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Settings of a novel electrosurgical generator to enable efficient and safe submucosal endoscopic procedures

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ABSTRACT

Background and study aims A novel electrosurgical generator unit (ESU), ConMed Beamer, was recently introduced to facilitate endoscopic submucosal dissection (ESD) by employing Automatic Cutting Effect (ACE) technology. Its use in submucosal endoscopy has yet to be investigated. The aim of this study was to evaluate the feasibility and safety of performing ESD and peroral endoscopic myotomy (POEM) using novel settings generated with ConMed Beamer ESU.

Patients and methods This was a single-center prospective study of 59 consecutive patients undergoing ESD/POEM at a tertiary referral center. ESU settings were initially generated by testing in live animal models prior to first in-human study. The primary outcome was technical success. Secondary outcomes were procedure times, rate of en bloc/R0 resection, and rate of adverse events (AEs).

Results A total of 44 patients (50 polyps) and 15 patients underwent ESD and POEM, respectively. En bloc resection, R0 resection, and curative resection rates were 90%, 77.1%, and 70.8%, respectively. Mean maximal length of the lesion was 3.07 cm ± 1.43 with an average dissection speed of 14.2 cm^2/hr ± 11.1. Technical success was achieved in 100% of POEM patients. Mean time (minutes) to complete the POEM procedure was 50.1 min ± 12.4. Two major AEs occurred among all patients (3.4%). All intraprocedural bleeding events were controlled using the ConMed Beamer ESU.

Conclusions ConMed Beamer ESU settings generated from this study were proven safe and effective in a prospective cohort of patients who underwent submucosal endoscopic procedures. This novel ESU can be added to the armamentarium of ESD capable generators.

Introduction

Endoscopic submucosal dissection (ESD) has revolutionized management of gastrointestinal polyps. Lesions that previously would have had to be removed, either by piecemeal endoscopic resection or by surgical means, could now be removed en bloc via meticulous endoscopic guided dissection [1]. In essence, ESD allowed for procurement of a surgical type specimen in a less invasive manner. The success and widespread adoption of this procedure was predicated on efficient and purposeful dissection of gastrointestinal tissue using established electrosurgical units (ESU) [2] and newly developed electrocautery knives [3].

However, existing ESUs used for ESD were initially developed for other purposes such as sphincterotomy and snare mucosal resection, where changes in tissue composition are not always accounted for. In ESD, constant changes in tissue composition (submucosa, fibrosis, etc) and patient related factors necessitate changes in electrocautery setting to allow for desired effects. Location within the gastrointestinal tract in addition to the presence of fibrosis also need to be accounted for by the ESU unit. There are even suggestions that certain electrocautery settings, may be implicated in short term complications, such as post ESD esophageal stricture [4]. Specifically, rate of stricture formation and degree of fibrosis vary significantly depending on the type of cut and coagulation current used, with the least degree of fibrosis occurring associated with EndoCut mode [4]. Most importantly, there is still no consensus for optimal electrocautery settings for ESD using current ESU systems. Thus, newer ESUs specifically dedicated toward precise dissection of various gastrointestinal tissue are needed.

A novel ESU, Beamer CE600 Electrosurgical Platform, was designed specifically to address variability in tissue composition during ESD. The Beamer features automatic cutting effect (ACE) which provides continuous spark monitoring around an active electrode. This electrode adjusts voltage, spark and power to deliver consistent, repeatable cutting and hemostatic effects. It also hosts five endo-modes, which are pulsed currents that deliver controlled cutting with varying, adjustable degrees of coagulation. With ninety-nine program memory slots, the Beamer ESU has the ability to save, store and recall unique settings for esophageal, gastric, colorectal ESD as well as peroral endoscopic myotomy (POEM) and gastric peroral endoscopic myotomy (G-POEM). However, its feasibility, effectiveness, and optimal settings have yet to be tested in routine clinical practice.

The main purpose of our study was to evaluate the feasibility of the Beamer CE600 Electrosurgical Platform during endoscopic dissection of various gastrointestinal tissue using the suggested settings generated from this study. In doing so, we hope to characterize the most effective third space endoscopy electrocautery settings using this novel ESU.

