A prospective randomized study comparing fibrin sealant to manual compression for the treatment of anastomotic suture-hole bleeding in expanded polytetrafluoroethylene grafts.

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Publication Date: 2012

Abstract:

OBJECTIVE: The ideal hemostatic agent for treatment of suture-line bleeding at vascular anastomoses has not yet been established. This study evaluated whether the use of a fibrin sealant containing 500 IU/mL thrombin and synthetic aprotinin (FS; marketed in the United States under the name TISSEEL) is beneficial for treatment of challenging suture-line bleeding at vascular anastomoses of expanded polytetrafluoroethylene (ePTFE) grafts, including those further complicated by concomitant antiplatelet therapies.

METHODS: Over a 1-year period ending in 2010, ePTFE graft prostheses, including arterio-arterial bypasses and arteriovenous shunts, were placed in 140 patients who experienced suture-line bleeding that required treatment after completion of anastomotic suturing. Across 24 US study sites, 70 patients were randomized and treated with FS and 70 with manual compression (control). The primary end point was the proportion of patients who achieved hemostasis at the study suture line at 4 minutes after start of application of FS or positioning of surgical gauze pads onto the study suture line.

RESULTS: There was a statistically significant difference in the comparison of hemostasis rates at the study suture line at 4 minutes between FS (62.9%) and control (31.4%) patients ($P < .0001$), which was the primary end point. Similarly, hemostasis rates in the subgroup of patients on

antiplatelet therapies were 64.7% (FS group) and 28.2% (control group). When analyzed by bleeding severity, the hemostatic advantage of FS over control at 4 minutes was similar (27.8% absolute improvement for moderate bleeding vs 32.8% for severe bleeding). Logistic regression analysis (accounting for gender, age, intervention type, bleeding severity, blood pressure, heparin coating of ePTFE graft, and antiplatelet therapies) found a statistically significant treatment effect in the odds ratio (OR) of meeting the primary end point between treatment groups (OR, 6.73; $P < .0001$), as well as statistically significant effects for intervention type (OR, 0.25; $P = .0055$) and bleeding severity (OR, 2.59; $P = .0209$). The safety profile of FS was excellent as indicated by the lack of any related serious adverse events.

CONCLUSIONS: The findings from this phase 3 study confirmed that FS is safe and its efficacy is superior to manual compression for hemostasis in patients with peripheral vascular ePTFE grafts. The data also suggest that FS promotes hemostasis independently of the patient's own coagulation system, as shown in a representative population of patients with vascular disease under single- or dual-antiplatelet therapies.