Effectiveness of a New Fibrin Dressing Compared to Gelfoam® in a Corpectomy Model

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INTRODUCTION

Blood loss associated with vertebral resection can be high, and is associated with increased morbidity and mortality. Strategies such as hypotensive anesthesia and tranexamic acid are used systemically, but local hemostatic agents are not effective. We tested the hypothesis that a new fibrin dressing that effectively controls arterial hemorrhage is more effective than Gelfoam® at controlling blood loss in a corpectomy model.

METHODS

Six adult, female, domestic pigs weighing 55-85 kg were used. The number of animals was chosen to be kept at a minimum and yet allow the study to be powered to provide meaningful data, and in accordance with FDA guidelines to assess non-inferiority. The animals were maintained in an FDA approved facility and criteria outlined in the Guide for the Care and Use of Laboratory Animals was followed. Following induction of anesthesia, a ventral retroperitoneal approach to the lumbar spine was made. The great vessels were mobilized by ligating and dividing the segmental vessels. Four vertebrae were exposed in each animal, and the disc spaces cranial and caudal to each vertebra were completely excised. An oscillating saw was used to make oblique cuts from the mid-portion of the body to either the postero-superior or the postero-interior corners of the body. The remaining wedge of bone was used for the study. Following the creation of the bone injury, animals were randomized to receive either a control or test dressing, and the dressing was applied for 3 minutes. The dressing was then removed, and the cut surface was observed for bleeding for 2 minutes. If bleeding was observed the surgeon applied a second dressing with moderate manual pressure for 3 minutes. At the conclusion of that period the surface was again observed for bleeding. The procedure was repeated until a maximum of 8 spinal injuries per animal were made and treated. The primary endpoint measure was the proportion of samples achieving hemostasis within 4 minutes. The two groups (control and test) were compared using a repeated measures logistic regression model. The secondary endpoint measure was whether or not a second dressing application was required. In addition, blood samples (CBC, chemistry profile, coagulation profile) were obtained before and after the surgery. Representative sections were obtained for histopathological analysis.

RESULTS

Of 38 injuries created and treated, 2 were not included in the analysis due to misapplication of the dressing. Of the remaining 36 injuries, 18 were treated with the control dressing and 18 were treated with the test dressing. The odds of achieving hemostasis within 4 minutes was 0.02 times lower with Gelfoam®-treated injuries (95% CI: 0.00-0.31) compared with that for the test dressing-treated injuries (see table).

	Success Rate						
Parameter	**TEST dressing % (n/N)**	**Gelfoam® % (n/N)**	**OR (95% CI)**	**Test**	**P-Value**	**Criteria for Success**	**Conclusion**
Hemostasis within 4 Minutes	88.9% (16/18)	11.1% (2/18)	0.02 (0.00, 0.31)	Non-Inferiority	0.004	Upper limit of 95% CI for odds ratio < 1.10	Non-Inferiority Achieved
				Superiority	0.006	Upper limit of 95% CI for odds ratio < 1.00	Superiority Achieved

After 3 minutes of dressing application and 2 minutes of observation, 11.1% (N-2/18) of the injuries treated with the test dressing and 94.4% (N-17/18) treated with Gelfoam® showed evidence of rebleeding. Overall, the recurrence of rebleeding was significantly lower ($p = 0.0002$) in the injuries treated with the test article. No significant abnormalities were noted in the blood studies. Necropsy and histopathological analysis showed no residual foreign material at the injury sites treated with the test dressing.

DISCUSSION

The test article, a new fibrin dressing, was significantly more efficacious at controlling bleeding in this corpectomy model. The dressing comprises lyophilized human thrombin and fibrinogen embedded in a matrix of solid electrospun dextran nanofibers. The dressing provides initial hemostasis by tamponade, but as blood saturates the dressing, the dextran dissolves, which allows the solubilization of thrombin and fibrinogen. These interact for form a fibrin clot that seals the injury. This dressing has been shown to control hemorrhage in a lethal arterial injury in coagulopathic swine. Additionally, the test dressing leaves no residual foreign material such as other local hemostatic agents, such as bone wax or xenographic collagen.

SIGNIFICANCE

This new fibrin dressing is effective at controlling hemorrhage in a variety of tissues, and may be useful in orthopedic procedures that involve cancellous bone bleeding, such as vertebral resection. It has the added advantage of leaving behind no residual foreign material that could elicit an inflammatory or foreign body response.