Methods

Determination of ESU settings

Before implementation into human subjects, two in vivo animal labs were utilized to determine the best current setting for ESD/POEM in the esophagus, stomach and colon. These settings were then adopted for human use. Institutional review board approval for animal labs was obtained from Baylor College of Medicine. Parameters included were ease of dissection, eschar score post resection, muscle injury and or perforation and bleeding control. Proposed settings were chosen and tested by principal investigator Mohamed O. Othman in one in vivo animal lab. Optimal settings were determined based on an assessment of tissue effects with multiple dissecting knives using the Beamer ESU. The proposed settings were retested in another in vivo animal lab to ensure the reproducibility of these settings.

ConMed Beamer ESU

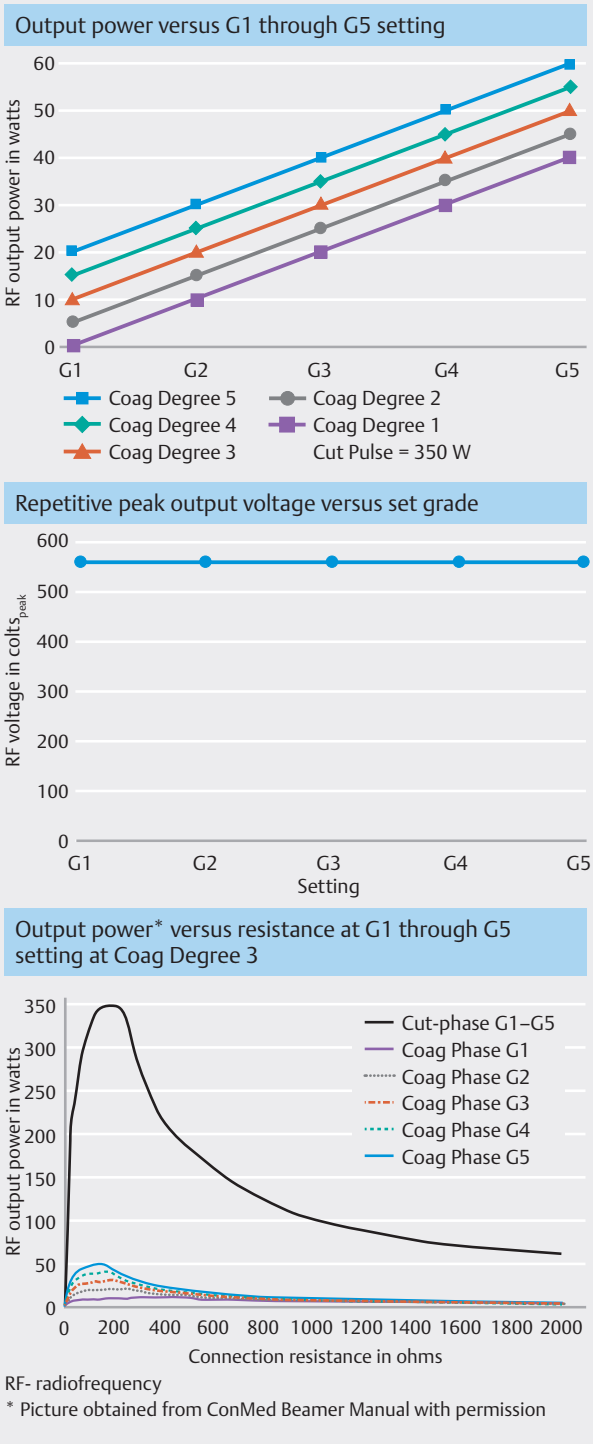
The ConMed Beamer ESU "ESD" setting was specifically designed to implement ACE technology to allow for dissection/hemostasis of varying consistency and resistance. It consists of a blended pulse current with a short cutting phase followed by a coagulation phase. In this current setting, the pulse rate is higher than in other settings, and together with ACE integration and variations in grade setting, a more uniform cutting result can be seen. The G nomenclature is the equivalent to cutting current (EndoCut I nomenclature on the ERBE ESU) (ERBE USA, Marietta, Georgia, United States) and corresponds to the yellow pedal. The blue pedal corresponds to the coagulation mode with the following nomenclature: Gentle coagulation (equivalent to soft coagulation in the ERBE ESU), Hot biopsy (equivalent to forced coagulation in the ERBE ESU) and spray coagulation. ▶ **Fig. 1** depicts expected power effect based on a combination of increased G settings and coagulation degree settings.

