

Randomized trial of a dry-powder, fibrin sealant in vascular procedures.

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Publication Date: 2015

Abstract:

OBJECTIVE: Topical hemostats are important adjuncts for stopping surgical bleeding. The safety and efficacy of Fibrocaps, a dry-powder, fibrin sealant containing human plasma-derived thrombin and fibrinogen, was evaluated in patients undergoing vascular surgical procedures.

METHODS: In this single-blind trial ([clinicaltrials.gov: NCT01527357](https://clinicaltrials.gov/ct2/show/study/NCT01527357)), adult patients were randomized 2:1 to Fibrocaps plus gelatin sponge (Fibrocaps) vs gelatin sponge alone. Results are presented for the patient subset undergoing vascular procedures with suture hole bleeding. The primary efficacy endpoint compared time to hemostasis (TTH) over 5 minutes. Safety follow-up continued to day 29.

RESULTS: A total of 175 patients were randomized and treated (Fibrocaps, 117; gelatin sponge, 58). Patients were predominately male (69%) and underwent arterial bypass (81%), arteriovenous graft formation (9%), or carotid endarterectomy (9%). Fibrocaps significantly reduced TTH compared with gelatin sponge (hazard ratio [HR], 2.1; 95% confidence interval [CI], 1.5-3.1; median TTH, 2 minutes; 95% CI, 1.5-2.5 vs 4 minutes; 95% CI, 3.0-5.0; $P < .002$). Significant reductions were also observed in patients receiving concomitant antiplatelet agents alone (HR, 2.8; 95% CI, 1.0-7.4; $P = .03$; $n = 33$), anticoagulants alone (HR, 2.0; 95% CI, 1.0-4.0; $P = .04$; $n = 43$), or both antiplatelet agents and anticoagulants (Fibrocaps vs gelatin sponge, HR, 2.3; 95% CI, 1.2-4.3; $P = .008$; $n =$

65). Incidences of common adverse events (procedural pain, nausea, constipation) were generally comparable between treatment arms. Anti-thrombin antibodies developed in 2% of Fibrocaps-treated patients and no-gelatin-sponge patients.

CONCLUSIONS: Fibrocaps, a ready-to-use, dry-powder fibrin sealant, was well-tolerated and reduced TTH in patients undergoing vascular procedures, including those receiving antiplatelet agents and/or anticoagulants, demonstrating its safety and usefulness as an adjunct to hemostasis.

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