



Intraoperative FLIP distensibility during POEM varies according to achalasia subtype

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Received: 31 March 2020 / Accepted: 12 June 2020 / Published online: 29 June 2020
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Abstract

Background The functional luminal imaging probe (FLIP) can be used to measure the esophagogastric junction distensibility index (DI) during myotomy for achalasia and increased DI has been shown to predict superior clinical outcomes. The objective of this study was to determine if the intraoperative DI and the changes produced by per oral endoscopic myotomy (POEM) differed between achalasia subtypes.

Methods FLIP measurements were performed during POEM for achalasia at a single institution. DI (defined as the minimum cross-sectional area (CSA) at the EGJ divided by distensive pressure) was measured at three time points: after induction of anesthesia, after submucosal tunneling, and after myotomy. Measurements were reported at the 40 mL fill volume for the 8 cm FLIP (EF-325) and at the 60 mL fill volume for the 16 cm FLIP (EF-322). Measurements were compared using chi-square and Kruskal–Wallis tests.

Results 142 patients had intraoperative FLIP performed during POEM for achalasia between 2012 and 2019 (30 type I, 68 type II, 27 type III, and 17 variant). Patients with type I achalasia had a significantly higher induction DI (median 1.7 mm²/mmHg) than type II (0.8 mm²/mmHg), type III (0.9 mm²/mmHg), and variants (1.1 mm²/mmHg; $p < 0.001$). These differences persisted after submucosal tunneling and final DI after myotomy was also significantly higher in type I patients (median 8.0 mm²/mmHg) compared to type II (5.8 mm²/mmHg), type III (3.9 mm²/mmHg), and variants (5.4 mm²/mmHg; $p < 0.001$). Achalasia subtypes were found to have similar CSA at all time points, whereas pressure differed with type I having the lowest pressure and type III the highest.

Conclusion The DI at each operative step during POEM was found to differ significantly between achalasia subtypes. These differences in DI were due to pressure, as CSA was similar between subtypes. Achalasia subtype should be accounted for when using FLIP as an intraoperative calibration tool and in future studies examining the relationship between DI and clinical outcomes.

Keywords Distensibility index · Achalasia subtype · POEM · FLIP

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Achalasia is an esophageal motility disorder classically characterized by loss of peristalsis and impaired relaxation of the lower esophageal sphincter (LES) during swallowing [1]. There are several disease subtypes that are defined by differing patterns of esophageal body contractility: absent contractility (type I), panesophageal pressurization (type II), and premature (spastic) distal esophageal contractions (type III). Patients with a failure of LES relaxation but preserved peristalsis are classified as having “esophagogastric junction outlet obstruction” and some such patients are thought to represent a variant of achalasia [2]. Treatments aim to lower LES pressure and improve esophageal emptying, with myotomy (endoscopic or laparoscopic) providing the most

durable outcomes [3–6]. Responses to treatment vary by achalasia subtype, with type III having the worst outcomes and type II the best [4, 7–9].

Current evidence suggests that the distensibility index (DI) as measured by the functional luminal imaging probe (FLIP) is a useful predictor of clinical outcomes. FLIP is a tool that uses impedance planimetry to assess esophageal physiology through real-time evaluation of contractility patterns and measurement of the DI at the esophagogastric junction (EGJ) [10, 11]. Multiple studies have shown that DI correlates with esophageal emptying, clinical symptoms, and treatment success [12–15]. Several target DI values or ranges have been identified based on comparisons to healthy volunteers or correlation with clinical outcomes, but these have been global values without accounting for achalasia subtype.

Variable responses to treatments based on achalasia subtype are well described, but little is known about the variability in DI among these groups. A comprehensive assessment of FLIP measurements during myotomy may allow for a better understanding of the variability between achalasia subtypes and a more specific prediction of outcomes. The objective of this study was to determine if intraoperative FLIP measurements and the changes produced by per oral endoscopic myotomy (POEM) differed between achalasia subtypes.

