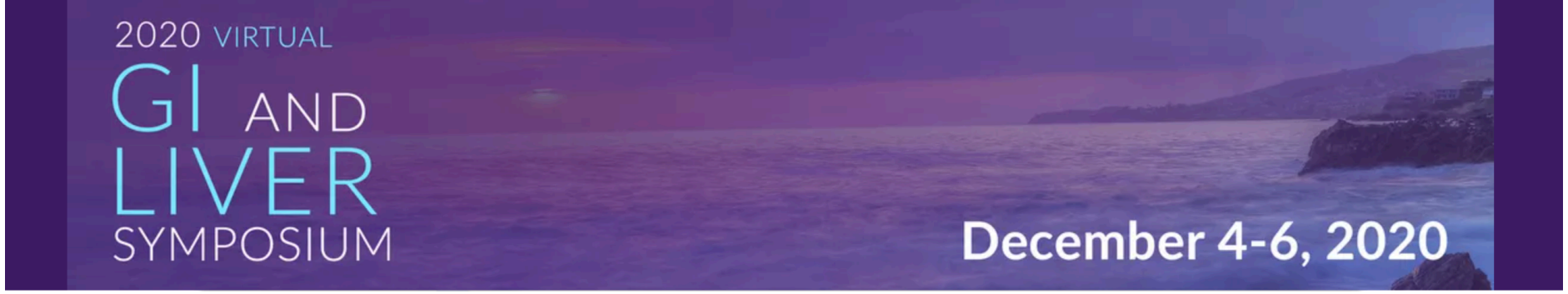


SOUTHERN CALIFORNIA SOCIETY OF GASTROENTEROLOGY

Advanced Endoscopy

POEM (Z-E-G), GERD, Endo-Bariatrics & Endo-Hepatology

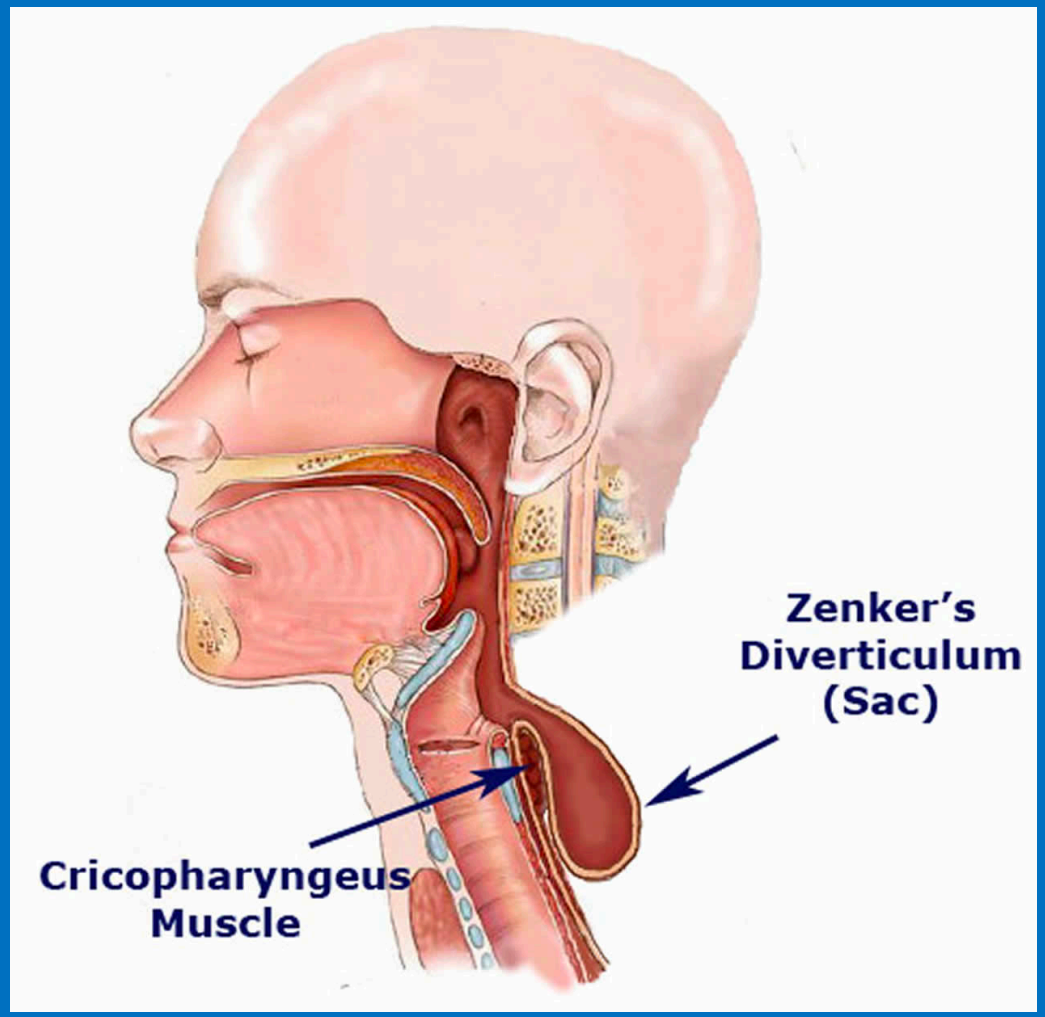
Kenneth J. Chang, MD, FACG, FASGE
Director, H.H. Chao Comprehensive Digestive Disease Center
Professor and Chief, Gastroenterology
Endowed Chair, GI Endoscopic Oncology

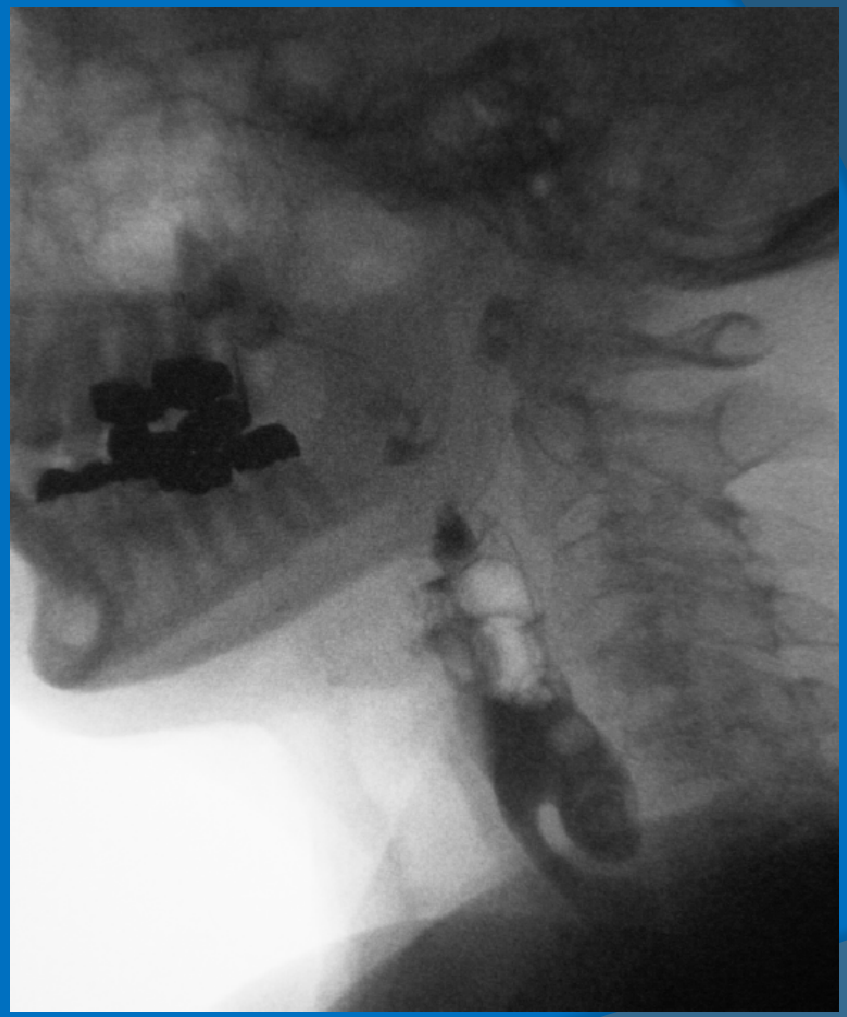
UC Irvine Health

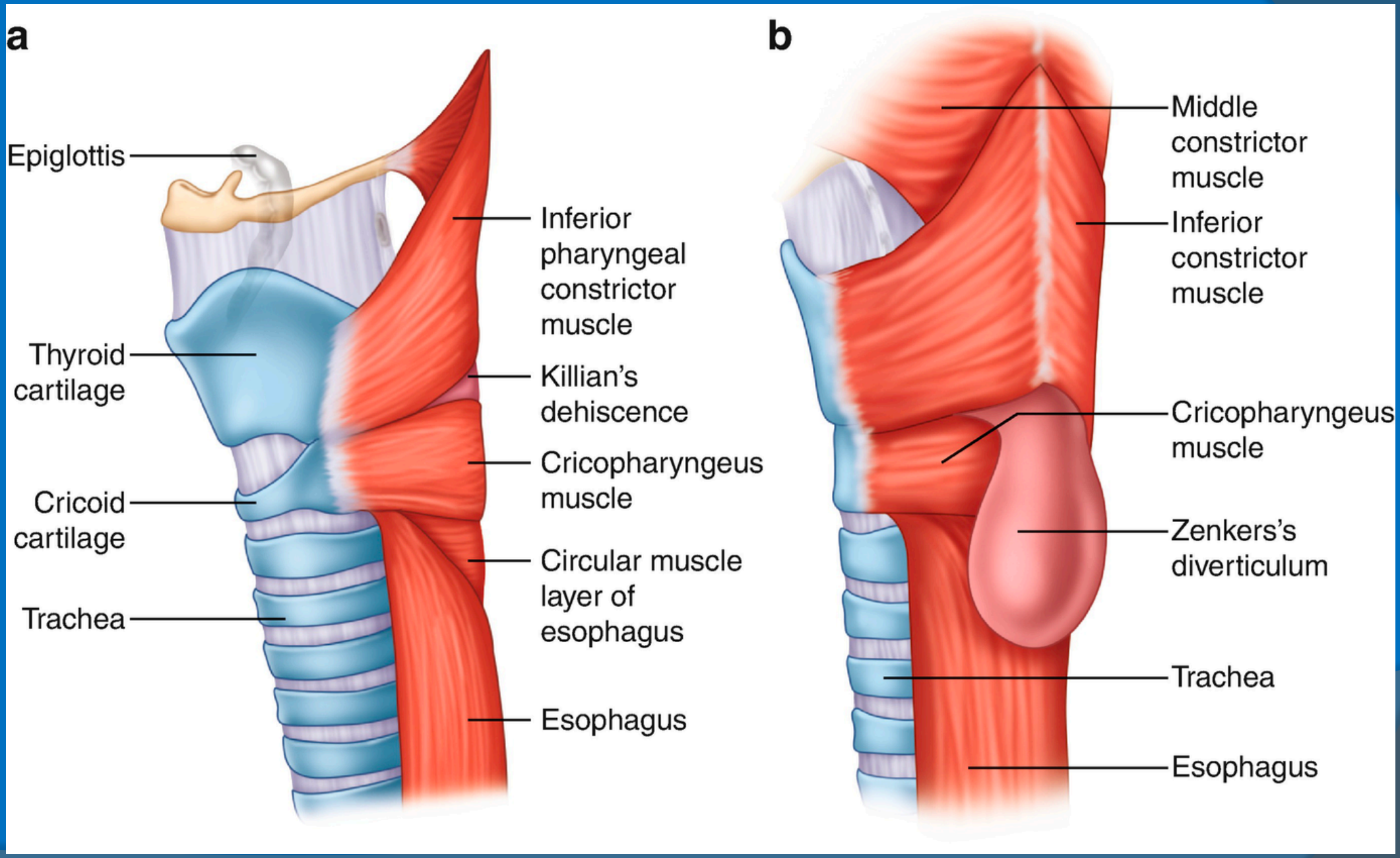
Disclosures

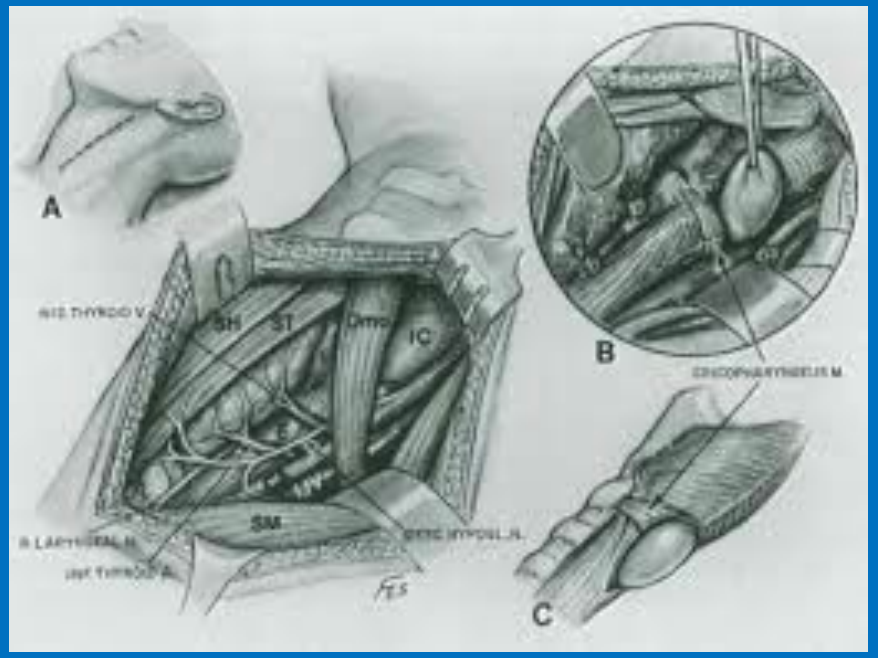
- Apollo
- Boston Scientific
- Cook
- Covidien
- Erbe
- Endogastric Solutions
- Mauna Kea
- Mederi
- Medtronics
- Olympus
- Ovesco
- Pentax
- Torax

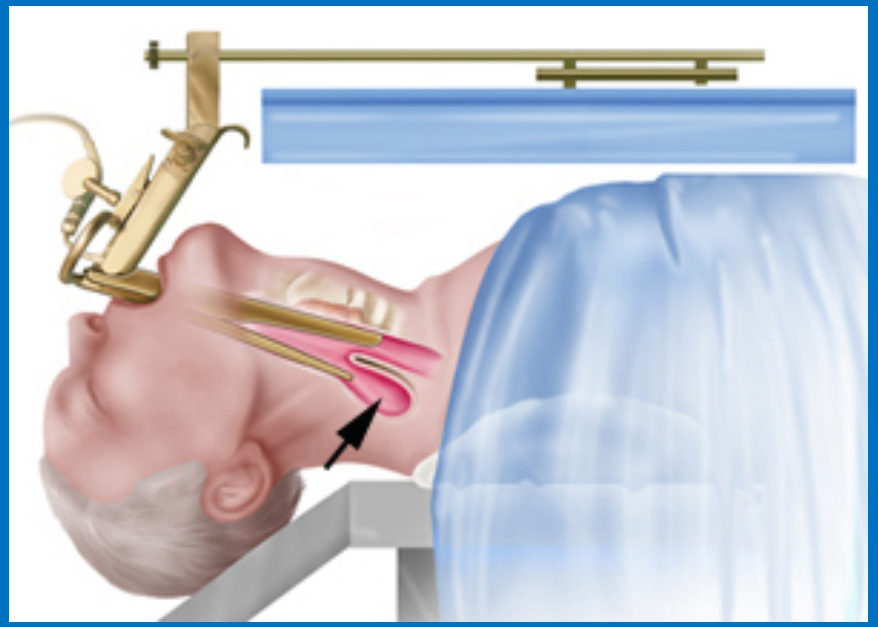
Zenker's Per-oral Endoscopic Myotomy (Z-POEM)

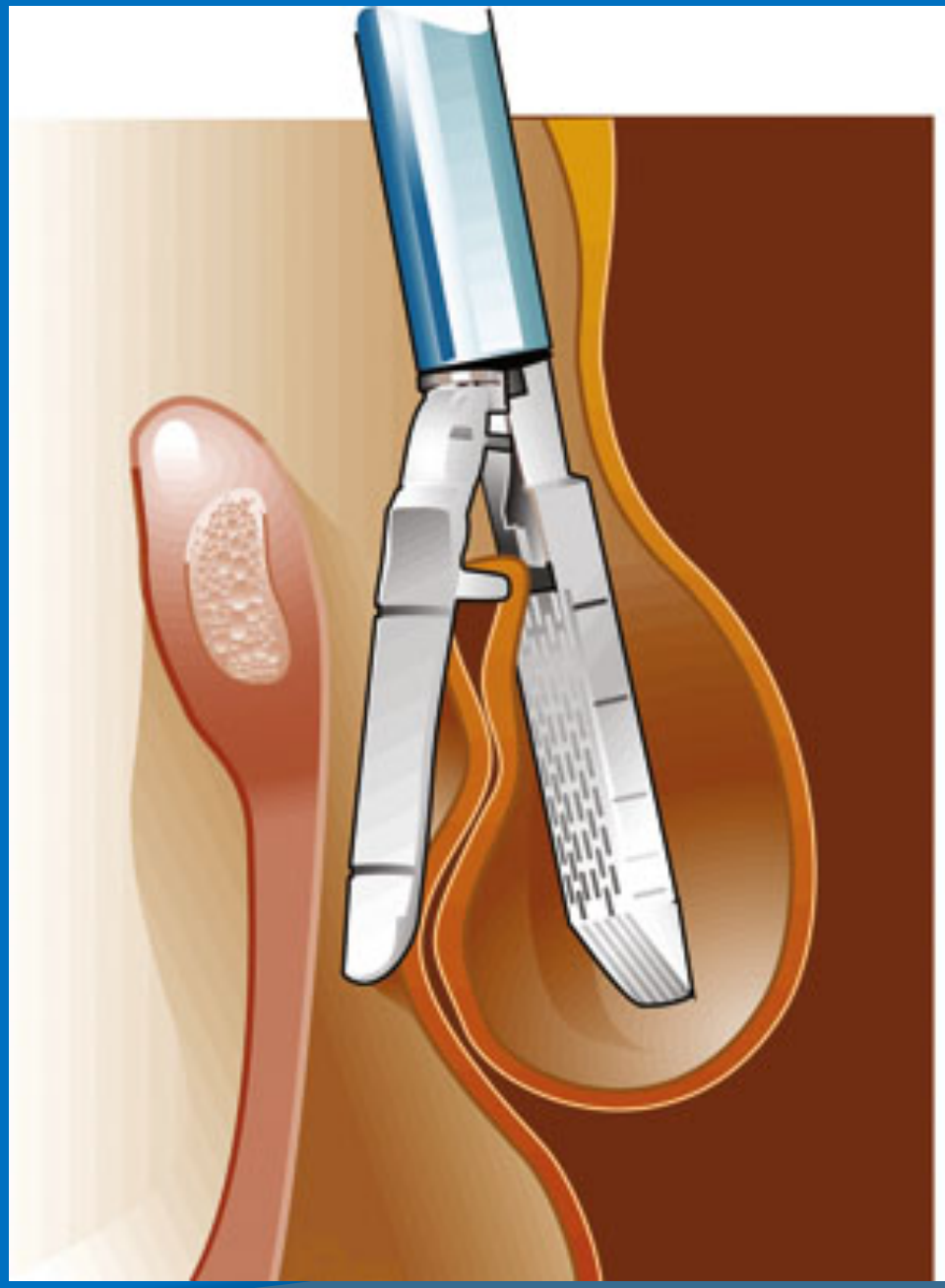

Zenker's
Diverticulum
(Sac)
Cricopharyngeus
Muscle

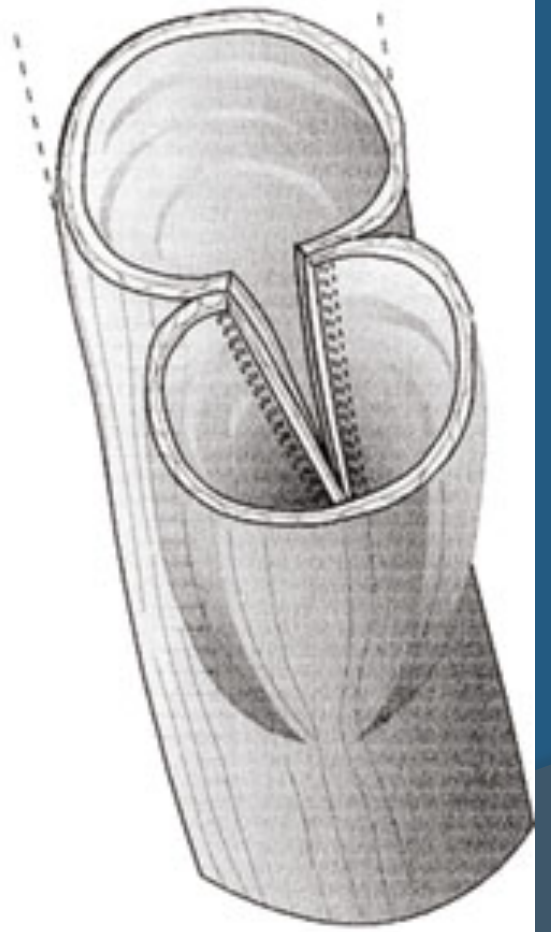



a
Epiglottis
Thyroid cartilage
Cricoid cartilage
Trachea
Inferior pharyngeal constrictor muscle
Killian's dehiscence
Cricopharyngeus muscle
Circular muscle layer of esophagus
Esophagus
b
Middle constrictor muscle
Inferior constrictor muscle
Cricopharyngeus muscle
Zenkers's diverticulum
Trachea
Esophagus


A
B
C
SH
ST
IC
SM







367

COMPARISON OF FLEXIBLE ENDOSCOPIC AND OPEN SURGICAL APPROACHES FOR ZENKER'S DIVERTICULA: A CASE-MATCHED STUDY

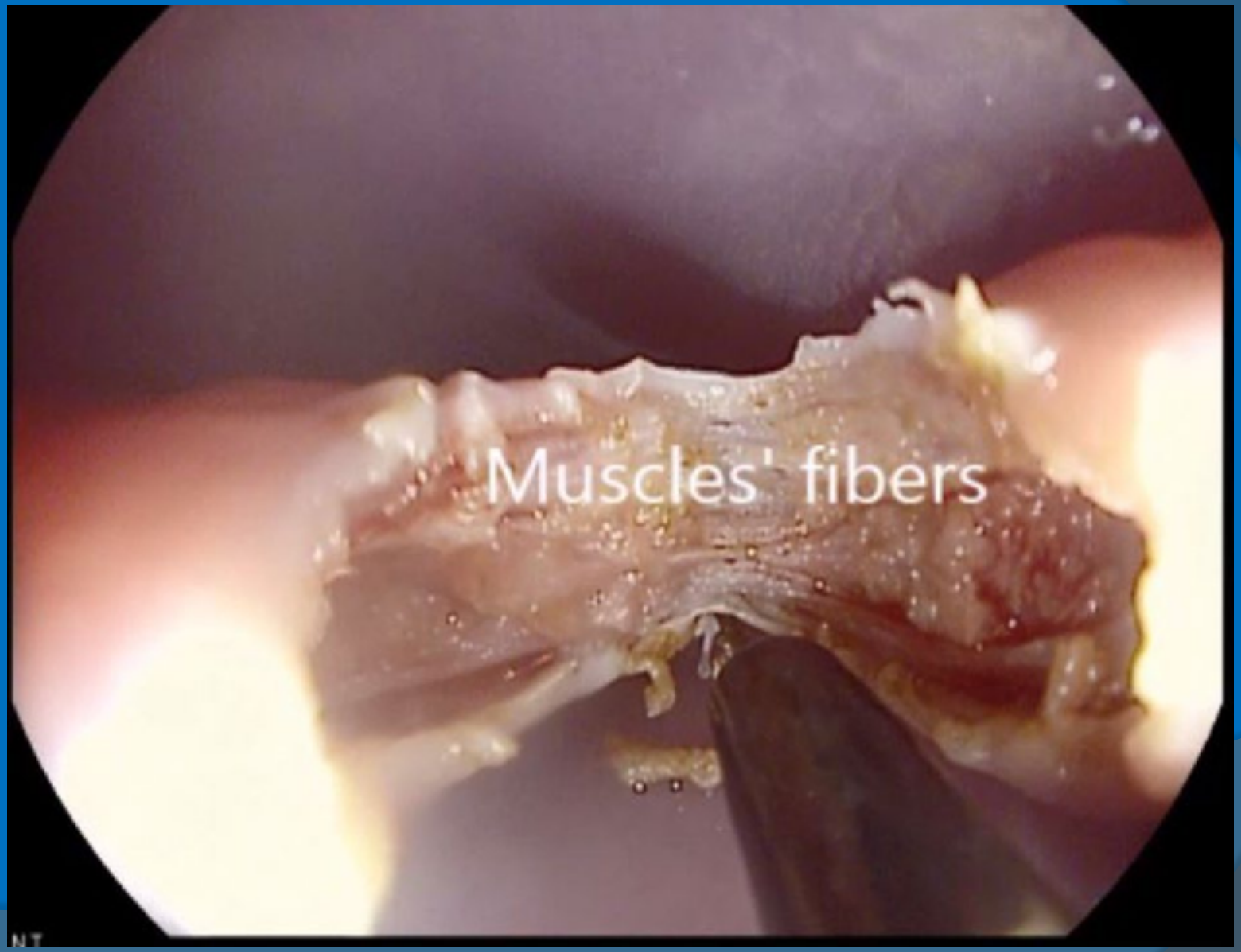
Thomas M. Runge*[2], Ethan D. Maahs[1], Matthew J. Fordham[3], David S. Kerner[3], Christopher C. Thompson[1]

