Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Endoscopic submucosal dissection

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, 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 adverse events 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, 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 April 2014 for relevant articles by using the key words "endoscopic submucosal dissection" and "ESD," combined with other relevant terms such as "gastric," "esophageal," "rectal," "colonic," and "adverse events," among others. 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

Endoscopic submucosal dissection (ESD) is a well-established technique of endoscopic resection that allows for en bloc removal of GI epithelial lesions. ESD differs from EMR, the other type of endoscopic resection. Both techniques involve injection of a substance under the targeted lesion to act as a cushion. With EMR, the lesion is then removed with a snare or suctioned into a cap and snared. With ESD, the submucosa is instead dissected under the lesion with a specialized knife. This enables removal of larger and potentially deeper lesions with a curative intent than can be accomplished with EMR. ESD was first described in 1988 as a technique to treat early gastric neoplasia nonoperatively.[1] Over the ensuing decades, procedural techniques and equipment for ESD have evolved significantly, and applications for ESD techniques have expanded to locations throughout the GI tract as well as to the treatment of deeper, nonepithelial lesions. The principles of ESD have also led to the development of procedures with a therapeutic intent other than the resection of neoplasia, including peroral endoscopic myotomy for the treatment of achalasia.

TECHNOLOGY UNDER REVIEW

Proper patient and lesion selection for ESD are essential. Endoscopic resection of neoplastic lesions should only be undertaken when endoscopic and/or endosonographic evaluations predict a curative resection. However, one of the benefits of ESD is that the pathologist is provided with an en bloc specimen, such that noncurative resections can be more easily detected and patients properly referred for further oncologic surgery.

ESD is accomplished in a sequential or stepwise manner, and a variety of devices are available to assist the endoscopist in performing each step. Typically, the ESD steps during resection of a mucosal neoplastic lesion are as follows: (1) the perimeter of the lesion is marked with cautery; (2) a lifting agent is injected into the submucosa around the perimeter of the lesion; (3) the mucosa is incised and then cut circumferentially around the lesion by using an electrosurgical knife; (4) the submucosa beneath the lesion is injected and then dissected in a free-hand manner by using an electrosurgical knife until the specimen has been completely resected; and (5) any intraprocedural bleeding that occurs during the mucosal incision or submucosal dissection is managed by using a water jet for washing and hemostatic forceps or an electrosurgical knife by using coagulation current for vessel coagulation.

Electrosurgical knives, discussed in the following, are the main devices used in ESD that differentiate it from

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2014.12.010

other types of endoscopic resection. The other tools used (eg, endoscope, electrosurgical unit [ESU], and other ancillary devices) are similar to those used for standard endoscopy. However, because of the complexity of the procedure, special considerations in choosing these types of equipment are also necessary.

Devices for ESD

The common attribute of all dedicated ESD devices is their ability to perform submucosal dissection. However, some devices are also useful in earlier stages of the procedure, such as marking or initial mucosal incision. The earliest dedicated ESD device simply added an insulated ball-like ceramic tip to an existing needle-knife to prevent inadvertently deep dissection and thus potential perforation.[2] In addition to uncovered and covered (insulated-tip) needle-knife–like devices, a group of forceps-like devices has now been developed. However, although a wide variety of dedicated ESD devices are manufactured worldwide, the number of ESD devices that are approved by the U.S. Food and Drug Administration and available in the United States is limited. Table 1 lists ESD devices approved by the U.S. Food and Drug Administration and their suitability for the different procedural steps in ESD. All ESD devices are designed for single use only. Most ESD devices feature catheter outer diameters that are compatible with a 2.8-mm endoscopic instrument channel. Some ESD devices are available in lengths compatible with use with a colonoscope.

Knives. *ITKnife.* The ITKnife and ITKnife2 (Olympus America, Center Valley, Pa) (Table 1, Figs. 1A and 1B) both feature a 2.2-mm ceramic ball mounted on the end of a 4-mm-long cutting knife. The ITKnife2 also has a triangular electrode beneath the ceramic ball that facilitates cutting. The principal applications of the ITKnife and ITKnife2 are for the circumferential incision and submucosal dissection phases of gastric ESD.

The ITKnife nano (Olympus America) (Table 1, Fig. 1C) features a 1.7-mm ceramic ball mounted on the end of a 3.5-mm-long cutting knife. There is a 0.9-mm diameter circular electrode beneath the ceramic ball that is relatively recessed from its lateral margins. The principal applications of the ITKnife nano are for the circumferential incision and submucosal dissection phases of esophageal and colorectal ESD.

HookKnife. The tip of the HookKnife (Olympus America) (Table 1, Fig. 1D) is bent at a right angle, creating an L shape. The knife extends to 4.5 mm in length with a 1.3-mm hook. Both the knife length and the direction of the hook are adjustable at the instrument handle. Extending the knife fully locks the direction of the hook. This knife is designed to allow the hooking and retraction of the tissue to be cut. The HookKnife is capable of marking, initial mucosal incision, circumferential incision, and submucosal dissection at any site in the digestive tract, but is particularly useful for dissecting fibrotic tissue.

Triangle Tip Knife. The Triangle Tip Knife (Olympus America) (Table 1, Fig. 1E) has a noninsulated triangular electrode at the tip of a 4.5-mm-long cutting knife. The triangular electrode measures 1.6 mm on each side and maximally extends 0.7 mm away from the central cutting knife. Although this knife is useful in multiple steps for ESD, care must be taken with the relatively large distal electrode on the Triangle Tip Knife to avoid perforation. For this reason, it may be used less commonly for ESD than other knives, although it was the knife used in the initial descriptions of peroral endoscopic myotomy.[3]

DualKnife. The DualKnife (Olympus America) (Table 1, Fig. 1F) features a very small noninsulated dome-shaped electrode at the tip of the cutting knife, which is 2.0 mm in length for the gastroscope-length model and 1.5 mm in length for the colonoscope-length model. For the initial marking phase, full retraction at the knife handle is used. In this position, only 0.3 mm of the knife tip protrudes beyond the catheter tip. The DualKnife is useful for all electrosurgical phases of ESD throughout the digestive tract.

FlexKnife. The FlexKnife (Olympus America) (Table 1, Fig. 1G) comprises a braided 0.8-mm diameter cutting knife with a looped tip at the distal aspect that may be extended a variable length from the catheter tip. The FlexKnife is useful for all electrosurgical phases of ESD throughout the digestive tract.

HybridKnife. The HybridKnife (ERBE USA, Marietta, Ga) (Table 1, Figs. 1H and 1I) has a central capillary within the cutting knife that can serve as an ultrafine 120-μm water jet when coupled with a foot pedal–activated, computerized jet lavage unit (ERBEJET 2 system; ERBE USA) (Fig. 2). As such, this device can accomplish all phases of ESD including lifting. The pressurized water jet delivered by the HybridKnife can penetrate the mucosa and accrue in the submucosa, thus providing a submucosal lift without requiring needle puncture. The HybridKnife features a 5-mm-long cutting knife with 3 tip configurations: the I type, which is straight with no added tip; the T type, which features a noninsulated, 1.6-mm diameter disk-shaped electrode at the tip; and the O type, which features an insulated, hemispherical, domelike tip. The I-type and T-type knives are approved by the U.S. Food and Drug Administration and available in the United States; the O-type HybridKnife is not yet available in the United States.

Hemostatic forceps and other devices. Monopolar and bipolar hemostatic forceps have been developed to treat bleeding with coaptive thermocoagulation. The Coagrasper (Olympus America) is a monopolar hemostatic forceps available in 165-cm and 230-cm lengths designed for gastric and colonic indications and is available in the