Title

Inter- and intra-rater agreement of interpretation of functional lumen imaging probe in healthy subjects.

Journal

Neurogastroenterology & Motility, 35(3)

Authors

Lin, Haiying
Richter, Joel
Vela, Marcelo
et al.

Publication Date

2023-03-01

DOI

10.1111/nmo.14505

Peer reviewed

HHS Public Access

Author manuscript

Neurogastroenterol Motil. Author manuscript; available in PMC 2023 December 18.

Published in final edited form as:

Neurogastroenterol Motil. 2023 March ; 35(3): e14505. doi:10.1111/nmo.14505.

Inter- and intra-rater agreement of interpretation of functional lumen imaging probe in healthy subjects

Rena Yadlapati[1], **C. Prakash Gyawali**[2], **Dustin A. Carlson**[3], **John E. Pandolfino**[3], **Ronnie Fass**[4], **Abraham Khan**[5], **Haiying Lin**[6], **Joel E. Richter**[7], **Marcelo F. Vela**[8], **Michael Vaezi**[9], **John O. Clarke**[10]

[1]Division of Gastroenterology, University of California, San Diego School of Medicine, La Jolla, California, USA

[2]Division of Gastroenterology, Washington University School of Medicine, St. Louis, Missouri, USA

[3]Department of Medicine, Division of Gastroenterology and Hepatology, Feinberg School of Medicine, Northwestern University, Chicago, Illinois, USA

[4]Division of Gastroenterology and Hepatology, Metro Health Medical Center, Case Western Reserve University, Cleveland, Ohio, USA

[5]Center for Esophageal Health, Division of Gastroenterology & Hepatology, NYU Langone Health, New York, New York, USA

[6]Medtronic, Minneapolis, Minnesota, USA

Correspondence Rena Yadlapati, Division of Gastroenterology, University of California, San Diego School of Medicine, ACTRI Building 1W517, 9500 Gilman Drive MC 0956, La Jolla, CA 92093, USA. ryadlapati@health.ucsd.edu.

AUTHOR CONTRIBUTION

Rena Yadlapati, C. Prakash Gyawali, John O. Clarke contributed to study concept and design, data acquisition, data interpretation, drafting and editing the manuscript critically and approval of the final version. Dustin A. Carlson and John E. Pandolfino contributed to study concept and design, data interpretation, editing the manuscript critically and approval of the final version. Ronnie Fass, Abraham Khan, Joel E. Richter, Marcelo F. Vela, Michael Vaezi contributed to study concept and design, data acquisition, editing the manuscript critically and approval of the final version. Haiying Lin contributed to data analysis, data interpretation, editing the manuscript critically and approval of the final version.

CONFLICT OF INTEREST

Rena Yadlapati has served as a consultant for Medtronic, Ironwood Pharmaceuticals, Phathom Pharmaceuticals, provided research support to Ironwood Pharmaceuticals, and served on the advisory board with stock options for RJS Mediagnostix. C. Prakash Gyawali has served as a consultant for Medtronic, Diversatek, Ironwood, IsoThrive, Ardelyx, Dexcel Pharma, and Quintiles and served as a speaker for Takeda and Johnson & Johnson. Dustin A. Carlson serves as a consultant, speaker, and holds shared licensing agreements with Medtronic, Inc. and serves as a consultant for Phathom Pharmaceuticals. Holds shared intellectual property rights and ownership surrounding functional luminal imaging probe panometry systems, methods, and apparatus with Medtronic, Inc. He additionally holds stock options in Crospon, Inc. has served as a consultant for Given Imaging, Sandhill Scientific, Medtronic, Torax, and Ironwood, has received grants from Given Imaging and Impleo, and has served as a speaker for Given Imaging, Sandhill Scientific, Takeda, Astra Zeneca, Medtronic, and Torax. Ronnie Fass has served as a consultant for Ironwood, Takeda, Daewoong, Medtronic, Phathom; served as a speaker for Astrazeneca, Takeda, Diversatek, Eisai; served on the Advisory Board for Phathom; and provided Research support from Ironwood, Salix; Royalties: UpToDate. Abraham Khan has served as a consultant and speaker for Medtronic. Haiying Lin is an employee of Medtronic. Joel E. Richter disclose no conflicts of interests. Marcelo F Vela has served as a consultant for Medtronic and provided research support to Diversatek. Michael F. Vaezi has served in an advisory capacity for Ironwood, Phathom, Cinclus, ISOThrive, Sanofi, Bayer, Neurogastric, Medtronic, Diversatek healthcare, has a patent for Mucosal Integrity Testing (Diversatek), and serves in legal consultation in litigation relating to acid suppressive agent. John O. Clarke has served as a consultant for Alnylam, Isothrive, Medtronic, Phathom, Regeneron, and Sanofi.

