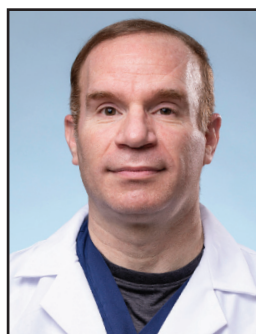


Douglas G. Adler MD, FACP, AGAF, FASGE, Series Editor

## Functional Lumen Imaging Probe (EndoFLIP) and EsoFLIP: Practical Indications, Interpretation, and Limitations



Vatsal Khanna



Douglas G. Adler

### INTRODUCTION

**A**dvances in gastrointestinal functional testing have highlighted the limitations of relying on high-resolution manometry (HRM) alone to characterize esophageal pathology, especially with regards to manometric disturbances in patients with dysphagia. While HRM remains the gold standard for evaluating esophageal motor disorders, it provides a pressure-based assessment that may not fully reflect tissue compliance during bolus transit. The functional lumen imaging probe (FLIP) (EndoFLIP developed by Crospon, now Medtronic, Minneapolis, MN, USA) is an impedance planimetry-based technology that provides real-time assessment of luminal geometry and distensibility during volumetric distension.

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EndoFLIP serves as an adjunctive diagnostic tool during upper endoscopy to clarify esophageal physiology/pathology when standard testing such as HRM and/or Timed Barium Esophagram (TBE) is inconclusive or discordant with the patient's symptoms. It is especially helpful in patients with dysphagia, chest pain, or refractory reflux when standard manometry appears normal or equivocal, as FLIP can reveal inadequate esophagogastric junction (EGJ) opening or reduced distensibility that may otherwise be missed.

In addition, EndoFLIP can be used before and after intervention to assess changes in esophagogastric junction opening and distensibility following pneumatic dilation, esophageal or gastric peroral endoscopic myotomy (POEM or G-POEM), laparoscopic Heller myotomy, fundoplication, transoral incisionless fundoplication (TIF), and endoscopic dilation of benign esophageal strictures.

EsoFLIP (Medtronic, Minneapolis, MN, USA) is a therapeutic version of FLIP designed

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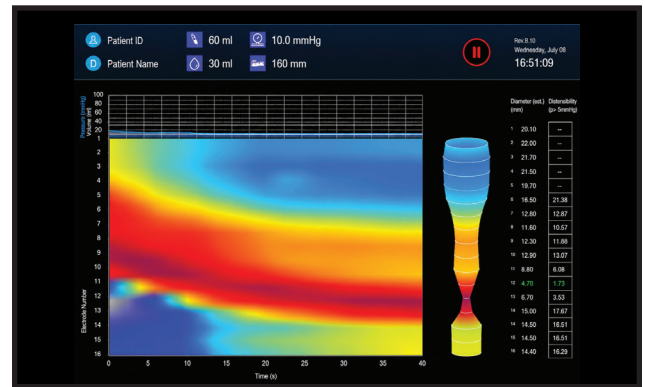
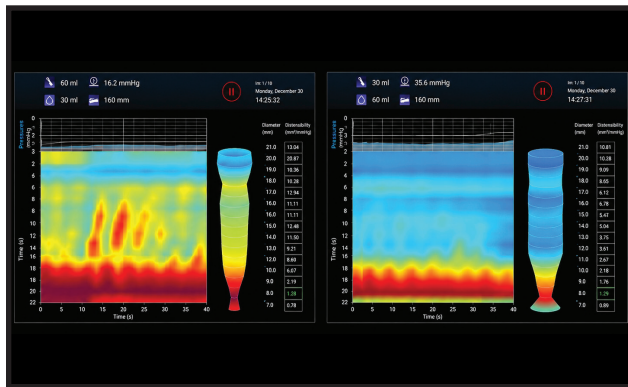


Figure 1a: Patient with achalasia type III showing rapid retrograde contractions and a DI of 1.29 referred for POEM.

