CLINICAL STUDY

Selective Arterial Embolization with Ethylene–Vinyl Alcohol Copolymer for Control of Massive Lower Gastrointestinal Bleeding: Feasibility and Initial Experience

José Urbano, MD, PhD, J. Manuel Cabrera, MD, Angeles Franco, MD, PhD, and Alberto Alonso-Burgos, MD, PhD

ABSTRACT

Purpose: To evaluate the efficacy, safety, and clinical outcomes of superselective embolization using ethylene–vinyl alcohol copolymer (Onyx Liquid Embolic System; ev3 Neurovascular, Irvine, California) as the primary treatment for acute and massive lower gastrointestinal bleeding (LGIB).

Materials and Methods: Between January 2008 and October 2013, all patients with focal massive LGIB who were treated by embolization were retrospectively analyzed. The study was approved by the hospital's ethics committee; informed consent was obtained in all cases. Onyx was chosen as the embolic agent in all cases in an intention-to-treat fashion. Embolization was indicated in 31 consecutive patients (mean age, 80 y ± 11.1). Multidetector computed tomography and digital subtraction angiography were performed in all patients.

Results: Active bleeding was detected in all cases. A colonoscopy was performed in 11 patients. The correlation between multidetector computed tomography and angiography findings was 96.7%. The causes of bleeding were diverticula in 15 patients, iatrogenic in 7 patients, neoplasia in 3 patients, hemorrhoids in 2 patients, angiodysplasia in 2 patients, and unknown in 2 patients. Embolization was not possible in one patient, who required urgent left hemicolectomy. The technical success rate was 93.5%. The embolic material refluxed in one patient, causing an undesired embolization, without any clinical consequences. In the 30 patients who received embolization, the immediate bleeding control rate was 100%. Rebleeding at 30 days occurred in three patients (10%). There were no major complications, intestinal ischemia, or deaths attributable to the treatment. No patient needed surgery or new embolization during a mean follow-up period of 23.7 months (range, 1–71 mo).

Conclusions: Control of massive LGIB using superselective embolization with Onyx is feasible and safe.

ABBREVIATIONS

DMSO = dimethyl sulfoxide, GI = gastrointestinal, LGIB = lower gastrointestinal bleeding

Embolization is currently proposed as the first step in the treatment of severe, acute, life-threatening lower gastrointestinal bleeding (LGIB) in cases in which the endoscopic approach is not possible or not useful (1,2). Emergency surgery of the lower gastrointestinal (GI) tract has a high morbidity rate and mortality of up to 20% (3). A meta-analysis showed that embolization yields results equal to or better than urgent surgery for LGIB (4). Transcatheter embolization has been used for the treatment of colonic diverticular bleeding since 1977 (5).

Embolization to treat LGIB has been performed with gelatin sponges; particles; coils and microcoils; and, more recently, glue (6–8). There are no guidelines for the choice of embolic material used, and the final decision is specific to each case. The most commonly used embolic material is 0.018-inch pushable microcoils. The efficacy of embolization depends on a combination of bleeding site occlusion, the patient's clot-forming

From the Vascular and Interventional Radiology (J.U., M.C., A.A.-B.), Jiménez Díaz Foundation University Hospital, c/ Jalón no. 11, 28221 Majadahonda, Madrid, Spain; and Cardiac and Abdominal Radiology (A.F.), Universidad Autonoma de Madrid, Madrid, Spain. Received November 29, 2013; final revision received February 16, 2014; accepted February 17, 2014. **Address correspondence to** J.U.; E-mail: jurbano@fjd.es

None of the authors have identified a conflict of interest.

ability, and local vasospasm. The main concern with embolic agents is rebleeding and the risk of secondary bowel ischemia (9,10).

Microcoils are a permanent embolic agent; the fibers of the coils induce clot formation. Gelatin sponge is a temporary embolic agent that also induces clot formation. The efficacy of both products is dependent on a normal coagulation status, and the rate of clinical failure after embolization is higher when the patient has coagulopathy (11). The efficacy of particles is also dependent on thrombosis rather than on the embolic material itself; the particles cannot be directly visualized or precisely deposited and may reflux into nontarget vessels (10). Glue has a high hemostasis effect with a low recurrent bleeding rate, but vascular glue penetration can be difficult to control and requires considerable experience (12).