DISCLAIMER

Results from this study are intended to inform and facilitate proper on-label use of FLIP™ technology in symptomatic patients.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

[7]Joy McCann Culverhouse Center for Esophageal and Swallowing Disorders, University of South Florida Morsani College of Medicine, Tampa, Florida, USA

[8]Division of Gastroenterology and Hepatology, Mayo Clinic, Scottsdale, Arizona, USA

[9]Division of Gastroenterology, Vanderbilt University Medical Center, Nashville, Tennessee, USA

[10]Division of Gastroenterology and Hepatology, Stanford University School of Medicine, Stanford, California, USA

Abstract

Background: The functional lumen imaging probe (FLIP) evaluates esophagogastric junction (EGJ) opening and esophageal contractility. Both post hoc and real-time analyses are possible, but reproducibility and reliability of analysis remain undefined. This study assesses inter- and intra-rater agreement of normative FLIP measurements among novice and experienced users.

Methods: Eight motility experts from different institutions independently evaluated de-identified video recordings from 27 asymptomatic healthy subjects using FLIP. Interpretation methods simulating a post-procedure and a live procedure setting were tested. Novice FLIP users (n = 3) received training prior to post-procedure interpretation. Experienced FLIP users (n = 5) interpreted using both methods. Users recorded maximum EGJ and distal esophageal body diameter, distensive pressure, and EGJ distensibility index (EGJ-DI), at balloon fill volumes of 50-, 60-, and 70 ml, as well as repetitive antegrade contractions (RACs). Inter- and intra-rater agreements of diameters, distensive pressure and EGJ-DI were assessed by intra-class correlation coefficient (ICC) and Pearson's correlation coefficient (PCC). Percentage agreement evaluated inter- and intra-rater reliability for RACs.

Key Results: Novice and experienced users acquired normative FLIP metrics. Good-to-excellent inter- and intra-rater reliability were achieved for all variables at 60 ml balloon fill volumes. Median parameters at 60 ml balloon fill volume were as follows: EGJ-DI 5.5 mm^2/mmHg, maximum EGJ diameter 18.6 mm, distensive pressure at maximum EGJ diameter 48.1 mmHg, and distal esophageal body diameter 19.5 mm.

Conclusions and Inferences: Normative FLIP parameters can be reliably extracted from FLIP videos using both real-time and post hoc analyses, with high reliability between experienced and novice users.

Keywords

achalasia; esophageal motility; manometry; per oral endoscopic myotomy

1 | INTRODUCTION

The functional lumen imaging probe (FLIP™) assesses esophageal physiology during sedated endoscopy. FLIP uses impedance planimetry technology to measure esophageal luminal dimensions and esophageal distensibility in response to controlled volumetric distension of a catheter-mounted balloon.[1] In addition, FLIP assesses secondary peristaltic contractile response to distension in the esophageal body, which is distinct from primary peristalsis initiated by a cued water swallow during esophageal high-resolution manometry

(HRM).[2] FLIP can be performed during index endoscopy if a mechanism for obstructive esophageal symptoms is not evident and/or if an esophageal motility disorder is suspected.[3] Alternatively, FLIP may be utilized as a complementary test to corroborate findings from HRM and/or barium esophagram.[4] Other applications of FLIP include objective evaluation of esophageal luminal diameter in the management of esophageal strictures or eosinophilic esophagitis, and monitoring during or following foregut interventions such as myotomy or fundoplication.[5–9]

The current version of FLIP displays impedance planimetry data on screen during the procedure, permitting real-time interpretation in addition to traditional post-procedure interpretation of archived data.[3] Real-time interpretation provides the potential for efficient diagnosis and management of the patient during index endoscopy.[1] As utilization of FLIP grows among gastroenterologists and surgeons in clinical practice, reliability of real-time vs. post hoc data interpretation, as well as the learning curve to accurately interpret FLIP data remain incompletely understood. The aim of this study was to assess inter- and intra-rater agreement of normative FLIP measurements among novice and experienced users in healthy subjects, as well as between real-time and post-procedure analyses.