Figure 1b. Patient with an achalasia variant depicted by spastic changes in the distal esophagus, but poor motility in the mid and proximal esophageal body, with a DI of 1.73

for controlled endoscopic dilation. It uses a stiff, noncompliant balloon that dilates the lumen while measuring diameter in real time. Unlike standard through-the-scope balloons, EsoFLIP allows direct three-dimensional visualization of luminal opening during dilation, adjustment to a target diameter, and dilation without fluoroscopy.

This manuscript summarizes current evidence on EndoFLIP and EsoFLIP with an emphasis on practical indications, clinical interpretation, and recognized limitations. Using common clinical scenarios including Achalasia, Esophagogastric Junction Outlet Obstruction (EGJOO), Esophageal strictures, and anti-reflux or myotomy based therapies, we aim to provide clinicians with a practical guide for applying these technologies in routine clinical practice.

## INTRODUCTION

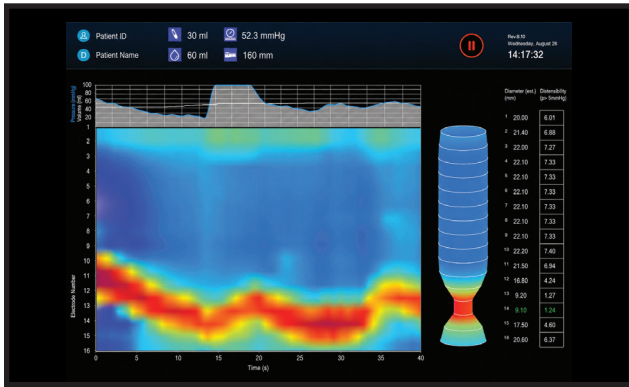
### Principle of Impedance

Compliance refers to how easily a hollow organ stretches and increases in volume when pressure is applied, which reflects how well ingested contents can pass through the segment.<sup>1</sup> Impedance planimetry measures this by calculating compliance (volume change relative to pressure) and distensibility (cross-sectional area relative to pressure).<sup>1</sup> EndoFLIP was first developed by Hans Gregersen in the 1980s to measure EGJ compliance and distensibility in conditions like GERD and achalasia.<sup>2,3,4,5</sup>

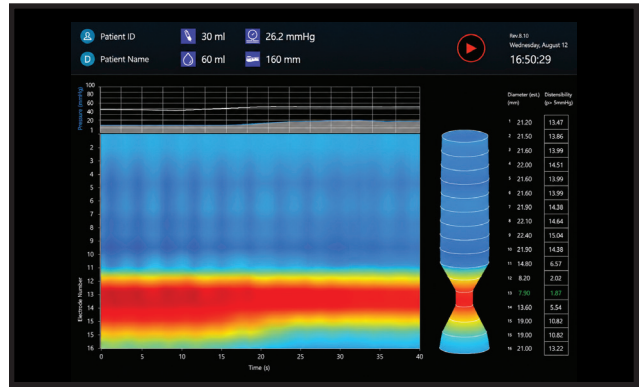
Eventually, in 2009, the first commercially available device of the functional lumen imaging probe (EndoFLIP developed by Crosson, now Medtronic, Minneapolis, MN, USA) was introduced.<sup>6</sup> The EndoFLIP device helps to assess the biomechanical properties of a sphincter or a tubular organ in the gastrointestinal (GI) tract by providing a three-dimensional image of said structure.<sup>6</sup> It uses a balloon catheter with impedance electrodes to calculate luminal diameter, cross-sectional area, and distension pressure, allowing for the evaluation of luminal distensibility and compliance.<sup>7</sup> This provides a more detailed understanding of sphincter function compared to HRM and also helps to evaluate esophageal wall stiffness.<sup>7</sup>

