ORIGINAL ARTICLE

A prospective multicenter study using a new multiband mucosectomy device for endoscopic resection of early neoplasia in Barrett's esophagus

Roos E. Pouw, MD, PhD,[1] Torsten Beyna, MD, PhD,[2] Kamar Belghazi, MD,[1] Arjun D. Koch, MD, PhD,[3] Erik J. Schoon, MD, PhD,[4] Rehan Haidry, MD, PhD,[5] Bas L. Weusten, MD, PhD,[6] Raf Bisschops, MD, PhD,[7] Nicholas J. Shaheen, MD, PhD,[8] Michael B. Wallace, MD, PhD,[9] Norman Marcon, MD, PhD,[10] Rachel Heise-Ginsburg, MD, PhD,[2] Anniek W. Gotink, MD,[3] Kenneth K. Wang, MD, PhD,[11] Cadman L. Leggett, MD, PhD,[11] Jacobo Ortiz-Fernández-Sordo, MD, PhD,[12] Krish Ragunath, MD, PhD,[12] Massimiliano DiPietro, MD, PhD,[13] Oliver Pech, MD, PhD,[14] Horst Neuhaus, MD, PhD,[2] Jacques J. Bergman, MD, PhD[1]

Amsterdam, Rotterdam, Eindhoven, Nieuwegein, Netherlands; Düsseldorf, Regensburg, Germany; London, Nottingham, Cambridge, United Kingdom; Leuven, Belgium; Chapel Hill, North Carolina; Jacksonville, Florida; Rochester, Minnesota, USA; Toronto, Ontario, Canada

Background and Aims: Early neoplasia in Barrett's esophagus (BE) can be effectively and safely removed by endoscopic resection (ER) using multiband mucosectomy (MBM). This study aimed to document performance of a novel MBM device designed for improved visualization, easier passage of accessories, and better suction power compared with other marketed MBM devices.

Methods: This international, single-arm, prospective registry in 14 referral centers (Europe, 10; United States, 3; Canada, 1) included patients with early BE neoplasia scheduled for ER. The primary endpoint was successful ER defined as complete resection of the delineated area in 1 procedure. Secondary outcomes were adverse events and procedure time.

Results: A total of 332 lesions was included in 291 patients (248 men; mean age, 67 years [standard deviation, 9.6]). ER indication was high-grade dysplasia in 64%, early adenocarcinoma in 19%, lesion with low-grade dysplasia in 11%, and a lesion without definite histology in 6%. Successful ER was reached in 322 of 332 lesions (97%; 95% confidence interval [CI], 94.6%-98.4%). A perforation occurred in 3 of 332 procedures (.9%; 95% CI, .31%-2.62%), all were managed endoscopically, and patients were admitted with intravenous antibiotics during days 2, 3, and 9. Postprocedural bleeding requiring an intervention occurred in 5 of 332 resections (1.5%; 95% CI, .65%-3.48%). Dysphagia requiring dilatation occurred in 11 patients (3.8%; 95% CI, 2.1%-6.6%). Median procedure time was 16 minutes (interquartile range, 12.0-26.0).

Conclusions: In expert hands, the novel MBM device proved to be effective for resection of early neoplastic lesions in BE, with successful ER in 97% of procedures. Severe adverse events were rare and were effectively managed endoscopically or conservatively. (Clinical trial registration number: NCT02482701.) (Gastrointest Endosc 2018;■:1-7.)

(footnotes appear on last page of article)

Endoscopic resection (ER) is the treatment of choice for early neoplastic lesions in Barrett's esophagus (BE).[1] ER is not only a therapeutic tool to remove neoplastic lesions, it is also an important step in staging neoplasia because it provides adequate tissue specimens for accurate histologic diagnosis. Endoscopic treatment with ER has excellent long-term follow-up results reported for mucosal neoplasia in BE and more recently also for low-risk submucosal cancers.[2,3]

Currently, the most widely used ER technique for Barrett's neoplasia is multiband mucosectomy (MBM). This technique is based on variceal band ligation, but instead of banding varices, the esophageal mucosa is sucked into the cap and captured in a rubber band. The created pseudo-polyp can then be resected with a snare using electrocautery, and the resected specimen can be retrieved for histologic assessment. Because the rubber bands are not strong enough to hold the proper muscle layer, MBM is associated with a low risk of perforations even without prior submucosal lifting with fluids.[4-8] The Duette device (Cook Medical, Limerick, Ireland) has been available for MBM since 2005.[4] Most endoscopists performing ER

using the MBM technique for Barrett's neoplasia therefore have experience with this device. Studies have demonstrated that MBM using the Duette device is equally safe and effective but quicker and cheaper than the classic ER-cap technique, which requires submucosal lifting of the mucosa and prelooping of a snare in the cap to capture the mucosa.[6,7]