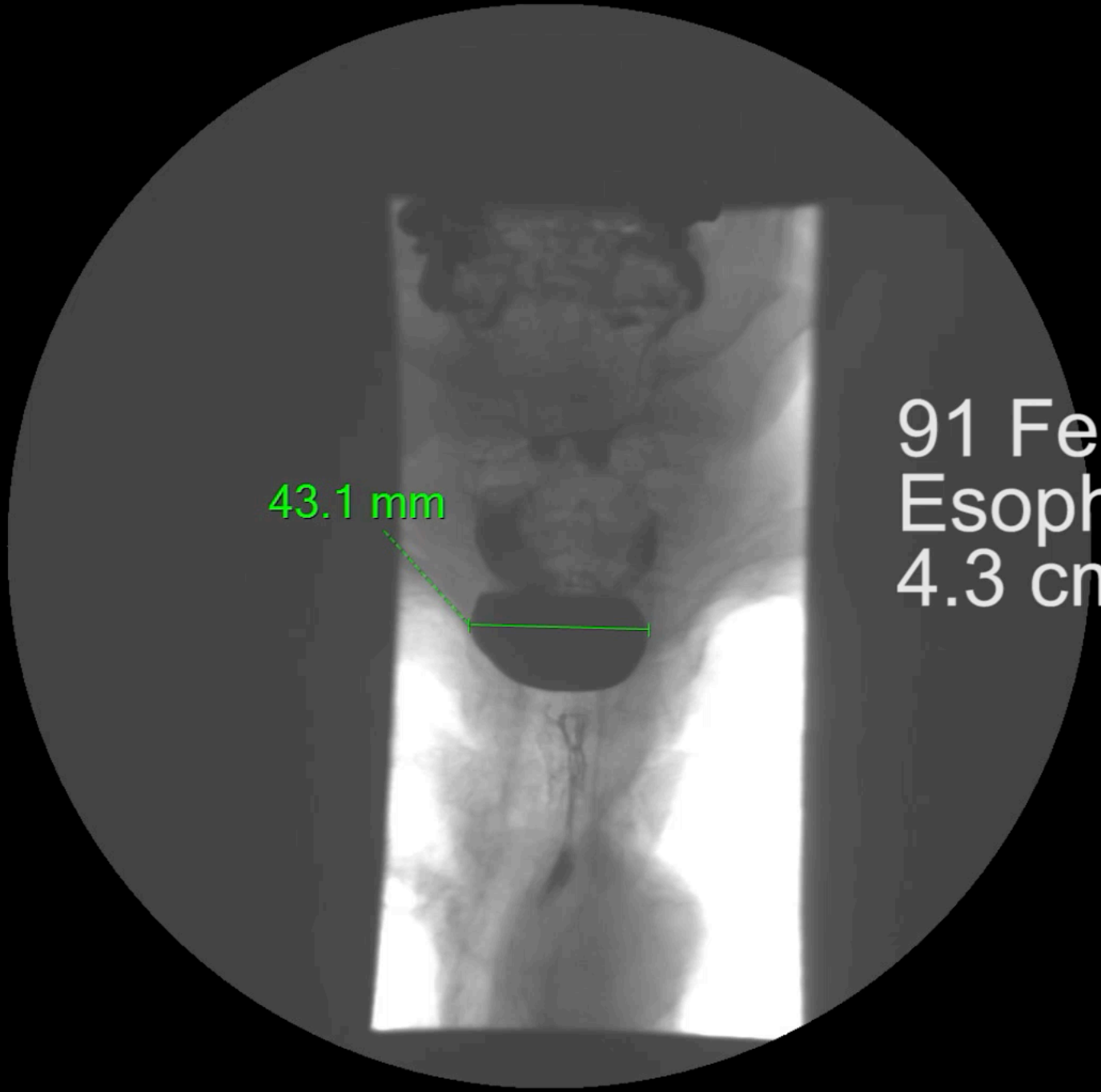
[1]Brigham & Women's Hospital, Boston, MA; [2]Johns Hopkins Medicine, Division of Gastroenterology and Hepatology, Baltimore, MD; [3]North Carolina School of Medicine, Division of Gastroenterology and Hepatology, Chapel Hill, NC

Background: Zenker's diverticula (ZD) are saccular outpoutchings of esophageal mucosa originating proximal and posterior to the upper esophageal sphincter (UES). Historically, treatment for ZD has involved surgery via a transcervical neck incision. Newer flexible endoscopic approaches offer an alternative to surgical procedures, but comparative data are lacking. The aim of this study was to compare efficacy and safety between the two approaches using a matched cohort study design. Methods: This was a matched cohort study of patients who underwent repair of Zenker's diverticulum. Patients who underwent any Zenker's repair were identified from a comprehensive institutional database. From this database patients who underwent either open transcervical surgical repair or peroral flexible endoscopic repair were identified. Cases were matched 3:1, surgery to endoscopy, based on age and Charlson comorbidity index. Primary outcome variables included clinical response (lack of ongoing or recurrent symptoms attributable to ZD) and adverse events associated with ZD repair. Adverse events were graded according to ASGE lexicon. Secondary outcomes included hospital length of stay (LOS), radiographic persistence of ZD, complete resolution of all swallowing symptoms, results of post-procedure swallowing studies, and ongoing swallowing symptoms attributed to causes other than ZD. Results: 60 patients who underwent flexible endoscopic treatment for Zenker's diverticulum were identified. 209 patients who underwent open transcervical repair of Zenker's diverticulum were identified as potential cases for matching. From these, 180 patients who underwent surgical therapy were matched in a 3:1 ratio to those who underwent flexible endoscopic therapy, yielding 240 included patients in the study. Technical success was high in both groups, 98% in the endoscopy group (59/60) and 100% in the open surgery group. 87% of patients in the endoscopy group had resolution of ZD-related symptoms, compared to 90% in the open surgical group ($p=0.59$). Adverse events (AEs) occurred in 15% (9/60) following endoscopic repair, compared to 17% (30/150) of patients following surgical repair ($p=0.76$). Perforation occurred in 7 patients (4%) following surgery, and 1 patient (1.7%) after endoscopy ($p=0.68$). Permanent vocal cord paralysis occurred in 5 patients following surgery, and none following endoscopic repair ($p=0.20$). Using the ASGE lexicon, there were 14 AEs graded as severe in the surgery group, compared to 0 in the flexible endoscopy group. ($p=0.03$). Hospital LOS on average was significantly less in the flexible endoscopy group (1.2 ± 2.5 days vs 3.4 ± 4.1 days, $p<0.01$). Conclusion: Flexible endoscopic myotomy for Zenker's diverticulum has comparable efficacy to that of surgical techniques, but is associated with significantly fewer serious adverse events and shorter hospital LOS.

- Matched cohort: Trans-cervical vs Flex

	Flex	Open	p-value
#	60	180	
Tech Success	98%	100%	ns
Clinical Success	87%	90%	.59
AE	15%	17%	.76
Perforation	1 (1.7%)	7 (4%)	.68
Vocal cord paral	0	5	.2
SAE	0	14	.03
LOS	1.2 d	3.4 d	.01


Muscles' fibers



91 Female, Upper Dysphagia
Esophagram shows
4.3 cm Zenker's Diverticulum

51

INTERNATIONAL MULTICENTER STUDY COMPARING Z-POEM AND FLEXIBLE/RIGID ENDOSCOPIC ZENKER'S DIVERTICULOTOMY

Sarah S. Al Ghamdi*[1], Jad Farha[1], Mohamad Aghaie Meybodi[1], Mathieu Pioche[7], Frédéric Moll[7], Oscar V. Hernández Mondragón[8], Michael Ujiki[5], Harry Wong[5], Alina Tantau[4], Alireza Sedarat[3], M. Phillip Fejleh[3], Gregory G. Ginsberg[6], Monica Saumoy[6], Ariana C. Lopez[1], Omid Sanaei[1], Muhammad N. Yousaf[2], Manol Jovani[1], Nasim Parsa[1], Yervant Ichkhanian[1], Olaya I. Brewer Gutierrez[1], Vivek Kumbhari[1], Anthony N. Kalloo[1], Mouen A. Khashab[1]

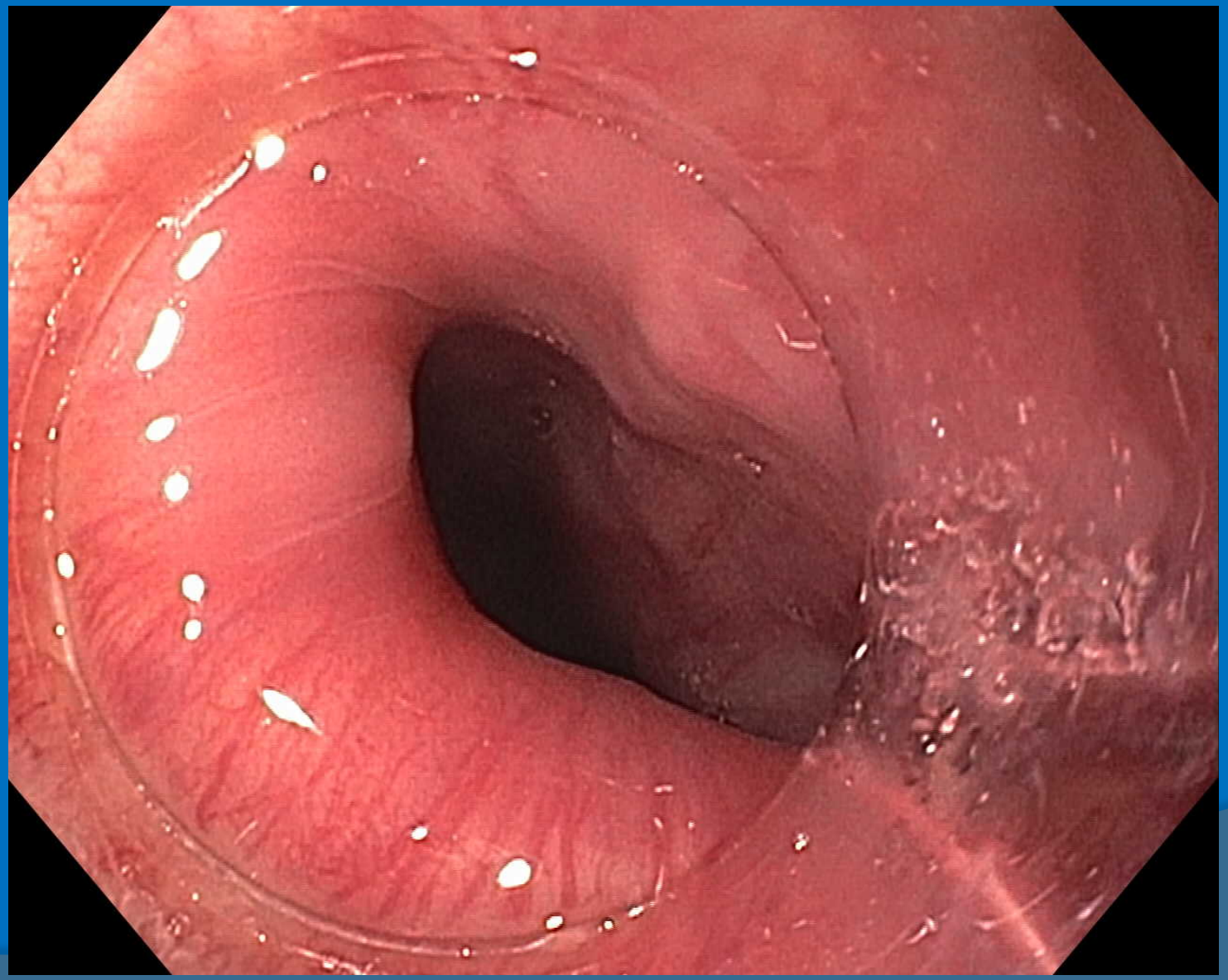
[1]The Johns Hopkins Hospital, Baltimore, MD; [2]Medstar Union Memorial Hospital, Baltimore, MD; [3]Ronald Reagan UCLA Medical Center, Los Angeles, CA; [4]Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania; [5]NorthShore Grainger Center for Simulation and Innovation, Chicago, IL; [6]University of Pennsylvania Division of Gastroenterology, Philadelphia, PA; [7]Edouard Herriot Hospital, Lyons, France; [8]IMSS, Mexico, Mexico

Background: Treatment of Zenker's diverticulum (ZD) has evolved from open surgical techniques to several endoscopic techniques, including flexible and rigid endoscopic diverticulotomy (ED), and more recently Per-Oral Endoscopic Myotomy (Z-POEM). The comparative efficacy of these techniques has not been evaluated. Aims: To compare Z-POEM to ED (flexible/rigid) with regards to clinical success, technical success, adverse events (AEs), and recurrence. Methods: Patients who underwent ED (flexible/rigid) or Z-POEM for the management of ZD between 1/2016 and 9/2019 were included. Primary outcome was clinical success (defined as decrease in Dakkak and Bennett dysphagia score to ≤1; and to 0 in patients with baseline score of 1; and complete resolution of other symptoms if no dysphagia at baseline). Secondary outcomes included technical success (defined as successful completion of all procedural steps) and rate of AEs (severity graded per ASGE lexicon). Results: A total of 158 patients (72F, mean age 71yr) from 7 centers were included. Z-POEM was the most common management modality (n=91), followed by flexible (n=49) and rigid (n=18) ED. There were no significant differences in baseline patient characteristics between all groups. The most common symptoms at the time of the index procedure were dysphagia (63%) and regurgitation (34%), with a mean pre-procedure dysphagia score of 1.7±0.9. Mean size of diverticulum was 30mm. Technical success was achieved in 93.4% of Z-POEM, 100% flexible ED, and 94% rigid ED groups (p=0.2). Septotomy was complete in 98% of patients who underwent Z-POEM, which was significantly higher in comparison to flexible (90%, p=0.04) and rigid ED (78%, p=0.03). Rate of clinical success was significantly higher in the Z-POEM group (86.8%) in comparison with flexible ED (81.4%, p=0.03), and was equivalent to the rigid ED group (88.2%, p=0.30). Mean procedure time for flexible ED (27min) was shorter than rigid ED (58min, p=0.003) and Z-POEM (43min, p=0.001). Median LOS was similar in the Z-POEM and flexible ED groups (1d), followed by the rigid ED group (3.5d). Mild/moderate procedure-related AEs occurred in 6 (6.6%) Z-POEM patients, 5 (27.8%) rigid and 1 (2%) flexible ED patients (p=0.002). Finally, 1 severe (bleeding, 5.6%) and 1 fatal (esophageal perforation, 5.5%) AE occurred in the rigid ED group. Fourteen patients were lost to follow-up: (7 Z-POEM, 6 flexible and 1 rigid ED). Most patients with clinical success had persistent resolution of symptoms (90.9% Z-POEM, 85% flexible and 100% rigid ED) during follow-up Median follow-up time was 63d for Z-POEM, compared to 195d for flexible and 341d for rigid ED patients. Conclusion: Z-POEM leads to significantly higher clinical success than flexible ED, and significantly higher complete septotomy than flexible and rigid ED. Severe/fatal AEs only occurred in the rigid ED group.

- Non-randomized trial, 158 pts, 7 centers

	Z-POEM	Flex	Rigid	p-value
#	91	49	18	
Tech Success	93.4%	100%	94%	.2
Septo Complete	98%	90%	78%	.03
Clinical Success	86.8%	81.4%	88.2%	.03
Time	43 min	27 min	58 min	.001
LOS	1 day	1 day	3.5 days	
SAE	-	-	bleed, death	
Long Term F/U	90.9%	85%	100%	

What if the CP Bar is TIGHT, but there's NO diverticulum?



984

PER ORAL ENDOSCOPIC MYOTOMY FOR CRICOPHARYNGEAL BAR

B. Joseph Elmunzer*, Robert Moran

Medical University of South Carolina, Charleston, SC

Background: Cricopharyngeal dysfunction (CPD), or failure of the cricopharyngeus muscle to relax in response to swallowing, is an uncommon but potentially severe cause of dysphagia that manifests as Zenker's diverticulum (ZD) or cricopharyngeal bar (CB) on contrasted fluoroscopy. In ZD, the cricopharyngeus forms a septum between the esophageal lumen and the diverticulum, serving as an identifiable target for intraluminal endoscopic and surgical treatment. In CB, the landmarks are less reliable and thus treatment options are more limited. Endoscopic dilation can be effective, but many patients experience inadequate or transient response. Cricopharyngeal per oral endoscopic myotomy (c-POEM) may be a viable treatment option. Cases: In this video series, we present three cases of patients between 75 and 83 years of age with multiple medical problems who presented with lifestyle-limiting dysphagia ranging from 2 months to 15 years in duration. All patients had radiographic evidence of a cricopharyngeal bar and had symptoms refractory to endoscopic dilation. Following c-POEM, all patients reported complete resolution of dysphagia and tolerated an unrestricted diet. Endoscopic methods: The approach to c-POEM is similar to that in the distal esophagus for the treatment of achalasia. The location of the cricopharyngeus muscle is initially estimated endoscopically. This can be challenging as the muscle is not always apparent and may vary in position relative to the esophageal introitus. A submucosal injection and overlying mucosal incision are performed ideally 1.5-2 cm upstream of the location of the cricopharyngeus. In a similar manner to conventional per oral endoscopic myotomy, the endoscope is then advanced into the expanded submucosa through the mucosotomy and a tunnel is created by sequential fluid expansion of the space followed by electrosurgical dissection of submucosal fibers. Once the muscle is fully exposed, the cricopharyngeus and a small amount of distal muscle is transected. The entry site into the submucosa is then closed using endoscopically deployed clips. Clinical implications: For patients with refractory cricopharyngeal bar who have limited treatment options, c-POEM allows reliable muscular division and may represent a safe and effective solution for this potentially debilitating and challenging condition.

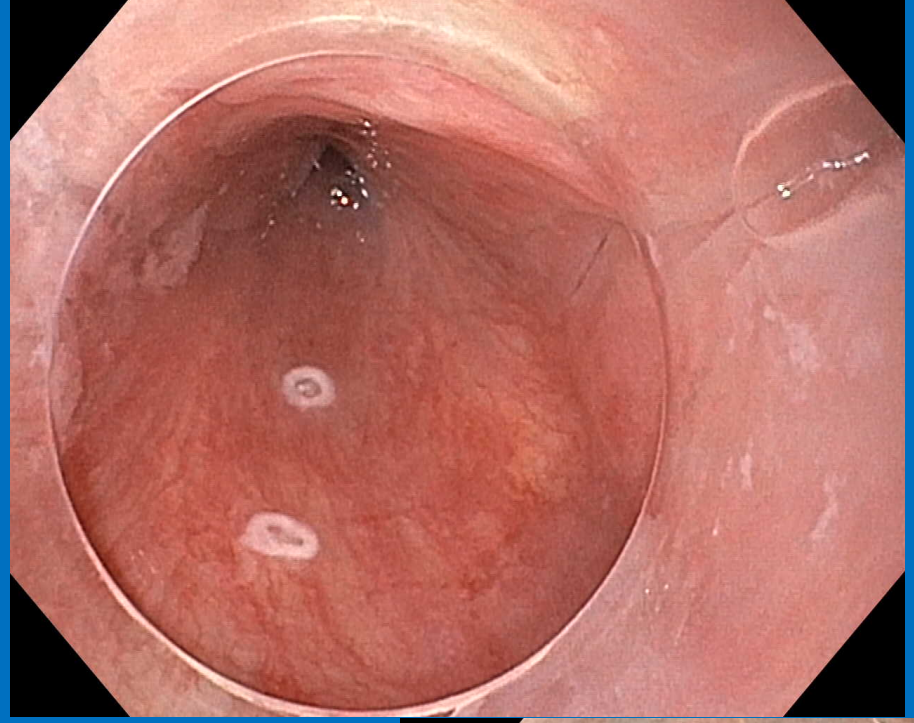
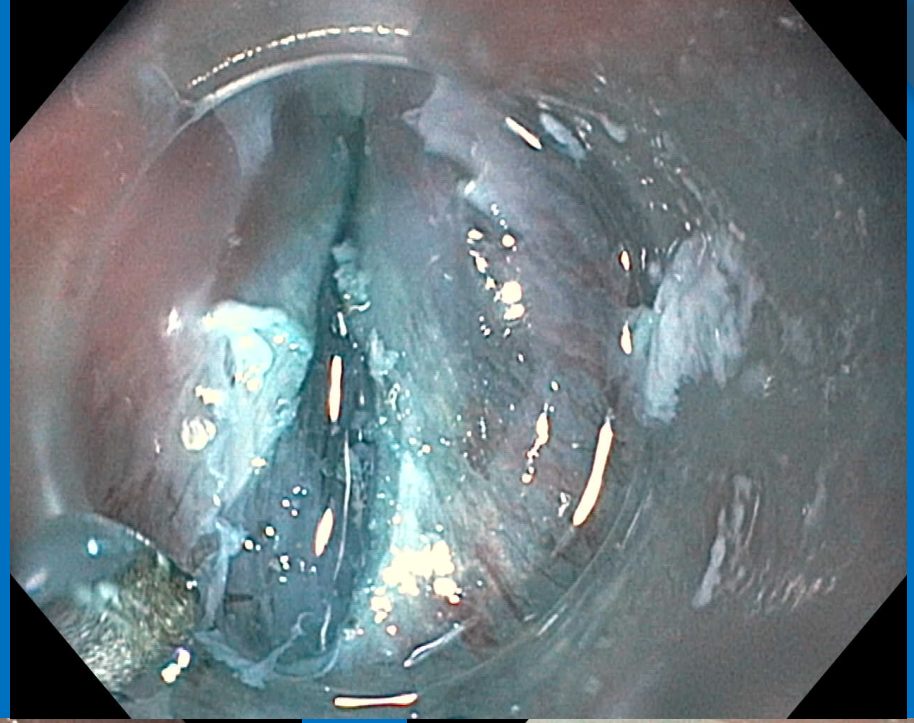
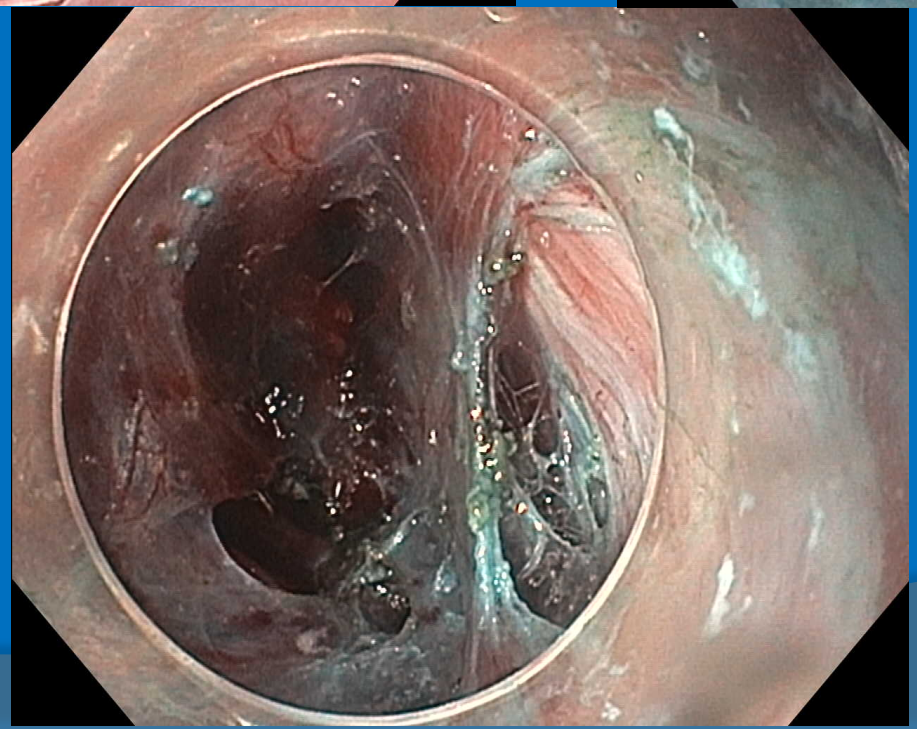
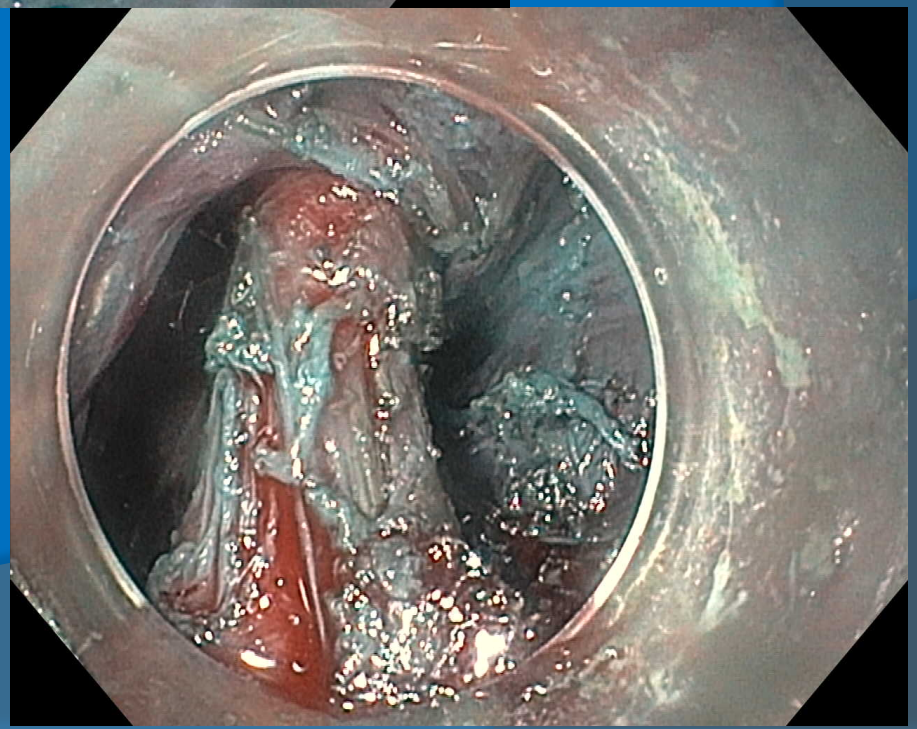
1072

