GI Alliance

Advancing GI Patient Care 2021

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Accredited by:

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Clinical Applications of Endoflip and Esoflip

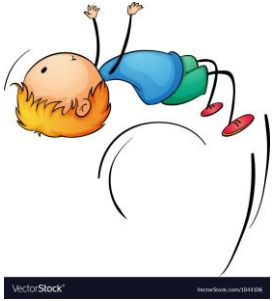
Scott D. Pollack, MD
Metropolitan Gastroenterology Associates
New Orleans, LA

Disclosures

- None
- Nothing
- Zero
- Zilch
- Zip
- Nil

What the “**Flip**” Is Endoflip?!

- **Endo**scopic
  - **F**unctional
  - **L**umen
  - **I**maging
  - **P**robe



- Available commercially since 2009
- Medtronic acquired in 2017 (Crospon)
- Currently utilizing version 2.0

Indications

ENDOFLIP™ IMPEDANCE PLANIMETRY SYSTEM APPLICATIONS

AGA EXPERT REVIEW[1]

Achalasia

Additive information beyond manometry for patient management

- Evaluation of patient with achalasia (post HRM and/or barium swallow)
- Intraoperative use during Heller myotomy or POEM
- Impedance planimetry system dilation without fluoroscopy

Eosinophilic Esophagitis

Potential role in severity assessment and therapeutic monitoring

- Objective and accurate measurement of esophageal narrowing
- Estimation of remodeling effects

GERD

Potential for physiological evaluation and management

- Further studies needed to substantiate utility in GERD management

[1]Hirano, Pandolfino, & Boeckxstaens. Functional Lumen Image Probe for the Management of Esophageal Disorders: Expert Review from the Clinical Practice Updates Committee of the AGA Institute; *Clin Gastroenterol Hepatol*. 2017 Mar;15(3):325-334.

Indications

ENDOFLIP™ IMPEDANCE PLANIMETRY SYSTEM APPLICATIONS

INTRAOPERATIVE USE[1,2]

Antireflux Surgery-Procedures

Distensibility measures of the EGJ to guide procedures

- May help guide laparoscopic Nissen fundoplication by prompting intraoperative modification
- Demonstrated utility in intraoperative anti-reflux surgery to assess EGJ distensibility pre and post-fundoplication

Heller Myotomy & POEM

Ability to assess LES myotomy in real-time

- Provides additional information to aid in the treatment in achalasia
- May provide a method to tailor myotomy to help improve dysphagia

Bariatric Surgery

FDA approved to guide therapy during bariatric procedures

- Technique to tailor bariatric procedures is still being assessed

1. Hirano, Pandolfino, & Boeckxstaens. Functional Lumen Image Probe for the Management of Esophageal Disorders: Expert Review from the Clinical Practice Updates Committee of the AGA Institute; *Clin Gastroenterol Hepatol*. 2017 Mar;15(3):325-334; 2. Illczyszyn A, Botha A. Feasibility of esophagogastric junction distensibility measurement during Nissen fundoplication. *Dis Esophagus*. 2014 Sep-Oct;27(7):637-44.

Contraindications

- Where endoscopy is contraindicated…..
- Actively bleeding varices in the esophagus…..

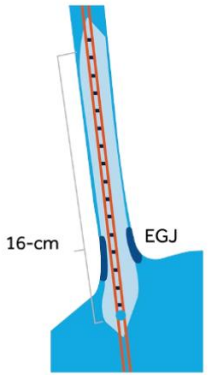
Limitations

- Quality of available evidence is low
- Comparative studies are limited
- Limited availability and high cost
  - $65,000 + $350 per catheter

How Does It Work / What Do I Do?

