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Endoscopic ultrasound-Directed transgastric ERCP (EDGE): A single center U.S. experience with follow up data on fistula closure

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Abstract

Background—Endoscopic ultrasound-directed transgastric ERCP (EDGE) by creating an anastomosis from the gastric pouch or jejunum to the excluded stomach allows performance of ERCP in Roux-en-Y gastric bypass (RYGB) anatomy. Concern for persistent fistula following stent removal and sparse data limit adoption.

Methods—Retrospective review of consecutive patients undergoing EDGE over a two-year period.

Results—19 RYGB patients underwent EDGE; 3 had previously failed ERCP by device-assisted method. Indications for ERCP were choledocholithiasis (8), recurrent acute pancreatitis (6), benign postsurgical stricture (3), elevated bilirubin and papillary stenosis (1 each).

EDGE was technically successful in all 19 patients with jejunogastric anastomosis in 11 patients and gastrogastric in 8 using a 15mm lumen apposing metal stent. Stent malposition occurred in 6 and was managed by rescue maneuvers. ERCP was performed in the same session in 4 patients; the remainder were delayed after a mean of 48 days. Diagnostic EUS was performed in 4. No severe adverse events occurred; clinical success was 100%. Stents were removed after a mean dwell time of 182 days. Argon plasma coagulation (APC) was used to promote fistula closure in 12 patients.

Upper GI series to assess fistula closure was obtained in 11 patients after a mean of 182 days following stent removal. One persistent fistula was identified and closed endoscopically.

Conclusions—EDGE is an effective modality for performing ERCP in patients with RYGB anatomy and can be performed via gastrogastric or jejunogastric approaches. Persistent fistula is uncommon and can be managed endoscopically. APC may promote fistula closure.

Keywords

Endoscopic ultrasound; gastric bypass; Roux-en-Y; ERCP; EDGE; EUS-GG-ERCP

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1. 0 Introduction

Roux-en-Y gastric bypass (RYGB) surgery is the second most common weight loss surgery in the United States.[1] RYGB anatomy makes it difficult to access the biliary tree, a requirement for endoscopically treating pancreaticobiliary diseases. It is estimated that 36% of patients who have undergone RYGB develop gallstones,[2] and of those, 5.3% require an ERCP.[3] In RYGB patients the two most commonly used approaches for transpapillary biliary interventions are device-assisted enteroscopy (DAE) endoscopic retrograde cholangiopancreatography (ERCP) and laparoscopically-assisted transgastric (TG) ERCP.[4] DAE-ERCP is limited by forward-viewing optics and imperfect accessories resulting in relatively low technical success rates.[5][6] TG-ERCP requires laparoscopic assistance, which introduces additional risks and must be coordinated with surgical colleagues. Sterility requirements of TG-ERCP and the often sub-optimal fluoroscopic equipment available in the operating suite are additional limitations.

Endoscopic ultrasound-directed transgastric ERCP (EDGE) was first described in 2014 as a means of performing ERCP in patients with RYGB anatomy.[7] This technique involves creation of a fistulous tract by placing a lumen-apposing metal stent (LAMS) under EUS guidance between either the jejunum or gastric pouch to the excluded stomach, and subsequently performing conventional ERCP through the LAMS. A recently published midterm analysis demonstrated a technical success rate of 100% in 16 patients. [8] However, while this procedure has shown promise, clinicians have been reluctant to adopt EDGE out of concern for persistent fistula following stent removal. Some clinicians performing EDGE have described routinely closing the fistula using over-the-scope clips and/or endoscopic suturing.[8] It is known that spontaneous gastrogastric or jejunogastric fistula following RYGB is associated with weight regain and worsening of glycemic control. [9] Despite this concern and current practice patterns, sparse data exist on EDGE performance and persistence of gastroenteric fistula following EDGE procedure and related effects.

The present study aimed to describe the outcome of patients undergoing EDGE for biliary and/or pancreatic intervention and assess fistula closure after stent removal, describe the associated signs and symptoms of persistent fistula and methods of fistula closure.

