Functional Luminal Imaging Probe in the Management of Pediatric Esophageal Disorders

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ABSTRACT

Background: Functional luminal imaging probe (FLIP) measures pressure–geometry relationships of digestive luminal space. When used in esophageal disorders, it provides several luminal parameters that help better understand the pathophysiology. Data about the potential utility of FLIP in pediatrics are scarce and there is no standardized use in children. We aim to describe the use of FLIP in our center, its safety, feasibility, and clinical impact in esophageal disorders in children.

Methods: Consecutive FLIP recordings performed at the Centre Hospitalier Universitaire-Sainte-Justine, Montréal, Canada between February 2018 and January 2021 were extracted. A chart review was conducted for demographics and medical history. Symptomatology after the procedure was evaluated with validated dysphagia scores.

Key Results: Nineteen patients were included (11 girls, median age 16 years, range 3.2–19.6) with achalasia (n = 5), post-Heller's myotomy dysphagia (n = 3), esophagogastric junction outflow obstruction (n = 3), congenital esophageal stenosis (n = 2); post-esophageal atresia repair stricture (n = 3), and post-fundoplication dysphagia (n = 3). There was no significant correlation between integrated relaxation pressure measured with high resolution manometry and distensibility index (DI). The use of FLIP made it possible to differentiate between dysphagia related to an esophageal obstruction (DI $< 2.8\,mm^2/mmHg$) and dysphagia without major motility disorder (DI $> 2.8\,mm^2/mmHg$) that guided the indication for dilation. FLIP led to a change in management in 47% of the patients. Forty-seven percent of the patients were symptom free at the time of the evaluation.

Conclusions & Inferences: FLIP provides key esophageal luminal values and therefore can play an important role in pediatric esophageal disorders management.

Key Words: achalasia, esophagogastric junction outflow obstruction, functional luminal imaging probe, fundoplication, Heller's myotomy, pediatrics, stenosis

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What Is Known

- Functional luminal imaging probe (FLIP) metrics help to better understand the pathophysiology of esophageal diseases.
- FLIP predicts efficacy or outcomes after surgical procedures.
- FLIP provides real-time measurements without radiation.

What Is New

- Esophageal FLIP measurements can be done routinely with a balloon inflation volume of 20 and 30 mL in pediatrics.
- Distensibility index of the esophagogastric junction is not dependent on weight or age of the children.
- FLIP led to a change in management in 47% of the patients.

Functional luminal imaging probe (FLIP) measures pressure-geometry relationships of esophageal luminal space (1). In contrast to high-resolution impedance manometry (HRIM), considered as the gold standard for characterizing esophageal motility, the FLIP system does not measure the tonic state of the esophagogastric junction (EGJ), but measures and displays dynamic biophysical properties and compliance in response to distension (2). FLIP provides several luminal parameters including diameter, compliance, cross-sectional area (CSA), pressure and distensibility index (DI) (a calculated value which equals the smallest CSA divided by the median

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pressure required to maintain the smallest CSA in a real-time manner) (3). In adults, these metrics allow to achieve a better understanding of the pathophysiology of esophageal diseases, including achalasia, eosinophilic esophagitis and gastroesophageal reflux disease (3–10). FLIP has been also used to predict efficacy or outcomes after surgical procedures such as fundoplication, Heller myotomy, peroral endoscopic myotomy, and hiatal hernia repair (3,11–17).

Data about the potential utility of FLIP in the pediatric population are scarce. So far, studies have reported pediatric case reports after peroral endoscopic myotomy (18), eosinophilic esophagitis (19,20) fundoplication (21), and stenosis (22). There is no standardized protocol for its use in children.

The aims of this study were to review pediatric cases of FLIP recordings in various clinical situations and to describe feasibility, safety, and clinical utility of FLIP in the pediatric population.

