

Minimally Invasive and Novel Therapeutics (M.I.N.T.) in Foregut Disease
September 29th – October 1st, 2022

POEM + Endoscopic Fundoplication (POEM+F)

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Disclosures

- No Relevant Disclosures

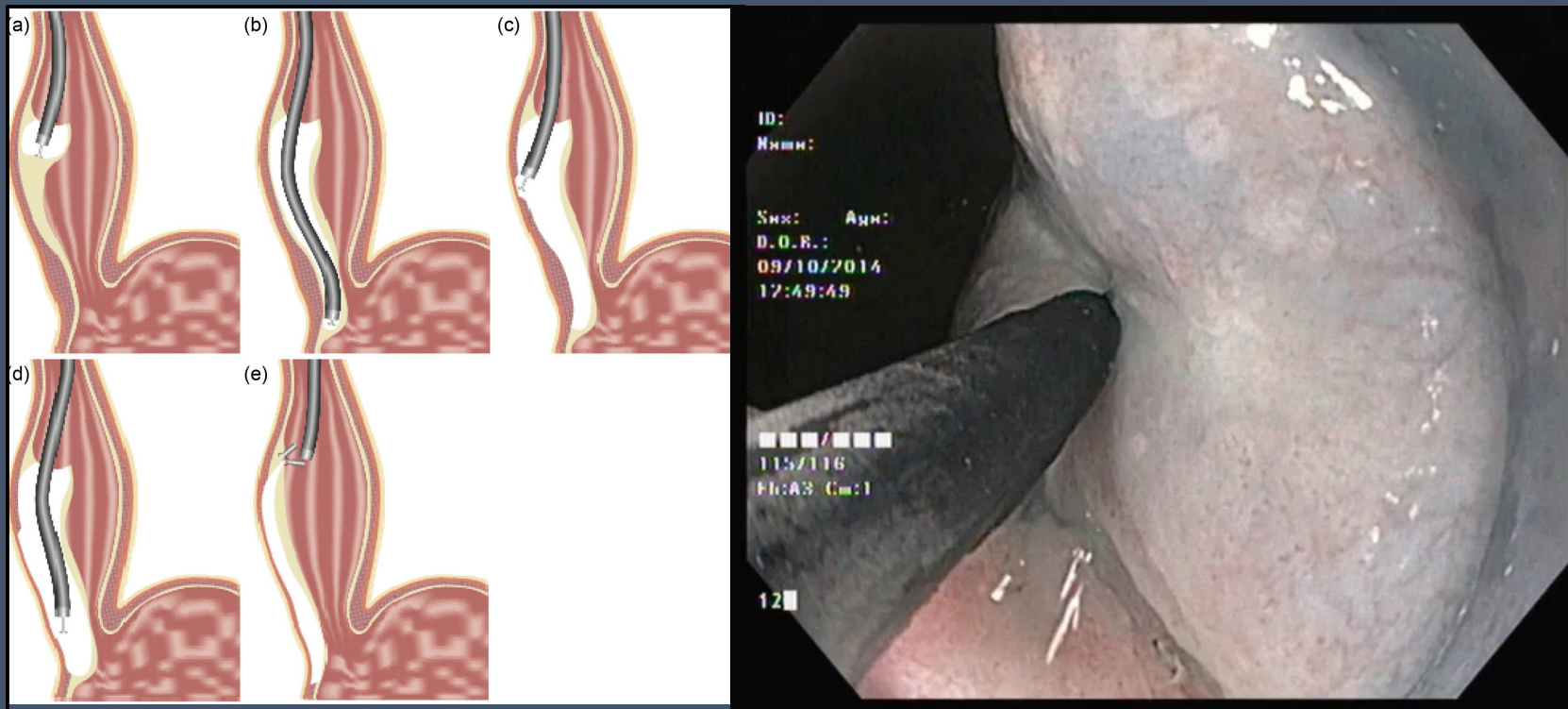
Peroral endoscopic myotomy (POEM) for esophageal achalasia*

Authors

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Institution

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- Excellent short-, medium- & long-term outcomes
- Highly popular procedure
- Highly effective for all achalasia subtypes
- Effective in prior treatment failures

Bapaye A et al. *J Clin Gastroenterol* 2020



Gastroesophageal Reflux after Peroral Endoscopic Myotomy: Myth or Reality?