2.0 Patients and Methods

All adult patients (age ≥18 y) who underwent EDGE by one endoscopist at a large tertiary referral center between January 2016 through January 2018 were identified. Endoscopy reports, medical charts and relevant laboratory data were reviewed and recorded in accordance with Institutional Review Board protocol. For this type of study formal consent is not required. Clinical and procedural data were collected, including etiology of biliary disease, indication for EDGE, endoscopic data (length and diameter of stent, anastomotic location, procedural findings), procedure-related adverse events, post-procedural symptoms, and clinical success, when available. Adverse events were graded according to the American Society for Gastrointestinal Endoscopy lexicon. [10] As this was a retrospective study of previously collected data, individual informed consent does not apply.

Statistical analyses were performed using Stata version 15.1 (StataCorp, TX). All continuous variables are expressed as mean ± standard deviation, and skewed variables are expressed as median and interquartile range. Categorical variables are expressed as proportions (%). Student's t-test was used to compare continuous measures, and 2-tailed Fisher exact test was used to compare differences in proportions between groups. Univariate binary logistic regression was used to identify predictors of procedural success. Because of a small number of events, we did not perform a multivariate logistic regression analysis. A p value < 0.05 was considered statistically significant.

3.0 Results

Twenty patients with RYGB anatomy were initially considered for EDGE; 17 were outpatient at the time of EUS. One patient was censored from analysis because the excluded stomach could not be identified by EUS. Of the 19 patients who underwent EDGE, 15 were female (79%), (median age, 56 years), mean pre-procedure weight of 89.8 kg (SD ± 31.0 kg) and 3 had previously failed ERCP by device-assisted (single balloon enteroscopy) method. The indications for ERCP were choledocholithiasis in 8 patients (42%), recurrent acute pancreatitis in 6 (32%), benign post-surgical stricture in 3 (16%), elevated bilirubin in 1 (5%), and papillary stenosis in 1 (5%). Patient demographic data are presented in Table 1.

3.1 Procedure

General anesthesia was used in all cases and mean procedure time was 116 minutes (SD ± 88 minutes). Pre-procedural antibiotics were not routinely administered. The technique of EDGE was performed as follows: a standard therapeutic channel oblique linear echoendoscope (GF-UCT180, Olympus America, Center Valley, PA) was passed into the gastric pouch or the jejunum just beyond the gastrojejunostomy to visualize the excluded stomach. A 19G needle (Expect™, Boston Scientific, Marlborough, MA) preloaded with water soluble contrast was used to puncture through the excluded stomach and entry confirmed by contrast injection under fluoroscopy. The needle was flushed with saline and a 0.025", 450 cm long hydrophilic-tipped guidewire (VisiGlide, Olympus) was advanced through the needle and coiled within the lumen of the excluded stomach. The LAMS (Axios; Boston Scientific) was then passed over the guidewire followed by stent deployment into the excluded stomach. When an electrocautery enhanced system was used, dilation of the fistulous tract was not required prior to stent deployment and the device was passed over the wire using pure cutting current.

The distal flange of the stent was deployed under fluoroscopic and endosonographic guidance into the excluded stomach and the proximal flange was deployed under direct endoscopic visualization. The stent was variably dilated to 15mm using dilating balloon (CRE; Boston Scientific). ERCP or EUS was typically delayed to allow for fistula maturation and to reduce the risk of stent dislodgement, however in cases of a single session procedure, ERCP was performed using a 9.3 mm forward-viewing adult upper endoscope, again to reduce the risk of stent dislodgement. Once ampullary access was no longer required, the LAMS was removed using a standard large diameter polypectomy snare or grasping forceps. After the first five patients, we routinely applied argon plasma coagulation

(APC) to the tract at the time of stent removal in order to promote re-epithelialization and fistula closure.

The procedure was technically successful in all 19 patients. The anastomosis was jejunogastric in 11 patients and gastrogastric in 8. A self-expandable LAMS was deployed initially in all patients, however it was malpositioned in 6 patients and required rescue maneuvers including the use of a fully covered metal esophageal stent (Niti-S, Taewoong Medical) in 4 patients. All LAMS were 15 mm in diameter; 14 with electrocautery enhancement and 5 without electrocautery. Niti-S stents were 60 mm in length with diameters of 18 mm (3 patients) or 20 mm (one patient).

ERCP was performed in the same session as EUS-guided anastomosis in 4 patients. In patients who had a two-step procedure, the mean length of time between anastomosis and ERCP was 48 days (SD ± 70 days). Four patients underwent diagnostic EUS through the anastomotic tract; fine needle biopsy was performed in 2 patients and resulted in a diagnosis of pancreatic adenocarcinoma in one. There were no serious events in this cohort and all patients went on to have clinical success.

