A multicentre, prospective, randomized, controlled trial comparing EVARRESTTM fibrin sealant patch to standard of care in controlling bleeding following elective hepatectomy: anatomic versus non-anatomic resection.

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Publication Date: 2016

Abstract:

Background This multicentre, randomized clinical trial assessed the safety and effectiveness of the EVARRESTTM Fibrin Sealant Patch (FP) in treating parenchymal bleeding following anatomic and non-anatomic liver resections. Methods One hundred and two patients were stratified according to the type of hepatic resection (anatomic/non-anatomic), and randomized (1:1) after identification of an appropriate bleeding site, to FP vs Standard of Care (SoC, manual compression +/- topical haemostat). The primary endpoint was haemostasis at 4 min from bleeding site identification with no re-bleeding requiring re-treatment. Results The FP was superior in achieving haemostasis at 4 min (96%, 48/50) to SoC (46%, 24/52; $p < 0.001$). Stratification for resection type showed treatment differences for primary endpoint for anatomic (24/25 FP vs 13/23 SoC; $p = 0.001$) and non-anatomic liver resections (24/25FP vs 11/29 SoC; $p < 0.001$). Adverse events related to the study procedure were reported in 40/50 patients (80%) in the FP group and 43/52 patients (83%) in the SoC group. One (2%) adverse event (infected intra-abdominal fluid collection) was possibly related to study treatment. Conclusion This clinical trial confirms that the FP is safe and highly effective in controlling parenchymal bleeding following hepatectomy regardless of the type of resection. ClinicalTrials.gov NCT01993888.