Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Devices for the endoscopic treatment of hemorrhoids

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, performing a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature sof PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the Committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through February 2013 for relevant articles by using the key words "endoscopic treatment of hemorrhoids," "hemorrhoid therapy," "rubber band ligation," "infrared coagulation," "bipolar diathermy," "injection sclerotherapy," "Doppler guided laser photocoagulation," and "cryotherapy." Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

BACKGROUND

Hemorrhoids are pathologically dilated vascular sinusoids in the anal canal that can cause rectal bleeding, pruritus, and pain. The pathogenesis of hemorrhoids remains controversial; vascular congestion (eg, prolonged sitting, pregnancy) and mucosal prolapse (eg, caused by aging or constipation/straining) may play a role. The most widely accepted theory is that they result from destructive changes to the supporting connective tissue.[1] It has been estimated that more than 50% of adults greater than 50 years of age in the United States have experienced symptoms due to hemorrhoids.[2] Internal hemorrhoids are graded based on protrusion and reducibility (Table 1). External hemorrhoids are not graded. When medical treatment fails, most patients with symptomatic grade I, II, and III internal hemorrhoids may be treated with office-based procedures.[3] Surgical therapy is usually reserved for patients with larger grade IV hemorrhoids that may be refractory to medical therapy or office procedures.[4,5] This report provides an overview of equipment used in the endoscopic treatment of internal hemorrhoids.

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TECHNOLOGY UNDER REVIEW

Several techniques are available for nonsurgical treatment of hemorrhoids, all with the goal of causing fibrosis, retraction, and fixation of the hemorrhoidal cushions. These techniques include rubber band ligation (RBL), infrared coagulation (IRC), bipolar diathermy, laser photocoagulation, injection sclerotherapy, and cryotherapy. Nonsurgical treatment of hemorrhoids is generally done in the office or endoscopy suite. Patients are usually unsedated to allow for patient feedback from inadvertent treatment below the dentate line. Patients may be in the jackknife position or in the left lateral decubitus position with the right knee drawn up. No bowel preparation is required.

Rubber band ligation

Considered the most popular nonsurgical intervention in the treatment of grade I and II hemorrhoids, RBL can be performed with or without an endoscope.[6]

Endoscopic RBL. Endoscopic band ligation devices comprise a transparent plastic cap with preloaded bands that fits on the tip of an endoscope. Suction or forceps are used to capture and position the hemorrhoid before placement of a small-diameter circular band around the base of the tissue. A trip-wire or string runs from the cap to the endoscope handle via the accessory channel, and, when tightened by rotating a retracting spool fixed to the biopsy port, shortening of the string causes band deployment around the hemorrhoidal cushion.[7] Placement of the band causes ischemic necrosis, ulceration, and scarring, which result in fixation of the connective tissue

TABLE 1. Grading system for internal hemorrhoids

Grade	
I	Prominent hemorrhoidal vessels with bleeding, but without prolapse
II	Prolapse, reduces spontaneously
III	Prolapse, requiring manual reduction
IV	Prolapse, not reducible

Figure 1. Stiegman-Goff Bandito Ligator. Photo courtesy of ConMed Endoscopic Technologies.

to the rectal wall.[8] This technique is similar to the banding of esophageal varices, except that it is often performed in retroflexion. The only device specifically marketed for endoscopic band ligation of hemorrhoids is the Stiegmann-Goff Bandito Endoscopic Hemorrhoidal Ligator (ConMed Corp, Utica, NY), which fits on a 13- to 15-mm endoscope (Fig. 1). Standard endoscopic variceal band ligation devices have been used as well.[9-12]

RBL without an endoscope. The ShortShot Saeed Hemorrhoidal Multi-Band Ligator (Cook Medical, Winston-Salem, NC) is a single-use, disposable device designed for use with an anoscope. It is in the shape of a pistol, with a suction tubing port at the base of the handle (Fig. 2). The tip of the ligation device holds 4 preloaded bands and is placed through an anoscope to visualize internal hemorrhoids. Suction is activated by covering a vent on the anterior side of the handle with the index finger after the tip of the ligation device is placed on the hemorrhoid, taking care to remain just above the dentate line. The vessel is suctioned into the ligation device, and a wheel is turned using the thumb, leading to deployment of a band.

Figure 2. Shortshot™ Saeed Endoscopic Hemorrhoid Multi-band ligator. Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana.

The CRH O'Regan Disposable Hemorrhoid Banding System (CRH Medical Corp, Vancouver, BC, Canada) is a single-use device consisting of a plastic syringe with a band at its tip (Fig. 3). The plunger on the syringe is retracted to suction the hemorrhoid into the device, and the band pusher is moved forward to deploy the band.[13] The procedure can be performed with a slotted anoscope or by using a "blind" or "touch" technique.

The McGivney Hemorrhoidal Ligator (Miltex, York, Pa) is a stainless steel device advanced through an anoscope that applies latex or latex-free O-rings or bands directly to hemorrhoids with the aid of grasping forceps rather than suction (Fig. 4). The device has a compressible handle and a 7- or 10-inch long shaft that can be rotated to obtain the optimal angle for band placement. Under direct vision, the hemorrhoid is grasped with forceps and traction is applied. The ligator tip is approximated to the hemorrhoid, and the handle is squeezed, causing O-ring deployment. A new O-ring must be manually loaded to the tip of the device for each hemorrhoid treated.

Infrared coagulation

IRC uses direct application of heat to induce coagulation and fibrosis in the submucosal layer. The Precision Endoscopic Infrared Coagulator (Precision Endoscopic Technologies, Sturbridge, Mass) uses a single-use, 3.2-mm outer diameter, 300 cm long flexible fiberoptic probe that is passed through an endoscope channel. The distal tip of the probe is placed in contact with the hemorrhoid tissue, ideally at the pedicle of the hemorrhoid's 3, 7, and 11 o'clock positions, and short 1- to 5-second bursts of infrared radiation are delivered to by depressing a foot pedal.[14] The procedure can be performed at the time of sigmoidoscopy or colonoscopy in a retroflexed position and is approved by the U.S. Food and Drug Administration (FDA) for treatment of grade I, II, and III internal hemorrhoids.