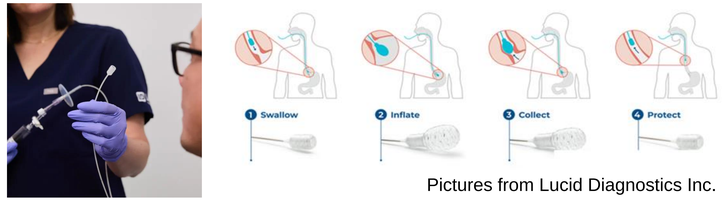
A SINGLE-INSTITUTION STUDY OF ESOCHECK/ESOGUARD IN DETECTING BARRETT'S ESOPHAGUS AMONG PATIENTS UNDERGOING HIATAL HERNIA REPAIR

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INTRODUCTION

Chronic GERD is associated with an increase in the risk of developing Barrett's esophagus (BE), which is the precursor for esophageal adenocarcinoma. The current gold standard in screening and diagnosing BE is endoscopic biopsy utilizing the Seattle protocol; however, it has shortcomings as general anesthesia is required, under-sampling routinely occurs, and prevalence of screening is low. EsoCheck is a non-endoscopic, swallowable balloon-based device used to capture esophageal DNA samples for methylation analysis through EsoGuard. The primary objective was to assess EsoGuard to screen for and detect BE compared with the current gold standard in patients undergoing hiatal hernia repair, a population with a high prevalence of chronic GERD.



Pictures from Lucid Diagnostics Inc.

METHODS

We recruited patients undergoing hiatal hernia repair at Tampa General Hospital. Patients were ≥18 years of age with no history of esophageal malignancy or esophageal surgery. On presentation to the operating room and prior to hiatal hernia repair all study participants completed esophageal sampling using EsoCheck, followed by endoscopic biopsies using the Seattle protocol.

RESULTS

Figure 1. Flowchart of patient recruitment

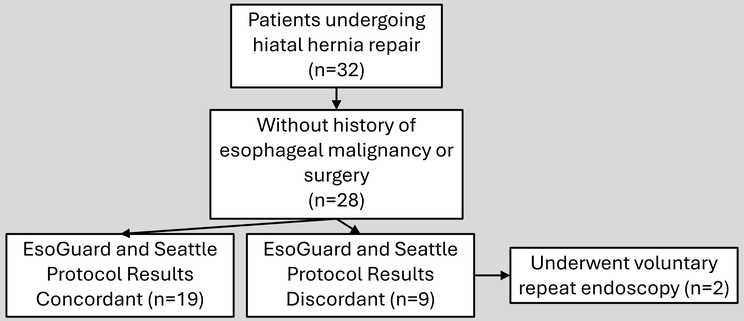


Table 1. Overall Patient Characteristics	
Age	56.9 (14.9)
BMI	28.6 (6.2)
Sex	
Male	8 (28.6%)
Female	20 (71.4%)
Race	
White	22 (78.6%)
Non-White	6 (21.4%)
Smoking	
Never	17 (60.7%)
Current	4 (14.3%)
Former	7 (25.0%)
Pack Years	3.3 (6.0)
Alcohol Use	
Yes	21 (75.0%)
No	7 (25.0%)
No. of Risk Factors	3.5 (1.1)

n (%); mean (std. dev.)

Confusion Matrix and Statistics

EsoGuard	Seattle Protocol	
	Positive	**Negative**
Positive	5	8
Negative	1	14

Sensitivity	83.3% (35.9–99.6)
Specificity	63.6% (40.7-82.8)
Positive Predictive Value	38.5% (24.4-54.7)
Negative Predictive Value	93.3% (69.5-98.9)

value (95% confidence interval)

CONCLUSIONS

Our study shows the strong potential for EsoCheck/EsoGuard as a non-invasive screening tool for BE, with excellent sensitivity and negative predictive value in a population undergoing hiatal hernia repair. While EsoGuard has value in ruling out BE, the lower specificity shows that positive results should be corroborated with the current gold standard of endoscopic biopsies following the Seattle protocol.

REFERENCES

1. Ghosal A, Verma S, Le IT, et al. Analytical Validation of a DNA Methylation Biomarker Test for the Diagnosis of Barrett's Esophagus and Esophageal Adenocarcinoma from Samples Collected Using EsoCheck®, a Non-Endoscopic Esophageal Cell Collection Device. *Diagnostics*. 2024; 14(16):1784.
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DISCLOSURES

EsoCheck devices and EsoGuard analysis were provided by Lucid Diagnostics Inc.