A New Approach: Endoscopic Submucosal Dissection Using the Clutch Cutter[®] for Early Stage Digestive Tract Tumors

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Key Words

Endoscopic submucosal dissection • Novel device • Grasping-type scissor forceps • Clutch Cutter[®] • Training • Safety • Early stage digestive tract tumor • Endoscopic therapy

Abstract

Endoscopic submucosal dissection (ESD) is accepted as minimally invasive therapy for early stage digestive tract tumors. It has allowed the achievement of histologically curative en-bloc resection of early stage digestive tract tumors regardless of size, including the resection of previously non-resectable tumors. Although numerous electrosurgical knives have been developed for ESD, technical difficulties and high complication rates (bleeding and perforation) have limited their use worldwide. Furthermore, conventional ESD usually needs several devices for each session. We developed the Clutch Cutter[®] (CC), which can grasp and incise the targeted tissue using electrosurgical current, to resolve such ESD-related problems. The ESD procedure using the CC is as follows: after marking using the CC and the injection of a solution into the submucosa, the lesion is separated from the surrounding normal mucosa by complete incision around

the lesion using the CC. A piece of submucosal tissue is grasped and cut with the CC using electrosurgical current to achieve submucosal exfoliation. Intraoperative bleeding is also treated by the CC. Reported clinical studies showed that ESD using the CC is a safe, simple, easy-to-learn, technically efficient (en-bloc resection rate 100%), and a single-device method for the dissection of early stage digestive tract tumors. This new approach is promising to become the worldwide method of choice for early stage digestive tract tumors because it is technically simple and safe to perform.

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Introduction

Endoscopic submucosal dissection (ESD) is a new endoscopic therapeutic technique involving the use of knife devices to permit a larger resection of the tissue over the muscularis propria in the digestive tract [1–8]. It has been reported that ESD improves the rate of tumor eradication and recurrence in early stage digestive tract tumors as compared with endoscopic mucosal resection. However, ESD using knives has three major problems: (1) it has high complication rates compared with endo-

Fig. 1. **a** Whole image of the CC. **b** Distal tip of the long-type CC (the length of the blade is 5 mm). **c** Distal tip of the short-type CC (the length of the blade is 3.5 mm).

scopic mucosal resection; (2) it is hard to learn due to technical difficulties, and (3) it requires several devices in each ESD [3, 6, 8–11]. What is needed is a safe, simple, and single-device method to accomplish successful en-bloc resection. Conventional knife devices merely contact the knife to the targeted tissue and cut using an electrosurgical current. Inability to fix the knife to the target, to lift it up from the muscularis propria, and to compress the blood vessel, leads to a potential risk of major complications such as perforation and bleeding, the need for highly skilled endoscopists, and the use of several special devices in each ESD [1, 3, 4, 10, 11]. We believe that the most effective approach to overcoming such problems is to grasp and cut the targeted tissue using a single device [12]. The grasping step provides fixation, lift-up, and compression effects [3, 12–16]. We have therefore developed the Clutch Cutter® (CC), which can grasp and cut the targeted tissue using electrosurgical current [12]. In this paper we review the mechanism, techniques, clinical usefulness, and possibilities of ESD using the CC.

Newly Developed Grasping-Type Scissor Forceps (CC)

The CC (DP2618DT; Fujifilm, Tokyo, Japan) (fig. 1) can grasp and cut a piece of tissue with electrosurgical current [3, 12–16]. It has a 0.4-mm-wide and 3.5- or 5-mm-long serrated cutting edge to facilitate grasping the tissue. The outer side of the forceps is insulated so that electrosurgical current energy is concentrated at the closed blade to avoid unintentional incision. Furthermore, the forceps is rotatable to the desired orientation.

Fig. 2. Schematic shows ESD using the CC. Step 1: marking dots are made on the circumference of the lesion to outline the incision line using the CC (in closed mode). Step 2: a sodium hyaluronate solution mixed with a small volume of epinephrine and indigo carmine dye is injected into the submucosal layer around the target lesion to lift the entire lesion. Step 3: the lesion is separated from the surrounding normal mucosa by complete incision around the lesion using the CC. Steps 4 and 5: a piece of submucosal tissue is grasped, lifted up and cut with the CC using electrosurgical current to effect submucosal excision. Step 6: the lesion is resected in one piece. m = Mucosa; sm = submucosa; mp = muscularis propria.

