Opinion

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The Role of Clinical Situations and Surgical Fields

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Description

Traditionally, children presenting with appendicitis are referred for urgent appendectomy. Recent improvements in the quality and availability of diagnostic imaging allow for better pre-operative characterization of appendicitis, including severity of inflammation; size of the appendix; and presence of extra-luminal inflammation, phlegmon, or abscess. These imaging advances, in conjunction with the availability of broad spectrum oral antibiotics, allow for the identification of a subset of patients with uncomplicated appendicitis that can be successfully treated with antibiotics alone. Recent studies demonstrated that antibiotics alone are a safe and efficacious treatment alternative for patents with uncomplicated appendicitis.

Fibrin Sealant

A sealant hemostat causes blood to clot while creating a barrier that prevents bleeding by polymerizing on its own. The intended benefits of Fibrin Sealant (FS) application are to support local hemostasis and sutures, stich surfaces of injured tissues to obtain adaptation or sealing of surfaces, or improve repair and healing. FS products may differ in their composition and are used in a variety of clinical situations and surgical fields, including but not limited to cardiac and vascular surgery, thoracic surgery, neurosurgery, plastic and reconstructive surgery, gastrointestinal surgery, hepatic and splenic surgery, and dental surgery. Human pooled plasma is one of the sources from FS hemostats are obtained. The efficacy as a hemostat in vascular surgery of liquid FS from pooled plasma has been demonstrated in several multicenter, prospective, randomized trials.

The primary efficacy end point was met by 76.1% of patients (83/109) for the FS Grifols group versus 22.8% of patients (13/57) for the MC group (P < .001). The cumulative proportion of patients at 5, 7, and 10 minutes was 80.7%, 84.4%, and 88.1%, respectively, in the FS Grifols treatment group, and 28.1%, 35.1%, and 45.6% in the MC treatment group. The median time to hemostasis was shorter in the FS Grifols group. The nature of AEs reported were those expected in the study patient profile. The percentage of patients experiencing treatment-emergent AEs was similar in both the FS Grifols and MC groups, most recurrent being procedural pain and pyrexia.

Fibrin Sealant Grifols is a two-component FS solution composed of purified sterile frozen solutions of human fibrinogen and human thrombin with calcium chloride that generates a cross-linked fibrin clot in a process that mimics the final steps of the physiological coagulation cascade. Following nonclinical studies that validated the safety and efficacy of FS Grifols in liver and vascular surgery in animal models, a clinical development plan was designed to assess the safety and efficacy of FS Grifols in the surgical setting as adjunct to local hemostasis.

Manual Compression

This study was a pivotal confirmatory phase III based on the design of a prior successful phase II/III study conducted to confirm that, after conventional surgical technique (suture), FS Grifols' application provides a measurable benefit in terms of proportion of patients achieving hemostasis at a given time point compared with standard hemostatic action, such as pressure through Manual Compression (MC).

Patients meeting eligibility criteria are offered a choice of non-operative management or appendectomy. Primary outcomes include determining the success rate of non-operative management and comparing differences in disability days, and secondarily, complication rates, quality of life, and healthcare satisfaction, between patients choosing non-operative management and those choosing appendectomy.

New formulations and applications of hemostatic adjuncts such as fibrin sealant (FS) to support local hemostasis and sutures continue to be developed. In a pivotal, confirmatory, controlled, prospective, single-blinded, randomized, multicenter phase III clinical trial, the efficacy and safety of FS Grifols during vascular surgeries were evaluated.

The objective of this study is to perform a multi-institutional trial to examine the effectiveness of non-operative management of uncomplicated pediatric appendicitis across a group of large children's hospitals. A prospective patient choice design was chosen to compare non-operative management to surgery in order to assess effectiveness in a broad population representative of clinical practice in which non-operative management is offered as an alternative to surgery. The risks and benefits of each treatment are very different and a “successful” treatment depends on which risks and benefits are most important to each patient and his/her family. The patient-

choice design allows for alignment of preferences with treatment.

Patients undergoing a nonemergency, open, peripheral vascular surgical procedure with moderate arterial bleeding were recruited. In an initial preliminary part of the study, all patients were treated with FS Grifols. In a subsequent primary part, patients were randomized (2:1) to FS Grifols or Manual Compression (MC). The primary efficacy end point was the proportion of the primary part patients achieving hemostasis by 4 minutes after the start of treatment. Cumulative proportion and time to hemostasis were secondary efficacy end points. Safety end points (in pooled preliminary and primary parts) included adverse events (AEs), vital signs, physical assessments, clinical laboratory tests, viral markers, and immunogenicity.