Materials and methods

Study design and inclusion criteria

A single-institution retrospective cohort study of patients undergoing POEM for achalasia from 2012 to 2019 was performed using a prospectively maintained database. All patients 18 years or older who were diagnosed with achalasia or an achalasia-variant motility disorder (e.g., EGJ outflow obstruction) based on Chicago classification v3.0 and who had intraoperative FLIP performed were eligible for inclusion in the study. Patients who had undergone prior endoscopic or laparoscopic myotomy were excluded. FLIP measurements were obtained in compliance with a protocol approved by the Northwestern Institutional Review Board. Patients were divided into cohorts based on their achalasia classification resulting in four patient cohorts as follows: type I, type II, type III, and achalasia variants. The patient cohorts underwent the standard preoperative workup and procedural technique.

Operative technique

A single surgeon (ESH) performed POEM using a technique that has previously been described in detail [16]. In brief, an anterior, 8–10-cm selective myotomy of the circular muscle

layer, including a 2–3-cm extension onto the stomach was performed in patients with non-spastic achalasia (i.e., not type III). For patients with type III achalasia, an extended myotomy was performed based on preoperative high-resolution manometry (HRM) identification of the most proximal contractile segment.

FLIP system and distension protocol

A commercially available FLIP system (previously EndoFLIP; Crospon Inc, Galway Ireland, now EndoFLIP, Medtronic, Minneapolis, MN) was used to collect intraoperative EGJ DI data. The concept and function of the FLIP system have previously been described in detail [10, 11, 17]. Briefly, the FLIP system is a machine that uses a long catheter to collect impedance planimetry data. The distal end of the catheter contains a solid-state pressure transducer and equally spaced electrodes within a distensible bag. The machine fills the bag with saline up to a maximum fill volume depending on catheter size (50 mL in 8-cm catheter, 70 mL in 16-cm catheter), and a cross-sectional area (CSA) is calculated at each electrode pair. DI is calculated by dividing the minimum CSA by intra-bag pressure, which is derived from the pressure transducer.

Intraoperative FLIP measurements were obtained by performance of the following described protocol. The catheter was purged of air and zeroed to atmospheric pressure, following which the probe was positioned under endoscopic guidance with approximately 1–3 channels distal to the EGJ. Appropriate probe placement was confirmed via a distal narrowing or waist seen on the FLIP display monitor. Measurements were recorded when using a balloon fill volume of 40 mL for 8-cm catheters (EF-325) or 60 mL for 16-cm catheters (EF-322). FLIP measurements were collected at three operative time points: (1) following induction of anesthesia, (2) after submucosal tunneling, and (3) after myotomy completion. Intraoperative FLIP data were analyzed using MATLAB software (MathWorks; Natick, MA).

Statistical analysis

All statistical analyses were performed using Stata v15.1 (StataCorp, College Station, TX). Associations between cohorts and covariates were examined using chi-square and ANOVA or Kruskal–Wallis tests depending on data distribution. Dichotomous variables were compared using a Fischer's exact test or chi-square test as appropriate. Comparisons of median FLIP measurements stratified by achalasia subtype were made at each operative time point using Kruskal–Wallis tests. A post hoc analysis of pairwise comparisons were performed on any significant findings using Mann–Whitney *U* tests and were corrected for multiple

comparisons. Tests of significance were two sided with p values <0.05 considered significant.

Results

Overall, 142 patients had intraoperative FLIP performed during POEM for achalasia or an achalasia-variant motility disorder between 2012 and 2019 (30 type I, 68 type II, 27 type III, and 17 variants). The median age was 57 years with significant differences by subtype (median 51.5 years in type I, 54 years in type II, 60 years in type III, 63 years in variants; $p=0.04$). There were no significant differences in gender by subtype with 54% male patients overall. Achalasia-variant patients were significantly more likely to have undergone prior treatment (53% vs 23% type I, 12% type II, and 22% type III; $p=0.005$). Detailed baseline characteristics by cohort can be seen in Table 1.