NO POUCH, NO PROBLEM: SUCCESSFUL ENDOSCOPIC DIVISION OF A SYMPTOMATIC CRICOPHARYNGEAL BAR USING A MODIFIED Z-POEM TECHNIQUE

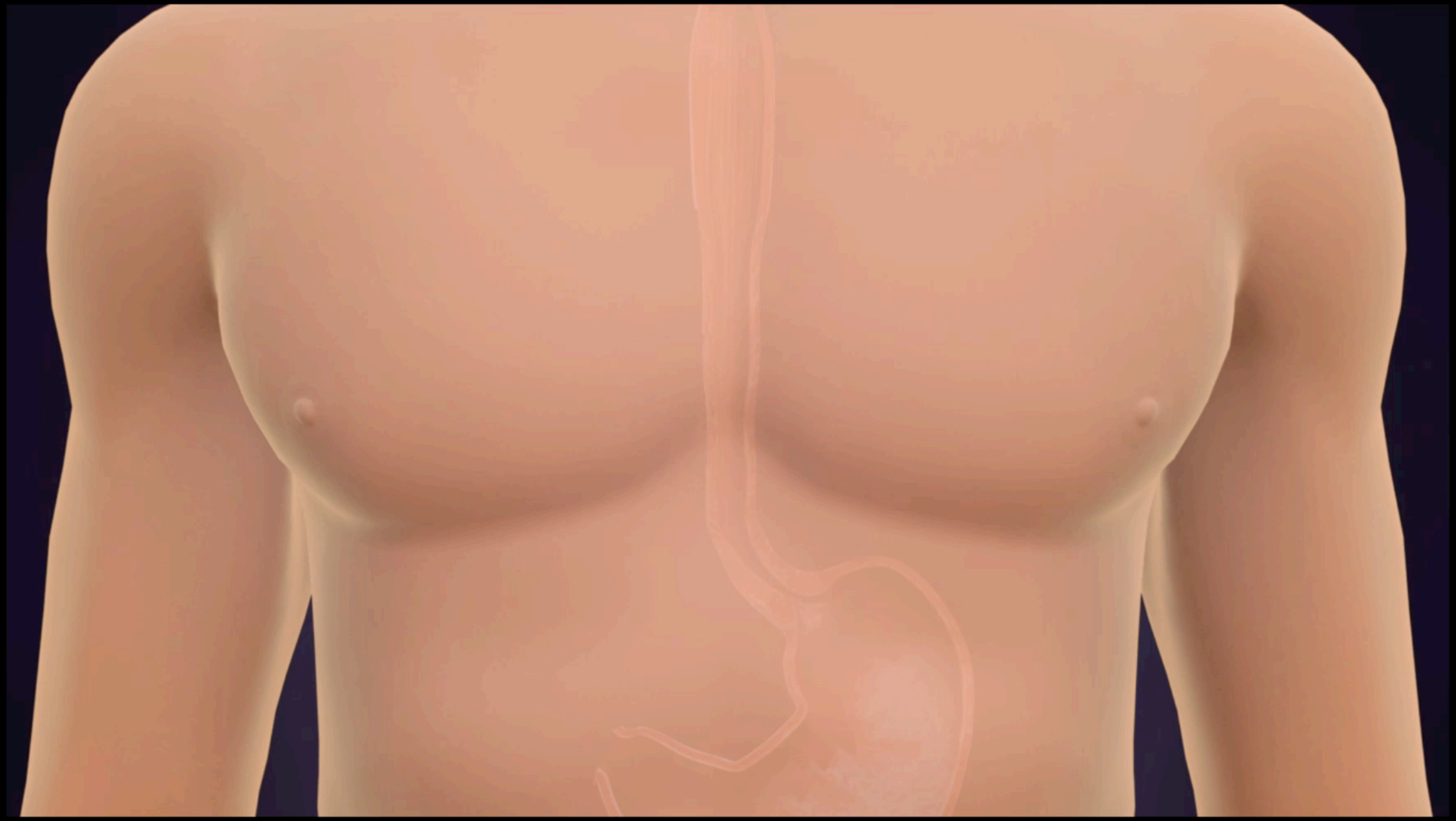
Sarah S. Al Ghamdi*, Jad Farha, Thomas M. Runge, Yervant Ichkhanian, Mouen A. Khashab

The Johns Hopkins Hospital, Baltimore, MD

Background: Cricopharyngeal bars (CPBs) are fibrous thickenings of the cricopharyngeal (CP) muscle that can rarely lead to dysphagia. Established treatment modalities include: esophageal dilatation, endoscopic botulinum toxin injection and surgical CP myotomy. There has been no reported experience on per-oral endoscopic myotomy (POEM) for isolated CPBs. Case Presentation: A 78-year old male with a history of congestive heart failure, hypertension, coronary artery disease, asthma, and hypothyroidism presented to an ENT specialist with intermittent dysphagia to solids and liquids for 3 months. Dysphagia was associated with coughing episodes and aspiration pneumonia. Modified barium swallow study revealed mild oropharyngeal dysphagia with a prominent CPB. He later underwent direct laryngoscopy with CP botulinum toxin injection, with no improvement of symptoms. Barium swallow was repeated several weeks later, with similar findings. He was then referred for endoscopic management. Endoscopic Methods: A diagnostic EGD was performed, during which significant resistance was felt when traversing a prominent CPB. Submucosal injection was performed slightly proximal to the CP muscle. A premixture of saline, 1% indigo carmine and diluted epinephrine was injected to create a mucosal bleb. A 1cm mucosal incision was performed using a triangular-tip (TT) knife. Submucosal tunneling was then performed with clear identification of the thickened muscle fibers of the septum. This was done with the TT knife, spray coagulation current and injection of saline with indigo carmine solution via a pump. During dissection, mild fibrosis was noted due to prior botulinum toxin injection. CP muscle fibers of the septum were identified. Using an insulated tip (IT) knife, full thickness myotomy was started at the level of the CP muscle and

Per-oral Endoscopic Myotomy (E-POEM)



666

WHAT TO DO WHEN HELLER MYOTOMY FAILS? INTERNATIONAL MULTICENTER COMPARATIVE STUDY ON THE OUTCOMES OF REDO HELLER MYOTOMY VS PERORAL ENDOSCOPIC MYOTOMY VS PNEUMATIC DILATATION IN PATIENTS WITH FAILED HELLER MYOTOMY

Nasim Parsa*, Rintaro Hashimoto, Mikhail Attaar, Nikolas P. Eleftheriadis, Chen-Shuan Chung, Simon Hew, Jose Nieto, Elena Finati, Gaia Pellegatta, Fermin Estremera-Arevalo, Swati Pawa, Andrew S. Nett, Nikhil A. Kumta, Yutaka Tomizawa, Qais M. Dawod, Manol Jovani, Geri Keane, Yervant Ichkhanian, Sarah S. Al Ghamdi, Thomas M. Runge, Mohamad Aghaie Meybodi, Sahiljeet Singh, Reem Z. Sharaiha, David L. Carr-Locke, Rishi Pawa, Eduardo Albeniz, Roberta Maselli, Robert Bechara, Michael Ujiki, Kenneth J. Chang, Mouen A. Khashab

Gastroenterology, University of Missouri Health System, Baltimore, MO

Background: Heller myotomy (HM) is highly effective for achalasia treatment. Nonetheless, recurrent/persistent symptoms occur in 10–20% of patients. Management options include POEM, redo-HM, or pneumatic dilatation (PD). It is currently unknown which of these options is more effective. Aims: To compare the efficacy and safety of POEM, redo-HM, or PD in patients with previous failed HM. Methods: This was an international experience at 14 centers between 10/2010 and 11/2019. Adults with failed HM who underwent POEM, redo-HM, or PD were included. Technical success was defined as successful completion of the procedure. Clinical success was defined as a decrease in Eckardt score (ES) to ≤3 without the need for reinterventions. Adverse events (AEs) were graded according to the ASGE Lexicon/Clavien-Dindo classification. Results: A total of 162 patients (51% F, mean age 54yr) with failed HM were included, of whom 108 underwent POEM, 23 redo-HM, and 31 PD. The baseline mean ES was 6.1, 6.6 and 6.2 (p=0.6), and baseline mean integrated relaxation pressure was 18.7, 16.1 and 22.0 (p=0.5). Technical success was achieved in all patients. After a mean follow up of 16.9 months (14.4 POEM, 26.0 redo-HM, 18.4 PD), the POEM group had the lowest mean post treatment ES (1.8 vs 4.4 vs 5.0, p<0.001) and rate of clinical relapse (11.7% vs 68.1% vs 48.2%, p=0.02). At 6-12 months follow up, clinical success was achieved in 90% of POEM patients, 60% redo-HM, and 50% PD (p=0.01), and higher in the POEM group vs redo-HM (OR 6.01, p=0.03). At 12-24 months follow up, 83.3% of POEM patients, 40% redo-HM, and 28.5% PD remained in clinical success (0.004), which was higher in the POEM group vs redo-HM (OR 4.5, p=0.001) and lower in the PD group vs POEM (OR 0.17, p=0.01). In patients with >24 months follow up (n=41, mean 38.6 mo), 72.7% of POEM patients, 40% redo-HM and 22% PD remained in clinical success (p=0.03), which was higher in the POEM group vs redo-HM (p=0.07), and lower in the PD group vs POEM (OR 0.11, p=0.02). Patients who underwent redo-HM experienced more AEs (26% vs 8% POEM vs 13% PD, p=0.05). Based on Clavien-Dindo/ASGE Lexicon, redo-HM group experienced more grade 3 and 4 AEs (13% vs 1% POEM vs 0% PD, p=0.02) and more severe AEs (9% vs 0% PEOM vs 0% PD; p=0.007). The PD group had the shortest mean procedure time (31.1 min, p<001) and LOS (p<0.001). The redo-HM group had longer procedure duration (167 vs 84 min, p<0.001) and LOS (5 vs 2 d, p<00.1), compared with the POEM group (Table 1). Univariable logistic regression analysis demonstrated that patients who underwent retreatment with POEM have a higher likelihood of achieving clinical success compared with redo-HM (OR 7.6, p<0.001) (Table 2). Conclusion: POEM results in higher short/mid-term clinical success and lower rate of clinical relapse compared with alternative treatments in patients with failed HM.

Retrospective, 14 centers
162 pts w/failed prior Heller myotomy

Table1. Comparison of Outcomes between the three Groups

	Total (N=162)	POEM (N=108)	Redo-HM (N=23)	Pneumatic dilatation (N=31)	OR	P Value
Estimated blood loss, Overall, mean ± SD, mL	8.2 ± 21.9	3.1 ± 11.1	42.1 ± 38.0	0		<0.001
- POEM vs redo HM						<0.001
- Redo HM vs Pneumatic dilatation						<0.001
- POEM vs Pneumatic dilatation						0.02
Procedural time, mean ± SD, min	85.4 ± 53.1	84.0 ± 36.8	167 ± 57.7	31.1 ± 9.9		<0.001
- PEO M vs redo HM						<0.001
- Redo HM vs Pneumatic dilatation						<0.001
- POEM vs Pneumatic dilatation						<0.001
Length of hospital stay, mean ± SD, day	2.2 ± 3.6	1.9 ± 1.3	4.9 ± 7.5	0.6 ± 1.3		<0.001
- POEM vs redo HM						0.07
- Redo HM vs Pneumatic dilatation						0.01
- POEM vs Pneumatic dilatation						<0.001
Technical success, %	100	100	100	100		1
Follow up duration, Mo, mean ± SD	16.9± 15.7	14.4 ± 13.6	26.0 ± 18.0	18.4 ± 18.7		0.006
Postoperative Eckardt score, mean ± SD	2.8 ± 2.5	1.8 ± 1.8	4.4 ± 2.5	5.0 ± 2.5		<0.001
Clinical success, 6-12 months post intervention, %	56/70 (80)	45/50 (90)	6/10 (60)	5/10 (50)	-	0.01
- POEM vs redo HM					6.01	0.03
- Redo HM vs Pneumatic dilatation					-	0.6
- Pneumatic dilatation vs POEM					-	0.08
Clinical success, 12-24 months post intervention, %	31/47 (49.2)	25/30(83.3)	4/10 (40)	2/7 (28.5)	-	0.004
- POEM vs redo HM					4.5	0.001
- Redo HM vs Pneumatic dilatation					-	0.7
- Pneumatic dilatation vs POEM					0.17	0.01
Clinical success, >24 months post intervention, %	22/41 (53.6)	16/22(72.7)	4/10 (40)	2/9 (22)	-	0.03
- POEM vs redo HM					-	0.07
- Redo HM vs Pneumatic dilatation					-	0.6
- Pneumatic dilatation vs POEM					0.11	0.02
Adverse events, n (%)						0.05
- Total	19 (12)	9 (8)	6 (26)	3 (13)		
- Mucosotomy	4	4	0	0		
- Bleeding	5	1	2	2		
- Esophageal leak	1	0	1	0		
- Symptomatic Pneumoperitoneum	2	2	0	0		
- Pain	3	1	2	0		
- Subcutaneous emphysema	1	1	0	0		
- Perforation	2	0	0	1		
- Mediastinal abscess	1	0	1	0		
Adverse events according to the ASGE Lexicon system, n (%)						
- Mild	12 (7.5)	6 (6)	2 (9)	4 (13)		-
- Moderate	5 (3)	3 (3)	2 (9)	0		-
- Severe	2 (1)	0	2 (9)	0		0.007
- Fatal	0	0	0	0		-
Recurrence during the follow up duration, n (%)	41/153 (26.7)	12/102 (11.7)	15/22 (68.1)	14/29 (48.2)		0.02

Table1. Comparison of Outcomes between the three Groups

	Total (N=162)	POEM (N=108)	Redo-HM (N=23)	Pneumatic dilatation (N=31)	OR	P Value
Estimated blood loss, Overall, mean ± SD, mL	8.2 ± 21.9	3.1 ± 11.1	42.1 ± 38.0	0		<0.001
- POEM vs redo HM						<0.001
- Redo HM vs Pneumatic dilatation						<0.001
- POEM vs Pneumatic dilatation						0.02
Procedural time, mean ± SD, min	85.4 ± 53.1	84.0 ± 36.8	167 ± 57.7	31.1 ± 9.9		<0.001
- PEO M vs redo HM						<0.001
- Redo HM vs Pneumatic dilatation						<0.001
- POEM vs Pneumatic dilatation						<0.001
Length of hospital stay, mean ± SD, day	2.2 ± 3.6	1.9 ± 1.3	4.9 ± 7.5	0.6 ± 1.3		<0.001
- POEM vs redo HM						0.07
- Redo HM vs Pneumatic dilatation						0.01
- POEM vs Pneumatic dilatation						<0.001
Technical success, %	100	100	100	100		1

Table1. Comparison of Outcomes between the three Groups (Con't)

	Total (N=162)	POEM (N=108)	Redo-HM (N=23)	Pneumatic dilatation (N=31)	OR	P Value
Postoperative Eckardt score, mean ± SD	2.8 ± 2.5	1.8 ± 1.8	4.4 ± 2.5	5.0 ± 2.5		<0.001
Clinical success, 6-12 months post intervention, %	56/70 (80)	45/50 (90)	6/10 (60)	5/10 (50)	-	0.01
- POEM vs redo HM					6.01	0.03
- Redo HM vs Pneumatic dilatation					-	0.6
- Pneumatic dilatation vs POEM					-	0.08
Clinical success, 12-24 months post intervention, %	31/47 (49.2)	25/30(83.3)	4/10 (40)	2/7 (28.5)	-	0.004
- POEM vs redo HM					4.5	0.001
- Redo HM vs Pneumatic dilatation					-	0.7
- Pneumatic dilatation vs POEM					0.17	0.01
Clinical success, >24 months post intervention, %	22/41 (53.6)	16/22(72.7)	4/10 (40)	2/9 (22)	-	0.03
- POEM vs redo HM					-	0.07
- Redo HM vs Pneumatic dilatation					-	0.6
- Pneumatic dilatation vs POEM					0.11	0.02

Table1. Comparison of Outcomes between the three Groups (Con't)

	Total (N=162)	POEM (N=108)	Redo-HM (N=23)	Pneumatic dilatation (N=31)	OR	P Value
Adverse events, n (%)						0.05
- Total	19 (12)	9 (8)	6 (26)	3 (13)		
- Mucosotomy	4	4	0	0		
- Bleeding	5	1	2	2		
- Esophageal leak	1	0	1	0		
- Symptomatic Pneumoperitoneum	2	2	0	0		
- Pain	3	1	2	0		
- Subcutaneous emphysema	1	1	0	0		
- Perforation	2	0	0	1		
- Mediastinal abscess	1	0	1	0		
Adverse events according to the ASGE Lexicon system, n (%)						
- Mild	12 (7.5)	6 (6)	2 (9)	4 (13)		-
- Moderate	5 (3)	3 (3)	2 (9)	0		-
- Severe	2 (1)	0	2 (9)	0		0.007
- Fatal	0	0	0	0		-
Recurrence during the follow up duration, n (%)	41/153 (26.7)	12/102 (11.7)	15/22 (68.1)	14/29 (48.2)		0.02

Table 2. Univariable Logistic Regression Analysis of Factors Associated with Clinical Success

	Unadjusted OR	P Value
Age	-	0.98
Sex, male vs female	-	0.21
Achalasia subtype (type III)		
Type II	-	0.35
Type I	-	0.57
Duration of symptoms	-	0.31
Previous PD vs no prior treatment	-	0.51
Prior Botox, yes vs no	-	0.51
Sigmoid vs non sigmoid	-	0.36
Eckardt score post failed index HM,	-	0.11
Redo HM		
- Retreatment with POEM	7.69	<0.001
- Retreatment with PD	-	0.23
High-resolution manometry post failed index HM		
- 4s IRP	-	0.80
- Resting pressure	-	0.85

Gastric Per-oral Endoscopic Myotomy (G-POEM)

55

GASTRIC PERORAL ENDOSCOPIC MYOTOMY COMPARED TO SURGICAL PYLOROMYOTOMY IN THE TREATMENT OF GASTROPARESIS: A CASE-MATCHED MULTICENTER STUDY

Jad P. AbiMansour*[1], Mohamad Aghaie Meybodi[1], Yervant Ichkhanian[1], Harry Wong[2], Michael Ujiki[3], Alexander J. Podboy[4], Joo Ha Hwang[4], Ameya A. Deshmukh[5], Jose Nieto[5], Rishi Pawa[6], Kenneth L. Koch[6], Swati Pawa[6], Chen-Shuan Chung[7], Alexander Schlachterman[9], Thomas E. Kowalski[9], Vivek Batra[9], Nikhil A. Kumta[8], Mouen A. Khashab[1]

[1]The Johns Hopkins Hospital, Baltimore, MD; [2]University of Chicago, Chicago, IL; [3]NorthShore HealthSystem, Evanston, IL; [4]Stanford University School of Medicine, Redwood City, CA; [5]Borland-Groover Clinic, Jacksonville, FL; [6]Wake Forest Baptist Health Medical Center, Winston Salem, NC; [7]Far Eastern Memorial Hospital, New Taipei City, Taiwan; [8]Mount Sinai Hospital, New York, NY; [9]Thomas Jefferson University Hospitals, Philadelphia, PA

Background: Gastric peroral endoscopic myotomy (GPOEM) has emerged as an effective and safe treatment for refractory gastroparesis; however, its performance compared to surgical pyloromyotomy (SPM) remains unclear. Aims: To compare symptom response and clinical outcomes in patients with gastroparesis who were treated with GPOEM or SPM. Methods: We conducted an international, multi-center retrospective review of consecutive patients with gastroparesis who underwent either GPOEM or surgical pyloromyotomy between January 2013 and September 2019 at 8 tertiary-care centers (7 USA, 1 Asia). For each surgical case, three GPOEM cases were randomly selected by matching for gender and etiology. Demographics, baseline symptoms, procedural details, and follow up information were abstracted chart review. The primary outcome assessed was patient reported symptom improvement or resolution. Secondary outcomes included gastric emptying on scintigraphy, use of prokinetic agents, and change in Gastroparesis Cardinal Symptom Index (GCSI). Results: A total of 112 patients (85 female) with gastroparesis (26 diabetic, 35 postsurgical, 38 idiopathic, 13 other) were identified. At baseline, 61(55%) were prescribed prokinetic agents, 11(13%) opioids, 47 (55%) antiemetics, and 15 (18%) received nutrition via PEG or TPN. Average 4 hour gastric emptying was 47±27%. A total of 84 (75 %) patients underwent GPOEM and 28 (25 %) SPM. Average procedure time was 60.6±29.6 and 151.8±72.0 minutes, respectively ($p < 0.0001$). A total of 9 adverse events (5 mild, 1 moderate, 3 severe) were reported in the GPOEM compared to 11 (10 mild, 1 moderate, 0 severe) in the surgical cohort (11% vs. 39%, $p = 0.01$). Length of hospital stay was 1.5±2.7 days in the GPOEM group compared to 10.9±20.8 days for SPM ($p=0.05$). Average follow up time was 7.56±9.20 months overall and 6.1±4.7, 12.1±15.8 for GPOEM and SPM respectively ($p=0.05$). Symptom improvement was noted in 67 (80%) of GPOEM patients compared to 21 (75%) for SPM (OR 1.3, 95% CI 0.48 to 3.60). Gastric emptying improved in 51% of GPOEM patients and 75% of surgical patients ($p=0.13$) and normalized in 25% and 50% respectively ($p = 0.08$). There was no difference in GCSI scores (11.1 vs. 23.0, $p=0.13$) or number of patients on prokinetic agents (10% vs 18%, $p=0.26$), opiates (14% vs 11%, $p=0.66$), antiemetics (42% vs 57%, $p = 0.18$), or parenteral nutrition (7% vs 18%, $p = 0.14$). Overall, 8 (9%) patients required reintervention in the GPOEM group (3 surgery, 4 GPOEM, and 1 botulinum toxin injection) and 2 (7%) (1 botulinum injection, 1 gastrojejunostomy tube placement) in the surgical group ($P=0.71$). Conclusion: This multicenter study comparing currently available procedures for the treatment of gastroparesis shows that GPOEM is a safe, effective and less invasive treatment alternative to SPM in patients with refractory gastroparesis.

