

# Determining A Clinically Significant Paraoesophageal Hernia Recurrence: Post-Hoc Analysis of a Randomized Controlled Trial

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# Disclosures

- Dr. Petro serves as a consultant for Advanced Medical Solutions, TelaBio, Medtronic, Bard-Davol, and Surgimatix, and has received an institutional research grant from Merck.
- Dr. Prabhu is on the advisory board (received consulting fees) for Surgimatix, DistalMotion, and CMR Surgical.
- Dr. Miller is a consultant for Boston Scientific, received a research grant from the American Hernia Society and research funding from Integra.
- Dr. Rosen serves as the medical director of the ACHQC and receives salary support, received institutional research grants from TelaBio and Medtronic.
- The remaining authors have no disclosures to report.



# 20,000 Feet

- After MIS repair, paraesophageal recurrence <sup>\*</sup>is common
  - But what is a recurrence?
  - When should we care?
- Reoperation for recurrence is not common
  - When do we reoperate?
    - Size
    - Symptoms

# 20,000 Feet

- After MIS repair, paraesophageal recurrence is <sup>\*</sup> common

**Does  $\uparrow$  size  $\approx$   $\uparrow$  symptoms?**

**Which symptoms  $\approx$   $\uparrow$  reoperation?**

- R
- when do we reoperate?
  - Size
  - Symptoms

# 20,000 Feet

- Data from an RCT looking at **MIS-PEHR recurrence**
- Images @ 1 year+ were stratified by **size**

0 cm

0.1 – 1.9 cm

2 – 4.9 cm

$\geq 5$  cm

- PRO surveys were time-matched to images
- Comparison across recurrence size groups and reop vs non-reop groups

# Background

- ~50% of adults over 60 years have hiatal hernia
- 5 – 15% of hiatal hernias are paraesophageal (HH Types II, III, or IV)
- Recurrence<sup>\*</sup> rates are quoted as high as 60% after repair within 4-5 years
- Repair for recurrence is 5-15%



# PEH Recurrence Definitions

- Any stomach above diaphragm
  - Nguyen 2023
- $\geq 2$  cm
  - Oelschlager 2006, Oelschlager 2012
  - Luketich 2011
  - Lidor 2013
  - Lazar 2017
  - Inaba 2022
  - Petro 2024
- $\geq 3$  cm
  - Dallemagne 2011
  - Braghetto 2018

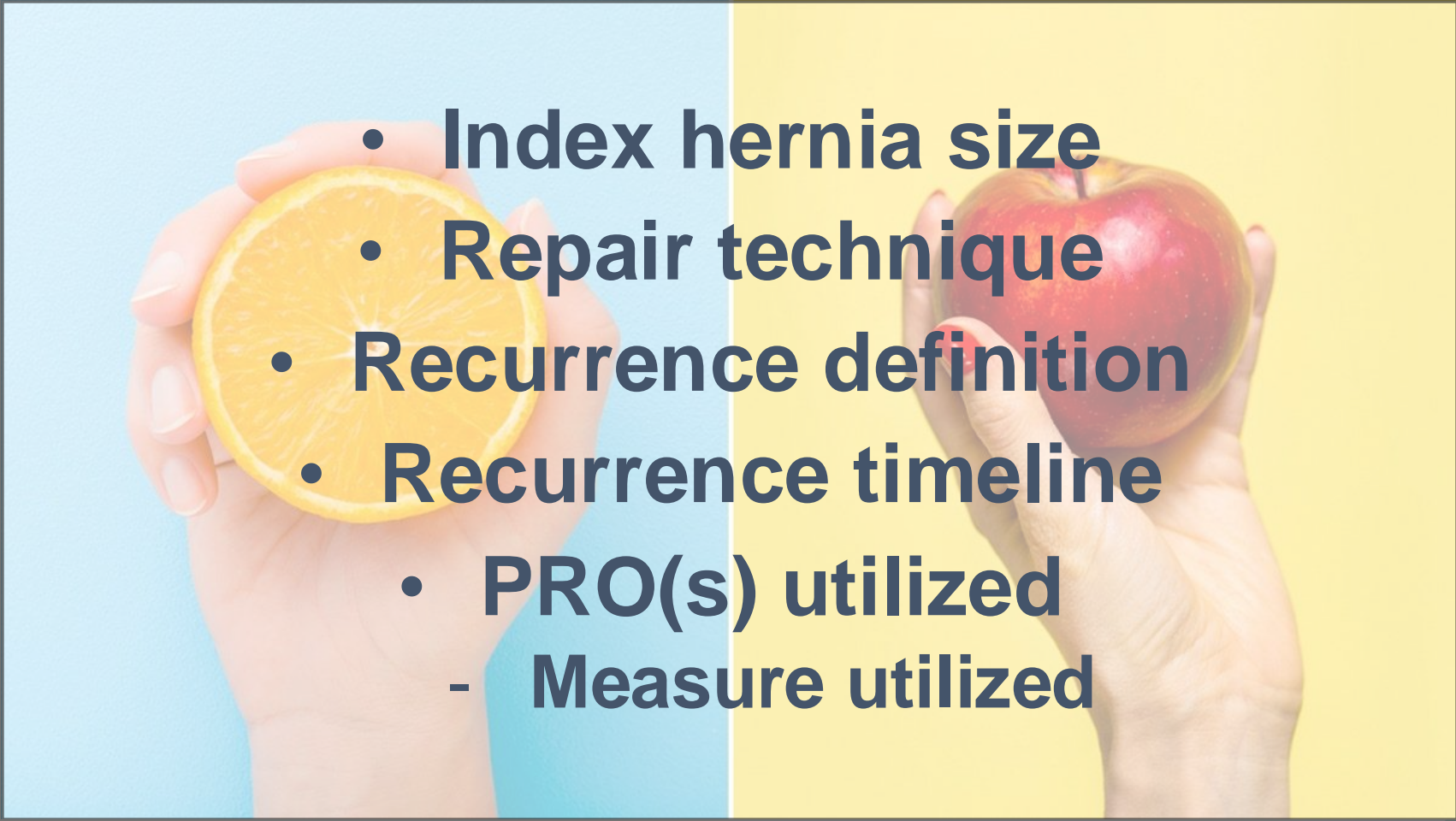


Does *Recurrence* Size Correspond to  $Sx$ ?

Yes, but...

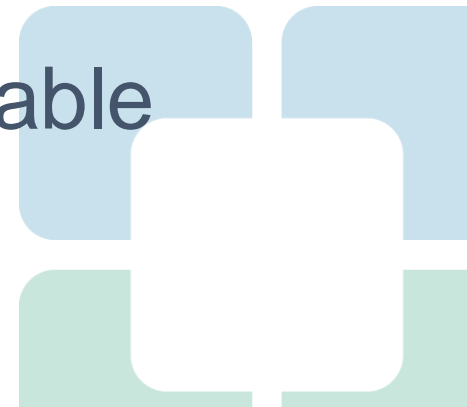


# Does Size Correspond to Sx?

- 
- **Index hernia size**
  - **Repair technique**
  - **Recurrence definition**
  - **Recurrence timeline**
  - **PRO(s) utilized**
    - **Measure utilized**

# Aims

1. For large PEH's (index  $\geq 5$ cm) what do **patient-reported outcome (PROs)** suggest about **clinically significant** recurrence size?
2. Do 2-5 cm recurrences behave like  $\geq 5$ cm recurrences? (Or 0-2cm?)
3. Did patients receiving **reoperation** have detectable trends in their **PRO** measures?



# Methods

- Post-hoc of RCT evaluating PEH radiographic recurrence and PROs @ 1 year ( $\pm$  6 months) after MIS-PHER
- Patients with *non-immediate* reoperation identified (immediate reoperations **excluded**)
- Blinded review of CT, MRI, or UGI series by at least 3 surgeons to characterize recurrence size

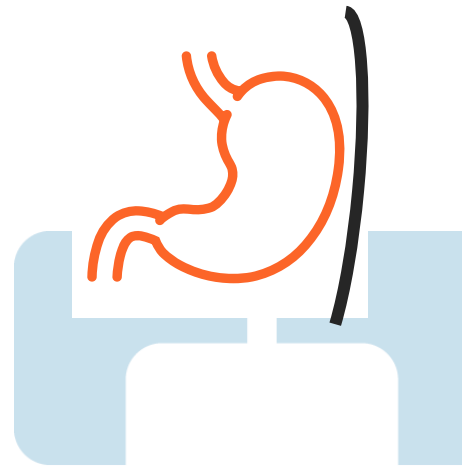


# Anterior Gastropexy *Petro et al.*

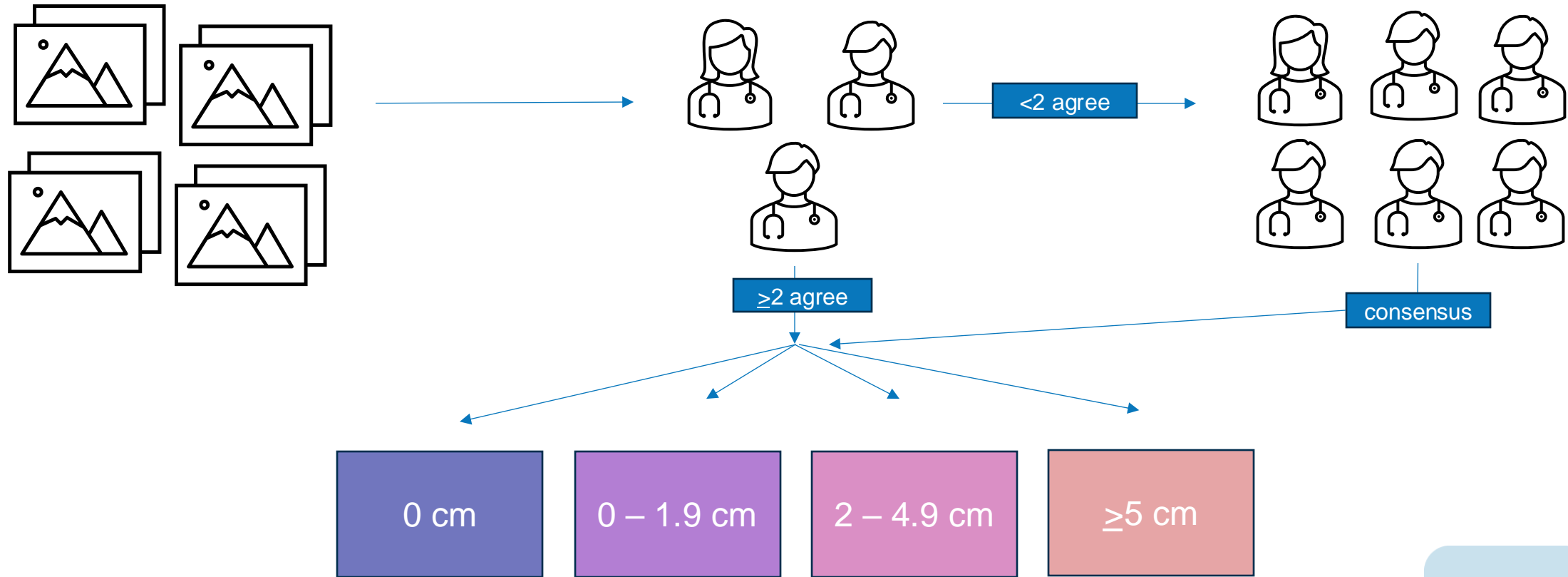
- 240 adult patients underwent MIS-PEHR for Type II to IV hiatal hernias  $\geq 5$ cm height (no mesh, no Collis)
- Randomized to **anterior gastropexy** or **no gastropexy**
- Exclusion: recurrent PEH, h/o gastric operation, mesh use, emergent operations
- Operative characteristics and stored in in registry
- Follow-up:
  - PROs captured at 30 days (+/-15d), 1 (+/- 6m)
    - GERD-HRQL
    - Foregut VAS
  - Imaging (CT, UGI, MRI, EGD) @ 1 (+/- 6m)



