Concomitant Laparoscopic Hernia Repair with Trans-oral Incisionless Fundoplication (c-TIF): What do the data show?

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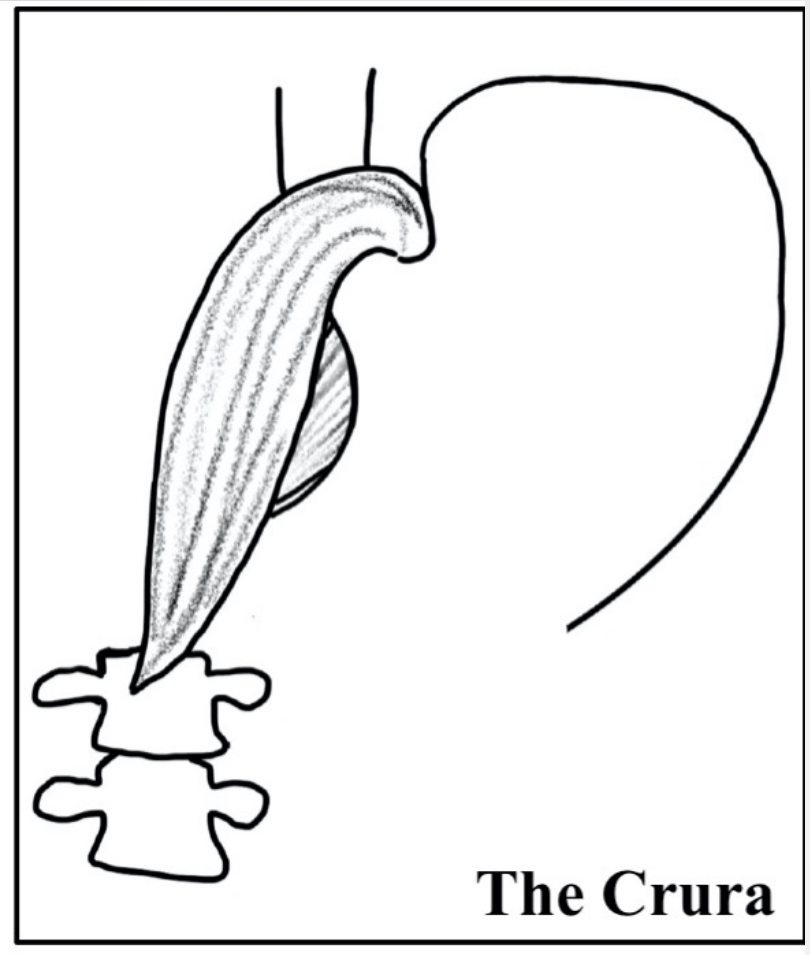
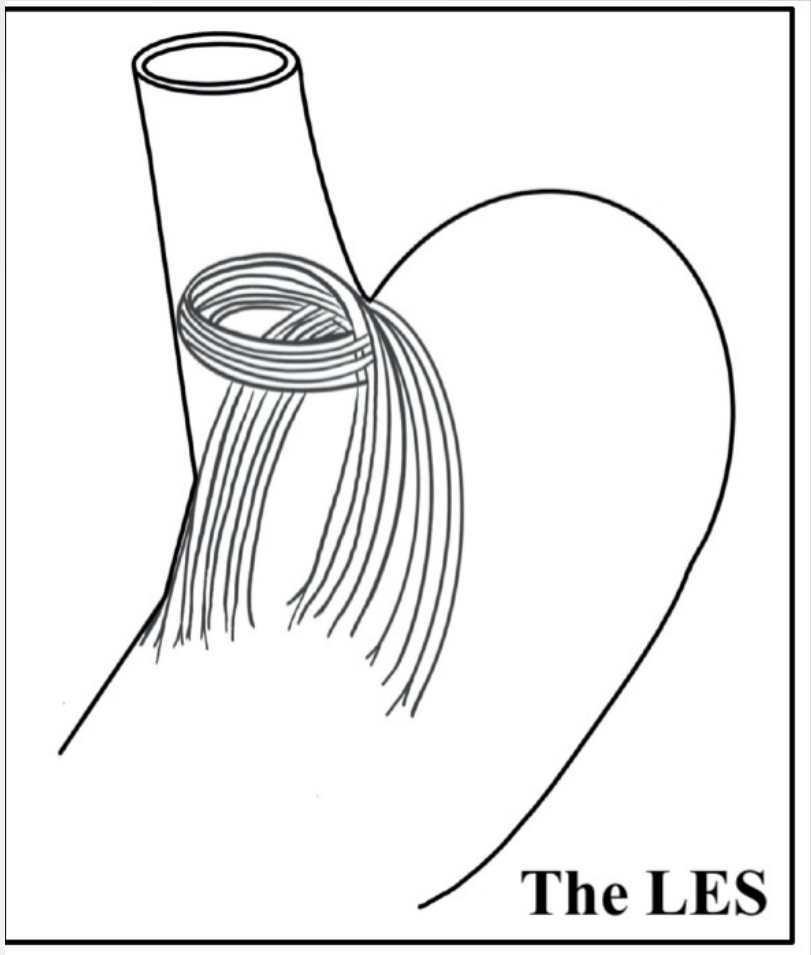
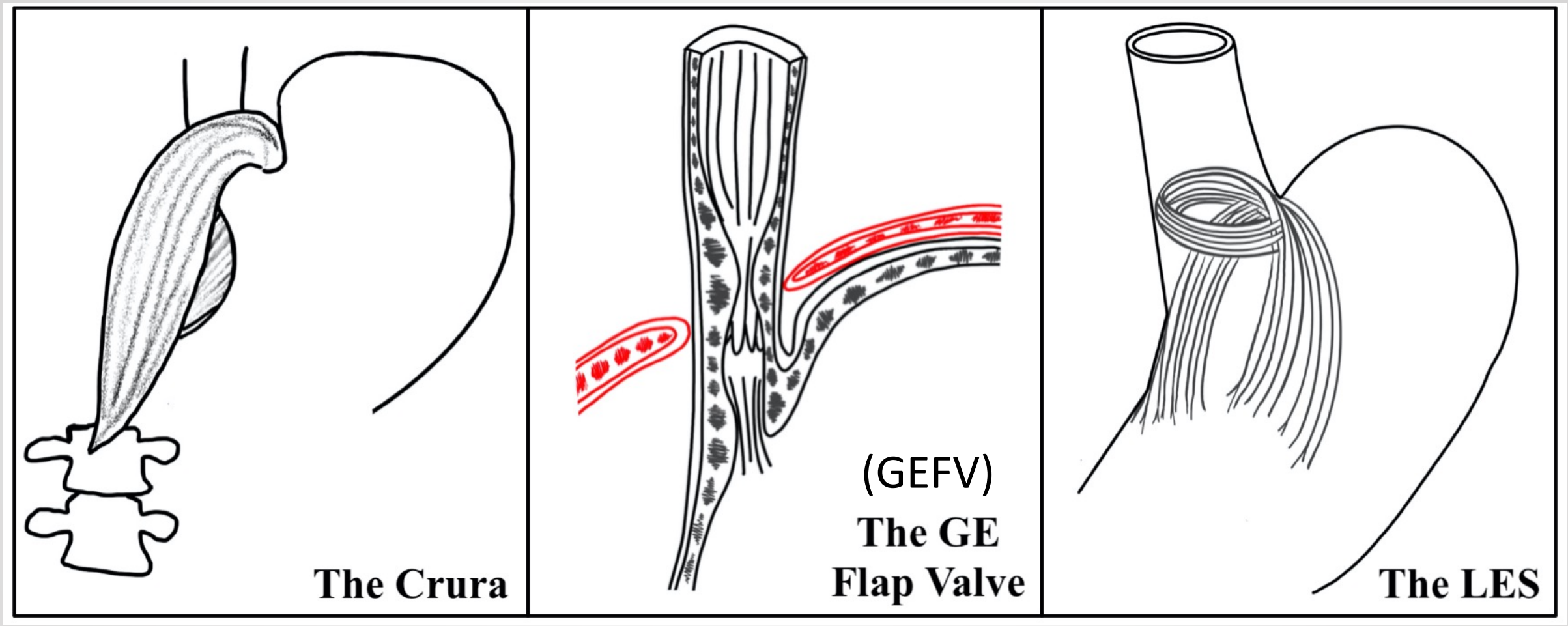
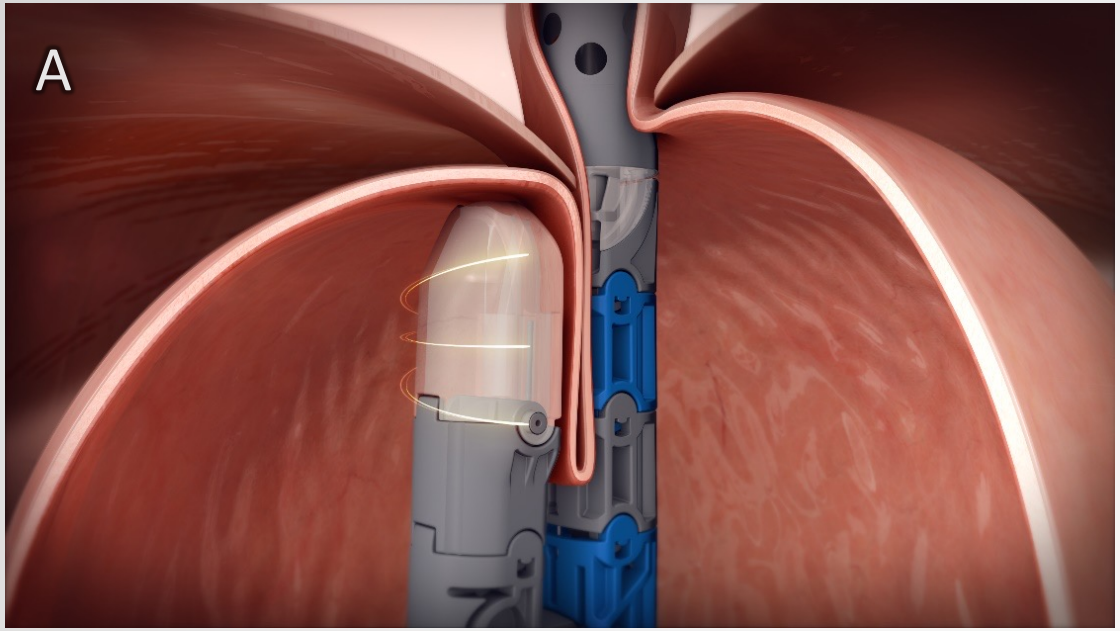
Conflicts of Interest