Amol Bapaye¹ Ashish Gandhi¹ Jay Bapaye²

Third Space Endoscopy Lessons Learnt From a Decade of Submucosal Endoscopy

Amol Bapaye, MD (MS), FASGE, Sravan K. Korrapati, MD, DM,
Siddharth Dharamsi, MD, DM, and Nachiket Dubale, MD, DNB

Author (year)	Study design	N	Follow-up (mo)	Incidence of GER (%)
von Renteln et al (2011) ³	SC, pros, single arm	16	3	0
Stavropoulos et al (2013) ⁴	MC, retro, single arm	841	9.3	12
Sharata et al (2014) ⁷	SC, pros, single arm	100	16	38
Inoue et al (2015) ⁸	SC, pros, single arm	500	Short (2 mo)	16.8 (2 mo)
			Long (3 y)	21.3 (3 y)
Familiari et al (2016) ⁹	SC, retro, single arm	103	24	50.5
Hungness et al (2016) ¹⁰	SC, retro, single arm	115	28	40
Repici et al (2018) ²⁵	Comparative POEM vs. LHM, SRM	POEM: 1,542	–	POEM: 39
		LHM: 2581	–	LHM: 16.8
Kumbhari et al (2017) ¹³	MC, CC	282	12	57.8
Martinek et al (2018) ²¹	SC, pros, single arm	133	24	3 mo: 41.5
Teitelbaum et al				(symptoms) flux pathological
Schlottmann et al				
Werner et al (2019) ¹⁶	MC, RCT, POEM vs. LHM + F	POEM: 112 LHM: 109	24	3 mo: POEM: 57 LHM: 20 2 y: POEM: 44 LHM: 29
Shiwaku et al (2020) ¹⁷	MC, retro, single arm	1,346	12	63
Aiolfi et al (2019) ²²	Comparative POEM, LHM, PD, SRM	N = 4,407 LHM: 50.4% PD: 42.8% POEM: 6.8%	–	POEM > LHM (RR = 1.75; 95% CI = 1.35–2.03; I ² = 6.3%) POEM > PD (RR = 1.36; 95% CI = 1.18–1.68)
Arevalo et al (2020) ²³	SC, retro, single arm	46	12	41.7
Nabi et al (2020) ²⁶	SC, retro, single arm	209	3	3 mo (n = 167): 47.9
				1 y (n = 106): 37.6
Modayil et al (2021) ⁷⁶	SC, retro, single arm	610	30	4 mo: 57.1

Incidence of post-POEM GER ~ 30% to 60%



Post-POEM GER – Hard Facts

- Post POEM GER has emerged as a growing concern during recent years^{1, 2, 3,4}
- Reported incidence 23 – 57% in clinical trials^{1, 2, 3, 4}
- Chronic consequences of long-term GER are infrequent but do occur – ⁵
 - Stricture – 3 reported cases – dilatation + PPI
 - Barrett's – 3 reported cases (1 – pre-existing Barrett's)

¹ Kumbhari V et al, *Endoscopy* 2017

² Rosch T et al (Editorial), *Endoscopy* 2017

³ Werner et al, *NEJM* 2019

⁴ Bapaye A et al, *J Clin Gastroenterol* 2019

⁵ Bechara R et al, *Dis Esophagus* 2020



The Surgeon's Debate

- During LHM, anti-reflux procedure is conventionally added
- Argument –
 - During POEM, anti-reflux procedure is not added
 - POEM therefore causes significant post-procedure GERD
- Is this argument valid ?
- Can something be done to address this issue ?



