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Case Report

Multiple Bioabsorbable Corticosteroid-Eluting Stent Placement With Associated Skull Base Injury

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Bioabsorbable corticosteroid-eluting sinus stents (BCES) are used to optimize healing after sinus surgery. We report a patient with BCES placed through a dural defect. A 70 year old underwent sinus surgery. Postoperatively, the patient developed mental status changes. The patient was taken to the operating room and eight BCES were identified, with one extending through the skull base. The stents were extracted and the defect was repaired. The patient recovered well. This is the first significant complication associated with BCES. Thorough review of preoperative imaging, understanding of skull base anatomy, and careful use of BCES are critical for safety.

Key Words: Stent, corticosteroid-eluting stent, sinus surgery, Propel, skull base injury.

Level of Evidence: NA

INTRODUCTION

Bioabsorbable corticosteroid-eluting sinus stents (BCES) are widely used at the conclusion of endoscopic sinus surgery (ESS) to prevent synechiae, reduce inflammation, and optimize postoperative healing. New designs have emerged creating stents tailored for specific sinuses. When applied appropriately, there are minimal adverse effects. There have not been any reports of major complications from use of a BCES. However, without appropriate understanding of endoscopic anatomy, harm can still come to patients with use of this technology. We report a case of multiple BCES placement in a single patient including introduction of a BCES through a skull base defect with concomitant mental status changes and pneumocephalus.

CASE REPORT

A 70-year-old male with a history of chronic rhinosinusitis underwent elective septoplasty, bilateral maxillary antrostomies, total ethmoidectomies, frontal sinusotomies, and sphenoidotomies with placement of BCES. The patient’s postoperative course was complicated by epistaxis requiring placement of nonabsorbable nasal packing. The patient developed headache, confusion, and nausea, and was transferred to a tertiary care center. A computed tomography (CT) scan was obtained. This revealed a right fovea ethmoidalis defect with associated massive pneumocephalus and a radio-opaque foreign body, which appeared to be partially protruding through the osseous defect (Figs. 1 and 2). The decision was made to proceed to the operating room for exploration and repair. Intraoperatively, a total of seven BCES were identified in the paranasal sinuses, which were extracted. A defect was noted in the right anterior fovea ethmoidalis just posterior to the frontal sinus. Upon closer examination, a BCES was identified protruding through the defect from within the intracranial cavity (Fig. 3). The BCES was extracted and a dural defect was noted. A Draf IIB frontal sinusotomy was then performed for adequate visualization, and the mucosa was removed from the area of the defect to prepare for skull base repair (Fig. 4). The dural defect was repaired using a DuraMatrix (Stryker, Kalamazoo, MI) button graft placed in an inlay–onlay fashion. A free mucosal graft from the inferior turbinate was placed over the defect, and layered fibrin sealant and oxidized cellulose packing were applied for support. Postoperatively, the patient recovered well. The patient’s mental status returned to baseline. A postoperative CT
scan showed improvement of the pneumocephalus. At 1-year follow-up, the patient is doing well with no signs of CSF leakage.

**DISCUSSION**

Use of biomaterials after ESS has been well described. These materials are designed to promote healing, prevent postoperative hemorrhage, decrease formation of synechiae, and medialize the middle turbinates. Nonabsorbable materials have fallen out of favor due to mucosal sheering, bleeding, and patient discomfort associated with removal. Additional complications have been described, including aspiration, Eustachian tube dysfunction, foreign body reaction, and toxic shock syndrome. Due to these complications, there has been a shift to increased use of resorbable biomaterials.

The design of the BCES is based on mometasone furoate embedded in a biodegradable polymer consisting of polyactic-co-glycolic acid (PLGA) in a lattice pattern (Propel, Intersect ENT, Menlo Park, CA). The implant is designed to simultaneously deliver topical corticosteroids and mechanically stent a postoperative sinus.

BCES has a proven record of safety. Among the three large prospective clinical trials of BCES that
included 386 implants, there were three adverse events. 3–5 One patient experienced sinus pressure and tenderness thought to be secondary to crusting adherent to the stent. 4 Another patient developed adhesions and granulation tissue requiring debridement. 5 The last patient experienced acute sinusitis in the contralateral sinus after removal of a control stent. 6 None of these complications required rehospitalization or reoperation.

Studies have also addressed the safety of mometasone embedded in the stent. Each stent contains 370 μg of mometasone furoate, which is gradually released over the course of 30 days. In a study by Murr et al., 3 plasma mometasone concentration levels were below the detection limit of liquid chromatography at multiple intervals after placement of BCES. The ADVANCE 4 study investigated the ophthalmologic effects of the implant, noting no significant change in intraocular pressure or dilated slit-lamp examination after placement of a stent.

PLGA has been used extensively in the past, most commonly as the base of resorbable suture material. Studies have been performed using PLGA stents in an in vivo rabbit model, which showed degradation and absorption of the stent by 6 weeks. 6 By 18 weeks, there was no inflammation or residual implant noted in the tissue.

Previous clinical trials have focused on deployment of a single BCES per side to prevent postoperative adhesions and aid in healing. Studies have shown decreased formation of adhesion and inflammation after use of a single stent placement in the ethmoid or frontal sinuses. 3,7 However, no studies to date address the use of multiple BCES on a single side. Placement outside the ethmoid or frontal sinuses is also not well studied. The efficacy and cost-effectiveness of placement of multiple BCES must still be defined.

Although rare, skull base injury during routine ESS is a known serious complication. Risk factors include asymmetry of the skull base and surgeon inexperience. 8 A radiographic study of patients who experienced iatrogenic skull base injury revealed that patients with a steep skull base angle in the sagittal plane, a greater slope of the skull base in the coronal plane, and a low cribriform height relative to the fovea ethmoidalis were at increased risk for injury. 9 Additionally, this patient had a narrow anteroposterior diameter of the frontal sinus outflow tract. These factors may have increased the risk of skull base injury during this patient’s initial ESS and may have led to the misidentification of the skull base defect as the frontal sinus ostium prior to the placement of the BCES. Although it was not mentioned in the original operative report, injury to the skull base was likely caused during the ethmoidectomy/frontal recess dissection, with a BCES subsequently place through this defect. Thorough review of preoperative imaging and understanding of skull base anatomy are critical for safe surgery and stent deployment.

CONCLUSION

This is the first report of a severe complication associated with deployment of a bioabsorbable steroid-eluting stent. Although there are studies that demonstrate the benefit of placement of a single BCES per side, the role of placing multiple implants per side remains to be elucidated. Thorough understanding of the skull base anatomy and judicious use of BCES is advised.

BIBLIOGRAPHY