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





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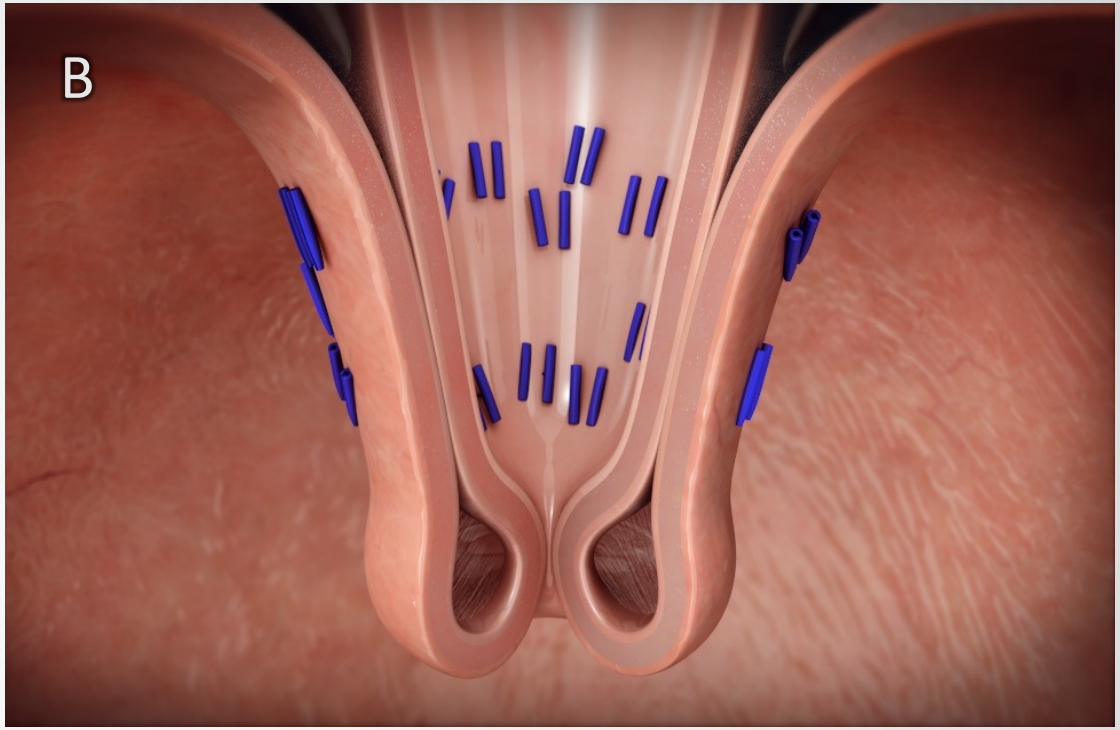
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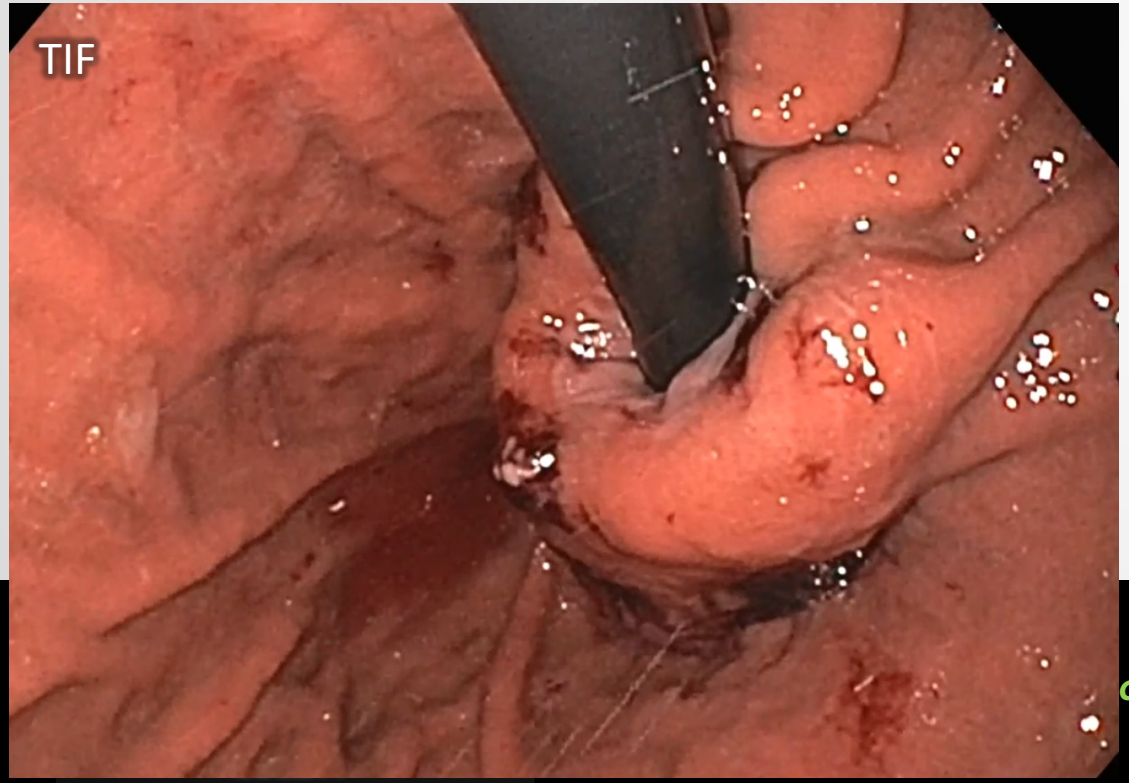
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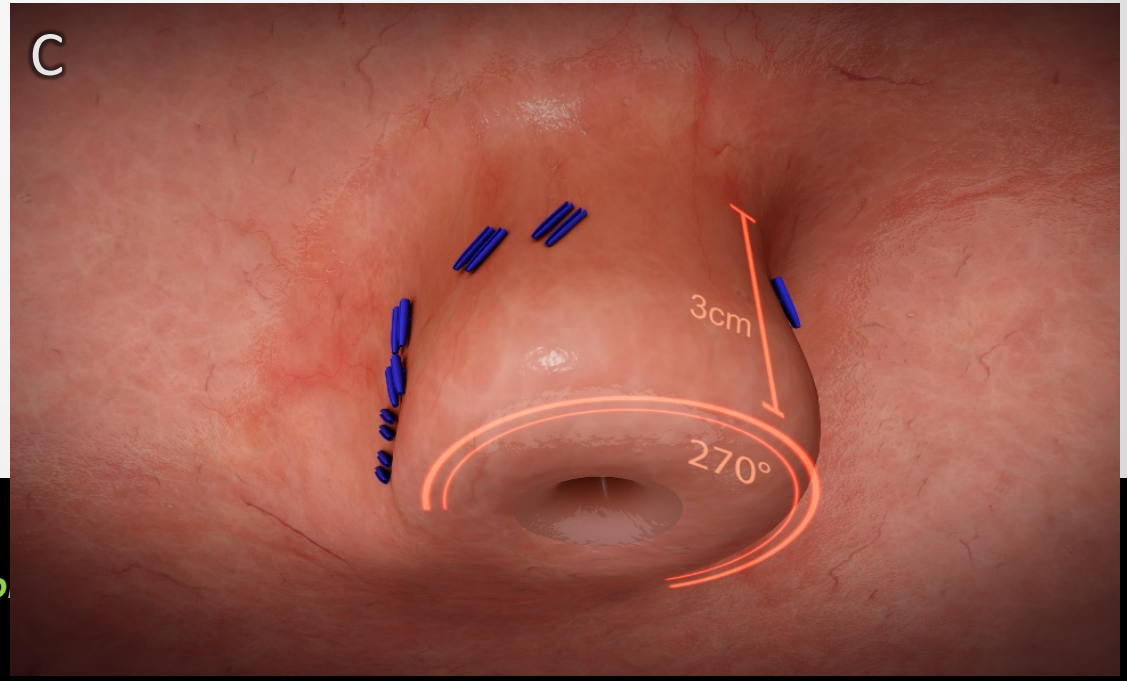