Study design

This is a single-center prospective feasibility study of 59 consecutive patients undergoing ESD POEM/G-POEM at a tertiary referral center between May 2021 to February 2022. Given previously reported ESD-related perforation rates of 3% to 13%, it was determined that a sample size of 50 endoscopic resections would be sufficient to detect any abnormal increase in the rate of immediate or delayed perforation using this ESU [5, 6]. The study was approved by Baylor College of Medicine IRB (H-49160 IRB Pr. No.: 20204663).

Patient recruitment

Inclusion criteria were patients scheduled to undergo ESD of gastrointestinal polyps or undergo esophageal/gastric POEM at Baylor St. Luke's Medical Center, Houston, Texas, United States. ESD of gastrointestinal polyps at our institution is performed if the following criteria are met: endoscopist feels en bloc resection is only feasible via ESD or hybrid ESD regardless of polyp size, previously manipulated polyps, or lesions with suggestions of aggressive morphological features. Exclusion criteria were any patients who were under the age of 18. If inclusion criteria were met, patients were approached by trained research staff and informed consent was obtained in a preprocedural clinic visit or in the preoperative area. Patients with multiple polyps were evaluated independently of each other and were assigned separate IDs. Patients were recruited consecutively over a period of 12 months. Detailed description of this novel ESU was provided to potential participants during the consent process. Before consent was obtained, it was explained to all potential subjects that we were attempting to evaluate the efficacy of this new ESU to determine its feasibility in routine practice. A trained research coordinator was present for the entire procedure and collected all procedural information relevant to the study. Patients were interviewed in recovery area 30 minutes after the procedure for any immediate post-procedure adverse event (AE). Patients were contacted 24



RF- radiofrequency

* Picture obtained from ConMed Beamer Manual with permission

▶ **Fig. 1** Expected power output in watts generated with increasing G (cutting current) settings. Expected power output in watts generated when tissue resistance is factored in.

hours and 30 days post-procedure to assess for delayed post-procedure AEs.

Procedure techniques

All procedures were performed by two expert submucosal endoscopists (M.O and S.J) using a single-channel video endoscope with water jet function Pentax EC38-i10 L (Pentax America, Montvale, New Jersey, United States). At the time of patient recruitment, endoscopist M.O. had 5 years of ESD experience and over 500 ESD/POEM procedures performed. Endoscopist S.J. had 1 year of experience and approximately 75 ESD/POEM procedures performed. For all procedures, a tapered distal cap was attached to the end of the endoscope. All procedures were performed using either the Dual J -knife (Olympus America, Center Valley, Pennsylvania, United States) or ProKnife (ORISE ProKnife; Boston Scientific, Tokyo, Japan). All POEM procedures were performed using the ORISE ProKnife 3.0 mm. Coagulation graspers (Olympus America, Center Valley, Pennsylvania, United States) were used to control intraprocedural bleeding.

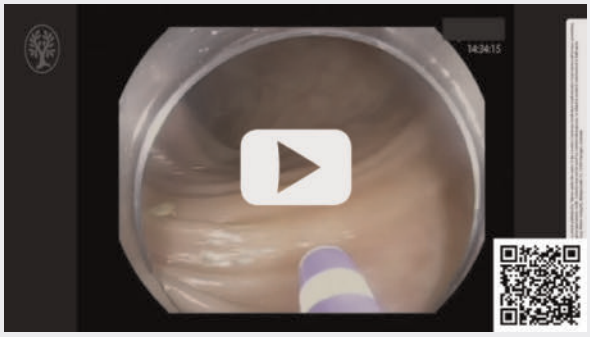
Outcomes

The primary outcome was technical success, which was defined as the ability to perform the entire intended procedure (ESD or POEM) using the Beamer CE600 ESU (▶ **Video. 1** and ▶ **Fig. 2**). For polyps, technical success was defined as en bloc removal of the polyp via ESD settings using the Beamer CE600 ESU. This included lesions that underwent complete ESD or hybrid ESD. Hybrid ESD was defined as complete circumferential mucosal incision followed by completing enough submucosal dissection to deploy a snare around the entire lesion. If the polyp was removed en bloc but fragmented upon removal, this was considered technical success but not R0 resection. If the polyp was removed piecemeal, this was considered technical failure. Secondary outcomes were dissection speed, rate of en bloc and R0 resection, rate of AEs, and detailed outcomes of the ESU settings. En bloc resection was defined by visible endoscopic removal of the entire polyp in one piece. R0 resection and curative resection were determined using European Society of Gastrointestinal Endoscopy and expanded Japanese criteria [5, 6, 7].