MATERIALS AND METHODS

Patient Selection and Data Collection

FLIP recordings of patients <18 years were extracted from a database of studies conducted in the pediatric gastroenterology division of Centre Hospitalier Universitaire Sainte Justine, Montréal, Canada, between February 2018 and January 2021. All consecutive FLIP studies conducted for an esophageal indication were included. FLIP studies (EndoFLIP) were performed at the same time of a scheduled possible esophageal dilation procedure indicated for dysphagia symptoms. A chart review was conducted. The following data were collected: demographics (sex, age), medical history (diagnosis, indication for the procedure, previous treatment), surgical history (fundoplication, Heller myotomy), HRIM study and barium imaging results.

Functional Luminal Imaging Probe Analysis

All FLIP studies were performed under general anesthesia. The use of intravenous drugs (midazolam, fentanyl, and propofol) were left to the judgment of the anesthetist. We used the EndoFLIP EF-325 catheter series (8 cm length) with 16 points 0.5 cm apart within the balloon with the 1.0 computer (Medtronics, Dublin, Ireland). Each patient had FLIP measurements performed with 20 mL and 30 mL balloon inflation volume at the EGJ or narrowing site. Because of the lack of data on optimal balloon volume in children, clinical judgment based on balloon pressure, DI and diameter achieved determined the inflation volume. Additional inflations (at 40 mL and 50 mL) were left to the clinical judgment of the endoscopist. Balloon pressure was monitored during inflation to verify that pressure did not reach a value >50 mmHg. The greatest DI measured was used for intraoperative decision-making. In patients who underwent a dilation during the procedure, DI was assessed before and after dilation.

All the recordings were reviewed by a trained gastroenterology fellow (O.C.), under the supervision of a motility gastroenterologist (C.F.) using EndoFLIP 1.0.0.1 analysis software (Medtronics, Dublin, Ireland). We determined and collected DI and maximum EGJ diameter at each balloon volume available (before and after dilation procedure). We also determined maximum diameter and maximum balloon size during the dilation itself (EsoFLIP, Medtronics Dublin, Ireland). The variation of DI was the greatest difference between the maximal DI at each filling volume.

High Resolution Impedance Manometry Analysis

HRIM was performed with a standardized procedure, in an outpatient setting after a 4-hour fast as previously described (23). Briefly, the procedure was conducted without sedation in all patients, with the child placed in a 30° inclined position using the catheter and Sierra Scientific Instruments system (Sierra Scientifics, Los Angeles, CA, USA). Saline liquid boluses (5.0 mL) were administered by syringe every 30 seconds. Esophageal pressure topography data were derived using the ManoView ESO Analysis software version 3.0 (Sierra Scientific Instruments, Los Angeles, CA, USA).

Symptoms Analysis

All patients were contacted via telephone or e-mail. Symptoms of dysphagia experienced before the FLIP procedure, at 3 months, 6 months, 12 months after the procedure and at the time of the review were evaluated. Two dysphagia questionnaires were completed by the child or his primary caregiver: Eckardt (24) and Dakkak score (25), validated in French, at each evaluation time point.

The Eckart score reflects the sum of the symptoms of dysphagia, regurgitation and chest pain (0 = absent, 1 = occasional, 2 = daily, 3 = at each meal), to which is added a weight-loss score (0 = no loss weight, 1 = <5 kg, 2 = 5–10 kg, 3 = >10 kg) (24). The score ranges from zero to 12 and the higher the score the more severe the symptoms. After treatment, an Eckardt score of three or less is considered therapeutic success.

The Dakkak score assesses the symptoms of dysphagia experienced when ingesting nine different food items, ranging from water to meat (25). A score is assigned to each element based on its viscosity and solid appearance. For every item that the child was able to eat completely, the related score was assigned. The sum of all these scores obtained is calculated at the end (scale of 0–45). A score of 45 (every item could be fully eaten) is considered therapeutic success.

The Questionnaires were completed after the recordings review. A therapeutic success was defined as an Eckardt score <3 AND a Dakkak score = 45 AND an absence of a new dilation procedure. A relapse was defined by the presence of a new dilation procedure or any abnormal dysphagia score.

Statistical Analysis

Descriptive data are expressed as median and interquartile range. n-Values represent the number of subjects included in the dataset. To compare means or medians between the sub-groups we used respectively the Student t test or Mann-Whitney *U* test and the Fisher exact test for count data. The variation of DI was the greatest difference between the maximal DI at two balloon inflation volume points. Spearman correlations between the variables were performed as indicated. Level of statistical significance was set at $P = 0.05$.