There were significant differences in DI by subtype at induction (medians type I: 1.7 mm²/mmHg, IQR 0.9–3.0; type II: 0.8 mm²/mmHg, IQR 0.6–1.4; type III: 0.9 mm²/

mmHg, IQR 0.5–1.0; variants: 1.1 mm²/mmHg, IQR 0.5–1.9; $p<0.001$, Fig. 1). Pairwise comparisons demonstrated that this difference was due to higher induction DI in type I compared to both type II and type III (both $p<0.001$, adjusted significance threshold <0.008). Following submucosal tunneling, there remained significant differences in DI by subtype (medians type I: 3.4 mm²/mmHg, IQR 2.3–6.5; type II: 2.6 mm²/mmHg, IQR 1.9–3.9; type III: 1.5 mm²/mmHg, IQR 1.0–2.7; variants: 3.1 mm²/mmHg, IQR 1.8–3.9; $p=0.002$). Pairwise comparisons demonstrated that this difference was due to higher submucosal tunnel DI in type I compared to type III ($p<0.001$, adjusted significance threshold <0.008). The final DI after myotomy was also significantly different by subtype (medians type I: 8.0 mm²/mmHg, IQR 5.7–10.6; type II: 5.8 mm²/mmHg, IQR 4.4–7.3; type III: 3.9 mm²/mmHg, IQR 3.5–6.1; variants: 5.4 mm²/mmHg, IQR 4.0–7.1; $p<0.001$). Pairwise comparisons demonstrated that this difference was due to higher postmyotomy DI between type I and both type II ($p=0.003$) and type III ($p<0.001$) as well as differences between type II and type III ($p=0.002$).

Table 1 Demographic and baseline clinical characteristics by achalasia subtype

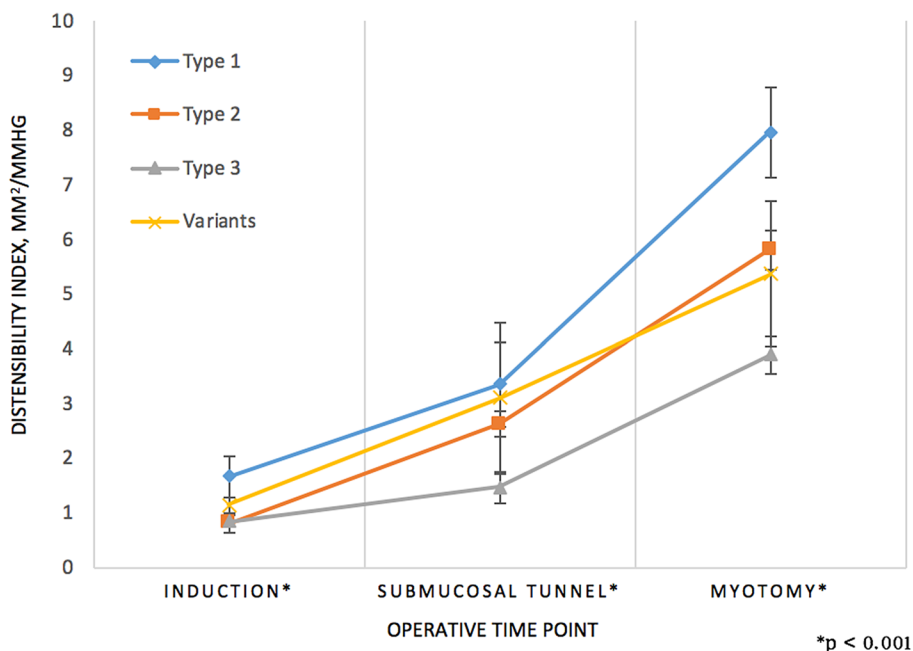
	Overall	Type 1	Type 2	Type 3	Variants	p value
Patients (%)	142	30 (21.1)	68 (47.9)	27 (19.0)	17 (12.0)	–
Age (IQR)	57 (44–67)	51.5 (44–63)	54 (39–65.5)	60 (52–71)	63 (57–69)	0.04
Gender— n (%)						0.367
Female	65 (46)	13 (43)	28 (41)	13 (48)	11 (65)	
Male	77 (54)	17 (57)	40 (59)	14 (52)	6 (35)	
BMI (IQR)	26 (23–31)	23 (21–26)	26 (23–31.3)	28.6 (24.3–34)	26 (23–31)	0.004
Baseline ES ^a (IQR)	7 (6–8)	6 (6–8)	8 (5.5–9)	7 (6–8)	7 (5–7)	0.365
Catheter type— n (%)						0.016
8 cm	75 (53)	17 (57)	42 (62)	7 (26)	9 (53)	
16 cm	67 (47)	13 (43)	26 (38)	20 (74)	8 (47)	
Symptom duration—years (IQR)	3 (1–4.25)	3 (1–5)	2 (1–4.25)	3 (2.5–4)	3 (1–4)	0.682
ASA class— n (%)						0.008
1–2	90 (64)	22 (76)	49 (72)	11 (41)	8 (47)	
3–4	51 (36)	7 (24)	19 (28)	16 (59)	9 (53)	
Insurance						0.004
Private	80 (56)	24 (83)	51 (75)	11 (41)	7 (47)	
Medicare	37 (26)	4 (14)	15 (22)	14 (52)	8 (47)	
Medicaid	6 (4)	1 (3)	2 (3)	2 (7)	1 (6)	
Prior treatment						0.011
None	112 (79)	23 (79)	60 (88)	21 (78)	8 (47)	
Botox injection(s)	18 (12)	3 (10)	4 (6)	3 (11)	7 (41)	
Pneumatic dilation(s)	10 (7)	2 (7)	3 (4)	3 (11)	2 (12)	
Botox and PD	2 (1)	1 (3)	1 (1)	0	0	

