Vivostat system autologous fibrin sealant: Preliminary study in elective coronary bypass grafting.

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Abstract:

Background. The Vivostat System is a medical device for the preparation of an autologous fibrin sealant from 120 mL of the patient's blood in the operating room. The system is fully automated and microprocessor controlled and is made up of three components: an automated processor unit, an automated applicator unit, and a disposable, single-patient-use unit, which includes a preparation set and a Spraypen applicator. The biochemical process is initiated by batroxobin, which acts upon the fibrinogen in the patient's plasma. The completion of the process depends entirely on endogenous thrombin in producing the sealant. Methods. Twenty-four volunteer patients undergoing elective primary coronary artery bypass grafting were randomized to either conventional hemostasis (control group) or the use of Vivostat fibrin sealant as an adjunct to conventional hemostasis. The patients were followed up at 1 month and 1 year. Results. The preparation process was completed in 30 minutes. No safety issues associated with the use of the sealant were identified. From 120 mL of the patient's blood the yield of fibrin sealant was 4.5 mL (range, 3.9 to 4.8 mL). There was a favorable trend toward lower amounts of chest tube drainage in the Vivostat group. In the Vivostat group, 1 of 11 patients (9%) required a perioperative transfusion and in the control group 3 of 12 patients (25%) required a perioperative transfusion. Conclusions. It is possible to prepare autologous fibrin sealant with the Vivostat system in 30 minutes. No exogenous thrombin is required. The sealant has no known adverse effects and may prove to be a useful adjunct to hemostasis in cardiothoracic surgery.