Treatment of post-POEM GER

- Standard PPI therapy is mainstay – ¹
 - Current recommendation – PPI x 24-mths post-POEM
 - Later On-demand
- Lifelong surveillance for Esophagitis / Barrett's ?
- Anti-reflux surgery – occasionally required
- Endoscopic anti-reflux procedures –
 - POEM + TIF – concomitant / subsequent ^{2, 3}
 - POEM+F / POEF ^{4, 5, 6}

¹ Bechara R et al. *Dis Esophagus* 2020

² Tyberg A et al. *Endosc Int Open* 2018

³ Brewer Gutierrez OI. *Am J Gastro* 2020

⁴ Inoue H et al. *Endoscopy* 2019

⁵ Toshimori A et al. *Video GIE* 2020

⁶ Bapaye A et al. *Endoscopy* 2020



Peroral endoscopic myotomy and fundoplication: a novel NOTES procedure

Authors

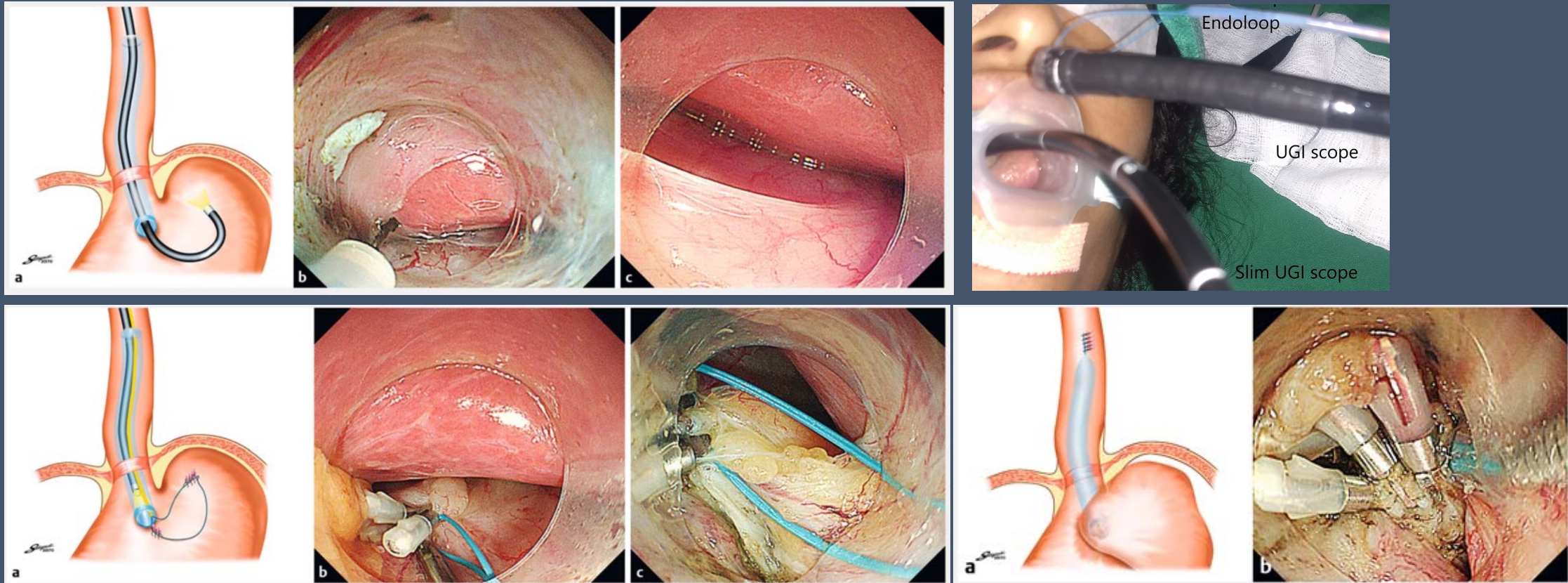
Haruhiro Inoue, Akiko Ueno, Yuto Shimamura, Anastassios Manolakis, Ashish Sharma, Shin Kono, Masayuki Nishimoto, Kazuya Sumi, Haruo Ikeda, Kenichi Goda, Manabu Onimaru, Noriko Yamaguchi, Hiroaki Itoh