The diameter of this forceps is 2.7 mm. The CC is available for standard endoscopes with a working channel width of 2.8 mm or over. This device is disposable. The CC is available for all steps of ESD, such as marking, circumferential marginal incision, submucosal dissection, and hemostatic treatment.

ESD Technique Using CC

ESD technique using CC is as follows (fig. 2, 3). Circumferential markings are made by using a CC in closed mode. Next, hyaluronic acid solution (MucoUp; Johnson & Johnson, Tokyo, Japan) supplemented with diluted epinephrine (0.0002%) and indigo carmine (0.0002%) is injected into the submucosal layer to lift up the lesion. The target mucosal and submucosal tissue are grasped, and lifted up and cut with the CC using electrosurgical current to achieve circumferential incision and submucosal excision. Finally, the lesion is completely resected by the CC. Bleeding during the procedure is treated by coagulation with the CC. A high-frequency power supply (VIO300D; ERBE, Tübingen,

Color version available online

Fig. 3. Endoscopic view of the procedure of ESD using the CC. **a** Chromoendoscopy with indigo carmine to demarcate the lesion. **b** Marks are made at several points along the outline of the lesion with a coagulation current. **c** The mucosa is incised outside the marker dots to separate the lesion from the surrounding non-neoplastic mucosa using the CC. **d** The submucosal connective tissue immediately beneath the lesion is gradually dissected using the CC from the muscle layer. **e** The large blood vessel is seen during the submucosal excision. **f** The large blood vessel is grasped, lifted up and coagulated sufficiently using the CC. **g** The large blood vessel is cut without bleeding. **h** The lesion is cut completely from the muscle layer. **i** The resected specimen shows en-bloc resection of the lesion.

Germany) is used. Power settings for each step are as follows. Marking is performed with forced coagulation mode 30 W, effect 3. Circumferential incision and submucosal excision are performed with autocut mode 120 W, effect 4 with or without soft coagulation mode 100 W, effect 5. Hemostatic treatment and prophylactic coagulation are performed with soft coagulation mode 100 W, effect 5.

Treatment Outcomes of ESD Using CC

The reported technical outcome of ESD using CC [15, 16] or conventional knife devices [2, 4, 17–24] is summarized in table 1. Previous studies [15, 16] for ESD using CC show a relatively high en-bloc resection rate (100%), long procedure time (104–155 min), and a low procedure-related complication rate (0–3%) compared with ESD using conventional knife devices. Up to March 2011 (including our previously reported studies), in our institute

we performed ESD using CC for 257 consecutive patients with a diagnosis of early stage digestive tract tumor (lower pharynx, 2 patients; esophagus, 18; stomach, 175; duodenum, 2; colon and rectum, 60) without lymph node involvement. The rates of en-bloc resection, ESD-related bleeding, and ESD-related perforation, and the mean operation time were 98, 2, and 1%, and 104 min, respectively [unpubl. data].

Advantages of ESD Using CC in Safety

During ESD using conventional knife devices, we may encounter problems, i.e. unintentional incision due to body motions such as cardiac or respiratory movement, perforation due to thin gut wall, and bleeding [3, 12–16]. Our proposed measures for each problem are fixation of the device to the target tissue plus outside insulation, sufficient lift-up of the target tissue from the underlying muscularis propria, and compression of the blood vessel, respectively [3]. We concluded that no current knives could achieve these goals. Therefore, we developed the CC (fig. 1, 2) to overcome the shortcomings of conventional knife devices [3, 6–9]. CC has four safe effects: (1) fixation, (2) outside insulation, (3) lift-up, and (4) compression [3, 12]. (1) CC can grasp and cut the tissue using electrosurgical current. The grasping step prior to electrosurgical incision provides the fixation effect to the targeted tissue to avoid unintentional incision. (2) CC has a thin serrated cutting edge and an insulated coating on the outer side of the forceps. These characteristics facilitate grasping the targeted tissue and concentrate electrosurgical current energy at the blade to avoid burning the surrounding tissue (closed discharge system). (3) We can pull back and lift up the grasped tissue by maneuvering the scope and CC. The lift-up effect at the targeted tissue can sufficiently separate the grasped tissue from the underlying proper muscle layer before incision and helps prevent perforation. The lift-up step before cutting the targeted tissue also provides good visualization of the interest and allows the use of sufficient pre-cut coagulation to reduce the risk of intra- and post-ESD bleeding. (4) CC has a compression effect, which is effective for pre-cut coagulation and hemostatic treatment of post-cut hemorrhage. From our recent clinical experiences, there is no need for any other electrosurgical hemostatic device in ESD using CC. We think that these advantages reduce the risk of ESD-related complications.