- Retrospective, Case-matched 3:1
- 7 centers, 112 patients
- Gastroparesis:
  - Diabetic - 26
  - Post-surgical - 35
  - Idiopathic - 38

Table 4. Gastroparesis Cardinal Symptom Index

Symptom	*None*	*Very mild*	*Mild*	*Moderate*	*Severe*	*Very severe*
1. Nausea (feeling sick to your stomach as if you were going to vomit)	0	1	2	3	4	5
2. Retching (heaving as if to vomit but nothing comes up)	0	1	2	3	4	5
3. Vomiting	0	1	2	3	4	5
4. Stomach fullness	0	1	2	3	4	5
5. Not able to finish a normal-sized meal	0	1	2	3	4	5
6. Feeling excessively full after meals	0	1	2	3	4	5
7. Loss of appetite	0	1	2	3	4	5
8. Bloating (feeling like you need to loosen your clothes)	0	1	2	3	4	5
9. Stomach or belly visibly larger	0	1	2	3	4	5

NOTE: *Tracking scores over time is useful to assess change. An individual score (calculated as an average of the three primary areas: nausea/vomiting [rows 1 to 3], postprandial fullness/early satiety [rows 4 to 7], and bloating [rows 8 and 9]) is not clearly linked to degree of severity.*

Adapted with permission from Revicki DA, Reintz AM, Dubois D, et al. Gastroparesis Cardinal Symptom Index (GCSI): development and validation of a patient reported assessment of severity of gastroparesis symptoms. Qual Life Res. *2004;13(4):843.*

	Overall (n=112)	GPOEM (n=84)		
Age, years (mean±SD)	49.50±17.01	50.6±16.85		
BMI, kg/m2 (mean±SD)	25.89±5.88	26.2±6.09		
Female, no. (%)	85 (76%)	63 (75%)		
Gastroparesis etiology				
Diabetic	26 (23%)	23 (27%)		
Postsurgical	35 (31%)	23 (27%)		
Idiopathic	38 (34%)	27 (32%)		
Other	13 (12%)	11 (13%)		
Predominant symptom				
Nausea/vomiting, no. (%)	65 (58%)	52 (62%)		
Abdominal pain, no. (%)	15 (13%)	13 (15%)		
Other, no (%)	31 (28%)	18 (21%)		
Baseline 4h gastric emptying % (mean±SD)	0.47±0.27	0.46±0.25		
Abnormal 4h gastric emptying, no. (%)				
Average duration of disease, mo. (mean±SD)				
GCSI Score (mean±SD)				
Pre procedure therapies				
Prokinetic pharmacotherapy, no. (%)				
Opiates, no. (%)				
Antiemetics, no. (%)				
Nutrition via PEGJ or TPN, no. (%)				
Botox injection, no. (%)				
Transpyloric stenting, no. (%)				
Procedure information				
Procedure duration, min (mean±SD)				
Concomitant procedure performed, no. (%)	14 (12%)	0	14 (50%)	>0.001
Gastric myotomy length, cm (mean±SD)		2.54±1.27	N/A	
Duodenal myotomy length, cm (mean±SD)		N/A	2.56±1.34	
Lesser curvature myotomy, no. (%)	3 (2%)	0	3 (23%)	>0.001
Length of stay, days (mean±SD)	3.33±9.97	1.51±2.37	10.86±20.78	0.05
Total Adverse Events	20 (18%)	9 (11%)	11 (39%)	0.01`
Mild, no. (%)	15 (13%)	5 (6%)	10 (36%)	>0.001
Moderate, no. (%)	2 (2%)	1 (1%)	1 (4%)	0.41
Severe, no. (%)	3 (3%)	3 (4%)	0	0.31
Follow Up				
Follow up time, mo. (mean±SD)	7.56±9.20	6.05±4.73	12.12±15.83	0.05
Patient reported symptoms improved or resolved, no. (%)	88 (78%)	67 (80%)	21 (75%)	0.59
Abnormal 4h gastric emptying, no. (%)	43/61 (71%)	37/49 (75%)	6/12 (50%)	0.08
GES improvement (>50% decrease in retention), no. (%)	33/59 (56%)	24/47 (51%)	9/12 (75%)	0.13
GCSI Score (mean±SD)	12.06±13.0	11.06±12.83	23.0±11.35	0.13
Post procedure therapies				
Prokinetic pharmacotherapy, no. (%)	12/100 (12%)	7/72 (10%)	5/28 (18%)	0.26
Opiates, no. (%)	11/85 (13%)	8/57 (14%)	3/28 (11%)	0.66
Anitemetics, no. (%)	39/83 (47%)	23/55 (42%)	16/28 (57%)	0.18
Nutrition via PEGJ or TPN, no. (%)	9/83 (11%)	4/55 (7%)	5/28 (18%)	0.14
PPI use, no. (%)	62 (55%)	41(49%)	21 (75%)	0.01
Need for reintervention, no. (%)	10/97 (10%)	8/73 (11%)	2/24 (8%)	0.71
Surgical pyloroplasty	3	3	0	
GPOEM	4	4	0	
Botox injection	2	1	1	
Other	1	0	1	
Esophagitis on EGD, no. (%)	3/29 (10%)	2/19 (10%)	1/10 (10%)	0.96

	GPOEM (N = 84)			SPM (N = 28)			
	Pre-	Post-	Change (Δ)	Pre-	Post-	Change (Δ)	P value
Prokinetic use	46%	7%	39%	15%	5%	10%	0.12
Antiemetic use	30%	23%	7%	17%	16%	1%	0.13
Opiate use	8%	8%	0%	3%	3%	0%	–
PPI use	78%	41%	37%	75%	21%	54%	0.04
PEG/TPN dependent, no. (%)	9%	4%	5%	6%	5%	1%	0.28
GCSI, mean±SD	22.47±14.41	11.06±12.83	17.55± 16.38	33.33±2.31	23.0±11.35	10.33±9.07	0.30

	G-POEM (n=84)			Surgical Pyloro-myotomy (n=28)			
	Pre	Post	Change	Pre	Post	Change	p-value
PEG/TPN Dep	9%	4%	**5%**	6%	5%	**1%**	.28
GCSI, mean	22.47	11.06	**17.55**	33.33	23.0	**10.33**	.3

Retrospective, 4 centers 102 pts: 39 GPOEM vs 63 Surg

162

GASTRIC PER-ORAL ENDOSCOPIC MYOTOMY VERSUS PYLOROMYOTOMY: AN INTERNATIONAL COMPARATIVE STUDY

Lauren Pioppo*[1], Debashis Reja[1], Monica Gaidhane[1], Romy Bareket[1], Augustine Tawadros[1], Ana L. Madrigal Méndez[2], Jose Nieto[3], Felipe Zamarripa[4], Ma Guadalupe Martínez[4], Mine C. Carames[5], Juan C. Carames[5], Jennifer Liu-Burdowski[1], Marina Kim[1], Ameya A. Deshmukh[3], Resheed Alkhiari[1], Iman Andalib[6], Haroon M. Shahid[1], Avik Sarkar[1], Amy Tyberg[1], Michel Kahaleh[1]

[1]Robert Wood Johnson University Hospital, New Brunswick, NJ; [2]Caja Costarricense de Seguro Social, San Jose, Costa Rica; [3]Borland-Groover Clinic, Miami, FL; [4]Hospital Juarez, Ciudad Juarez, Mexico; [5]Santander Hospital, Reynosa, Mexico; [6]Mount Sinai , New York, NY

Introduction: Gastroparesis is a potentially debilitating gastric motility disorder with limited treatment options. Symptoms can result in hospitalization and poor nutrition requiring nutritional support. Treatment options with highest efficacy include gastric peroral endoscopic myotomy (GPOEM) and surgical pyloromyotomy. Limited information is available comparing these two techniques. Aim: We aim to compare the efficacy and safety of GPOEM versus surgical pyloromyotomy in patients with gastroparesis. Methods: A retrospective analysis of patients who underwent GPOEM or surgical pyloromyotomy for refractory gastroparesis from 4 centers across the US and Latin America were included. Electronic medical records were used to collect data on patient demographics, relevant imaging studies and laboratory values, technical success, clinical success, gastroparesis cardinal symptom index (GCSI), procedure time, pre- and post-op gastric emptying times, adverse events, and hospital length of stay (LOS). Results: A total of 102 patients were included (mean age 47; 32.4% male): GPOEM n=39, surgical pyloromyotomy n=63. Age and pre-op BMI were not statistically different between the two groups (p=0.232, p=0.059, respectively). Patient demographics are outlined in Tables 1 and 2. Technical success rate was 100% in both groups. Clinical success rate was 92.3% in the GPOEM group and 82.5% in the surgery group (p=0.164). The GPOEM group had a significantly higher post-op GSCI score reduction by 1.3 units (p<0.00001), post-op retention reduction at 2 hours by 18% (p<0.00001), post-op retention reduction at 4 hours by 25% (p<0.00001) and a lower procedure time by 20 minutes (p<0.00001) as compared to surgery. GPOEM also had a lower hospital LOS by 2.8 days (p<0.00001). Adverse event rates were significantly lower in the GPOEM group (13%) compared to the surgery group (33.3% ; p=0.021). Mean blood loss in the GPOEM group was only 3.6 ml as compared to 866 ml in the surgery group. Conclusions: GPOEM may be a less invasive, safer, and more efficacious procedural treatment for refractory gastroparesis as compared to surgical pyloromyotomy.

Table: Comparison of GPOEM vs surgical pyloromyotomy

Mean	GPOEM	Pyloromyotomy	p-value
Age (years)	49.0 +/- 16.5	45.8 +/- 10.3	0.232
BMI	27.7 +/- 7.7	25.4 +/- 4.4	0.059
Post-op GCSI reduction	2.8 +/- 0.84	1.5 +/- 0.65	<0.00001
Post-op reduction in retention at 2 hours (%)	20.12 +/- 16.1	3.03 +/- 3.8	<0.00001
Procedure time (min)	58.0+/- 27.6	78.4+/- 13.1	<0.00001
Hospital LOS (days)	1.3+/- 1.0	4.2+/- 0.7	<0.00001
Adverse events	5 (13%) *2 bleeding* *2 infection* *1 post-op ileus*	21 (33.3%) *8 bleeding* *5 infection* *4 ulcers* *2 gastric outlet obstruction* *2 pain*	0.021
Clinical Success (%)	36/39 (92.3%)	52/63 (82.5%)	0.164

667

GASTRIC PERORAL ENDOSCOPIC MYOTOMY (G-POEM) FOR THE TREATMENT OF REFRACTORY GASTROPARESIS: FINAL RESULTS FROM THE FIRST INTERNATIONAL PROSPECTIVE TRIAL

Kia Vosoughi*[1], Yervant Ichkhanian[1], Petros C. Benias[2], Larry S. Miller[2], A. Aziz Aadam[3], Joseph Triggs[3], Ryan Law[4], Nicole Bowers[4], Dalton Chaves[5], Alberto M. da Ponte[5], Peter V. Draganov[6], Andrey I. Kotzev[6], Maan El Halabi[9], Omid Sanaei[1,7], Olaya I. Brewer Gutierrez[1], Anthony N. Kalloo[1], Robert S. Bulat[1], John E. Pandolfino[8], Mouen A. Khashab[1]

[1]Division of Gastroenterology and Hepatology, Johns Hopkins Medical Institution, Baltimore, MD; [2]Division of Gastroenterology, Zucker School of Medicine at Hofstra/Northwell, Long Island Jewish Medical Center, Northwell Health System, New Hyde Park, NY; [3]Division of Gastroenterology, Northwestern University, Chicago, IL; [4]Division of Gastroenterology, University of Michigan, Ann Arbor, MI; [5]Gastroenterologia, Unidade de Endoscopia Gastrointestinal, Faculdade de Medicina da Universidade de São Paulo, São Paulo/SP, Brazil; [6]Division of Gastroenterology, Hepatology and Nutrition, University of Florida, Gainesville, FL; [7]Department of Medicine, MedStar Union Memorial Hospital, Baltimore, MD; [8]Department of Medicine, Feinberg School of Medicine, Northwestern University, Chicago, IL; [9]Internal medicine department, Mount Sinai West-St. Luke's hosp, New York, NY

Background: We previously reported the preliminary short-term outcomes of our prospective trial on gastric per-oral endoscopic myotomy (G-POEM) with promising results. Aim: To prospectively 1) evaluate the efficacy and safety of G-POEM and 2) assess factors associated with clinical success of G-POEM. Methods: In this prospective multicenter (4 US, 1 South America) study, patients with refractory gastroparesis - defined as symptoms refractory to standard medical therapy - underwent G-POEM between 11/2015 and 11/2018, and were followed for one year. Clinical symptoms (measured by Gastroparesis Cardinal Symptom Index [GCSI]) and quality of life (measured by Short Form 36 [SF-36]) were evaluated before and at 1-, 3-, 6-, and 12-month followups. Clinical success was defined as one score decrease in average GCSI with >25% decrease in at least 2 sub-scales. Gastric emptying study (GES) was performed before and 3 months after the G-POEM. Pylorus characteristics were measured by endoscopic functional luminal imaging probe (EndoFLIP) device pre and post G-POEM. Results: A total of 80 patients (F 71%, mean age: 49yr) were enrolled. The most common etiology was idiopathic (41.3%), followed by postsurgical (35%) and diabetes (23.8%). All procedures were technically successful (technical success 100%). A total of 67 (84%) patients were followed up to one year with clinical success rate of 59.7%. GCSI and its subscales improved significantly following G-POEM ($p<0.05$) (Figure 1). Furthermore, 5 out of 8 domains of SF-36 including physical functioning, physical role, energy, emotional well-being, social functioning, general health, and health change improved significantly after G-POEM ($p<0.05$). A total of 5 adverse events, all rated as mild, were reported and included 3 symptomatic capnoperitoneum (treated by needle decompression), 1 mucosotomy (treated with stent replacement), and 1 thermal mucosal injury (treated with clipping). Pre and 3-month post G-POEM GES were performed in 53 (66.3%) patients. GES improvement and normalization were achieved in 34/53 (64.2%) and 25/53 (47.2%) patients, respectively. Following G-POEM, pylorus distensibility index (DI), measured with EndoFLIP, increased from 4.99 ± 2.57 to 6.74 ± 4.34 $mm^2/mmHg$, and from 4.97 ± 3.02 to 6.99 ± 3.92 $mm^2/mmHg$ using 40- and 50-ml volume bags, respectively ($p<0.05$). Lower pre G-POEM DI using 40 ml bag was significantly associated with pre G-POEM disease severity ($p=0.039$). Baseline disease severity and increase in pylorus DI following G-POEM were significantly associated with clinical success (Table 1). Conclusion: G-POEM is safe and improves clinical symptoms and pylorus characteristics of patients with refractory gastroparesis. Disease severity predicts the one-year clinical success; thus, the procedure may be considered for patients with more severe gastroparesis symptoms.

- Prospective, 5 centers, 1-yr f/u
- 80 pts: 43% idiopathic, 35% p-op, 24% DM
- Clinical Success= 1pt dec. GCSI plus >25% dec in 2 sub-scales
- 59.7% clinical success at 1 yr

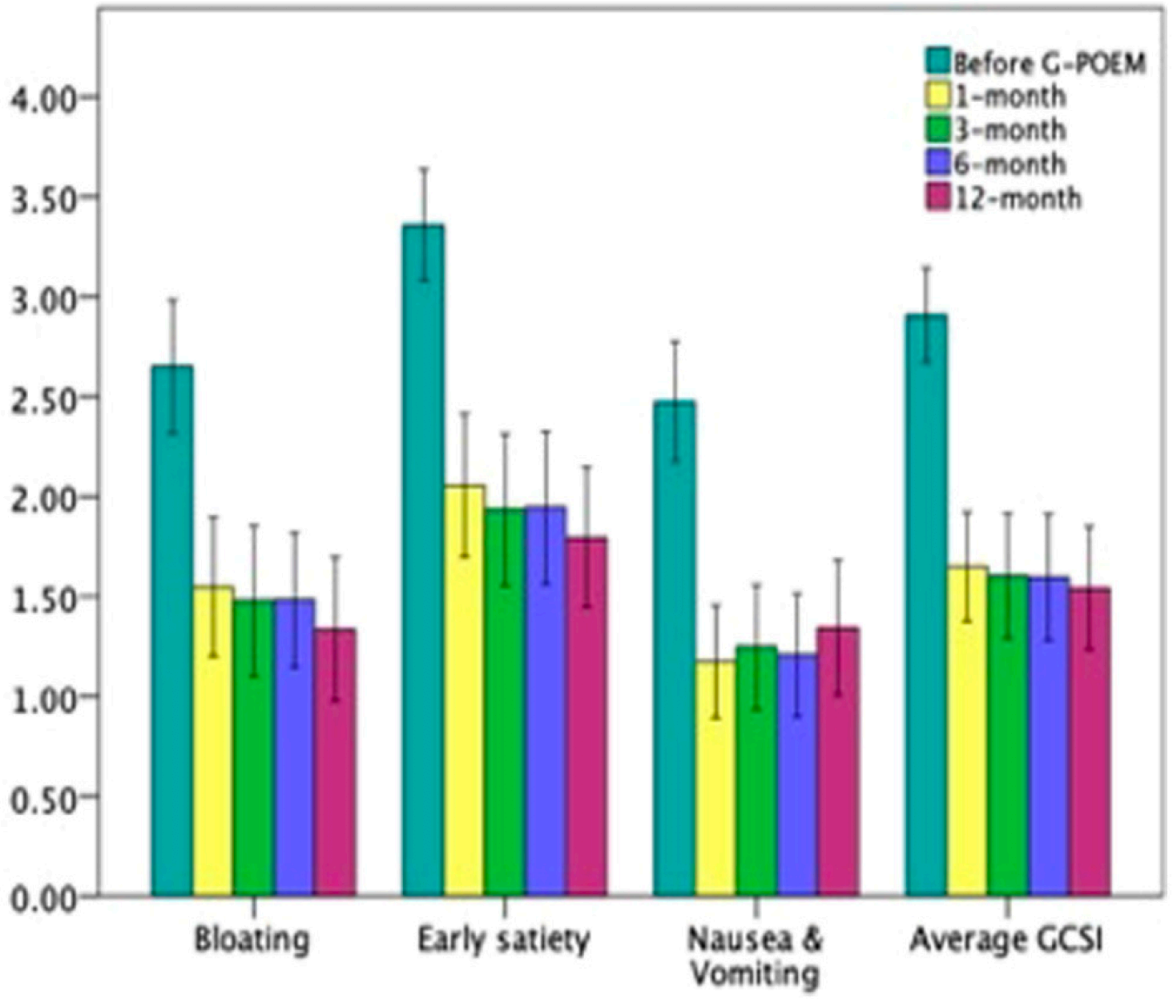
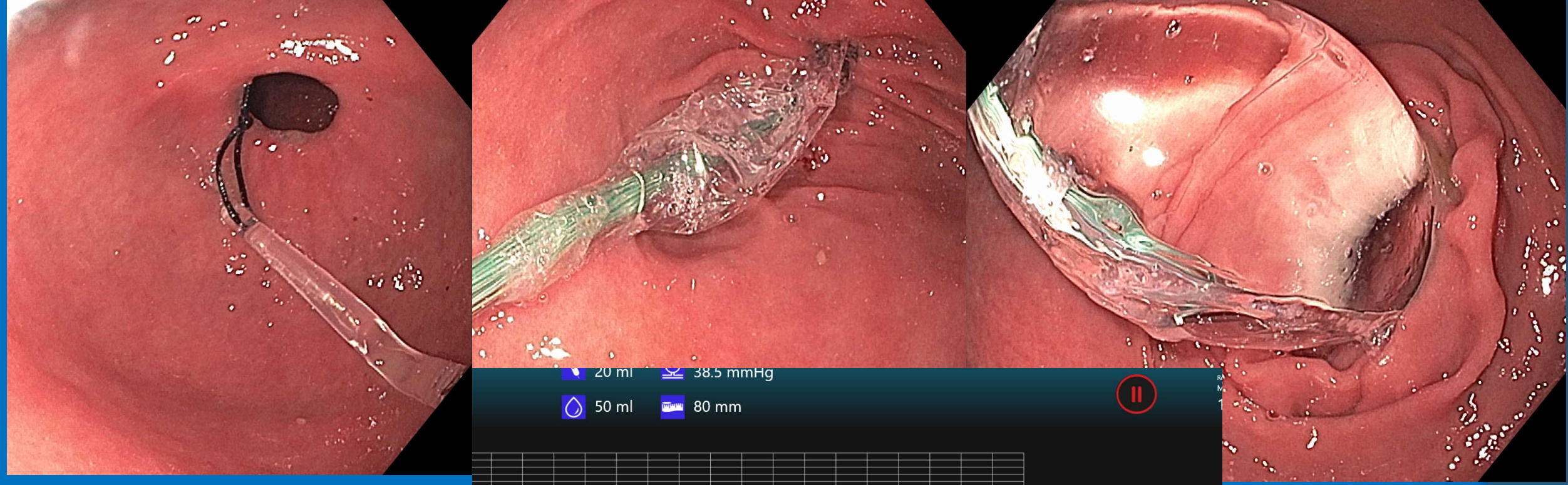


Figure 1. Improvement of GCSI and the subscales during the one year followup period after the G-POEM

Predictors of response to G-POEM

	One-year clinical success	
	OR (95% CI)	p-value
Disease severity before G-POEM (Baseline GCSI)	1.73 (1.04 - 2.88)	**0.036**
Disease duration	1.01 (1 - 1.02)	0.177
Etiology (ref: idiopathic)		
Diabetes	1.44 (0.41 - 5.07)	0.412
Post-surgical	1.63 (0.52 - 5.06)	0.522
GES improvement	1.65 (0.45 - 6.03)	0.452
Change in pylorus distensibility using 40ml volume bag	1.23 (1.03 - 1.46)	**0.021**
Change in pylorus distensibility using 50ml volume bag	1.24 (1.03 - 1.5)	**0.020**

Table 1. association between disease characteristics and one-year clinica success of G-POEM


20 ml
38.5 mmHg
50 ml
80 mm
10
15
20
25
30
35
40

668

SAFETY AND FEASIBILITY OF PERFORMING A SINGLE TUNNEL DOUBLE MYOTOMY FOR GASTROPARESIS

Petros C. Benias*[1], Larry S. Miller[1], Arvind J. Trindade[1], Mary Cheung[1], Matthew J. Whitson[1], Beth Monteverde[1], Nicole Bowers[2], Lydia Watts[2], William L. Hasler[2], Ryan Law[2]

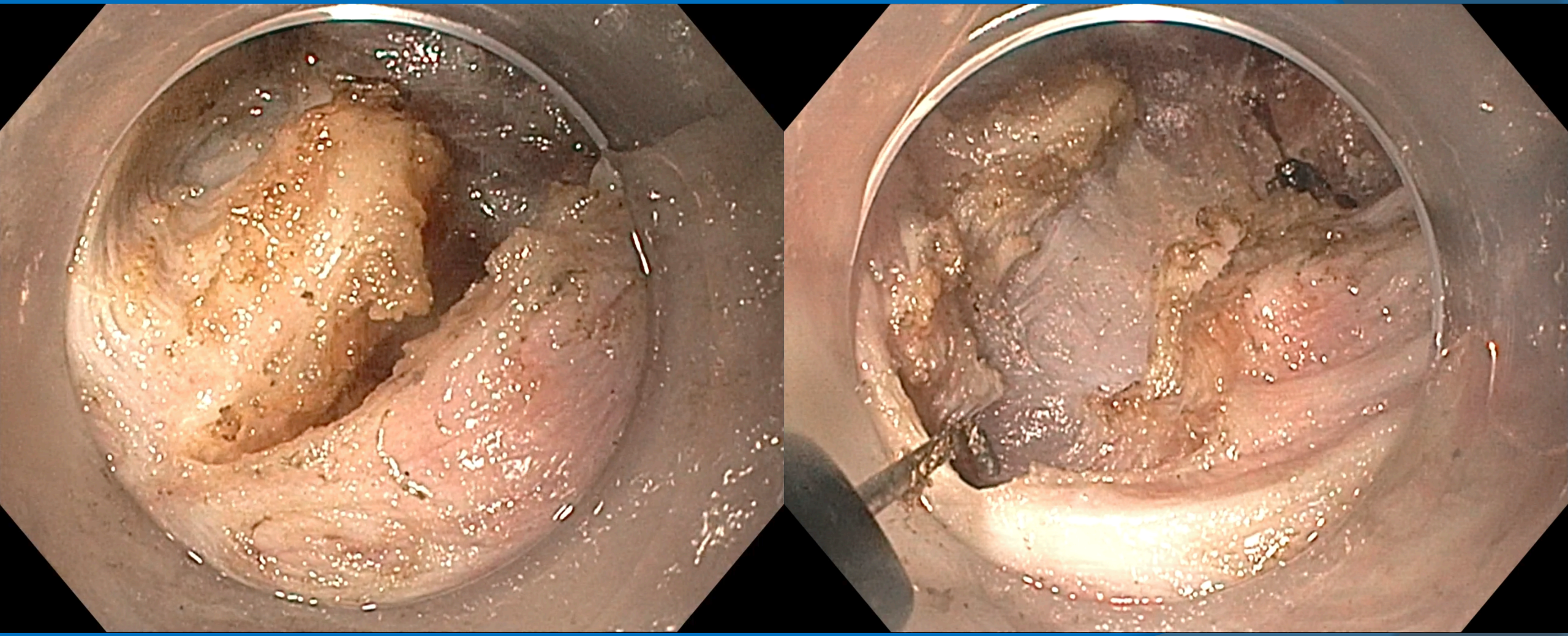
[1]*Digestive Diseases, Zucker School of Medicine Hoftsra, Manhasett, NJ;* [2]*University of Michigan, Ann Arbor, MI*

Background: Gastric peroral endoscopic myotomy (G-POEM) is a promising therapy for patients with gastroparesis because of its safety and efficacy. Most prospective studies suggest up to 75% of patients may see an improvement in symptoms and gastric emptying. Recent meta-analyses also suggest that results may be comparable to laparoscopic pyloroplasty (LP); however, LP continues to have a more robust improvement in gastric emptying and higher rates of complete normalization. A single tunnel double myotomy may offer an incremental advantage to help bridge the gap with LP. Methods: We performed an analysis of 30 patients that underwent G-POEM for refractory gastroparesis using a single tunnel double myotomy technique. Data is from consecutive patients at two centers from January 2019 to the present. A submucosal tunnel was initiated and extended to the pylorus along the greater curvature of the gastric antrum. After identification and exposure of the pyloric ring (6 o'clock), the first myotomy was performed at 7 o'clock followed by a second myotomy at 5 o'clock, both within the same tunnel (Fig 1). EndoFLIP® impedance planimetry was performed with measurements taken before the submucosal incision, and after each myotomy. Gastric emptying studies (GES-4Hr), and Gastroparesis Cardinal Symptom Index (GCSI) scores were recorded at baseline, 1-month and 3-months. Results: A total of 30 patients (23 Females) with refractory gastroparesis (9 diabetic, 10 post-surgical, 11 idiopathic) successfully underwent a G-POEM using the single tunnel double myotomy approach. There was 1 mild procedural adverse event (AE), and no AEs at 48 hours or 30 days. The total procedure time was 37.2+/-7.2 minutes. The addition of a second myotomy added 2.2+/-2 minutes overall. A second myotomy was associated with a significant incremental increase in diameter, especially at 40 and 50ml (Table 1). The average final improvement in diameter was 4.2mm (range 1.2 to 9mm). In addition, there was a significant change in distensibility, which was noted only after the second myotomy (Table 1). At 3-months (n=21), 85.7% of the patients had an objective improvement in gastric emptying with an absolute reduction of 30.1+/-16.8%. This correlated with an improvement in GCSI from 1.8 at baseline to 1.1 at 1-month and 0.9 at 3-months. None of the patients reported any symptoms of dumping syndrome. Conclusions: A single tunnel double myotomy is both safe and feasible and can be performed with minimal incremental effort when compared to a conventional G-POEM. It results in a significant improvement in final diameter and distensibility which correlates to significant clinical improvement and objective response in gastric emptying.

