

Evaluation of ICARUS Guidelines and Recommendations Not Supported by Randomized Controlled Trials



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Abstract

BACKGROUND

The ICARUS guidelines are a systematic review and Delphi process that provide recommendations in the treatment and management of patients with gastroesophageal reflux disease (GERD). Many of the recommendations were supported by randomized trials; some were not. This study assesses guidelines with limited evidence and weak endorsement.

METHODS

Four ICARUS guidelines were chosen: the role of fundoplication for patients with BMI>35, regurgitation, chest pain, and extra-esophageal symptoms. A multicenter database of patients undergoing fundoplication surgery for GERD between 2015-2020 was used.

RESULTS

Five institutions performed a fundoplication on 462 patients for GERD with a median of follow-up of 14.7 months (IQR 14.2). On multivariate analysis, patients with the chosen pre-operative comorbidities achieved comparable post-operative benefits.

DISCUSSION

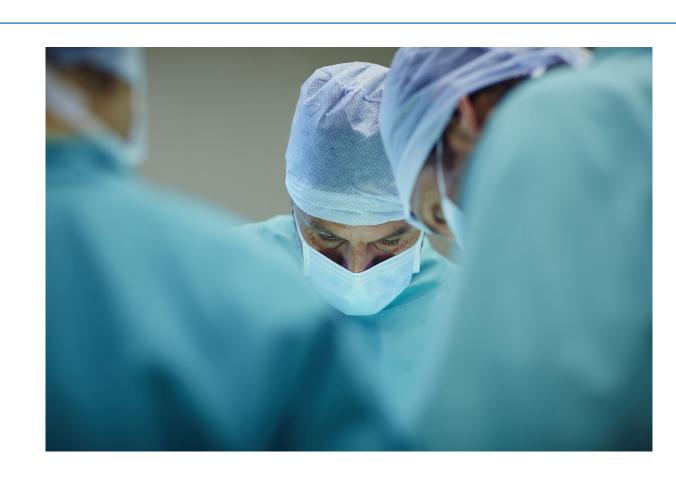
The results of this multicenter study evaluated outcomes of patients with various pre-operative conditions: BMI >35, chest pain attributable to reflux, extra-esophageal symptoms attributable to reflux, and regurgitation. Our findings endorse patients with these characteristics as candidates for antireflux surgery.

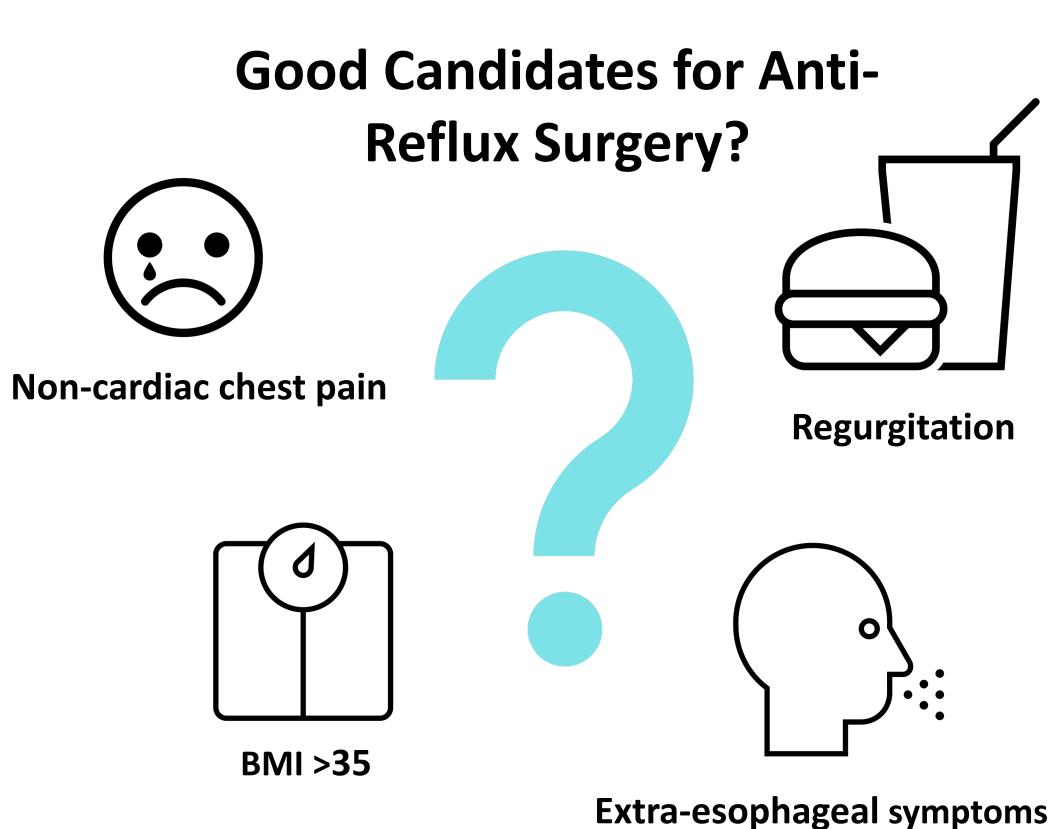
Introduction

- Gastroesophageal reflux disease (GERD) is the most prevalent gastrointestinal disorder in the United States, affecting approximately 20% of the population.
- Fundoplication surgery is known to be effective in treating GERD, with an 80% success rate at 20-year follow-up.
- The ICARUS guidelines, published in August 2019, provide current best practices for selecting patients for antireflux surgery.
- Some of the statements provided by the ICARUS guidelines were not endorsed. The ICARUS consensus group did not agree on whether patients with the following conditions are good candidates for antireflux surgery:
 - BMI >35
 - Pre-operative regurgitation symptoms
 - Non-cardiac chest pain
 - Extra-esophageal symptoms