vs



# Post-Hoc Image Review



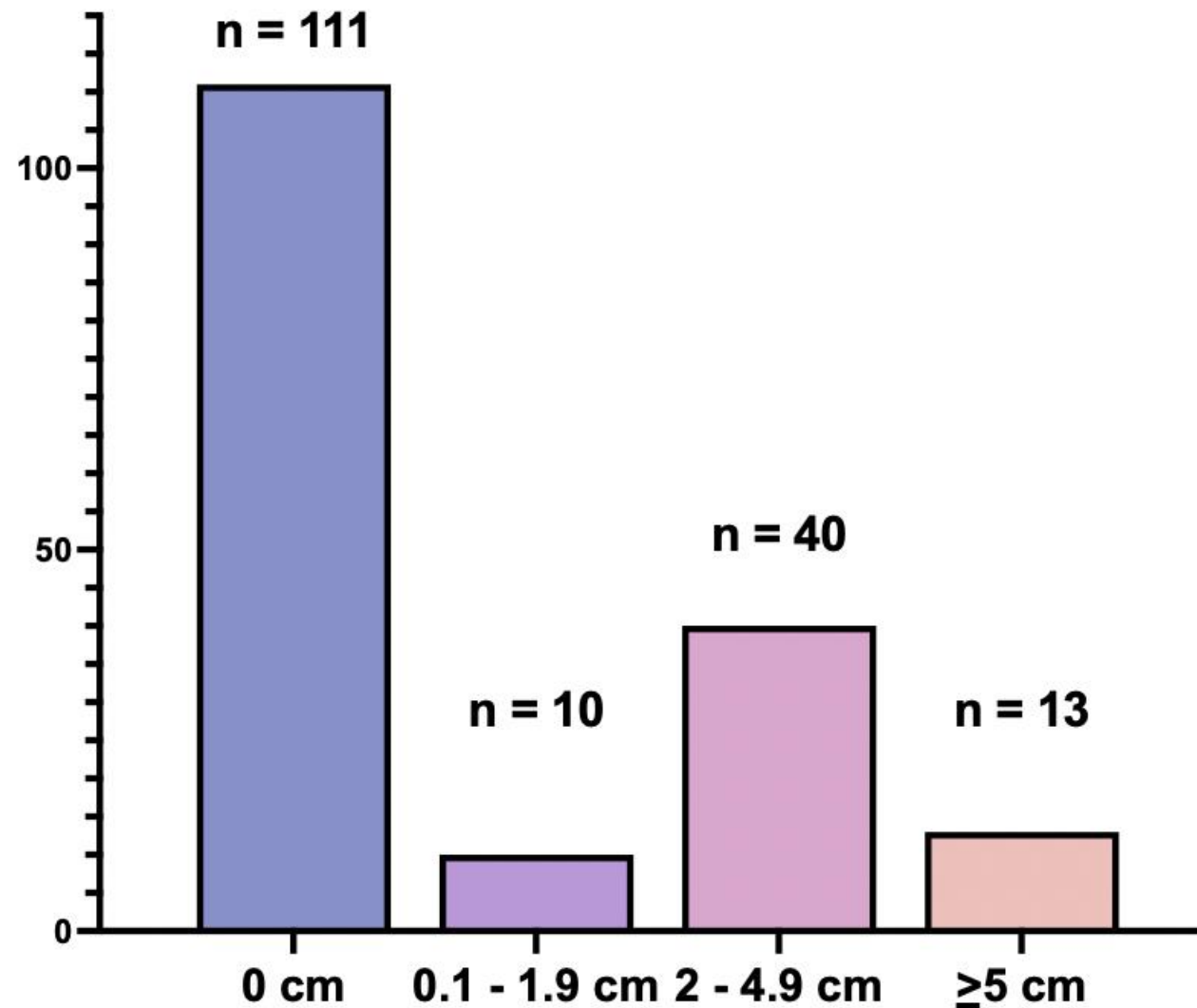
- Images reviewed by  $\geq 3$  of 6 surgeons for majority rules consensus
- If no consensus, all 6 discussed the image until consensus reached

# Post-Hoc Cohorts

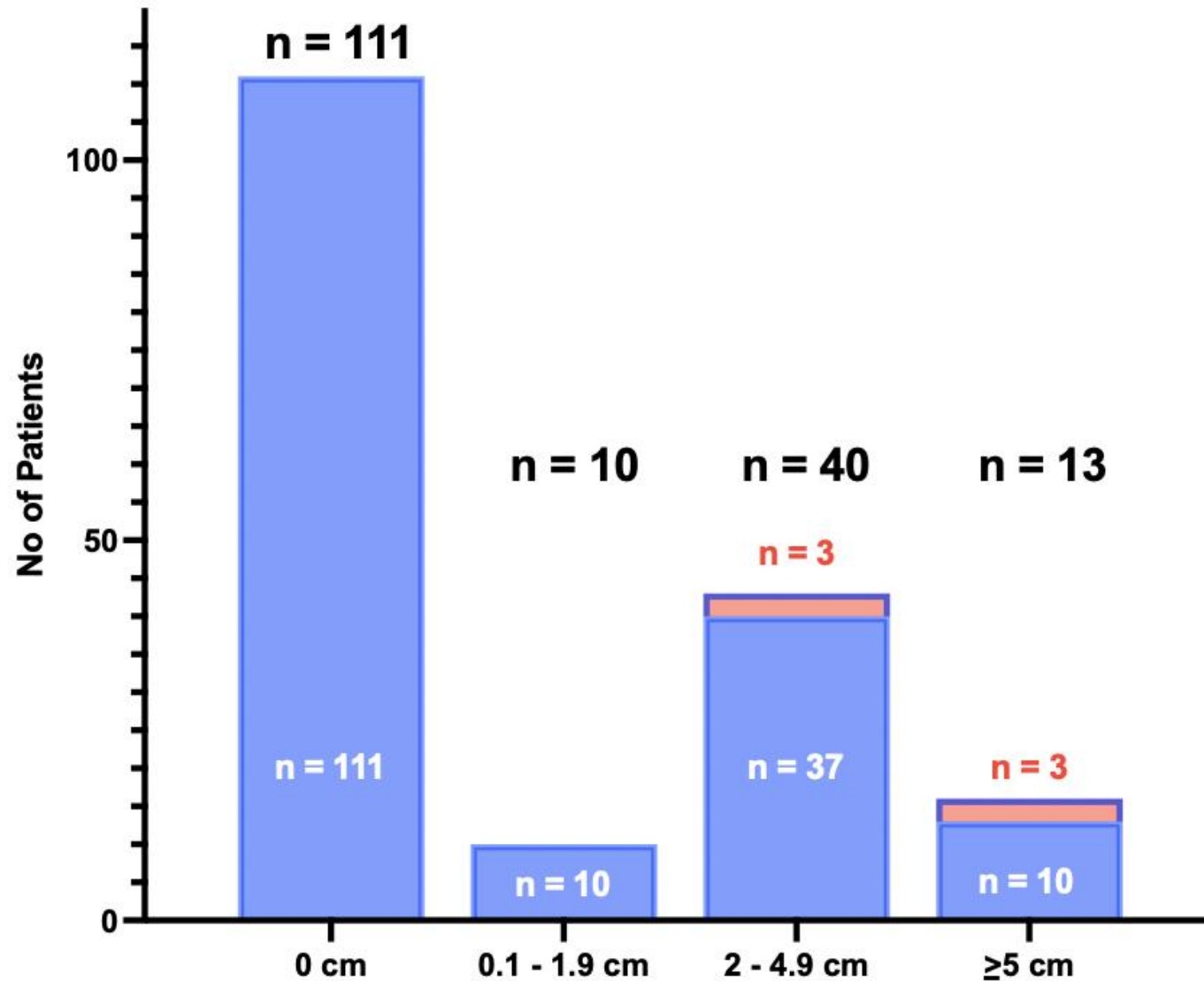
- 174 (72.5%) patients with imaging study and PROs
  - 6 (3.4%) had a non-immediate reoperation
- Baseline Characteristics
  - Median age of 70 years [IQR 64, 75.3]
  - 86.2% were female (n=150)
  - No differences between size groups or reoperation groups
- Operative Characteristics
  - 23% received fundoplication (n=40)
  - Anterior gastropexy inversely associated with size ( $p=0.0015$ )
  - Anterior gastropexy not associated with reoperation



# Recurrence Groups by Size



# Groups with Reoperation



# Post-Hoc Cohort Timing

- Follow-up timing (all) median [IQR1, IQR3]
  - Surgery to survey of 290 days [219, 346.8]
  - Surgery to image of 363.5 days [292.3, 429]
  - Absolute difference of survey to image of 53 days [17.3, 181.8]



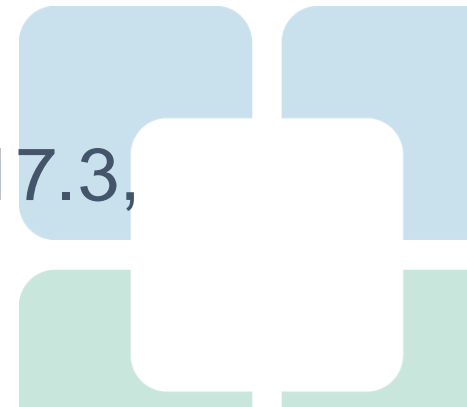
# Post-Hoc Cohort Timing

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# Post-Hoc Cohort Timing

- **Follow-up timing (all)** median [IQR1, IQR3]
  - Surgery to survey of 290 days [219, 346.8]
  - Surgery to image of 363.5 days [292.3, 429]
  - Absolute difference of survey to image of 53 days [17.3, 181.8]
- **Follow-up timing (reoperative)**
  - Surgery to reoperation of 248 days [131.5, 309]
  - Survey to reoperation was 154.5 days [91, 188]
  - Image to reoperation was 26 days [3, 78.3]
  - Absolute difference of survey to image of 53 days [17.3, 181.8]



# PROs – GERD-HRQL

<u>GERD-HRQL</u>						
<b>1. How bad is your heartburn?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>2. Heartburn when lying down?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>3. Heartburn when standing up?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>4. Heartburn after a meal?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>5. Does heartburn change your diet?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>6. Does heartburn wake you from sleep?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>7. Do you have difficulty swallowing?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>8. Do you have pain with swallowing?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>9. Do you have bloating or gassy feelings?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>10. If you take medications, does this affect your daily life?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>11. How satisfied are you with your present condition?</b>						
	<input type="radio"/> Satisfied	<input type="radio"/> Neutral	<input type="radio"/> Dissatisfied			

**Scale 0-5**  
0 = No symptoms  
1 = Symptoms are noticeable, but not bothersome  
2 = Symptoms are noticeable and bothersome, but not every day  
3 = Symptoms are bothersome every day  
4 = Symptoms affect daily activities  
5 = Symptoms are incapacitating, unable to do daily activities



# PROs – GERD-HRQL

**GERD-HRQL**

**1. How bad is your heartburn?**  
 0    1    2    3    4    5

**2. Heartburn when lying down?**  
 0    1    2    3    4    5

**3. Heartburn when standing up?**  
 0    1    2    3    4    5

**Scale 0-5**  
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↑ **Score** ≈ **Worse** QoL

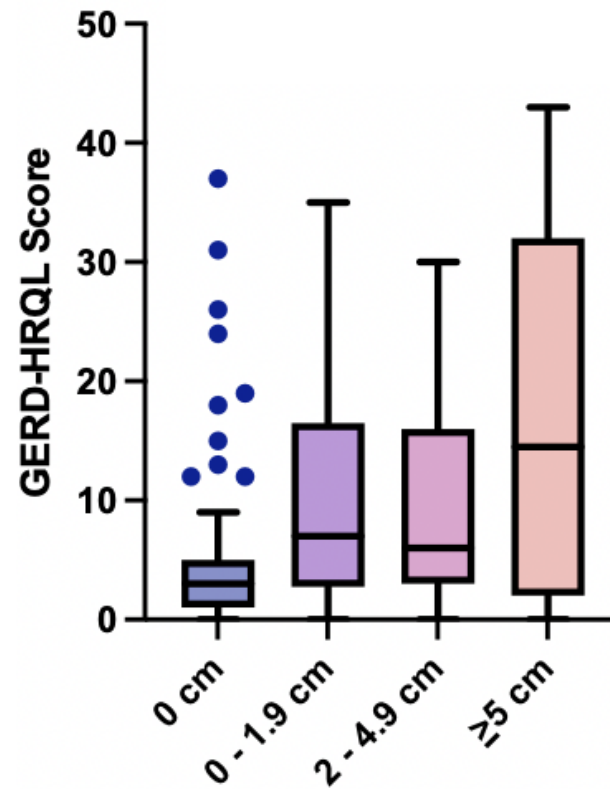
**9. Do you have bloating or gassy feelings?**  
 0    1    2    3    4    5