Ethics

Written informed consent was obtained from the parents or guardians of the children and, when appropriate, from the subjects themselves. FLIP is approved for children in Canada. The study project was approved by the research ethics committee of the Centre Hospitalier Universitaire Sainte Justine (2021–2890).

RESULTS

Patients

Nineteen patients (11 girls, median age 16 years (7.8;17.8), range 3.2–19.6 years) were enrolled in the study. The median

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TABLE 1. Median distensibility index (IQR) for each pathology in mm^2/mmHg with a 20 mL and 30 mL balloon inflation volume

	Distensibility index 20 mL	Distensibility index 30 mL
Achalasia (n = 5)	1.9 (1.6;2)	2 (1.6;2.3)
EGJOO (n = 3)	1.7 (1.3;2.2)	1.5 (1.2;2.1)
EA/TEF (n = 3)	4.3 (3;7.5)	3.2 (2.3;7.4)
Congenital stenosis (n = 2)	1.6 (1.6;1.7)	1.2 (1.1;1.2)
Post-fundoplication dysphagia (n = 3)	1.9 (1.8;2.2)	2.4 (2.1;3)
Post HM dysphagia (n = 3)	9.1 (2.3;9.9)	7.7 (7.2;8.1)

EA/TEF = esophageal atresia-tracheoesophageal fistula; EGJOO = esophagogastric junction outflow obstruction; HM = Heller's myotomy.

weight, height and body mass index (BMI) of the participants were respectively 41 kg (21.8;53.2), 148 cm (120;170), and 17.7 kg/m^2 (15.5;20.2). Indications for FLIP evaluation and dilation were symptoms of dysphagia associated with achalasia (n = 5) including type 2 (n = 4), and type 3 (n = 1), persistent dysphagia after Heller's myotomy (n = 3), EGJ outflow obstruction (EGJOO) (n = 3), dysphagia suspected to be associated with anastomotic stricture after esophageal atresia repair (EA/TEF) (n = 3), congenital esophageal stenosis (n = 2), and dysphagia post Nissen fundoplication (n = 3). Ten patients were taking proton pomp inhibitors (PPI) at the time of the procedure. Finally, all patients had one FLIP procedure (n = 19; 100%), 11 had 2 (58%), 3 had 3 (16%) and one patient had 4 procedures (5%).

Functional Luminal Imaging Probe Analysis

Distensibility Index

For each condition, median DI values with a 20 mL or 30 mL balloon inflation volume at the beginning of the procedure are reported in Table 1.

Patients with achalasia, EGJOO and congenital esophageal stenosis had the lowest DI (median DI < 2 mm^2/mmHg) whereas patients with dysphagia post Heller myotomy had the highest DI (median DI > 7 mm^2/mmHg). Two patients out of the three with dysphagia post EA/TEF repair with suspected anastomotic stricture had a DI higher than 2.8 mm^2/mmHg at the level of the anastomosis. The three patients with post fundoplication dysphagia had a median DI <2.8 mm^2/mmHg.

Impact of Balloon Inflation Volume on Distensibility Index Measurement

DI variations according to the balloon inflation volume are displayed in Figure 1. DI value remained stable for all inflation volumes with a median variation of 0.4 mm^2/mmHg. DI values remained upon or above the 2.8 mm^2/mmHg threshold (considered