2 | MATERIALS AND METHODS

2.1 | Study design and FLIP users

Eight gastroenterologists with expertise in diagnosing and managing esophageal motility disorders across academic institutions with motility centers in the United States were invited and consented to participate in the study. Participating motility experts were separated into two groups based on prior experience with FLIP: experienced (>5 years clinical experience with FLIP) and novice (<1 year or with no clinical experience with FLIP) users. Experienced reviewers had an average of 5.8 years of experience (range 3–8 years) and had completed an average of 610 procedures (range 100–1500). Novice users had an average of 0.5 years of experience (range 0–1.5) and had completed an average of 5 procedures (range 0–15). Users evaluated de-identified FLIP video recordings from an existing cohort of healthy asymptomatic adult patients. Interpretation was compared to the source interpretation of the healthy adults performed at Northwestern University, by a single reviewer using a customized program that generated FLIP panometry plots for analysis (https://www.wklytics.com/nmgi/); data analysis and normative thresholds from some of this cohort have been previously published.[10,11] Investigators from Northwestern University were not included in the group of participating motility experts. Since interpretation methodology involved review of de-identified FLIP videos with no links to actual human subjects, institutional review board (IRB) approval was not deemed necessary for this study.

2.2 | Healthy volunteer cohort

FLIP videos used for this study were derived from a cohort of healthy, asymptomatic adults free of esophageal symptoms including dysphagia, heartburn, and chest pain, who were part of a prospective study at Northwestern University.[10] Included subjects were not taking any medications that could interfere with esophageal motility. Additional exclusion criteria consisted of previous diagnosis of esophageal, autoimmune, or eating disorders, use of

antacids or proton pump inhibitors, body mass index >30 kg/m^2, or a history of tobacco use or alcohol abuse. All healthy volunteers underwent upper endoscopy after a fast of at least 6 h, using conscious sedation with 5–10 mg midazolam and 100 to 200 mcg fentanyl. The 16 cm FLIP catheter (EF-322 N, Medtronic, Inc) was calibrated to atmospheric pressure before transoral placement. The balloon was positioned within the esophagus such that 1–3 impedance sensors were located distal to the lower esophageal sphincter (LES). Stepwise 5 ml or 10 ml balloon distensions were performed for 30–60 s each, with confirmed adequate FLIP positioning across the EGJ maintained through the 20–40 fill volumes. Analysis focused on the 50–70 ml fill volumes. Each FLIP study was recorded from insertion of the catheter-to-catheter removal using a digital video recorder in real-time. The study protocol for FLIP studies in healthy volunteers was approved by the Northwestern University IRB, and informed consent was obtained from all individuals prior to participation.

2.3 | Interpretation methodology

Two methods of FLIP video analyses were utilized for the current study. Post hoc analysis (Method 1) provided scroll through, rewind and pause capabilities of FLIP videos to simulate post hoc FLIP interpretation at a post-procedure setting. Real-time analysis (Method 2) required users to play the video to simulate a live procedure; although scroll through and pause capabilities were provided, the rewind function was not available.

Novice users were provided training in FLIP methodology, acquisition, and interpretation, and only used Method 1 for interpretation. Novice users used the first randomly selected ten videos for training and used the next five randomly selected videos for independent testing. If novice users achieved accurate independent assessment of the five testing videos, based on clinical input and comparison to experienced user's analysis of the same five cases, they were deemed to have successfully completed training and moved on to independently assess 22 videos (the remaining 12 videos and the original ten training videos which were re-randomized and independently interpreted after washout of at least a week), for a total of 27 videos independently assessed (Figure 1). Experienced users interpreted using Methods 1 and 2 at least a week apart. For each interpretation method and FLIP video, the users documented their readings on a standardized data form created a priori for this purpose (See Appendix S1).

2.4 | Data collection and management

Data were collected on standardized data forms at each fill volume of 50, 60, and 70 ml. Three measurements were collected at each fill volume for esophagogastric junction distensibility index (EGJ-DI), maximum EGJ diameter, and distensive pressure at maximum EGJ diameter. Three measurements were collected at each fill volume for distal esophageal body diameter at the maximal esophageal body opening. The contractile pattern was noted at each fill volume including the rate of antegrade contractions (ACs) and presence or absence of repetitive antegrade contractions (RACs). The direction of contractions (antegrade or retrograde) was categorized based on a tangent line placed at the onset of contraction. The contractile response to distension was further categorized as *repetitive* if contractions of similar directionality occurred consecutively at a consistent time interval and then by

contraction direction (antegrade or retrograde).[12] Data forms were uploaded by each user into individual folders in a secure web-based application for analysis.

