

# OUTCOMES AMONG MAGNETIC SPHINCTER AUGMENTATION AND FUNDOPLICATION PATIENTS IN THE ROARS REGISTRY

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# DISCLOSURES

- Dr. F. P. Buckley and Dr. Reginald Bell are Consultants for Ethicon Endo-surgery.
- Ziyu Tan is an employee of Ethicon Endo-surgery.
- This was an Investigator Initiated Study funded in part by a grant from Ethicon Endo-surgery.



# BACKGROUND


## Laparoscopic vs Laparosc A Matched-F

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2019 SAGES ORAL

**Comparison of surgical payer costs and implication on the healthcare expenses between laparoscopic magnetic sphincter augmentation (MSA) and laparoscopic Nissen fundoplication (LNF) in a large healthcare system**

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e (GERD)



# BACKGROUND

- Few studies evaluate MSA versus partial fundoplication
- Multicenter study at 1 year MSA vs. Laparoscopic Fundoplication (LF)—Nissen, Toupet, other<sup>1</sup>
  - 249 patients
  - MSA less regurgitation, less PPI use, less bloating, better able to belch and vomit
- Same patients at 3 years MSA vs LF—Nissen, Toupet, other<sup>2</sup>
  - 631 patients
  - Similar outcomes for GERD symptom resolution, freedom from PPIs, belching
  - MSA better able to vomit

1. *Surg Endosc* (2015) 29:1123-1129

2. *Surg Endosc* (2021) 35:3449-3458



# FILLING THE NEED

- Registry of Outcomes in Anti-Reflux Surgery (ROARS) created to be a multi-center database
- Data collected prospectively after patients give consent
- Large multicenter database allows:
  - ✓ Comparison of outcomes across many groups, increasing generalizability
  - ✓ Variances decrease and potential biases have less effect on the data
- Use ROARS to compare long-term outcomes for Laparoscopic Fundoplication versus Magnetic Sphincter Augmentation across multiple centers.



# METHODS

- Review of ROARS prospectively collected data between 3/1/2016 and 3/1/2020
- Inclusion
  - Provided informed consent
  - Age >21 years
  - Underwent MSA or Laparoscopic Fundoplication procedure
  - > 6 months of postoperative follow up
- Exclusion
  - Incomplete demographic data
  - Incomplete or missing GERD-HRQL

