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Use of a novel endoscopic suturing device to treat recalcitrant marginal ulceration (with video)

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Roux-en-Y gastric bypass is a common treatment for morbid obesity, and marginal ulceration is a relatively frequent complication, occurring in up to 16% of patients.¹

DISCLOSURE: C. Thompson is a consultant for Apollo Endosurgery and a consultant for and grant recipient of Olympus. Apollo Endosurgery supplied all prototype devices. No other financial relationships relevant to this publication were disclosed.



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http://dx.doi.org/10.1016/j.gie.2012.03.681

Received September 6, 2011. Accepted March 20, 2012.

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Most marginal ulcerations occur between 2 and 6 months postoperatively, with 95% occurring within 12 months.^{2,3} Etiologies for marginal ulceration often are multifactorial and may include the presence of a gastrogastric fistula, foreign material, tissue ischemia, acid production by the gastric pouch, diabetes, smoking, *Helicobacter pylori* infection, and the use of nonsteroidal anti-inflammatory drugs.⁴

Management of marginal ulceration is problematic because medical therapy may be inadequate, and surgical repair carries significant morbidity. One study reported an incidence of marginal ulceration in 7.6% of patients, despite patients being treated with prophylactic proton pump inhibitors postoperatively.⁵ On the other hand, surgical revision, which typically involves reconstruction of the gastrojejunostomy, carries significant morbidity and a 7.7% recurrence rate.⁶

Endoscopic suturing for marginal ulceration is a potential solution for those who fail medical therapy. In this article, we assess a single tertiary-care center's initial clinical experience with using a novel endoscopic suturing device to oversew marginal ulceration and report on technical feasibility, safety, and efficacy outcomes.

TABLE 1. Clinical profiles of patients who underwent marginal ulceration oversewing with a novel endoscopic suturing device

No.	Age/sex	Symptoms	Comorbidity	Interval from RYGB to oversewing, months	Ulcer size
1	71/M	Recurrent hemorrhage	CAD, PVD, DM, HTN, OSA, COPD	5	About 1/2 stomal circumference
2	38/M	Recurrent hemorrhage	HTN	29	>1/3 stomal circumference
3	38/F	Severe abdominal pain	DVT, Von Willebrand's disease	55	>1/3 stomal circumference

RYGB, Roux-en-Y gastric bypass; CAD, coronary artery disease; PVD, peripheral vascular disease; DM, diabetes mellitus; HTN, hypertension; OSA, obstructive sleep apnea; COPD, chronic obstructive pulmonary disease; DVT, deep vein thrombosis.

PATIENTS AND METHODS

Patients

Three patients (age range 38-71; 2 male) with chronic marginal ulceration underwent the suturing procedure after a detailed informed consent. All patients were referred by the surgical team after the patients had failed medical therapy with proton pump inhibitors and sucralfate and had been considered for surgical treatment. Presenting symptoms included recurring hemorrhage with transfusion dependency (n = 2) and severe pain with malnutrition requiring prolonged total parenteral nutrition (n = 1). Two of the 3 patients were deemed poor surgical candidates because of complicated medical histories that included coronary artery disease, peripheral vascular disease, diabetes mellitus, chronic obstructive pulmonary disease, obstructive sleep apnea, deep vein thrombosis, and von Willebrand's disease (Table 1). The interval from surgery to attempted endoscopic marginal ulceration repair ranged from 5 to 55 months.

The study was approved by the institutional review board. The outcomes measured were immediate technical success, number of sutures placed, procedure time, intraprocedural and postprocedural complications, symptoms at 6-week and 1-year follow-up periods, and endoscopic findings at 6-week follow-up.

Technique

Ulcer oversewing was performed by using a novel endoscopic suturing system that has general approval for tissue apposition in the GI tract (Overstitch Endoscopic Suturing System; Apollo Endosurgery, Austin, Tex). A Guardus overtube (US Endoscopy, Mentor, OH) was used in all cases in order to safely pass the device into the gastric pouch. The system attaches to a double-channel endoscope (GIF-2T160; Olympus America, Central Valley, Pa) and allows placement of a variety of stitch patterns with a single insertion of the endoscope. A curved suture arm extends from one of the channels, and an anchor exchange catheter extends from the other. When the handle is closed, the curved suture arm with attached needle is advanced through the tissue. The needle is then passed from the suture arm to the anchor exchange (Fig. 1). Interrupted

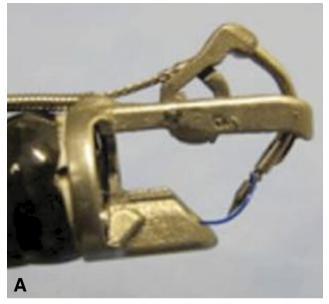




Figure 1. Overstitch endoscopic suturing system. **A,** A cap-based suturing system with the curved suture arm extending from one of the channels and the anchor exchange extending from the other. **B,** The handle of the suturing system attached to a double-channel endoscope.

stitches were placed in healthy tissue at the ulcer margin, proximally to distally, across the ulcer bed. The sutures were then tightened so that the ulcer bed folded onto itself (Video 1, available online at www.giejournal.org). Suturing was deemed technically successful when the ulcer bed was no longer visible. Tisseel fibrin glue (Fibrin Sealant;

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