ABSTRACT

Objective: The purpose of this study was to determine whether steroid-eluting frontal sinus stents are effective in patients with chronic frontal sinusitis.

Study Design: Retrospective review of all patients (N=20) with placement of drug-eluting frontal sinus stents with chronic frontal sinusitis from June 2009 to 2011 at a University Hospital. Post-operative interventions, adhesions and patency of nasofrontal outflow tract were reviewed.

Results: Drug-eluting stents were placed in a total of 34 frontal sinus outflow tract in patients with findings of mucosal thickening on CT scan who had failed conservative medical or surgical therapy. A total of 15 patients had previous surgical intervention. The stents were placed for duration of 3 weeks. All patients had a minimum 7 month follow-up. There was an evidence of patent nasofrontal outflow tracts in 32 out of 34 of the frontal sinuses on follow-up office nasal endoscopy.

Conclusion: This study provides evidence that the use of steroid-releasing stents are effective in treating patients with chronic frontal sinusitis that are refractory to surgical or medical management.

INTRODUCTION

Frontal sinus eluting stents have emerged as a unique minimally invasive way to dilate and promote patency of the sinuses. Ideally, a mucosal preserving technique should be used when operating on these sinuses. If frontal sinus mucosa is stripped and instrumented, formation of synchia and scar tissue will result potentially leading to iatrogenic frontal sinusitis requiring more invasive revision surgery.

In order to preserve sinonasal mucosa, several devices have recently been introduced in the market including bioabsorbable steroid-releasing implants and drug eluting stents. A recent study by Murr et al demonstrated safety and efficacy of a steroid-impregnated sinus implant that is bioabsorbable and directly releases steroid in a sustained manner into the ethmoido-cavernous space. It was also found to reduce inflammation, polyph formation and synchie. The MicroFlow Spacer System is also another minimally invasive stent that has been introduced for usage within the ethmoid sinuses with an option for targeted local delivery of pharmaceutical agents.

Although frontal stents have been available over the past decade there is limited data on this type of treatment. Current drug eluting stents for the frontal sinuses are only Food and Drug Administration (FDA) approved to elute saline. The only steroid eluting stent available, that is FDA approved, is indicated for the ethmoid and not the frontal sinus. To investigate frontal sinus steroid elution, a retrospective review of patients with frontal sinusitis undergoing balloon dilation with stent placement using a steroid solution was performed at Georgetown University Hospital.

RESULTS

Fifteen patients underwent stent placement of the frontal ostium after revision sinus surgery. Three patients were excluded from the study because of short follow-up periods (2 - 4 months). A total of twenty patients were included in the study, and a total of 29 ostia were treated with drug eluting frontal sinus stents. The patients had a mean age of 53 years (range 23 - 79) and included twelve women and eight men. The mean number of sinus surgeries prior to stent placement was 2 (range 1 - 5). One patient had stenting of the right frontal sinus tract twice given evidence of scarring after placement of the first stent.

Post stenting follow-up occurred at a mean of 18 months (range 7 - 30). At follow-up, 33 out of 34 frontal ostia maintained patency, for a rate of 94%. Of the 33 ostia that remained patent, 10 ostia in 5 patients received triamcinolone injections to retain patent.

One frontal outflow tract in one patient closed requiring revision using balloon dilation and subsequent injection with the previously described steroid solution. On further follow-up this patient had a patent nasofrontal outflow tract. Two ostia in two patients required in office marsupialization of cysts near the nasofrontal outflow tract. Subsequent injection using the aforementioned steroid solution was also given. Both patients demonstrated patency nasofrontal outflow tracts on follow-up examination. A complication in one patient developed with a retained stent in the left ostia. This patient was taken back to the operating room with removal of the stent and reinsertion of a new one. On follow-up exam, the nasofrontal outflow tract remained patent. Persistence of facial pain and pressure was found in 15% of patients (3 of 20) at follow-up. Nasal congestion was found in 20% of patients (4 of 20). Finally, persistent hyposmia was noted in five percent of patients (1 of 20).

METHODS AND MATERIALS

After obtaining Institutional Board Review approval, a retrospective review of all patients undergoing revision frontal sinus surgery with a drug eluting frontal sinus stent between May 2009 and December of 2010 was performed. Patients with less than 7 months of postoperative follow-up were excluded from the review. All, but eight patients had previously failed endoscopic sinus surgery. All procedures involved primarily the frontal recess with minimal dissection of the outflow tract prior to stent placement.

The MicroFlow Spacer and Deployment Guide were the two components used. The MicroFlow Spacer is a membrane reservoir that surrounds a catheter shaft with several hundred precision-formed micropores that permit slow seepage of the instilled therapeutic agent in the frontal sinus outflow tract. The MicroFlow Spacer has a one-way valve that prevents backflow and a set of flexible retention wings to secure the device within the frontal sinus outflow tract. The frontal sinus stent was removed in the office three weeks after surgery. Frontal ostium patency was evaluated after removal by 45 degree rigid endoscopy. To preserve patency, patients with persistent mucosal edema or polypoid changes at the frontal ostium were treated with steroid injection using a mixture of one half 1% lidocaine with epinephrine 1:100,000 and one half triamcinolone acetonide 40mg/mL.

DISCUSSION

Failure of frontal endoscopic sinus surgery due to stenosis is a difficult and challenging problem. David Kennedy has found that stenosis develops in 11.9% of patients when frontal sinus dissection is performed. Over the past 25 years, a variety of stents have been introduced to ensure patency of the frontal sinus outflow tract after sinus surgery. Topical steroids have been shown to enhance early frontal sinus mucosalization, reduce swelling of the frontal sinus ostia and reduce granulation, adhesions & synchie formation. It has been demonstrated that bioabsorbable steroid eluting sinus implants for the ethmoid sinus are safe and effective in reducing adhesion formation and inflammation. Although studies have been conducted looking at the use of frontal sinus stents and topical steroid usage in treatment of frontal sinus disease no study has looked at the use of the combination of both. The MicroFlow Spacer leads to reduction in scar formation within the frontal sinus outflow tract by sustained release of steroid over a three-week period. In our small group of patients, improvement of both subjective facial pain and pressure as well as evidence of patency was shown.

CONCLUSIONS

Our retrospective review of patients undergoing revision frontal sinus recess dissection using balloon dilation and a steroid eluting stent demonstrated a post operative patency rate of 94% with one year follow up. Although, our patient numbers are small, this finding is encouraging. Further studies on a larger number of patients using a randomized double blind method will be necessary to confirm these results but appear to be well worth the effort.

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REFERENCES