**10. If you take medications, does this affect your daily life?**  
 0    1    2    3    4    5

**11. How satisfied are you with your present condition?**  
 Satisfied    Neutral    Dissatisfied



# GERD-HRQL by Size



$p < 0.0001$

↑ Score ≈ **Worse** QoL

# PROs – “Heartburn”

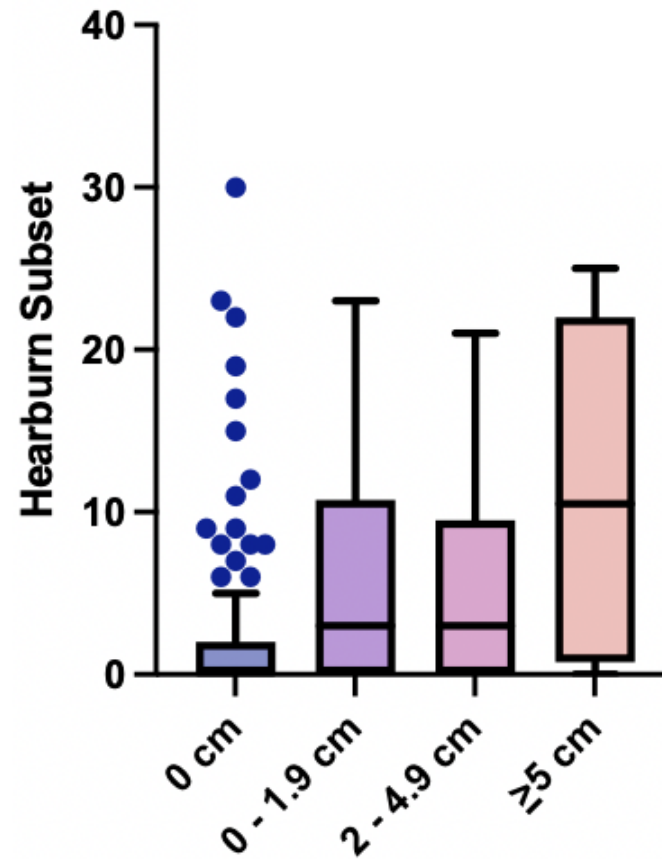
**GERD-HROI**

<b>1. How bad is your heartburn?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>2. Heartburn when lying down?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>3. Heartburn when standing up?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
<b>4. Heartburn after a meal?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
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<b>6. Does heartburn wake you from sleep?</b>	<input type="radio"/> 0	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
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↑ Score ≈ **Worse** QoL

# GERD-HRQL Heartburn Subset



$p < 0.0001$

↑ Score ≈ **Worse** QoL

# PROs – “Dysphagia”

**GERD-HRQL**

**1. How bad is your heartburn?**  
 0  1  2  3  4  5

**2. Heartburn when lying down?**  
 0  1  2  3  4  5

**3. Heartburn when standing up?**  
 0  1  2  3  4  5

**4. Heartburn after a meal?**  
 0  1  2  3  4  5

**5. Does heartburn change your diet?**  
 0  1  2  3  4  5

**6. Does heartburn wake you from sleep?**  
 0  1  2  3  4  5

**7. Do you have difficulty swallowing?**  
 0  1  2  3  4  5

**8. Do you have pain with swallowing?**  
 0  1  2  3  4  5

**9. Do you have bloating or gassy feelings?**  
 0  1  2  3  4  5

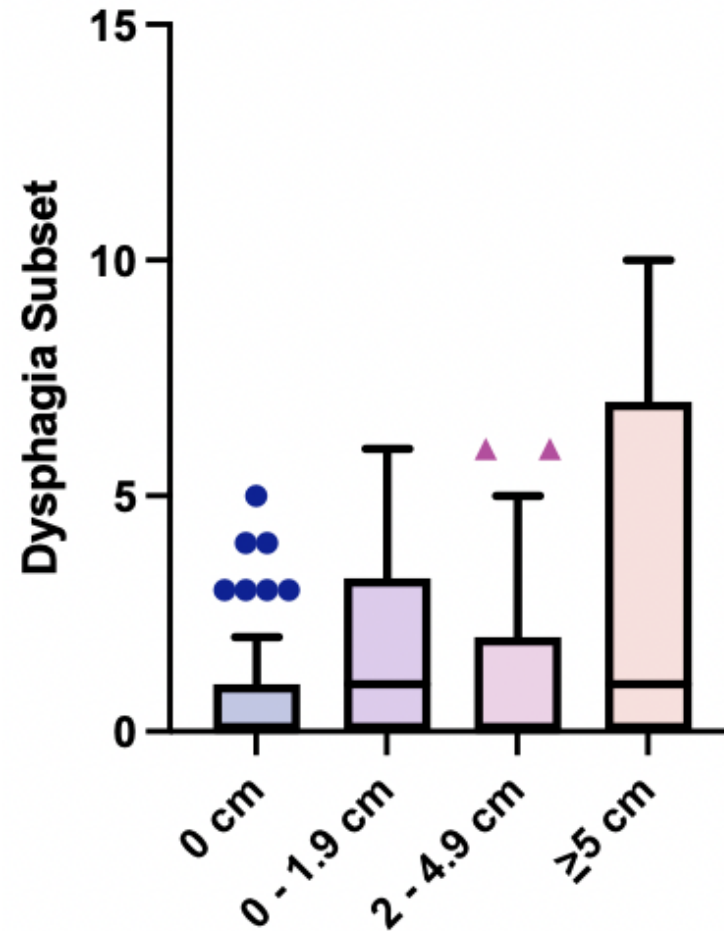
**10. If you take medications, does this affect your daily life?**  
 0  1  2  3  4  5

**11. How satisfied are you with your present condition?**  
 Satisfied  Neutral  Dissatisfied

**Scale 0-5**  
**0 = No symptoms**  
**1 = Symptoms are noticeable, but not bothersome**  
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↑ Score ≈ **Worse** QoL

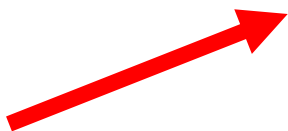
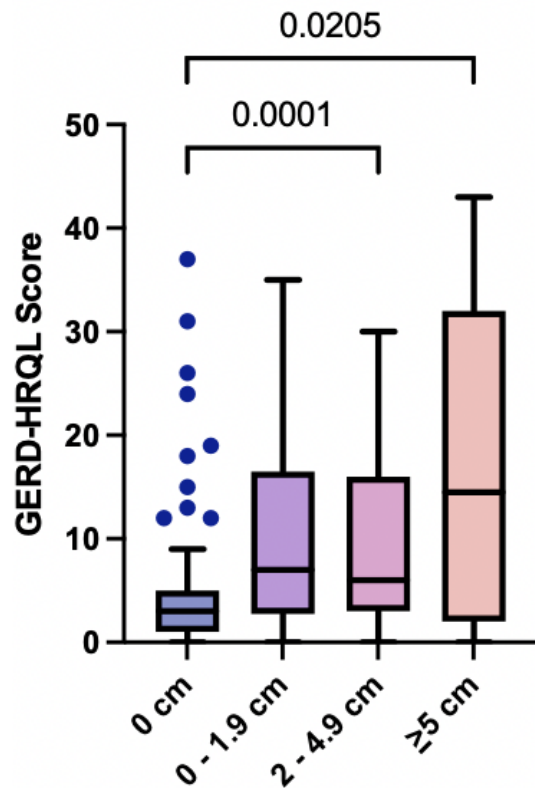
# GERD-HRQL Dysphagia Subset



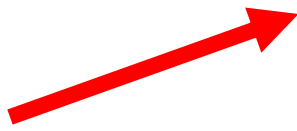
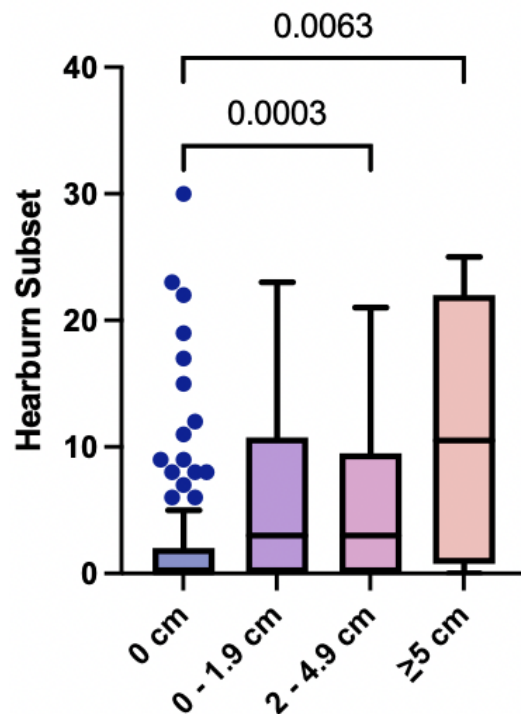
p = 0.0139

