

Randomized controlled multicenter trial on the effectiveness of the collagen hemostat Sangustop compared with a carrier-bound fibrin sealant during liver resection (ESSCALIVER study, NCT00918619).

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Abstract:

Background: Despite improvements in liver surgery over the past decades, hemostasis during hepatic resections remains challenging. This multicenter randomized study compares the hemostatic effect of a collagen hemostat vs. a carrier-bound fibrin sealant after hepatic resection.

Methods: Patients scheduled for elective liver resection were randomized intraoperatively to receive either the collagen hemostat (COLL) or the carrier-bound fibrin sealant (CBFS) for secondary hemostasis. The primary endpoint was the proportion of patients with hemostasis after 3 min. Secondary parameters were the proportions of patients with hemostasis after 5 and 10 min, the total time to hemostasis, and the complication rates during a 3 months follow-up period. Results: A total of 128 patients were included. In the COLL group, 53 out of 61 patients (86.9 %) achieved complete hemostasis within 3 min after application of the hemostat compared to 52 out of 65 patients (80.0 %) in the CBFS group. The 95 % confidence interval for this difference [-6.0 %, 19.8 %] does not include the lower noninferiority margin (-10 %). Thus, the COLL treatment can be regarded as noninferior to the comparator. The proportions of patients with hemostasis after 3, 5, and 10 min were not significantly different between the two study arms. Postoperative mortality and morbidity were similar in both treatment groups. Conclusion: The collagen hemostat is as effective as the carrier-bound fibrin sealant in obtaining secondary hemostasis during liver resection with a comparable complication rate. © 2014 The Author(s).