Methods and Materials

- A retrospective chart review was conducted on all patients who underwent fundoplication surgery at five institutions from June 2015-March 2020.
- Patients were excluded if they did not meet a pre-op diagnosis of GERD (based on EGD, pH probe, and self-report symptoms).
- Univariate analysis was performed using chi square for categorical outcomes and a two-tailed t-test or Mann Whitney U test for continuous outcomes.
- Multivariable logistic regression analysis was performed choosing independent variables based on the selected ICARUS guidelines. Additional variables that were controlled for included age, gender, race, and institution.





Patient Variables		
Patient Variables	N= 462	
Age , y, mean ± SD	54 ± 13.1	
African American, n (%)	40 (8.7%)	
Hispanic, n (%)	114 (24.7%)	
White , n (%)	236 (51.1%)	
Gender, female, n (%)	309 (66.9%)	
BMI, kg/m2, mean ± SD	29.7 ± 5.3	
COPD , n (%)	15 (3.2%)	
Diabetes mellitus, n (%)	50 (10.8%)	
Current smoker, n (%)	44 (9.5%)	
Prior abdominal surgery, yes, n (%)	205 (44.4%)	

Results

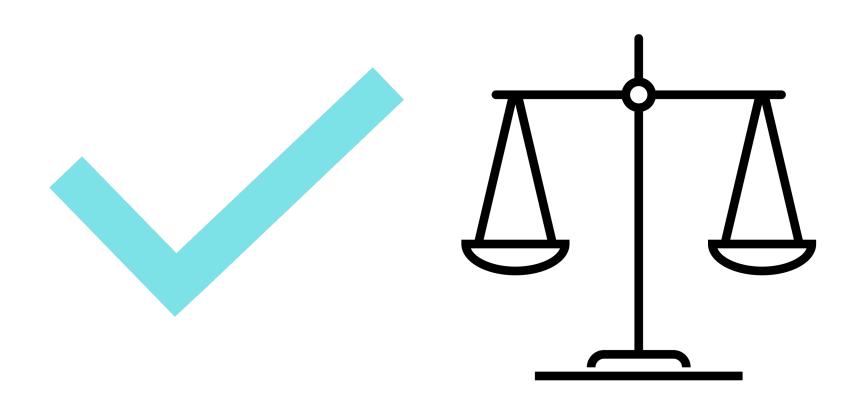
- Five institutions performed a fundoplication on 462 patients for GERD with a median of follow-up of 14.7 months (IQR 14.2).
- Patients with BMI >35 did not have statistically significantly higher rates of anatomic failure (OR 1.78, 95% CI 0.90-1.04).
- Patients with preoperative regurgitation had similar symptom recurrence rates to those without (OR 1.06, 95% CI 0.55-2.06).
- Patients with non-cardiac chest pain had comparable rates of symptom recurrence (OR 1.55, 95% CI 0.92-2.62) to patients without this preoperative symptom.
- Patients with chronic cough attributable to reflux had similar symptom recurrence rates postoperatively to patients without (OR 0.79, 95% CI 0.42-1.49).

Multivariable Regression				
Post-op Radiographic Hiatal Hernia				
Variables	Odds Ratio	95% Confidence Interval	p-value	
BMI, >35	1.779	0.90-1.04	0.099	
Post-op Symptom Recurrence				
Variables	Odds Ratio	95% Confidence Interval	p-value	
Preoperative Regurgitation	1.060	0.55-2.06	0.864	
Preoperative Chest pain	1.554	0.92-2.62	0.099	
Preoperative Cough	0.794	0.42-1.49	0.470	

Discussion

- Our findings provide support for current literature endorsing obese patients as suitable candidates for fundoplication surgery.
- Previous studies suggest that surgery is likely superior to PPIs for patients experiencing regurgitation. Our results also indicate that patients with regurgitation should consider antireflux surgery.
- When we compared post-op outcomes of patients with pre-op isolated atypical symptoms to those without, there were no significant differences. However, further studies are needed.
- Our study has several limitations, including being a retrospective review, selection bias, variability in site reporting, and length of follow-up.

Comparable Post-op Outcomes



Conclusions

- Our multicenter review examining good candidates for antireflux surgery supported several ICARUS guidelines lacking endorsement, indicating that the patient factors of BMI >35, preoperative regurgitation, non-cardiac chest pain, and extraesophageal symptoms do not limit patients from experiencing similar post-operative outcomes to patients without these preoperative characteristics.
- Additional high-quality studies are needed to improve the ICARUS guidelines further.

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