2.5 | Outcomes

The primary continuous outcomes assessed were EGJ-DI, maximum EGJ diameter, distensive pressure at maximum EGJ diameter, distal esophageal body diameter, and rate of ACs. The categorical outcome assessed was contractile pattern (presence or absence of RACs at balloon fill volumes of 50, 60, and 70 ml).

2.6 | Statistical analysis

Descriptive statistics are used to present the data and to summarize the results. Categorical variables are reported using frequency distributions and cross tabulations. Continuous variables are summarized as median and 5th and 95th percentile values.

Intraclass correlation coefficients (ICCs) measured inter-rater reliability between experienced and novice users (Method 1) and among experienced users (Method 2). Pearson's correlation coefficients (PCCs) assessed intra-rater reliability among experienced users to compare Methods 1 and 2. The level of clinical significance for both ICC and PCC is as follows: poor for coefficients <0.40, fair for 0.40 ≤ coefficients ≤0.59, good for 0.60 ≤ coefficients ≤0.74, and excellent for 0.75 ≤ coefficients ≤1.00.[13]

To assess the inter-rater agreement for presence or absence of RACs, percentage agreement analyses evaluated the reliability of measurements among experienced and novice users (Method 1), among experienced users (Method 2), and among experienced users to compare Methods 1 and 2.

Finally, interpretation metrics acquired from both Method 1 and Method 2 were compared to the normative value interpretation from the source institution (Northwestern University), which have been published as part of prior reports.[10,11]

All statistical analyses were performed using Statistical Analysis System (SAS) for Windows (version 9.4, SAS Institute Inc.).

3 | RESULTS

3.1 | Healthy volunteers

The healthy volunteer cohort consisted of 27 individuals (19 females and 8 males) with a mean age of 31.2 years (range 23–45 years) and BMI of 23.7 kg/m^2 (range 18–30 kg/m^2).

3.2 | Normative measurements

All novice users successfully analyzed FLIP data after the first cycle of training as assessed by clinical comparison to experienced users. Based on interpretation by the entire cohort of experienced and novice users, median values at 60 ml balloon fill volumes were 18.6 mm (5th–95th percentile values of 12.8–21.6) for maximum EGJ diameter, 5.5 mm^2/mmHg (2.8–8.0) for EGJ-DI, 48.1 mmHg (36.0–64.9) for distensive pressure, and 19.5 mm (15.0–21.6) for distal esophageal body diameter (Table 1). Median values for all evaluated fill

volumes are presented in Table 2. At 60 ml, the median rate of ACs was 6.7 per minute (3.0, 8.0). Representative patterns of ACs at all balloon fill volumes are shown in Figure 2.

Cumulative RAC presence at any of the three fill volumes evaluated consisted of 96.3% using Method 1 and 94.1% using Method 2. Users had ≥88.9% agreement on detection of the presence (vs absence) of cumulative RACs and 97.8% intra-rater agreement.

3.3 | Inter-rater reliability

Inter-rater reliability was good to excellent among novice and experienced users (Figure 3). Inter-rater agreement (ICC [95% confidence interval [CI]]) among novice and experienced users using Method 1 at 60 ml fill volume consisted of 0.83 (0.79, 0.86) for maximum EGJ diameter, 0.77 (0.72, 0.81) for EGJ-DI, 0.76 (0.71, 0.81) for distensive pressure, and 0.87 (0.84, 0.90) for distal esophageal body diameter.

3.4 | Intra-rater reliability

Experienced users reported consistent values when using Methods 1 and 2. Intra-rater reliability values (PCC (95% CI)) were good to excellent for all measures: 0.79 (0.75, 0.82) for maximum EGJ diameter, 0.72 (0.66, 0.76) for distensive pressure, 0.74 (0.69, 0.78) for EGJ-DI, and 0.85 (0.82, 0.88) for distal esophageal body diameter (Figure 3).

3.5 | Comparison to metrics from source interpretation

Interpretation metrics from source interpretation at 60 ml balloon fill volume were as follows: median value for EGJ-DI: 5.5 mm^2/mmHg (5th–95th percentile 3.2–7.0); maximum EGJ diameter: 19.2 mm (15.3–20.5); distal esophageal body diameter: 19.8 mm (18.3–21.0); and distensive pressure: 49.0 mmHg (37.0–69.0). Inter-rater agreements for each of these metrics between all users and source interpretation obtained from Method 1 analyses are shown in Figure 3. Agreements were similar between all users and source interpretation. Overall inter-rater agreements (ICC [95% confidence interval [CI]]) across the novice, experienced, and source interpretation metrics are as follows: maximum EGJ diameter, 0.82 (0.78, 0.85); distensive pressure, 0.76 (0.71, 0.81); EGJ-DI, 0.76 (0.71, 0.81); and distal esophageal body diameter, 0.86 (0.83–0.89).

