Randomized clinical trial of tranexamic acid-free fibrin sealant during vascular surgical procedures.

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Abstract:

Background: This study evaluated the safety and haemostatic effectiveness of a fibrin sealant (EVICELTM Fibrin Sealant (Human)) during vascular surgery. Methods: This prospective randomized controlled trial compared the haemostatic effectiveness of fibrin sealant (75 patients) or manual compression (72) in polytetrafluoroethylene (PTFE) arterial anastomoses. The primary endpoint was the absence of bleeding at the anastomosis at 4 min after randomization. Secondary endpoints included haemostasis at 7 and 10 min, treatment failures and the incidence of complications potentially related to bleeding. Adverse events were recorded. Results: A higher percentage of patients who received fibrin sealant versus manual compression achieved haemostasis at 4 min (85 versus 39 per cent respectively; odds ratio 1134, 95 per cent confidence interval 467 to 2752; P < 0001). Similarly, a higher percentage of patients who received fibrin sealant achieved haemostasis at 7 and 10 min (both P < 0001). The incidence of treatment failure was lower in the fibrin sealant group (P < 0001). The rate of complications potentially related to bleeding was similar (P = 0426). Some 64 per cent of patients who received fibrin sealant experienced at least one adverse event, compared with 71 per cent who received manual compression. Conclusion: This fibrin sealant was safe, and significantly shortened the time to haemostasis in vascular procedures using PTFE. Registration number: NCT00154141 (http://www.clinicaltrials.gov).