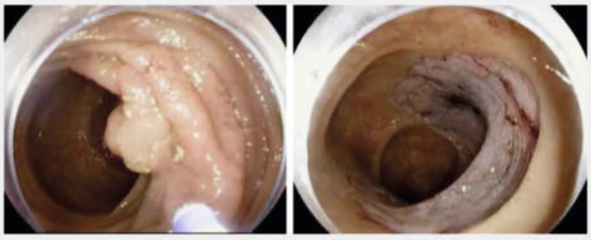
AEs were defined by American Society of Gastrointestinal Endoscopy lexicon [8]. These included intra-procedure muscularis propria (MP) damage (excluding visible perforation), macro-perforation (defined as a visible MP defect during endoscopy and micro- perforation (defined as free air seen on imaging with no visible MP defect on endoscopy) [9], post-electrocautery coagulation syndrome, delayed bleeding (that required endoscopy or surgery up to 14 days post ESD), abdominal pain 1 day after procedure (defined as pain rated greater than 4 of 10 on visual pain analog scale), and abdominal pain 30 days post ESD.

Dissection speed for polyps was calculated by first measuring the area of the polyp (length multiplied by width based on histological measurements). This area was then divided by dissection time to get dissection speed in cm^2/hr. Dissection time was defined as time from first mucosal incision to final removal of the polyp. For the POEM procedure, distance was calculated

VIDEO



▶ **Video 1** ESD of a large rectal polyp using the ConMed Beamer ESU. Traction was provided with the assistance of a novel retraction tool



▶ **Fig. 2** ESD resection bed using the ConMed Beamer ESU.

in a linear fashion and consisted of the distance of submucosal tunneling + distance of myotomy.

Statistical analysis

The significance of differences in patient characteristics and clinicopathological features was determined using chi-square test, Fisher exact test. Factors associated with R0 resection, dissection changes, and dissection speed were analyzed using logistic regression analysis. $P < 0.05$ was considered statistically significant.

Results

Study characteristics

Patients

Fifty-nine consecutive subjects were enrolled over a period of 12 months (15 = POEM/G- POEM and 44 = ESD) (▶ **Table 1**). For esophageal POEM, indications were type 1 achalasia (n = 3), type 2 achalasia (n = 5), type 3 achalasia (n = 2), EGJOO (n = 1). G-POEM was performed for idiopathic gastroparesis (n = 3) and diabetic gastroparesis (n = 1). Among the 44 ESD subjects, in total 50 polyps were planned to be removed via ESD.

▶ **Table 1** Polyp characteristics, including lesion location, fibrosis, and final pathology.

Male, n (%)	**22 (50)**
Age, mean (years)	65.6 ± 23.2
Anticoagulant/antiplatelet use, n (%)	11 (25)
ASA ≥ 3, n (%)	33 (75)
Location, n (%)	
▪ Esophagus	10 (20.0)
▪ Stomach	10 (20.0)
▪ Duodenum	7 (14.0)
▪ Colon/rectum	23 (46.0)
▪ Previous attempted resection, n (%)	3 (6.0)
▪ Tattoo under lesion, n (%)	3 (6.0)
▪ Previous biopsy, n (%)	28 (56.0)
▪ Fibrosis, n (%)	11 (22.0)
Pathology, n (%)	
▪ Tubular adenoma	10 (20.0)
▪ Tubular adenoma with HGD	4 (8.0)
▪ Tubulovillous adenoma	3(6.0)
▪ Tubulovillous adenoma with HGD	4 (8.0)
▪ Tubulovillous adenocarcinoma	2 (4)
▪ Sessile serrated adenoma	5 (10)
▪ GIST	1 (2.0)
▪ NET	8 (16.0)
▪ Intramucosal adenocarcinoma	1 (2.0)
▪ Invasive adenocarcinoma	5 (10.0)
▪ Hyperplastic	2 (4.0)
▪ Other	5 (10.0)

HGD, high-grade dysplasia; GIST, gastrointestinal; stromal tumor; NET, neuroendocrine tumor.

Lesions

The most common location was the colon (46%), esophagus (20%), stomach (20%), and then duodenum (14%). The mean diameter of the lesions was 3.07 $cm^2 \pm 1.43$. The average surface area size of all lesions was 9.1 cm^2 (▶ **Table 1**).