- Case series, 30 patients
- Single tunnel, Double Myotomy
- GCSI from 1.8 to 0.9 at 3 mo

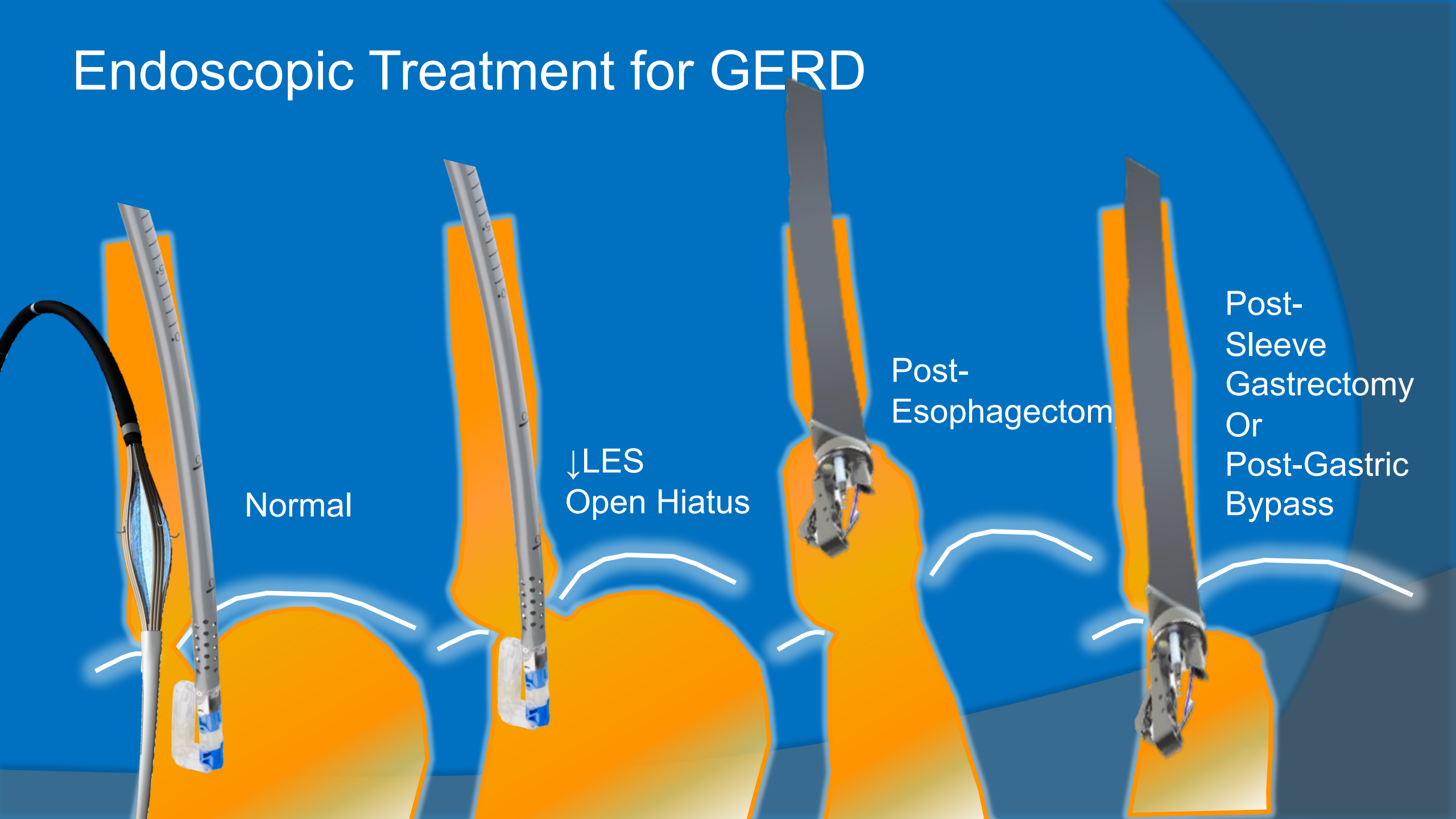
	Diameter (mm)	Distensibility Index (mm^2/Pressure)
Pre Myotomy		
30 mL	10.8 +/- 1.5	7.4 +/- 3.8
40 mL	12.5 +/- 1.6	7.2 +/- 3.7
50 mL	14.4 +/- 1.9	5.4 +/- 2.7
Single Myotomy		
30 mL	11.3 +/- 2.6 (p=3.654)	7.1 +/- 4.2 (p=0.772)
40 mL	13.9 +/- 2.5 (p=0.012)	8.3 +/- 4.5 (p= 0.305)
50 mL	16.5 +/- 2.5 (p=0.0005)	7.5 +/- 3.6 (p= 0.013)
Double Myotomy		
30 mL	12.7 +/- 2.2 (p=0.034)	9.6 +/- 2.4 (p= 0.006)
40 mL	15.4 +/- 2.4 (p=0.021)	10.8 +/- 4.8 (p= 0.0418)
50 mL	18.6 +/- 2.2 (p=0.001)	9.9 +/- 3.4 (p= 0.0102)

Table 1. Incremental Increase in diameter and distensibility of pylorus following first and second myotomy



GERD

Endoscopic Treatment for GERD



881

MULTICENTER COMPARATIVE STUDY OF HIATAL HERNIA REPAIR WITH TRANSORAL INCISIONLESS FUNDOPLICATION VERSUS NISSEN FUNDOPLICATION FOR THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE

Veeravich Jaruvongvanich*[1], Reem Matar[1], Sneha Singh[1], Glenn Ihde[3], Peter Janu[4], Peter Mavrelis[5], Michael j. Murray[6], Daniel B. Maselli[1], Shanda H. Blackmon[1], Kenneth J. Chang[7], Janani S. Reisenauer[1], David A. Katzka[1], Marcia I. Canto[2], Barham K. Abu Dayyeh[1]

[1]Gastroenterology, Mayo Clinic - Rochester, Rochester, MN; [2]John Hopkins Hospital, Baltimore, MD; [3]San Angelo Community Medical Center, San Angelo, TX; [4]Affinity Health Systems Appleton, Chilton, WI; [5]Methodist Hospitals, Merrillville, IN; [6]northern nevada medical center, Reno, NV; [7]H.H. Chao Comprehensive Digestive Disease Center, University of California, Irvine, Irvine, CA

- Retrospective, 3 centers
- 125 HH+TIF vs 70 HH+NF
- BMI, Hernia size matched

Background: Transoral incisionless fundoplication (TIF) is a lesser invasive endoscopic procedure for gastroesophageal reflux disease (GERD) alternative tolaparoscopic Nissen fundoplication (LNF). Many patients with GERD require hiatal hernia (HH) repair. The US Food and Drug Administration expanded the indication of TIF for patients with hiatal hernia > 2 cm with concomitant HH repair. Recent studies demonstrated favorable outcomes of TIF with HH repair. Data comparing this modality with conventional LNF is lacking. Aim: We therefore compared clinical outcomes and adverse events between TIF with HH repair and LNF with HH repair. Methods: This was a multicenter retrospective comparative study of LNF with HH repair (3 centers) versus TIF with HH repair (3 centers) in patients with GERD and moderate hiatal hernia (2-5 cm) from 2001 to 2019. Patients who had open surgical approach, a follow-up of less than 6 months, and prior anti-reflux surgery were excluded. Early (<30 days) and late (30 days to 12 months) adverse events (not including dysphagia and bloating) were assessed using Clavien-Dindo classification, in which severe adverse events were defined as grade III-V. Symptoms (heartburn/regurgitation, bloating, and dysphagia) at 6 and 12 months were assessed using GERD-HRQL questionnaire in the TIF cohort and chart review in the LNF cohort. Results: A total of 125 patients with TIF and HH repair and 70 with LNF with HH repair (BMI and hernia size-matched, mean BMI 29.2±4.7 kg/m^2, mean age 57.2±14.3 years) were compared. The length of hospital stay (TIF: 1 (interquartile range [IQR] 1-2) days vs. LNF: 2 (IQR 1-2) days), 30-day readmission (0 vs. 4.3%), early adverse events (0 vs. 18.6%), and early serious adverse events (0 vs. 4.3%) favored TIF (all $P < 0.05$) (Table 1). There were no late adverse events in both groups. The rate of discontinued or decreased proton pump inhibitor (PPI) use and the number of patients with no GERD and no PPI use were similar in both groups at 6 and 12 months (all $P > 0.05$). PPI non-users at baseline did not start PPI. A higher incidence of bloating (new or worse than baseline) was observed in the LNF group at 6 months (30.0% vs. 13.8%, $P = 0.009$) and a trend at 12 months (24.2% vs. 14.9%, $P = 0.18$). The incidence of dysphagia (new or worse than baseline) was similar in both groups. In those who had pre-and post treatment endoscopy within 6-12 months after procedure, the rate of improvement/resolution of esophagitis and recurrence of hiatal hernia were not different between the two groups ($P > 0.05$) (Table 2). Conclusions: In this large retrospective case-match study TIF with HH repair was equivalent to LNF with HH repair for symptom control up to 12 months with a lower rate of adverse events, gas-bloat syndrome, and a shorter hospital stay. A randomized clinical trial is warranted to validate our findings.

Table 1 Baseline characteristics and complications

	TIF group (N=125)	LNF group (N=70)	P-value
Age (years, mean ± SD)	55.1 ± 14.5	60.9 ± 13.4	0.005
Female [n (%)]	56.8	61.4	0.53
BMI (kg/m², mean ± SD)	29.1 ± 5.0	29.2 ± 4.2	0.97
PPI use at baseline [n (%)]	119 (95.2)	66 (94.3)	0.78
Length of hospital stay (days, median [IQR])	1 (1-1)	2 (1-2)	< 0.001
Readmission in 30 days [n (%)]	0	3 (4.3)	0.013
1-year mortality [n (%)]	0	0	-
Adverse events [n (%)]			
Early adverse events (< 30 days)	0	13 (18.6)	< 0.001
Early serious adverse events	0	3 (4.3)	< 0.001
Late adverse events (30 days to 1 year)	0	0	-
Late serious adverse events	0	0	-
At 6 months [n (%)]			
Discontinued PPI use	76 (73.8)	40 (60.6)	0.07
Decreased PPI use	88 (85.4)	55 (83.3)	0.71
Start PPI use	0	0	-
Bloating (new or worse than baseline)	15 (13.8)	21 (30.0)	0.009
Dysphagia (new or worse than baseline)	9 (8.3)	10 (14.3)	0.21
No PPI use with no symptoms	65 (60.8)	44 (62.9)	0.78
PPI use with no symptoms	11 (10.3)	23 (32.9)	< 0.001
PPI use with continued symptoms	14 (13.1)	3 (4.3)	0.04
At 12 months [n (%)]			
Discontinued PPI use	50 (73.5)	35 (58.3)	0.07
Decreased PPI use	57 (83.8)	47 (78.3)	0.43
Start PPI use	0	0	-
Bloating (new or worse than baseline)	10 (14.9)	15 (24.2)	0.18
Dysphagia (new or worse than baseline)	7 (10.1)	8 (12.9)	0.62
No PPI use with no symptoms	32 (52.5)	36 (58.1)	0.53
PPI use with no symptoms	8 (13.1)	22 (35.5)	0.003
PPI use with continued symptoms	8 (13.1)	3 (4.8)	0.10

Abbreviations: BMI: body mass index; LNF: laparoscopic Nissen fundoplication; PPI: proton pump inhibitor; TIF: transoral incisionless fundoplication

Table 2 Endoscopy findings

	TIF group (N=27)	LNF group (N=19)	P-value
Baseline EGD [n (%)]			0.003
No esophagitis	4 (14.8)	11 (57.9)	
LA class A	10 (37.0)	2 (10.5)	
LA class B	9 (33.3)	1 (5.3)	
LA class C	3 (11.1)	2 (10.5)	
LA class D	1 (3.7)	3 (15.8)	
Improvement of esophagitis [n (%)]	22 (95.7)	7 (87.5)	0.45
Resolution of esophagitis [n (%)]	19 (82.6)	7 (87.5)	0.74
Recurrence of hiatal hernia [n (%)]	4 (14.8)	2 (11.1)	0.72

Abbreviation: EGD: esophagogastroduodenoscopy; LNF: laparoscopic Nissen fundoplication; TIF: transoral incisionless fundoplication

- Conclusion: HH+TIF appears comparable to HH+NF in symptom control to 12 months, with less AE's, gas-bloat and shorter hospital stay
- Randomized study coming soon

981

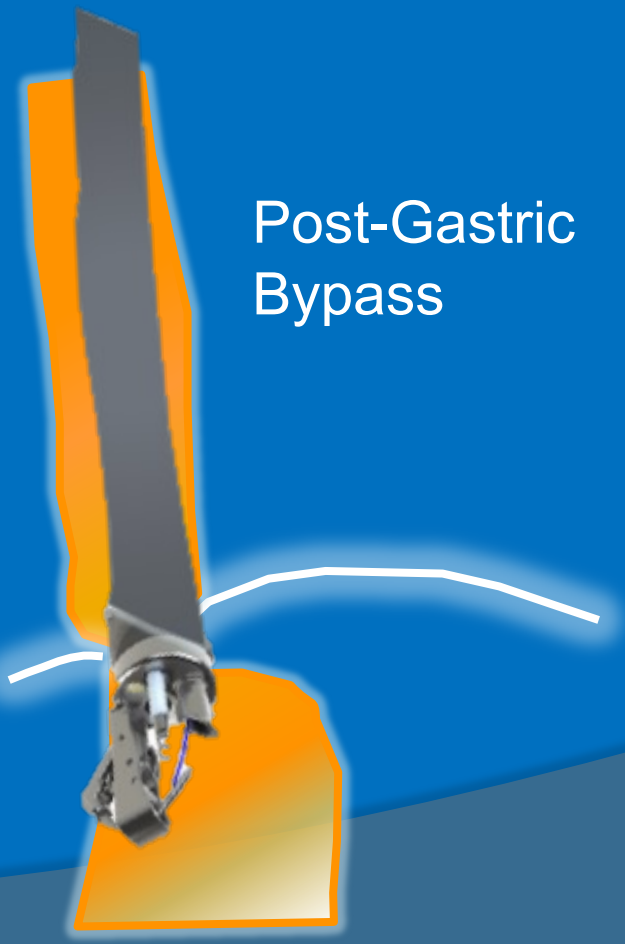
RESECTION AND PLICATION (RAP): AN ENDOSCOPIC ANTI-REFLUX SOLUTION IN ALTERED ANATOMY

Piotr Sowa*, David Lee, Jason Samarasena, Kenneth J. Chang

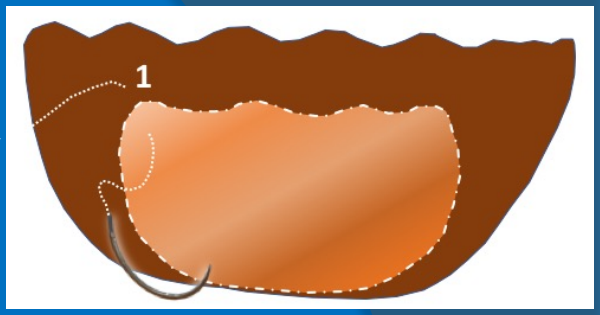
Gastroenterology, University of California Irvine, Orange, CA

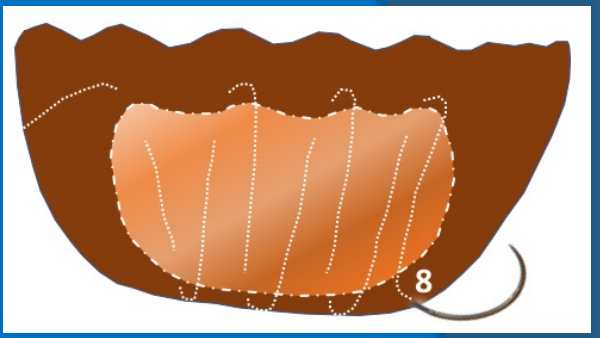
Background: In recent years, significant advances have been made in the treatment of gastroesophageal reflux disease (GERD). Options for therapy have expanded in the surgical field, and new endoscopic options have emerged as alternative means of treating GERD in select populations. However, GERD remains a common problem in many polulations that do not quality for these new therapies, either due to severe co-morbidities or altered anatomy. The Resection and Plication (RAP) procedure is a novel endoscopic option for the treatment of medication refractory GERD. The RAP procedure can uniquely be empolyed in patietns unable to undergo surgical or alternate endoscopic anti-reflux therapies due to gastroesophageal junction (GEJ) anatomy that has been altered, for example in patients with prior nissen fundoplication, roux-en-Y gastric bypass, sleeve gastrectomy, or esophagectomy. Methods: The RAP procedure involves band endoscopic mucosal resection (EMR) semi-circumferential mucosectomy at the GEJ followed by full-thickness plication (RAP). Endoscopic suturing creats a gastro-gastric plication which serves to tighten the GEJ and decrease the rate of reflux into the esophagus. The following video demonstrates the RAP procedure in 2 patients with altered anatomy. Case 1, 66-year-old female with GERD previously treated with Nissen Fundoplication 10 years ago presents with refractory GERD symptoms. Case 2, 44-year-old female with history of morbid obesity treated with roux-en-Y gastric bypass with initial weight loss, now with significant weight gain and morbid obesity who is presenting with persistent GERD symptoms. Results: 26 patients have undergone the RAP procedure at our institution. The average procedure time is 31 minutes. Ninety percent of were discharged the same day without major complications. Eighteen patients had altered anatomy (5 Fundoplication, 4 Gastric Bypass, 4 Esophagectomy, 2 failed TIF, 2 Endoscopic Sleeve Gastroplasty, 1 Sleeve Gastrectomy). We observed dramatic improvements in Reflux Disease Questionnaire (RDQ) and GERD Health Related Quality of Life (HRQL) questionnaires (RDQ Frequency 80%, RDQ Severity 76%, GERD-HRQL 85%). Sixty percent of patients were able to stop or decrease PPI use at follow-up. The average follow-up period was 6 months. Conclusion: The Resection and Plication (RAP) procedure is a novel endoscopic endoscopic anti-reflux procedure which results in gastro-gastric plications just below the level of the GEJ, thereby reducing the rate of reflux of gastric contents into the esophagus. This provides an effective endoscopic option in patients who otherwise cannot get other surgical or endoscopic therapies, specifically due to prior surgeries. This is a same day procedure and is overall safe, well tolerated and patients report a high degree of satisfaction following therapy.

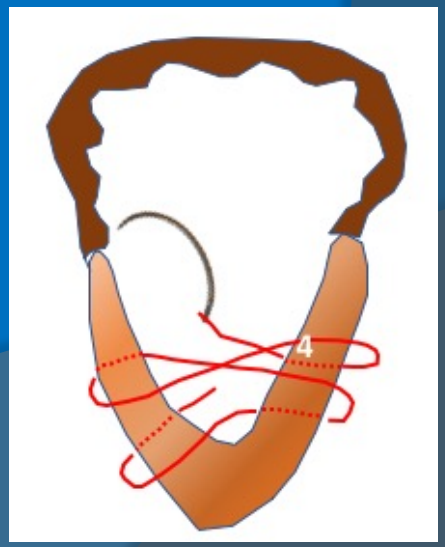
- Video Plenary
- 18 altered anatomy
- 2 video demos



Post-Gastric Bypass







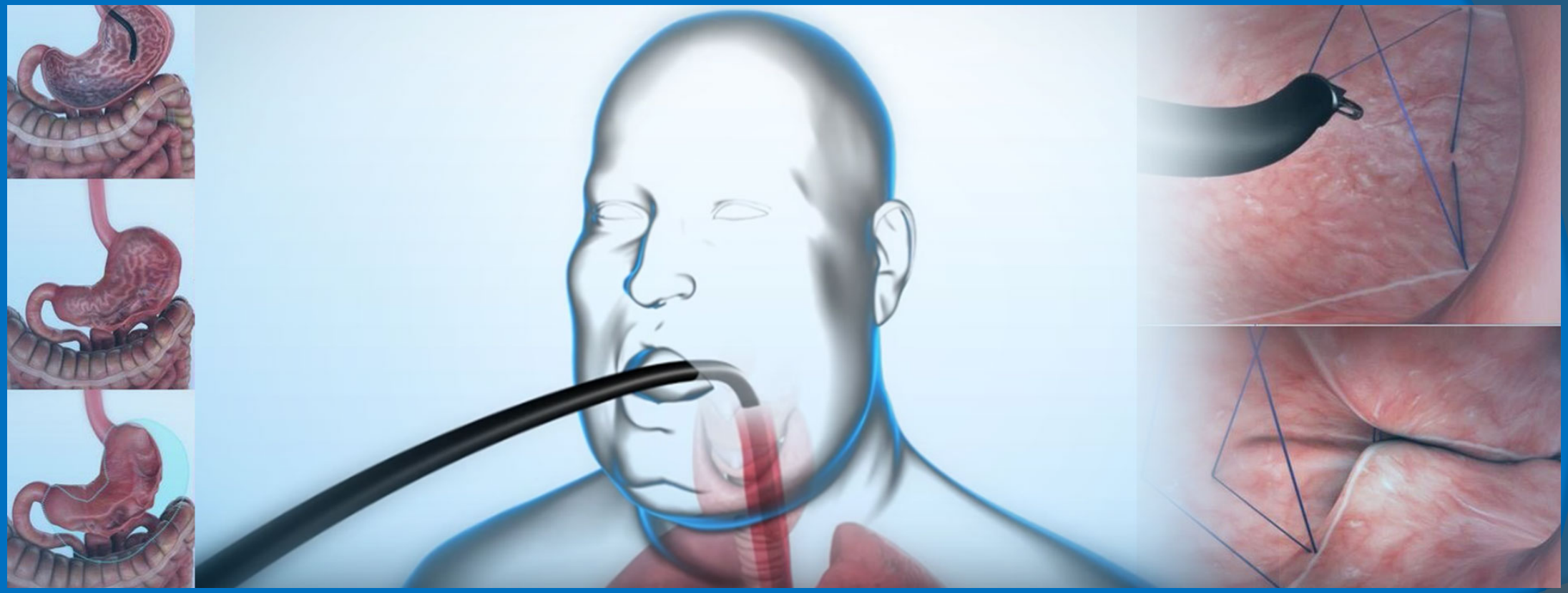
Resection and Plication (RAP): An Endoscopic Anti-Reflux solution in Altered Anatomy