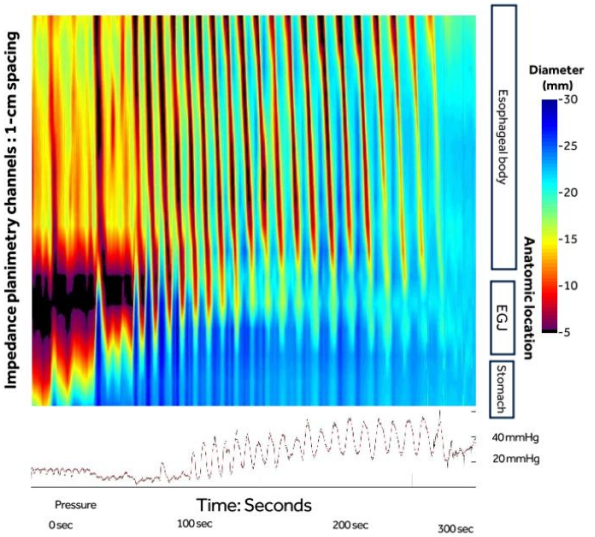
- Initial endoscopy performed to rule out mechanical obstruction and provide estimated distance to EGJ
- Balloon catheter placed orally (+/- direct visualization)
- Balloon should extend beyond the LES (3-4 cm)
- Balloon filled with 60 – 70 mL of “a specially formulated conductive solution”
- Measurements obtained
- **Voltage → Diameter/CSA → Distensibility (Ohm’s Law)**

Balloon placement



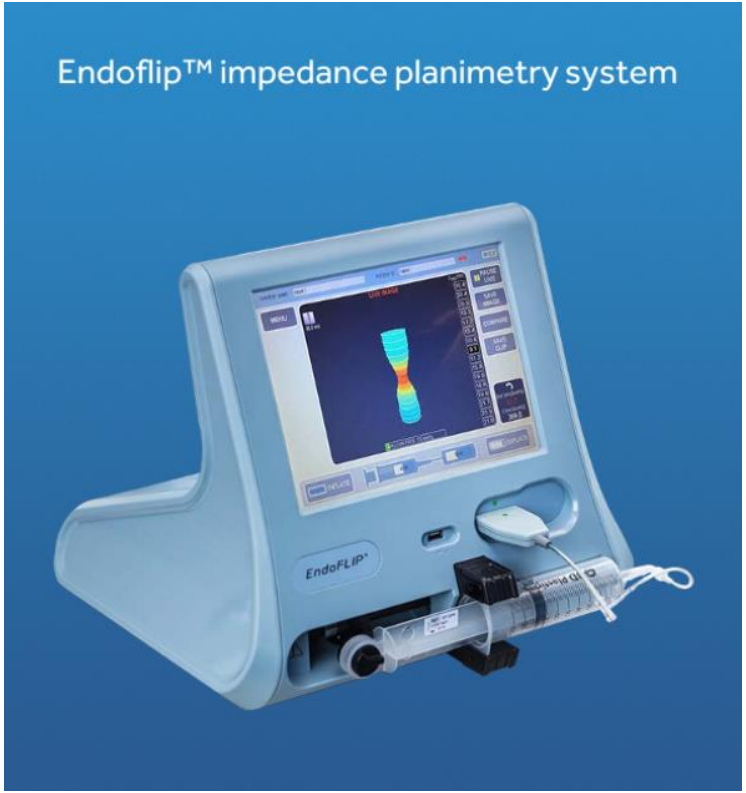
1.0 image

Endoflip™ 2.0 impedance planimetry system image



Provided by: Esophageal Center at Northwestern

Equipment (What Am I Buying?)



Equipment (What Am I Buying?)

EF-325N

INDICATION

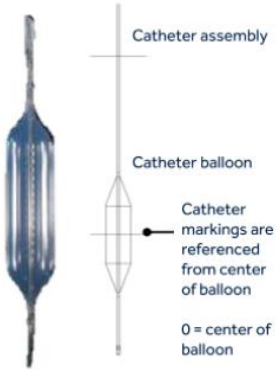
The EF-325 series of catheters can make pressure and dimensional measurements in the esophagus, pylorus and anal sphincters

FEATURES

8cm field

16 electrodes

5mm spacing



Shaft Diameter

Endo flip ← EF – 325N → Nasal tip

25mm Balloon Diameter

EF-322N

INDICATION

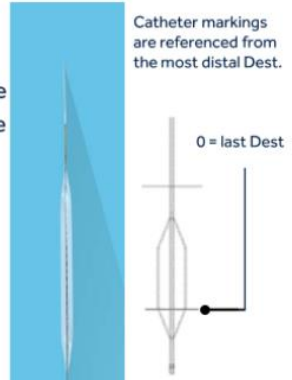
The EF-322 catheter is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity

FEATURES

16cm field

16 electrodes

1cm spacing



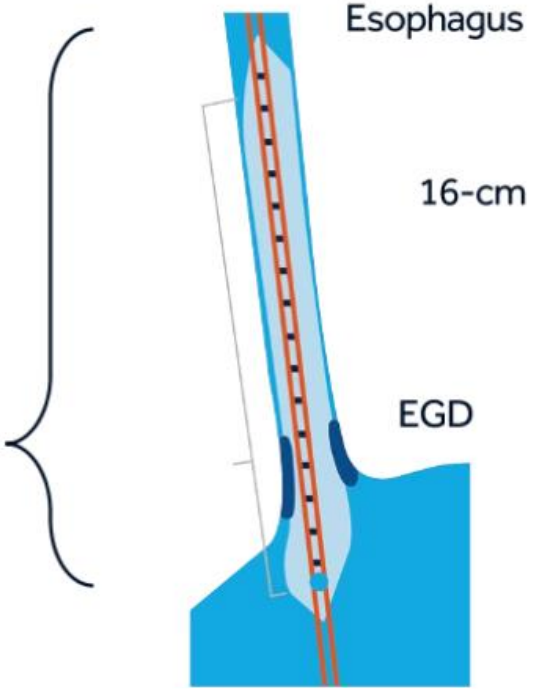
Shaft Diameter

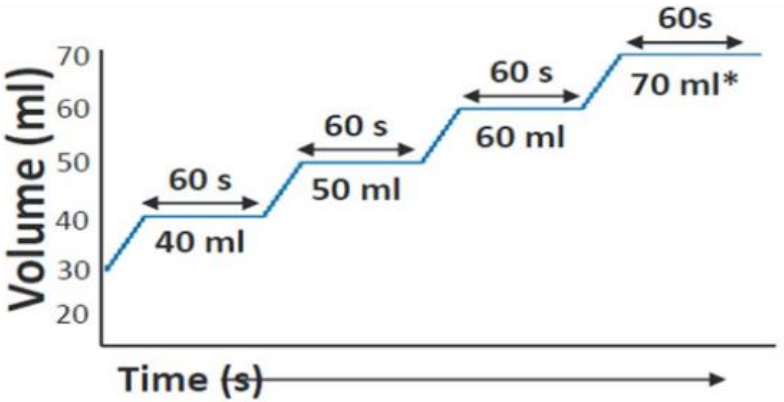
Endo flip ← EF – 322N → Nasal tip

22mm Balloon Diameter

*5-minute calibration time required prior to catheter use/placement

Procedure Details (Endoflip)

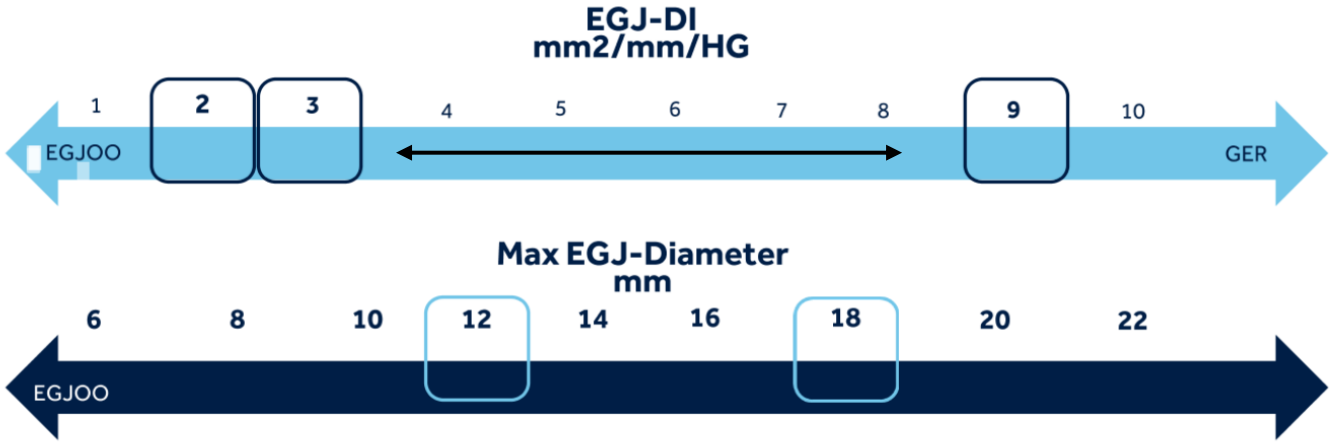




Record measurements for Luminal Diameter and Distensibility Index (DI) at 60 mL +/- 70 mL