4 | DISCUSSION

In this study evaluating inter- and intra-rater agreement of FLIP interpretation using real-time and post hoc review methodology of FLIP videos acquired from healthy asymptomatic volunteers, we demonstrate that both intra- and inter-user reliability were good to excellent using either review methodology. Further, there was high reliability in post hoc interpretation of FLIP videos between novice and experienced users, and between these users and source interpretation, indicating that with simple training, even novice users can interpret normal FLIP studies, and extract reliable data. Additionally, metrics from real-time interpretation matched post hoc interpretation among experienced users with good-to-excellent reliability, indicating that real-time interpretation of normal FLIP studies is feasible and reliable. Finally, the cumulative normative FLIP metrics extracted from the

healthy volunteer cohort by the experienced panel resembles that reported from the source data,[14] further reinforcing these normative values.

Clinical application of FLIP has expanded over the past decade, and the technology is increasingly utilized by clinicians in patient management across various esophageal and foregut symptomatic states. When utilized outside of tertiary academic motility centers, especially when used during index endoscopy, the likelihood of normal studies will be higher than that encountered in advanced centers. For this reason, the ability of especially novice users to extract accurate metrics and recognize normal studies is of high importance. In this study, we demonstrate that novice users can perform just and experienced users in extracting normative FLIP metrics post hoc. Novice users could be trained for accurate interpretation of normal studies with didactics and limited supervised review of FLIP videos (Ten videos in this study). These findings support use of FLIP by endoscopists in identifying normal studies, although further studies are needed to determine whether abnormal studies can be recognized with similar reliability.

An important finding of this study is that there was good-to-excellent intra-rater agreement in normative metrics extracted post hoc vs. real time by experienced users. This adds to the value and clinical utilization of FLIP, since real-time interpretation as the study is being performed can allow the operator to plan management strategies during the index endoscopy. For instance, if the FLIP study is normal in a symptomatic patient with chest pain, a wireless pH probe can be placed at the same setting to determine a reflux-related mechanism for chest pain. Previous real-time interpretation studies have indicated that FLIP findings correspond well to subsequent HRM studies, and may identify abnormal EGJ opening even in patients where HRM is not abnormal.[3] The lowest (though still good-to-excellent) agreement was for distensive pressure. This is expected since distensive pressure changes related to breathing and esophageal peristaltic activity.

This study addressed several existing limitations surrounding clinical application of FLIP and reinforces several practical implications. These data imply that novice FLIP users can be trained relatively quickly to identify normal FLIP studies. Further, these results demonstrate the reliability of the extraction technique from FLIP videos when utilized by both novice and experienced users from other institutions.[10] Finally, data highlight that real-time interpretation is feasible and reliable in identifying normal studies, indicating that the clinician or provider can plan patient management based on real-time data extraction such as at the time of index endoscopy.

There are several limitations to our study that need to be acknowledged. First, even our “novice users” were experts in esophageal disease and may not be representative of the general endoscopist who may be using FLIP. Second, the FLIP videos utilized in interpretation were generated from studies performed with a structured distension protocol, which may not be representative of the average FLIP study, though perhaps lends support to following the recommended FLIP study protocol. Third, our analysis and agreement are limited to studies from healthy asymptomatic volunteers and it is unclear if the same level of agreement would apply to disease states. Finally, the sample size of studies reviewed was still relatively small. Future studies with larger numbers of healthy volunteers, symptomatic

patients, and abnormal FLIP studies are needed, involving a broader cross-section of FLIP users, to determine how FLIP functions in real-life clinical situations. From a technical standpoint, the ability to incorporate the customized software analysis utilized into future software versions of the FLIP technology may further simplify use of FLIP in clinical and research applications.

5 | CONCLUSION

In summary, our data suggest that experts from multiple academic centers have good-to-excellent agreement on key FLIP metrics from normal FLIP studies acquired from healthy volunteers, and that FLIP novices perform as well as experienced FLIP users after limited training and supervision.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

ACKNOWLEDGMENTS

Kara Saddoris (Medtronic) provided editorial support.

Open access funding enabled and organized by Projekt DEAL.

FUNDING INFORMATION

Medtronic provided funding for the study.