Median values are reported with interquartile ranges in parentheses. Percentages may not total 100 because of rounding

BMI body mass index, *ES* Eckardt symptom score, *ASA* American Society of Anesthesiologists, *PD* pneumatic dilation

^aEckardt symptom score (ES) is a validated questionnaire with four symptom domains (dysphagia, regurgitation, chest pain, and weight loss) graded from 0 to 3. The maximum ES is 12 with higher scores indicating more severe symptoms

Fig. 1 Median distensibility index at operative time points by achalasia subtype. Median distensibility index measurements based on achalasia subtype are compared at each operative time point. There were significant differences between subtypes at each operative time point as indicated by asterisk (*). I bars indicate standard error



*p < 0.001

There were no significant differences in cross-sectional area at any of the operative time points between cohorts (Fig. 2). Type III patients had the highest pressure at induction (median 47.8 mmHg, IQR 39.1–59) followed by variants (median 42.1 mmHg, IQR 33.3–47.6), then type II (median 35.1 mmHg, IQR 28–43.7), and type I had the lowest pressure at induction (23.4 mmHg, IQR 17.3–29; $p < 0.001$). All subtypes experienced a decrease in pressure over the course of the operation, however, differences

between subtypes persisted with type III patients having the highest pressure and type I patients having the lowest pressure at each time point (Fig. 3). Pairwise comparisons demonstrated that this was due to significant differences between type I and all other subtypes (all $p < 0.008$) as well as type II compared to type III ($p < 0.008$).

The overall change in DI (post-myotomy DI—induction DI) was highest in type I patients (median 5.5 mm²/mmHg, IQR 3.5–8.4), followed by type II (median 4.8

Fig. 2 Median cross-sectional area at operative time points by achalasia subtype. Median cross-sectional area measurements based on achalasia subtype are compared at each operative time point. There were no significant differences between subtypes at any of the operative time points. I bars indicate standard error