EndoFLIP was initially used to evaluate the EGJ in patients with gastroesophageal reflux disease (GERD) and achalasia.<sup>7</sup> Over the past decade, its use has expanded to other esophageal conditions like eosinophilic esophagitis (EOE), and other locations of the GI tract, mostly to the stomach for pylorus measurements in patients with gastroparesis undergoing evaluation and therapy.<sup>7</sup> It can also be used before or after foregut procedures (POEM, G-POEM, TIF, surgical myotomy, and fundoplication) to assess treatment response and guide management.<sup>6</sup>

EsoFLIP (Medtronic, Minneapolis, MN, USA) is a variant of EndoFLIP which combines the advantage of both a diagnostic and a therapeutic tool.<sup>6</sup> It is being used as an alternative device for



**Figure 2a. Patient with achalasia type I with a DI of 1.24 successfully treated with a 30 mm EsoFLIP balloon**



**Figure 2b. Patient with achalasia type I with a distensibility index of 1.87 treated with a 30 mm EsoFLIP balloon**

*Photo Credit: Lawrence E. Stawick, MD, AGAF, Clinical Professor, Michigan State University*

dilation of functional and structural stenoses in the GI tract.<sup>6</sup>

### Technology Overview: What These Tools Actually Measure

#### EndoFLIP

The EndoFLIP system comprises a 24 cm long catheter with a 3-mm outer diameter and a highly compliant balloon integrated into its tip.<sup>7</sup> The catheter is available in two lengths: EF-322 (16 cm) and EF-325 (8 cm).<sup>7</sup> The 16 cm catheter consists of 16 electrode pairs spaced 1 cm apart and measures both EGJ metrics and esophageal body contractile response, whereas the 8 cm catheter consists of 16 electrode pairs spaced 0.5 cm apart and primarily measures EGJ metrics.<sup>8,9,10,11</sup>

FLIP measurements utilize impedance planimetry, a technique that is based on Ohm's Law (voltage is proportional to the impedance which increases with the filling of the balloon) to determine luminal cross-sectional area (CSA), distensibility of the EGJ and/or esophageal body, and esophageal body contractile response to volumetric distention.<sup>12</sup> The equipment consists of a FLIP catheter with impedance planimetry electrodes, and a pressure transducer located inside of polyurethane bag, as well as a digital data acquisition and display system.<sup>8</sup>

The Dallas Consensus (2025) is an expert statement that standardizes how FLIP panometry is to be performed and interpreted during endoscopy in patients with suspected esophageal motility

disorders.<sup>13</sup> This is important because it brings consistency to a test that has been used variably, making FLIP findings easier to interpret and compare across centers.<sup>13</sup>

EndoFLIP is performed after a standard upper endoscopy to inspect the mucosa and clear luminal contents, typically under monitored anesthesia care (MAC) or general anesthesia.<sup>7</sup> The deflated balloon catheter is zeroed to atmospheric pressure and advanced transorally or transnasally into the esophagus or stomach.<sup>7</sup> After positioning is confirmed, the balloon is inflated stepwise, starting at 30 mL and increasing in 10 mL increments up to 60 mL for the 16-cm balloon, or from 20 mL up to 50 mL for the 8-cm balloon.<sup>7</sup> At each volume, measurements of diameter, cross-sectional area (CSA), intraballoon pressure (IBP), distensibility index (DI), maximum EGJ diameter, and esophageal body contractile pattern are recorded during stable distension for 15–30 seconds to account for respiration and esophageal contractions.<sup>7</sup> The balloon is deflated before removal.<sup>7</sup>

### Clinical Indications: When EndoFLIP Adds Value Use of EndoFLIP in the Esophagus

As per American Gastroenterological Association (AGA) clinical practice update guidelines 2025, clinicians should perform a high-quality upper endoscopy evaluating for esophageal pathology immediately prior to considering FLIP to evaluate for any structural and mucosal abnormalities.<sup>8</sup> Physicians should document any visible pathology

such as strictures, Eosinophilic Esophagitis (EoE), post operative surgical anatomy, hiatal hernia, as it can impact FLIP catheter placement.<sup>14,15,16</sup> FLIP can be performed when alternate investigations like HRM or TBE are inconclusive in patients with symptoms of esophageal obstruction such as dysphagia, esophageal-type regurgitation and/or meal-related chest pain.<sup>8</sup>

