Hemostatic efficacy of latest generation fibrin sealant after hepatic resection; a randomized controlled clinical study.

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Abstract:

The objective of this randomized, controlled, multicenter study was to evaluate the hemostatic efficacy of latest generation fibrin sealant (FS) containing synthetic aprotinin as fibrinolysis inhibitor as supportive treatment to improve hemostasis in adult patients (>=18 years) undergoing partial hepatectomy involving resection of at least one anatomical liver segment. Subjects were randomized (1:1) to receive either FS or manual compression with a surgical gauze swab (MC) to control oozing from the cut liver surface persisting after primary hemostasis of major vessels had been achieved using sutures, ligations, clips, vascular staplers, point electrocautery or focal radiofrequency ablation. The primary endpoint, hemostasis at 4 minutes from the start of treatment application, was achieved in 82.9% (29/35) of FS-treated subjects compared to 37.1% (13/35) of subjects receiving MC ($p < 0.001$ in the likelihood ratio chi-squared test with a 5% two-sided significance level). In addition, significantly more FS-treated subjects achieved hemostasis at 6 (91.4% vs. 57.1%; $p < 0.001$), 8 (91.4% vs. 71.4%; $p = 0.028$), and 10 minutes (94.3% vs. 74.3%; $p = 0.017$). The number of intra and postoperative re-bleedings was small in both groups. Transfusion requirements and 48-hour drainage volumes were similar between FS and MC. (For categorical outcomes see Table 1.) This randomized, controlled, multicenter study demonstrated that FS is safe and its efficacy superior to MC for hemostasis in subjects undergoing hepatic resection. The use of synthetic aprotinin further improves the safety margin of FS by eliminating the risk of transmission of bovine spongiform encephalopathy and other bovine pathogens. (Table Presented).