Inoue H et al, Endoscopy Feb 2019; 51: 161–164

Principle based on partial fundoplication (DOR) after LHM

Creation of an anterior partial fundoplication endoscopically after POEM

POEM-F – New Anti-reflux procedure

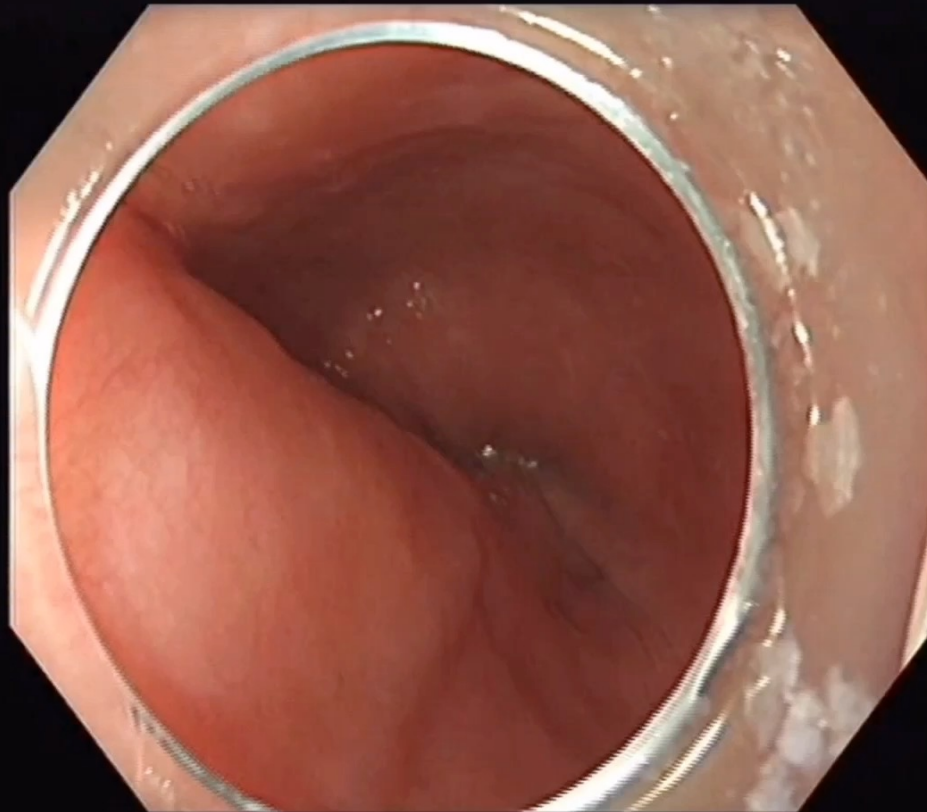


Patient Preparation & Equipment

- Standard preop workup as for POEM ± pH studies
- Standard POEM equipment – gastroscope; CO2 insufflator; irrigation pump; distal attachment; injection needle & injectate; TT-knife[®] / Hybridknife[®]; Coagrasper[®]; diathermy etc.
- Additional Endoscopist
- Additional instruments –
 - Trans-nasal ultraslim gastroscope (with separate tower & CO2 insufflator)
 - Insulated tip IT2Knife[®]
 - Reconstrainable clips - 6 to 8 nos. (additional to those required for mucosal closure)
 - Endoloop + Applicator + Endoloop cutter / endoscopic scissors
 - Equipment for abdominal paracentesis



Technique of POEM-F



Peroral endoscopic myotomy and fundoplication: a novel NOTES procedure

Inoue H et al, Endoscopy 2019; 51: 161– 164

	POEM+ F (n= 21)
Age, mean (SD), years	45.4 (14.0)
Sex, male/female, n	10/11
Type, straight/sigmoid, n	18/ 3
Degree of dilation, I/II/III, n	9/10/2
Chicago classification, I/II/III/other, n	13/5/1/2 ¹
Preoperative IRP pressure, mean (SD), mmHg	22.8 (12.2)
Duration of disease, mean (SD), years	7.2 (7.4)
Primary procedure, none/PBD/other, n	18/3/0
Baseline Eckardt score, mean (SD)	5.7 (1.8)
Procedure completion rate, n (%)	21 (100)
Total operation time, minutes	
▪ Mean (SD)	118.9 (20.2)
▪ Median (range)	115 (92 – 178)
Fundoplication time, minutes	
▪ Mean (SD)	51.3 (18.5)
▪ Median (range)	44 (28 – 88)
Acute adverse event ² , n (%)	0 (0)
Postoperative stay, mean (SD), days	4.7 (0.8)