DATA AVAILABILITY STATEMENT

The data and analytic methods may be made available to other researchers on request to the sponsor

REFERENCES

1. Savarino E, di Pietro M, Bredenoord AJ, et al. Use of the functional lumen imaging probe in clinical Esophagology. Am J Gastroenterol. 2020;115(11):1786–1796. [PubMed: 33156096]
2. Krause AJ, Carlson DA. Dysphagia: novel and emerging diagnostic modalities. Gastroenterol Clin North Am. 2021;50(4):769–790. [PubMed: 34717870]
3. Carlson DA, Gyawali CP, Kahrilas PJ, et al. Esophageal motility classification can be established at the time of endoscopy: a study evaluating real-time functional luminal imaging probe panometry. Gastrointest Endosc. 2019;90(6):915–923. e911. [PubMed: 31279625]
4. Yadlapati R, Kahrilas PJ, Fox MR, et al. Esophageal motility disorders on high-resolution manometry: Chicago classification version 4.0(c). Neurogastroenterol Motil. 2021;33(1):e14058. [PubMed: 33373111]
5. Carlson DA, Shehata C, Gonsalves N, et al. Esophageal dysmotility is associated with disease severity in eosinophilic esophagitis. Clin Gastroenterol Hepatol. 2021;20(8):1719–1728. [PubMed: 34768010]
6. Carlson DA, Hirano I, Zalewski A, Gonsalves N, Lin Z, Pandolfino JE. Improvement in esophageal distensibility in response to medical and diet therapy in eosinophilic esophagitis. Clin Transl Gastroenterol. 2017;8(10):e119. [PubMed: 28981080]

7. DeWitt JM, Siwiec R, Kessler WR, et al. Comparison of functional lumen imaging probe and high-resolution manometry to assess response after peroral endoscopic myotomy. Gastrointest Endosc. 2022;95:855–863. [PubMed: 34979118]
8. Samo S, Mulki R, Godiers ML, et al. Utilizing functional lumen imaging probe in directing treatment for post-fundoplication dysphagia. Surg Endosc. 2021;35(8):4418–4426. [PubMed: 32880014]
9. Su B, Callahan ZM, Novak S, Kuchta K, Ujiki MB. Using impedance planimetry (EndoFLIP) to evaluate myotomy and predict outcomes after surgery for achalasia. J Gastrointest Surg. 2020;24(4):964–971. [PubMed: 31939098]
10. Carlson DA, Kou W, Lin Z, et al. Normal values of esophageal distensibility and distension-induced contractility measured by functional luminal imaging probe Panometry. Clin Gastroenterol Hepatol. 2019;17(4):674–681.e1. [PubMed: 30081222]
11. Carlson DA, Prescott JE, Baumann AJ, et al. Validation of clinically relevant thresholds of esophagogastric junction obstruction using FLIP Panometry. Clin Gastroenterol Hepatol. 2021;20:e1250–e1262. [PubMed: 34216821]
12. Carlson DA, Baumann AJ, Prescott JE. Validation of secondary peristalsis classification using FLIP panometry in 741 subjects undergoing manometry. Neurogastroenterol Motil. 2022;34(1):e14192. [PubMed: 34120383]
13. Cicchetti DV. Guidelines, criteria, and rules of thumb for evaluating normed and standardized assessment instruments in psychology. Psychological Assessment. 1994;6(4):284–290.
14. Carlson DA, Gyawali CP, Khan A, et al. Classifying esophageal motility by FLIP Panometry: a study of 722 subjects with manometry. Am J Gastroenterol. 2021;116(12):2357–2366. [PubMed: 34668487]

Key Points

- Functional Lumen Imaging Probe (FLIP) evaluates esophagogastric junction opening and esophageal contractility.
- Normative FLIP parametiers can be reliably interpreted among experienced as well as novice FLIP users.
- Normative FLIP parameters can be reliably extracted using real-time as well as post-hoc interpretation.