Recently, a new MBM device became available, the Captivator EMR device (Boston Scientific, Marlborough, Mass). Because of a different design of the cap and trigger wires, the Captivator device has some practical advantages. First, because the rubber bands are located more proximally onto the cap, the bands are not in the endoscopic view, improving intraprocedural visibility.[9] Second, the thin steel trigger wires of the Captivator device do not swell when in contact with fluids in the working channel of the endoscope, as the stringy trigger wires of the Duette device tend to do. In an experimental setup, this has been shown to result in easier passage of accessories through the working channel and more suction power.[9]

In a recent pre-esophagectomy study comparing both devices for ER of esophageal mucosa before scheduled esophagectomy, no significant difference was found in the diameters of resection specimens obtained with both MBM devices. That study also included a small prospective series of 5 patients undergoing MBM with the Captivator device, in which successful resection of the target area was achieved in all cases, without any adverse events (Belghazi K, et al. Unpublished data). The aim of this study was to assess the performance of the Captivator device for treatment of early Barrett's neoplasia in a large, prospective, multicenter series.

METHODS

This was a prospective, multicenter, single-arm study in 14 tertiary referral centers for Barrett's neoplasia in 6 countries (Belgium, Canada, Germany, the Netherlands, United Kingdom, and United States).

Patient selection

Patients were included when they met all inclusion criteria and none of the exclusion criteria. Inclusion criteria were age ≥18 years; BE with a visible abnormality, defined as any Paris type lesion[10] suspicious for neoplasia and amenable for ER (prior biopsy specimen–proven diagnosis of high-grade dysplasia [HGD] or cancer was not required if a lesion was endoscopically suspicious for neoplasia, for which ER was indicated); no suspicion on deep submucosal invasion based on macroscopic appearance and/or endosonography, if performed; ability to take a proton pump inhibitor twice daily; and signed informed consent. Exclusion criteria were prior endoscopic treatment for esophageal neoplasia, presence of an esophageal stenosis preventing passage of a gastroscope, endoscopically visible scarring by any cause of the intended treatment zone, presence of esophageal varices, and coagulation disorders or anticoagulant therapy that could not be discontinued (aspirin was allowed).

ER device

All ERs were performed using the Captivator device (Boston Scientific), which is commercially available and is 510(k) cleared by the U.S. Food and Drug Administration and CE marked. The Captivator device consists of a plastic control handle that can be attached to the endoscope, a steel trigger wire, a transparent plastic cap with 6 rubber bands, and a 5F (17 mm) stiff hexagonal snare (Fig. 1).

Endoscopic procedures

At each participating center, procedures were performed by endoscopists with experience in performing ER using MBM. Each participating endoscopist was required to perform 2 ex vivo training cases to get familiar with the Captivator device or to already have in vivo experience with the Captivator device. During the endoscopy, visible lesions were classified according to the Paris classification.[10] The lateral margins of the target lesion were delineated with electrocoagulation markings. After marking of the target area, the endoscope was removed and the Captivator device was assembled onto the endoscope and reintroduced. If preferred by the endoscopist, submucosal lifting was performed using a mix of saline solution and adrenaline. The mucosa of the target lesion was sucked into the cap, and a rubber band was released by turning the control handle. The created pseudopolyp could then be resected with electrocoagulation using the stiff hexagonal snare. The snare was generally placed below the band but could also be placed above the band according to the discretion of the endoscopist. If necessary, additional resections were performed to remove the target area in a piecemeal fashion. After the procedure, resection specimens were retrieved for histologic assessment.

Postprocedural follow-up

Most patients were prescribed proton pump inhibitors 40 mg twice daily for the entire study period and if available sucralfate 1 g 3 to 4 times daily and ranitidine 300 mg before bedtime for a period of 2 weeks after the ER. Patients were followed up with a telephone call 48 hours and 30 days after the procedure to check for any adverse events. Patients reached the end of the study after completion of the 30-day telephone call.

Histologic evaluation

Depending on the standard operating procedure at each center, ER specimens were pinned on paraffin or cork, fixed in a specially designed tissue cassette that comes with the Captivator kit, or fixed in formalin without