

A Two-Armed Single-Blinded Registry-Based Randomized Control Trial Comparing Anterior Gastropexy to No Anterior Gastropexy for Paraesophageal Hernia Repair

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- No relevant disclosures





Ryan Ellis



Bryan Ellis



A man with a mustache, wearing a dark blue flight suit and a matching beret with a pilot's wings emblem, stands on an airfield. He is looking down and to the left. In the background, there are white wooden structures, possibly part of an aircraft carrier's deck. The overall tone is serious and professional.

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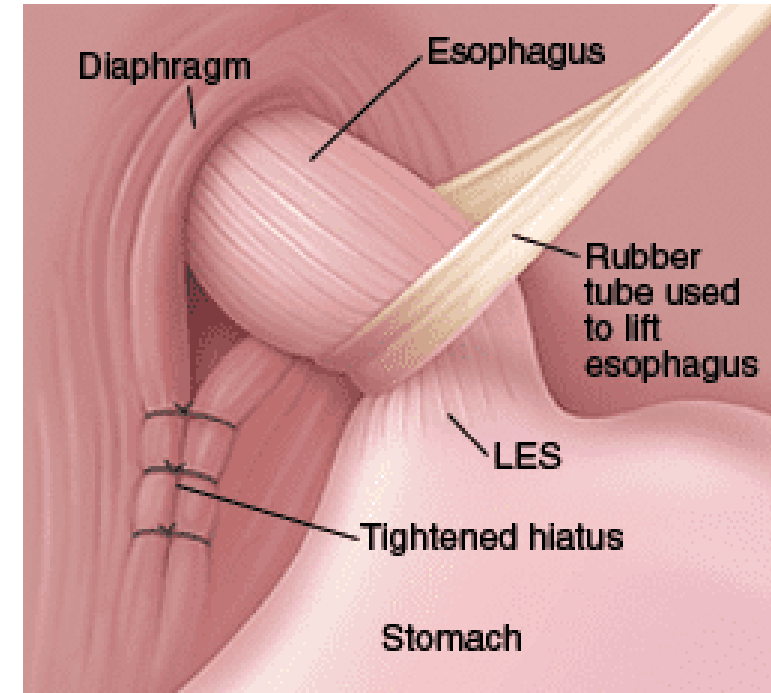
Fighter pilot is an attitude. It is cockiness. It is aggressiveness. It is self-confidence. It is a streak of rebelliousness, and it is competitiveness. But there's something else - there's a spark. There's a desire to be good. To do well; in the eyes of your peers, and in your own mind.

Colonel Robin Olds



Background

- Paraesophageal hernia repair (PEHR) is technically challenging
- Data supports significant recurrence rates



Support for gastropexy

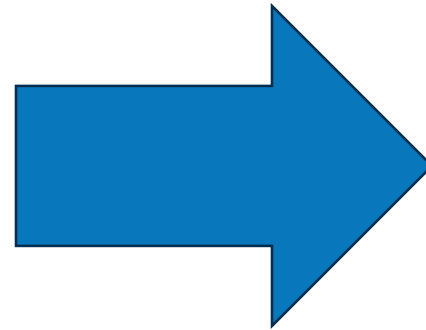
Ponsky et al. (2003): series of 28 PEHR in which anterior gastropexy was routinely used

- 0 recurrences at 1 year



Background

- Peet (1998)
- Diaz (2002)
- Poncet (2010)
- Oelschlager (2011)
- Pallabazzer (2011)
- Daigle (2014)
- Lidor (2015)



Average 30%
recurrence rate



Study Design

- Registry-based, superiority prospective RCT
- Minimally invasive (laparoscopic or robotic) paraesophageal hernia repairs 6/2019-7/2023
- **Anterior gastropexy vs no gastropexy**
- Blinding: patient blinded to treatment; blinded imaging review





Hypothesis

- Anterior gastropexy would result in a 15% reduction in **radiographic** PEH recurrence after MIS repair compared to no gastropexy



Inclusion Criteria

- Adult (≥ 18 years) patients with symptomatic PEH
- Non-emergent, MIS (laparoscopic or robotic) repairs
- Primary paraesophageal hernias
 - At least 5cm in height on CT, UGI, or endoscopy



Exclusion Criteria

- Ineligibility for MIS repair
- Hernia determined <5 cm
- Recurrent PEH
- Prior gastric operations
- Concurrent gastric operations
 - Collis gastroplasty
- Mesh use during repair