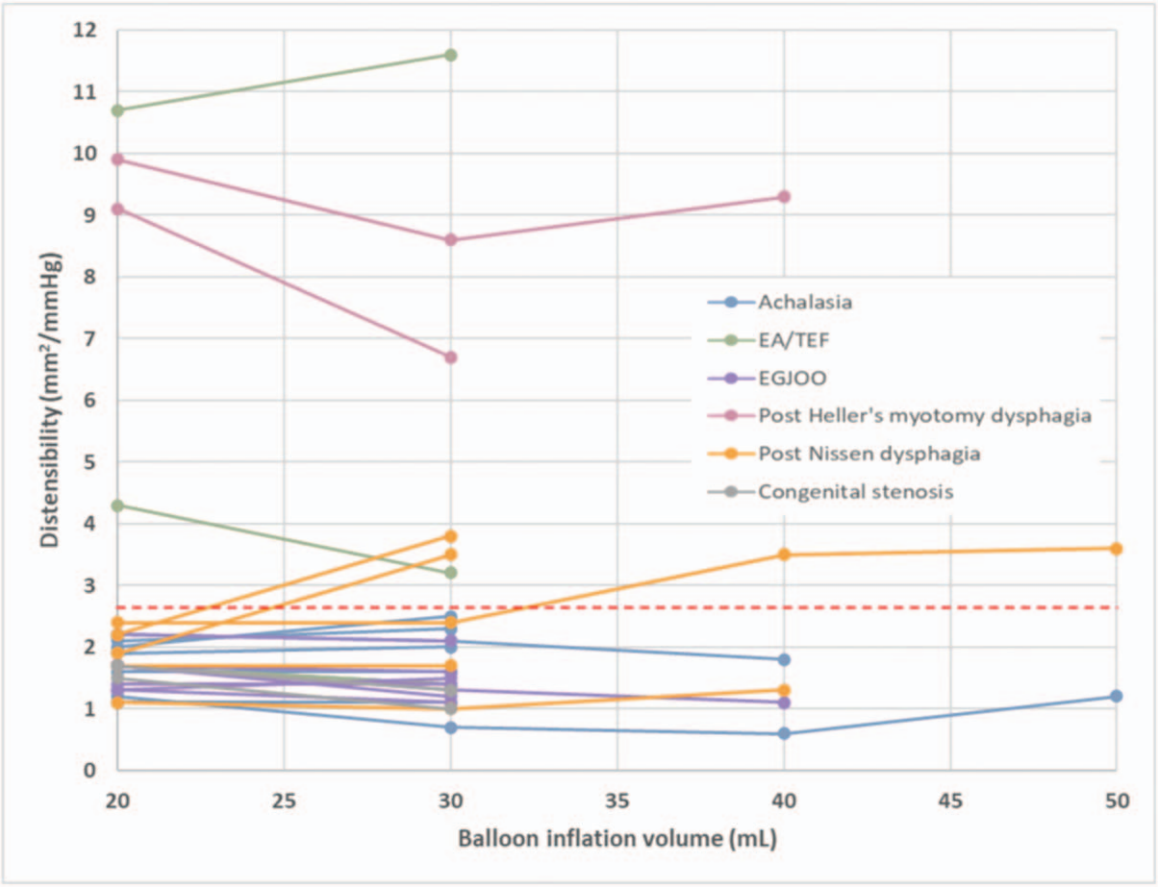

FIGURE 1. Distensibility index curves pre-procedure per patient at each balloon inflation volume. The red line illustrates the 2.8 mm^2/mmHg threshold considered as the cut-off for indication of dilation (26).

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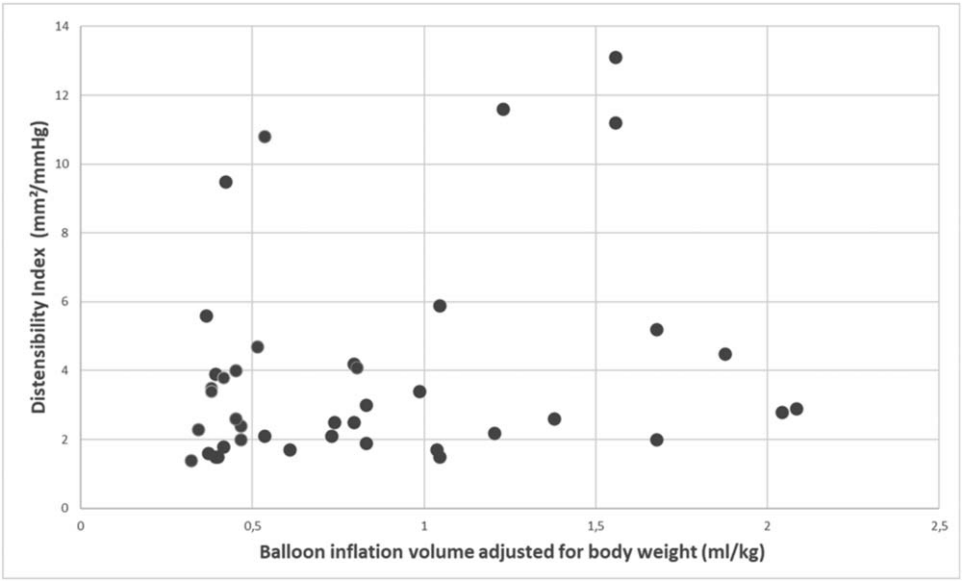