↑ Score ≈ **Worse** QoL

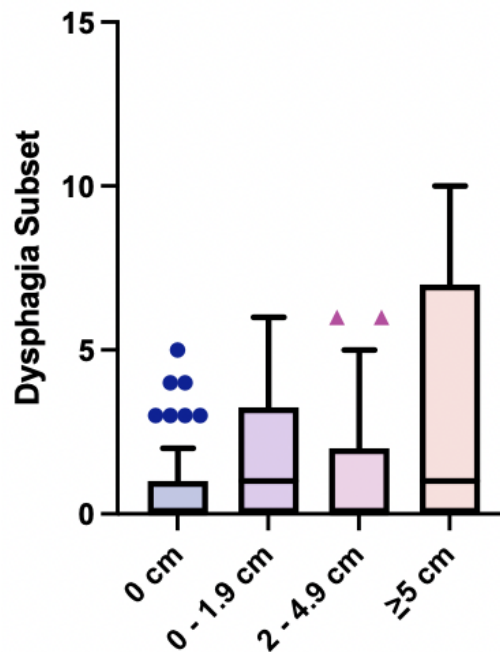
# GERD-HRQL by Size



$p < 0.0001$



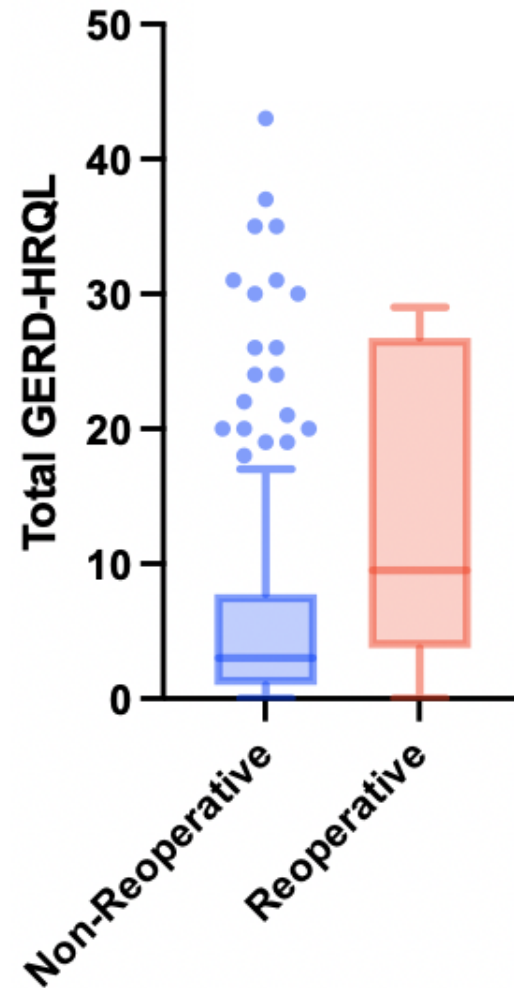
$p < 0.0001$



$p = 0.0139$

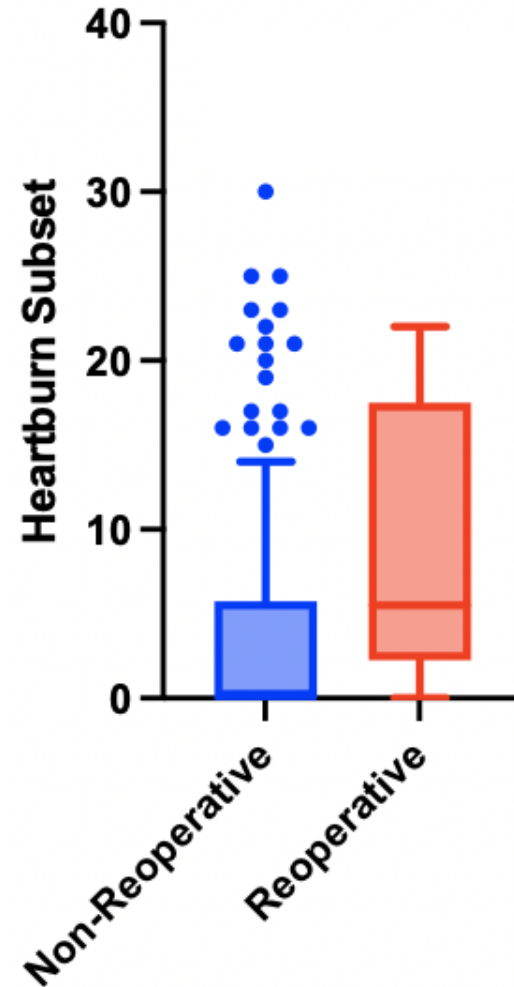
↑ Score ≈ **Worse** QoL

# GERD-HRQL by Reoperation



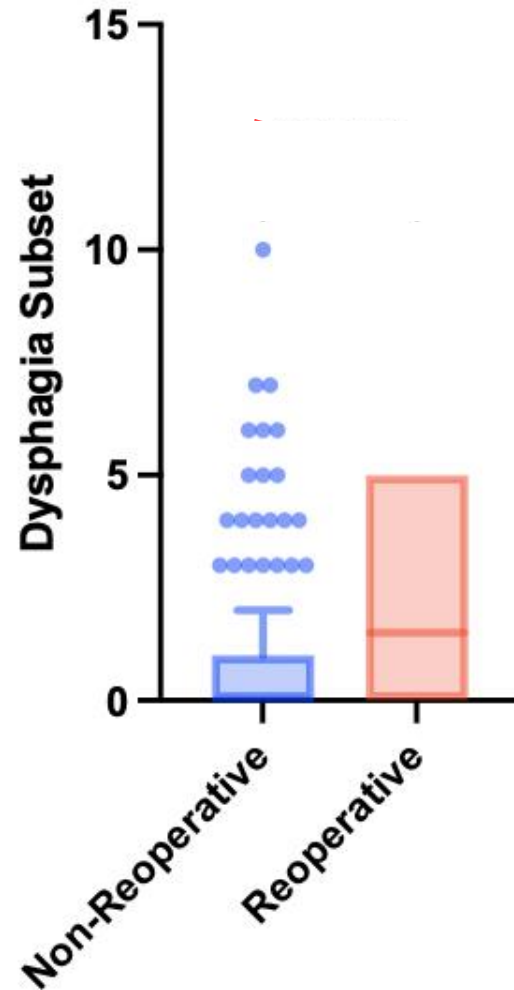
↑ Score ≈ **Worse** QoL

# Heartburn and Reoperation



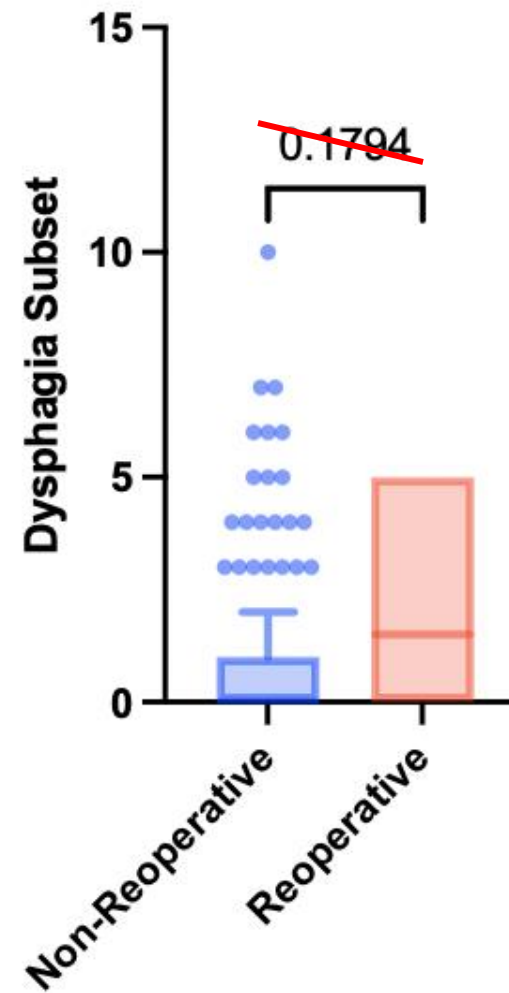
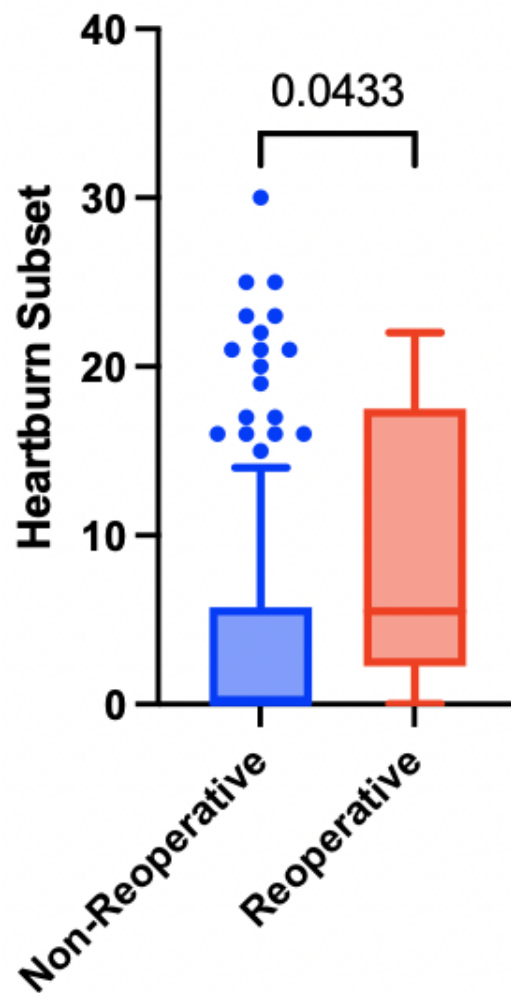
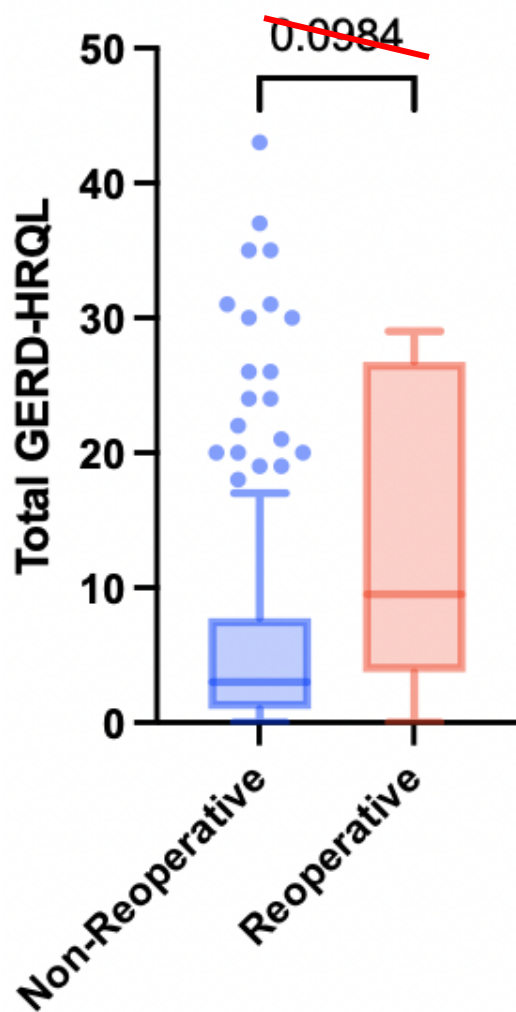
↑ Score ≈ **Worse** QoL

# Dysphagia and Reoperation



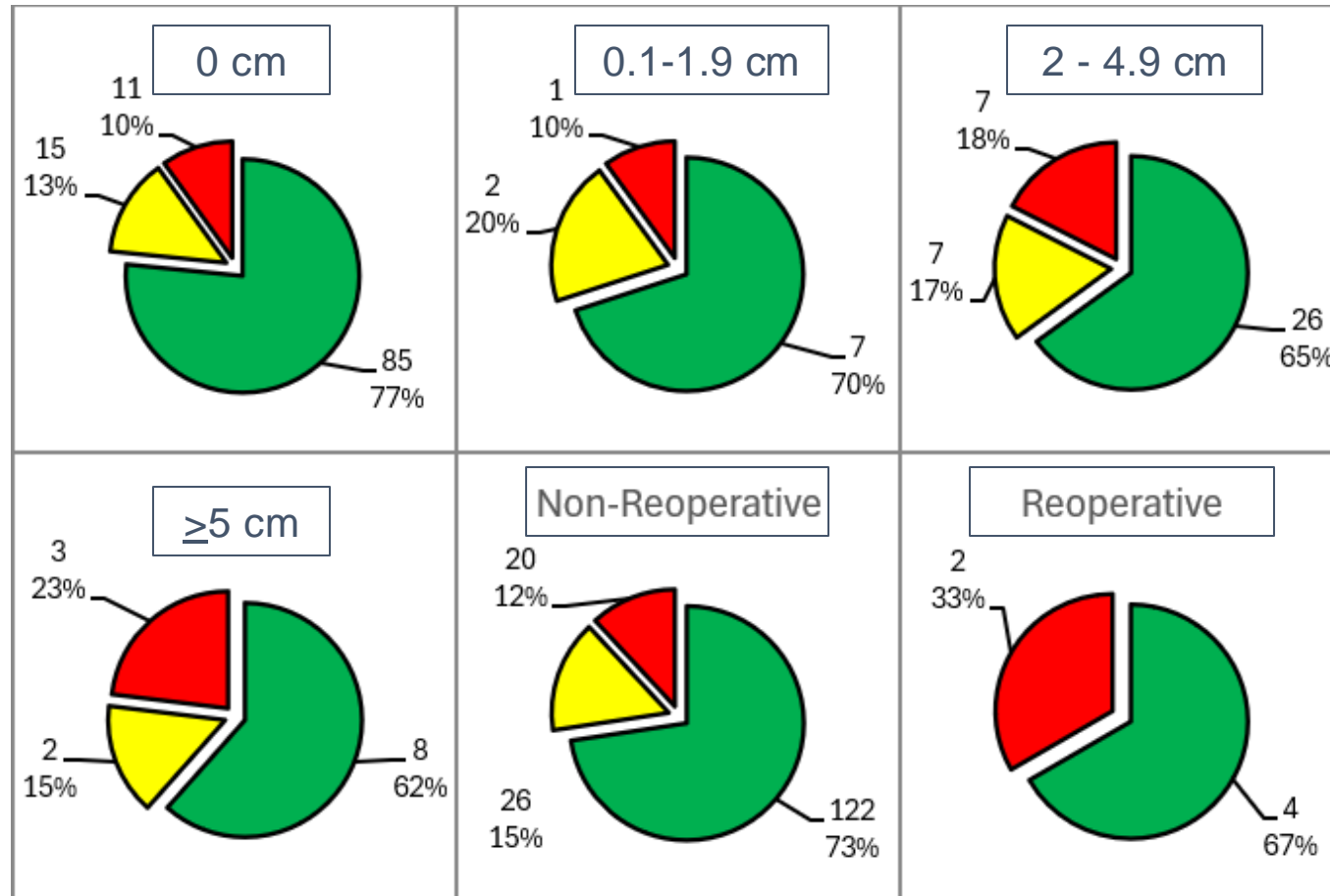
↑ Score ≈ **Worse** QoL

# GERD-HRQL by Reoperation



↑ Score ≈ **Worse** QoL

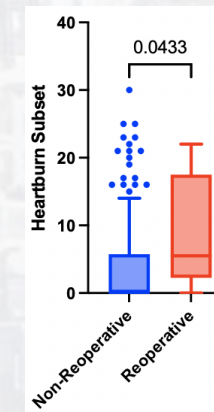
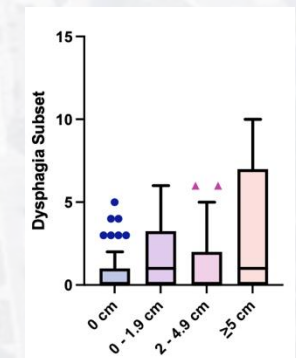
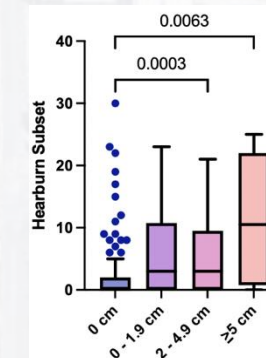
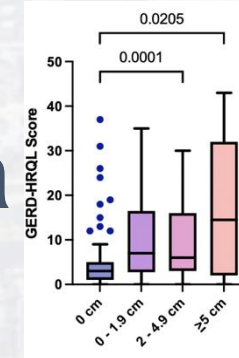
# GERD-HRQL Patient Satisfaction



p=0.3167

# 20,000 Feet: GERD-HRQL

- Size and GERD-HRQL
  - Total, **Heartburn**, and Dysphagia
  - No difference in satisfaction
- Reoperation
  - **Heartburn**
  - No difference in satisfaction