Stents were removed in all patients after a mean dwell time of 182 days (SD ± 158 days). As noted above, after the first five patients APC was routinely applied to the fistulous tract in all patients except for two with need for recurrent pancreaticobiliary intervention; one with underlying pancreatic cancer and one in whom a temporary pancreatic duct stent was placed to aid cannulation. In two patients including the patient with pancreatic cancer, a plastic double pigtail stent was placed across the fistula to facilitate repeat antegrade ERCP. This plastic stent was removed in one of these patients followed by treatment with APC to the fistulous tract. Figure 1 demonstrates fistula closure around plastic stent prior to removal and treatment with APC.

3.2 Fistula closure and weight change

Upper GI series with oral contrast to assess fistula closure was intended in all but the aforementioned patient with pancreatic cancer (18 out of 19 patients) and was obtained in 11 patients (61%) after a mean of 182 days (SD ± 158 days) from the time of stent removal. A patent fistula was discovered in 1 patient out of 11 (9%) following transjejunal EDGE (Figure 2). This patient had gained 5.6 kg in the seven month period following EDGE and sought medical attention prior to our practice of obtaining routine upper GI series. Upper endoscopy with APC of the fistulous tract followed by over-the-scope clip placement (OVESCO™, Ovesco Endoscopy Cary, NC) was performed. After temporary loss of follow-up, upper GI series 401 days later demonstrated eradication of the fistulous tract (Figure 3) and 2.8 kg weight loss. Mean length of follow-up in all patients was 281 days (SD ± 177 days). Mean cohort weight at last follow up was 91.7 kg (SD ± 31.2 kg) with a mean weight gain of 1.7 kg (SD ± 8.6 kg) from their pre-procedure weight. Patient specific procedure details and outcomes data are presented in Table 2.

4.0 Discussion

The growing number of patients with surgically-altered upper GI anatomy has created new challenges for endoscopists, particularly in the management of pancreaticobiliary disease. As an alternative to surgical and percutaneous approaches, endoscopists have attempted to approach these patients in thoughtful and pioneering ways. Originally described by Kedia et al., EDGE represents an important advancement in the treatment of pancreaticobiliary disease for patients with RYGB anatomy. Previous reports of technical success have yielded promising results, and the present study, which represents the largest case series to date, serves to reinforce both the technical success as well as the safety and efficacy of this method for performing ERCP or EUS in patients that would have otherwise required more elaborate measures.

Concerns about a patent fistula following stent removal are real [11], as demonstrated by one patient in our series with a persistent fistula on upper GI series that was associated with weight gain when APC was not applied to the fistulous tract at the time of stent removal. Fistula closure was confirmed on repeat imaging following OTSC placement. We have not adopted routine OTSC placement or endoscopic suturing at the time of stent removal at our center, both for cost conscious reasons and to minimize potential risk to the patient, though we routinely apply APC when it is certain that pancreaticobiliary reintervention will not be needed. The use of APC to promote re-epithelialization and gastrogastric fistula closure following stent removal in EDGE patients has previously been described.[12]

Interestingly, we found weight gain complaints after LAMS removal even when fistula had closed and thus weight reporting may not be a reliable measure of fistula status. We recommend that either an upper endoscopy or upper GI series should be obtained in all patients undergoing EDGE to determine the presence of persistent fistula and if present, closure is warranted.

The present study shows EDGE to be a safe and effective approach to pancreaticobiliary disease in patients who do not require urgent endoscopic treatment. APC at the time of stent removal may facilitate closure, though we believe these fistulous tracts are prone to spontaneous closure. Comparative studies, including cost-analysis of approaches are needed.