ESU settings used during ESD

Initial incision

The most common initial incision setting for all locations was G5 with only two polyps incised using the G2 setting. The incision setting for these two polyps were ultimately changed to G5 to complete the incision successfully (▶ **Table 2**).

▶ **Table 2** Referenced optimal electrocautery settings based on location and procedure type for ConMed Beamer and the equivalent nomenclature for ERBE.

CONMED Beamer ESU	ERBE ESU equivalent setting
POEM	
▪ Incision and myotomy: G2 35W	Incision and myotomy: Endocut I Mode
▪ Submucosal tunneling: 37 W spray Coagulation	Submucosal tunneling: 37 W spray Coagulation
▪ Coagulation grasper (hemostasis): 50 W gentle coagulation	Coagulation grasper (hemostasis): 50 W soft coagulation
ESD esophageal	
▪ Incision: G5 35W	Incision: EndoCut I mode
▪ Dissection: 35 W hot biopsy setting	Dissection: 35 W forced coagulation
▪ Coagulation grasper (hemostasis): 50 W gentle coagulation	Coagulation grasper (Hemostasis): 50 W soft coagulation
ESD gastric	
▪ Incision: G5 35W	Incision: EndoCut I mode
▪ Dissection: 35 W hot biopsy setting	Dissection: 35 W forced coagulation
▪ Coagulation grasper (hemostasis): 50 W Gentle coagulation	Coagulation grasper (hemostasis): 50 W soft coagulation
ESD duodenum	
▪ Incision: G5 35W	Incision: EndoCut I mode
▪ Dissection: 30 W hot biopsy setting	Dissection: 30 W forced coagulation
▪ Coagulation grasper (hemostasis): 50 W gentle coagulation	Coagulation grasper (hemostasis): 50 W Soft coagulation
ESD colon	
▪ Incision: G5 35W	Incision: EndoCut I mode
▪ Dissection: 30 to 35 W hot biopsy setting	Dissection: 30 to 35 W forced coagulation
▪ Coagulation grasper (hemostasis): 50 W Gentle coagulation	Coagulation grasper (Hemostasis): 50 W soft coagulation

ESD, endoscopic submucosal dissection; POEM, peroral endoscopic myotomy.

Initial dissection

The most common initial dissection setting in all locations was hot biopsy setting 35 W. Dissection watts were changed most frequently (more often wattage was decreased) in the duodenum (66.7%) and colon (55%) due to concern that the wattage may have led to inadvertent MP injury in the thin-walled duodenum and ascending colon.

Coagulation

Of the polyps, 54% (n = 27) required use of coagulation forceps to control bleeding. The most common setting was gentle coagulation using 50 W.

ESU settings used during POEM

All POEM procedures were performed using an anterior approach with full-thickness myotomy. The most common incision and myotomy setting used was G2 with only one patient undergoing incision with G5 due to increased bleeding during mucosal incision. Initially, submucosal tunneling was performed using 35 W spray coagulation but after the third patient, we realized 37 W spray coagulation was more effective (▶ **Table 2**).

Procedures

The ProKnife was used for 36 polyps (72%) and the Dual Knife was used in 14 polyps (28%). Five polyps required the IT Nano knife as a secondary knife to complete dissection. When knives were switched, it was only to switch to the IT Nano knife to improve cutting angle. A stabilizing overtube (double balloon endoluminal interventional platform, n = 10 and rigidizing overtube, n = 4) was used during colon ESD for 14 polyps (58.3%). Among all polyps, 14 (28%) required non-gravity-assisted tissue traction (band traction, clip in line traction, suture traction, or novel retraction device). Closure of the resection bed was performed for 42 cases (84%) on a whole with 100% of colon resection beds closed. Closure was accomplished using through the scope clips and/or suturing devices.

Study outcomes

ESD

Overall technical success was achieved in 90.0% (n = 45) with an R0 resection rate of 77.1% (n = 37) and curative resection rate of 70.8% (n = 34) (▶ **Table 3**). The two polyps that were removed en bloc but became fragmented were not included in the R0 re-

▶ **Table 3** ESD-related procedure outcomes including en bloc resection rate, R0 resection rate, dissection speed, and complications.