Piotr Sowa MD, David Lee MD MPH, Jason Samarasena MD, Kenneth Chang MD

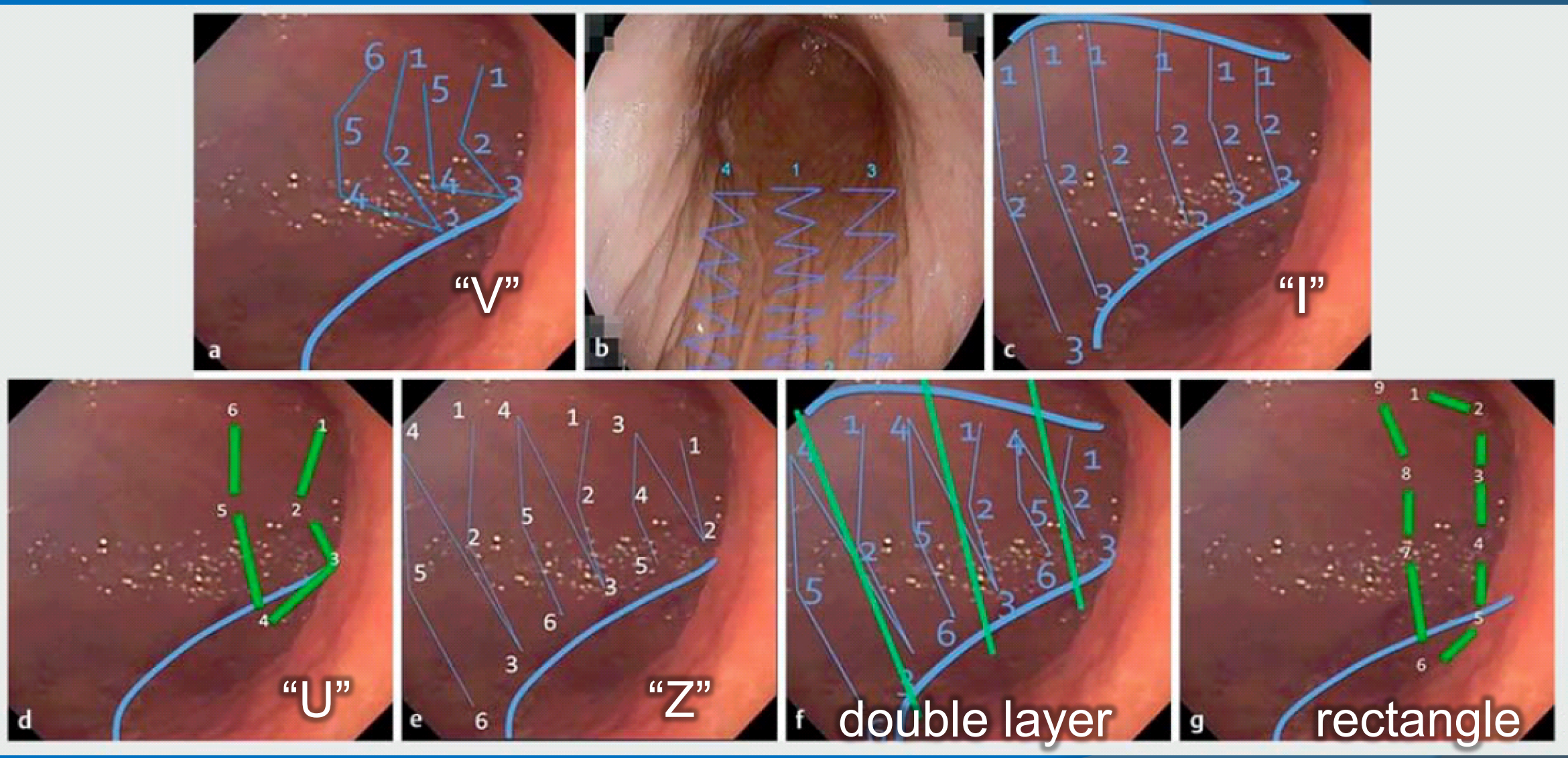
ASGE DDW Video Forum 2020

EndoBariatrics

Endoscopic Sleeve Gastroplasty (ESG)



- Suture patterns - where, how, how many?


a
"V"
b
c
"I"
d
"U"
e
"Z"
f
double layer
g
rectangle

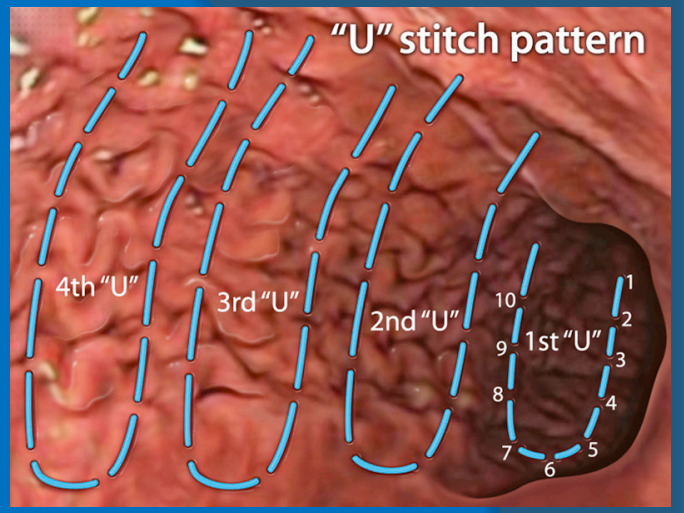
EUROPEAN ENDOSCOPIC SUTURING REGISTRY FOR TREATMENT OF OBESITY

Gontrand Lopez-Nava*[1], Inmaculada Bautista-Castaño[1], Ravishankar Asokkumar[1], Anuradha Negi[1], Christine Stier[2], Silvana Perretta[3], Andrea Formiga[4], Ricardo Zorron[5], Manos Thierry[6], Javier Graus[7], Heyman Stijn[8], Ellen Liekens[8]

[1]HOSPITAL UNIVERSITARIO HM SANCHINARRO - MADRID, Madrid, Spain; [2]Sana Klinikum Offenbach, Wurzburg, Germany; [3]ircad university of strasbourg, Strasbourg, France; [4]San Donato Group Milan, Milan, Italy; [5]Ernst Von Bergman Klinikum, Potsdam, Germany; [6]Clinic Bouchard, Marsielle, France; [7]Instituto Medico Europeo de la Obesidad, Madrid, Spain; [8]Hospital Network Antwerp, Antwerp, Belgium

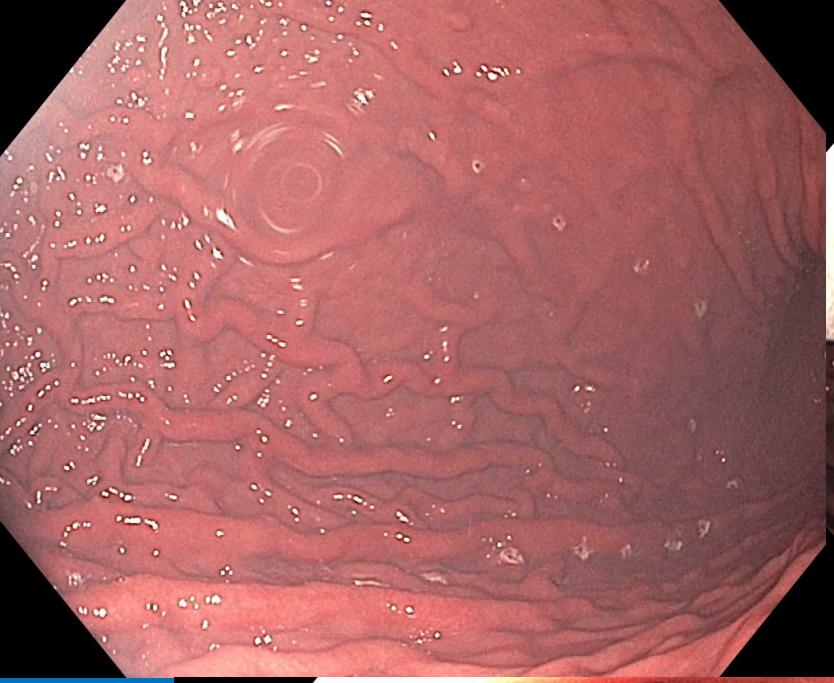
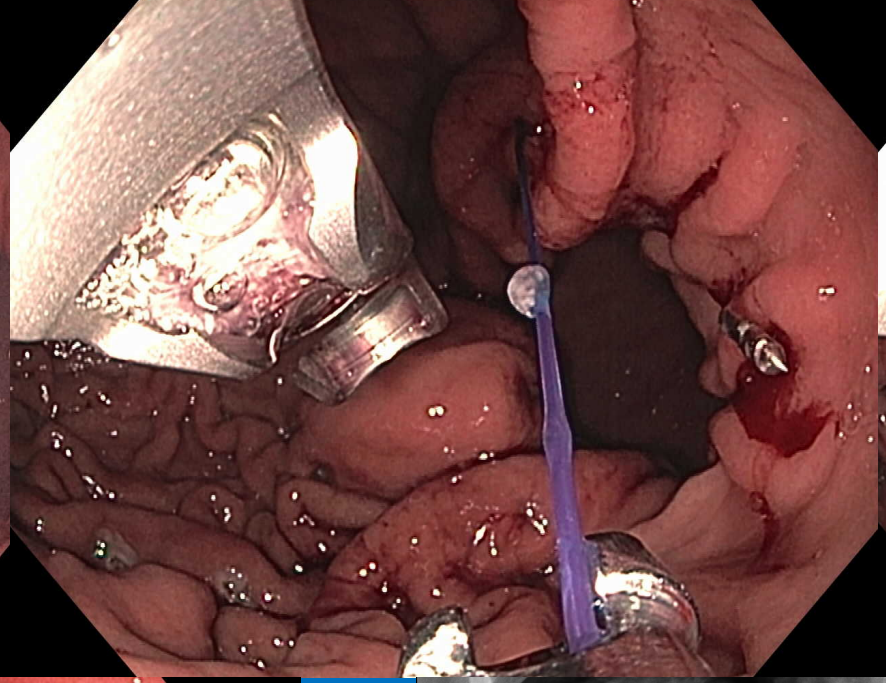
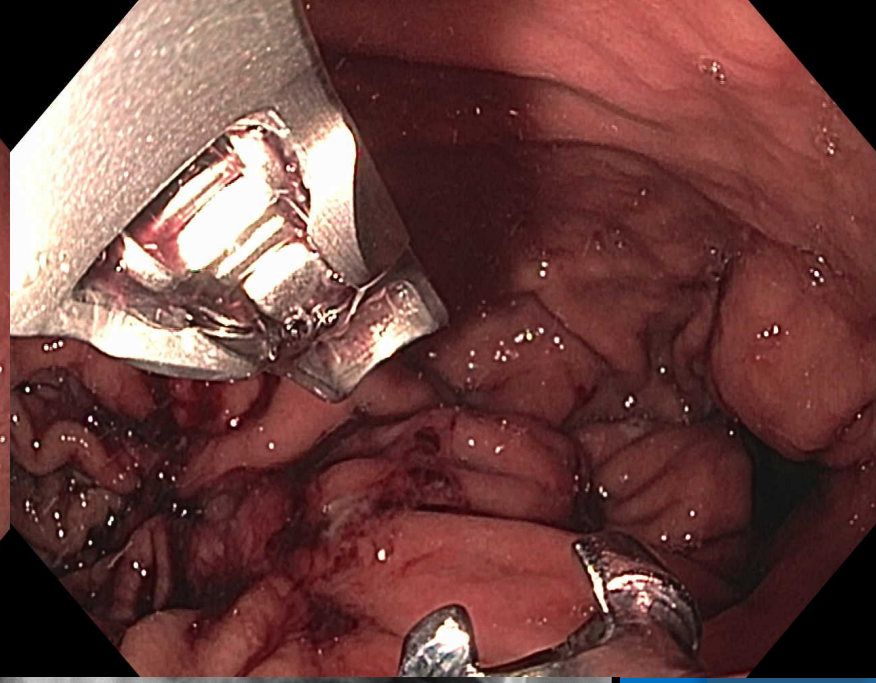
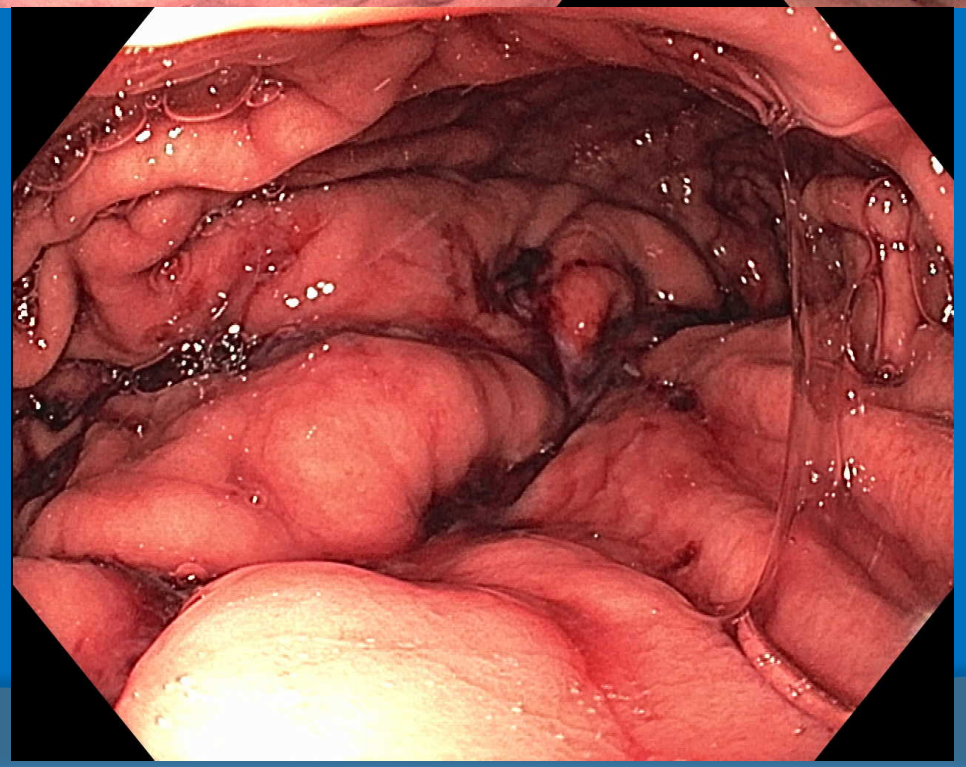
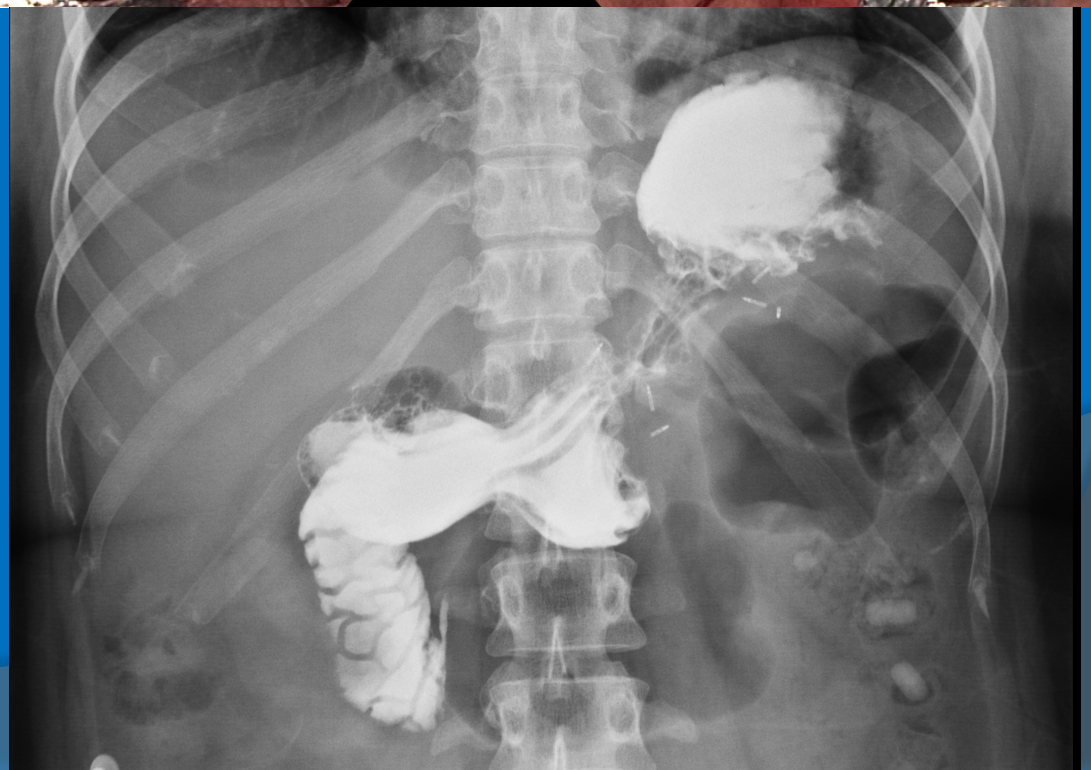
Introduction: Endoscopic full-thickness suturing has grown in clinically utility. The endoscopic sleeve gastroplasty (ESG) is increasingly performed as a primary endoluminal therapy for obesity. The trans-oral outlet reduction (TORE) effectively addresses weight regain after bariatric surgery. We created a prospective multicenter registry in Europe to monitor the outcomes after ESG and TORE. The aim of the registry is to determine the practice patterns, weight loss outcomes, and adverse events after ESG and TORE. Methods: Six European centers participated in this prospective data registry. Consecutive patients were enrolled from January 2018. Patient information was de-identified before registering into the database. Demographics, technical specifications, weight loss, and follow-up outcomes were recorded. The data was captured and managed using the REDCap software. Consent was obtained from all patients. We expressed the outcome as mean ± SD. We reported the technique, safety, and weight loss outcome at 1 year. We used ANOVA statistics with Bonferroni correction to compare weight loss results. We performed a logistic regression to identify the suture pattern that predicted >10% TBWL after adjusting for age, sex, and initial BMI. Results: We enrolled 800 patients (764 ESG and 36 TORE) between January 2018 to November 2019. The mean age was 44.4 ± 11 years, and the majority were female (80%). The mean BMI was 36 ± 5.2 kg/m^2. ESG was performed as primary obesity therapy in 723 cases and as a bridge procedure in 41 patients. The mean procedure time for ESG was 54 minutes (range,15-187). The suture pattern was multi-bite "V" shaped (45%), "Z" shaped (36%), or "U"-shaped (18%).At 12 months, the TBWL, %TBWL and BMI decline in the "U"-shaped pattern was significantly higher (21.9 kg , 21.1%, 8.3 Kg/m^2, p<0.001) as compared to the "Z"-shaped pattern (16.9 kg, 16.9%, 6. kg/m^2) and "V" pattern (10.3 kg, 10.7%, 3.8 Kg/m^2) (Table-1). In logistic regression after adjusting for age, sex, and initial BMI, we found the "U"-shaped suture pattern significantly predicted >10%TBWL at 12 months (p<0.01). Adverse events were reported in 21 (2.7%) patients and included: 15 minor bleeding, 4 gastric perforations, 2 aspiration events, and 1 esophageal mucosal laceration. All the gastric perforations were treated endoscopically. There were no mortalities. For the TORE procedure, an average of 2 sutures was required to reduce the outlet and one suture to reduce the pouch volume. The majority (67%) were interrupted stitiches compared to running sti-

- European Registry
- 6 centers
- 764 ESG cases
- Prospective data
- near 2 year f/u



Time	Variable	"V-Pattern"	"Z-Pattern"	"U-Pattern"
Baseline Mean (95% CI)	BMI, Kg/m^2	35.1 (34.5-35.6)	35.8 (35.2-36.3)	38.6 (37.6-39.5)
	Weight, Kg	98.2 (96.3-100.2)	98.2 (96.3-100.2)	107.3 (103.8-110.7)
6 months Mean (95% CI)	TBWL, Kg	12.1 (10.9-13.2)	15.3 (14.3-16.3)	19.6 (18-21.3)
	%TBWL	12 (11-13)	15.5 (14.5-16.4)	18.5 (17.1-19.9)
	BMI decline, Kg/m^2	4.3 (3.9-4.7)	5.6 (5.2-5.9)	7.1 (6.6-7.7)
	>10% TBWL	60%	78.3%	92%
	>20% TBWL	10.5%	26%	42.5%
12 months Mean (95% CI)	TBWL, Kg	10.3 (7.5-13.2)	16.9 (15.6-18.2)	21.9 (18.6-25.2)
	%TBWL	10.7 (7.8-13.6)	16.9 (15.7-18.1)	21.1 (18.5-23.7)
	BMI decline, Kg/m^2	3.8 (2.8-4.9)	6.1 (5.7-6.6)	8.3 (7.1-9.5)
	>10%TBWL	56%	79%	93%
	>20% TBWL	15%	34%	48%

- "U" pattern was significant with p<0.05

720

PRIMARY OBESITY SURGERY ENDOLUMINAL 2 (POSE2): AN INTERNATIONAL MULTICENTER PROSPECTIVE TRIAL

Gontrand Lopez-Nava*[2], Roman Turro[3], Daniel B. Maselli[1], Inmaculada Bautista-Castaño[2], Reem Matar[1], Ravishankar Asokkumar[2], Jorge C. Espinos[4], Alfredo Mata[5], Eric J. Vargas[1], Veeravich Jaruvongvanich[1], Andrew C. Storm[1], Manoel Galvao Neto[6], Barham K. Abu Dayyeh[1]

[1]Gastroenterology and Hepatology, Mayo Clinic - Rochester, Rochester, MN; [2]Madrid Sanchinarro University Hospital, Madrid, Spain; [3]Centro Medico Teknon, Barcelona, Spain; [4]H Mutua Terrassa, Barcelona, Spain; [5]Hospital Moises Broggi, Sant Joan Despi, Barcelona, Spain; [6]Florida International University, Miami, FL

Introduction: Endoscopic bariatric and metabolic therapies that remodel the stomach offer an alternative to removable intragastric devices or bariatric surgery. The Primary Obesity Surgery Endoluminal 2 (**POSE2**) procedure, performed with the Incisionless Operating Platform (USGI, San Clemente, CA), involves full-thickness plications by suture anchor pairs that shorten and tubularize the stomach along its greater curvature (Figure 1). Aims: Our aim, through an international, protocol-driven, prospective multicenter trial, was to determine the 1) safety and efficacy of POSE2 for obesity, and 2) to study its impact on gastric physiology. Methods: 41 patients enrolled under an IRB protocol in three centers (2 Spain, 1 USA under FDA IDE). Prescribed moderate intensity lifestyle intervention and follow-up was implemented similarly across centers. Nuclear scintigraphy or ^{13}C-Spirulina breath test (Cairn Diagnostics, Brentwood, TN) determined time to half gastric emptying (**$GE_{1/2}$**) of solids. Satiety and satiation was assessed by standardized questionnaires. Impact of Weight on Quality of Life questionnaire occurred at baseline and at 6 months. Hepatic steatosis was measured by controlled attenuation parameter (**CAP**) with elastography. Results: 41 subjects (mean age 44.3 ± 9.4 years, mean body mass index 37.3 ± 1.7 kg/m^2, 61% female) underwent POSE2 with 19 (IQR 13-21) suture anchor pairs over a mean duration of 37 min ± 11 min under general anesthetic. Total body weight loss was 13.9% ± 4.1% at 3 months (n=35/36), 17.3% ± 6.4% at 6 months (n=35/36) and 17.5% ± 6.6% at 9 months (n=32/33). Percent achieving ≥10% total body weight loss was 89% at 3 months (n=35/36), 94% at 6 months (n=32/33), and 91% at 9 months (n=32/33). One patient was lost to follow-up. No serious adverse events were reported. All plications were intact with preservation of remodeled gastric shape on repeat upper GI series at 6 months. 85% of the cohort had significant changes in gastric emptying at 6 months compared to baseline. Gastroparesis Cardinal Symptom Index did not change at 6 weeks compared to baseline (p=0.18). Fasting and post-prandial satiety and satiation scores improved significantly at 2 and 6 months compared to baseline (p<0.001) (Figure 2). Alanine aminotransferase (n=36) improved from a baseline of 33.4 mg/dL to 19.1 mg/dL at 6 months (p=0.0074), with a corresponding improvement in hepatic steatosis from a baseline CAP (n=15) of 299 dB/m to 220 dB/m at 6 months (p=0.00024). Impact of Weight on Quality of Life (n=35) improved from 2.40 to 1.44 at 6 months (p< 0.001). Conclusion: POSE2 is a novel, safe, and effective endoscopic bariatric and metabolic therapy with mid-term results approaching the response rate of bariatric surgery. Given its durability, influence on appetite, and patient tolerance, it is poised to become an impactful EBMT to manage obesity and metabolic disease.

