A multicentre, randomized clinical trial comparing the VerisetTM haemostatic patch with fibrin sealant for the management of bleeding during hepatic surgery.

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Abstract:

Background: Bleeding during hepatic surgery is associated with prolonged hospitalization and increased morbidity and mortality. The VerisetTM haemostatic patch is a topical haemostat comprised of an absorbable backing made of oxidized cellulose and self-adhesive hydrogel components. It is designed to achieve haemostasis quickly and adhere to tissues without fixation. Methods: A prospective, randomized, multicentre, single-blinded study (n = 50) was performed to compare the use of a VerisetTM haemostatic patch with a fibrin sealant patch (TachoSil) (control) in the management of diffuse bleeding after hepatic surgery. Patients were randomized following the confirmation of diffuse bleeding requiring the use of a topical haemostat. Time to haemostasis was assessed at preset intervals until haemostasis was achieved. Results: Both groups were similar in comorbidities and procedural techniques. The median time to haemostasis in the group using the VerisetTM haemostatic patch was 1.0 min compared with 3.0 min in the control group (P 0.001; 3-min minimum application time for the control patch). This result was independent of bleeding severity and surface area. Both products had similar safety profiles and no statistical differences were observed in the occurrence of adverse or device-related events. Conclusions: Regardless of bleeding severity or surface area, the VerisetTM haemostatic patch achieved haemostasis in this setting significantly faster than the control device in patients undergoing hepatic resection. It was safe and easy to handle in open hepatic surgery.

Association.