Fibrin sealant improves hemostasis in peripheral vascular surgery: a randomized prospective trial.

Authors: Schenk WG 3rd, Burks SG, Gagne PJ, Kagan SA, Lawson JH, Spotnitz WD

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Abstract:

OBJECTIVE: To evaluate the efficacy and safety of an investigational fibrin sealant (FS) in a randomized prospective, partially blinded, controlled, multicenter trial.

SUMMARY BACKGROUND DATA: Upper extremity vascular access surgery using polytetrafluorethylene (PTFE) graft placement for dialysis was chosen as a reproducible, clinically relevant model for evaluating the usefulness of FS. The FS consisted of pooled human fibrinogen (60 mg/mL) and thrombin (500 NIH U/mL). Time to hemostasis was measured, and adverse events were monitored.

METHODS: Consenting adult patients (n = 48) undergoing placement of a standard PTFE graft were randomized in a 2:1:1 ratio to the treatment group using FS (ZLB Bioplasma AG, Bern, Switzerland), oxidized regenerated cellulose (Surgicel, Johnson & Johnson, New Brunswick, NJ), or pressure. Patients received heparin (3,000 IU IVP) before placement of vascular clamps. If the treatment was FS, clamps were left in place for 120 seconds after the application of study material to permit polymerization. If treatment was Surgicel, clamps were left in place until the agent had been applied according to manufacturer's instructions. If the treatment was pressure, clamps were released as soon as the investigator was ready to apply compression. Immediately after release of the last clamp, the arterial and venous suture lines were evaluated for bleeding. The time to hemostasis at both the venous and arterial sites was recorded.

RESULTS: Significant (P < or =.005) reduction in time to hemostasis was achieved in the FS group. Thirteen (54.2%) patients randomized to FS experienced immediate hemostasis at both suture lines following clamp removal compared to no patients using Surgicel or pressure. Only one patient (7.1%) in the Surgicel group and no patients in the pressure group experienced hemostasis at 120 seconds from clamp removal, compared to 13 (54.2%) patients for FS. Adverse events were comparable in all groups. There were no seroconversions.

CONCLUSIONS: FS achieved more rapid hemostasis than traditional techniques in this peripheral vascular procedure. FS use appeared to be safe for this procedure.