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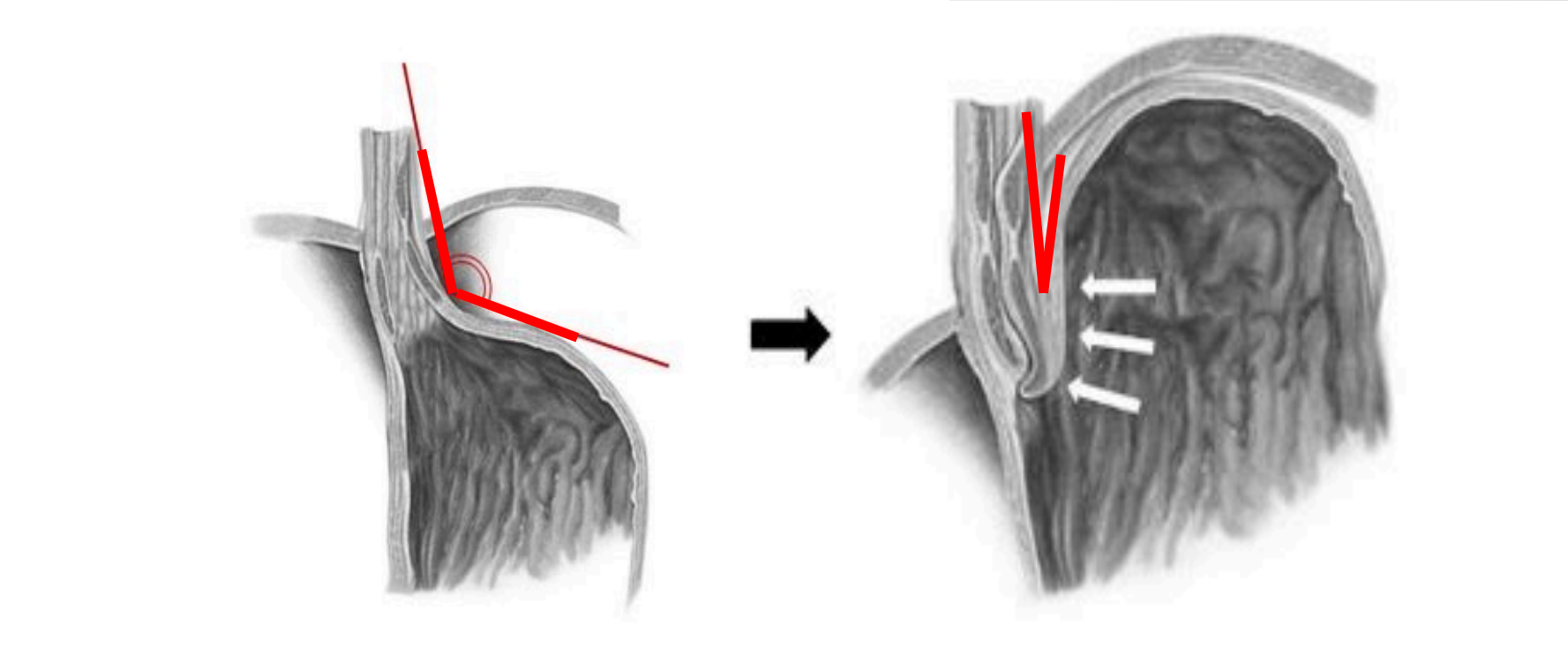
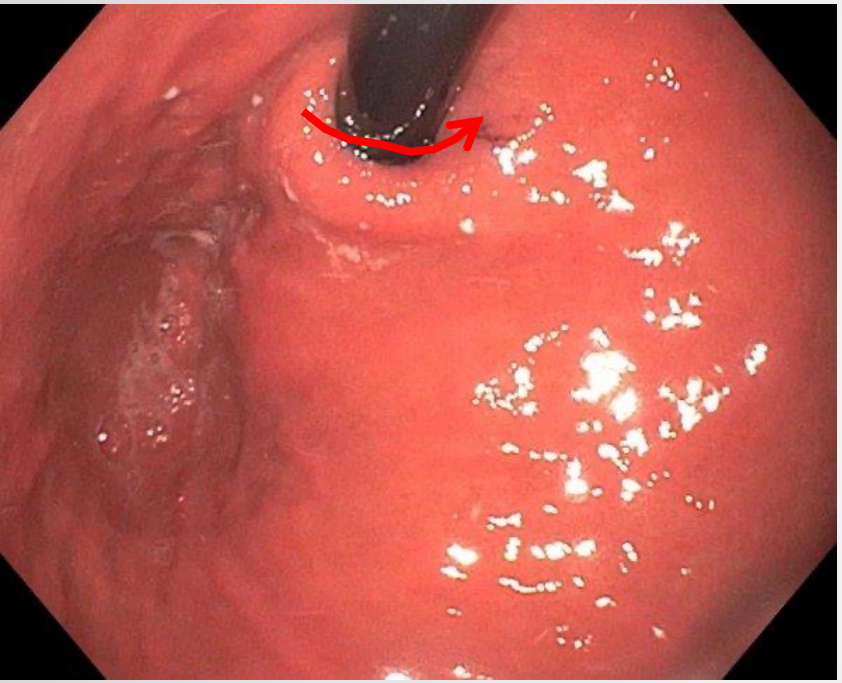


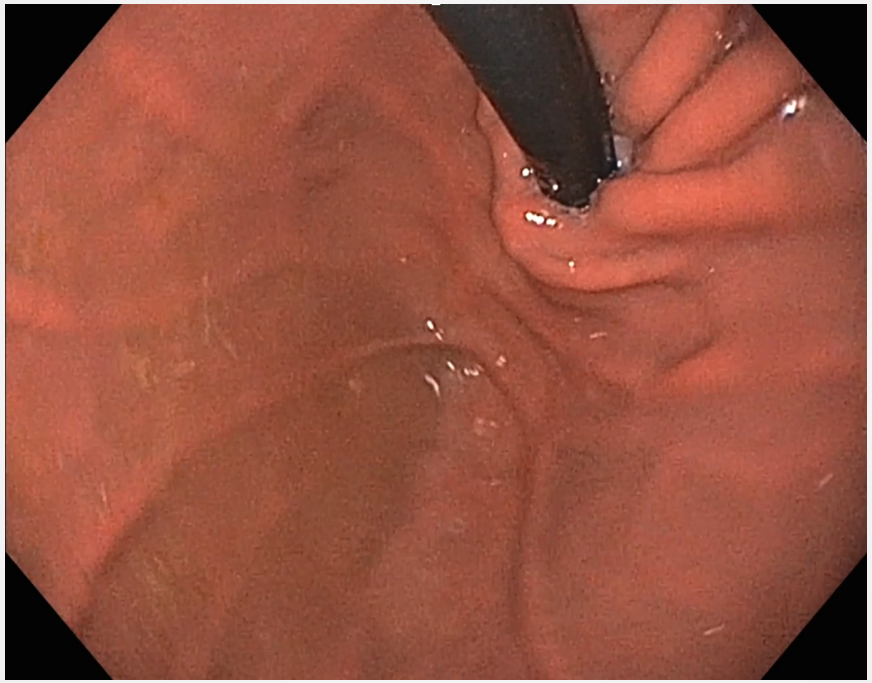
- GEFV Factors influencing flow into esophagus:
    1. Diameter
    2. Length (esp. intra-abdominal)
    3. Medial/Lateral movement (Flap)
    4. Orientation (from Greater to Lesser curve