# Foregut VAS

## Other Symptoms Over Past 7 Days

**1. Regurgitation (food and/or acid backing up in your throat)**

0  1  2  3  4  5  6  7  8  9  10

**2. Chest pain**

0  1  2  3  4  5  6  7  8  9  10

**3. Abdominal (belly) pain**

0  1  2  3  4  5  6  7  8  9  10

**4. Nausea**

0  1  2  3  4  5  6  7  8  9  10

**5. Vomiting**

0  1  2  3  4  5  6  7  8  9  10

**6. Postprandial pain (pain after you eat a meal)**

0  1  2  3  4  5  6  7  8  9  10

**7. Cardiovascular (heart pain or discomfort)**

0  1  2  3  4  5  6  7  8  9  10

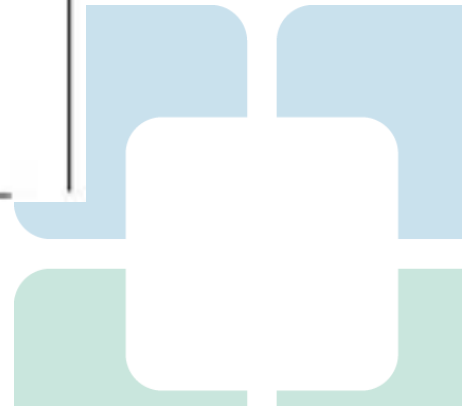
**8. Pulmonary (breathing difficulty or discomfort)**

0  1  2  3  4  5  6  7  8  9  10

**Scale 0-10**

**0 = No effect on life**

**10 = Extreme effect on life**



# Foregut VAS

## Other Symptoms Over Past 7 Days

1. Regurgitation (food and/or acid backing up in your throat)

0  1  2  3  4  5  6  7  8  9  10

Scale 0-10

0 = No effect on life

2. Chest pain

0  1  2  3  4  5  6  7  8  9  10

10 = Extreme effect on life

3. Abdominal pain

0  1

4. Nausea

0  1

5. Vomiting

0  1

6. Postprandial discomfort

0  1  2  3  4  5  6  7  8  9  10

7. Cardiovascular (heart pain or discomfort)

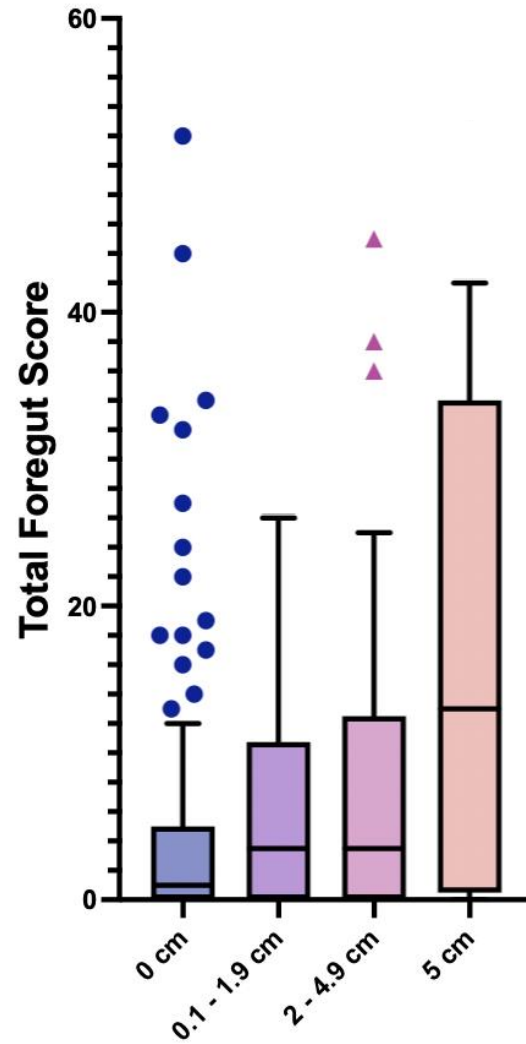
0  1  2  3  4  5  6  7  8  9  10

8. Pulmonary (breathing difficulty or discomfort)

0  1  2  3  4  5  6  7  8  9  10

↑ Score ≈ **Worse** QoL

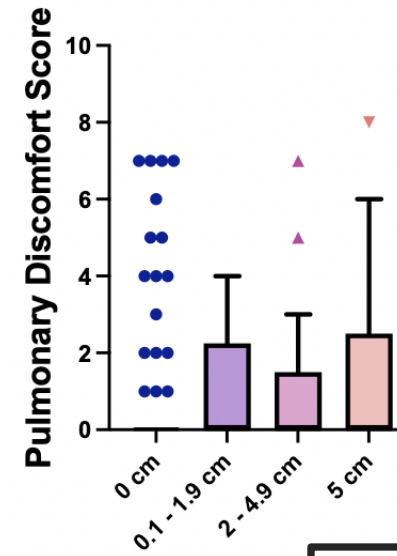
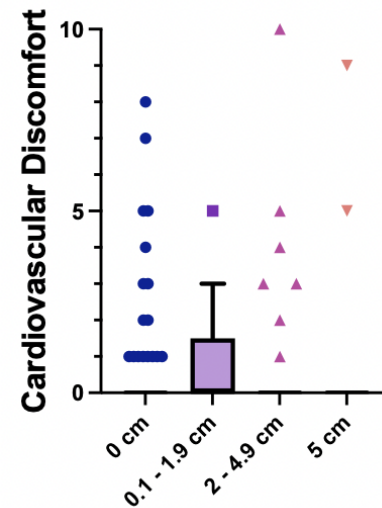
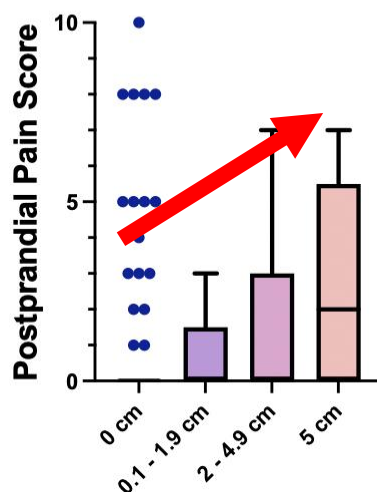
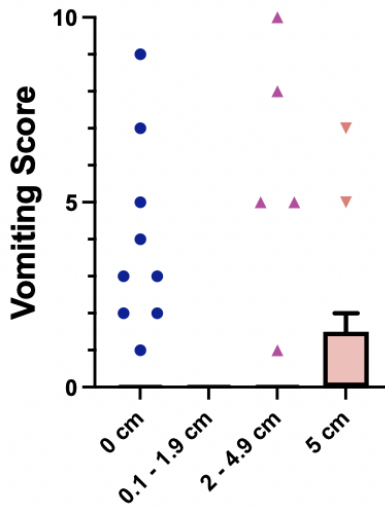
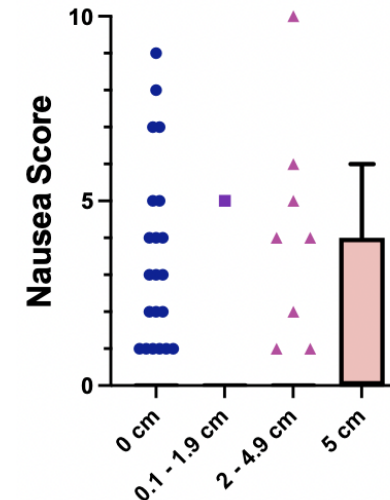
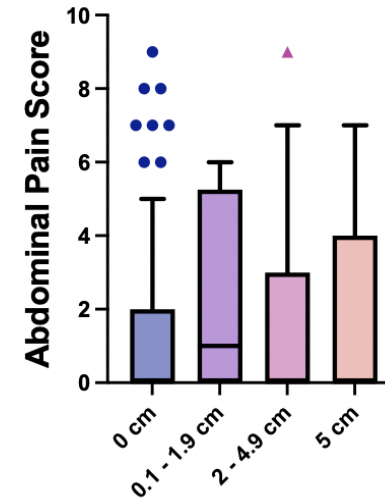
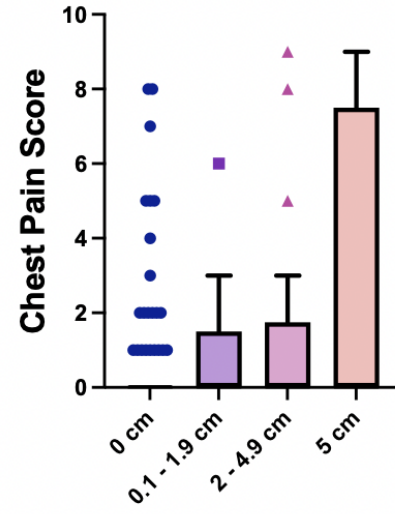
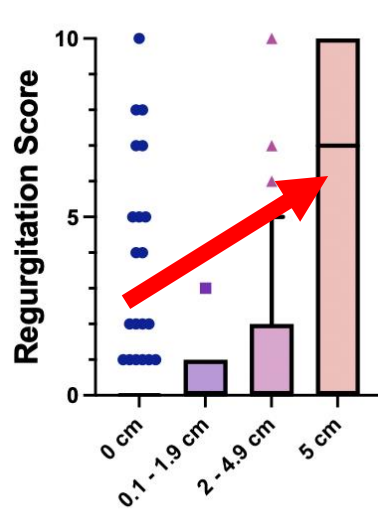
# Foregut VAS and Size Group



