Hemostatic effectiveness of Fibrin pad after partial nephrectomy in swine.

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Abstract:

BACKGROUND: Current management of severe surgical or traumatic bleeding is often achieved by manual tamponade or occlusion using devices such as tourniquets or ligatures. There are some clinical scenarios where these options are either marginally effective or impractical. The present study evaluates a new combination device (Fibrin pad) consisting of biologically active components (human thrombin and fibrinogen) delivered to the targeted site by an absorbable synthetic matrix (oxidized regenerated cellulose and polyglactin 910) in a swine severe bleeding model. In this model, severe bleeding can be managed by concurrent use of several currently available treatments, or a more convenient option that offers performance and safety advantages.

MATERIALS AND METHODS: Partial nephrectomies were performed on swine and treated with either Fibrin pad (FP) or conventional therapy (CTR)-temporary occlusion of renal artery, electrocautery, SURGIFLO, EVITHROM, SURGICEL NU-KNIT, and PDS II suture). After intraoperative hemostasis was confirmed, the animals were closed and recovered, then survived for 2, 14, or 56 d.

RESULTS: Hemostasis was achieved at surgery and maintained in all FP and CTR treated animals. FP was as effective as CTR at establishing durable hemostasis. Treatment with FP did not require temporary occlusion of the renal artery and decreased the total treatment time by half. No animals in

either group had complications related to postoperative bleeding at any time during the study. There was no evidence of pulmonary thrombi or evidence of thrombotic complications. No biologically significant adverse local tissue response was present in association with the Fibrin pad at any study interval, and no biologically relevant or consistent changes in blood parameters were identified.

CONCLUSIONS: Fibrin pad was as effective as CTR for the primary management of severe bleeding without occlusion of the renal artery and a shorter surgical time. No evidence of a systemic or local adverse response was identified due to exposure to the Fibrin pad.