Inguinal hernia repair in patients with coagulation problems: Prevention of postoperative bleeding with human fibrin glue

Silvestro Canonico, MD, Guido Sciaudone, MD, Fabio Pacifico, MD, *and* **Antonio Santoriello, MD,**
Naples, Italy

Background. *Our purpose was to establish the efficacy of human fibrin glue (HFG) in preventing coagulative complications after inguinal hernia repair in patients with coagulation disorders.*
Methods. *A randomized controlled trial of 50 patients with coagulation disorders undergoing hernia repair was performed. Patients had concurrent coagulopathies as a consequence of liver disease or long-term treatment with anticoagulants. Coagulopathies were defined according to the following criteria: prothrombin time <10.5 seconds, activated partial thromboplastin time <21 seconds, and fibrinogen <230 mg/dL. Patients were randomized in a 1:1 ratio with (group A) or without (control group B) use of HFG.*
Results. *Postoperative hemorrhagic complications were significantly reduced in group A (4%) compared with group B (24%).*
Conclusion. *This study shows that HFG is effective in preventing local hemorrhagic complications after herniorrhaphy in patients with concurrent coagulation disorders. This implies that the use of HFG reduces the costs of prolonged hospitalization related to such complications. (Surgery 1999;125:315-7.)*

From the Institute of General Surgery, School of Medicine, Second University of Naples, Naples, Italy

BECAUSE OF THE EVER-EXPANDING use of tension-free techniques and local anesthesia, inguinal hernia repair is now associated with a low incidence of local and general complications. Nevertheless, some complications related to bleeding and hemostasis, such as hematomas and wide ecchymoses, are still frequent, their incidence exceeding 4% in some studies.[1-11] There is no doubt that errors in technique with failure to identify and properly ligate vessels plays a significant role in preventing postoperative hematomas, but these often result from small vessel bleeding only after surgery, especially when local anesthetics contain epinephrine or when patients have coagulopathies.[10,11] Although hematomas and wide ecchymoses rarely cause serious sequelae, they alarm patients, delay their discharge, and increase costs. In a previous article[12] we reported that concurrent coagulopathies, primarily related to liver disease or anticoagulant therapy, were often associated with hemorrhagic complications after herniorrhaphy. The aim of this study was to establish the efficacy of human fibrin glue (HFG) in preventing the coagulative complications that can occur after inguinal hernia repair in patients with concurrent coagulation disorders.

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Reprint requests: Silvestro Canonico, MD, Via Messocannone 53, 80134 Naples, Italy.

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MATERIAL AND METHODS

A prospective, randomized, controlled trial was performed from January to December 1997. A total of 50 patients with coagulation disorders (age range 32 to 90 years, mean 47 years) were seen for primary inguinal hernia and were operated on according to Lichtenstein's technique, under local anesthesia, with use of Marlex mesh (CR Bard, Billerica, Mass). Coagulopathies were defined according to the following criteria: prothrombin time <10.5 seconds, activated partial thromboplastin time <21 seconds, and fibrinogen <230 mg/dL. These disorders were related to fatty liver (ultrasonographic diagnosis) in 26 patients (52%), to cirrhosis (clinical and histologic diagnosis) in 14 patients (28%), and to anticoagulant therapy for ischemic heart disease or cardiac rhythm disturbances in 10 patients (20%). Surgery was performed by 1 surgeon with advanced personal expe-

Table I. Hemorrhagic complications and patient characteristics

	A		B		
Cause of coagulopathy	*n*	*%*	*n*	*%*	*Statistical significance**
Cirrhosis	1/7	14.2	3/7	42.85	
Fatty liver	0/13	0	2/13	15.38	
Heart disease	0/5	0	1/5	20.0	
Total	1/25	4.0	6/25	24.0	$P = .049$

*Two-tailed Fisher test.

rience in hernia repair, and electrocautery was always used to minimize postoperative bleeding. The groin hernias were indirect in 42 patients (84%), direct in 6 (12%), and double (indirect and direct) in 2 (4%); no recurrent hernia was considered. The series consisted of 2 groups (25 patients each) of patients treated (group A) or not (group B) with HFG (Tissucol, Immuno AG, Vienna, Austria) by unrestricted randomization in a 1:1 ratio. The glue is aprotinin (3000 kallidinogenase inactivator units/mL) and lyophilized thrombin (500 units/mL) mixed during the operation to form fibrin and sprayed by a spraying device, allowing an even covering of all layers of the wound. All wounds were inspected by a blinded observer at days 1 and 7 after surgery to find hemorrhagic complications, defined as palpable hematomas or wide ecchymoses gravitating from the groin into the scrotum and the penis or into the lateral abdominal wall. A 6-month follow-up was planned to inspect for late complications resulting from the application of the fibrin glue. Statistical analysis was performed by Fisher test, and a 2-tailed *P* value of .05 was considered significant; the BMDP statistical SOLO software package was used for analysis.

RESULTS

No intraoperative complication occurred in any patient. Those in group A were discharged after 24 hours: no scrotal hematoma was observed; 1 ecchymosis (4%) occurred and subsided after 15 days, but the hospital stay was not prolonged (Table). In 6 patients from group B (24%), 2 hematomas and 4 wide ecchymoses occurred: there were 2 hematomas and 1 ecchymosis in patients with cirrhosis, 2 ecchymoses in patients with fatty liver, and 1 ecchymosis in a patient receiving anticoagulants for ischemic heart disease. In this case anticoagulant therapy was discontinued until the fifth postoperative day and coagulation parameters were assessed daily. One hematoma required surgical incision to drain the scrotal collection, but all 6 patients prolonged their hospitalization for medical therapy and complication assessment: a total hospital stay of 46 days was necessary for these patients. No sepsis or mesh rejection occurred in those with complications. The incidence of hemorrhagic complications was significantly reduced in group A ($P = .049$). At the 6-month follow-up no late complications from the application of HFG, such as scar immobility or fibrosis, occurred. Total costs were $23,000 US in the group B patients who had prolonged hospitalization; each day in our department costs $500. Total HFG cost was $5650 for group A patients.

DISCUSSION

The incidence of hemorrhagic complications after inguinal hernia surgery is up to 7.9%[7]; they are related to the type of hernia, to the surgical technique, or to the surgeon's experience. We found that concurrent coagulation disorders, particularly those from cirrhosis, are of particular relevance.[12] Over the last few years continued experience with HFG has been reported for various types of surgery.[13-18] A preliminary experience[19] reported the use of another sealant in tension-free inguinal hernia repair, but butyl-2-cyanoacrylate can clog mesh pores, promoting septic complications; conversely, HFG naturally coagulates and is reabsorbed without changing mesh characteristics. This study demonstrates that HFG significantly reduces the incidence of hemorrhagic complications after inguinal hernia operations in patients with concurrent coagulation disorders. In addition, the use of HFG is not expensive: prolonged hospitalization as a consequence of postoperative hemorrhagic complications is significantly reduced. Whether this approach is worthy of widespread use will depend on further study and evaluation.

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