Discordance between esophageal test findings is not unusual in patients with symptoms of esophageal dysmotility or dysphagia.<sup>8</sup> In a study of 126 symptomatic patients who underwent HRM, TBE, and FLIP, concordance among all the 3 tests assessing lower esophageal sphincter was only 57%.<sup>17</sup> When initial tests are discordant, clinicians should consider using more than one physiologic test to improve diagnostic confidence before proceeding with irreversible lower esophageal sphincter (LES) disruption.<sup>18,19</sup>

By measuring distensibility, EndoFLIP helps to diagnose both obstructive and reflux-related processes at the LES and complements the assessment of gastrointestinal motility disorders, particularly achalasia.<sup>7</sup>

Recent studies involving healthy controls have defined normal EGJ distensibility as EGJ-DI > 2.8 mm<sup>2</sup>/mm Hg and a maximum EGJ diameter >18 mm.<sup>20</sup> The EGJ opening is described using two parameters, EGJ-DI and maximum EGJ diameter as normal EGJ opening (NEO), reduced EGJ opening (REO), or inconclusive EGJ opening (IEO).<sup>13</sup> Esophageal body contractile response patterns can be normal (multiple distinct antegrade contractions and/or repetitive antegrade contractions) or abnormal (absent, diminished, disordered, or spastic contractile response patterns).<sup>13</sup> FLIP pressure measurements discriminate diminished (<40 mm Hg) from disordered (>40 mm Hg) contractility when distinct antegrade contractions or spastic contractile response are not seen.<sup>21</sup>

### **Use of FLIP Findings in Making Obstructive Structural and Motor Diagnoses**

FLIP panometry aids in distinguishing obstructive structural and motor disorders by combining EGJ opening metrics with esophageal body contractile patterns.<sup>8</sup>

**Normal EGJ opening** (EGJ-DI  $\geq$  2.0 mm<sup>2</sup>/mm Hg and maximum EGJ diameter  $\geq$  16 mm) with normal

antegrade contractions suggests that a major motor disorder is unlikely.<sup>8</sup>

**Reduced EGJ opening** (EGJ-DI < 2.0 mm<sup>2</sup>/mm Hg and maximum EGJ diameter < 12 mm) supports a structural or motor obstruction in the presence of compatible symptoms and endoscopy findings.<sup>8</sup>

Absent or weak esophageal contractions, defined as no contractions or a pressure increase < 40 mm Hg, suggest non-spastic achalasia.<sup>8</sup> Spastic contractile patterns, such as sustained LES contraction or sustained occluding contractions, are more consistent with spastic achalasia.<sup>8</sup> If EGJ opening is reduced but contractility is preserved, a mechanical obstruction should be considered.<sup>8</sup>

**Inconclusive EGJ opening** refers to isolated EGJ-DI < 2.0 mm<sup>2</sup>/mm Hg or a maximum EGJ diameter < 16 mm that does not meet criteria for reduced opening.<sup>8</sup> This can be seen with any contractile pattern, and both motor and mechanical obstruction remain possible, requiring further evaluation.<sup>8</sup>

### **Role of FLIP in Evaluating Esophageal Motility Disorders**

#### **Achalasia**

Achalasia is characterized by LES dysfunction and abnormal esophageal peristalsis.<sup>7</sup> HRM remains the gold standard test to diagnose achalasia, with EndoFLIP providing supplementary information in some patients.<sup>7</sup> HRM has high sensitivity and can identify three distinct achalasia subtypes but may yield inconclusive results in patients with borderline pressure values.<sup>7</sup>

