Evaluation of GI bleeding after implantation of left ventricular assist device CME

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Background: Left ventricular assist devices (LVADs) have revolutionized the management of end-stage heart failure (ESHF). However, unexpectedly high rates of GI bleeding (GIB) have been described, and etiology and outcome remain unclear.

Objective: To determine the prevalence, etiology, and outcome of GIB in LVAD recipients.

Design: Retrospective case series.

Setting: Tertiary care academic university hospital.

Patients: 154 ESHF patients (55.4 years, 122 men/32 women) with LVADs implanted over a 10-year period.

Main outcome measurements: Overt or occult GIB prompting endoscopic evaluation ≥7 days after LVAD implantation.

Results: Over a mean of 0.9 ± 0.1 years of follow-up, 29 patients (19%) experienced 44 GIB episodes. Patients with GIB were older and received anticoagulation therapy before devices were implanted ($P \leq .02$ for each). GIB was overt (n = 31) rather than occult (n = 13), and most patients presented with melena (n = 22, 50%); hemodynamic instability was observed in 13.6%. Each bleeding episode required 2.1 ± 0.1 diagnostic or therapeutic procedures, and a source was localized in 71%. Upper endoscopy provided the highest diagnostic yield; peptic bleeding (n = 14) and vascular malformations (n = 8) dominated the findings. Endoscopy was safe and well tolerated. Overall mortality was 35%, none directly from GIB.

Limitation: Retrospective design.

Conclusions: Rates of GIB with LVADs are higher than that seen in other patient populations, including those receiving anticoagulation and antiplatelet therapy. GIB episodes are mostly overt and predominantly from the upper GI tract. Endoscopy is safe in the LVAD population. (Gastrointest Endosc 2012;75:973-9.)

Over 5 million people are affected by congestive heart failure (CHF) in the United States, with a quarter of these developing end-stage heart failure (ESHF).[1] Medical therapies have significantly reduced morbidity and mortality, but heart transplantation remains the criterion standard for management.[1,2] Given the large discrepancy between the demand for heart transplants and the supply of donor organs, mechanical circulatory support (ie, left ventricular assist devices [LVADs]) has evolved rapidly over the past 2 decades.[3-5] Overall survival after 1 year of LVAD support can be as high as 72%, more than twice that seen with optimal medical therapy.[4] The first-generation LVADs

Abbreviations: BTT, bridge to transplant; CHF, congestive heart failure; DT, destination therapy; ESHF, end-stage heart failure; GIB, GI bleeding; HM II, HeartMate II; ICU, intensive care unit; INR, international normalized ratio; IQR, interquartile range; LVAD, left ventricular assist device; NSAID, nonsteroidal anti-inflammatory drug; PPI, proton pump inhibitor; PUD, peptic ulcer disease; vWF, von Willebrand factor.

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were based on a pulsatile mechanism, compressed air driving a pump for pressure-driven flow. However, poor reliability, high rates of infection, and the need for extensive surgical dissection during implantation led to the development of continuous-flow LVADs, which are smaller, do not require a large drive line, and are more reliable than pulsatile LVADs.[6,7] Thromboembolic complications are countered by antithrombotic therapy, most commonly with a combination of aspirin and warfarin.[4]

The long-term implications of a lack of pulsatile blood flow on organ function are not well understood. Early animal studies showed that nonpulsatile blood flow adversely affected renal and hepatic perfusion, but limited studies after continuous-flow LVAD implantation suggest preservation and even improvement of hepatic and renal function.[8-11] Several investigators have recently reported rates of luminal GI bleeding (GIB) as high as 40% in patients after the implantation of continuous-flow LVADs.[12-18] These reports have left many unanswered questions regarding the risk factors for GIB during LVAD support, the role and safety of endoscopy, and outcomes in this population.

The aim of this retrospective study was to determine the prevalence, etiology, and outcome of GIB in patients receiving LVAD support and to assess the safety and efficacy of GI endoscopy in this population.

Take-home Message

- GI bleeding has a high prevalence in patients using left ventricular assist device (LVAD) support, but the overall outcome is good. An upper endoscopy should be the first test unless the presentation is clearly colonic bleeding.
- Proton pump inhibitors do not provide good prophylaxis, and alternative mucosal protection or coating agents may need to be studied. Endoscopy is safe and well tolerated by the LVAD population.

METHODS

Patients

Adult patients (>18 years old) who had undergone either HeartMate XVE (HM XVE, pulsatile flow) or HeartMate II (HM II, continuous flow) LVAD implantation (Thoratec, Pleasanton, CA) for ESHD over a 10-year period (2001-2010) were identified from our institutional database. Patients were excluded if they died in the operating room during LVAD implantation or if only a right ventricular assist device was placed. The review of clinical data for the purpose of this study was approved by the Institutional Review Board at Washington University School of Medicine.

LVAD implantation

The LVADs were implanted as a bridge to transplant (BTT) or as destination therapy (DT) in patients deemed not to be candidates for transplantation. From 2001 to May 2005, HM XVE, a pulsatile LVAD, was used exclusively. After the continuous-flow HM II became available, our institution transitioned to this device, which was used exclusively in the last 4 years of the study period.

All patients received anticoagulant therapy postoperatively with unfractionated heparin or bivalirudin, and later transitioned to oral warfarin, with a goal international normalized ratio (INR) of 2 to 3. Aspirin at a dosage of 81 to 325 mg was used universally. Clopidogrel, dipyridamole, or both were added at the discretion of the attending cardiologist and cardiac surgeon in selected patients. All patients received maintenance therapy with intravenous proton pump inhibitor (PPI) until they were transferred out of the intensive care unit (ICU), after which further PPI administration was at the discretion of the treating cardiologist and cardiac surgeon.

GI bleeding

For the purpose of this study, GIB was defined as (1) the development of *overt bleeding* from the upper or lower GI tract as reported by treating or emergency room physicians or (2) *occult bleeding*, with a ≥2 g/dL drop in hemoglobin from recorded baseline values and hemoccult-positive stool with no alternative explanation for anemia. Bleeding events within 7 days after LVAD implantation were deemed procedure related and were excluded. GIB was classified as early (within 8-30 days after LVAD implantation) or late (>30 days). In patients with multiple GIB events, a new episode of GIB was defined as bleeding >30 days from the initial event. A potential source of bleeding on endoscopy was defined as a lesion in the luminal GI tract with stigmata or recent bleeding (active bleeding, adherent clot, nonbleeding visible vessel, pigmented material at lesion base) in patients with overt bleeding, or any luminal GI tract lesion known to cause blood loss in patients with occult bleeding. Hemodynamic instability was defined as clinically significant end-organ hypoperfusion requiring emergent blood transfusion, vasopressor support, or both.

Endoscopy

All endoscopic procedures were performed in the inpatient endoscopy suite or ICU. Conscious sedation (fentanyl, midazolam) or monitored anesthesia (including propofol) was administered at the discretion of the endoscopist and consulting anesthesiologist, and no set protocol was in place for choosing one method over the other. Heart rate, pulse oximetry, and LVAD flow parameters were monitored at frequent intervals during the procedure. When endoscopic therapy was required for control of bleeding, injection (1:10,000 epinephrine), thermal therapy (bipolar or monopolar electrocautery, argon plasma laser), or mechanical therapy with hemostatic clips was used. Video capsule endos-