Primary Outcome

- Hernia recurrence by 1-year
 - Routine imaging (CT, UGI, EGD)
 - $\geq 2\text{cm}$ recurrence*
 - Blinded consensus (2/3) of the operating surgeons
 - Reoperation for recurrence at any time before 1 year

*Definition based on Oelschlager (2011)



Secondary Outcomes

- GERD Health-related Quality of Life (GERD-HRQL)
 - Baseline, 1 month, 1 year
- Other eight foregut symptoms
 - Baseline, 1 month, 1 year
- Patient satisfaction (satisfied, neutral, dissatisfied)
 - 1 month, 1 year

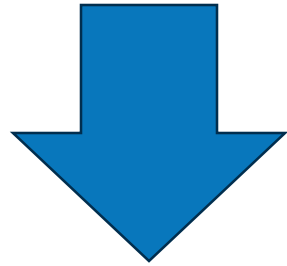


Procedure

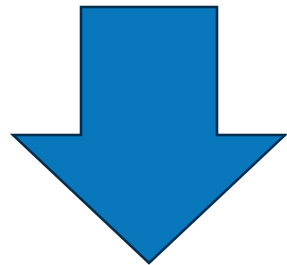
- Technique for crural closure +/- fundoplication: discretion of the surgeon
 - Mediastinal esophagus is mobilized to allow for 3-4cm of intraabdominal esophagus
 - Hernia sac is excised from the mediastinum
 - Cruroplasty with permanent suture, no bougie required



Mobilization of mediastinal esophagus and
dissection of the hernia sac from the
mediastinum