Procedure Details (Endoflip)

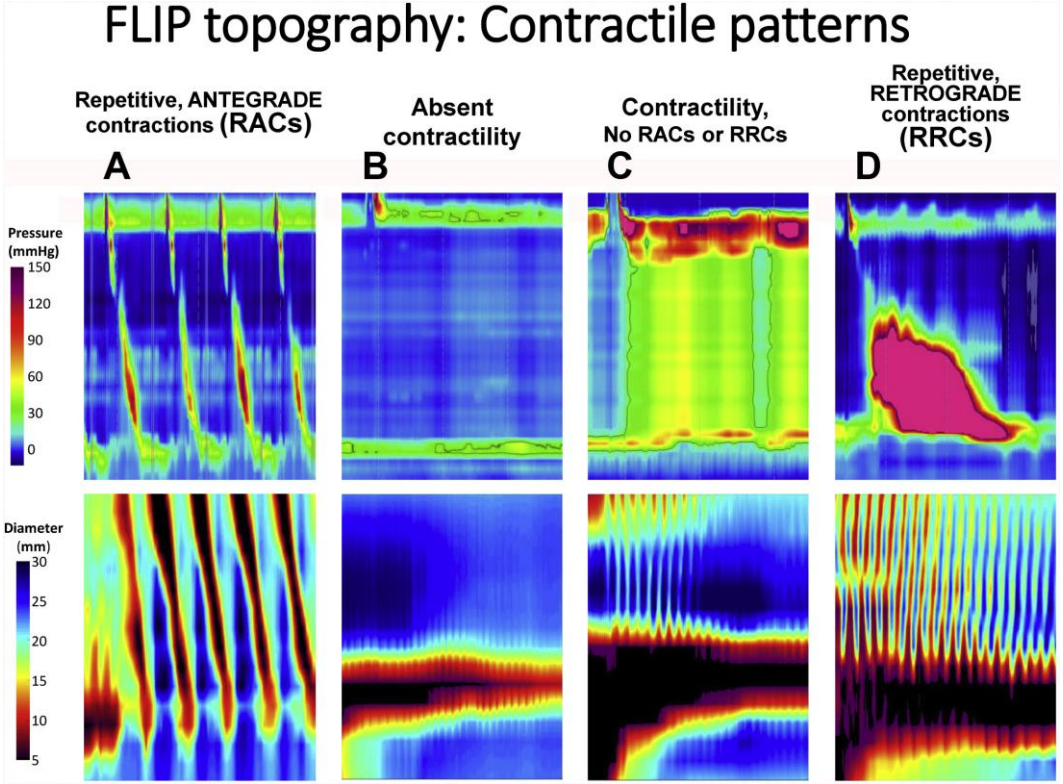
EGJ-DI AT 60ML



0-2 mm2/mmHg	2.1 - 3.0 mm2/mmHg		3.1-9.0 mm2/mmHg	>9.0 mm2/mmHg
EGJOO-DI	Max D < 12mm	Max D > 12mm	NORMAL	GER

Provided by: Esophageal Center at Northwestern

Procedure Details (Endoflip)



EndoFLIP in the Esophagus

Assessing Sphincter Function, Wall Stiffness, and Motility to Guide Treatment

Erica N. Donnan, MD[a,b,*], John E. Pandolfino, MD, MSCI[a,b].

Gastroenterol Clin N Am. 49. (2020) 427-435.
https://doi.org/10.1016/j.gtc.2020.04.002.

gastro.theclinics.com

Procedure Details (Endoflip)

Clinical suspicion reflected by color intensity: Orange – consider achalasia. Blue – consider GERD. Green – consider a spastic disorder.