GEFV - medial to lateral movement (flap)

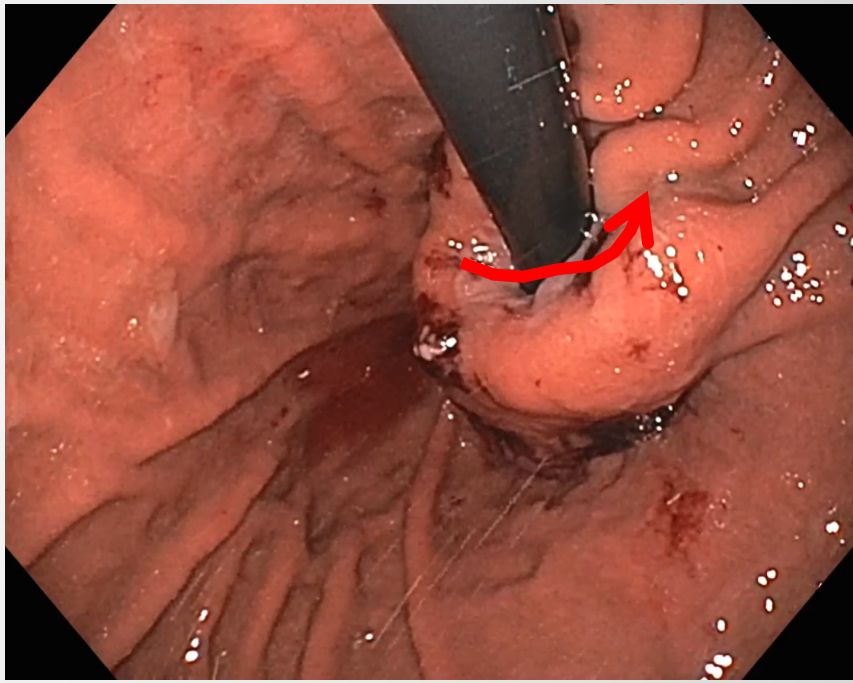
Normal GEFV

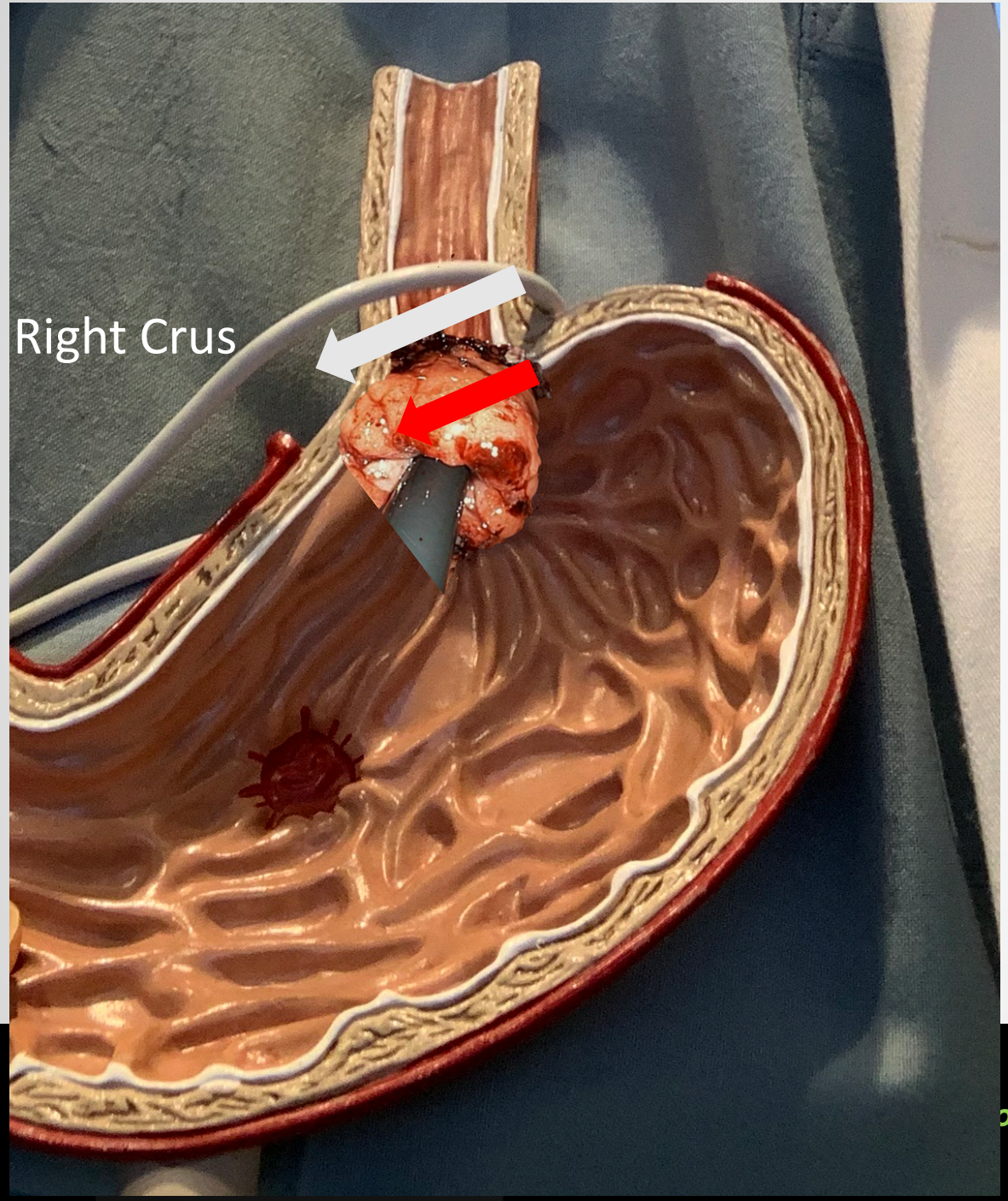


Hill 2 GEFV

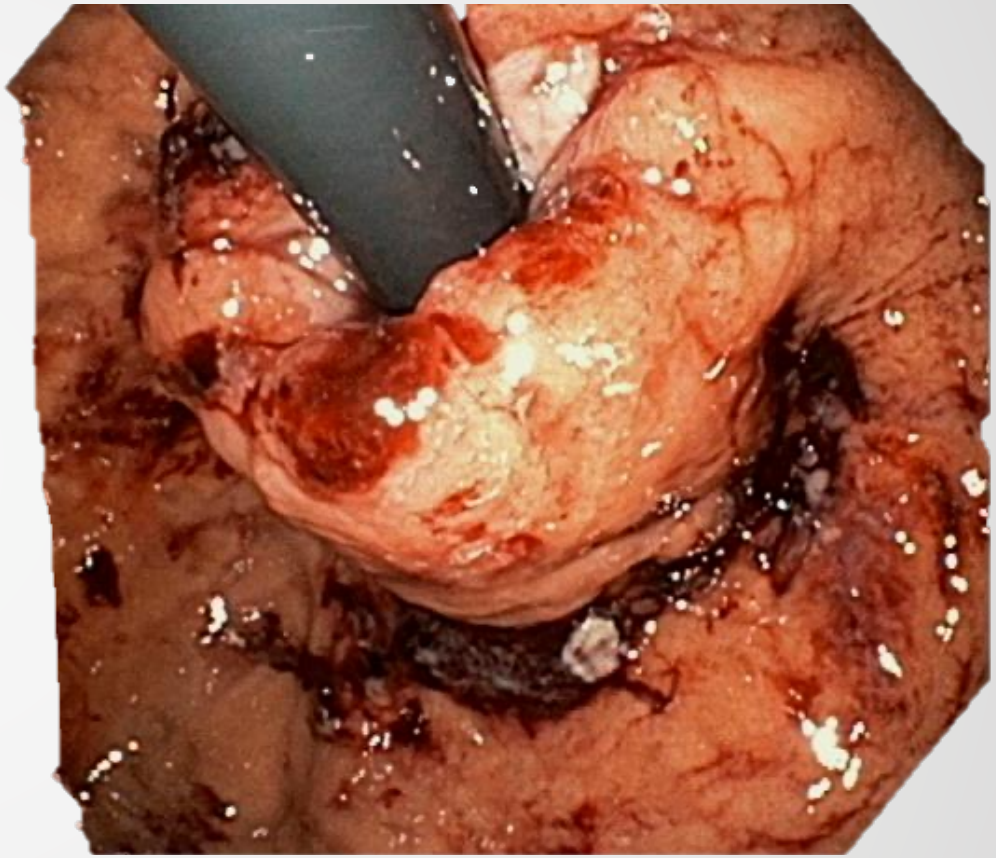


TIF GEFV

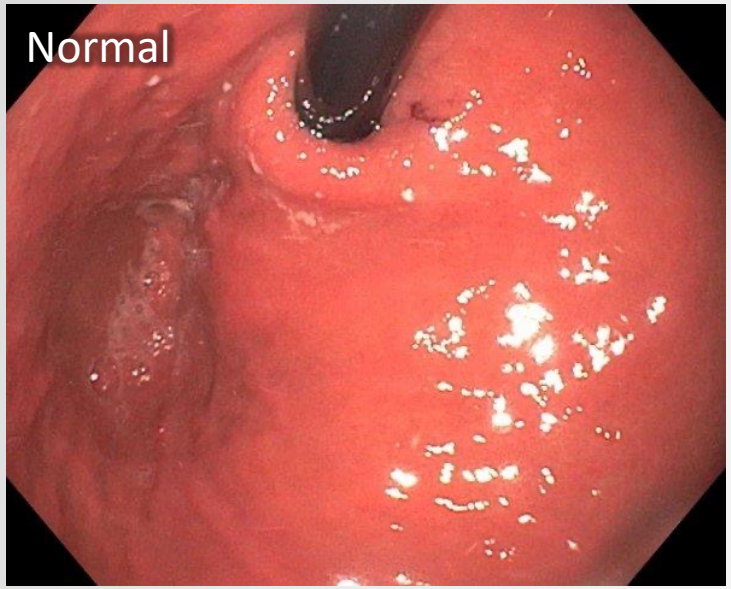


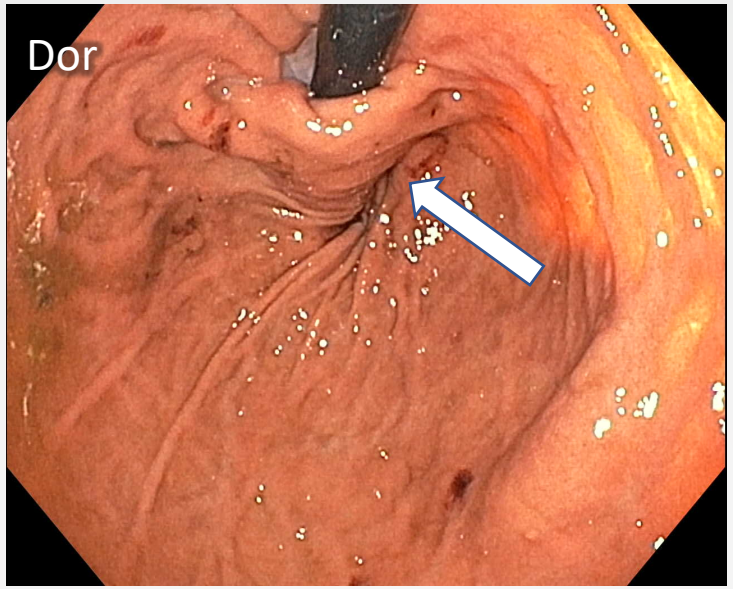


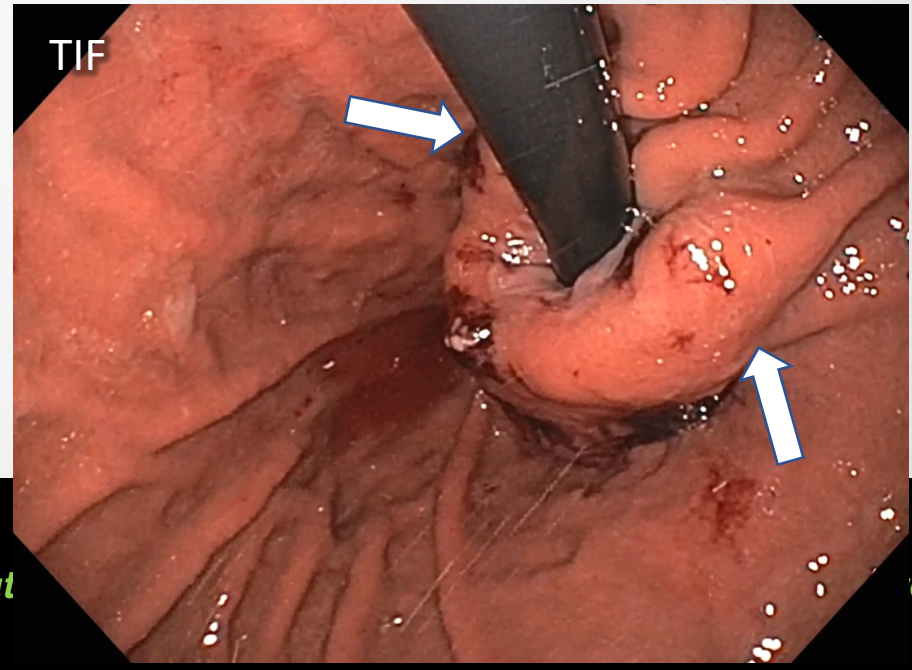
GEFV in synchrony w/right crus



Orientation of the GEFV