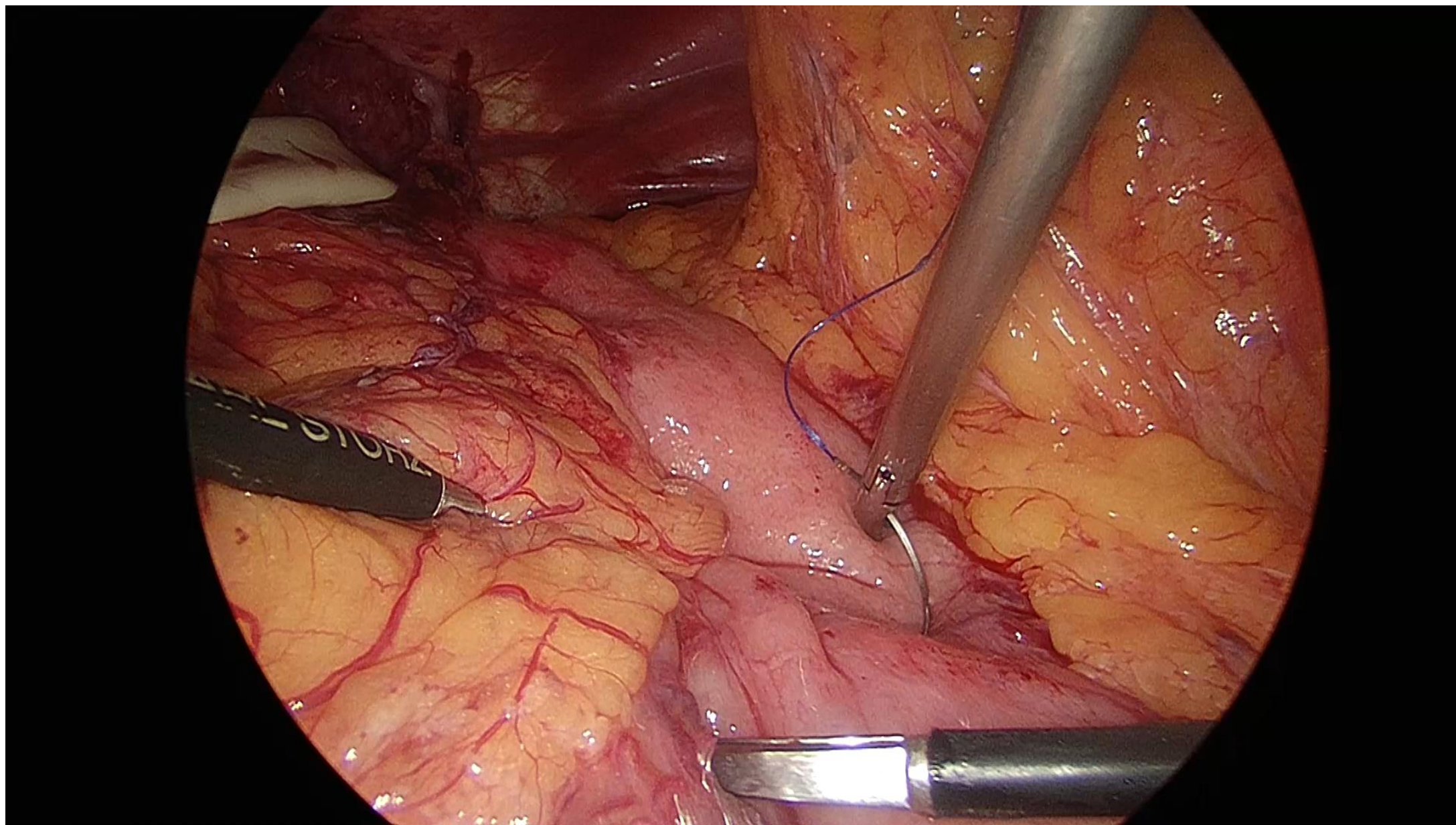


Cruroplasty +/- fundoplication
No other additional procedures needed



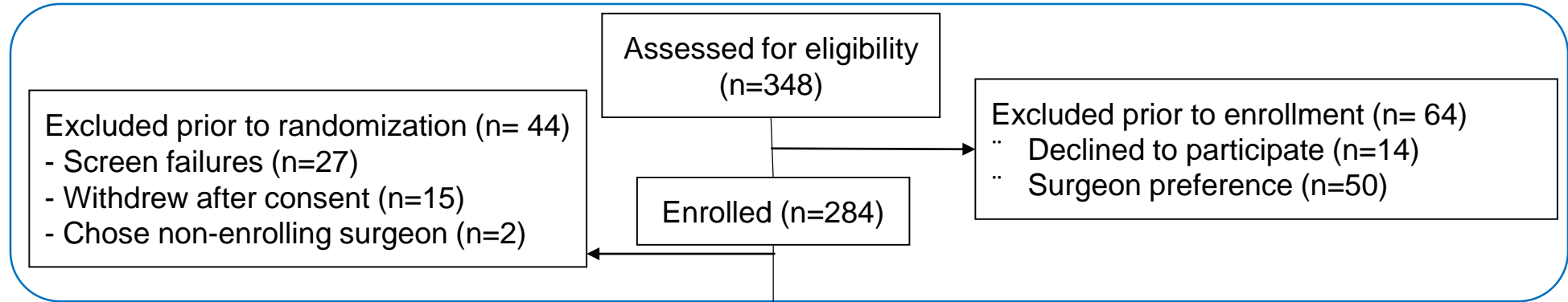
Randomization



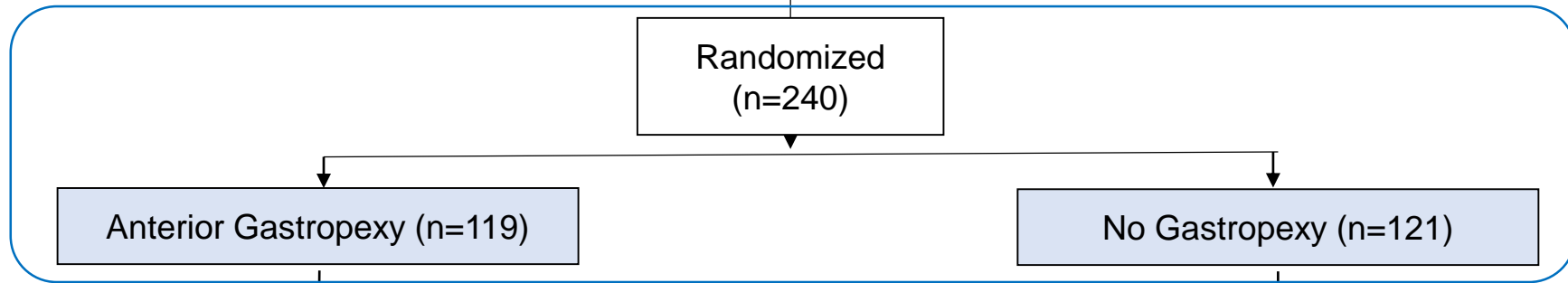


CONSORT 2010 Flow Diagram

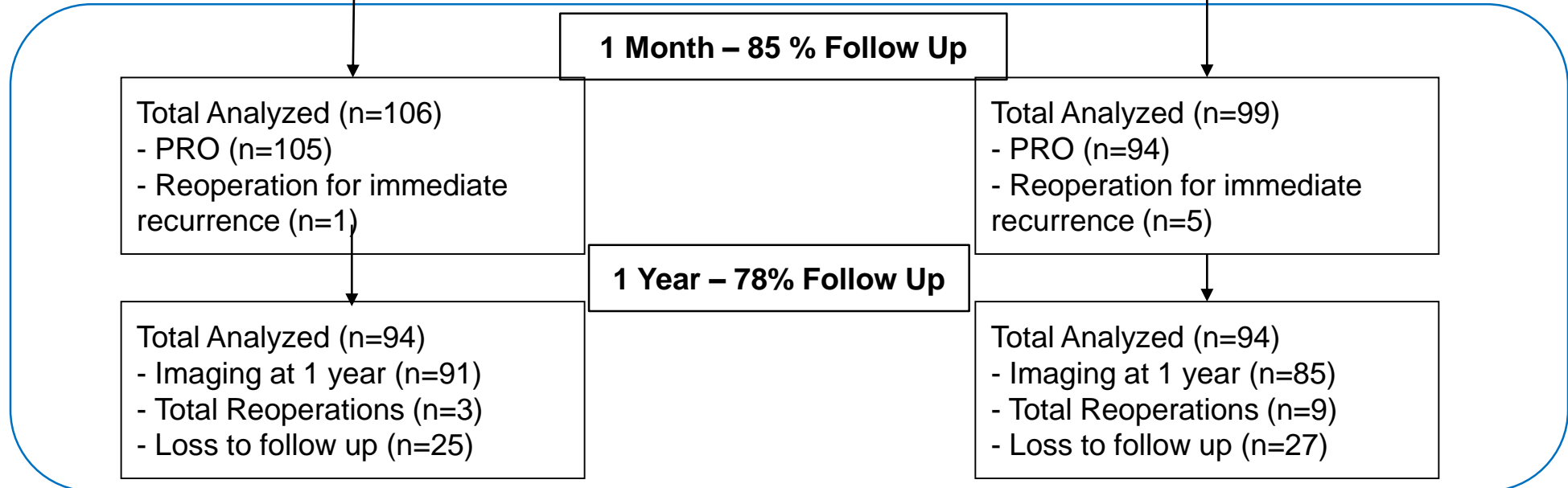
Enrollment



Allocation



Follow up



Patient Characteristics

	No Gastropexy (n=121)	Gastropexy (n=119)
Gender (male), N (%)	24 (19.8%)	15 (12.6%)
Age, median [IQR]	68.3 [62, 72.9]	69.7 [64, 75.4]
BMI, median [IQR]	29.2 [26.7, 32]	28.9 [26.1, 32.4]
HTN, N (%)	68 (56%)	68 (57%)
COPD , N (%)	14 (12%)	11 (9%)
Dialysis, N (%)	1 (1%)	0
DM, N (%)	7 (6%)	12 (10%)
Immunosuppression, N (%)	6 (5%)	2 (2%)
Anticoagulation, N (%)	5 (4%)	8 (7%)
Smoking, N (%)	3 (2%)	3 (3%)
CHF, N (%)	3 (2%)	2 (2%)

Operative Details

	No Gastropexy (n=121)	Gastropexy (n=119)	p value
Approach			
Laparoscopic, N (%)	114 (94%)	110 (92%)	0.769
Robotic, N (%)	7 (6%)	9 (8%)	
Length of Stay (days), median [IQR]	2 [2,3]	2 [2.4]	0.554
Wound Class			0.863
Clean, N (%)	108 (89%)	108 (91%)	
ASA, median [IQR]	3 [3, 3]	3 [3, 3]	0.511
Operative time (min), median [IQR]	134 [105, 166]	140 [116.5, 176.5]	0.096
EBL (cc), median [IQR]	10 [10, 20]	10 [10, 20]	0.995
Conversion to open	0	0	-