$p < 0.0186$

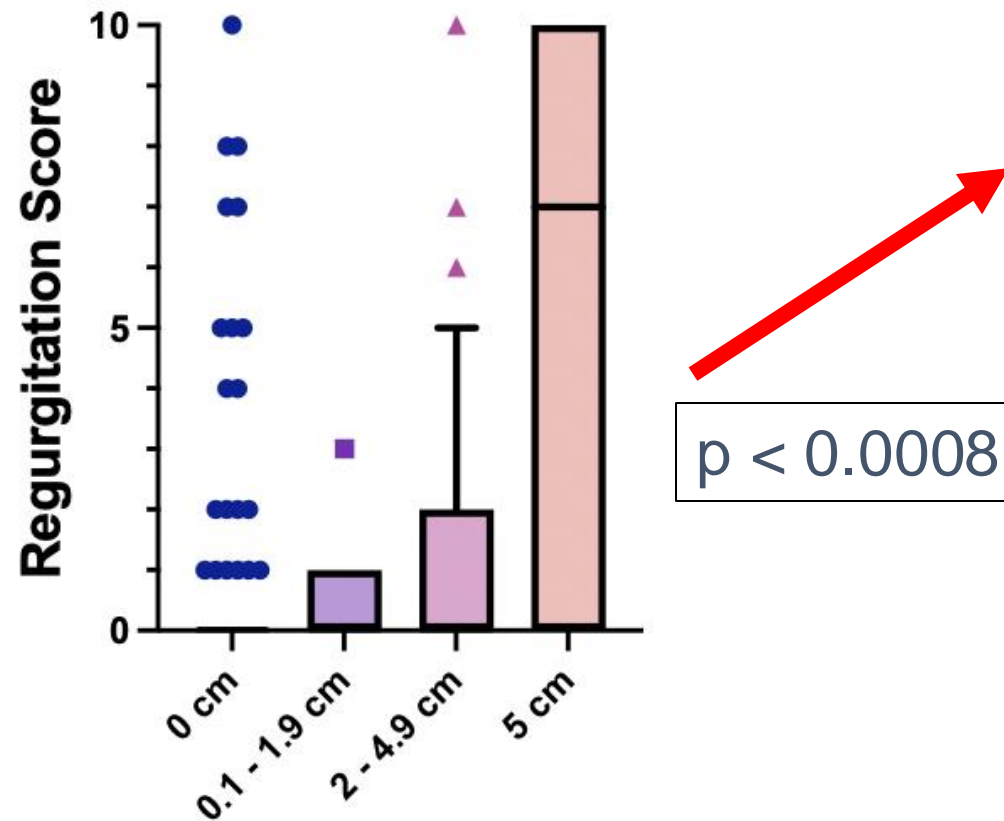
↑ Score ≈ **Worse** QoL

# Foregut VAS and Size Group



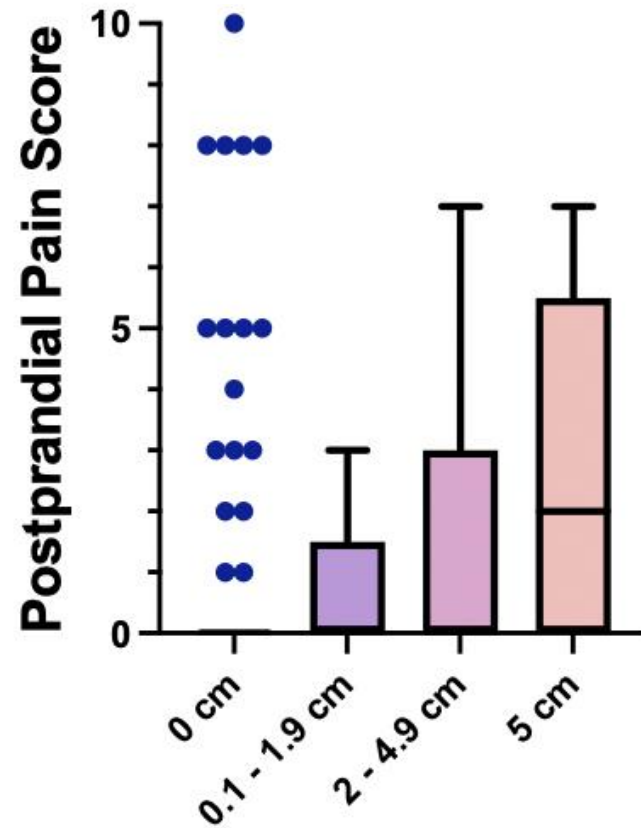
↑ Score ≈ **Worse** QoL

# Foregut VAS – Regurgitation



↑ Score ≈ **Worse** QoL

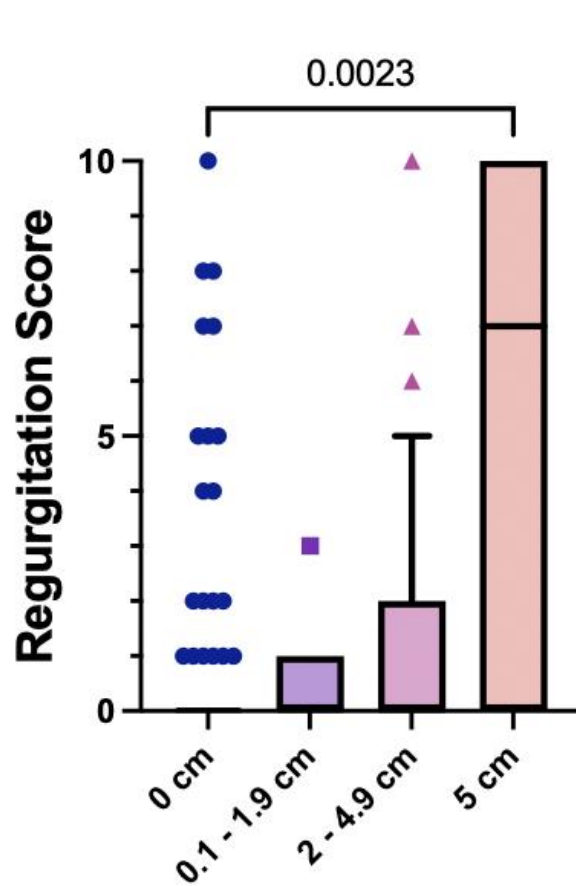
# Foregut VAS – Postprandial Pain



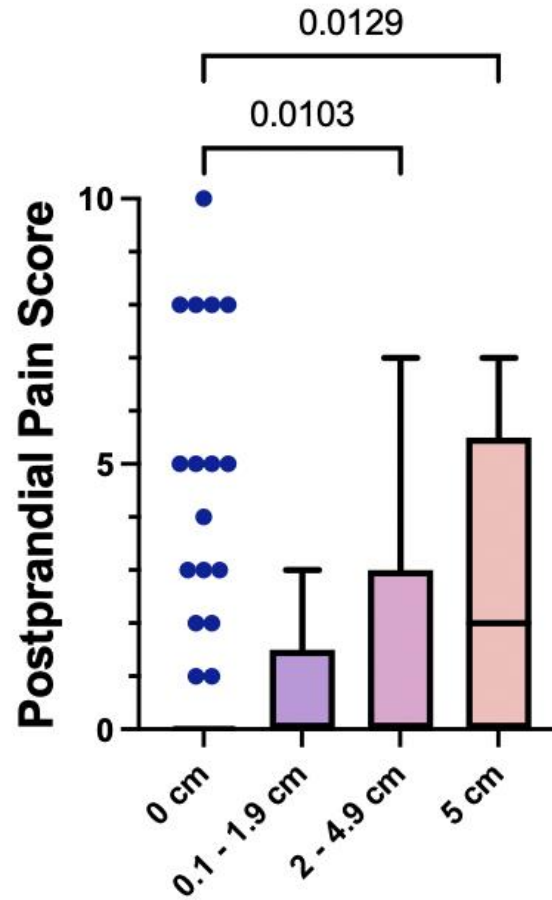
$p < 0.0007$

↑ Score ≈ **Worse** QoL

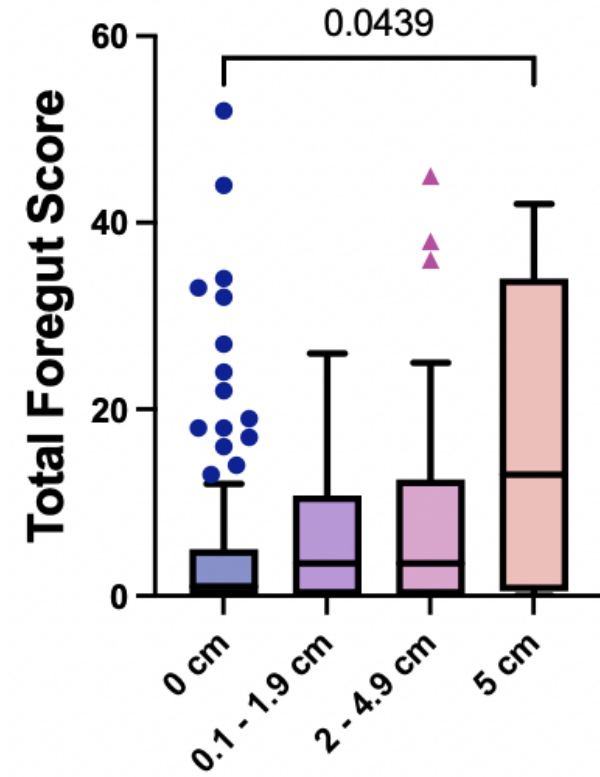
# Foregut VAS by Group



$p < 0.0008$

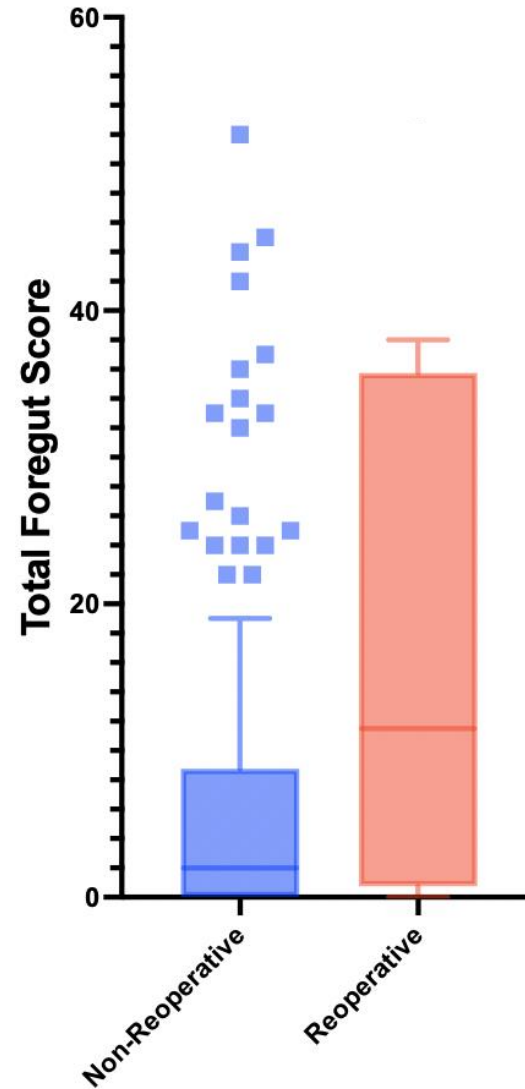


$p < 0.0007$



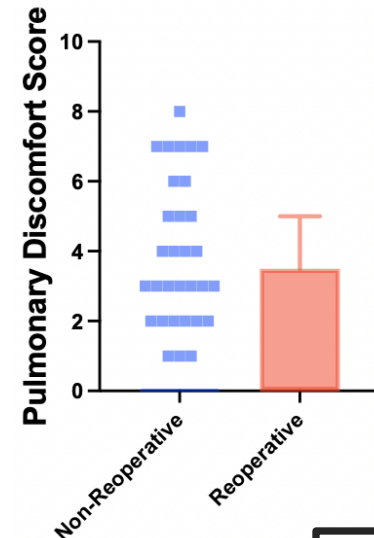
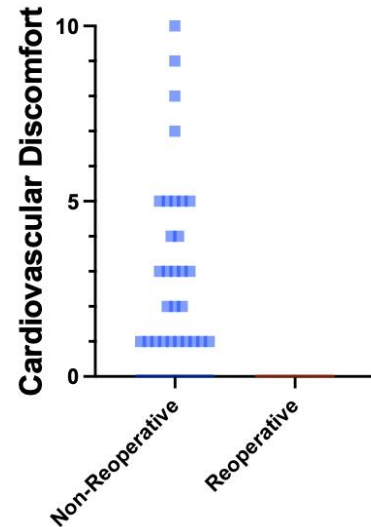
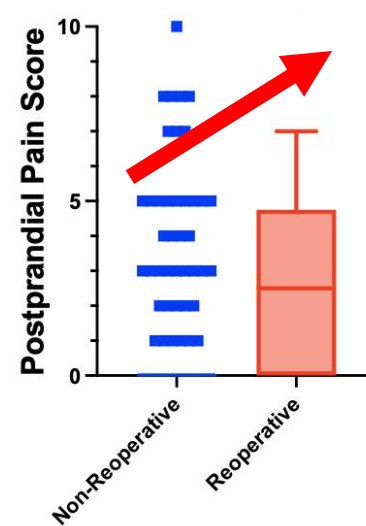
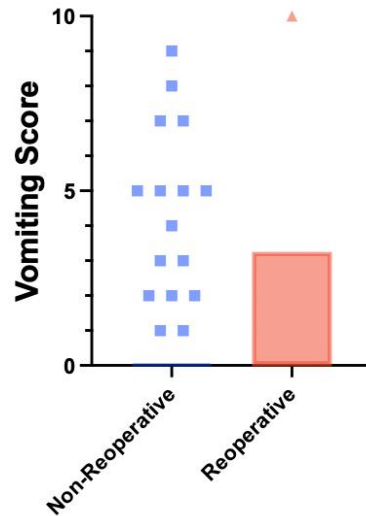
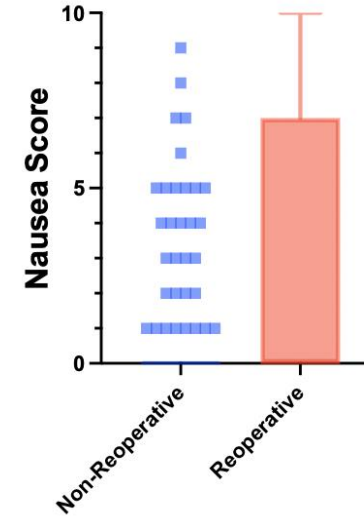
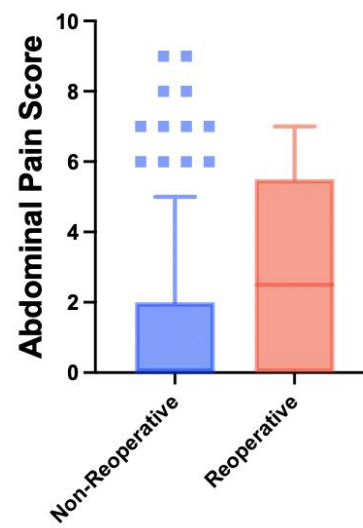
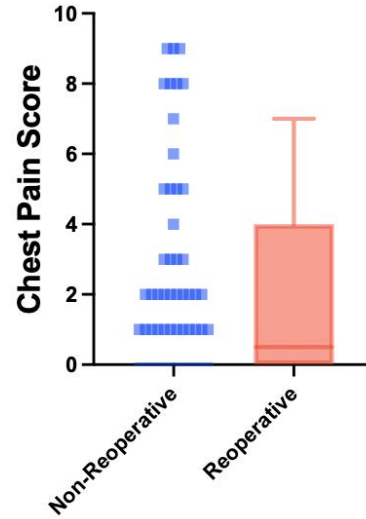
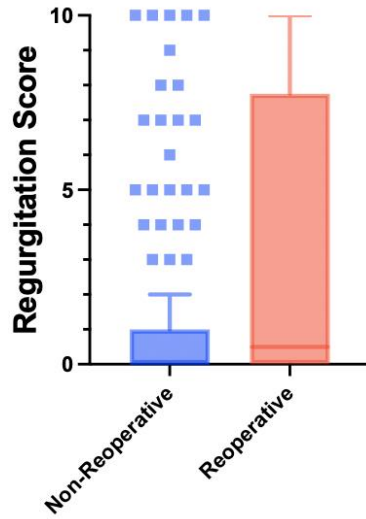
$p < 0.0186$

