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

P. Perry Phillips, M.D. • Aurora Sheboygan Clinic, Aurora Health Care

Abstract

This is a prospective analysis of microporous polysaccharide hemospheres (Arista Powder) to prevent postoperative nasal bleeding in 155 patients undergoing nasal septal surgery. 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 ooze from her hematoma incision. No other patients required any treatment for postoperative bleeding. All patients did well with no necessity for intervention for obstructive synchia. No septal hematomas occurred. Universal improvement in patient satisfaction and decreased postoperative bleeding was noted by nursing personnel.

Introduction

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 surgical wound they absorb serum coagulation factors and attract platelets. The rapid formation of stable clots reduces bleeding time from wounds. 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. 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. 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. MPH has also been shown to be safe for use in a rat neurosurgical model. 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. 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 absorbable dressing and packing materials.

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 synchiae 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 ooze from her hematoma incision. No other patients required any treatment for postoperative bleeding. All patients did well with no necessity for intervention for obstructive synchia. 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 surgical wound they absorb serum coagulation factors and attract platelets. The rapid formation of stable clots reduces bleeding time from wounds. Following administration they are rapidly metabolized over several days by the body and leave no residue or antigenic traces to induce fibrosis or synchia. 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. 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. 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. MPH has also been shown to be safe for use in a rat neurosurgical model. 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. 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 synchiae noted. The cost of Arista is also significantly less than other intranasal absorbable dressing and packing materials.

Conclusions

MPH (Arista Powder) is an excellent alternative to traditional intranasal products for postsurgical hemostasis. It is cost effective with no allergies, drug reactions, or significant synchiae 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 resorption, no fibrin, and minimal risk for adverse reactions. Its ease of use, patient tolerance, lack of patient tissue necrotiy, and hemostatic qualities make it an excellent choice as a dissolvable postsurgical nasal dressing material.

Contact

P. Perry Phillips, M.D. • Aurora Sheboygan Clinic
E-mail: Perry.Phillips@aurora.org
Phone: 920-457-4661 ext. 1571
Website: Aurora Health Care

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