

Esophagogastric junction distensibility assessed with an endoscopic functional luminal imaging probe (EndoFLIP)

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Background: Increased esophagogastric junction (EGJ) compliance is a key abnormality in GERD leading to increased volumes of reflux. To date, EGJ distensibility has been measured only with investigational barostat-based prototype devices.

Objectives: The aim of the study was to test the endoscopic functional luminal imaging probe (EndoFLIP), a new commercially available technology designed to measure intraluminal distensibility, by assessing the EGJ of GERD patients and controls.

Design: Prospective case-control series.

Setting: Tertiary referral center.

Subjects: Twenty GERD patients and 20 controls studied during a routine esophagogastroduodenoscopy.

Methods: The EndoFLIP was passed through the endoscopic instrumentation channel and positioned across the EGJ. The EndoFLIP uses impedance planimetry to measure 16 cross-sectional areas (CSA) along with the corresponding intrabag pressure within a 4.6-cm cylindrical segment of a fluid-filled bag.

Main Outcome Measurement: EGJ distensibility was assessed with 10- to 40-mL volume-controlled distentions.

Results: In both groups, the least distensible locus at the EGJ was usually at the hiatus. As a group, GERD patients exhibited two- to threefold increased EGJ distensibility compared with controls, particularly at 20- to 30-mL distention volumes, values quantitatively similar to previous measurements with barostat-based devices. The endoscopic estimation of EGJ distensibility, the flap valve grade, correlated poorly with EndoFLIP measurements.

Limitations: Heterogeneity of GERD patients.

Conclusions: Measurement of EGJ distensibility with EndoFLIP is feasible during clinical endoscopy. Stratifying GERD patients according to this physiological parameter may facilitate the identification of patient subgroups responsive or unresponsive to medical or surgical treatments. (*Gastrointest Endosc* 2010;72:272-8.)

Excessive esophagogastric junction (EGJ) compliance is a primary pathophysiological abnormality in many cases of GERD.¹⁻⁴ Increased EGJ compliance allows greater volumes of gastric content to reflux into the esophagus,⁵ increases the frequency with which transient lower esoph-

ageal sphincter (LES) relaxations are elicited by proximal gastric distention,⁶ and allows gastric juice to track within the contracted sphincter.⁷⁻⁹ These physiological aberrations result in an increased number of reflux events, increased spatial distribution of refluxate within the esoph-

Abbreviations: CSA, cross-sectional area; EGJ, esophagogastric junction; FLIP, functional luminal imaging probe; LES, lower esophageal sphincter.

DISCLOSURE: The following author disclosed a financial relationship relevant to this publication: J.E. Pandolfino Scientific Advisory Board member; Croson Ltd. The other authors disclosed no financial relationships relevant to this publication. Supported and sponsored by Croson Ltd, Galway, Ireland; grant R01 DC00646 (P.J. Kahrilas and J.E. Pandolfino) from the Public Health Service; and the 2008 AGA June and Donald O. Castell Esophageal Clinical Research Award (J.E. Pandolfino).

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0016-5107/\$36.00
doi:10.1016/j.gie.2010.01.069

Received November 23, 2009. Accepted November 26, 2009.

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agus, and increased esophageal acid exposure, all of which increase the likelihood of esophageal mucosal injury and reflux-related symptoms. Hence, quantifying EGJ compliance may discern clinically relevant subsets of GERD patients. The current clinical assessment of EGJ function is limited to endoscopic or radiographic imaging, manometric measures, or reflux testing with pH-metry. Although these studies can confirm excessive reflux, contractile defects in the LES pressure or crural diaphragm, and misalignment between the 2 manifest as a sliding hiatal hernia, which are all common in GERD,^{3,10,11} they do not quantify EGJ compliance. Inherent in the definition (change in volume when subject to an applied force), measuring EGJ compliance requires it being challenged with intraluminal distention.¹²