Patients with clinically suspected achalasia who do not meet the HRM criteria of the Chicago Classification v 4.0 (Integrated Relaxation Pressure (IRP) >15 mm Hg in supine position) can be recognized by the FLIP by decreased EGJ-DI or abnormal esophageal contractions.<sup>22,23</sup> FLIP findings of REO and abnormal contractile response patterns are strongly associated with achalasia.<sup>8</sup> (Figure 1)

Endoscopic findings of achalasia are quantified as the CARS (content, anatomy, resistance, and stasis) score.<sup>24</sup> A CARS score  $\geq$  4 has a specificity of 99% and a sensitivity of 68-72% to identify achalasia.<sup>25</sup> A CARS score of 0-1 combined with NEO on FLIP had a negative predictive value (NPV) of 100% for achalasia and a CARS >4

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with REO on FLIP had a positive predictive value (PPV) of 97% for non-spastic achalasia.<sup>26</sup> If upper endoscopy does not demonstrate findings suggestive of achalasia, abnormal EGJ opening on FLIP should prompt further testing with HRM and/or TBE to confirm the diagnosis.<sup>8</sup>

### **EGJOO**

EndoFLIP plays an important role in evaluating non-achalasia EGJOO.<sup>7</sup> EGJOO is a manometric diagnosis with elevated IRP and normal esophageal peristalsis and requires additional testing to confirm EGJ obstruction by either TBE or EndoFLIP to be considered clinically significant.<sup>6</sup>

In a validation study by Carlson et al., FLIP panometry identified clinically relevant EGJOO in 93% (229/245) of patients when the EGJ-DI was  $\geq 3.0$  mm<sup>2</sup>/mm Hg and the maximum EGJ diameter was  $> 12$  mm.<sup>27</sup> These thresholds help to differentiate clinically relevant EGJOO from borderline or incidental findings.<sup>27</sup>

### **Role of FLIP in Eosinophilic Esophagitis (EoE)**

Eosinophilic esophagitis (EoE) is characterized by chronic immune-mediated inflammation of the esophagus, leading to fibrous changes, stiffening of the esophageal wall with a decrease in esophageal compliance, luminal narrowing, and the formation of strictures.<sup>28,29</sup> EoE surveillance normally involves upper endoscopy with biopsies and/or dilation as needed to assess histologic activity and guide treatment.<sup>30</sup>

EndoFLIP offers an alternative approach by providing an objective measurement to evaluate esophageal remodeling as well as detection and localization of esophageal narrowing and strictures.<sup>31</sup> EndoFLIP measures esophageal distensibility by recording cross-sectional area and intraluminal pressure during controlled balloon distension.<sup>7</sup> This helps to identify the distensibility plateau which corresponds to the luminal opening of the esophagus at its narrowest point.<sup>32</sup>

Patients with EoE have significantly reduced

esophageal compliance compared to healthy individuals, with lower distensibility plateaus associated with endoscopic findings such as rings, strictures, increased risk of food impaction and the need for periodic dilation.<sup>33</sup>

The distensibility plateau is defined as a static esophageal diameter despite increasing distention volume and pressure.<sup>8</sup> A distensibility plateau of  $>225$  mm<sup>2</sup> (diameter  $> 17$  mm) was associated with a lower risk of food impaction and the need for dilation in EoE patients.<sup>33</sup> The severity of reduced distensibility plateau correlates with symptom duration and diagnostic delay.<sup>34</sup> In a study by Araujo et al., abnormal esophageal distensibility ( $\leq 17$  mm) was present in 23% of patients with symptoms for less than 5 years, compared to 64% in those with symptoms for 25 years or more.<sup>34</sup> This progressive decline in distensibility supports the concept of EoE as a fibrostenotic disease that worsens over time, particularly in patients with persistent mucosal eosinophilia ( $\geq 15$  eosinophils per high-powered field).<sup>34</sup>

Carlson et al. evaluated 215 patients with EoE using FLIP panometry and found abnormal composite measures of esophageal body compliance, contractile response, EGJ distensibility, and maximal diameter were associated with higher eosinophil counts and worse endoscopic severity.<sup>35</sup>

