Evaluation of a Novel Hemostatic Patch (Veriset™) for Use on Actively Bleeding Anastomoses in a Porcine CABG Model

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Purpose of Study
Achieving hemostasis during surgical procedures is a common challenge across all surgical specialties. The rapid control of intraoperative bleeding is imperative in order to retain visualization of the surgical site and to avoid potential injury.1 Friable target vessels and perioperative coagulopathy have made bleeding from vascular anastomoses an increasingly challenging problem during cardiac surgery. Veriset™ is a polyethylene glycol and oxidized cellulose hemostatic patch that is capable of creating rapid hemostasis at actively bleeding sites. The Veriset™ Hemostatic Patch is a resorbable topical hemostatic device intended for use in surgical procedures as an adjunct to hemostasis when conventional methods are ineffective or impractical. Veriset™ is comprised of oxidized cellulose impregnated with buffer salts, Trilysine, and a reactive polyethylene glycol (PEG).

The purpose of this study was to assess the safety and effectiveness of the Veriset™ Hemostatic Patch after application to a bleeding coronary artery bypass graft (CABG) anastomosis.

Material & Methods
Domestic swine (n=24) weighing 30 to 40 kg underwent end-to-side anastomosis between the left internal thoracic artery (LITA) and left anterior descending (LAD) coronary artery. All animals received intraoperative heparin to maintain an activated clotting time greater than 300 seconds. In addition, oral antiplatelet therapy consisting of aspirin (81 mg/day) and clopidogrel (75 mg/day) was administered throughout the study. Target treatment sites were manipulated so that bleeding was approximately equivalent (oozing to moderate blood flow) prior to treatment with Surgicel™ Nu-Knit™ absorbable hemostat (Ethicon, Somerville, NJ) or the Veriset™ Hemostatic Patch (Covidien, Bedford, MA). The Veriset™ Hemostatic Patch was cut to a 2 cm x 2 cm dimension then the interior was cut in a “star” configuration using a #11 scalpel blade and template.

Efficacy of treatment was quantified by: 1) the time to achieve complete hemostasis, 2) total blood loss after initiating treatment, and 3) the need to apply additional hemostat material. The safety of applying Veriset™ around an anastomosis was assessed via intergroup comparisons of histopathology at 28 and 84 days as well as contrast angiography serially performed at 1, 7, 14, and 28 days to determine anastomosis patency and diameter. Six animals in each group underwent further angiography at 56 and 84 days. Discrete variables were analyzed for significance using 2-sample t-Test.

Results
Complete hemostasis was achieved for Veriset™ in 91.9 ± 19.0 seconds and for Surgicel™ Nu-Knit™ in 343.2 ± 105.7 seconds (mean ± standard error). This difference was statistically significant as determined by 2-sample t-Test (p=0.037). Blood loss from the anastomosis sites was less with Veriset™ versus Surgicel™ Nu-Knit™ (1.81 ± 0.56 g versus 4.93 ± 1.82 g, respectively). Twelve of the 12 sites treated with the Veriset™ Hemostatic Patch achieved hemostasis with a single application of hemostat material, while 7 of the 12 sites treated with Surgicel™ Nu-Knit™ required a single application and the remaining 5 of 12 sites required multiple applications. Angiography showed patent vessel in all treatment groups and no appreciable distortion of the anastomoses at any time point. There were favorable healing characteristics with no thrombosis, full reendothelialization, no mural inflammation or degeneration, and expected degrees of adventitial and epicardial fibrosis in response to the surgical trauma. Histology confirmed full patency with no or slight neointima formation observed within each graft.

Conclusions
The application of Veriset™ Hemostatic Patch to coronary artery bypass graft anastomoses stopped active bleeding with a greater than two-fold reduction in blood loss and the time required to achieve full hemostasis compared to Surgicel™ Nu-Knit™. Evaluation of the safety of Veriset™ showed no short or long-term adverse effects on the treated anastomoses in terms of altered graft geometry or perivascular inflammation.

References

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