A prospective, multi-center, randomized, single-blind study to compare the VerisetTM hemostatic patch to fibrin sealant (Tachosil) in subjects undergoing hepatic surgery.

Authors: Troisi R.I., Bektas H., Pratschke J., Topal B., Buchler M., Schuhmacher C.P., Buchler P.

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Abstract:

Introduction: Blood loss during hepatic surgery can be associated with unfavorable outcomes: prolonged hospitalization, increased morbidity and patient mortality. Currently, the available options to treat bleeding do not fully address the medical need. The VerisetTM Hemostatic Patch is a novel topical hemostat comprised of an absorbable backing with hydrogel components. VerisetTM is designed to achieve hemostasis quickly, adhere to tissues without fixation and be absorbed over time by the body. Methods: This study was a prospective randomized, EU multi-center, single-blind study, performed to compare the VerisetTM Hemostatic Patch (Investigational Device) to TachoSil (Control) for the management of diffuse bleeding after hepatic surgery. A total of 50 subjects at 6 centers were included in the study. Subjects underwent hepatic surgery according to the standard practices of each institution and randomized to either VerisetTM (G1) or TachoSil (G2), following confirmation of diffuse bleeding from the hepatic resection surface requiring the use of a topical hemostat. Post application of either device, time to hemostasis was assessed at preset intervals until hemostasis was achieved. Subjects were followed for 30 days post procedure. Results: Both groups were similar in comorbidities, use of the Pringle maneuver, type of resection and cutting techniques. The median time to hemostasis (mTTH) for G1 was 1.0 minute compared to 3.0 minutes for G2 ($p = 0.0001$). This result was independent of both the severity of bleed (minor vs. moderate) and area of the bleeding surface (<100 cm2 vs. >=100 cm2). In patients with moderate blood loss the mTTH for G1 was 1.0 minute compared to 3.0 minutes for G2 ($p = 0.0002$). For subjects with a

large bleeding area (>=100 cm2), the mTTH for G1 was 0.50 minutes compared to 3.75 minutes for G2 ($p = 0.007$). VerisetTM and TachoSil had similar safety profiles and no statistical differences were observed for adverse and device related events. Conclusion: Overall time to hemostasis was shorter with VerisetTM compared to TachoSil. This result was statistically significant and was independent of bleeding severity or bleeding surface area. Safety data generated in this study was similar between the two products. There were no statistical differences in the adverse event profile or other safety assessments at the 30-day follow-up visit. Overall, surgeons perceived VerisetTM to be easy to use, easy to apply and conformed to tissue.