Table 1. Outcomes of ESD: comparison between the CC and conventional knife devices (KD)

Site	Device	En-bloc resection rate, %	Procedure time, min	Complications, %	
				bleeding rate	perforation rate
Esophagus	CC (n = 18) [pers. unpubl. data]	100	89	0	5.5
	KD [2, 17, 18]	95–100	64–89	0	3.2–10
Stomach	CC (n = 35) [15]	100	104	3	0
	KD [4, 19–21]	79–95.3	47.8–92.4	5–16.2	0–4.3
Colorectum	CC (n = 10) [16]	100	155	0	0
	KD [22–24]	80–91.5	70.5–90	1–2	5–10

Advantages of ESD Using CC in Training

All steps of ESD can be achieved by the following three operations: (1) grasping the targeted tissue (fixation); (2) lifting up the grasped tissue (separation of the grasped tissue from the underlying proper muscle layer), and (3) cutting the grasped tissue (or coagulating the blood vessel) using electrosurgical current. These operations are simple and easy like a bite biopsy technique. In the grasping confirmation step, the trainee can sufficiently discuss the adequacy of the grasped tissue with the attending endoscopist and obtain his permission for cutting prior to stepping on the electrosurgical current pedal [3]. Furthermore, CC can be used to grasp the targeted tissue again if the grasped site is inadequate, before electrosurgical cutting [12]. Therefore, the trainee can perform effective ESD at the same level of the attending endoscopist without complications. In our institute, all trainees were able to perform en-bloc resection safely under the supervisor's guidance. This pre-cut confirmation step is the greatest advantage of this method and is very useful for safety and for training in ESD.

Advantages of ESD Using CC in Cost Performance

The conventional ESD technique needs several corresponding specific knives or devices for each step of ESD [10, 11]. Before introduction of the CC (JPY 43,000) in our institute, we used a needle knife (KD-IL-1; Olympus, JPY 27,500) for marking and making a starting hole, an insulation-tipped diathermic knife (KD-611L; Olympus, JPY 38,000) for circumferential incision and submucosal excision steps, and a hemostatic forceps (FD-410LR; Olympus, JPY 15,000) for intraoperative bleeding. The total number of devices for one session of ESD was at least

three (JPY 80,500). After the introduction of CC, we use only one device, a CC, in all steps of ESD (JPY 43,000). The CC reduces the cost of devices in ESD.

Disadvantages of ESD Using CC

Difficulties frequently occur in rotating the CC to the desired orientation during the retroflex approach [3, 12–16]. Further mechanical refinement is needed to resolve the problem of rotating the CC.

Future Possibilities

Because ESD reliably achieves curative en-bloc resection of early stage digestive tract tumors and reduces local recurrence, ESD has been widely used in Japan and a few other Asian countries despite its technical difficulties [4–8, 12]. Although ESD requires high-level endoscopic skills, it is becoming safe and easier because of the development of many new devices [3, 11, 12, 25]. From our previous studies [3, 12–16] and experiences, we believe that ESD using the CC is likely to become the worldwide method of choice for early stage digestive tract tumors because it is technically simple, cost-effective, and safe for performing ESD and its training. However, further refinements, experience, and clinical studies of this method are needed in order to more easily achieve the curative en-bloc resection of early stage digestive tract tumors.

Disclosure Statement

Kazuya Akahoshi and Hidefumi Akahane (Fujifilm, Japan) have applied for the patent in Japan, EU, USA, and China for the Clutch Cutter® described in this article.

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