### **Role of FLIP in Foregut Interventions**

Clinicians can consider performing EndoFLIP interprocedurally during myotomy [per-oral endoscopic myotomy (POEM) or laparoscopic Heller Myotomy (LHM)].<sup>8</sup>

The LES can be evaluated while performing POEM or LHM and can help direct the length of myotomy and adequacy of LES disruption in real time.<sup>36,37</sup> Intra-operative EGJ-DI  $< 2-3$  mm<sup>2</sup>/mm Hg may predict persisting symptoms and may prompt additional myotomy.<sup>38,39,40</sup> In contrast, high intraoperative EGJ-DI may be associated with increased postoperative reflux symptoms, and increase risk of erosive esophagitis after POEM or LHM.<sup>41,42,43</sup>

### **Role of FLIP in Symptom Evaluation after Foregut Interventions**

Clinicians should consider performing EndoFLIP in patients who have persistent symptoms of

esophageal obstruction after treatment of achalasia spectrum disorders by POEM or LHM.<sup>8</sup> An EGJ-DI  $<2\text{--}3\text{ mm}^2/\text{mm Hg}$  after LES disruption is associated with suboptimal esophageal emptying, suggesting ineffective LES disruption, and may warrant consideration of additional LES-directed therapy.<sup>44,45,46</sup> In contrast, NEO on FLIP should prompt consideration of alternative explanation for symptoms, including abnormal esophageal body anatomy and gastroesophageal reflux disease (GERD).<sup>46</sup>

FLIP can also be used to assess symptoms after antireflux surgery (ARS), such as fundoplication or bariatric intervention.<sup>9</sup> EGJ-DI has been used to tailor fundoplication in attempts to prevent postoperative dysphagia.<sup>47,48</sup> Tightness of hiatal closure impacts EGJ-DI more than the actual fundoplication.<sup>49</sup> Ideal EGJ-DI ranges have been proposed for Toupet (EGJ-DI  $2.6\text{--}3.7\text{ mm}^2/\text{mm Hg}$ ) and Nissen ( $>2.2\text{ mm}^2/\text{mm Hg}$ ) fundoplication, which helps with intraoperative decision making such as altering the type of ARS, or loosening or tightening the wrap.<sup>48</sup>

### Use of EndoFLIP in the Stomach

Pylorospasm (decreased pyloric distensibility) during gastric contraction plays a key role in the pathophysiology of gastroparesis.<sup>50</sup> Pylorus targeted therapy such as G-POEM can help patients in reducing the symptoms of gastroparesis.<sup>6</sup> While EndoFLIP can assess pyloric distensibility, its correlation with gastric emptying and symptoms in gastroparesis remains inconsistent, and the European Society of Gastrointestinal Endoscopy (ESGE) does not currently recommend routine use for pylorus-targeted therapy.<sup>51</sup>

Malik et al. assessed pyloric distensibility in 54 patients with idiopathic and diabetic gastroparesis, the mean distensibility index was  $10.7 \pm 2.57\text{ mm}^2/\text{mm Hg}$ , but a wide range of values for both distensibility ( $1\text{--}55\text{ mm}^2/\text{mm Hg}$ ) and diameter ( $5.6\text{--}22.1\text{ mm}$ ) was observed.<sup>52</sup> Snape et al. demonstrated that patients presenting with nausea and vomiting and confirmed delayed gastric emptying had decreased pyloric distensibility compared to patients with normal gastric emptying ( $8\text{ mm}^2/\text{mm Hg}$  vs.  $12.4\text{ mm}^2/\text{mm Hg}$ ).<sup>53</sup> An upper cut-off of  $9\text{--}10\text{ mm}^2/\text{mm Hg}$  was used by most of the authors to define pylorospasm while using