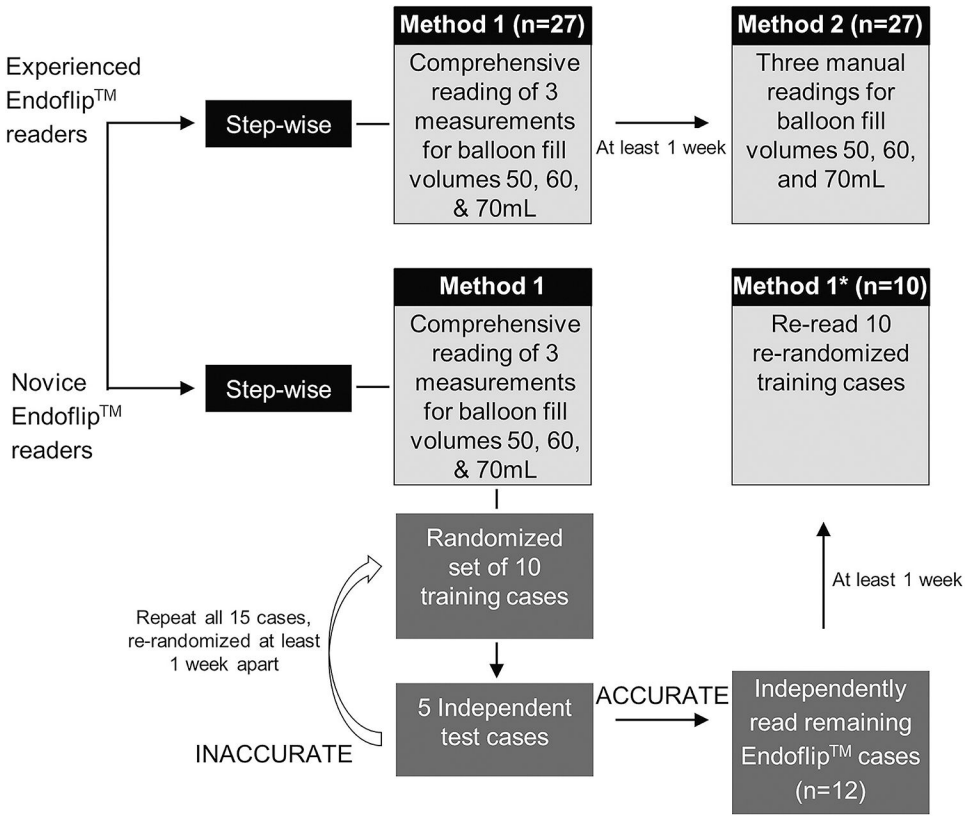

FIGURE 1.
Study flow chart.

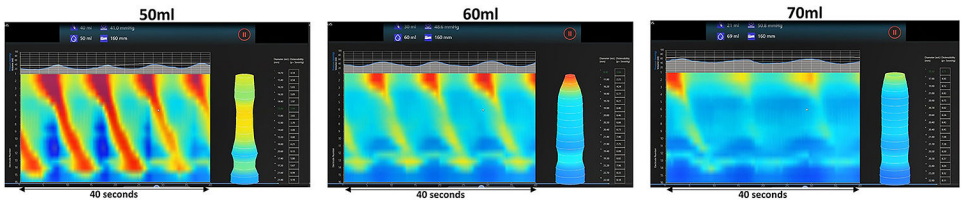

FIGURE 2.

Antegrade contractions (ACs) at 50, 60, and 70 ml balloon fill volumes. The pattern of ACs observed at the 50 and 60 ml volumes is indicative of RACs. The pattern observed at 70 ml volume may be classified as ACs by some physicians but not others. Figure used with permission from the Esophageal Center of Northwestern University.

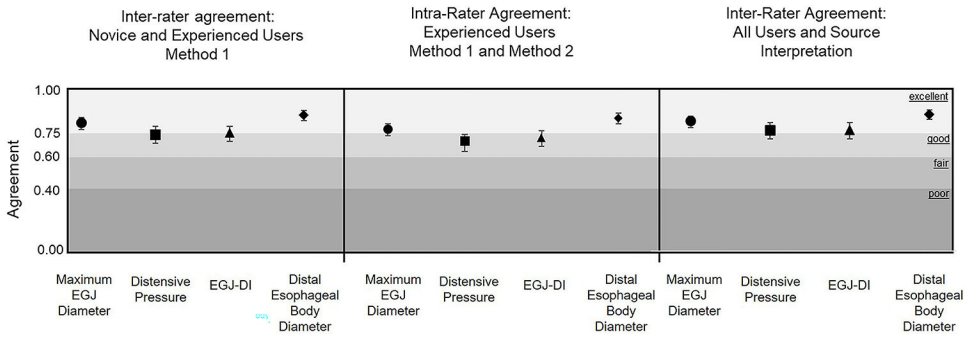

FIGURE 3.

