

Comparative study of the hemostatic efficacy of a new human fibrin sealant: is an antifibrinolytic agent necessary?.

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Abstract:

BACKGROUND: Sustained hemostasis by fibrin sealant (FS) is critically important when it is used in trauma surgery. To purportedly delay fibrin degradation and prevent premature hemostatic failure, some FS products added an antifibrinolytic agent (e.g., bovine aprotinin). The purpose of this study was to compare the overall hemostatic efficacy of a new inhibitor-free FS obtained from the American Red Cross (ARC-FS) to a clinically available aprotinin-containing FS preparation (Tisseel). The need for addition of an antifibrinolytic agent was assessed under normal and high-fibrinolytic conditions.

METHODS: The abdominal aortas of anesthetized rabbits were transected and anastomosed, end-to end, using only four interrupted sutures. The suture line was covered with approximately 2 mL of either type of FS and blood flow was restored. Blood loss was absorbed by gauze and measured. All rabbits were recovered and underwent histologic examination 4 weeks after operation. The efficacy of FS was also tested under a high-fibrinolytic state by treating the rabbits with human recombinant tissue plasminogen activator (0.15 mg/kg, 3-hour infusion). The investigators were blinded to the treatment groups.

RESULTS: The majority (11 of 12) of deaths occurred because of bleeding at the suture line within 7 days of surgery. Sustained hemostasis by FS (>1 week) was required for normal tissue healing and long-term survival of animals. Application of ARC-FS to the suture line produced immediate

hemostasis in 43% of animals (three of seven), with mean blood loss of 4.8 ± 1.8 mL, and 86% long-term survival. Tisseel application produced immediate hemostasis in 13% of animals (one of eight), with mean blood loss of 26.9 ± 7.0 mL ($p < 0.05$ vs. ARC-FS) and survival rate of 37% (three of eight). Under high-fibrinolytic conditions, ARC-FS produced immediate and complete hemostasis in seven of eight animals (88%), whereas the Tisseel demonstrated complete hemostasis in one of seven ($p < 0.01$). The ARC-FS rabbits had a blood loss of 1.9 ± 1.9 mL and survival rate of 75% (six of eight), whereas the Tisseel animals had a mean blood loss of 30 ± 6.0 mL and survival rate of 43% (three of seven) ($p < 0.01$). No detrimental effect on healing was noted with either product.

CONCLUSION: ARC-FS provides effective and secure hemostasis against high-pressure arterial bleeding under both normal and high-fibrinolytic conditions. Addition of an antifibrinolytic agent such as aprotinin is not required to sustain the hemostatic function of this fibrin sealant.