

# **Hemostatic efficacy of fibrin sealant (human) on expanded polytetrafluoroethylene carotid patch angioplasty: A randomized clinical trial.**

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## **Abstract:**

Purpose: The efficacy of solvent-detergent-treated fibrin sealant (human [FSH]) for controlling anastomotic bleeding from expanded polytetrafluoroethylene (ePTFE) patch angioplasty during carotid endarterectomy was evaluated, and FSH was compared with thrombin-soaked gelatin sponge (Gelfoam; TSG). Methods: The study was of a randomized, open-label, single-site, single-treatment, parallel design that took place in a referral center with hospitalized patients. Forty-seven adult patients (33 men, 14 women) underwent elective carotid endarterectomy. Patients were randomized to receive either FSH (N = 24) or TSG (N = 23). FSH was obtained as an investigational new drug. FSH was applied as a liquid by means of a dual-syringe technique. Heparin anticoagulation, patch thickness, and suture type were standardized. Two different needle sizes were used (CV-6, PT-13: N = 21 [FSH: N = 10, TSG: N = 11]; CV-6, PT-9: N = 26 [FSH: N = 14, TSG: N = 13]). The FSH or TSG was applied to the ePTFE patch, and then blood flow was restored through the carotid artery. Degree of anticoagulation was assessed by anti-factor Xa activity. The time from restoration of carotid blood flow until achieving hemostasis was recorded. The blood loss from patch suture hole bleeding was measured. Completion intraoperative duplex ultrasound scanning was performed in all cases. Heparin was reversed with protamine sulfate. The primary end point was successful hemostasis within 15 minutes of restoration of carotid blood flow. The secondary end points were the amount of blood loss caused by suture line bleeding and the

time to achieve hemostasis. Results: There was no difference in the number of patients with complete hemostasis at 15 minutes (TSG, 13 of 23; FSH, 12 of 24;  $P = .77$ ). The measured blood loss was  $99.0 \pm 119.9$  (SD) mL for TSG, and  $105.0 \pm 107.9$  mL for FSH ( $P = .86$ ). The time to hemostasis was the same for both groups (TSG,  $16.5 \pm 16.5$  minutes; FSH,  $16.6 \pm 14.2$  minutes;  $P = .97$ ). Within both treatment groups, the use of larger needles (PT-13) was associated with greater blood loss (FSH,  $169.7 \pm 124.2$  mL; TSG,  $172.7 \pm 151.5$  mL) than was the use of smaller needles (PT-9; FSH,  $58.8 \pm 66.3$  mL; TSG,  $34.1 \pm 25.6$  mL;  $P = .036$ ,  $P = .001$ , respectively). There were no postoperative strokes or bleeding complications in either group. No abnormalities were shown in either group by means of completion carotid duplex ultrasound scanning. Conclusion: FSH was equivalent, but not superior to, TSG in achieving hemostasis during carotid endarterectomy performed with ePTFE patch angioplasty. Adhesion properties of FSH to ePTFE are possibly different than those to native tissue and warrant additional investigation.