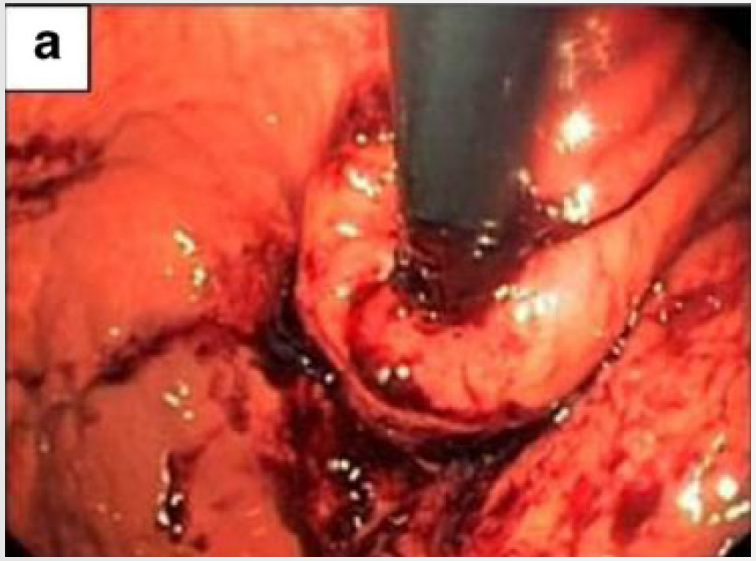
TIF GEFV Data

- TIF without hernia repair (RCTs; Level 1)
- TIF with hernia repair (Case/control, series; Level 3,4)

Transoral Incisionless Fundoplication 2.0 Procedure Using EsophyX™ for Gastroesophageal Reflux Disease

Toshitaka Hoppo · Arul Immanuel · Matthew Schuchert · Zdenek Dubrava · Andrew Smith · Peter Nottle · David I. Watson · Blair A. Jobe

