

The FINISH-3 trial: A phase 3, international, randomized, single-blind, controlled trial of topical fibrocaps in intraoperative surgical hemostasis.

Authors: Bochicchio G.V., Gupta N., Porte R.J., Renkens K.L., Pattyn P., Topal B., Troisi R.I., Muir W., Chetter I., Gillen D.L., Zuckerman L.A., Frohna P.A.

Publication Date: 2015

Abstract:

Background This Phase 3, international, randomized, single-blind, controlled trial (FINISH-3) compared the efficacy and safety of Fibrocaps, a ready-to-use, dry-powder fibrin sealant containing human plasma-derived thrombin and fibrinogen, vs gelatin sponge alone for use as a hemostat for surgical bleeding in 4 indications (ie, spinal, hepatic, vascular, soft tissue dissection).

Study Design Adults with mild to moderate surgical bleeding (randomized 2:1; Fibrocaps vs gelatin sponge) were treated at a single bleeding site (day 1). Time to hemostasis (TTH) during 5 minutes was compared (log-rank statistic) within each indication. Safety follow-up continued to day 29.

Results Patients were treated (Fibrocaps, n = 480; gelatin sponge, n = 239) when undergoing spinal (n = 183), vascular (n = 175), hepatic (n = 180), or soft-tissue (n = 181) procedures. Fibrocaps was applied by spray device in 53% of all procedures (94% of hepatic and soft-tissue procedures). Fibrocaps significantly reduced TTH compared with gelatin sponge; estimated hazard ratios were 3.3, 2.1, 2.3, and 3.4 for the 4 surgical indications, respectively (each $p < 0.001$; primary end point). Fibrocaps significantly reduced median TTH for each indication ($p < 0.001$) and was superior for secondary efficacy end points of restricted mean TTH ($p < 0.001$) and probability of hemostasis at 3 ($p < 0.001$) and 5 ($p \leq 0.002$) minutes. Adverse event incidences were generally similar between treatment arms. Non-neutralizing, anti-thrombin antibodies developed in 2% of Fibrocaps-treated and 3% of gelatin sponge-treated patients.

Conclusions Fibrocaps was well tolerated and significantly reduced TTH relative to gelatin sponge alone in all 4 surgical indications. These findings demonstrate the broad utility of Fibrocaps as a hemostatic agent for mild to moderate surgical bleeding.