- N = 21; M/F = 10/11
- Technical success = 100%
- Operating time = 118.9 (20.2)
- Fundoplication time = 51.3 (18.5)
- AE = Nil
- LOS = 4.7 (0.8)
- Wrap maintained @ f-up = 20/21 (95%)

Single-session endoscopic fundoplication after peroral endoscopic myotomy (POEM+F) for prevention of post gastro-esophageal reflux – 1-year follow-up study

Endoscopy 2020 DOI 10.1055/a-1332-5911

Authors

Amol Bapaye , Parag Dashatwar, Siddharth Dharamsi, Rajendra Pujari, Harshal Gadhikar

- Single-center retrospective analysis of prospectively maintained database
- N = 25
- Duration – March 2019 – 2020
- All patients with proven Achalasia on EGD & HRM
- Naïve / post PBD failures included; post LHM failures excluded
- Post-procedure follow up – EGD, pH studies, GerdQ scores

Procedure Details

Parameter		Value	P-value
Technical success of POEM (%)		25 / 25 (100%)	
Technical success of POEM+F (%)		23 / 25 (92)	
Mean total procedure time		115.6 ± 27.2	
(Moving average graph)	Initial 5 cases	88 ± 23.4	
	Subsequent cases	51.2 ± 9.1	< 0.05
Mean additional time for fundoplication ± S.D. (min)		46.7 ± 12.4	
Mean baseline Eckardt score ± S.D. (pre-POEM+F)		8.21 ± 1.08	
Mean Eckardt score ± S.D. (post-POEM+F)		0.1 ± 0.3	0.0001
Adverse events	Acute	Nil	
	Delayed (minor) (%)	3 / 23 (13)	
Mean hospital stay ± S.D. (days)		2.1 ± 0.5	



POEM+F – GER evaluation during Follow-up

GER Parameter		Value	Percent
N		23	
Median Follow up (months) (IQR)		12 (9 – 13)	
GerdQ score \geq 8		1 / 23	4.3
EGD findings available		22 / 23	95.7
Esophagitis LA Grade A		4 / 22	18.2
Wrap integrity	Intact	19 / 23	82.6
	Loose	1	4.3
	Indistinct	2	8.7
	Not done	1	4.3
pH studies available		18 / 23	78.3
pH studies	Abnormal DeMeester score	2 / 18	11.1
	Abnormal EAET (> 6%)	2 / 18	11.1

Details of Patients post-POEM+F GER

No.	Age	Sex	Post op ES	GerdQ	Esophagitis	DeMeester	EAET (m)	Wrap integrity
1	67	M	0	6	None	228.3	82.5	Adequate
2	42	F	1	11	None	45	45	Loose
3	55	M	0	6	A	2.4	0.3	Adequate
4	53	M	0	6	A	ND	ND	Indistinct
5	27	M	1	7	A	10.5	2.2	Indistinct
6	25	M	0	6	A	19.9	5.3	Adequate

**As per revised GERD definition (Lyon consensus 2018) –
 Conclusive post-POEM GER seen in 2/18 (11.1%)
 Borderline evidence – only Gr. A esophagitis, normal EAET**



Single-session endoscopic fundoplication after peroral endoscopic myotomy (POEM+F) for prevention of post gastro-esophageal reflux – 1-year follow-up study