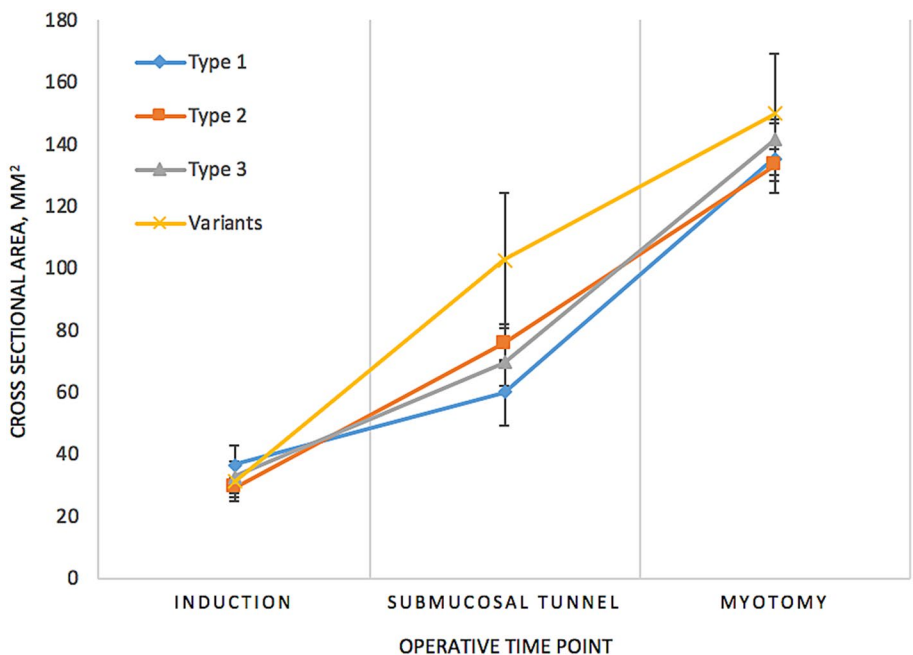
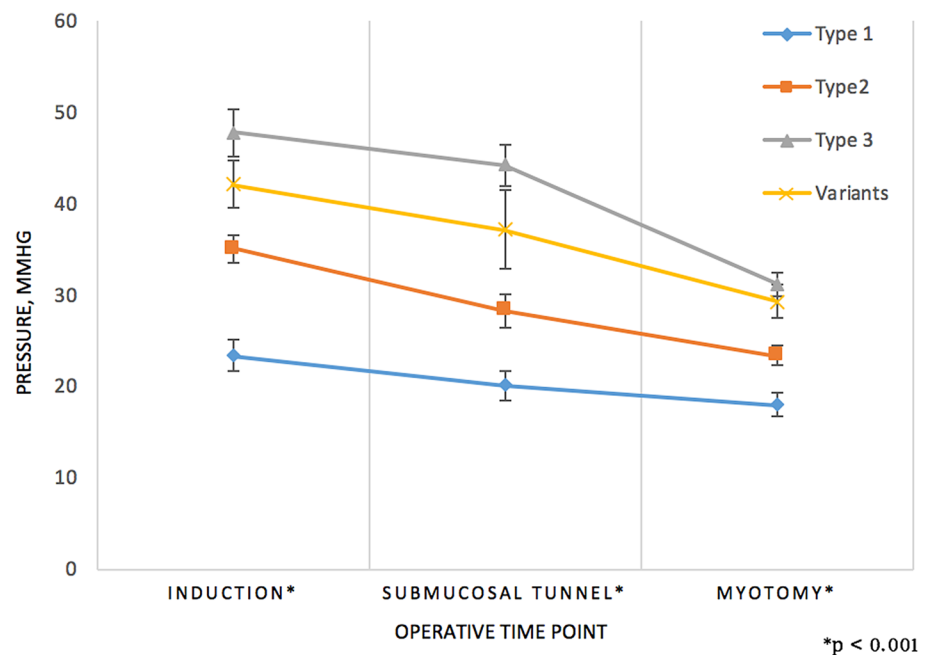


Fig. 3 Median pressure at operative time points by achalasia subtype. Median pressure measurements based on achalasia subtype are compared at each operative time point. There were significant differences between subtypes at each operative time point as indicated by asterisk (*). Pairwise comparisons demonstrated significant differences between type I and all other subtypes (all $p < 0.008$) as well as type II compared to type III ($p < 0.008$) at each operative time point. I bars indicate standard error