# Foregut VAS and Reoperation



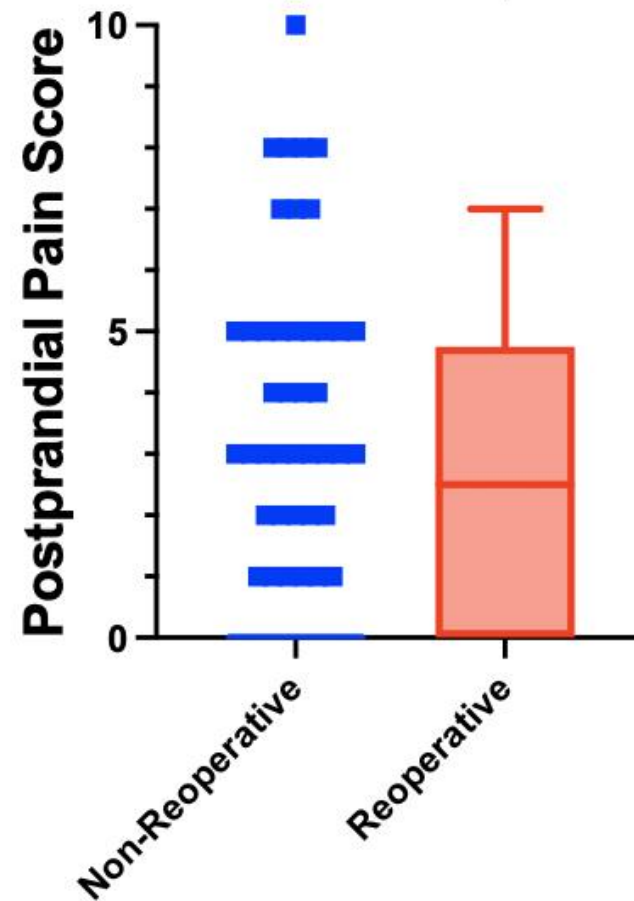
↑ Score ≈ **Worse** QoL

# Foregut VAS and Reoperation



↑ Score ≈ **Worse** QoL

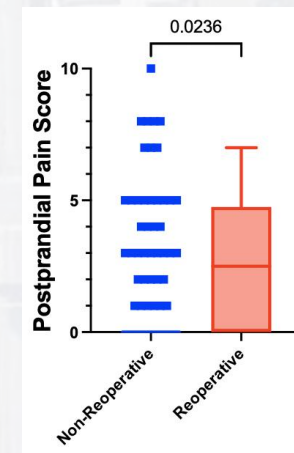
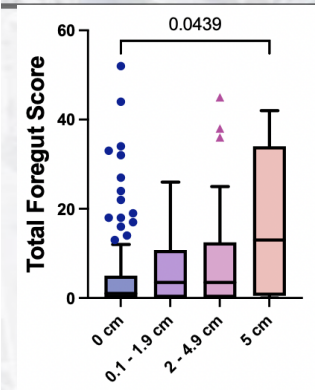
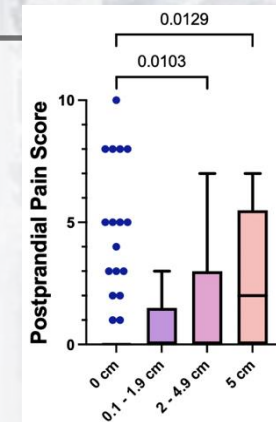
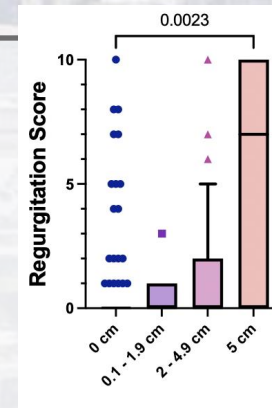
# Foregut VAS Postprandial Pain



↑ Score ≈ **Worse** QoL

# 20,000 Feet: Foregut VAS

- Size and Foregut VAS
  - Total, Regurgitation, and **Postprandial Pain**
- Reoperation and Foregut VAS
  - **Postprandial Pain**



# Can We Use Any of this Clinically?

- Screening with GERD-HRQL for recurrence  $\geq 2$ cm
- If GERD-HRQL score  $\geq 2$ 
  - Sensitivity of **90.5%** for a  $\geq 2$ cm recurrence
  - NPV **90%**
- Limited value of Foregut VAS



# Reoperation and PROs

- If GERD-HRQL Heartburn  $\geq 5$  and Post-prandial score of  $\geq 2$ 
  - Sensitivity for receiving reoperation: 67%
  - Specificity: 85%
  - NPV: 99%



# Revisiting Aims

1. For large PEH's (>5cm) what recurrence size constitutes **clinically significance** via **patient-reported outcome (PROs)** measures?
  - >2 cm and >5 cm were demonstrably different from 0cm
2. Do 2-5 cm recurrences behave like  $\geq 5$ cm recurrences?
  - Yes, no difference between groups in our analysis
3. Did patients receiving **reoperation** have detectable trends in their **PRO** measures?
  - Heartburn and Postprandial Pain



# Limitations and Considerations

- Beware “time-matching”
  - Temporal gap between PROs and surveys
  - Did *surveys* beget images, or did *acute changes* (w/o PRO representation) beget new images?
- Reoperations and PRO timing
- Small “0.1 - 1.9 cm” cohort prevented consideration of the importance of “any recurrence”



# Future Directions

- Validated (recurrent) Paraesophageal Hernia Questionnaire
  - GERD-HRQL is not validated for PEH or rPEH
  - POST survey (Menon 2023)
- Changes from baseline scores
- Further consideration of baseline and operative characteristics (index size, fundoplication)



# Future Directions

FREQUENCY						SEVERITY				
<b>Heartburn</b> (burning sensation behind breastbone)										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Regurgitation</b> (food, liquid or acid coming back into your mouth)										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Difficulty swallowing solid foods</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Chest Pain</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Abdominal Pain</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Bloating</b> (feeling of distention of the abdomen)										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Nausea</b> (feeling of vomiting)										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Pain in throat while swallowing</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4

FREQUENCY						SEVERITY				
<b>Feeling of fullness in the back of your throat</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Hoarseness</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Food or liquid getting into windpipe particularly at night</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Wheezing</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Coughing</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Shortness of Breath</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Sore Throat</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
<b>Diarrhea</b>										
	Never	Once/Month	Once/week	Once/day	several/day	Never	Mild	Moderate	Severe	Worst
Off Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4
On Anti-reflux Meds	0	1	2	3	4	0	1	2	3	4

# Conclusions

- Total GERD-HRQL (and subsets) are associated with recurrence size
- Our data support use of  $\geq 2$ cm definition
- Heartburn and Postprandial pain appear relevant for **size** and **reoperation**
- Dysphagia with limited difference between patients who did/didn't undergo **reoperation**





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# GERD-HRQL and Fundoplication

- **Total GERD-HRQL** and **Heartburn** question set were associated with fundoplication status

	<u>GERD-HRQL Total Score (0-50)</u>				<u>Heartburn Questions Score (0-35)</u>			<u>Dysphagia Questions Score (0-10)</u>		
	n	mean (SE)	median (IQR1, IQR3)	p	mean (SE)	median (IQR1, IQR3)	p	mean (SE)	median (IQR1, IQR3)	p
Fundoplication	38	3.632 (0.9547)	2.5 (0.75, 4)	<b>&lt;0.0001</b>	0.868 (0.61)	0 (0, 0)	<b>&lt;0.0001</b>	0.95 (0.26)	0 (0, 2)	0.9523
No Fundoplication	134	7.82 (0.808)	4 (1, 11)		4.9 (0.603)	2 (0, 8)		1.1 (0.17)	0 (0, 2)	

# GERD-HRQL and Fundoplication Across Recurrence Size

- The difference in **heartburn** scores persisted despite recurrence sizes

	<u>GERD-HRQL Total Score (0-50)</u>				<u>Heartburn Questions Score (0-35)</u>			<u>Dysphagia Questions Score (0-10)</u>		
	n	mean (SE)	median (IQR1, IQR3)	p	mean (SE)	median (IQR1, IQR3)	p	mean (SE)	median (IQR1, IQR3)	p
Fundo A	31	2.419 (0.425)	2 (0, 3)	0.1044	0.19 (0.11)	0 (0, 0)	0.0001	0.74 (0.24)	0 (0, 2)	0.7154
No Fundo A	80	5.58 (0.85)	3 (0.25, 7.75)		3.34 (0.68)	0 (0, 4)		0.73 (0.17)	0 (0, 0.75)	
Fundo AB	32	3.44 (1.098)	2.5 (0, 2.75)	0.1016	0.91 (0.72)	0 (0, 0)	0.0003	0.91 (0.28)	0 (0, 2)	0.636
No Fundo AB	89	5.79 (0.80)	3 (1, 8.5)		3.42 (0.63)	0 (0, 4)		0.77 (0.16)	0 (0, 1)	
Fundo CD	6	4.67 (1.59)	2.5 (2, 8.75)	0.0802	0.67 (0.42)	0 (0, 2)	0.0049	1.16 (0.65)	0.5 (0, 2.5)	0.9403
No Fundo CD	41	12.22 (1.71)	7 (3.5, 20)		8.12 (1.215)	6 (1.5, 15)		1.732 (0.4)	0 (0,3)	



# Fundoplication and Recurrence

- Fundoplication was associated with decreased risk of recurrence  $\geq 2\text{cm}$

	RR	95 lower	95 upper	RRR	X <sup>2</sup>	p
Any herniation (Group B, C, or D)	0.48	0.24	0.97	0.52	5.267	0.0217
$\geq 2\text{cm}$ herniation	0.501	0.23	1.09	0.499	3.62	0.0571
$\geq 5\text{cm}$ herniation	0.38	0.05	2.91	0.62	0.968	0.968



# Baseline Characteristics

		All Patients n = 174		Non-Reoperative Patients n = 168		Reoperative Patients n = 6	
Characteristic		Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]
Baseline	Female Gender	150	86.21%	144	85.71%	6	100.00%
	Age	70	[64, 75.3]	69	[64.51, 75.57]	60	[55.6, 63.9]
	BMI	29.07	[26.44, 31.79]	29.07	[26.44, 31.79]	31.05	[28.04, 32.7]
	Reflux	114	65.52%	110	65.50%	4	66.67%
	Dysphagia						
	None	123	70.69%	118	70.24%	1	16.67%
	Solid	22	12.64%	21	12.50%	1	16.67%
	Liquid	1	0.57%	1	0.60%	0	0.00%
	Both	24	13.79%	24	14.29%	0	0.00%
	Odynophagia	6	3.45%	6	3.57%	0	0.00%
	Regurgitation	46	26.44%	45	26.79%	1	0.60%
	Obstruction	26	14.94%	26	15.48%	0	0.00%
	Respiratory Symptoms	41	23.56%	41	24.40%	0	0.00%
	Chest Pain	86	49.43%	84	50.00%	2	33.33%
	Early Satiety	39	22.41%	37	22.02%	2	33.33%
	Anemia	9	5.17%	7	4.17%	2	33.33%
Barrett's Esophagus	12	6.90%	12	7.14%	0	0.00%	
Esophageal Stricture	1	0.57%	1	0.60%	0	0.00%	

