

Fibrin sealant patch (TachoSil) vs oxidized regenerated cellulose patch (surgicel original) for the secondary treatment of local bleeding in patients undergoing hepatic resection: A randomized controlled trial.

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Abstract:

Background Local hemostatic agents are important for the control of bleeding during liver resection when standard surgical techniques are insufficient. Study Design This was a multicenter, randomized, open-label study to compare fibrin sealant patch (FSP; TachoSil; Takeda Pharma A/S) with oxidized regenerated cellulose gauze (ORCG; Surgicel Original; Ethicon) for the secondary treatment of local bleeding after hepatic resection in adult and pediatric patients. Primary end point was the proportion of adult patients with intraoperative hemostasis at the target bleeding site within 3 minutes of application of treatment. Results Of 321 adult patients screened, 224 patients had minor to moderate bleeding from the hepatic resection area after primary hemostatic treatment and were intraoperatively randomized to FSP (n = 114) or ORCG (n = 110). Hemostasis within 3 minutes was achieved in 92 patients in the FSP group (80.7%) and 55 patients in the ORCG group (50.0%) (odds ratio = 4.87; 95% CI, 2.55-9.29; $p < 0.001$). The proportion of patients with hemostasis at 5 minutes was also higher in the FSP group (94.7% vs 76.4%; odds ratio = 6.24; 95% CI, 2.39-16.30; $p < 0.001$), and time to hemostasis was shorter ($p < 0.001$). At 10 minutes, hemostasis was achieved in all patients in the FSP group and 12 patients in the ORCG group (10.9%) had visible bleeding and required hemostatic rescue therapy. In pediatric patients, hemostasis at 3 minutes was achieved in 17 of 20 (85.0%) patients with FSP and 4 of 9 (44.4%) patients with ORCG. Both treatments were well tolerated in adults and children. Conclusions The FSP (TachoSil) was safe and

superior to ORCG (Surgicel Original) for achieving hemostasis in patients undergoing hepatic resection. ClinicalTrials.gov ID NCT01192022.

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