EndoFLIP.<sup>6</sup> Lower pyloric distensibility index in gastroparesis has been linked to better outcomes after G-POEM.<sup>54</sup>

### EsoFLIP: The Therapeutic Dilatation Catheter

Bougie and balloon dilation are widely used for benign gastrointestinal strictures but provide limited real-time feedback on luminal properties despite endoscopic or fluoroscopic guidance.<sup>6</sup> EsoFLIP (Medtronic, Minneapolis, MN) is a more recently developed therapeutic device for esophageal hydraulic balloon dilation and uses the same hardware and technology platform as EndoFLIP, but comes with a stiffer balloon to generate sufficient pressure for dilation.<sup>6</sup> The EsoFLIP system offers three catheter sizes: 10 mm (ES-310) and 20 mm (ES-320) balloons for esophageal strictures and a 30 mm (ES-330) balloon, mainly used for patients with achalasia and esophago-gastric junction outflow obstruction.<sup>7</sup>

### Indications for EsoFLIP

EsoFLIP balloons are used in adults for LES dilation in achalasia and for treatment of esophageal strictures due to surgery, GERD, or radiation as well as the pylorus.<sup>55</sup> (Figure 2)

The inflation of the balloon is manually controlled via an electrohydraulic pump, allowing adjustments based on the target diameter.<sup>7</sup> Initial measurements of the diameter or CSA at partial filling volume (20 mL for ES-320 and 30 mL for ES-330) are followed by gradual, stepwise filling to approximately 30 mL/50 mL, with additional increments of 1–3 mL to reach the target diameter. The maximum filling volume of 42 mL/75 mL (ES-320/ES-330) is used to achieve a target diameter of 20–30 mm.<sup>7</sup>

The advantages of using EsoFLIP over traditional methods of dilation include dilation without the need for fluoroscopy, reducing radiation exposure, precise control of the balloon filling to a desired diameter, and measurement of stricture size and assessment of dilation effect in real time.<sup>7</sup> However, these benefits may come at the expense of higher procedural costs.<sup>7</sup>

Although clinical outcome studies on EsoFLIP are limited, small series have demonstrated its technical feasibility, safety, and short-term efficacy.<sup>7</sup> In a feasibility study of 10 patients with

achalasia, EsoFLIP achieved dilation to 28–30 mm without serious adverse events with improvement in esophageal symptoms assessed by the Eckardt score as well as improved esophageal emptying recorded with TBE.<sup>56</sup>

### Limitations of EndoFLIP and EsoFLIP

#### EndoFLIP

These include high costs, lack of real-time data processing software, and limited data storage solutions.<sup>7</sup> CSA and pressure measurements can vary during stable distension volumes due to respiratory artifacts, vascular effects, and both spontaneous and balloon-induced esophageal contractions.<sup>57</sup> There is limited penetrance outside specialized centers despite commercial availability since 2009, due to lack of data supporting utility in general practice.<sup>58</sup>

#### EsoFLIP

Although EsoFLIP offers several advantages, it has practical limitations, including lack of through-the-scope capability, the need to remove the external guidewire before dilation, reliance on an external pressure monitor, additional time for balloon filling and emptying, and higher procedural costs.<sup>55</sup>

### CONCLUSION

The EndoFLIP is an advanced diagnostic tool that helps with the evaluation of sphincters and GI luminal organs by providing real-time dynamic monitoring of distensibility, luminal geometry, and biomechanical properties. It was originally used to assess EGJ, but its application has expanded to other locations including the esophageal body and the pylorus. The device's ability to measure distensibility can guide the tailoring of specific endoscopic and surgical therapies, such as dilation, fundoplication, and myotomy, to achieve desired outcomes during a single session.

The EsoFLIP is a therapeutic modification of the EndoFLIP catheter that provides real-time visualization and monitoring of dilation as it is being performed via controlled volumetric filling. EsoFLIP represents a useful addition to the treatment of esophageal disorders, although further studies are needed to better define its role and outcomes. ■

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