Operative Details

	No Gastropexy (n=121)	Gastropexy (n=119)	p value
Hernia Type			0.238
Type 1, N (%)	0	2 (2%)	
Type 2, N (%)	4 (3%)	1 (1%)	
Type 3, N (%)	103 (85%)	98 (82%)	
Type 4, N (%)	14 (12%)	18 (15%)	
Short Gastrics divided, N (%)	49 (40%)	55 (46%)	0.445
Fundoplication, N (%)	28 (23%)	27 (23%)	1
Dor	1	0	
Nissen	10	10	
Toupet	17	17	
Intraop Complication, N (%)	0	3 (3%)	0.496
Gastric injury, N (%)	0	1	
Liver injury, N (%)	0	1	
Bowel injury, N (%)	0	1	

Postoperative Details - Readmissions

	No Gastropexy (n=121)	Gastropexy (n=119)	p value
Readmissions, N (%)	7 (6%)	4 (3%)	0.556
Pain	0	1	
Dehydration	3	1	
Bleeding requiring transfusion	0	1	
Electrolyte abnormality	0	1	
Respiratory complication	1	0	
Wound	1	0	
Dysphagia	1	0	
Ileus	1	0	

Postoperative Details - Reoperations

	No Gastropexy (n=121)	Gastropexy (n=119)	p value
Non-hernia Reoperations, N (%)			
	1 (1%)	1 (1%)	1
Fundoplication revision	0	1	
Crural suture removal	1	0	
Reoperations for hernia recurrence, N (%)			
	9 (7%)	3 (3%)	0.096
Before 30 days	5	1	
After 30 days, before 1 year	4	2	



Primary Outcome – Paraesophageal Hernia Recurrence $\geq 2\text{cm}$

	No Gastropexy (n=94)	Gastropexy (n=94)	p value
Recurrence	44 (46.8%)	18 (19.1%)	0.004

Absolute Risk Reduction: 28%



Primary Outcome – Paraesophageal Hernia Recurrence $\geq 2\text{cm}$

	No Gastropexy (n=94)	Gastropexy (n=94)	p value
Recurrence	44 (46.8%)	18 (19.1%)	0.004

Number needed to treat: 3.6



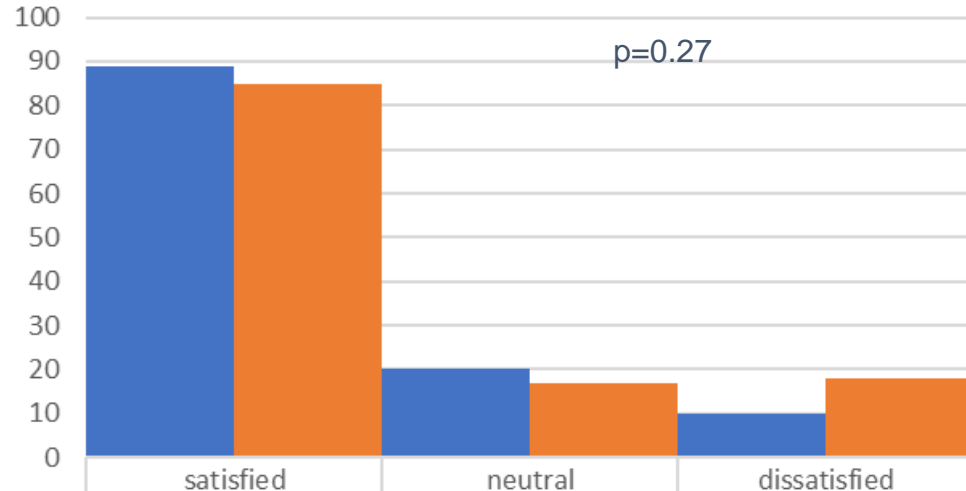
Recurrence: Breakdown by Size

	Small (0-2cm)	Medium (2-5cm)	Large (>5cm)	p value
No Gastropexy, N	6	25	9	0.274
Gastropexy, N	4	15	1	