Acknowledgments

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Abbreviations:

ERCP	endoscopic retrograde cholangiopancreatography
EUS	endoscopic ultrasound
EDGE	endoscopic ultrasound-directed transgastric ERCP
DAE-ERCP	device-assisted enteroscopy ERCP

TG-ERCP transgastric ERCP

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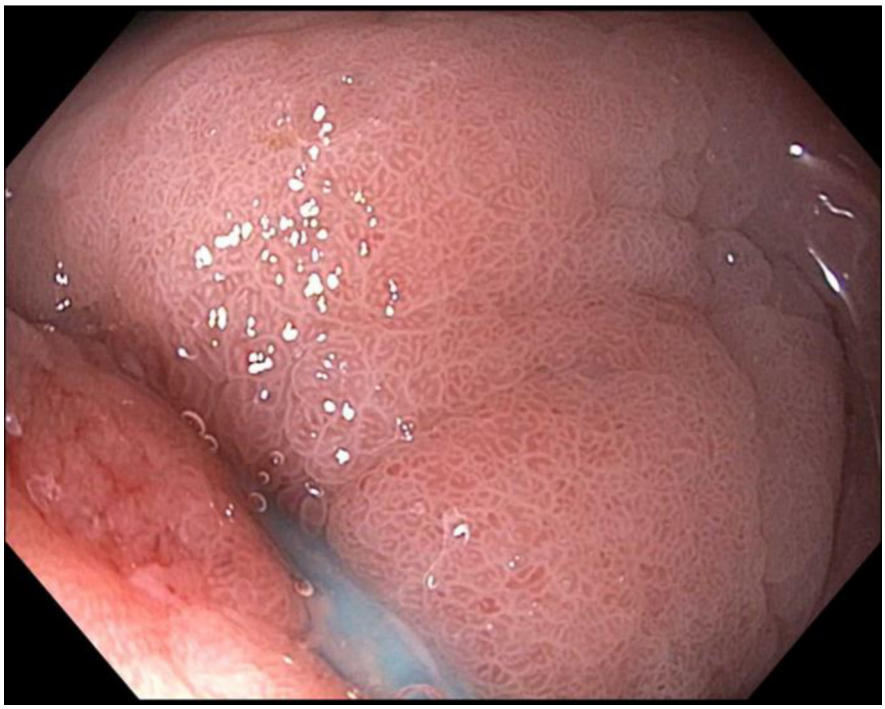

Figure 1.
Jejunogastric fistula with spontaneous closure around a plastic stent prior to removal and treatment with APC.