	EGJ-DI 0-2 mm^2/mmHg	EGJ-DI 2.1-3.0 mm^2/mmHg		EGJ-DI 3.1-9.0 mm^2/mmHg	EGJ-DI > 9.0 mm^2/mmHg
		Max D < 12 mm Bag pressure >20 mmHG	Max D > 12 mm Bag pressure >20 mmHG*		
RACs	EGJOO with normal contractile response	EGJOO with normal contractile response	Normal contractile response	Normal contractile response	Normal contractile response with increased EGJ distensibility
DDCR	EGJOO w/ DDCR	EGJOO w/ DDCR	DDCR	DDCR	DDCR with increased EGJ distensibility
Absent	EGJOO w/ absent contractile response	EGJOO w/ absent contractile response	Absent contractile response	Absent contractile response	Absent contractile response with increased EGJ distensibility
RRCs	EGJOO w/ retrograde contractile response	EGJOO w/ retrograde contractile response	Retrograde contractile response	Retrograde contractile response	Retrograde contractile response with increased EGJ distensibility

Definitions:

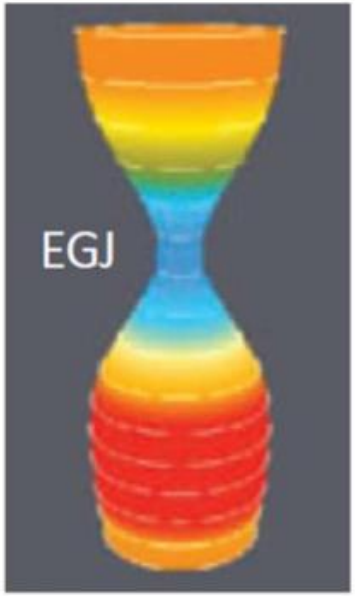
- RACs: three or more consecutively and consistently spaced antegrade contractions. They typically occur at rates of every 6-10 seconds, but a firm criterion was not applied pending further studies.
- RRCs: three or more consecutive retrograde contractions. They typically occur at rates of every 4-6 seconds, but a firm criterion was not applied pending further studies.
- DDCR: evidence of a contractile response not meeting criteria for RACs, RRCs, or absent contractile response.

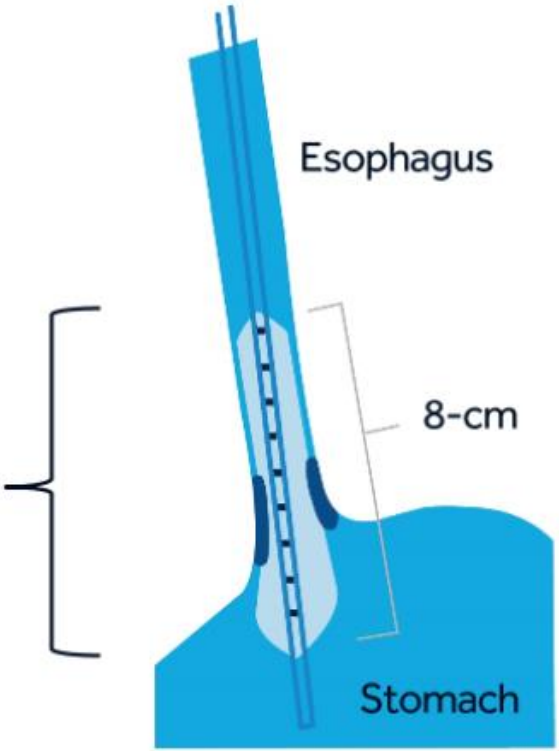
*Rule out mechanical stricture if maximum diameter is less than 18 and there is a fixed plateau max diameter during volumetric distention

