sinonasal mucosal inflammation after FESS. Furthermore, we hope to bring to the forefront the concerning widespread application and availability of a device that has not been fully investigated. Neither a small-scale study nor a cadaveric model is sufficient to delineate the potential for harm to patients. The introduction of any novel medical technology should be accompanied by stringent investigations to maximize patient safety and improve surgical outcomes.

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