

## Endoscopic banding devices

*The American Society for Gastrointestinal Endoscopy (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 with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (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 of 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, are 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 June 2007 for articles related to banding devices by using the keywords “banding,” “ligation,” and “band ligation” plus “tumor,” “polypectomy,” and “bleeding.” Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, safety, and socioeconomic aspects of these technologies.*

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### BACKGROUND

Esophageal and gastric variceal bleeding is a major source of morbidity and mortality in patients with portal hypertension from various causes, including end-stage liver disease and cirrhosis. Nearly 90% of patients with cirrhosis will develop esophageal varices sometime in their lifetime, of which 30% will bleed.<sup>1,2</sup> Once developed, varices will usually increase from small to large. An endoscopic variceal banding device was initially introduced in 1986.<sup>3</sup> Endoscopic band ligation is now established as standard therapy for the management of bleeding esophageal varices. The applications of endoscopic banding devices now include nonvariceal bleeding, hemorrhoid ligation, and EMR.<sup>4,5</sup>

### TECHNICAL CONSIDERATIONS

All band ligating devices use a means of capturing a lesion or mound of target tissue while a small-diameter circular band made of rubber, latex, or similar material is deployed around the base of the tissue to accomplish tight compression that leads to vascular compromise (or hemostasis) and subsequent thrombosis, necrosis, and sloughing. Both endoscopic and nonendoscopic ligating devices are available for use based on accessibility of the target tissue.

Several components are common to all endoscopic band ligating devices: a short transparent cylindrical cap that carries 1, 4, 5, 6, 7, or 10 stretched bands (depending on the specific ligator), which attaches via friction fitting of its back end to the leading end of the endoscope; a tripwire that runs from the cap through the accessory channel to the control handle; a control handle with a retracting spool that is fixed to the biopsy port for attachment and firing of the trip wire; and an irrigation adapter or catheter that allows irrigation of the accessory channel. All band ligators are designed for single use. Before use, the banding device must be assembled. Assembly instructions are similar but device specific.

A diagnostic endoscopy is commonly performed to evaluate the lesion or lesions before passage of the banding ligator. The endoscope is then withdrawn for attachment of the banding device. After reintubation, the target lesion is drawn into the cap with continuous suction until significant prolapse of tissue is achieved and then the band is deployed. For ligation of esophageal varices, the optimal technique involves initial application of

bands distally, followed by progressive proximal placement of a variable number of bands until all protruding varices are captured. Starting distally allows for complete visualization and avoids the potential risk of dislodging a band during advancement of the endoscope past a previously captured varix. During variceal-band ligation, transient bleeding can occur because of rupture of the varix. Band ligation may be repeated at 1-week to 4-week intervals until the varices are obliterated.

Endoscopic banding devices that are commercially available include single-band and multiband devices. The only single-band ligation device (Stiegmann-Goff Bandito; ConMed Corp, Utica, NY) uses an overtube for repeated intubation to facilitate placement of multiple bands. The multiband ligators include the Auto-band Ligator (Scandimed International, Glostrup, Denmark), the Speed-band Superview Super 7 Multiple Band Ligator (Boston Scientific Corp, Natick, Mass), and the Saeed Multi-band Ligator (Cook Endoscopy, Winston-Salem, NC). Multiband ligators do not require the placement of an overtube.

Esophageal band ligation cannot be performed in children who weigh less than 8 kg because of the size of the ligating tip and the need to use a standard-caliber endoscope. In these patients, sclerotherapy is a satisfactory alternative. For children who weigh between 8 and 10 kg, the single-band ligating device can usually be passed without the use of an overtube and without obstruction of the endoscopic view. The multiband ligation devices can be used in children more than 10 kg in weight.

