Comparison of a new fibrin sealant with standard topical hemostatic agents.

Authors: Schwartz M, Madariaga J, Hirose R, Shaver TR, Sher L, Chari R, Colonna JO 2nd, Heaton N, Mirza D, Adams R, Rees M, Lloyd D

Publication Date: 2004

Abstract:

BACKGROUND: Bleeding following liver resection continues to be a significant morbidity of the procedure. Fibrin sealants represent an improvement over conventional topical hemostatic agents, because they contain components that actively form clot. However, most available agents contain nonhuman protein, which represents an immunologic risk.

HYPOTHESIS: An investigational surgical fibrin sealant (Crosseal; American Red Cross, Washington, DC) composed of human clottable proteins and human thrombin is more effective than standard topical hemostatic agents in reducing the time required to achieve hemostasis after liver resection.

DESIGN: Prospective, randomized, controlled trial.

SETTING: Fifteen major referral centers in the United States and the United Kingdom.

METHODS: After liver resection using standard surgical techniques, 121 patients seen between May 1999 and May 2000 were randomized to treatment with a 2-component fibrin sealant (n=58) or to standard topical hemostatic agents, used singly or in combination (n=63). Up to 10 mL of Crosseal was administered by a spray applicator, as recommended by the manufacturer, whereas

agents used in the control group were applied according to their instructions for use.

MAIN OUTCOME MEASURES: The primary outcome measured was time to hemostasis. Secondary outcomes measured included blood loss between application of the hemostatic agent and closure of the abdomen, duration of postoperative biliary drainage, and the occurrence of complications, defined a priori as reoperation for any reason, development of abdominal fluid collections, or bilious appearance of drained fluid for at least 1 day postoperatively.

RESULTS: The mean time to hemostasis was 282 seconds with Crosseal, compared with 468 seconds with standard agents (2-sided; P =.06), for the 116 efficacy-evaluable patients. Hemostasis was achieved within 10 minutes in 53 patients (91.4%) treated with the study fibrin sealant and in 44 control patients (69.8%) (2-sided; P =.003). Intraoperative blood loss was similar in the 2 groups. In the Crosseal group, the percentage of patients developing postoperative complications was 17.2%, compared with 36.5% in the control group (2-sided; P =.02).

CONCLUSIONS: Compared with the use of standard topical hemostatic agents, Crosseal fibrin sealant significantly reduced the time to achieve hemostasis following liver resection. Patients treated with the new fibrin sealant also experienced significantly fewer postoperative complications.