19 pts

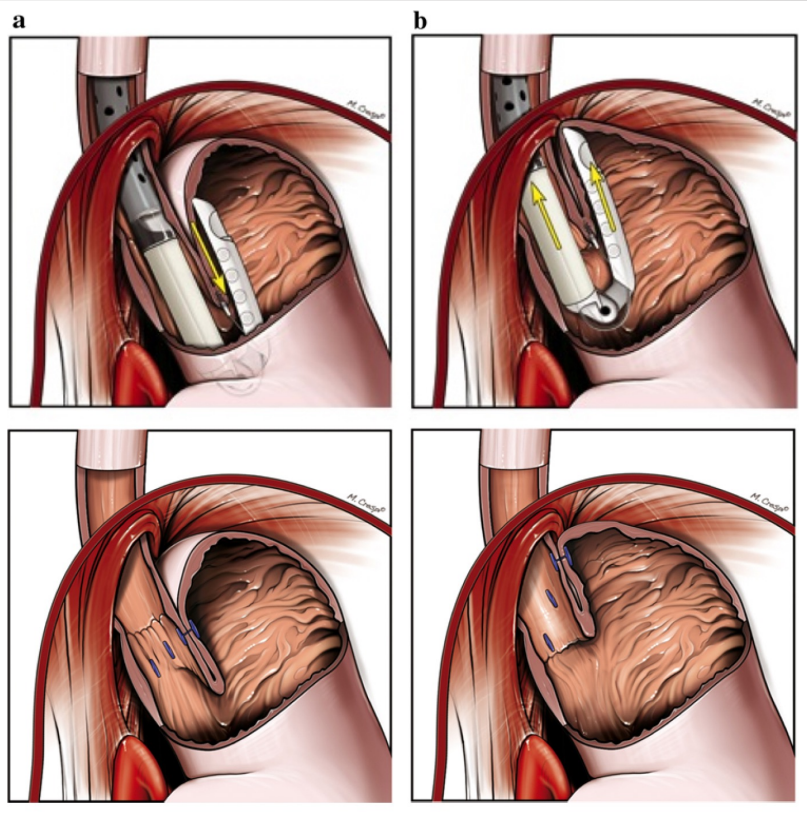


Hoppo, T. Jobe, B. et al J Gastrointest Surg (2010) 14:1895–1901

Transoral rotational esophagogastric fundoplication: technical, anatomical, and safety considerations

Reginald C. W. Bell · Guy-Bernard Cadière

>100 pts



Bell, R. Cadiere, G. Surg Endosc (2011) 25:2387–2399

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Multidisciplinary Collaboration. Personalized Treatment Strategies. Patient Advocacy.

Transoral Incisionless Fundoplication Effective in Eliminating GERD Symptoms in Partial Responders to Proton Pump Inhibitor Therapy at 6 Months: The TEMPO Randomized Clinical Trial

Karim S. Trad, MD[1,2], William E. Barnes, MD[3], Gilbert Simoni, MD[4], Ahmad B. Shughoury, MD[5,6], Peter G. Mavrelis, MD[5,6], Mamoon Raza, MD[7,8], Jeffrey A. Heise, MD[9], Daniel G. Turgeon, MD[1,2], and Mark A. Fox, MD[10,11]

- Multi-center, open-label, RCT: TIF vs PPI
- 63 pts: 2:1 Randomization TIF (40 pts) or PPI (23 pts)
- 6-mo f/u: troublesome regurgitation eliminated 97% TIF vs 50% PPI (p=.006)
- Esophageal acid exposure (AET) normalized in 54% TIF vs 52% PPIs
- Off PPI: 90% TIF pts

Trad, KS et al Surgical Innovation 2015, Vol. 22(1) 26–40

The TEMPO Trial at 5 Years: Transoral Fundoplication (TIF 2.0) Is Safe, Durable, and Cost-effective

Karim S. Trad, MD, FACS[1,2], William E. Barnes, MD, FACS[3], Elizabeth R. Prevou, MPH, PA-C[2], Gilbert Simoni, MD[4], Jennifer A. Steffen, BA[2], Ahmad B. Shughoury, MD[5,6], Mamoon Raza, MD[7,8], Jeffrey A. Heise, MD, FACS[9], Mark A. Fox, MD, FACS[10,11], and Peter G. Mavrelis, MD[5,6]

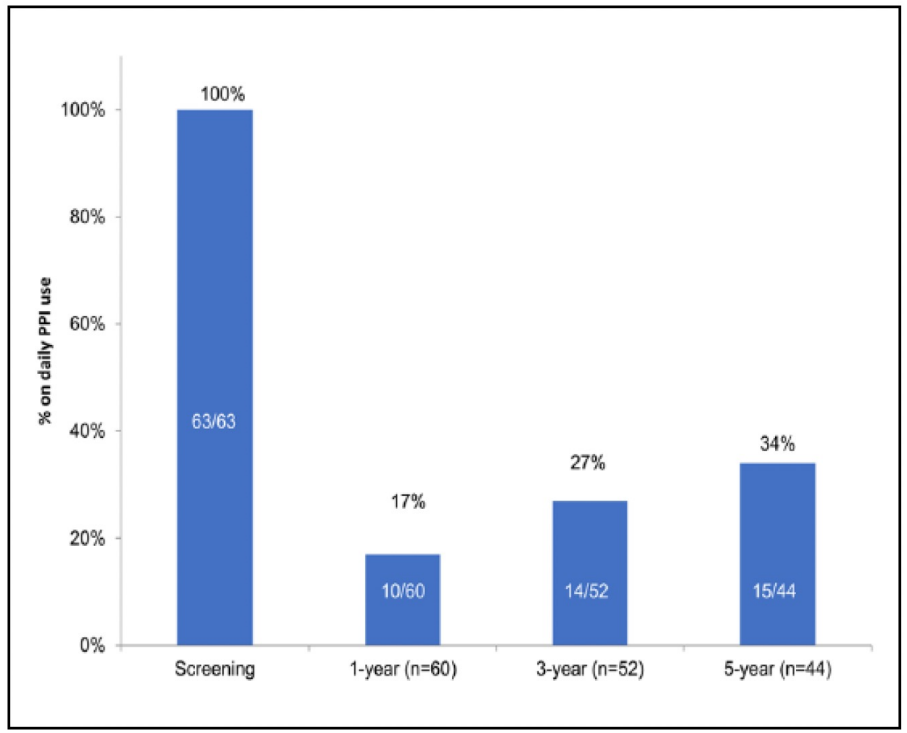

Figure 6. Percentage of patients on daily proton-pump inhibitor (PPI) therapy at screening and 1-, 3-, and 5-year follow-up assessments.

- 63 pts, f/u: 1 yr (60), 3 yrs (52), 5 yrs (44)
- Troublesome regurgitation eliminated
  - 1 yr (88%), 3 yrs (90%), 5 yrs (86%)
- No SAE's
- 3 of 63 (5%) reoperations by 5 yrs
- 66% remained off PPI at 5 years

Trad, KS et al Surgical Innovation 2015, Vol. 22(1) 26–40

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Efficacy of Transoral Fundoplication vs Omeprazole for Treatment of Regurgitation in a Randomized Controlled Trial

John G. Hunter,[1,*] **Peter J. Kahrilas**,[2,*] Reginald C. W. Bell,[3] Erik B. Wilson,[4] Karim S. Trad,[5,6] James P. Dolan,[1] Kyle A. Perry,[7] Brant K. Oelschlager,[8] Nathaniel J. Soper,[2] Brad E. Snyder,[4] Miguel A. Burch,[9] William Scott Melvin,[7] Kevin M. Reavis,[1,10] Daniel G. Turgeon,[5,6] Eric S. Hungness,[2] and Brian S. Diggs[1]

- Prospective, sham-controlled trial
- Primary endpoint: determine if TIF reduced troublesome regurgitation in PPI-refractory pts
- Screened 696 patients with troublesome regurgitation despite daily PPI (40mg)
- If HH ≤ 2 cm, 1:1 randomization TIF+placebo (87) vs sham+PPI (42)

Gastroenterology 2015;148:324–333

Efficacy of Transoral Fundoplication vs Omeprazole for Treatment of Regurgitation in a Randomized Controlled Trial

John G. Hunter,[1,*] **Peter J. Kahrilas**,[2,*] Reginald C. W. Bell,[3] Erik B. Wilson,[4] Karim S. Trad,[5,6] James P. Dolan,[1] Kyle A. Perry,[7] Brant K. Oelschlager,[8] Nathaniel J. Soper,[2] Brad E. Snyder,[4] Miguel A. Burch,[9] William Scott Melvin,[7] Kevin M. Reavis,[1,10] Daniel G. Turgeon,[5,6] Eric S. Hungness,[2] and Brian S. Diggs[1]