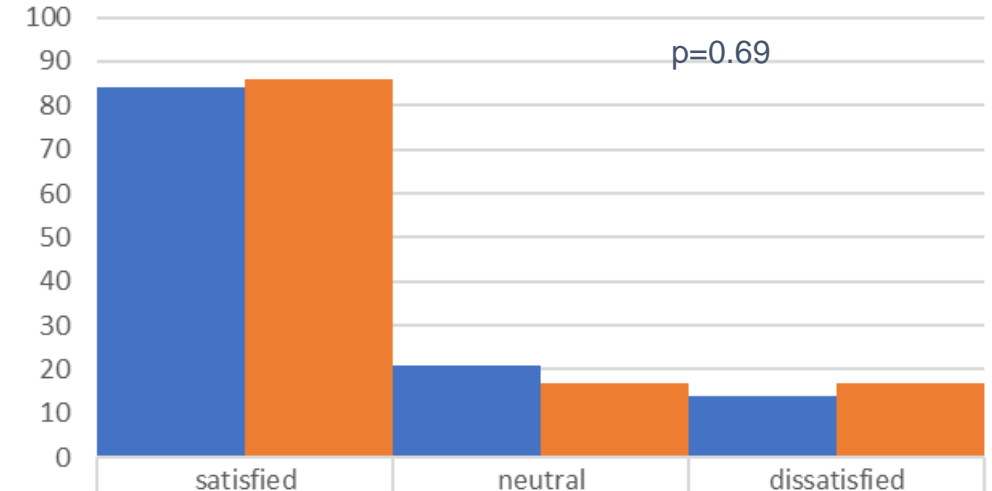
Secondary Outcomes – Patient Satisfaction

Satisfaction: 30 Day



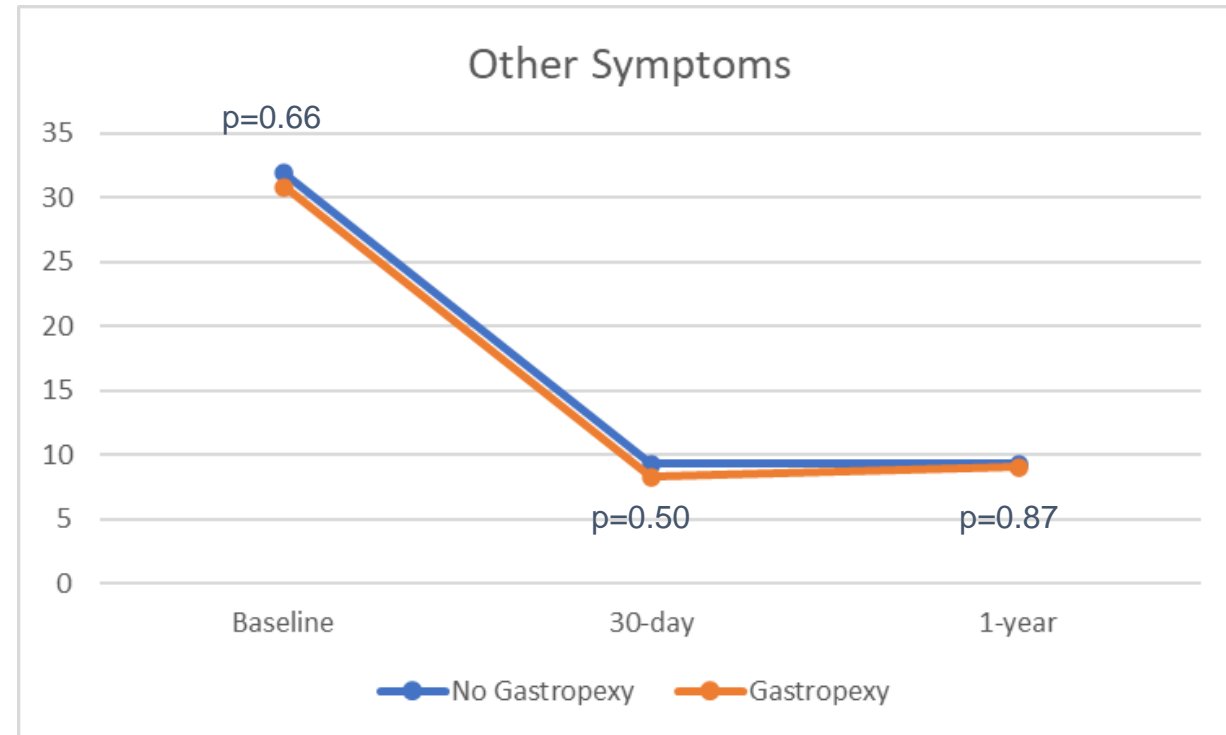
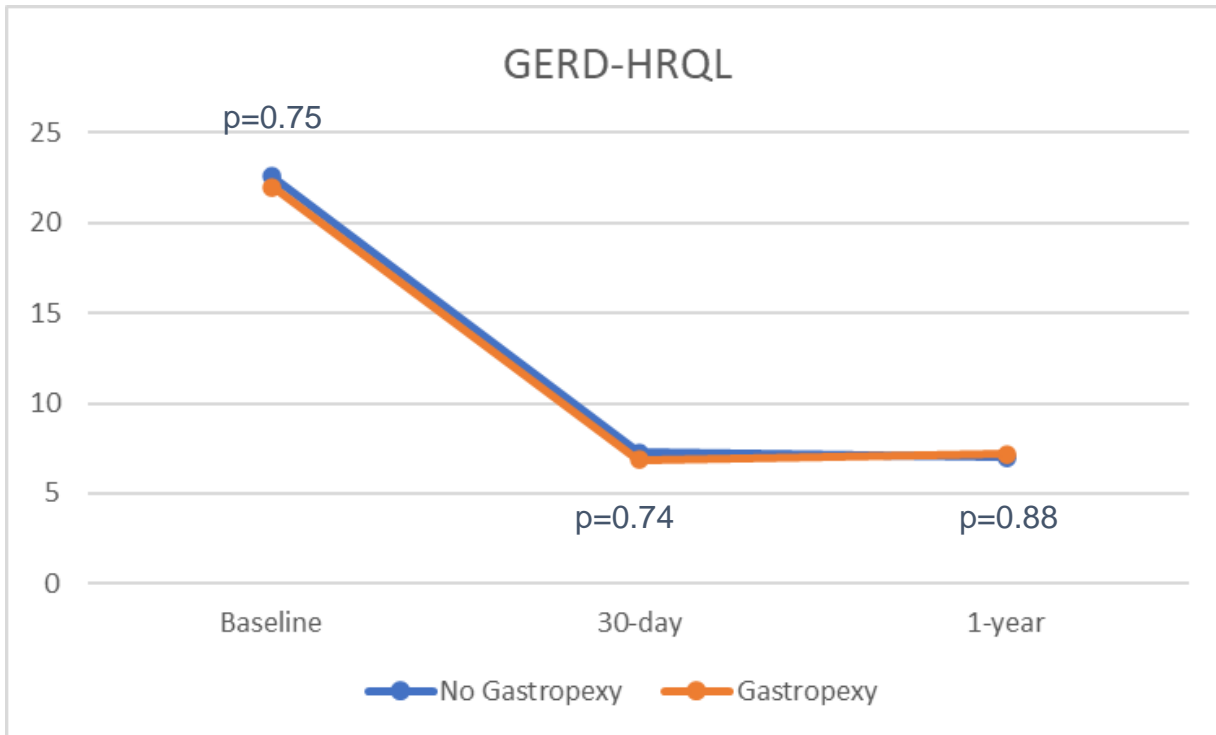
■ Gastropexy	89	20	10
■ No Gastropexy	85	17	18

