**Effect of Hemostatic Agent MPH® on Bleeding after Endoscopic Sinus Surgery: A Prospective Randomized Controlled Study**

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**ABSTRACT**

**OBJECTIVES:** Absorbable hemostatic agents are commonly used after endoscopic sinus surgery (ESS). MPH® (Microporous Polysaccharide Hemospheres) is a novel hemostatic powder that is rapidly absorbed. The goal of this study was to examine the effects of MPH on bleeding after ESS.

**STUDY DESIGN:** Prospective blinded randomized controlled study.

**METHODS:** Patients undergoing bilateral ESS for CRS by the same surgeon were randomized to treatment with MPH or placebo. The side that received treatment and a control were assigned as a control. All patients received standard postoperative management. Patients completed symptom diaries using visual analogue scales (VAS, scored out of 100) at baseline and through postoperative day (POD) 7. Outcomes including bleeding, pain, obstruction, and nasal discharge were recorded for left and right sides.

**RESULTS:** Forty patients (19 men, 21 women) with an average age of 48.6 yrs were included. There were no complications and all patients were discharged home the same day. The mean bleeding score on POD 1 for MPH-treated sides was 22.5 versus 39.0 for untreated controls (mean difference 16.5, p<0.0001, 95% CI 23.2 to 9.7). The scores for bleeding at baseline and all other post-treatment days were not significantly different (p>0.05). There were no other significant differences between MPH-treated and control sides in any of the other variables measured throughout the study period.

**CONCLUSION:** Application of MPH significantly reduces bleeding in the immediate postoperative period following ESS.

**INTRODUCTION**

At the conclusion of endoscopic sinus surgery (ESS), important issues include assuring postoperative hemostasis and preventing adherence formation in critical areas. Historically non-absorbable nasal packs were used. However, these are uncomfortable for the patient and reopen the wound during removal. A recent review found that both absorbable and non-absorbable packs were ineffective in the prevention of adhesion formation following sinus surgery. Controlled studies have clearly demonstrated that patients have a strong preference for absorbable packs. Due to their excellent hemostatic properties and superior patient comfort, a number of bioabsorbable agents have been developed and are routinely used after ESS. These materials differ substantially in their mechanisms of action, composition, method of delivery, and clearance profiles. Recently, concerns over the use of long-lasting bioabsorbables have been raised in response to studies demonstrating that these agents may interfere with normal mucosal healing and contribute to granulation and adhesion formation. Microporous Polysaccharide Hemospheres (MPH), commercially available as Arista® and Hemadex™, Medafor, Inc., Minneapolis, MN is a novel and rapidly cleared absorbable hemostatic powder. Importantly, MPH does not impact healing or intact sinus mucosa in animals. Acting as a ‘molecular sponge’ by osmotically extracting fluids from blood, MPH particle conjugate platelets and other elements promoting the formation of a fibrin clot. Unlike most agents which are derived from animal products, MPH is made from purified potato starch and is hypalergenic with no inherent risk of disease transmission. It comes in a ready to use container and does not require any preparation (燃料). Previous studies in other specialties have established its hemostatic properties. Although MPH was FDA-approved for use in Otolaryngology in 2005, its use in our practice was previously described. In this non-randomized, uncontrolled study, we reported our initial experience with the safety of this product in human sinuses.

**PURPOSE**

To examine the efficacy of MPH in reducing bleeding after sinus surgery and explore the impact of this substance on other sinonasal symptoms during the early recovery period.

**MATERIALS AND METHODS**

**PATIENT SELECTION**

The study population consisted of 40 patients undergoing unilateral symmetrical ESS by the senior author (RS) for medically refractory CRS with or without polyps. Patients were enrolled consecutively into this prospective, randomized, controlled, blinded study. Patients with massive nasal polyps, sinonasal neoplasia, personal history of bleeding disorders or use of anticoagulants were excluded. Patients that required septotomy or any unusual surgical approaches were also excluded. Approval from the Saint Louis University Institutional Review Board was obtained.

**OUTCOME MEASURES**

Patient-centered outcomes of this study were evaluated using a standardized symptom diary created to track symptoms experienced from the left and right sides of the nose following surgery. Questionnaires using visual analogue scales (VAS, scored from 0 to 100) were completed pre-operatively as baseline and as an post-operative day (POD) 1, 7, 14, and 30.

**RESULTS**

Patients were pre-op Harvard CT stage T3 or T4. 40% of cases used surgical navigation and 45% were revision procedures.

The mean bleeding score on POD 1 for the MPH treated sides was 22.5 versus 39.0 for untreated controls (mean difference 16.5, p<0.0001, 95% CI 23.2 to 9.7). The scores for bleeding at baseline and all other post-treatment days were not significantly different (p>0.05, Graph 1).

**CONCLUSION:** Although the risk of significant hemorrhage following ESS is small, some degree of epistaxis is encountered postoperatively when no packing is used. The extent of bleeding that is expected following ESS has been shown to be significantly underestimated by patients. This ‘nuisance bleeding’ can be alarming and may negatively impact the patient’s sense of overall recovery.

**MPH was found to be highly effective in reducing the amount of bleeding experienced during the early recovery period. Since MPH is quickly cleared, it follows that the hemostatic effects of this agent are pronounced for only a few days after application, which is when most post-operative bleeding occurs.** The rapid absorption kinetics and composition of MPH also explain why this material does not interfere with the mucosal regeneration and wound healing.

The ‘no treatment’ control used in this study permits comparison to what the patient would otherwise have experienced as ‘normal recovery’ from surgery. A noteworthy finding was that the use of MPH did not significantly alter the pain, obstruction, or discharge that patients experienced following ESS. There were no differences in MPH treated versus untreated sides at any time point for these symptoms. These sinonasal symptoms were studied to more thoroughly explore the impact of MPH. A substance which occupies the middle meatus for a variable length of time could potentially contribute to a number of sinonasal complaints during the recovery period. The effects of bioabsorbables on sinonasal symptoms (other than bleeding) have not been routinely reported in other investigations.

Our findings reinforce studies which have demonstrated that MPH is effective at significantly decreasing symptoms of CRS. This study is limited by its relatively small sample size and reliance on patient self-reporting of symptoms. It is possible that patients may not be able to reliably differentiate between the left versus right side of a particular symptom, although this was clearly not an issue with our primary endpoint of bleeding.

**REFERENCES**