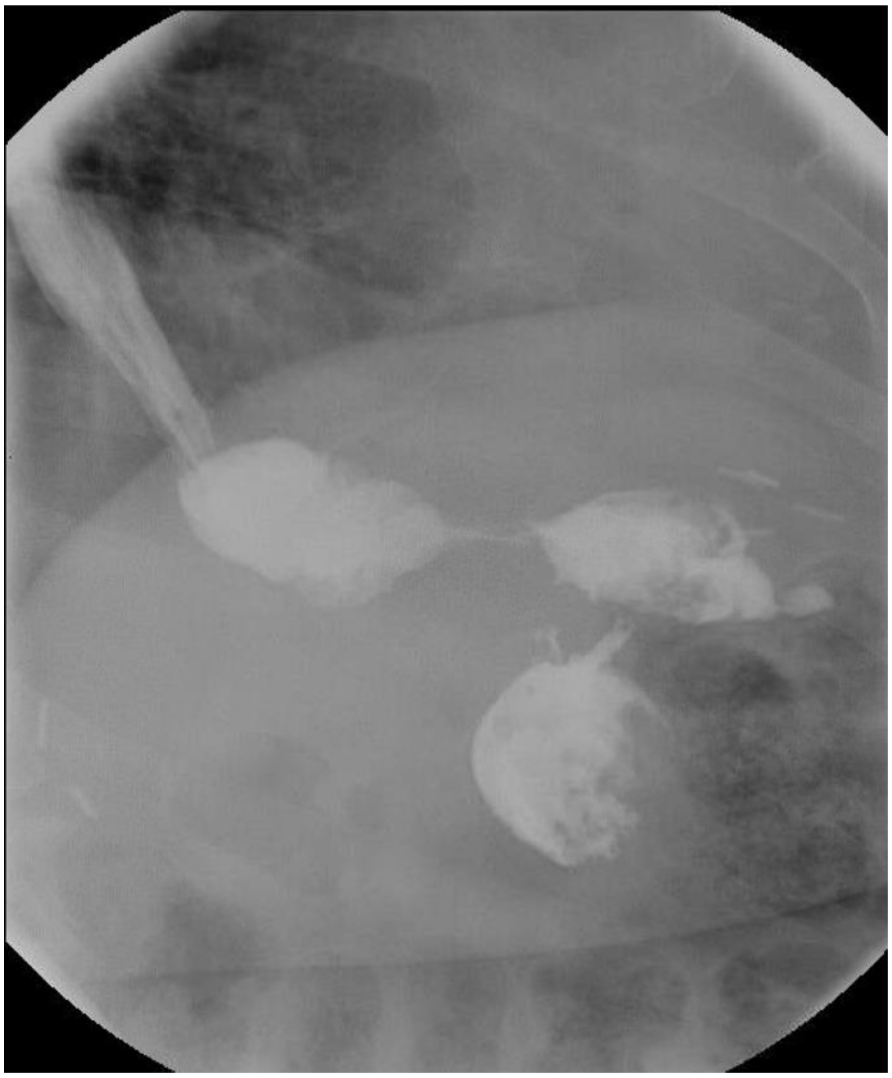

Figure 2.
Upper GI series demonstrating patent jejunogastric fistula following stent removal.

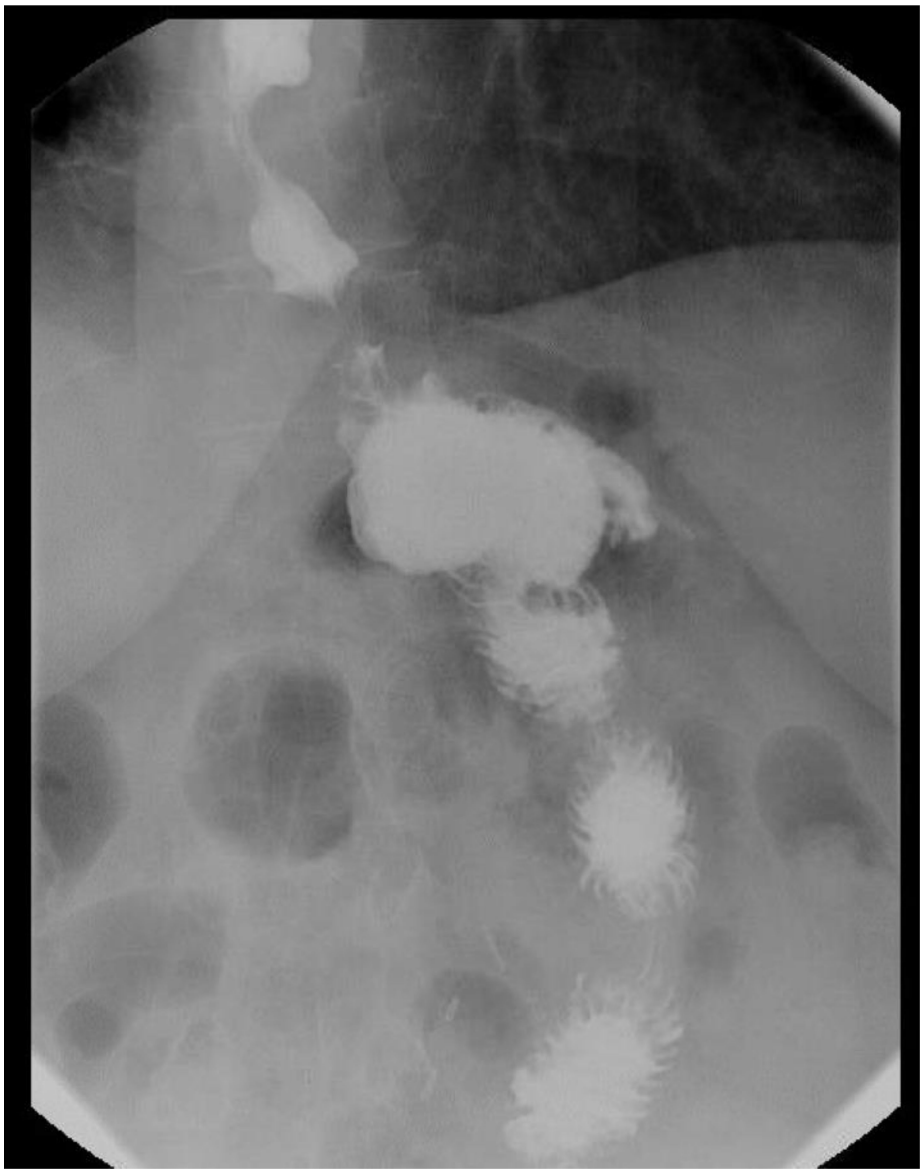

Figure 3.
Upper GI series demonstrating closure of jejunogastric fistula following argon plasma coagulation and over-the-scope clip placement to fistulous tract opening.