# Operative Characteristics

		All Patients n = 174		Non-Reoperative Patients n = 168		Reoperative Patients n = 6	
Characteristic		Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]
Operative and Hospital Course	Anterior Gastropexy	91	52.30%	89	52.98%	2	33.33%
	Approach						
	Laparoscopic	157	93.45%	153	91.07%	4	66.67%
	Robot	17	10.12%	15	8.93%	2	33.33%
	ASA Class						
	ASA2	40	23.81%	39	23.21%	1	16.67%
	ASA3	125	74.40%	121	72.02%	4	66.67%
	ASA4	9	5.36%	8	4.76%	1	16.67%
	Hernia Type						
	Type I	2	1.15%	2	1.19%	0	0.00%
	Type II	5	2.87%	5	2.98%	0	0.00%
	Type III	145	83.33%	139	82.74%	6	100.00%
	Type IV	22	12.64%	22	13.10%	0	0.00%
	Short Gastrics						
	Divided	78	44.83%	75	44.64%	3	50.00%
	Fundoplication	40	22.99%	38	22.62%	2	1.19%
	Dor	1	0.57%	1	0.60%	0	0.00%
	Nissen	14	8.05%	13	7.74%	1	16.67%
	Toupet	25	14.37%	24	14.29%	1	16.67%
	OpTime (minutes)	139	(110, 170)	140	(110.75, 170)	108.5	(102.5, 152)
EBL median	10	(10, 20)	10	(10, 20)	10	(2.5, 17.5)	
LOS median	2	(2, 3)	2	(2, 3)	2.2	(1.5, 3)	
Readmit	13	0.074712644	7	0.041666667	6	1	

# Operative Characteristics Between Recurrence Groups

		Group A n = 111 (66%)		Group B n = 10 (6%)		Group C n = 40 (22%)		Group D n = 13 (6%)		
Characteristic		Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]	Quantity or Median	Percent or IQR [25th%, 75th%]	p
Operative and Hospital Course	Anterior Gastropexy Approach	70	63.06%	4	40.00%	14	37.84%	3	2.91%	<b>0.0015</b>
	Laparoscopic	100	90.09%	9	90.00%	36	97.30%	12	7.48%	>0.999
	Robot	11	9.91%	1	10.00%	4	10.81%	1	0.83%	
	ASA Class									>0.999
	ASA2	24	21.62%	2	20.00%	10	27.03%	4	2.08%	
	ASA3	83	74.77%	7	70.00%	29	78.38%	8	6.03%	
	ASA4	4	3.60%	1	10.00%	4	10.81%	1	0.83%	
	Hernia Type									0.0663
	Type I	2	1.80%	0	0.00%	0	0.00%	0	0.00%	
	Type II	2	1.80%	2	20.00%	0	0.00%	1	0.00%	
	Type III	94	84.68%	5	50.00%	35	94.59%	11	7.28%	
	Type IV	13	11.71%	3	30.00%	5	13.51%	1	1.04%	
	Short Gastrics Divided	55	49.55%	3	30.00%	18	48.65%	4	3.74%	0.4527
	Fundoplication	31	27.93%	1	10.00%	7	18.92%	1	1.46%	0.2425
	Dor	0	0.00%	0	0.00%	0	0.00%	1	0.00%	0.0652
	Nissen	9	8.11%	1	10.00%	4	10.81%	0	0.83%	
	Toupet	22	19.82%	0	0.00%	3	8.11%	0	0.62%	
	OpTime median	144	[119.5, 171.5]	142.5	[114, 180]	130	[105, 157]	104	[91, 142]	<b>0.0266</b>
EBL median	10	[10, 20]	10	[10, 20]	10	[5, 15]	10	[10, 20]	>0.999	
LOS median	2	[2, 3]	2	[1, 2]	2	[1, 3]	2	[2, 3]	>0.999	
Readmit	4	3.60%	0	0%	6	16.22%	3	0%	<b>0.0127</b>	

# GERD-HQRL Response by Reoperation

	n	<u>GERD-HRQL Total Score (0-50)</u>			<u>Heartburn Questions Score (0-35)</u>			<u>Dysphagia Questions Score (0-10)</u>		
		<u>Median</u>	<u>(IQR1, IQR3)</u>	<u>p</u>	<u>Median</u>	<u>(IQR1, IQR3)</u>	<u>p</u>	<u>Median</u>	<u>(IQR1, IQR3)</u>	<u>p</u>
Non-Reoperations	168	3	(1, 7.8)	0.0984	0	(0, 5.75)	<b>0.0433</b>	0	(0, 1)	0.1794
Reoperations	6	9.5	(5.8, 22.25)		5.5	(3.5, 13.5)		1.5	(0, 4.5)	



# GERD-HQRL Response by Size

	n	GERD-HRQL Total Score (0-50)			Heartburn Questions Score (0-35)			Dysphagia Questions Score (0-10)		
		Median	(IQR1, IQR3)	p	Median	(IQR1, IQR3)	p	Median	(IQR1, IQR3)	p
All	174	4	(1, 9)		0.5	(0, 6)		0	(0, 1)	
Group A	111	3	(1, 5.5)		0	(0, 2)		0	(0, 1.0)	
Group B	10	7	(3.25, 13.75)	<b>&lt;0.0001</b>	3	(0.5, 8.5)	<b>&lt;0.0001</b>	1	(0, 2.75)	<b>0.0098</b>
Group C	40	6	(3, 15.5)		3	(0, 9.3)		0	(0, 2.3)	
Group D	13	10	(5, 26)		6	(2, 20)		0	(0, 5)	

	Groups	Mean Rank Difference	p
GERD-HRQL Total Score	A vs C	-39.18	<b>&lt;0.0001</b>
	A vs D	-46.73	<b>0.0026</b>
GERD-HRQL Heartburn Score	A vs C	-35.06	<b>0.0002</b>
	A vs D	-48.92	<b>0.0005</b>



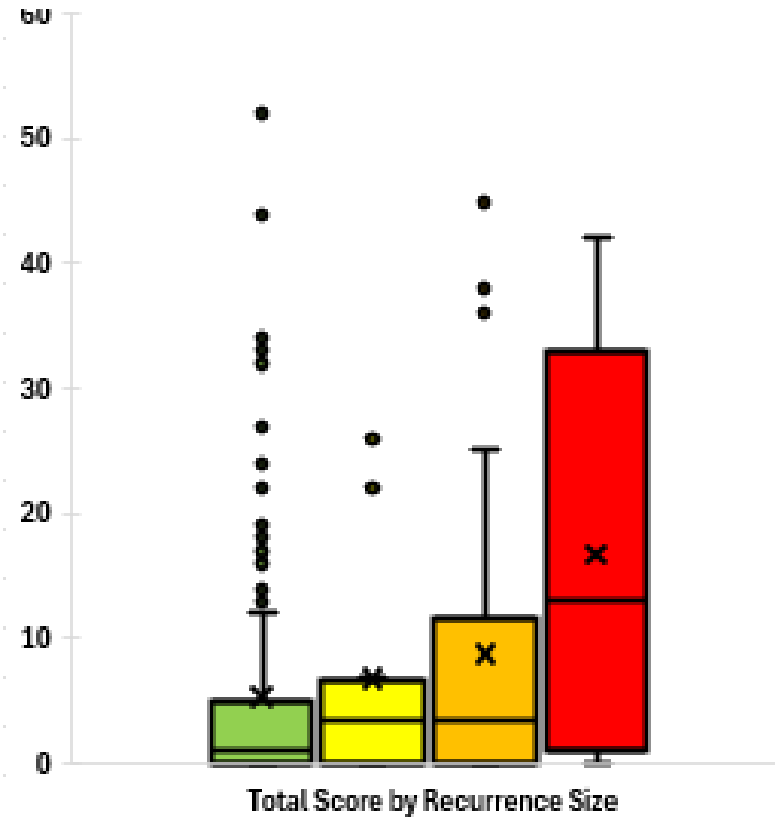
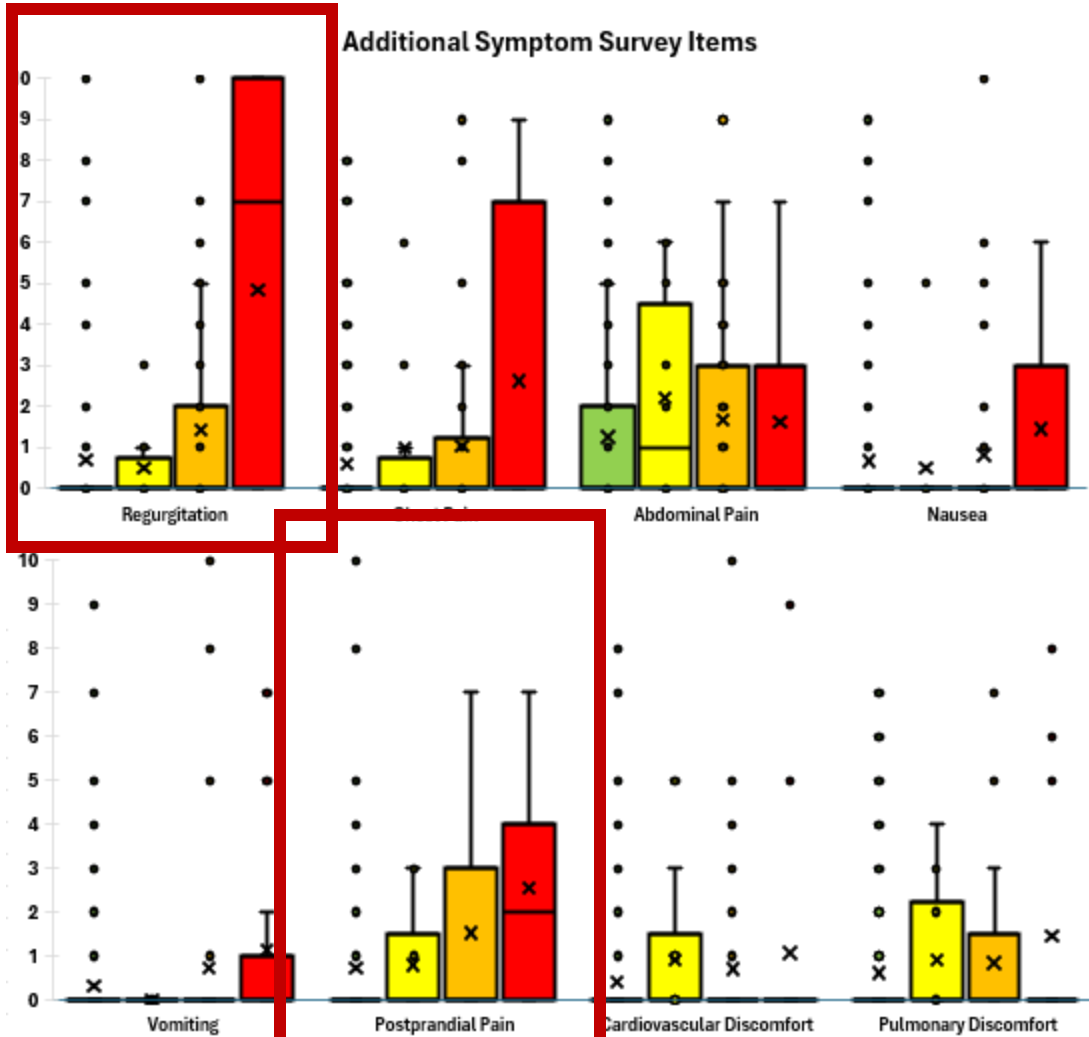
# GERD-HQRL Response by Size

	n	GERD-HRQL Total Score (0-50)			Heartburn Questions Score (0-35)			Dysphagia Questions Score (0-10)		
		Median	(IQR1, IQR3)	p	Median	(IQR1, IQR3)	p	Median	(IQR1, IQR3)	p
All	174	4	(1, 9)		0.5	(0, 6)		0	(0, 1)	
Group A	111	3	(1, 5.5)	<b>&lt;0.0001</b>	0	(0, 2)	<b>&lt;0.0001</b>	0	(0, 1.0)	<b>0.0098</b>
Group B	10	7	(3.25, 13.75)		3	(0.5, 8.5)		1	(0, 2.75)	
Group C	40	6	(3, 15.5)		3	(0, 9.3)		0	(0, 2.3)	
Group D	13	10	(5, 26)		6	(2, 20)		0	(0, 5)	

	Groups	Mean Rank Difference	p
GERD-HRQL Total Score	A vs C	-39.18	<b>&lt;0.0001</b>
	A vs D	-46.73	<b>0.0026</b>
GERD-HRQL Heartburn Score	A vs C	-35.06	<b>0.0002</b>
	A vs D	-48.92	<b>0.0005</b>



# Foregut VAS



Regurgitation	AvD	0.0023
Postprandial Pain	AvC	0.0103
	AvD	0.0129
Total	AvD	0.0439