Total polyps removed, n	50
ESD, n (%)	45 (90.0)
Hybrid ESD, n (%)	5 (10.0)
En bloc resection, n (%)	45 (90.0)
R0 resection rate, n (%)	37 (77.1)
Curative resection, n (%)	34 (70.8)
Length of lesion, mean (cm) ± SD	3.07 ± 1.43
Size of lesion, mean (cm^2) ± SD	9.1 ± 8.6
Total procedure time, mean (min) ± SD	86.8 ± 36.9
Total dissection time, mean (min) ± SD	48.6 ± 28.5
Dissection speed, mean (cm^2 /hour) ± SD	14.2 ± 1
Closure of resection bed, n (%)	42 (84.0)
Complications, n (%)	6(12.0)
Immediate perforation managed endoscopically	2
Delayed perforation requiring surgery	2
Bleeding managed endoscopically	1
Post-electrocautery syndrome	1
Hospitalization LOS, n (%)	13 (26.0)
1 day	8 (61.5)
2 days	3 (20)
4 days	1 (6.7)
5 days	1 (6.7)

ESD, endoscopic submucosal dissection; LOS, length of stay.

section analysis, since we did not know the true outcome of these two polyps. The five polyps that were not removed en bloc were converted to piecemeal EMR (3 severe fibrosis, 1 intraprocedural duodenal micro-perforation, 1 intraprocedural colonic macro-perforation).

Dissection speed was calculated in 35 patients (4 patients with multiple polyps and 5 patients with piecemeal resection were excluded from analysis) with an average dissection speed of 14.2 cm^2/hr (▶ **Table 3**).

All lesions in the esophagus and stomach were removed en bloc (100%) with an R0 resection rate of 95%. En bloc/R0 resection in the colon and duodenum were 87%/72.7% and 71.4%/33.3%, respectively (▶ **Table 4**). Dissection speed in the esophagus, stomach, duodenum, and colorectum were 20.3 cm^2/hr, 14.5 cm^2/hr, 2.9 cm^2/hr and 13.5 cm^2/hr, respectively.

POEM

Technical success of performing esophageal and gastric POEM was 100 %. All POEM procedures were performed using the ProKnife (▶ **Table 5**). All patients were admitted for routine post-procedure admission without any AEs.

Secondary analysis: Association of specific clinicopathologic characteristics with R0 resection

R0 resection was statistically higher in the esophagus (100%) and stomach (90%) in comparison to colon (72.7%) and duodenum (33.3%), ($P = 0.014$) (▶ **Table 6**). R0 resection was statistically higher if fibrosis was not present ($P = 0.036$). In multinomial logistic regression comparing clinical factors such as fibrosis, dissection changes and lesion location, the only predictor for R0 resection was absence of fibrosis (0.043).

Association of specific clinicopathologic characteristics with dissection watt changes

In the presence of fibrosis, dissection mode change was not varied based on location ($P = 0.131$) (▶ **Table 7**). Overall fibrosis ($P = 0.076$) and lesion location ($P = 0.064$), controlling for each

▶ **Table 4** ESD-related procedure outcomes based on location.

-	Esophagus	Gastric	Duodenum	Colorectum
Total polyps removed, n (%)	10 (20.0)	10 (20.0)	7 (14.0)	23 (46.0)
ESD, n (%)	10 (100.0)	10 (100.0)	6 (85.8)	19 (82.6)
Hybrid ESD, n (%)	0	0	1 (14.3)	4 (17.4)
En bloc resection, n (%)	10 (100.0)	10 (100.0)	5 (71.4)	20 (87.0)
R0 resection, n (%)	10 (100.0)	9 (90.0)	2 (33.3)	16 (72.7)
Size of lesion, mean (cm^2) ± SD	11.8 ± 8.2	8.4 ± 4.8	2.6 ± 1.4	11.4 ± 10.0
Total dissection time, mean (min) ± SD	34.7 ± 26.4	35.1 ± 26.1	52.5 ± 23.7	50.7 ± 26.6
Dissection speed, mean (cm^2 /hour)	20.3 ± 15.3	14.5 ± 8.4	2.9 ± 1.7	13.5 ± 9.9

ESD, endoscopic submucosal dissection.

▶ **Table 5** Outcomes of POEM procedures.

E-POEM	
▪ Submucosal tunnel length, mean (cm)	13 ± 1.7
▪ Myotomy length, mean (cm)	9.8 ± 2.2
▪ Total dissection and myotomy time, mean (min)	50.0 ± 24
G-POEM	
▪ Submucosal tunnel length, mean (cm)	5.25 ± 0.5
▪ Myotomy length, mean (cm)	2.75 ± 0.5
▪ Total dissection/myotomy time, mean (min)	46.3 ± 18.3
▪ Fibrosis, n (%)	3 (20)
▪ Complications, n (%)	0

POEM, peroral endoscopic myotomy.