Table 1.

Patient demographic data

EDGE Patients (n=19)	
Mean age, yrs (SD)	55.5 (± 3.2)
Females, n (%)	15 (78.9%)
Mean weight prior to EDGE, kg (SD)	90.1 (± 30.2)
Prior unsuccessful ERCP, n (%)	2 (10.5%)
Indication for ERCP	
· Choledocholithiasis	8 (42.1%)
· Recurrent acute pancreatitis	6 (31.6%)
· Benign post-surgical stricture	3 (15.8%)
· Elevated bilirubin	1 (5.3%)
· Papillary stenosis	1 (5.3%)

Table 2.

Patient specific procedure details and outcomes data. EDGE: EUS-Guided Transgastric ERCP; EUS: endoscopic ultrasound; ERCP: Endoscopic Retrograde Cholangiopancreatography; APC: Argon Plasma Coagulation; GI: Gastrointestinal; OTSC: Over-the-scope clip.

Patient	Age	Gender	Weight with in 30 day prior to EDGE, kg	Procedure Time, minutes	Stentinitially malpositioned	Stent proximalend location	Days between EUS and ERCP	Days stent was in place prior to removal	Plastic stent through fistula to maintain patency	Repeat ERCP through fistulo us tract	APC of fistulo us tract	Days between stent removal and upper GI series	Fistula present on upper GI series	OTSC for fistula patent closure	Fistula present on repeat upper GI series	Weight at Last Follow Up (kg)	Weight change from pre-procedure to last follow up date (kg)
1	62	F	94.3	96	N	Jejunum	0	50	N	N	N	145	Y	Y	N	98.0	+ 3.6
2	67	F	81.6	205	N	Jejunum	0	150	N	Y	N	445	N	-	-	83.0	+ 1.4
3	56	F	82.6	18	N	Jejunum	49	466	N	Y	N	58	N	-	-	80.7	− 1.8
4	51	F	67.1	76	N	Jejunum	46	70	N	N	N	402	N	-	-	68.9	+ 1.8
5	69	F	50.8	208	Y	Stomach	43	43	N	N	N	-	-	-	-	48.1	− 2.7
6	55	M	118.8	182	N	Stomach	0	37	N	N	Y	-	-	-	-	134.7	+ 15.9
7	41	F	68.0	29	N	Stomach	297	297	N	N	Y	22	N	-	-	93.0	+ 24.9
8	61	M	74.8	66	N	Jejunum	40	76	N	N	Y	-	-	-	-	64.0	− 10.9
9	43	F	122.9	176	Y	Stomach	18	18	N	N	Y	335	N	-	-	117.9	− 5.0
10	69	F	63.5	58	N	Jejunum	51	51	N	N	Y	-	-	-	-	68.9	+ 5.4
11	57	M	135.2	185	Y	Jejunum	0	19	Y	Y	N	-	-	-	-	131.5	− 3.6
12	61	F	81.6	340	Y	Stomach	19	56	N	N	Y	-	-	-	-	74.8	− 6.8
13	52	F	90.3	80	Y	Jejunum	6	70	Y	Y	Y	-	-	-	-	88.5	− 1.8
14	57	F	149.7	70	N	Jejunum	35	35	N	N	N	80	N	-	-	147.4	− 2.3
15	45	F	61.7	72	N	Stomach	18	103	Y	Y	Y	95	N	-	-	65.8	+ 4.1
16	39	F	62.1	18	N	Jejunum	28	42	N	N	Y	53	N	-	-	75.7	+ 13.6
17	71	M	154.2	73	N	Stomach	46	46	N	N	Y	58	N	-	-	157.4	+ 3.2
18	47	F	72.0	217	Y	Jejunum	10	10	N	N	Y	-	-	-	-	65.8	− 6.2
19	51	F	78.9	34	N	Stomach	21	21	N	N	Y	312	N	-	-	78.9	0