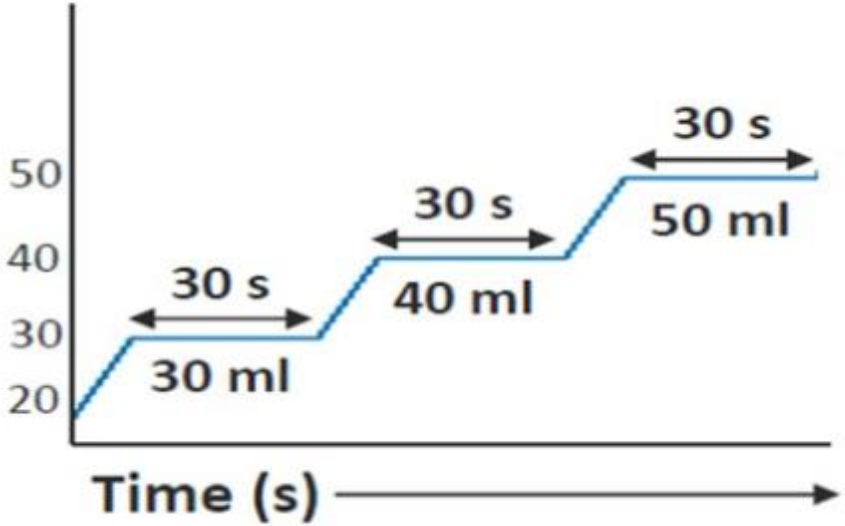
1. Pandolfino J, Clark J, Vela M, Gyawali P, Yadlapati R, Khan A, Carlson D. Endoflip™ impedance planimetry system protocol and interpretation. *Medtronic Review: White Paper*. 2018.

Note: This information is based on expert opinion. The White Paper has not been published externally nor peer-reviewed beyond the authors on record

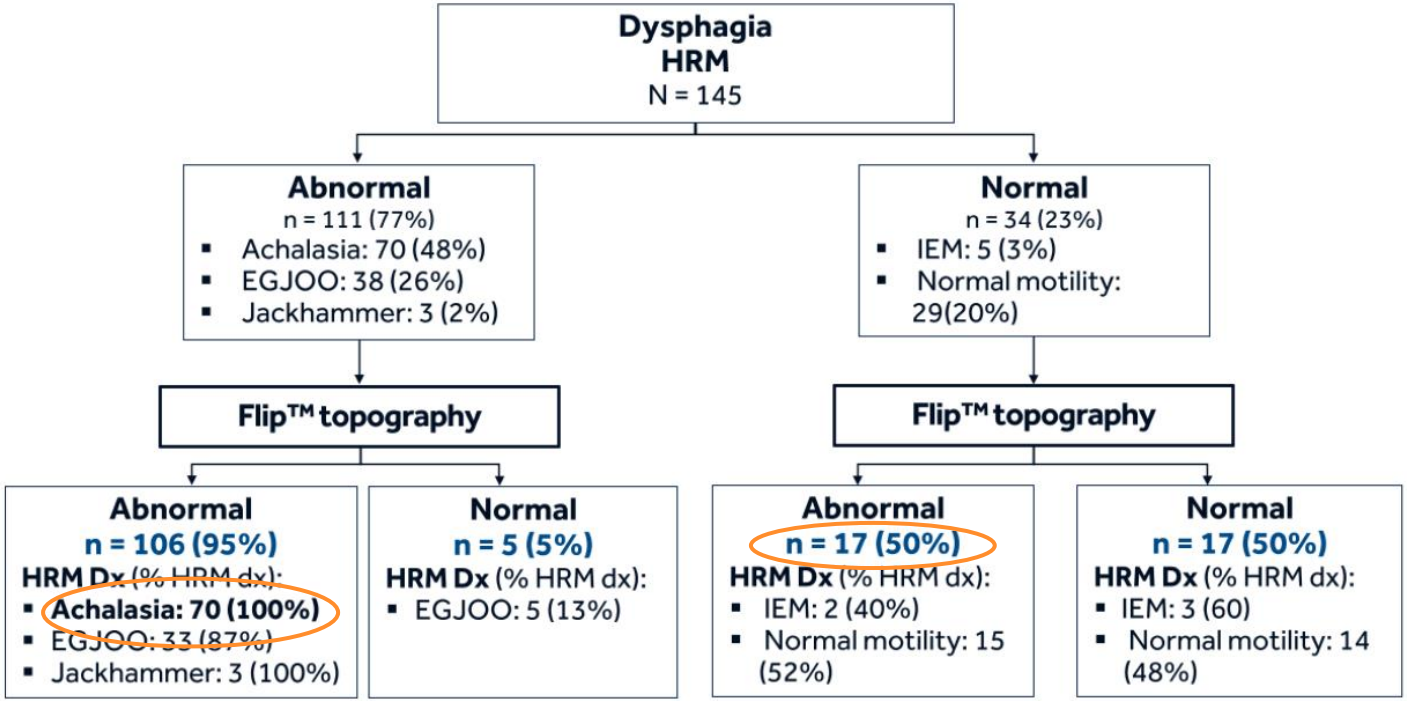
Procedure Details (Esoflip)







Does This Really Work?!



