Efficacy and Safety of Microporous Polysaccharide Hemospheres (Arista Powder) in 155 Nasal Surgery Patients

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Abstract

This is a prospective analysis of microporous polysaccharide hemospheres (Arista Powder) to prevent postoperative bleeding and avoid intranasal packing in 155 patients undergoing nasal septal and/or sinus surgery (211 total procedures). All patients were adults with no history of hemostatic defects. All patients were followed for a minimum of six weeks after surgical intervention. Outcome measures evaluated were postoperative bleeding requiring secondary intervention, obstructive synechiae formation, postoperative infections, allergic reactions, and intolerance to this medication. Patient acceptance and nursing staff evaluation of postoperative bleeding were noted. All patients in our study tolerated this hemostatic agent well without complication. Only one patient required placement of a rhino rocket for a persistent unilateral postoperative oozing. None of our patients experienced any obstructing synechiae, allergic reactions, or intolerance to the medication. In conclusion, microporous polysaccharide hemospheres offer a safe, cost-effective, highly efficacious hemostatic alternative to traditional nasal dressing materials. This material is biologically reabsorbed within 48 hours after application and does not create obstructive scarring or fibrosis in the nose. It is approved for human surgical use by the FDA and is simple to administer. It is also extremely cost-effective.

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Introduction

Microporous polysaccharide hemospheres (Arista Powder) is a new hemostatic agent used for intraoperative and postoperative bleeding control. It has shown great efficacy in vascular surgery, cardiac surgery, orthopedic surgery, urological surgery, and in the treatment of trauma. This study is a prospective analysis of Arista usage in nasal surgery. The goal in this study was demonstration of efficacy in intranasal bleeding control, safety of usage, and evaluation for potential complications of use. With efficacy previously demonstrated in other areas of the human body the hypothesis of this study was to confirm similar actions and safety in the human nose. Being an FDA approved agent this was designed as a prospective observational study rather than a placebo-controlled study. No patients with known bleeding disorders or coagulopathy were included in the study. All patients were sequentially enrolled and there were no exclusions for any reason in our study group. All of our patients reached or exceeded the six week follow-up required for completion of the study.

Methods and Materials

155 patients undergoing nasal surgery were prospectively accrued. All patients were treated with microporous polysaccharide hemospheres (MPH) to control postoperative bleeding. Patients were followed for a minimum of 6 weeks postoperatively. Patient tolerance, allergic reactions, postoperative bleeding requiring secondary intervention, obstructive synechial formation, septal hematoma, and nursing impressions of postoperative course were evaluated. No external funding was accepted for this study.

Results

All patients completed minimum 6 weeks follow-up. No patient intolerance was noted. No allergic reactions were encountered. One patient undergoing septal reconstruction required a unilateral nasal pack 3 days postop with persistent oozing from her hemitransfixion incision. No other patients required any treatment for postoperative bleeding. All patients did well with no secondary intervention for obstructive synechiae. No septal hematomas occurred. Universal improvement in patient satisfaction and decreased postoperative bleeding was noted by nursing personnel.

Discussion

Microporous polysaccharide hemospheres (Arista Powder) is a recent addition to our pharmacological armamentarium for postsurgical hemostasis. It is a derivative of the potato starch molecule and is biochemically engineered to form concentric microscopic spherical balls. When introduced into a bleeding wound they absorb serum coagulation factors and attract platelets. The concentration of serum clotting factors and the structure of the spheres allow for rapid formation of highly stable clots thus reducing bleeding time from wounds[1]. Following administration they are rapidly metabolized over several days by the body and leave no residue or antigenic traces to induce fibrosis or synechiae. Originally developed for use in vascular surgery and trauma, this novel material has been used in a wide variety of surgical procedures with promising results[2]. It is approved by the FDA for human surgical usage and the only contraindication for usage is a known allergy to potatoes. Previous bench research has established safety and efficacy in the rabbit sinus mucosal model[3]. In this study comparing FloSeal, MPH, and control treated animals the MPH showed no fibrosis and mucosal regeneration was identical to controls. Animals treated with FloSeal had significant ciliary loss, inflammation, and fibrosis. In a separate study MPH did not inhibit bone formation when compared to bone wax in human surgery[4]. MPH has also been shown to be safe for use in a rat neurosurgical model[5]. This study compared MPH, Surgicel, FloSeal, and Avitene. Residual MPH material was not seen at day 14 in any animals. 100% of the Avitene, FloSeal, and Surgicel treated animals had residual material in their surgical sites. More importantly, Avitene and FloSeal demonstrated a propensity to form granulomata whereas MPH and Surgicel did not. In human study after sinus surgery MPH has also shown excellent control of bleeding with no side effects and a significant decrease in postoperative bleeding[6]. In this series MPH (Arista) provided excellent surgical hemostasis. Nursing and physician observations confirmed a dramatic decrease in bleeding compared to traditional packing materials. There were no allergic reactions or intolerance noted in any patients. One patient after septal reconstruction had minor oozing treated with a rhino rocket. No other patients needed additional treatment for bleeding. At 6 week follow-up there were no obstructive synechiae noted. The cost of Arista is also significantly less than other intranasal absorbable dressing and packing materials.

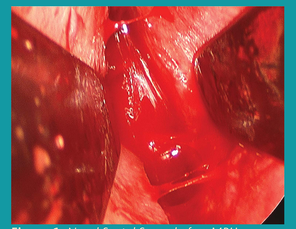


Figure 1. *Nasal Septal Space before MPH*

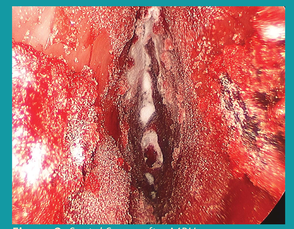


Figure 2. *Septal Space after MPH*

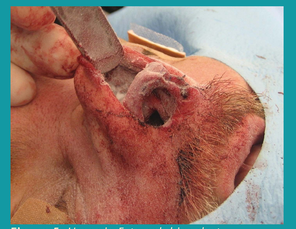


Figure 5. *Usage in External rhinoplasty*

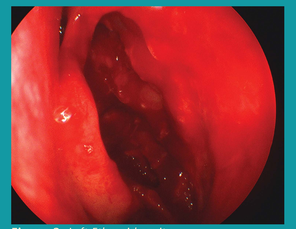


Figure 3. *Left Ethmoid cavity*

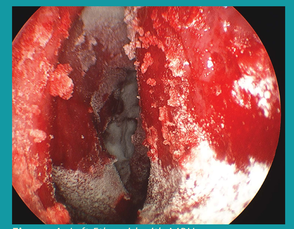


Figure 4. *Left Ethmoid with MPH*

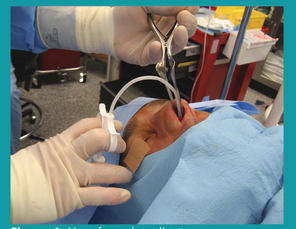


Figure 6. *Use of nasal applicator*

Conclusions

MPH (Arista Powder) is an excellent alternative to traditional intranasal products for postoperative surgical hemostasis. It is cost effective with no allergies, drug reactions, or significant synechiae noted in this study. Patient comfort is enhanced and hemostasis is excellent. It is FDA approved for control of intraoperative and postsurgical bleeding in humans with rapid reabsorption, no fibrosis, and minimal risk for adverse reactions. Its ease of use, patient tolerance, lack of patient tissue reactivity, and hemostatic qualities make it an excellent choice as a dissolvable postsurgical nasal dressing material.

References

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