To date, the EGJ distensibility has been measured only with purpose-built equipment prototypes within the domain of research laboratories, which found the narrowest locus to be greater in GERD patients compared with control subjects.^{3,4} Although a transorally placed esophageal hydrostat or barostat can apply distending pressure at the EGJ and thus restrict dimensional measurements to the area of interest, both techniques are cumbersome and require concurrent fluoroscopic imaging.²⁻⁴ A more robust method for measuring EGJ distensibility, providing cross-sectional area (CSA) measurements at multiple adjacent segments without the need for fluoroscopy, adapts the principle of impedance planimetry^{13,14} into a functional luminal imaging probe (FLIP). FLIP recordings allow dynamic imaging of EGJ distention as a cylinder of varying diameter based on instantaneous CSA measurements with concurrent pressure measurements. Quantifying intraluminal pressure along with the CSA permits calculation of EGJ distensibility.¹⁵⁻¹⁷ The original FLIP, designed for transnasal passage, was of relatively large diameter and too poorly tolerated for general clinical use. Consequently, a new smaller probe was designed to fit through the instrumentation channel of an endoscope. The distention bag can be localized at the EGJ for compliance measurements during routine clinical endoscopy, opening the possibility of measuring EGJ compliance as part of the diagnostic evaluation of GERD. Hence, the aim of the current study was to test the performance of the new endoscopic FLIP system (EndoFLIP; Crospon Ltd, Galway, Ireland) and to compare the EGJ distensibility in GERD patients with that of asymptomatic control subjects.

MATERIALS AND METHODS

Subjects

Twenty control subjects (4 men; age, 18-42; median age, 27 years) and 20 patients with GERD (10 men; age, 22-79 years; median age, 31 years) were studied. The control subjects were recruited from a pool of asymptomatic volunteers with no GERD-associated symptoms. GERD patients were recruited from a pool of volunteers

Take-home Message

- The EndoFLIP device yielded values for EGJ distensibility quantitatively similar to previous measurements with barostat-based devices. The least distensible locus within the EGJ was usually at the hiatus and was 2 to 3 times more distensible in GERD patients than controls. Stratifying GERD patients by EGJ distensibility can potentially match GERD patient subgroups to specific mechanistic treatments.

and patients reporting heartburn at least 2 to 3 days per week while not taking antisecretory medicines. None of the subjects had a history of GI surgery or significant medical disease. All subjects gave written informed consent. The study protocol was approved by the Northwestern University Institutional Review Board.

EndoFLIP system

EGJ distensibility was measured by using a commercially developed FLIP, the EndoFLIP, based on the concepts described previously.¹⁶ In brief, the EndoFLIP (Fig. 1) uses impedance planimetry to determine multiple adjacent CSAs within a cylindrical bag placed in a tubular organ during volumetric distention. The additional measure of the corresponding intrabag pressure allows assessment of the CSA pressure response (distensibility) of the distended area.

The EndoFLIP assembly was 240 cm long with a 3-mm outer diameter. A noncompliant bag (up to a fill-in volume of 40 mL) mounted on the distal 14 cm of the probe was designed to assume a cylindrical shape 7.0 cm long with maximal diameter of 2.5 cm, when fully distended, between the tapering cone-shaped ends sealed at the assembly. The minimal-to-maximal detectable CSA range was 10 to 450 mm². Within the bag was a 6.4-cm segment comprising 17 ring electrodes spaced 4 mm apart for impedance planimetry measurements. Excitation electrodes at either end emitted a constant low current making the voltage measured across each of the 16 adjacent pairs of ring electrodes proportional to the impedance between them. As the bag was filled with a specially formulated conductive solution, the impedance across each segment was inversely proportional to the CSA of the bag at that locus. The probe also contained 2 low-compliance perfusion channels connected to external pressure transducers housed within the recording unit that measured intrabag pressure.

Measurements from the 16 electrode pairs and pressure transducers were sampled at 10 Hz with the data acquisition system and transmitted to the recording unit, which displayed them in real time as a 6.4-cm cylinder of varying diameters along its length reflecting the 16 measured CSAs. The probe and the pressure transducers were pre-

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