Provided by: Esophageal Center at Northwestern.

1. Carlson DA, Kahrilas PJ, Lin Z, et al. Evaluation of Esophageal Motility Utilizing the Functional Lumen Imaging Probe. *AM J Gastroenterol*. 2016 Dec;111(12):1726-1735.

FLIP in Achalasia/GOO

Issues

- Imperfect HRM definition of EGJ disorders
- False positive IRP values
  - “Achalasia Variant”?
- Ineffective Esophageal Motility (IEM)

Recs

- Complementary tool to HRM and Barium Esophagram
  - FLIP can ID patients with EGJ outflow obstruction who are likely to benefit from EGJ disruption

Flip in Achalasia/GOO – Response to Therapy

Issues

- Impaired EGJ distensibility after therapy has a poor clinical response

Recs

- FLIP can be utilized in those patients having symptoms after therapeutic intervention

FLIP in GERD

Issues

- GERD is related to increased EGJ compliance and distensibility
- EGJ compliance should decrease after Reflux intervention (to a certain degree)

Recs

- FLIP is unable to currently diagnose GERD (EGJ-DI >9mm^2/mmHg)
- FLIP “can” assess distensibility during/after Reflux intervention

FLIP in Eoe

Issues

- EoE leads to remodeling and stricturing
- Narrow luminal diameter = lamina propria fibrosis = food impactions
- Impaired distensibility is potentially reversible

Recs

- Serial assessments of distensibility may show need for increased therapy (i.e. dilations)
- FLIP can be considered a secondary endpoint in EoE trials

Flip in Benign Esophageal Strictures

Issues

- Complex strictures that cannot be traversed often require fluoroscopy to define anatomy
- FLIP can more accurately define luminal diameter

Recs

- FLIP can be an alternative to Fluoroscopy
- FLIP can guide clinician in type of dilation performed as well as goal diameter to dilate to (Achalasia)

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Can I Go Straight to Flip?!

- Normal Endoscopy
- + RAC's
- EGJ-DI >3mm^2/mmHg
- EGJ diameter >18mm
- = Absence of Structural/Motor findings within both the esophageal body and EGJ

Can I Go Straight to Flip?!

- IF…subjective history and radiographic findings are consistent with Achalasia, then can perform EGD/FLIP first, and perform therapy in single session.
  - ESOFLIP Dilation
  - Botulinum Toxin

The Future of Flip…

- Obtain/Analyze further “normal” subjects and data
- FLIP as “first-line” tool
- FLIP intra-operatively during Myotomy/Fundoplication
- EoE
- FLIP in the Pylorus, Anal Sphincter, and UES

References

Functional Lumen Imaging Probe for the Management of Esophageal Disorders: Expert Review From the Clinical Practice Updates Committee of the AGA Institute

I Hirano*, JE Pandolfino*, and GE Boeckxstaens#

*Department of Medicine, Division of Gastroenterology and Hepatology, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

#Department of Gastroenterology, Translational Research Center for Gastrointestinal Disorders (TARGID), University Hospital Leuven, Catholic University of Leuven, Leuven, Belgium.

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Clin Gastroenterol Hepatol. 2017 March;15(3):325-334. doi:10.1016/j.cgh.2016.10.022.

References

Use of the Functional Lumen Imaging Probe in Clinical Esophagology

Edoardo Savarino, MD, PhD[1], Massimiliano di Pietro, MD[2], Albert J. Bredenoord, MD, PhD[3], Dustin A. Carlson, MD[4], John O. Clarke, MD[5], Abraham Khan, MD[6], Marcelo F. Vela, MD[7], Rena Yadlapati, MD[8], Daniel Pohl, MD[9], John E. Pandolfino, MD[4], Sabine Roman, MD, PhD[10] and C. Prakash Gyawali, MD, MRCP[11]

Am J Gastroenterol. 2020;115:1786-1796.
https://doi.org/10.14309/ajg.0000000000000773.

Thank You!