Endoscopy 2020 DOI 10.1055/a-1332-5911

Study Conclusions

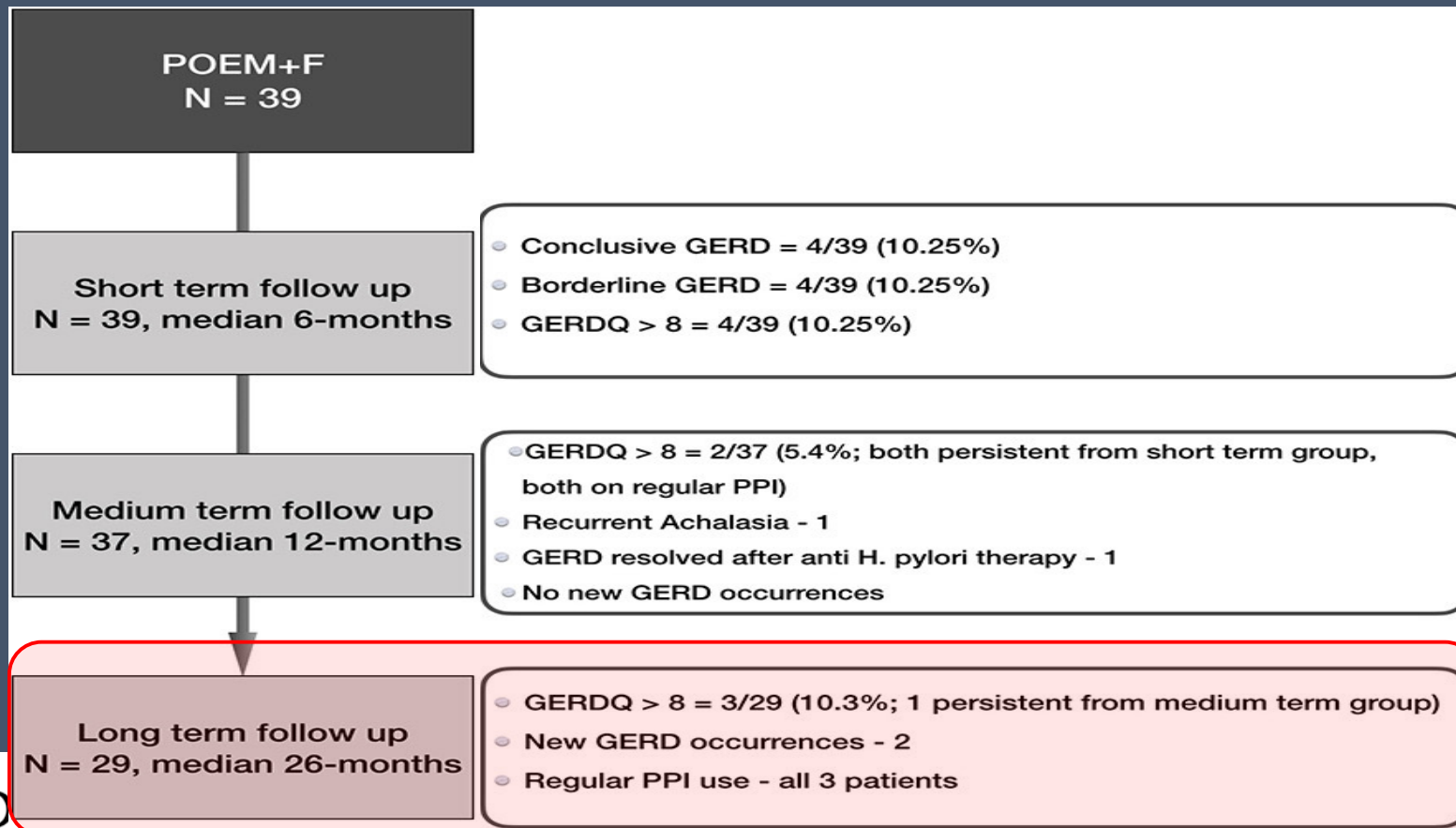
- POEM+F is safe & feasible
- Low post-POEM+F GER acceptable & comparable to that after LHM+F
- Long-term follow up & comparative data warranted

SESSION DAY & DATE: TUESDAY, MAY 24, 2022 SESSION START TIME: 4:00 PM SESSION END TIME: 5:30 PM CATEGORY: ENDOSCOPIC TECHNOLOGY - NEW TECHNOLOGY SESSION
FORMAT: LECTURE | VOLUME 95, ISSUE 6, SUPPLEMENT , AB272, JUNE 01, 2022

 PDF [564 KB]  Figures  Save  Share  Reprints  Request

CONCOMITANT ENDOSCOPIC FUNDOPLICATION AFTER PER ORAL ENDOSCOPIC MYOTOMY (POEM+F) FOR PREVENTION OF POST POEM GASTRO-ESOPHAGEAL REFLUX – SHORT, MEDIUM AND LONG-TERM OUTCOMES

Ashish Gandhi • Jay Bapaye • Jaseem Ansari • Harsh Bapaye • Tejas Nikumbh • Rajendra Pujari • Amol Bapaye • Show less