- Primary Obesity Surgery Endoluminal (POSE-2)
- Prospective, multi-center trial, 3 centers
- 41 patients (mean BMI 37.3); 19 sutures

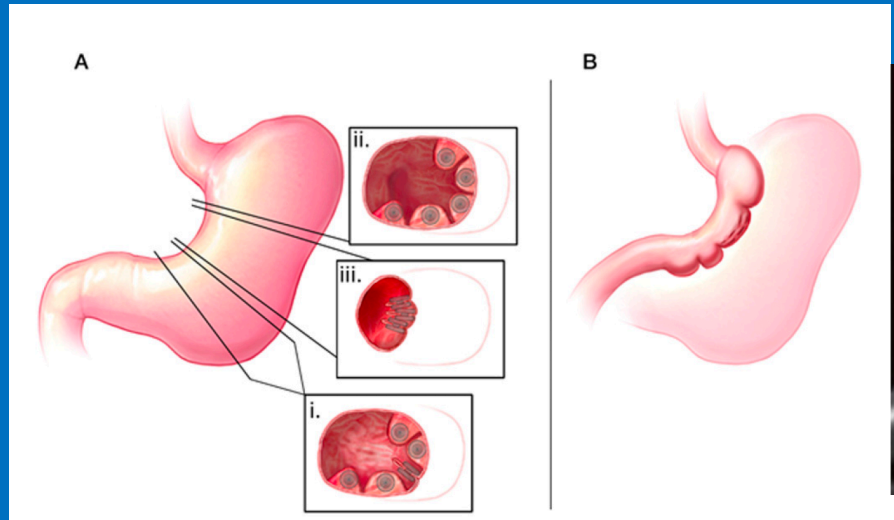
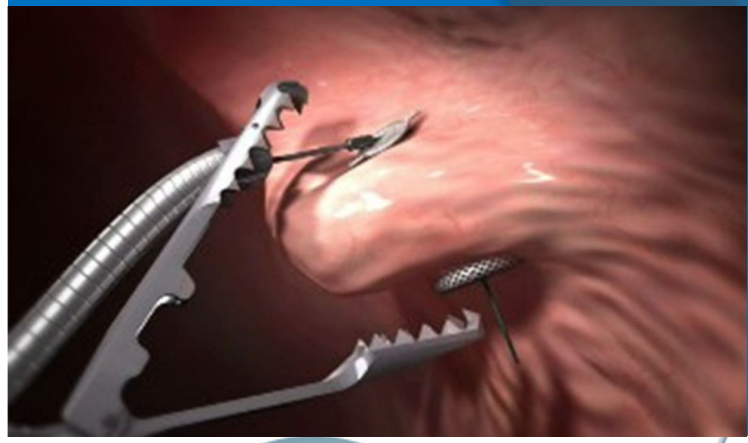
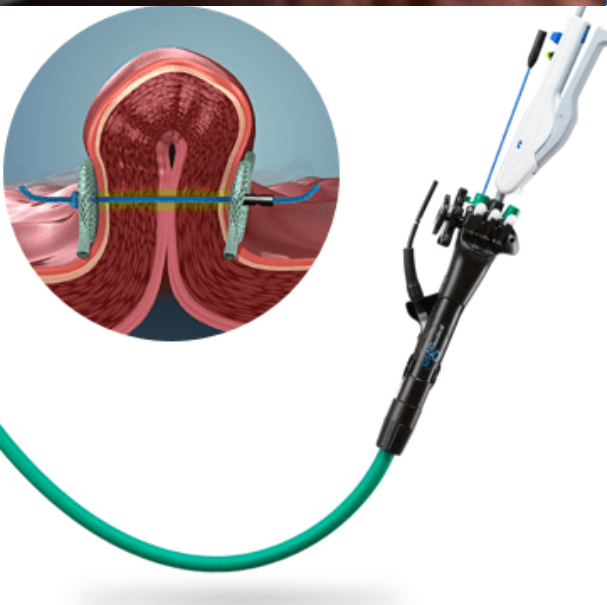


Figure 1. The POSE2 Procedure for Weight Loss. A) Plications are created by suture anchor pairs placed in i) two rows in the distal gastric body opposite the incisura, ii) one row at the border of the proximal gastric body and fundus (the majority of which shorten the stomach along the longitudinal axis) and iii) multiple rows in the intervening space to narrow the gastric aperture. B) Depiction of the shortened and tubularized gastric contour following the POSE2 procedure.





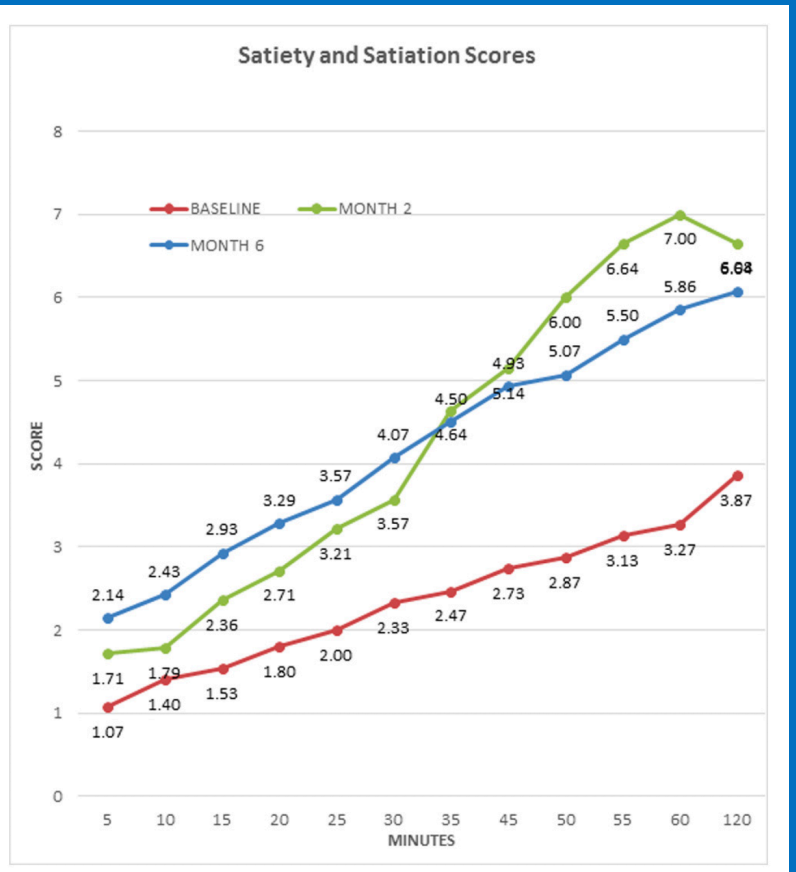
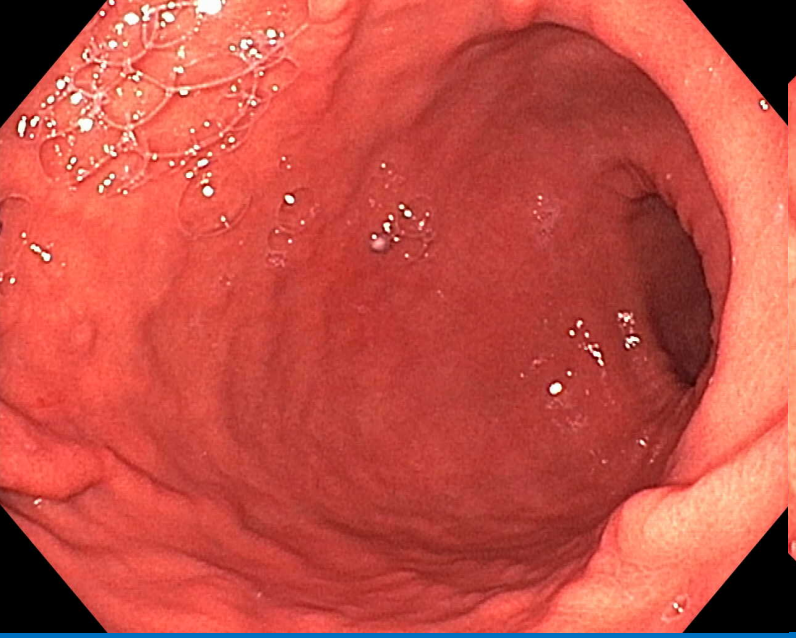
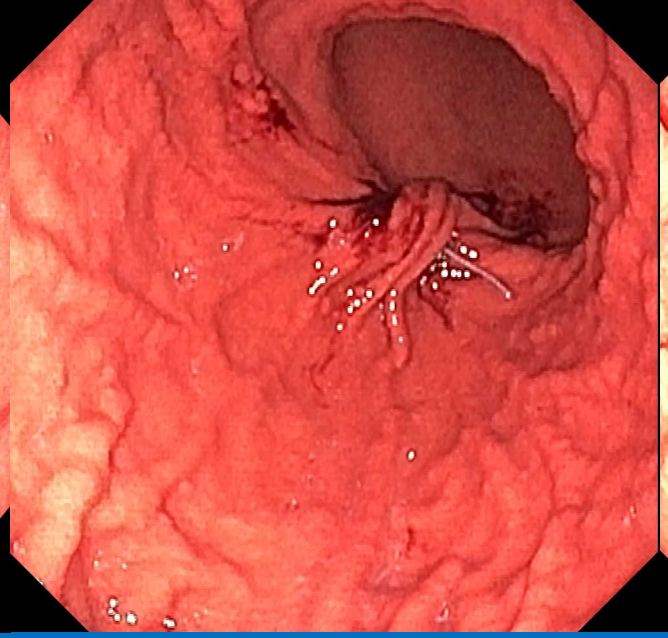
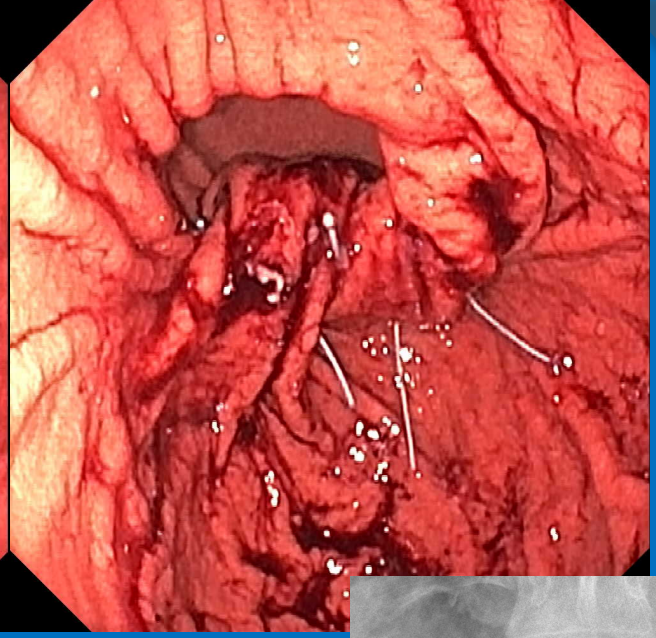
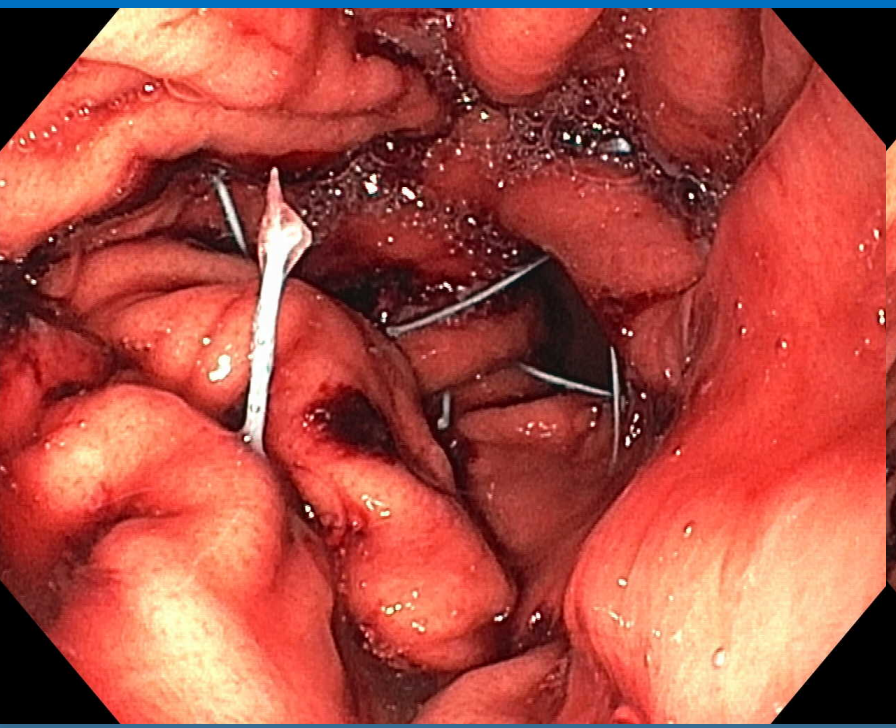
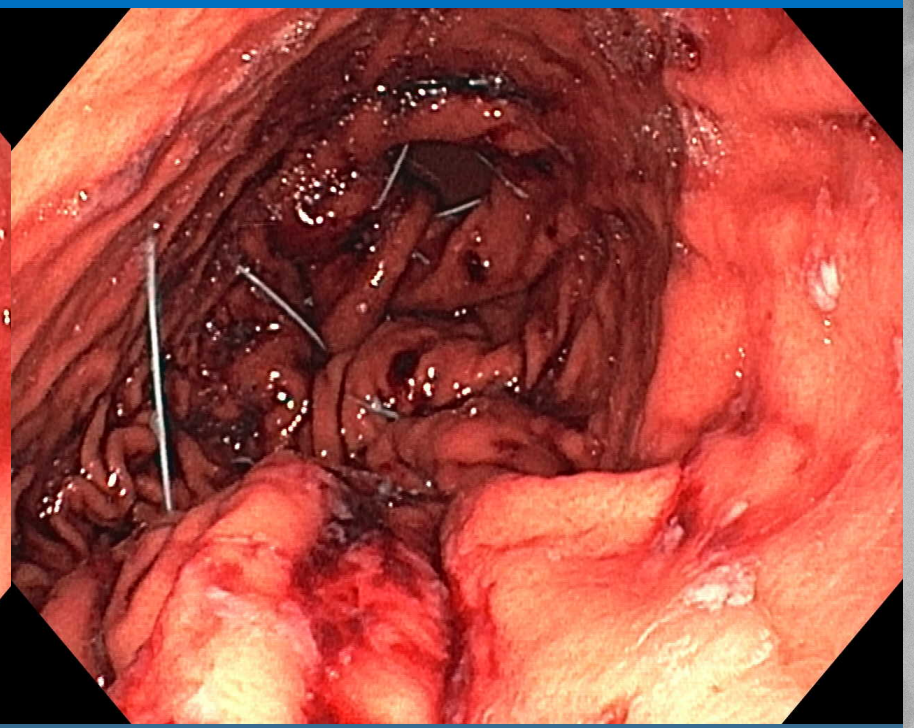
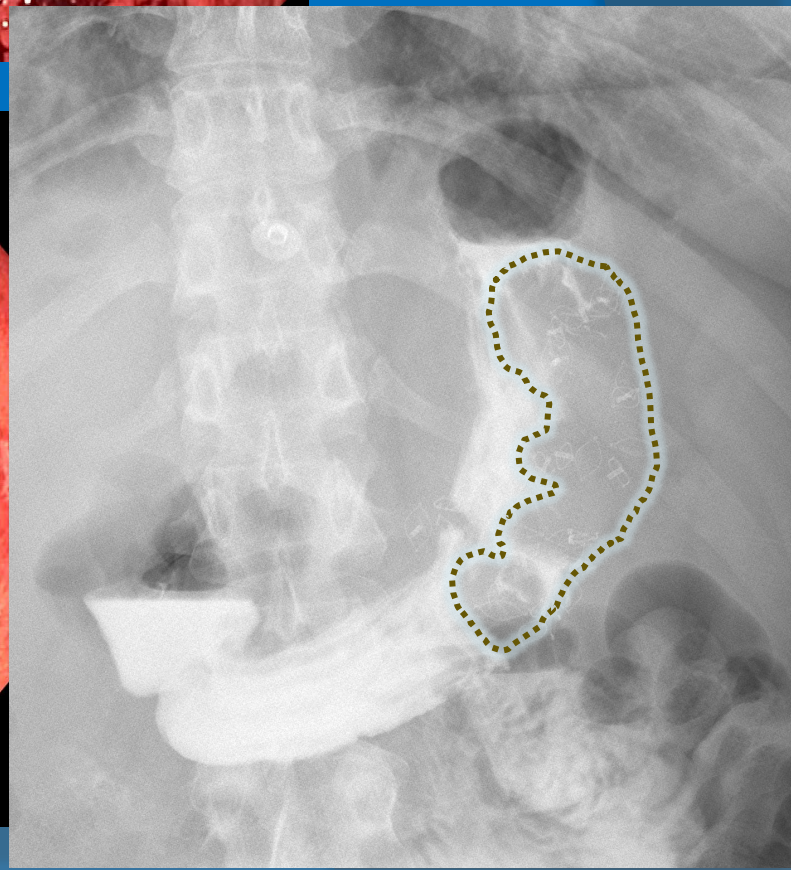


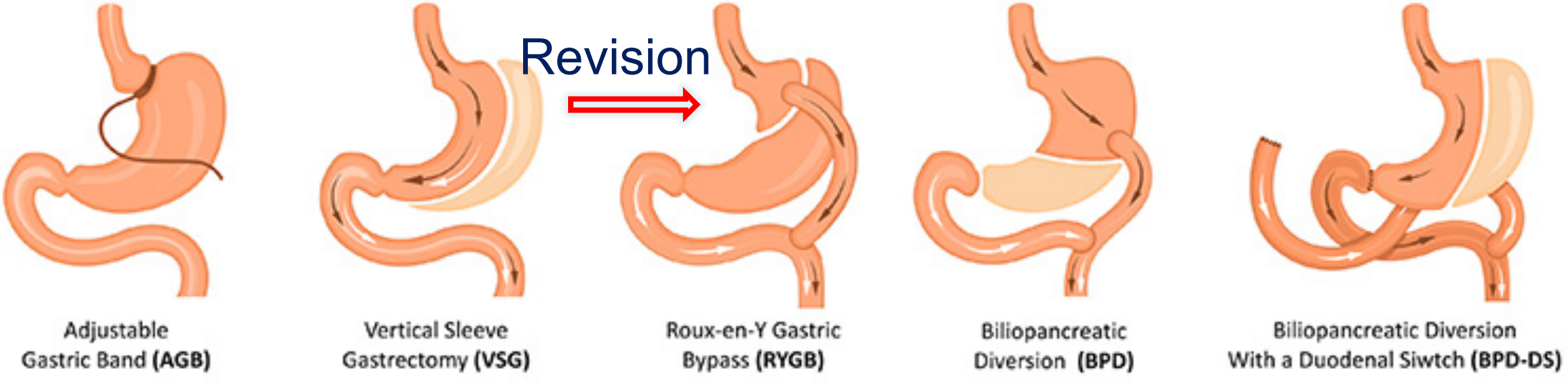
Figure 2. POSE2 and Appetite Physiology. Satiety and satiation scores after a standardized meal were recorded at baseline, 2 months post-POSE2, and 6 months post-POSE2.

- Procedure time: 37min
- GCSI - no change
- Fasting and post-prandial satiety and satiation improved at month 2 and 6
- 85% had significant changes on GES

	Base	3 mo	6 mo	9 mo	p-value
TBWL %		13.9	17.3	17.5	
≥ 10% TBWL		89%	94%	91%	
ALT (n=36)	33.4	-	19.1		.0074
Hepatic Steatosis (n=15)	299		220		.00024
QOL (n=37)	2.4		1.44		.001

TYPES OF BARIATRIC SURGERY



Adjustable Gastric Band **(AGB)**

Vertical Sleeve Gastrectomy **(VSG)**

Roux-en-Y Gastric Bypass **(RYGB)**

Biliopancreatic Diversion **(BPD)**

Biliopancreatic Diversion With a Duodenal Siwtch **(BPD-DS)**

ENDOSCOPIC REVISION OF LAPAROSCOPIC SLEEVE GASTRECTOMY IS SAFE, EFFECTIVE, AND DURABLE: A MULTI-CENTER STUDY

Daniel B. Maselli*[1], Mohamed Elahmedi[8], Barham K. Abu Dayyeh[1], Andrew C. Storm[1], Reem Matar[1], Eric J. Vargas[1], Veeravich Jaruvongvanich[1], Manpreet Mundi[1], Vivek Kumbhari[2], Mohamad I. Itani[2], Jad Farha[2], Andre Teixeira[3], Manoel Galvao Neto[4], Maryam s. Al Khatry[7], Jose Nieto[5], Ameya A. Deshmukh[5], Reem Z. Sharaiha[6], Aayed Alqahtani[8]

[1]Gastroenterology and Hepatology, Mayo Clinic - Rochester, Rochester, MN; [2]Johns Hopkins University Hospital, Baltimore, MD; [3]Orlando Health, Orlando, FL; [4]Florida International University, Miami, FL; [5]Borland Groover Clinic, Jacksonville, FL; [6]New York Presbyterian Hospital - Weill Cornell Medical Center, New York, NY; [7]Obaidulla Hospital, Ras Al Khaimah, United Arab Emirates; [8]New You Medical Center, Riyadh, Saudi Arabia

Introduction: The laparoscopic sleeve gastrectomy (**LSG**) is an effective bariatric surgery that facilitates approximately 60% excess body weight loss at five years; however, surgical revision for weight regain has been reported in over 10% of cases. Given the evolving role of endoscopic suturing as a therapeutic bariatric intervention, there is growing interest in endoscopic revision of LSG as a minimally-invasive alternative to surgical revision for weight recidivism. This study examined the procedural elements, outcomes, and safety associated with endoscopic revision of LSG. Methods: Seventy-seven adults at seven centers who experienced weight regain from post-LSG weight nadir underwent endoscopic revision to further restrict the surgical gastric sleeve using an endoscopic suturing device (OverStitch; Apollo Endosurgery, Austin, TX). Total body weight loss (**TBWL**) was followed (Figure 1). Univariate and multivariate analysis for TBWL >15% at 6 months post-revision was performed on inputs of age, weights, time to revision, use of weight loss medications, number of sutures, and presence of dilated stomach on baseline imaging (Table 1). Results: Seventy-seven subjects (baseline mean age 42.27 years ± 10.73 years, 92% female) who had mean pre-LSG weight of 151.66 kg ± 71.00 kg and post-LSG weight nadir of 98.61 kg ± 41.94 kg experienced 21.35 kg ± 33.25 kg weight regain from post-LSG weight nadir, prompting endoscopic revision of LSG. At time of revision, mean weight was 117.90 kg ± 47.79 kg. The revisions occurred at a median of 5 (IQR 4-7) years after LSG and used median of 4 (IQR 3-4) sutures over a mean procedural duration of 46.90 min ± 19.28 min. After revision, TBWL was 5.85% ± 3.50% at one month (n = 63), 10.60% ± 4.58% at 3 months (n = 57), 13.68% ± 7.63% at 6 months (n = 47), and 12.75% ± 12.80% at 12 months (n = 38). At 3 month follow up, the 31% of subjects on weight loss medications at time of revision experienced 12.30% ± 4.41% TBWL compared to 9.06% ± 4.08% TBWL for those not on weight loss medications (p = 0.013). By 6 months, those on weight loss medications at time of revision experienced 14.50% ± 8.19% TBWL compared to 11.95% ± 6.92% TBWL for those not on weight loss medications (p = 0.32). Univariate analysis for association with TBWL > 15% at 6 months post-revision was significant for older age (OR 1.07, p = 0.038), and presence of dilated stomach on baseline imaging (OR 4.33, p = 0.026). There were no reported adverse events from the endoscopic revisions. Conclusions: Endoscopic revision of LSG is a safe and effective means of facilitating weight loss in those with weight regain after LSG and should be considered prior to pursuing more invasive surgical revision options. Concurrent use of weight loss medications with the revision appears to provide short term improvement in TBWL but this difference was not sustained at 6 months.