- By ITT analysis, TIF eliminated troublesome regurgitation in a larger proportion of patients (67%) than PPIs (45%) (P=.023).
- Control of esophageal pH improved after TIF (mean 9.3% before and 6.3% after; P <.001), but not after sham surgery (mean 8.6% before and 8.9% after).
- SAE rare: 3% TIF (transient abd/chest pain) vs 2% sham (nausea)

Gastroenterology 2015;148:324–333

Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD

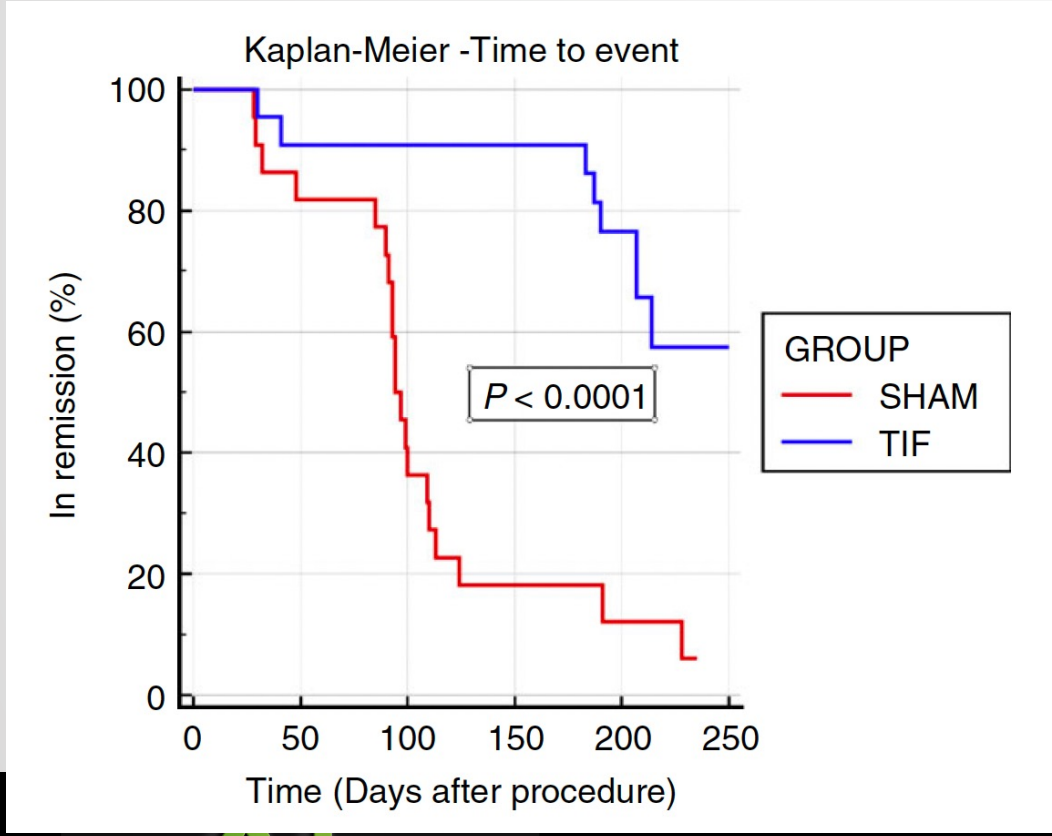
B. Håkansson*, M. Montgomery*, G. B. Cadiere†, A. Rajan†, S. Bruley des Varannes‡, M. Lerhun‡, E. Coron‡, J. Tack§, R. Bischops§, A. Thorell*, U. Arnelo¶ & L. Lundell¶

- Double-blind sham-controlled study in GERD patients who were chronic PPI users
- 44 pts randomized 1:1; 22 patients in each group
- Primary endpoint: clinical remission after 6-month follow-up
- 2-mo run-in period: adjust lowest possible dose of PPIs to control sxs

Aliment Pharmacol Ther 2015; 42: 1261–1270

Randomised clinical trial: transoral incisionless fundoplication vs. sham intervention to control chronic GERD

B. Håkansson*, M. Montgomery*, G. B. Cadiere†, A. Rajan†, S. Bruley des Varannes‡, M. Lerhun‡, E. Coron‡, J. Tack§, R. Bischops§, A. Thorell*, U. Arnelo¶ & L. Lundell¶



- After 6 months, 59% TIF vs 8% Sham in clinical remission
- Normalization of pH: 69% TIF vs 20% sham procedure (P = 0.04)

Aliment Pharmacol Ther 2015; 42: 1261–1270

TIF GEFV Data

- TIF without hernia repair (RCTs; Level 1)
- TIF with hernia repair (Case/control, series; Level 3,4)

Why do cTIF when I can just finish with a fundoplication in 20 min?

Article

The American Surgeon
00(0) 1–3

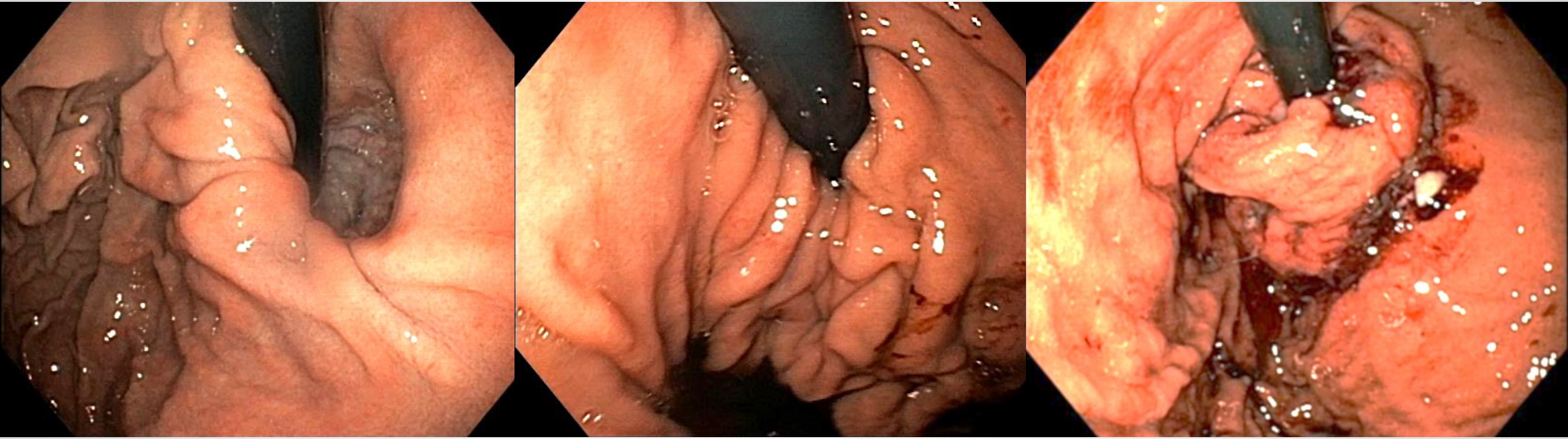
DOI: 10.1177/0003134820933608
journals.sagepub.com/home/asu
SAGE

Ten Reasons for Laparoendoscopic Repair of Hiatal Hernia: Case Presentation With Long-Term Follow-Up

Medhat Fanous, MD, FACS[1]

5 Reasons (my opinion)

1. Optimal Flap valve – high efficacy coupled with low side effect (min gas/bloat, dysphagia)
2. Best positioned for re-do's: spares fundus, no "take-down"
3. Reproducible and Scalable – valve construction standardized
4. Special populations – post-POEM GERD, scleroderma
5. Political/Relational – gastroenterologists who do TIF need surgical partnership, as cTIF greatly outnumbers TIF cases



Pre-Hernia Repair

Post-Hernia Repair

Post-TIF

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The Southwestern Surgical Congress

Short-term safety and symptomatic outcomes of transoral incisionless fundoplication with or without hiatal hernia repair in patients with chronic gastroesophageal reflux disease

- 42 pts: TIF alone (24 patients) or cTIF (18 patients)
  - Based on the presence of a hiatal hernia 3 cm or larger.
- There were no long-term postoperative complications
- GERD-HRQL scores: heartburn elimination 63%
- Daily PPI: eliminated in 76%
- Atypical symptoms (RSI) reduction (5 versus 22 on PPIs, P<.001)