## APPLICATIONS

The most common indication for endoscopic band ligation is for the prevention and treatment of esophageal variceal bleeding.<sup>4</sup> Banding can also be used for linear gastric varices on the most proximal portion of the lesser curve.<sup>6</sup>

Band ligation using direct rigid anoscopy was originally developed as a nonsurgical alternative for the treatment of hemorrhoids. More recently there have been reports on the use of endoscopic devices that are designed for esophageal variceal ligation.<sup>7,8</sup> This has led to the development of endoscopic devices designed for hemorrhoidal ligation. Other clinical applications of the endoscopic banding devices include treatment of postpolypectomy bleeding,<sup>9-11</sup> arteriovenous malformations,<sup>11,12</sup> Mallory-Weiss tears,<sup>13</sup> Dieulafoy's lesions,<sup>14,15</sup> blue rubber bleb nevus syndrome,<sup>16,17</sup> and diverticular bleeding.<sup>18</sup> Endoscopic mucosectomy by using a band ligation device with a snare has also been used for the removal of esophagogastric<sup>19-22</sup> and rectal tumors.<sup>23,24</sup>

## COMPARATIVE STUDIES

Multiple randomized controlled trials of therapy for acute esophageal variceal bleeding showed endoscopic band ligation to be superior to endoscopic sclerother-

apy.<sup>25-30</sup> For the primary prevention of esophageal variceal bleeding, endoscopic variceal ligation has been shown to be safer and possibly more effective than nonselective beta blockers (propranolol or nadolol).<sup>31-33</sup> In a meta-analysis of 8 randomized controlled trials that involved 596 patients, band ligation reduced the rate of the first variceal bleed by 43% compared with the beta-blocker group, although there was no effect on mortality.<sup>34</sup>

For secondary prevention of esophageal variceal bleeding, endoscopic ligation is shown to be preferable to sclerotherapy, by yielding faster reduction and obliteration of varices, and by requiring fewer procedures and a lower rate of complications and rebleeding before eradication.<sup>35</sup> In a randomized prospective trial that compared the multiband ligator with the conventional single-band ligator, the multiband device was associated with a significant reduction in sedation requirement, endoscopic time, and patient discomfort.<sup>25</sup>

The combination of endoscopic band ligation and sclerotherapy appears to offer no advantage over band ligation alone in the prevention of rebleeding and in a reduction in mortality, although combination therapy is associated with a higher complication rate of esophageal stricture.<sup>36,37</sup> Comparisons of transjugular intrahepatic portal systemic shunt (TIPS) to endoscopic band ligation showed no differences in mortality for up to 2 years.<sup>36-38</sup> TIPS is more effective than endoscopic band ligation for the prevention of variceal rebleeding; however, there is a considerable risk of hepatic encephalopathy.<sup>38-40</sup>

When compared with standard surgical techniques for hemorrhoidectomy, endoscopic band ligation has similar efficacy and complication rates.<sup>41</sup> Most studies reveal long-term success rates of 86% to 95% and may require fewer treatment sessions compared with band ligation using rigid surgical instruments.<sup>41-44</sup>

There are no prospective data or comparative studies that pertain to band ligation for the management of nonvariceal bleeding or for EMR. The data regarding band ligation for the management of nonvariceal bleeding conditions, such as post-polypectomy bleeding,<sup>9-11</sup> arteriovenous malformations,<sup>11,12</sup> Mallory-Weiss tears,<sup>13</sup> Dieulafoy's lesions,<sup>14,15</sup> blue rubber bleb nevus syndrome,<sup>16,17</sup> and diverticular bleeding,<sup>18</sup> are limited to case reports and nonrandomized prospective clinical studies. Similarly, the data for endoscopic mucosectomy when using the band ligation device is descriptive only.<sup>19-24</sup> Endoscopic mucosectomy with banding devices and purpose specific devices is reviewed in another technology report.<sup>45</sup>

## SAFETY

Common complications associated with banding devices include chest pain, bleeding, stricture formation, aspiration pneumonia, dysphagia, and perforation.<sup>37</sup> The