Inter-rater agreement and intra-rater agreement for normative parameters at 60 ml balloon fill volume. All values showed good-to-excellent agreement. Inter- and intra-rater agreement data are presented as ICC and PCC (95% CI). ICC and PCC agreement: <0.40 (poor); 0.40–0.59 (fair); 0.6–0.74 (good); and 0.75–1.00 (excellent). Upper and lower limits of error bars represent the 95% CI. CI, confidence intervals; ICC, Intraclass correlation coefficient; PCC, Pearson's correlation coefficient.

TABLE 1

Comparative analysis of normative FLIP metrics at 60 ml balloon fill volume

	Novice users (*n* = 3)	Experienced users (*n* = 5)	All users (*n* = 8)	Source interpretation
Number of studies	27	27	27	27
Cumulative number of interpretations	81	135	216	27
Maximum egj diameter (mm)	18.4 (12.3–21.5)	18.7 (13.4–21.7)	18.6 (12.8–21.6)	19.2 (15.3–20.5)
Distensive pressure (mmhg)	47.1 (32.8–61.4)	49.0 (38.9–66.0)	48.1 (36.0–64.9)	49.0 (37.0–69.0)
Egj-di (mm^2/mmhg)	5.5 (2.7–8.2)	5.6 (3.0–7.5)	5.5 (2.8–8.0)	5.5 (3.2–7.0)
Distal esophageal body diameter (mm)	20.0 (16.3–21.6)	19.0 (14.3–21.5)	19.5 (15.0–21.6)	19.8 (18.3–21.0)
Rac (%)	96.3%	96.3%	96.3%	92.6%

Note: Data are presented as median (5th–95th percentile).

TABLE 2

Normative values for maximum EGJ diameter, distensive pressure, EGJ-DI, and distal esophageal body diameter as measured by novice and experienced users at 50, 60, and 70 ml balloon fill volume for Method 1 and Method 2.

	Balloon fill volume		
	50 ml	**60 ml**	**70 ml**
Normative parameters of FLIP panometry (novice FLIP users)–Method 1			
Maximum EGJ diameter (mm)	16.0 (7.9–24.9)	18.4 (12.3–21.5)	19.6 (15.8–22.2)
Distensive pressure (mmHg)	37.8 (25.2–56.2)	47.1 (32.8–61.4)	56.3 (37.0–78.8)
EGJ-DI (mm^2/mmHg)	5.0 (1.6–9.9)	5.5 (2.7–8.2)	5.4 (3.1–9.0)
Distal esophageal body diameter (mm)	19.0 (14.2–21.0)	20.0 (16.3–21.6)	20.7 (19.0–22.0)
Normative parameters of FLIP panometry (Experienced FLIP users)–Method 1			
Maximum EGJ diameter (mm)	16.4 (8.1–21.5)	18.7 (13.4–21.7)	19.6 (16.2–22.0)
Distensive Pressure (mmHg)	39.8 (27.0–57.2)	49.0 (38.9–66.0)	56.0 (42.5–80.0)
EGJ-DI (mm^2/mmHg)	5.0 (1.6–8.8)	5.6 (3.0–7.5)	5.2 (3.2–7.5)
Distal esophageal body diameter (mm)	18.0 (13.2–21.2)	19.0 (14.3–21.5)	20.0 (17.4–21.8)
Normative parameters of FLIP panometry (Combined experienced and novice FLIP users)–Method 1			
Maximum EGJ diameter (mm)	16.3 (8.1–22.0)	18.6 (12.8–21.6)	19.6 (16.0–22.2)
Distensive Pressure (mmHg)	39.0 (26.5–57.0)	48.1 (36.0–64.9)	56.1 (41.8–79.5)
EGJ-DI (mm^2/mmHg)	5.0 (1.6–9.1)	5.5 (2.8–8.0)	5.3 (3.2–8.2)
Distal esophageal body diameter (mm)	18.4 (13.4–21.0)	19.5 (15.0–21.6)	20.0 (17.8–21.9)
Normative parameters of FLIP panometry (Experienced FLIP Users)–Method 2			
Maximum EGJ diameter (mm)	16.1 (8.5–21.0)	17.9 (13.1–21.2)	19.2 (16.0–21.9)
Distensive pressure (mmHg)	38.1 (26.5–55.3)	46.2 (34.9–63.5)	55.0 (39.2–77.3)
EGJ-DI (mm^2/mmHg)	4.9 (1.6–9.2)	5.4 (2.8–8.0)	5.3 (3.2–8.1)
Distal esophageal body diameter (mm)	18.0 (14.0–21.9)	19.2 (14.5–21.4)	20.0 (17.2–22.0)

Note: Data are presented as median (5th–95th percentile).