Ihde, G et al The American Journal of Surgery (2011) 202, 740–747

Laparoscopic Hiatal Hernia Repair Followed by Transoral Incisionless Fundoplication With EsophyX Device (HH + TIF): Efficacy and Safety in Two Community Hospitals

- cTIF in 99 patients with GERD and hiatal hernias 2-5 cm
- All patients were PPI-refractory
- At 12-month follow-up, median GERD-HRQL scores improved by 17 points, indicating that subjects had no bothersome symptoms
- The median GERSS: 25.0 to 1.0; 90% reported having effective symptom control (score <18) at 12 months

Janu, P et al Surgical Innovation 2019,26(6) 675–686

- 77% reported effective control of LPR symptoms at 12 mo with an RSI score of 13 or less
- 74% off PPI's at 12 months
- Conclusion: cTIF provides significant symptom control for heartburn and regurgitation with no long-term dysphagia or gas bloat normally associated with traditional LARS

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SCIENTIFIC PAPER JSLS

pH Scores in Hiatal Repair with Transoral Incisionless Fundoplication

- 55 pts cTIF: 29 (53%) pre/post-op validated surveys and pH evaluations
- No SAE's - mean follow-up 296 days
- GERD HRQL: 33.7 to 9.07 (P<.001)
- RSI score: 20.32 to 8.07 (P<.001).
- pH DeMeester score: 35.3 to (P<.001); 76% normalized pH score
- 22 of 29 pts (76%) had intact H repair & intact TIF
- Among these 22 pts, 21 (95%) had normal esophageal acid exposure
- Failures: 6 failed H repair; 1 failed TIF valve

Novel Interdisciplinary Approach to GERD: Concomitant Laparoscopic Hiatal Hernia Repair with Transoral Incisionless Fundoplication

- 60 pts cTIF (53% men, age 59.3 years), 100% technical success
- Mean HH size on endoscopy = 2.9 cm
- Reflux Disease Questionnaire (RDQ) for symptom frequency and symptom severity baseline vs 6 mo p cTIF: (17.4 to 4.72; $p < 0.01$ and 16.7 to 4.56; $p < 0.05$, respectively)
- GERD HRQL decreases in heartburn (23.26 to 7.37; $p < 0.01$) and regurgitation (14.26 to 0; $p< 0.05$)
- RSI decreased (17.7 to 8.1; $p < 0.01$)

Novel Interdisciplinary Approach to GERD: Concomitant Laparoscopic Hiatal Hernia Repair with Transoral Incisionless Fundoplication

- Mean GERD-HRQL score for gas bloat was 1.4 at baseline, 0.25 at 6 months (p=0.51), and 0.5 at 12 months post-cTIF (p=NS)
- GERD-HRQL score for dysphagia was 1.06 at baseline, 0.95 at 6 months, and 1.0 at 12 months (p=NS)
- 5 pts had >6mo post-cTIF pH analysis: Mean DeMeester score decreased from 43.7 to 4.9; Acid exposure time: 12.7% to 1.28% post cTIF (p=0.06)

Efficacy and patient satisfaction of single-session transoral incisionless fundoplication and laparoscopic hernia repair

- 33 pts had cTIF; median follow-up with symptom 9 months
- 27/33 (81%) of patients were off daily PPIs
- 31/33 (94%) of patients reported 75% or greater satisfaction with the procedure and outcomes
- 1 pt had a superficial mucosal laceration after the procedure, likely due to vomiting, which was treated conservatively

Response of Laryngopharyngeal Symptoms to Transoral Incisionless Fundoplication in Patients with Refractory Proven Gastroesophageal Reflux

- 49 pts had TIF (n = 26) or cTIF (n = 23) with at least 6 months follow-up

Table 2. Clinical and Patient-Reported Outcomes of TIF/cTIF.

Outcome	All Patients (n = 49)	Patients who underwent TIF (n = 26)	Patients who underwent cTIF (n = 23)	*P* value (TIF vs cTIF)
Patient-reported questionnaire based outcomes				
Normalization of RSI (<13); n (%)	41/48 (85%)	20/25 (80%)	21/23 (91%)	.42
Decrease of >50% in GERD-HRQL; n (%)	43/48 (90%)	22/25 (88%)	21/23 (91%)	1
Discontinuation of daily PPI; n (%)	31/39 (80%)	14/21 (67%)	17/18 (94%)	.05
Satisfied after procedure; n (%)	35/48 (73%)	15/25 (60%)	20/23 (87%)	.05
pH data at 6 months				
Change in AET; mean ± SD	−7.1 ± 6.8 (n = 25, *P* < .001)	−4.3 ± 6.3 (n = 15, *P* = .02)	−11.4 ± 5.5 (n = 10, *P* < .001)	<.001
Normal average AET (<6%) off PPI; n (%)	21/28 (75%)	13/18 (72%)	8/10 (80%)	1

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Snow, GE et al Annals of Otology, Rhinology & Laryngology 2021 (in-press)

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

- 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
- 125 patients with cTIF vs 70 with LNF/HH repair (BMI and hernia size-matched, mean BMI 29.2, mean age 57.2) were compared
- % off PPI at 6 mo: cTIF 73.8% vs LNF 60.6% (p=.07)
- Higher incidence of bloating observed in 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)

Multicenter Single-Blind RCT of **cTIF Versus LNF** For Treatment of GERD in Patients Requiring Hiatal Hernia Repair Combined With Transoral Incisionless Fundoplication Versus Laparoscopic Nissen Fundoplication for Treatment of Gastroesophageal Reflux Disease in Patients Requiring Hiatal Hernia Repair

Mayo Clinic
University of California, Irvine
Fox Valley Surgical Associates
University of Southern California
The University of Texas Health Science Center, Houston
University of Texas at Austin
Institute of Esophageal and Reflux Surgery

Aims of TIF Registry (PI: Canto, M.)

JOHNS HOPKINS MEDICINE

- To assess short- term (6 months) and long-term (3 and 5 years) patient-reported and procedural outcomes
- To evaluate the patient-related and procedure-related factors associated with TIF/cTIF failure, defined as
  - Recurrence of GERD symptoms or lack of improvement
  - Development of esophagitis/BE
  - Post-treatment abnormal pH testing
  - Repeat TIF
  - Surgical rescue procedure

Participating Sites

Site	GI/Surgery	Treatments
Johns Hopkins Medical Institutions	3 GI/2 Surgeons	TIF, cTIF
University of California Irvine	1 GI/1 Surgeon	TIF, cTIF
Mayo Clinic Rochester	1 GI/ Surgeon	TIF, cTIF
Cornell University Medical Center	3 GI/2 Surgeons	TIF/cTIF
University of Texas Health Houston	1 GI/1 Surgeon	TIF/cTIF
Geisinger Medical Center	1 GI	TIF
Matagorda Regional Med Ctr	1 Surgeon	TIF/cTIF
Fox Valley Surgical Associates	1 Surgeon	TIF/cTIF
UNR Med/Univ of Nevada	1 Surgeon	TIF/cTIF
Twin Rivers Gastroenterology	1 GI	TIF

Prospective TIF vs c-TIF (as of 9-8-21)

Registry Project Multi-sites Evaluable Totals								
Site	PI	TIF Registry Totals	TIF vs cTIF		6 month totals	12 month totals	24 month total	36 month totals
Johns Hopkins Medicine	Marcia Canto	72	53	19	61	48	26	8
Mayo Clinic	Abu Dayeh	3	3	0	0	0		
Geisinger	David Diehl	3	3	0	0	0		
The Matagorda Regional Medical	Glenn Ihde	50	0	50	31	19	4	
UCI Irvine Health	Ken Chang	67	4	54	43	26		
UNRMed-University of Nevada	Michael Murray	29	3	26	19	12		
UTHeath	Nirav Thosani	0	0		0	0		
Fox Valley Surgical Associates	Peter Janu	26	7	19	26	20		
Cornell University	Reem Sharaiha	0	0		0	0		
Twin Rivers GI Clinic	Amit Sohagia	14	12	2	9	5		
	TOTALS	263	85	170	189	130	30	8

Conclusions

- TIF GEFV in pts not requiring hernia repair is safe and effective, especially in PPI-refractory GERD (Level 1 evidence)
- TIF GEFV performed in conjunction with hernia repair (cTIF) appears to be safe and effective, and may have less gas/bloat side effects than LNF (Level 3,4 evidence)
- Level 1-2 evidence for cTIF is in progress

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