- Retrospective, 7 centers
- 77 pts wt regain post-LSG nadir
- Endoscopic Revision by suturing
- 92% female, pre-LSG 151 kg
- Post-LSG nadir = 98 kg
- Time of revision = 117 kg (median 5yrs)
- Procedure time = 46.9 min, 4 sutures

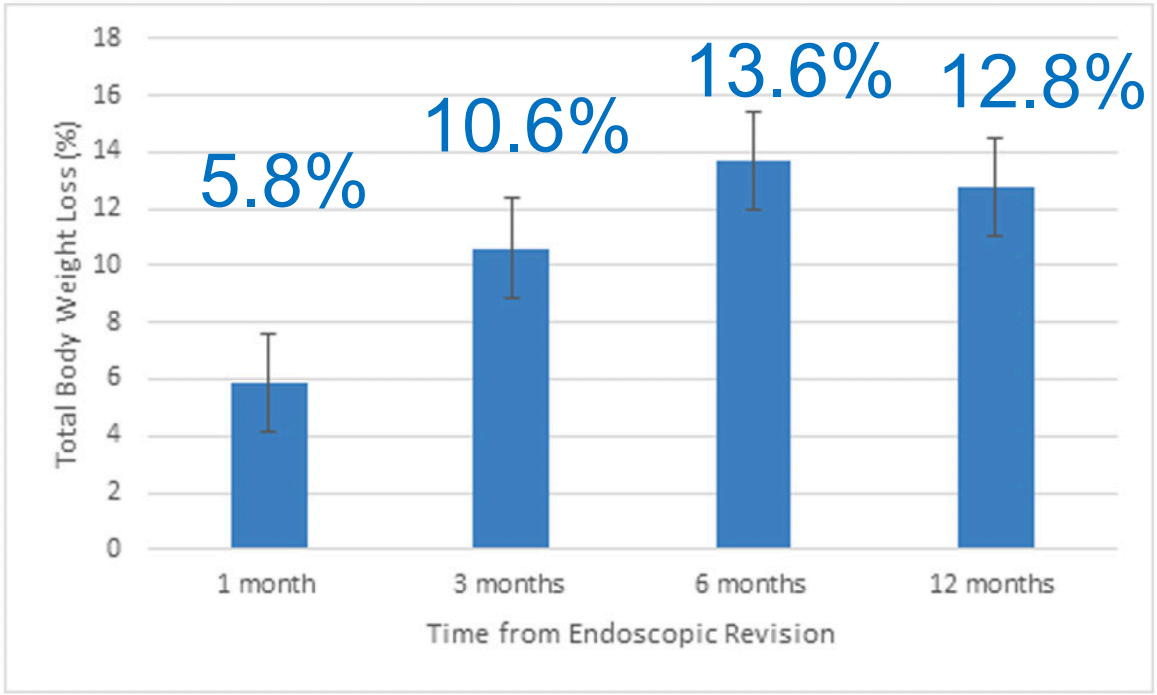
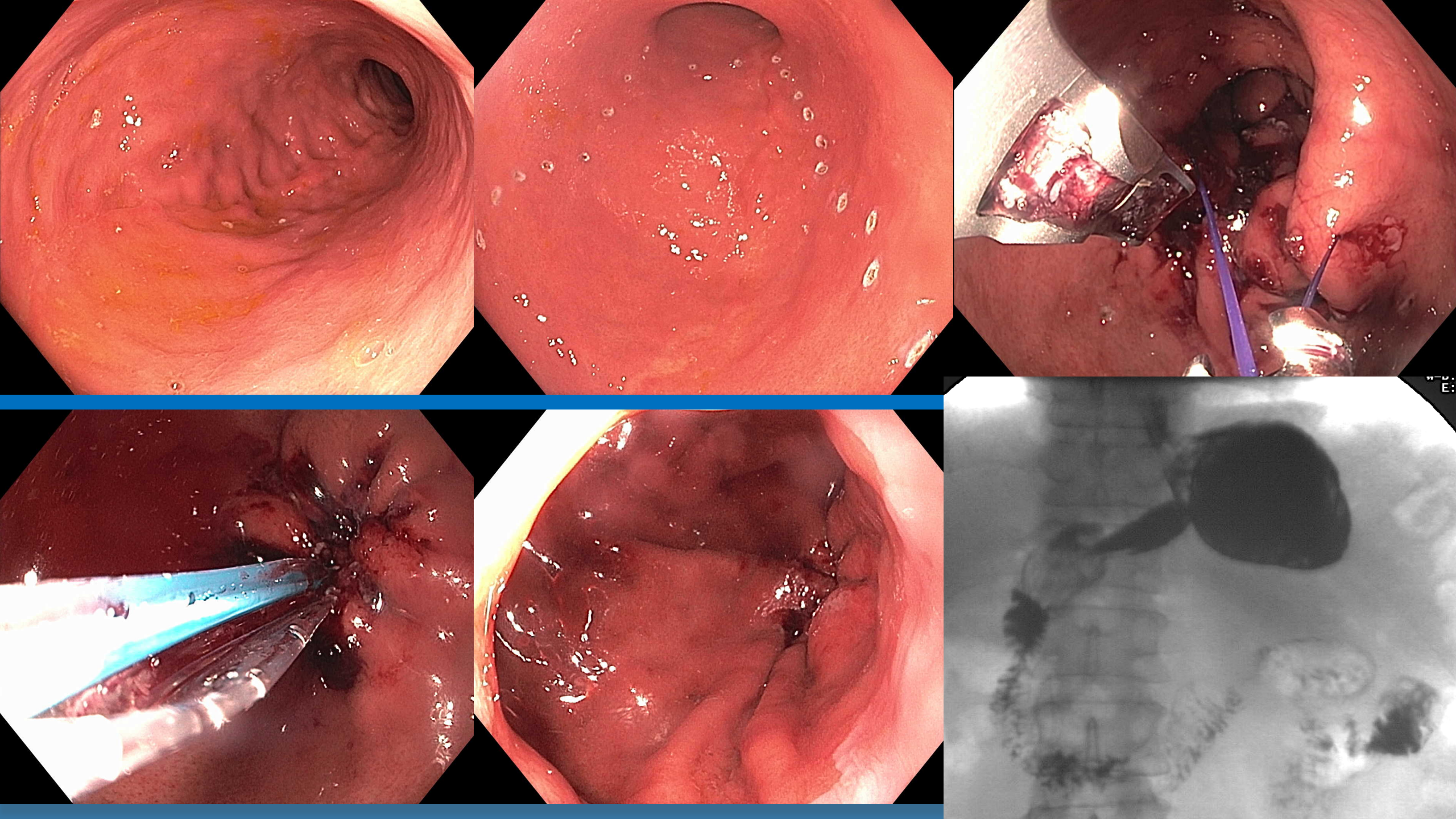


Figure 1. Percent total body weight loss after endoscopic revision of laparoscopic sleeve gastrectomy. Percent TBWL was calculated as follows: (weight at time of endoscopic revision - current weight)/weight at time of endoscopic revision x 100. This was reported at various time points following endoscopic revision of LSG for weight regain. TBWL was 5.85 ± 3.50% at one month (n = 63), 10.60 ± 4.58% at 3 months (n = 57), 13.68 ± 7.63% at 6 months (n = 47), and 12.75 ± 12.80% at 12 months (n = 38).

• Predictors of TBWL>15%

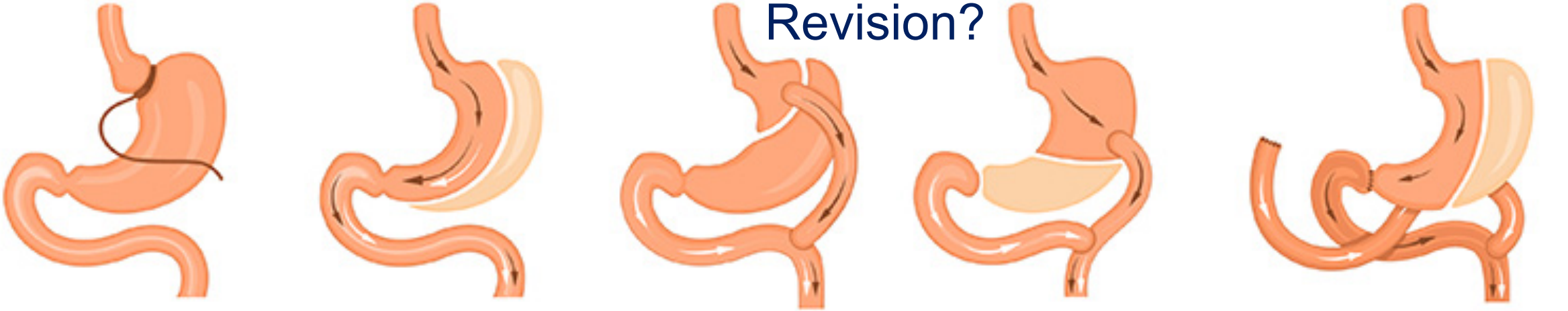
Variable	Unadjusted Univariate Analysis	Adjusted Multivariate Analysis
Age in years	**1.07; p = 0.038**	0.93; p = 0.26
Weight prior to surgery in kg	1.00; p = 0.46	0.99; p = 0.79
Lowest weight after surgery in kg	1.00, p = 0.56	1.04; p = 0.36
Weight at time of endoscopic revision in kg	1.01; p = 0.37	**1.06; p = 0.026**
Time from LSG to endoscopic revision in years	1.12; p = 0.27	1.11; p = 0.65
Use of weight loss medications	2.93; p = 0.14	0.94; p = 0.97
Number of sutures	1.25; p = 0.27	0.83; p = 0.73
Presence of dilated stomach on baseline imaging	**4.33; p = 0.026**	2.92; p = 0.67

Table 1. Univariate and Multivariate Analyses. Factors associated with endoscopic revision of LSG to achieve TBWL > 15% at 6 months after post-revision were subjected to univariate and multivariate analyses. Statistically significant p values and odds ratios are bolded. Older age and presence of dilated stomach on baseline imaging prior to revision were associated with TBWL > 15% on univariate analysis. On multivariate analysis, greater weight at time of endoscopic revision was most correlated with achieving TBWL > 15% at 6 months.



TYPES OF BARIATRIC SURGERY

Revision?



Adjustable Gastric Band **(AGB)**

Vertical Sleeve Gastrectomy **(VSG)**

Roux-en-Y Gastric Bypass **(RYGB)**

Biliopancreatic Diversion **(BPD)**

Biliopancreatic Diversion With a Duodenal Siwtch **(BPD-DS)**

721

PERSONALIZED ALGORITHM FOR THE MANAGEMENT OF WEIGHT REGAIN FOLLOWING ROUX-EN-Y GASTRIC BYPASS: SUTURING VERSUS PLICATION VERSUS ARGON PLASMA COAGULATION

Pichamol Jirapinyo*, Christopher C. Thompson

Brigham & Women's Hospital, Boston, MA

Background: There are currently several endoscopic techniques for the treatment of weight regain following Roux-en-Y gastric bypass (RYGB). These include argon plasma coagulation (APC) and transoral outlet reduction (TORe) using a suturing device (S-TORe) and a plication device (P-TORe), all of which reduce the size of the gastrojejunal anastomosis (GJA) and/or gastric pouch (Figure 1). While their efficacy is established, there is no personalized approach to guide procedure selection. Aims: 1) To assess the relationship between anatomic dimensions and procedure specific outcomes. 2) To construct a personalized care algorithm for the treatment of weight regain after RYGB. Methods: Study Design: A retrospective analysis of prospectively collected data was conducted. Our hospital registry was searched for all patients who underwent APC, S-TORe and P-TORe. Patients who underwent endoscopic revision with submucosal dissection or older platforms were excluded. Analysis: Sensitivity analysis was performed to determine the difference in 12-month percent total weight loss (%TWL) of each procedure for different GJA sizes. For pouch >5 cm, S-TORe and P-TORe were compared as APC is not typically applied to reduce pouch volume. For pouch ≤5 cm, only APC and S-TORe were compared, given the size of the plication device. ANOVA was used for three group comparison and Student's *t*-test was used for sensitivity analysis. Results: 751 patients met inclusion criteria. Of these, 35.6%, 56.1% and 8.3% underwent APC, S-TORe and P-TORe, respectively. Baseline characteristics were similar among groups. Average BMI and weight regain were 38.8±8.4 kg/m^2 and 47.4±37.0% of maximal weight lost. At 1 year, patients in the APC, S-TORe and P-TORe groups experienced 5.1±9.4%, 7.6±8.4% and 8.2±7.5% TWL, respectively (p=0.001).

Part I: **Pouch >5 cm (S-TORe vs P-TORe).** On sensitivity analysis, at a GJA size ≥ 30 mm, S-TORe resulted in greater weight loss than P-TORe (11.9±7.6% vs 2.7±1.4%, p=0.03). However, at a GJA size <30 mm, P-TORe resulted in greater weight loss than S-TORe (11.1±8.5% vs 7.9±7.5% TWL, p=0.05).

Part II: Pouch ≤5 cm (APC vs S-TORe). On sensitivity analysis, at a GJA size ≥ 18 mm, S-TORe resulted in greater weight loss than APC (7.6±8.1% vs 5.8±9.0% TWL, p=0.05). However, at a GJA size < 18 mm, there was no difference in %TWL between APC and S-TORe (5.2±9.1% vs 5.7±10.2% TWL, p=0.77).

Part III: Based on the parts I and II, an algorithm was constructed and demonstrated in Figure 2. Conclusion: Endoscopic treatment of weight regain following

- Retrospective analysis, single center
- 751pts: BMI 38.8, regain 47% max loss
- 36% APC, 56% S-TORe, 8.3% P-TORe

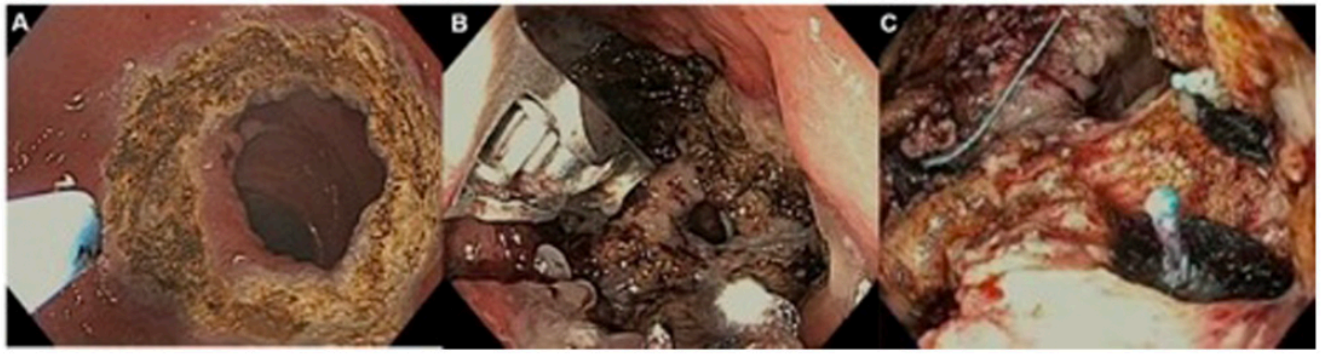


Figure 1. Currently available endoscopic therapies for weight regain following RYGB. (A) argon plasma coagulation (APC). (B) transoral outlet reduction via suturing (S-TORe). (C) transoral outlet reduction via plication (P-TORe).

RYGB can be individualized based on patients' anatomy. For pouch >5 cm, P-TORe should be considered when GJA is <30 mm, with S-TORe being performed when GJA is ≥30 mm. For pouch ≤5 cm, both APC and S-TORe may be considered for GJA <18 mm, with S-TORe being preferred when GJA is ≥18 mm.

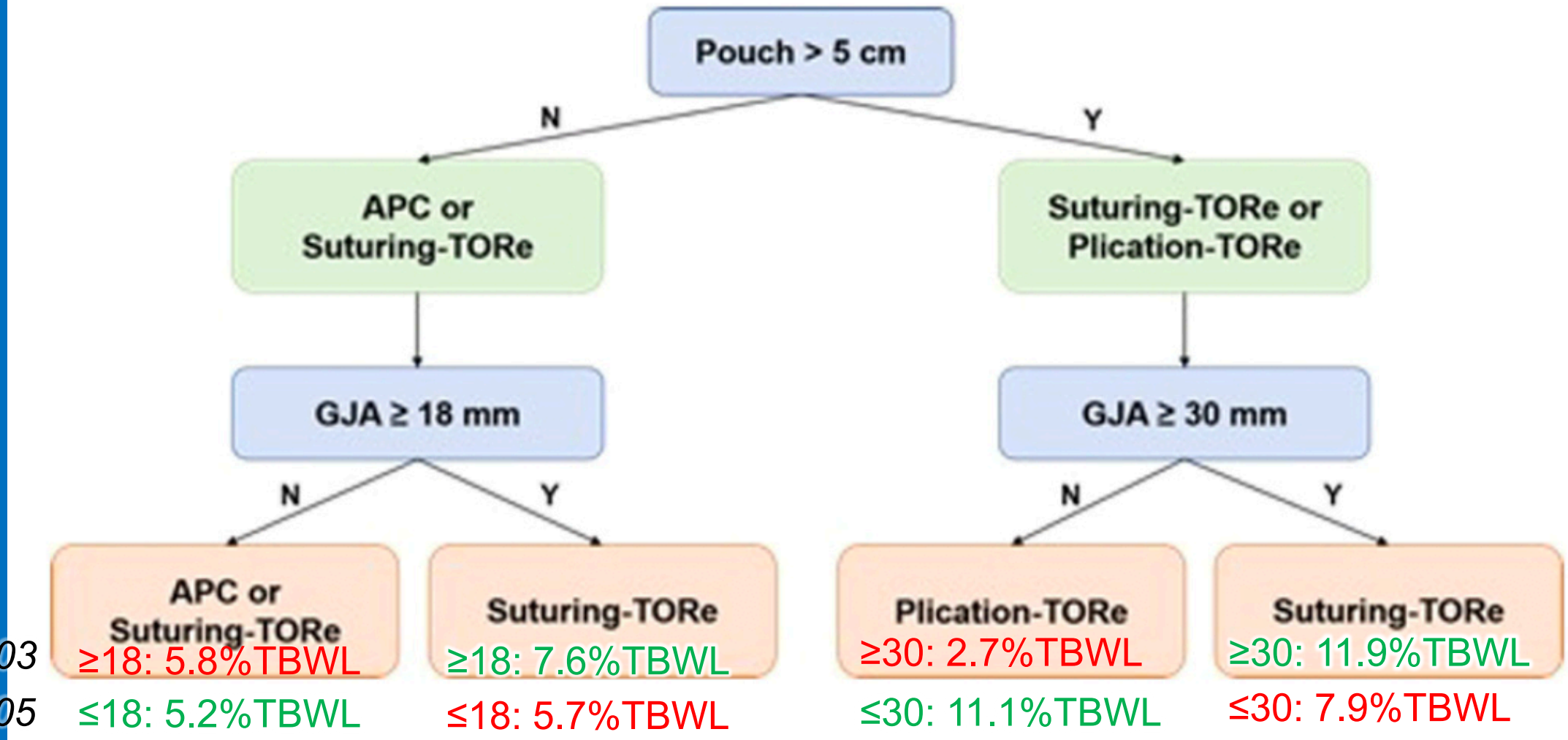


Figure 2. Proposed anatomy-based algorithm for endoscopic treatment of weight regain following RYGB

EndoHepatology

665

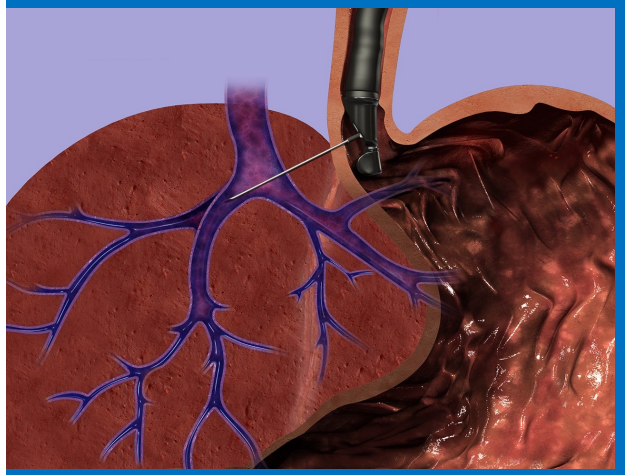
EUS-GUIDED PORTAL PRESSURE GRADIENT MEASUREMENT SAFELY PERFORMED WITH EUS-GUIDED LIVER BIOPSY: ENDOHEPATOLOGY IN PRACTICE

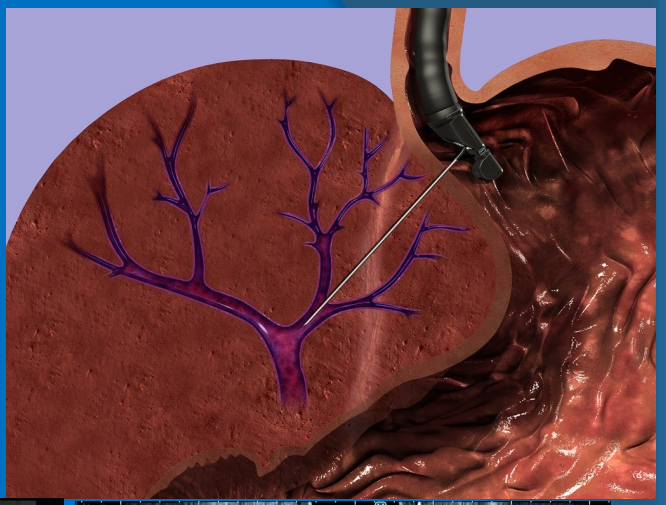
Jason Samarasena*, Alyssa Y. Choi, Arnie Shah, Rintaro Hashimoto, Nabil El Hage Chehade, Ke-Qin Hu, Kenneth J. Chang

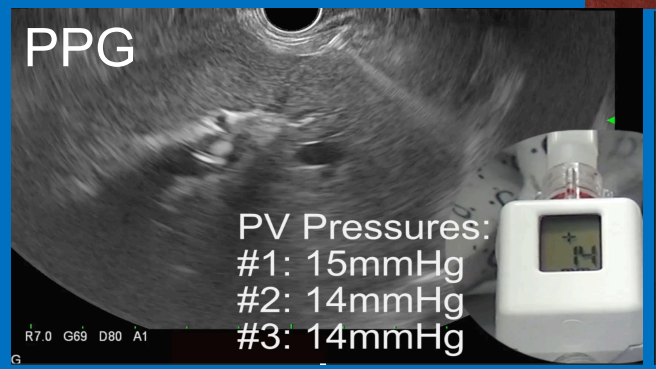
Gastroenterology, University of California Irvine , Orange, CA

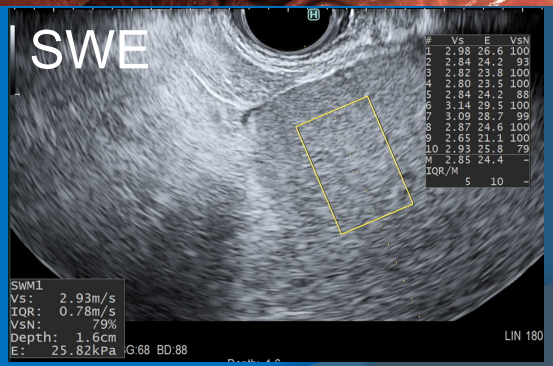
Background: The portal pressure gradient (PPG) is useful to predict the development of complications of portal hypertension (PH). Recently, we showed the feasibility and safety of a simple novel technique for Endoscopic ultrasound (EUS) guided PPG measurement (PPGM) in a pilot study. EUS-guided liver biopsy (EUS-LB) has been shown to be a safe and effective alternative to percutaneously or Interventional Radiology performed liver biopsy for the diagnosis of liver disease. We aimed to assess feasibility and safety of concomitant EUS-guided PPGM with EUS-LB in a single session. Secondarily, we aimed to evaluate the correlation between PPG and clinical markers of PH in an expanded clinical series. Methods: This was a retrospective study of EUS-PPGM at single tertiary endoscopy center that enrolled 76 consecutive patients suspected of liver cirrhosis between February 2014 and October 2019. Results: Technical success rate of EUS-PPGM was 100% without any severe adverse events. PPG ranged from 0 to 27.3 mm Hg. There was excellent correlation between PPG and clinical parameters of PH including the presence of clinical features of cirrhosis (11.12 vs 3.55 mmHg, $p < 0.001$), varices (14.01 vs 4.7 mmHg, $p < 0.001$), portal hypertensive gastropathy (16.37 vs 5.87 mmHg, $p < 0.001$), and thrombocytopenia (11.1 vs 4.51 mmHg, $p < 0.01$). Platelet count also had a moderate negative correlation with PPG ($R = -0.579$). EUS-guided liver biopsies were performed in 61 patients (80.2%). All biopsies were deemed adequate for achieving histologic diagnosis by our pathologists. There were no early or late major adverse events. Conclusion: This series is the largest on EUS guided portal pressure measurement to date. EUS-guided PPG measurement using a 25-gauge needle and compact manometer correlates well with clinical markers of portal hypertension and appears safe in this study with an expanded selection of patients. EUS-LB can be performed safely at the same session as EUS-PPGM further adding value to the endoscopic evaluation of the patient with liver disease.

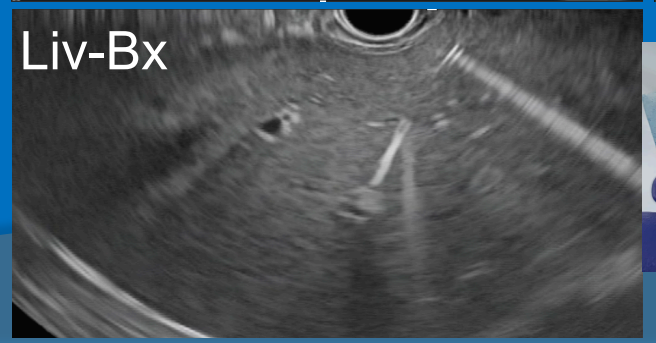
- Prospective, single-center
- 76 pts: EUS-PPG; 80% EUS-LivBx











Question 1:

- In patients with prior successful gastric bypass surgery for morbid obesity who are now regaining weight, which of the following is the least invasive option for a weight loss procedure:
  - A. Laparoscopic Sleeve Gastrectomy
  - B. Endoscopic Balloon Placement
  - C. Endoscopic Trans-oral Outlet reduction (TORe)
  - D. Revisional Gastric By-pass surgery

Answer 1:

C. Endoscopic Trans-oral Outlet reduction (TORe)

- Reference: ASGE Abstract #721 (GIE 2020:91:5S:AB60)
- Rationale: A laparscopic sleeve gastrectomy is not longer possible after a gastric by-pass. Endoscopic balloon placement is contraindicated in patient after gastric-bypass. Revisional gastric by-pass is very difficult and may not be possible if the pouch is small, and it is more invasive. Endoscopic Trans-oral Outlet reduction (TORe) is the best answer as an average of 7-11% of TBWL can be expected.

Question 2: (True or False)

- Endoscopic Ultrasound-guided Portal Pressure Gradient measurement can be used to diagnose portal hypertension in patients with liver disease.
  - A. True
  - B. False

Answer 2:

A. True

- Reference: ASGE Abstract #665 (GIE 2020:91:5S:AB55); also GIE 2017;85:996-1001
- Rationale: A simple hand-held manometer attached to a non-compressible tubing which is secured to the EUS needle is now an FDA approved device for the indication of measuring hepatic and portal vein pressures directly.

Question 3: (True or False)

- Per-oral Endoscopic Myotomy (POEM) is an appropriate management option in the treatment of dysphagia due to achalasia in patients who have failed prior Heller myotomy.
  - A. True
  - B. False

Answer 3:

A. True

- Reference: ASGE Abstract #666 (GIE 2020:91:5S:AB56); also Clinical Gastroenterology and Hepatology 2017;15:1531–1537
- Rationale: Re-do Heller myotomy is difficult due to scar tissue and the limited approach to the anterior aspect of the GE junction. POEM has been shown to be effective and safe in this scenario, with the ability to access the posterior aspect with less scar tissue.