* $p < 0.001$

mm^2/mmHg , IQR 3.5–6.2), then variants (median 4.7, IQR 3.2–6.6), and was lowest among type III patients (median 3.4 mm^2/mmHg , IQR 2.6–5.2; $p = 0.02$). There were no significant differences between cohorts when examining DI change following submucosal tunneling and DI change following myotomy (Table 2). There were no significant differences in CSA change at any operative time

point between cohorts (Table 2). The overall decrease in pressure (induction pressure—myotomy pressure) was significantly different between cohorts with type III patients experiencing the largest decrease (17.9 mmHg, IQR 8.0–23.7) followed by variants (13.1 mmHg, IQR 5.6–19.5), type 2 patients (8.7 mmHg, IQR 4.9–14.6), and lastly type 1 patients with the smallest overall decrease in pressure (6.4 mmHg, IQR 1.1–12.4; $p < 0.001$).

Table 2 Change in distensibility index, cross-sectional area, and pressure at each operative time point by achalasia subtype

	Achalasia subtype, median (IQR)				<i>p</i> value
	Type 1	Type 2	Type 3	Variants	
Distensibility index (mm^2/mmHg)					
Tunneling change ^a	1.5 (0.4–4.5)	1.4 (0.8–2.9)	0.6 (0.3–1.5)	1.5 (0.1–2.8)	0.118
Myotomy change ^b	4.4 (2.5–5.7)	3.1 (2–4.4)	2.6 (2–3.2)	3 (1.7–4.1)	0.077
Overall change ^c	5.5 (3.5–8.4)	4.8 (3.5–6.2)	3.4 (2.6–5.2)	4.7 (3.2–6.6)	0.022
Cross-sectional area (mm^2)					
Tunneling change	22.6 (15.5–50.5)	39.2 (21.9–70.9)	26.1 (13.3–52.1)	44.3 (19.2–82.4)	0.203
Myotomy change	62.2 (48.3–75.4)	53.1 (37.1–80.8)	55.9 (47.4–76.3)	60.9 (52.6–99.9)	0.650
Overall change	93.3 (67.7–135.3)	97.7 (76.2–121.6)	104.2 (77.7–121.6)	112 (95.9–141.7)	0.406
Pressure (mmHg)					
Tunneling change	– 2.3 (– 2.4 to – 4.9)	– 3.5 (+ 3.4 to – 11.9)	– 3.4 (+ 5.2 to – 14.3)	– 4.8 (– 4.2 to – 10.3)	0.920
Myotomy change	– 4.1 (– 1 to – 5.3)	– 5.6 (– 2.8 to – 10.9)	– 10.3 (– 5.3 to – 17.6)	– 8.5 (– 2.1 to – 20)	0.001
Overall change	– 6.4 (– 1.1 to – 12.4)	– 8.7 (– 4.9 to – 14.6)	– 17.9 (– 8 to – 23.7)	– 13.1 (– 5.6 to – 19.5)	<0.001

^aTunneling change is defined as the median increase in measurement from induction to submucosal tunneling

^bMyotomy change is defined as the median increase in measurement from submucosal tunneling to myotomy

^cOverall change is defined as the median increase in measurement from induction to myotomy

Discussion

In this study, DI was found to differ significantly between achalasia subtypes at each operation time point during POEM, with type III having the lowest DI at each step and type I having the highest. CSA measurements were similar between subtypes, so the differences in DI were mediated primarily by significant differences in pressure. The overall change in DI was also significantly different between subtypes with type I experiencing the largest change and type III the smallest.

Given the underlying differences in the esophageal motility on HRM between subtypes, it is not surprising to find that their intraoperative FLIP measurements differ significantly. Work by Smeets et al. found type II patients had a lower pre-treatment DI compared to type I patients (0.8 mm²/mmHg vs. 1.1 mm²/mmHg) and a higher pressure (27.6 mmHg vs. 21.0 mmHg), which is congruent with our results [18]. Our previous work on a small initial cohort demonstrated that type I achalasia patients had the largest change in DI with a mean increase of 5.2 mm²/mmHg, which is consistent with the results from this study. [19]. That study also showed a significant overall decrease in pressure among type III and variant patients, but not in type I and II patients. Our study shows significant differences in overall decrease in pressure between subtypes with type III and variants experiencing the largest decreases.