▶ **Table 6** Variables associated with R0 resection.

Variable	R0 Resection	R1 Resection	*P* value
Location, n (%)	–	–	–
Esophagus	10 (100)	0	–
Stomach	10 (100)	0	–
Duodenum	2 (33.3)	4 (66.7)	–
Colon	16 (72.7)	6 (27.2)	*P* = 0.014
No fibrosis, n (%)	32 (84.2)	6 (15.8)	*P* = 0.036
Dissection watts changes, n (%)	12 (63.1)	7 (36.8)	*P* = 0.85

▶ **Table 7** Variables associated with dissection watt.

Variable	Dissection settings changed	Dissection setting not changed	*P* value
Location, n (%)	–	–	–
Esophagus	3 (30)	7 (70)	–
Stomach	1 (10)	9 (90)	–
Duodenum	4 (66.6)	2 (33.3)	–
Colon	11 (50)	11 (50)	*P* = 0.176
Fibrosis, n (%)	7 (63.6)	4(36.3)	*P* = 0.131
Polyp size, n (%)	20 (40)	30 (60)	*P* = 0.02
ORISE Pro Knife, n (%)	18 (36)	16 (32)	*P* = 0.048
DualKnife J, n (%)	2 (4)	14 (28)	–

effect, were not predictors of dissection change in multinomial logistic regression. Ultimately, dissection watt changes were made per the discretion of the endoscopists and often occurred in the duodenum or colon, where there was a concern of inadvertent thermal damage to the MP rather than ineffective dissection.

Adverse events

All AEs were graded as mild, moderate or severe based on ASGE lexicon (8). The overall rate of AE in our cohort was 12.0 % (n = 6). Severe AEs were noted in two patients (4%): both had delayed perforation (3 days and 4 days after procedure) which required surgical right hemicolectomy in an outside hospital. One patient was confirmed to have post-electrocautery syndrome (presence of fevers, elevated white blood cell count and abdominal pain). This patient was treated conservatively with antibiotics and discharged 5 days later, and thus was categorized as a moderate AE. Intraprocedure macro-perforations in the colon and duodenum were noted in two patients and were managed endoscopically. The duodenal perforation was closed with sutures and through the scope clips and was admitted and observed for 4 days given post-procedure pain (moderate AE). The colon perforation was closed via TTS clips and did not require hospitalization (mild AE). One patient had delayed bleeding (patient was on anticoagulation 3 days after ESD and was managed endoscopically via clips and endoscopic suturing with 1 day of hospitalization (mild AE). There were no AEs in the POEM patient population, or patients undergoing esophageal or gastric ESD. Thirteen additional patients (26%) were admitted post-ESD for monitoring post procedure without evidence of perforation.

Discussion

Current ASGE guidelines for ESD provide electrocautery settings for two commercially available ESU only [10]. In the current study, we evaluated the feasibility and efficacy of a novel ESU settings designed specifically for endoscopic submucosal dissection using another commercially available ESU which was not used for submucosal endoscopy procedures previously. Our data illustrated that the use of the ConMed Beamer ESU, with the suggested electrocautery settings, allowed for safe and efficient submucosal dissection across all types of submucosal dissection procedures. We hope that our data, will expand the armamentarium of ESD capable ESUs in the United States.

The primary outcome of successful completion of the intended procedure using the Beamer CE600 system was met in 90% of patients during ESD and 100% of patients undergoing POEM. This is clinically acceptable based on previous published data [10, 11, 12], suggesting the novel ESU can support submucosal endoscopic procedures. Moreover, in cases where technical success was not achieved, lack of completion was not necessarily secondary to the ESU, but rather, due to specific polyp characteristics that are known to limit en bloc resection, such as fibrosis [13, 14, 15].

Certain quality metrics should be investigated when evaluating ESD outcomes using new devices [16]. These include, but

are not limited to, R0 resection, curative resection, and dissection speed. In our study, R0 resection rates and curative resection rates using the Beamer CE600 ESU, were on par with current ESD standards. Moreover, our speed of dissection during ESD of 14.2 cm^2/hr was higher than the minimum accepted ESD dissection speed of 9 cm^2/hr [17]. Based on meeting these specific quality metrics, our results indicate the novel ESU with the suggested settings can be used effectively and safely, while ensuring high quality metrics.