Ethylene–vinyl alcohol copolymer (Onyx Liquid Embolic System; ev3 Neurovascular, Irvine, California) is a liquid embolic agent that has some theoretical advantages owing to its controlled delivery injection, nonadhesive nature, high radiopacity, and high hemostasis effect. In the present study, we evaluated the feasibility and initial clinical experience of emergency transcatheter arterial embolization with Onyx as the primary treatment of massive LGIB.

MATERIALS AND METHODS

We analyzed all patients with acute severe LGIB who underwent superselective arterial embolization between January 2008 and October 2013 in a single tertiary care, academic university hospital. This retrospective study was approved by the institutional ethics committee of our institution. Informed consent was obtained from each patient or a family member. The decision to treat with embolization was made by consensus among surgeons and gastroenterologists. Onyx was chosen as the embolic agent in all cases in an intention-to-treat fashion.

During the study period, 31 consecutive patients 41–93 years old with massive LGIB that was not controllable endoscopically underwent urgent visceral digital subtraction angiography. Patient characteristics are summarized in **Table 1**. The data were collected during the embolization procedure and from the electronic medical records. Clinically, the patients presented with rectal bleeding with fresh blood or with melena. None of the patients exhibited significant abdominal pain or evidence of peritonitis during the physical examination.

Massive LGIB was defined as an acute intestinal hemorrhage originating distal to the Treitz ligament with a transfusion requirement of $\geq$ 2 units of packed red blood cells after the initial episode, a transfusion requirement of $\geq$ 4 units of packed red blood cells in 24 hours, or signs of hemodynamic instability (hypotension, systolic blood pressure $<$ 90 mm Hg, tachycardia $>$ 120 beats/min). Minor LGIB was defined as a self-limited acute intestinal hemorrhage that did not need embolization or surgery (13,14). Primary treatment was defined as the first therapeutic approach. Embolization was chosen as the initial treatment in all patients in an intention-to-treat manner.

Table 1. Characteristics of 31 Consecutive Patients with Massive Lower Gastrointestinal Bleeding

Average age ± SD (y)	80 ± 11.1
Gender (male/female)	16/15
Patients presenting with rectal bleeding	19
Patients presenting with melena	12
Patients receiving anticoagulation treatment	10
Patients receiving antiplatelet treatment	7
Patients with INR $\geq$ 1.5 during procedure	4
Bleeding site in the colon	24
Bleeding site in the small bowel	7
Multidetector CT as initial diagnostic examination	31
Active bleeding on multidetector CT	30
Colonoscopy	11
Colonoscopy with intent to treat	3
Active bleeding on DSA	30
Median systolic BP just before the procedure ± SD (mm Hg)	100 ± 31
Mean hemoglobin ± SD (g/dL)	8.3 ± 1.6
Mean PRBC transfusions ± SD	5 ± 3
Patients who needed fresh plasma transfusions	9
Patients who needed platelet transfusions	2
Patients who had $>$ 1 comorbidity	16
Patients with high BP*	18
Patients with atrial fibrillation*	9
Patients with COPD*	5
Patients with coronary artery disease*	6
Patients with DM*	6
Patients with hematologic diseases*	2

BP = blood pressure; COPD = chronic obstructive pulmonary disease; CT = computed tomography; DM = diabetes mellitus; DSA = digital subtraction angiography; INR = international normalized ratio; PRBC = packed red blood cell.
*Patient comorbidities.

Bleeding Diagnosis

The causes and bleeding sites were investigated using multidetector computed tomography (CT) (Brilliance 64-slice CT; Philips, Eindhoven, The Netherlands, or SOMATOM Definition 128-slice CT TurboFlash; Siemens, Erlangen, Germany). Active bleeding was defined as the presence of active extravasation of contrast-enhanced blood, characterized as a hyperattenuating intraluminal focal collection, visible in the arterial and portal venous phase. Reformations in maximum intensity projections were done to perform noninvasive angiography and for tailoring the embolization procedure. The causes of bleeding and the bleeding arteries are listed in **Tables 2 and 3**.