SESSION DAY & DATE: SATURDAY, MAY 21, 2022 | SUNDAY, MAY 22, 2022
 SESSION START TIME: 9:00 AM | SESSION END TIME: 12:00 PM
 CATEGORY: ESOPHAGUS 2 SESSION FORMAT: LECTURE | ILLUSTRATION
 VOLUME 95, ISSUE 6, SUPPLEMENT, AB386-AB387, JUNE 01, 2022

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SAFETY AND EFFICACY OF PERORAL ENDOSCOPIC MYOTOMY WITH ENDOSCOPIC FUNDOPLICATION (POEM-F) AND ANTI-REFLUX MUCOSECTOMY (ARMS) FOR POST-POEM REFLUX IN AN INTERNATIONAL COMPARATIVE MULTICENTER COHORT

Amy Tyberg · Jay Bapaye · Haroon M. Shahid · ... Ashish Gandhi · Michel Kahaleh · Amol Bapaye ·
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	POEM-F	POEM+ARMS	P value
Demo2raphics	N=43	N=42	
Mean age (SD)	42.8 (13.9)	48.6 (14.9)	
Gender (M:F)	22:21	22:20	
Procedure			
Type			
Anterior			
Myotomy			
Technical success rate			
Procedure time, mean (SD)	51.65 min (19.03)	24.6 min (5.03)	< 0.00001
Post-procedure len2th of stay	2.2 (0.5) days	0.6 (1.99) days	< 0.00001
Adverse events	2 - mucosal injuries (5%)	3 - chest pain (7%)	0.62
Clinical success indicators			
PPI Dose Reduction	26 (60.5%)	10 (24%)	0.663
PPI cessation	8 (18.6%)	30 (71%)	
DeMeester Score, mean (SD)	13.5 (35.15)	11(2.31)	0.654
Time of repeat ESD, mean (SD)	1.2 (0.51) months	7.7 (2.73) months	
Presence of esophagitis	7(16%)	3 (7%)	0.19
Esophagitis grade	A-5,B-1,C-1	A-3	
Need for repeat interventions	None required	Nissen fundoplication - 3, repeat ARMS - 7	<0.0001

GER Incidence comparable in both groups
Proc. time, LOS – lower for ARMS compared to POEM+F
Repeat interventions – higher for ARMS group, NIL for POEM+F





American Society for
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POEM+F – Identifying & Understanding the Technical Nuances and Challenges while Performing a Procedure in Evolution

Bapaye A et al. ASGE Video Plenary Best of the Best Award, DDW 2020

- Double scope transillumination to identify suitable location to open peritoneum
- Decompress gastric fundus to facilitate grasping of fundus
- Use long reconstrainable clip rather than rat-toothed forceps to grasp fundus
- Mark location on fundus for fixing endoloop using coagulation
- Do not include peri-gastric fat while fixing loop & clips to fundus
- Use detachable endoloop for fixation to reduce friction within the esophagus & tunnel
- Abdominal paracentesis to reduce capnoperitoneum & prevent omental fat from prolapsing into tunnel



Should Fundoplication be added to every POEM ?

For

- Replicates LHM+F
- Preliminary results are promising
- Feasible & safe
- Reproduceable
- Short learning curve
- Relatively inexpensive

Against

- Most post-POEM GER is mild & PPI responsive
- Technically challenging ? Additional resources ?
 - Intra-peritoneal entry
 - Double endoscope technique
- Evolving technique – Loop & clip / suture ?
- Long-term wrap integrity & outcomes ?
- Same session / 2nd stage ?