Traditional ESU often requires changes in dissection settings depending on tissue location and composition [18]. Interestingly, although changes to the dissection settings of the Beamer CE600 ESU needed to be made in some cases with fibrosis, statistical analysis did not suggest a correlation between fibrosis and need for dissection setting changes. Moreover, when changes to the dissection settings needed to be undertaken, it was most commonly in the setting of fear of inadvertent thermal injury in areas with thin walls (ascending colon and duodenum). Anecdotally, these results are consistent with our clinical experience, as dissection using this novel ESU, when compared to other ESU, allows for a more uniform and smooth dissection despite the variability in tissue composition.

During POEM procedures, the ESU also fared well with total dissection/myotomy times of under 60 minutes with no complications. Generator setting changes were not required when switching from submucosal tunneling to myotomy, which makes its clinical use quite relevant. Lastly, dissection during POEM was primarily carried out with the ProKnife, which has a central injection function, and may have expedited the procedure as a whole.

Most importantly, the Beamer CE600 ESU demonstrated an acceptable safety profile. The overall perforation rate of 6.7% was comparable to the published literature [19] with the majority managed via endoscopic treatment. In addition, all of our AEs occurred within the colon and duodenum, which have established high AE rates [20]. In fact, our perforation rate of 6.7% in these two locations was significantly lower than previously documented data [20]. Finally, although 13 patients required hospitalization after the procedure for pain, only one patient had verified post-electrocautery syndrome (1.6%).

Currently, limited validated data are available regarding optimal ESU settings for ESD [18]. In our study we aimed to test and reproduce optimal generator settings for quick easy reference, using the Beamer CE600 ESU. This was first determined after extensive testing in animal models and then brought to clinical practice. We found during ESD, an incision setting of G5 and dissection setting of 35 W hot biopsy setting was a good starting point for efficient dissection regardless of location (esophagus, stomach or colon) or tissue consistency. In the duodenum, 30 W hot biopsy setting may be more acceptable given the fragility of the duodenal wall. In POEM, it appeared settings set to G2 were most appropriate for incision and myotomy, with 37 W Spray Coagulation being an optimal setting for tunneling.

Our study has several limitations, beginning with its descriptive and non-blinded nature. However, the primary aim of this study was to introduce novel settings using this commercially available ESU and describe its efficacy. Second, dissection speed may have been overestimated or under-estimated, given some patients with multiple polyps were excluded from speed analysis, due to inability to calculate speed for each individual polyp within that patient. Third, we cannot say at this point that the Beamer CE600 is superior to other ESU because comparative analysis has not yet been performed. However, future studies are pending to help validate its true benefit during ESD and of its current electrocautery settings.

Conclusions

In a day and age in which ESD is becoming increasingly routine in clinical practice, diversification and evolution of the technology are needed. This is the first study evaluating the most optimal electrocautery settings during performance of ESD with the Beamer CE600. Submucosal endoscopic procedures, regardless of type of dissection knife used, location, or tissue composition, are feasible and safe with this novel ESU. In our practice, we will implement the Beamer CE600 for routine use during submucosal endoscopy procedures. However, further prospective randomized trials are needed to assess its clinical superiority over standard ESU.

Conflict of Interest

Mohamed O. Othman: Mohamed O Othman is a consultant for Olympus, Boston Scientific Corporation, Abbvie, ConMed, Creo Medical, Lumendi, Nestle and Apollo. Mohamed O Othman received research grants from Lucid Diagnostics, AbbVie, ConMed, Olympus and Boston Scientific. Salmaan Jawaid: Salmaan Jawaid is a consultant for ConMed, Creo Medical, and Lumendi. Tara Keihanian: Tara Keihanian is a consultant for Lumendi and Neptune medical. Mai Khalaf, Margarita Riojas-Barrett, Wesam Abdeljaber, Michael Mercado & Noor Zabad have no conflicts of interest. This study was investigator-initiated study funded by ConMed. The funding body was not involved with the study design, execution or results. The funding body did not contribute to the drafting of this manuscript.

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Clinical trial

Trial registry: ClinicalTrials.gov (http://www.clinicaltrials.gov/) | Registration number (trial ID): NCT04752670 | Type of Study: Prospective

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