# Prospective randomized multicenter trial of fibrin sealant versus thrombin-soaked gelatin sponge for suture- or needle-hole bleeding from polytetrafluoroethylene femoral artery grafts.

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## Abstract:

Objective: We evaluated the safety and efficacy of the fibrin sealant Beriplast P (FSBP; Aventis-Behring) for hemostasis in anastomosis of polytetrafluoroethylene (PTFE) grafts to the femoral artery. Methods: In a single-blinded randomized prospective multicenter clinical trial, FSBP was compared with thrombin-soaked gelatin sponge (TSG) for efficacy in stopping bleeding from needle or suture holes in PTFE grafts after anastomosis to the femoral artery. Patients were randomized to FSBP application, which requires a 3-minute period of arterial clamping to enable the fibrin clot to adhere, or to TSG application, which requires pressure from gauze sponges, after completion of the femoral artery anastomosis. The primary end point was hemostasis, defined as absence of any detectable bleeding as judged by the operating surgeon, by 4 minutes after randomization. Secondary end points included actual time from randomization to hemostasis, time to beginning of wound closure, measured blood loss (weighed sponges), incidence of recurrent bleeding, stay in the intensive care unit, and hospital length of stay. Data were analyzed with the intention-to-treat method. Results: Two hundred thirty-five subjects were enrolled at 26 medical centers; 34 were subsequently excluded from the study. Of the 201 randomized subjects, 100 received FSBP and 99 received TSG. Hemostasis was achieved by 4 minutes in 64 subjects (63%) in the FSBP group and 40 subjects (40%) in the TSG group (P = .0018). In the FSBP group, compared with the TSG group, time to hemostasis was shorter (median, 4.0 minutes; 95% confidence interval [CI], 3.8-4.18 minutes vs median, 5.6 minutes, 95% CI, 4.5-7.0; P = .008), blood

loss was less (mean, 4.0 +/- 29.7 g vs mean, 15. 6 +/- 28.4 g; P < .0001), and time to wound closure was shorter (median, 15 minutes; 95% CI, 10.47-18.67 minutes vs median, 22.8 minutes; 95% CI, 18.67-30.67; P = .005). There were no differences in recurrent bleeding or any other adverse events. There was no significant difference in ICU stay, but hospital length of stay was shorter in the FSBP group compared with the TSG group, and the difference approached significance (median, 6.5 days; 95% CI, 5.00-7.00 days vs median, 7.0 days; 95% CI, 6.00-8.00 days; P = .0565). Conclusion: FSBP is more effective than TSG for achieving hemostasis of needle or suture hole bleeding from PTFE femoral artery grafts.