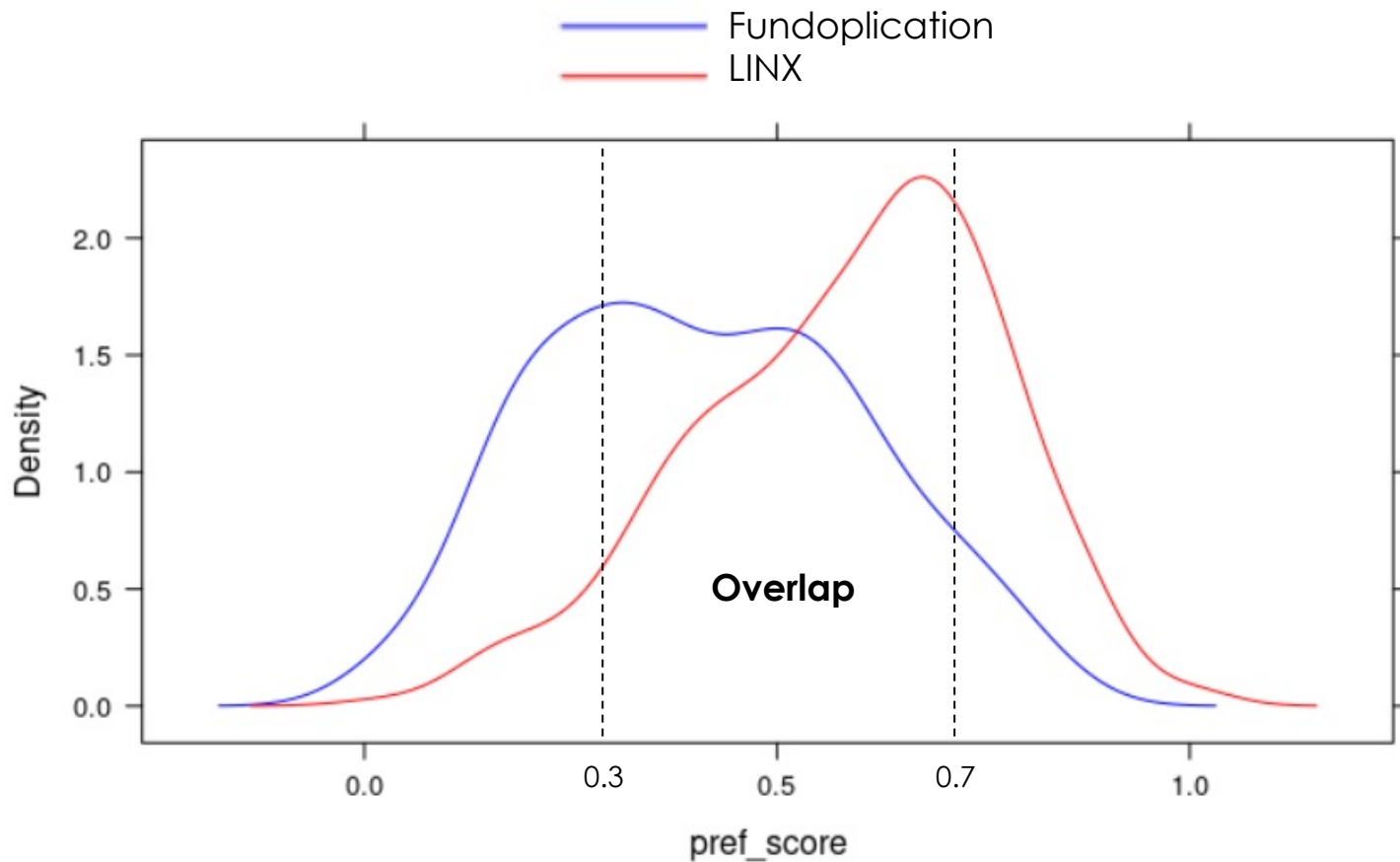


# OUTCOME EVALUATION

- Primary Outcomes
  - Ability to belch
  - Ability to vomit
- Secondary Outcomes
  - GERD Health Related Quality of Life (GERD-HRQL) Score post-operatively
  - Sub-group GERD-HRQL Scores: Regurgitation, Dysphagia, Bloating
  - Daily Acid-Suppressing Medication (ASM) use
  - Postoperative dilations
  - Reoperations
  - 30-day Complications



# METHODS



$$\ln\left(\frac{F}{1-F}\right) = \ln\left(\frac{S}{1-S}\right) - \ln\left(\frac{P}{1-P}\right)$$

F: Preference score  
S: Propensity score  
P: Group share

Percentage within the 0.3~0.7

	0	1
No	0.4013605	0.3709199
Yes(0.3~0.7)	0.5986395	0.6290801



# RESULTS

- 14 Centers contributed data to ROARS
- 959 patients consented to ROARS
- 687 (72%) met criteria including >6 month follow up
  - 436 MSA (63%)
  - 251 Laparoscopic Fundoplication (37%)
    - 186 Partial (75%)
    - 51 Nissen (21%)
    - 11 Unspecified (4%)
- Median follow-up 698 days (IQR 364-1098)



# PRE- AND PERI-OPERATIVE OUTCOMES

	LF N = 251	MSA N = 436	p-value
Age (yr, SD)	63 ( $\pm$ 13.9)	60 ( $\pm$ 13.8)	NS
BMI (SD)	29 ( $\pm$ 5.2)	29 ( $\pm$ 5.0)	NS
Female	64%	52%	<b>0.002</b>
Daily ASM	88.8%	88.7%	NS
GERD-HRQL 0-50 (IQR)	25 (4-39)	26 (12-33)	NS
Regurgitation 0-30 (IQR)	13 (6-21)	12 (4-20)	NS
Operative time (mins, IQR)	70 (51-102)	64 (45-95)	<b>0.036</b>



# POST-OPERATIVE OUTCOMES

## Primary Endpoints

	LF N = 251	MSA N = 436	p-value
Can Belch	80%	95%	<b>&lt;0.0001</b>
Can Vomit	58%	87%	<b>&lt;0.0001</b>
Dilation	5%	9%	<b>0.036</b>
Daily ASM use	18%	13%	NS
Reoperation	3%	3%	NS
Complications	2%	3%	NS

## Postoperative GERD-HRQL: median (IQR)

	LF N = 251	MSA N = 436	p-value
GERD-HRQL (0-50)	4 (4-11)	4 (4-9)	NS
Regurgitation (0-30)	0 (0-1)	0 (0-3)	NS
Dysphagia (0-10)	1 (0-2)	1 (0-3)	NS
Bloating (0-5)	1 (0-2)	0 (0-2)	<b>&lt;0.001</b>



# CONCLUSIONS

- MSA and LF(both complete and partial) control GERD symptoms equally
- Both result in low rates of dysphagia and regurgitation
- Both have low complication and reoperation rates
- MSA patients require more dilations postoperatively
- MSA results in better ability to belch and vomit postoperatively with less bloating



# ACKNOWLEDGMENTS

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THANK YOU! QUESTIONS?

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