**The Need for Fundoplication after Myotomy
has been debated for 60+ years !**

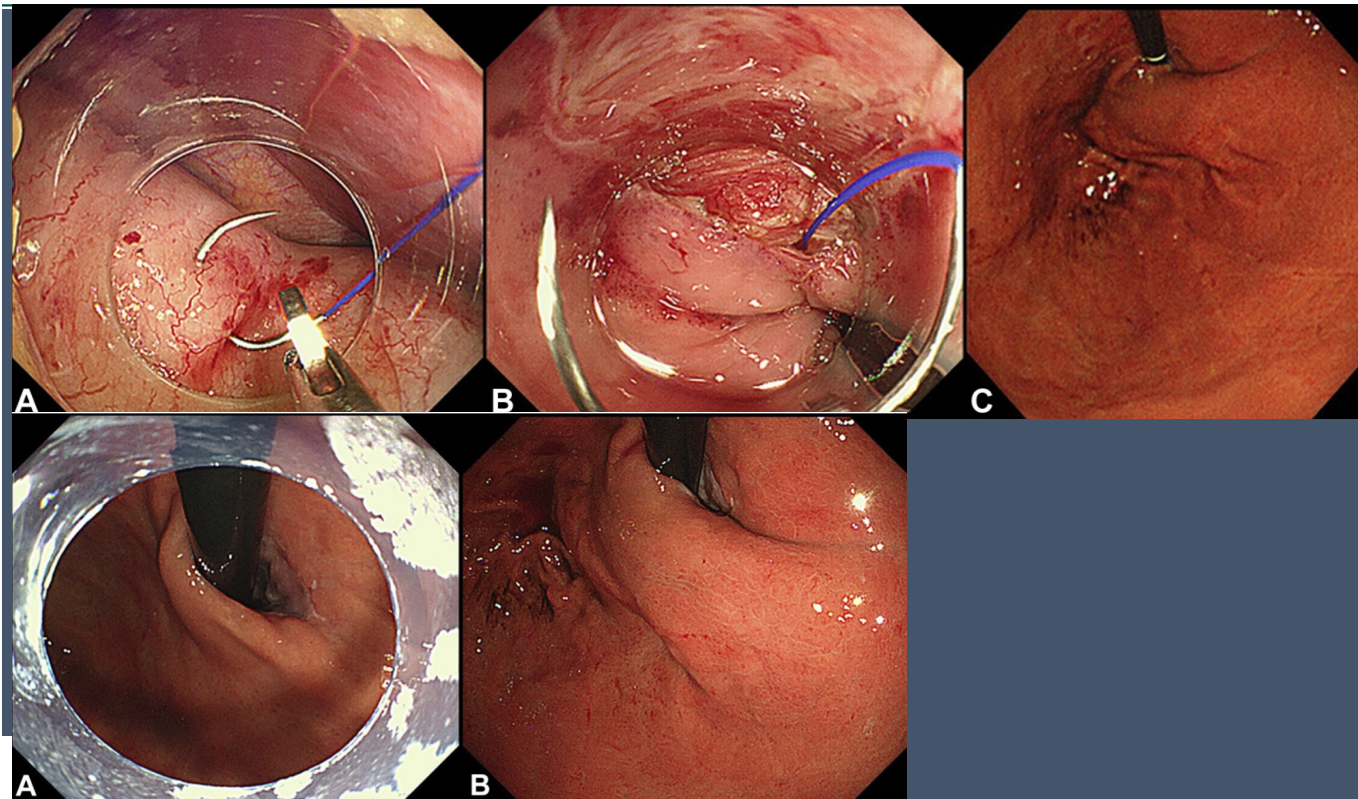


Per Oral Endoscopic Fundoplication (POEF)

VIDEO CASE REPORT

Peroral endoscopic fundoplication: a brand-new intervention for GERD

Akiko Toshimori, MD, Haruhiro Inoue, MD, PhD, Yuto Shimamura, MD, Mary Raina Angeli Abad, MD, Manabu Onimaru, MD, PhD



- Earlier posterior POEM
- Anterior tunnel
- Short myotomy distal to GEJ to enter peritoneal cavity
- Needle (using special needle holder) used to suture pledget through fundic wall & tightened to create wrap
- Wrap tightens the cardia – preventing GER
- Loop + Clip can also be alternatively used



Current Status & Future Directions

- POEM+F / POEF is feasible & safe
- Outcomes @ 12 & 24-months follow up are impressive
- Technique evolving – modifications have been described
- What is needed ?
 - Long-term, prospective & comparative data
 - Comparisons with alternative endoscopic anti-reflux methods & with lap. fundoplication
 - Optimal timing – concomitant vs. subsequent ?
- Who is likely to develop post-POEM GER?
- Can POEF be used as a stand-alone technique for treatment of refractory GER ?

Optimal Patient Selection is Key !!!





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Thank You !