Differences in outcomes by achalasia subtype are well documented in the literature, which calls for consideration of achalasia subtype when determining treatment approach. The DI, as measured by FLIP, has become a potential measure to predict outcomes following treatment for achalasia, but lacks subtype-specific data. Intraoperative FLIP data may provide insight into the mechanisms underlying varying outcomes following treatment based on achalasia subtype. For example, the same DI in patients of different achalasia subtypes may result in variable clinical outcomes due to differences in esophageal function and pathophysiology such as pressure generation in the esophageal body. Future work to investigate the relationship between FLIP measurements and outcomes should be stratified by achalasia subtype to further elucidate these differences.

Type III achalasia patients receive a tailored myotomy at our institution based on identification of the contractile segment on HRM. In spite of this subtype-specific treatment, pressure was still highest in this cohort at the conclusion of myotomy. Additionally, we were interested to find some patient-level characteristics that appear associated with type III and achalasia variants such as older age, higher ASA classification, and increased likelihood

of prior achalasia treatment. These factors may play an important role in clinical outcomes at the patient level as postoperative recovery may be quite different for older, medically comorbid patients.

Several small studies have investigated correlations between intraoperative FLIP measurements and postoperative clinical outcomes. Our previously published work found a final DI within the range of 4.5–8.5 mm²/mmHg (measured using the 8-cm FLIP at a 40 mL fill volume) to be mostly likely to provide symptomatic success while minimizing reflux symptoms [12]. Recent work by Su et al. found that a DI \leq 3.1 mm²/mmHg or a change in DI $<$ 3.0 mm²/mmHg (8-cm FLIP at 30 mL) was associated with clinical failure [20]. This is similar to work by Rohof et al. who found DI $>$ 2.9 mm²/mmHg (14-cm FLIP at 50 mL) when measured during follow-up endoscopy was associated with clinical success [15]. However, these studies are small, use different FLIP catheters and/or fill volumes, and none stratified the results by achalasia subtype. Unfortunately, at present we do not have sufficient clinical and physiologic follow-up data or power when stratified by achalasia subtype to perform a meaningful analysis of outcomes in this patient cohort. This will be an important area for future study.

There are several important limitations to this study. All procedures and measurements were performed at a single institution and by a single surgeon which may limit the generalizability of the results. The number of patients in this study, specifically among the achalasia-variant cohort, limits the ability to detect potentially meaningful differences and the type III cohort had a significantly larger percentage of 16-cm catheters used for FLIP measurements. Additionally, at this time, we do not have enough clinical and physiologic follow-up data from this patient cohort to perform a definitive evaluation of the predictive value of these intraoperative measurements for clinical outcomes.

In summary, this study showed that intraoperative FLIP measurements differed significantly by achalasia subtype. The DI at each operative step was found to differ significantly between achalasia subtypes, with these differences being driven largely by pressure. While the absolute change in DI was greatest in type I patients, patients with type III achalasia had the greatest change in pressure. Given these differences, achalasia subtype should be accounted for when using FLIP as an intraoperative calibration tool and in future studies examining the relationship between DI and postoperative outcomes.

Compliance with ethical standards

Disclosures Dr. Carlson: Medtronic, Inc.—speaking, consulting, shared intellectual property rights and ownership surrounding functional luminal imaging probe panometry systems, methods, and appa-

ratus. Dr. Hungness: Cook Medical—consulting; Boston Scientific—consulting; Baxter—consulting. Dr. Pandolfino: Medtronic, Inc.—grant funding, speaking, consulting, shared intellectual property rights and ownership surrounding functional luminal imaging probe panometry systems, methods, and apparatus; Sandhill Scientific—consulting, speaking; Crospon—stock options; Takeda—speaking; AstraZeneca—speaking. Dr. Teitelbaum: Cook Medical—educational speaker; Boston Scientific—consulting. Drs. Campagna and Holmstrom, and Jonathan Alhalel have no conflicts of interests or financial ties to disclose.

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