Satisfaction: 1 Year



■ Gastropexy	84	21	14
■ No Gastropexy	86	17	17

Secondary Outcomes – Quality of Life



Exploratory Outcome - Recurrence: Wrap vs. No Wrap

	Fundoplication (n=45)	No Fundoplication (n=143)	p value
Recurrence	10/45 (22%)	52/143 (36%)	0.14



Quality of Life: Recurrences and Funduplications at 1 year

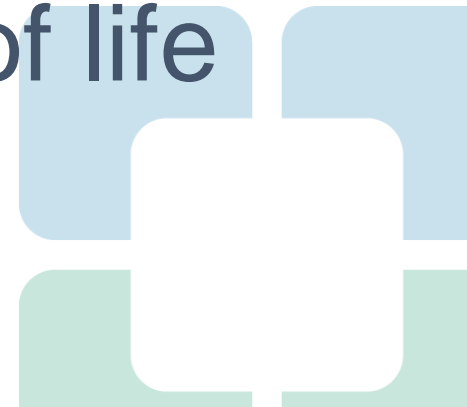
QoL measure, mean (SD)	Fundoplication	No Fundoplication	p value
GERD-HRQL	5.57 (4.28)	11.96 (10.6)	0.011
Other symptoms	10.8 (15.83)	11.02 (13.16)	1
Dysphagia	1.29 (1.38)	1.1 (1.49)	0.74



Conclusion

Placement of gastropexy sutures is superior in reducing radiographic recurrences in primary MIS paraesophageal hernia repair.

The association of radiographic recurrence with long term patient reported quality of life requires more study



Special shout out: Sara Maskal, MD

Thank you





Cleveland Clinic

Every life deserves world class care.