**TABLE 1. Variceal band ligators**

Manufacturer	ConMed (Utica, NY)	Scandimed International and ConMed	Boston Scientific	Cook Endoscopy
Name	Stiegmann-Goff and S-G ClearVue endoscopic ligators	Auto-Band Ligator multiple-band ligator	Speedband, SuperView Super 7 multiple band ligators*	4, 6, 10 Shooter Saeed multiband ligators
No. bands per cap	1	5, 7, 10	7	4, 6, 10
Endoscope tip diameter (mm)	9-11	8.6-11.5	8.6-11.5	8.5-9.2, 8.6-11.3, 9.5-11.5, 9.5-13, 11-14
Band color	Blue	Black	Blue	Black
Band material	Rubber	Latex-free rubber	Neoprene	Natural rubber latex
Costs	Stiegman-Goff† \$405 (5 preloaded bands), \$535 (10 preloaded bands); Stiegman-Goff "Clearvue" \$450 (5 preloaded bands), \$600 (10 preloaded bands)	\$220 (5 bands), \$325 (7 bands), \$370 (10 bands)	\$595 (2 kits/box); \$1190 (4 kits/box)	\$221 (4 bands), \$266 (6 bands), \$289 (10 bands)

\*Also approved for hemorrhoidal ligation.

†All prices are per box with 5 kits/box.

**TABLE 2. Hemorrhoid and mucosectomy ligators for flexible endoscopes**

Manufacturer	Scandimed International and ConMed	Cook Medical	Cook Medical
Name	Auto-Band Ligator- Colonic	ShortShot Saeed Hemorrhoidal Multi-Band Ligator	Duette Multi-Band Mucosectomy Kit
Application	Hemorrhoids	Hemorrhoids	Mucosectomy
No. bands	5	4	6
Endoscope type or size	11.5-14 mm	Integrated single-use TriView Anoscope	9.5-13 mm, or 11-14 mm
Components			Includes braided Hex-snare
Costs	\$160	\$50	\$295

incidence of these complications is very low.<sup>46</sup> Chest pain associated with band ligation is typically temporary in nature but may require intervention. Esophageal perforation secondary to ulcer formation or overtube placement has been reported. Anorectal pain and bleeding are common complications of hemorrhoidal banding, whereas acute thrombosis of external hemorrhoids and septic complications, eg, perianal abscess, are less common.<sup>43</sup>

Latex allergy is a commonly expressed concern pertaining to some banding devices. The U.S. Food and Drug Administration (FDA) mandates specific washing and leaching steps to reduce the presence of allergenic natural rubber latex proteins during the manufacture of medical products.<sup>47</sup> To date, no cases of death or serious allergic reactions after endoscopic placement of bands that contained natural latex rubber have been published in the literature.

Mortality because of endoscopic band ligation therapy has not been reported in the literature. A search of the FDA MAUDE database<sup>48</sup> for adverse events identified a number of deaths in patients treated with the Speedband SuperView Multiband Ligator between December 2000 to March 2001, primarily because of the failure of the bands to deploy, which prompted an FDA recall. There are also a number of reports of "device malfunction" in patients treated with the Rapidfire multiband ligators. In January 2002, there was an FDA Class I recall of the Rapidfire multiband ligation system because of inadequate chlorination of bands, which caused the bands to become adherent to each other and not deploy properly. The Rapidfire device is no longer marketed in the United States, but the Speedband Multiband Ligator has been remarketed.

## FINANCIAL CONSIDERATIONS

All commercially available band ligation devices are cleared by the FDA for single use only. The costs for each device vary by manufacturer and are listed in Table 1. The cost of the hemorrhoidal ligation devices for use with flexible endoscopy and the mucosectomy device are listed in Table 2.

The use of band ligation during the performance of an upper endoscopy can be billed by using the following Current Procedural Terminology (CPT)\* codes: 43205, Esophagoscopy, rigid or flexible with band ligation of esophageal varices; 43244, Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate, with band ligation of esophageal and/or gastric varices; 43251, Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate, with removal of tumor(s), polyp(s), or other lesion(s) by snare technique, in combination with unlisted code to reflect the banding portion of procedure 43999, Unlisted procedure, stomach. For internal hemorrhoid banding, use the code 46934, Destruction of internal hemorrhoids any method.

## SUMMARY

There is now a substantial body of data that suggests that endoscopic band ligation is a safe and effective treatment for both acute esophageal variceal bleeding and the prevention of bleeding. Use of band ligation in the management of a number of other bleeding and nonbleeding conditions also appears to be efficacious.

*Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CPT, Current Procedural Terminology; FDA, U.S. Food and Drug Administration; TIPS, transjugular intrahepatic portal systemic shunt.*

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