A Pilot, Open-label Study to Assess the Safety and Performance of a Maxillary Sinus Ostium Self-Dilation Device

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Abstract

Objective: To determine the safety and feasibility of a Maxillary Sinus Ostium (MSO) self-dilating expansion device in human subjects.

Methods: Chronic Rhinosinusitis (CRS) patients presenting with maxillary sinus inflammation requiring FESS were enrolled. The device was inserted at the start of surgery and removed after 60 minutes. Endoscopic evaluation for patency was performed immediately after removal, at 6 days, 1 month, and 3 months postoperatively. Adverse events were recorded at each visit.

Results: Twelve patients (n=19 MSO) were treated in this series. 17 (94%) devices remained inserted for 60 minutes and achieved a mean dilation to 4.8 ± 0.5mm. No adverse events occurred during insertion or removal of the device. Presently 14 MSO have been evaluated at 3 months post insertion of which 13 (93%) have been confirmed patent.

Conclusion: Placement of a novel osmotic self-dilating expansion device in human subjects is safe, achievable and effective.

Background

The maxillary sinus ostium (MSO) is commonly obstructed in patients suffering from Chronic Rhinosinusitis (CRS) and surgery may be required to re-establish drainage and enhance mucosal clearance. Recently, a novel osmotic self-dilating expansion device, Vent-Os™ Sinus Dilation System (Sinusys, Palo Alto, CA), has been developed for use in the office to expand sinonasal ostia without surgical resection. The device can be placed in the MSO under endoscopic visualization and is able to slowly enlarge its outer diameter to a predetermined dimension (Figure 1). The device functions on the principle of osmosis, imbibing a small amount of fluid from the surrounding tissues. Slow, low-pressure dilation of the maxillary sinus ostia has the potential to limit tissue damage and reduce the risk of scarring. This device has demonstrated successful placement and dilation of sinonasal ostia in an ovine model. We set out to establish the safety and feasibility of inserting this device in human subjects under general anaesthetic.

Methods

Open-label, prospective study conducted at St. Paul’s Sinus Centre, Vancouver, with approval from the University of British Columbia’s ethics review board.

Inclusion criteria: CRS patients with chronic maxillary sinusitis, between the ages of 18 and 75, for whom Endoscopic Sinus Surgery (ESS) is planned, were enrolled into the study.

Exclusion criteria: Patients with the following diagnoses: cystic fibrosis, aspirin sensitivity, nasal polyposis, sinonasal tumors, allergic fungal sinusitis. Any anatomic abnormality that precludes access to the maxillary sinus ostium (e.g. deviated septum). Previous middle-meatal antrostomy.

Eligible patients had a dilation device placed in one or both MSO under endoscopic visualization at the beginning of the surgery. ESS was performed as required, however, an uncinectomy and middle meatal antrostomy was not performed on the side a device had been placed. The device remained in the MSO for 1 hour and were removed before the end of the surgery. Endoscopic evaluation for patency was performed immediately after removal in the operating room, at 6 days, 1 month, and 3 months postoperatively. Adverse events were recorded at each visit.

Results

Pre-op CT

Pre-insertion (L)

Insertion of device (L)

Device in position (L)

Immediately post-removal of device (L)

3 months post-op (L)

12 patients were enrolled in the study (6 female, 6 male) with a mean age of 49. In total, devices were inserted into 18 MSO. 1 patient withdrew from the study.

17 (94%) devices remained inserted for 60 minutes and achieved a mean dilation to 4.8 ± 0.5mm. One device was dislodged during FESS prior to the 60 minute target time but was successfully retrieved by the surgeon.

Light bleeding during placement was reported in 12 (67%) cases. No adverse events occurred during insertion or removal of the device.

Presently 10 patients (14 MSOs) have been evaluated at 3 months post insertion and 13 MSO have been confirmed patent on endoscopy (93%).

Discussion

Placement of a novel osmotic self-dilating expansion device in human MSO is safe, technically achievable and preliminary results would suggest effective at maintaining MSO patency at 3 months following insertion.

There were no significant complications as a result of placing or removing these devices, or in the post-operative period.

Further studies are required to confirm long-term patency of the MSO following use of the device. Also, studies are underway looking into the feasibility of placement of the device in the office under local anesthesia.

References


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