Safety and efficacy of a novel, dry powder fibrin sealant for hemostasis in hepatic resection.

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Abstract:

BACKGROUND/AIMS: Fibrocaps is a dry powder fibrin sealant containing human plasma-derived fibrinogen and thrombin. The safety, efficacy, and application methods for Fibrocaps were evaluated in an exploratory, first-in-human, noncomparative, clinical study.

METHODS: Patients with minor bleeding/oozing after elective partial hepatic resection had Fibrocaps applied to the bleeding site either directly from the vial or from a spray device, with manual pressure applied using a cellulose, collagen, or gelatin sponge, if needed. Safety was evaluated at screening and postoperative days 1, 2, and 5, and weeks 4 and 12. The formation of anti-thrombin antibodies was assessed at baseline, and after 4 and 12 weeks. Time to hemostasis (TTH) within 10 min was determined.

RESULTS: Twenty-nine patients were treated with Fibrocaps; 6 experienced serious adverse events that were not related to the course of treatment. Adverse events occurring in >10% of patients were nausea, constipation, hypotension, obstipation, hypokalemia, and postoperative pain. Most adverse events were mild or moderate in severity. No patient developed anti-thrombin antibodies. The percentage of patients who achieved hemostasis was 93%; the median TTH was 3.8 min (range 0.3-10.3). Manual pressure was applied with Fibrocaps in 19 patients and considered beneficial in most.

CONCLUSION: Fibrocaps was well tolerated in patients undergoing elective hepatic resection and resulted in rapid hemostasis. These safety and efficacy results support further clinical testing of this ready-to-use fibrin sealant as an adjunct to surgical hemostasis.