FIGURE 2. Balloon inflation volume adjusted for body weight to obtain the maximum distensibility index. Spearman correlation $r = 0.3$ (−0.1;0.5) ($P = 0.08$).

as the threshold for indication of esophageal dilation) (26), except for two out of the three post-fundoplication dysphagia cases for whom the DI tended to increase for the volumes of inflation >30 mL. The median variation of DI measurement was significantly higher in the group of patients with the higher DI (>2.8 mm^2/mmHg) than in the patients with a DI <2.8 mm^2/mmHg, respectively 1.2 (1.1;1.6) versus 0.3 (0.1;0.5) mm^2/mmHg; $P = 0.0009$.

The median balloon inflation volume was 0.7 mL/kg (0.4;1.2). According to the children's weight, the volume was 1.6 mL/kg (1.3;1.8) for children <25 kg, 0.8 mL/kg (0.4;0.9) for 26–50 kg, and 0.5 mL/kg (0.4;0.5) for >51 kg with a significant difference between those three groups (Fig. 1, Supplemental Digital Content, *http://links.lww.com/MPG/C534*); however, there was no correlation between the inflation volume adjusted to body weight and the DI (Fig. 2).

High-Resolution Impedance Manometry and Barium Swallow Relationships

Fourteen patients (74%) had a HRIM before the procedure and median integrated relaxation pressure (IRP) was 27 (20:31) mmHg. Absent peristalsis was recorded in five patients. There was no significant correlation between IRP and DI: $r = -0.2$, $P = 0.5357$ (without considering the three EA/TEF patients who were evaluated for a possible anastomotic stricture). There was no significant difference in the median IRP in patients that had the indication for esophageal dilation procedure: 28.3 (15.9;52.6) mmHg versus those that had not: 24.4 (23.5;25.2) mmHg, $P = 0.31$ at the FLIP evaluation. Seventeen patients (89%) had a barium esophagram and main findings were: EGJ abnormalities (47%, n = 8), esophageal dilation (41%, n = 7), barium stasis (29%,

TABLE 2. Parameters of dilation procedures (IQR) with EsoFLIP and outcomes according to the different diagnosis

	Achalasia	EGJOO	EA/TEF*	Congenital stenosis	Post-Fundoplication dysphagia	Post-HM dysphagia†
Number of patients	5	3	2	2	3	1
Parameters of dilation procedures with EsoFLIP						
Diameter (mm)	24 (17;28)	24,2 (19;26)	14 (13;15)	18 (14;24)	25 (22;25)	27
Dilation balloon size (mL)	60 (48;75)	50 (42;59)	42 (37;42)	40 (36;57)	40 (40;40)	57
Post procedure distensibility index (mm^2/mmHg)	3.8 (2.5;4.1)	3.8 (1.9;9.7)	NA	3	4.6 (4;4.8)	4.6
Delta distensibility index (mm^2/mmHg)	1.5 (0.9;2.1)	2.5 (0.2;8)	NA	1.8	1 (0.3;2.3)	2.3
Therapeutic success according to diagnosis						
Median follow-up (months)	4.8	9.7	8.4	8.8	8.1	22
3 months	2/5	2/2	1/2	0/1	0/1	0/1
6 months	0/2	2/2	1/2	0/1	0/1	0/1
12 months	NA	1/1	1/1	0/1	NA	0/1

Delta distensibility index = the median difference between the maximum distensibility index before and after dilation. EA/TEF = esophageal atresia-tracheoesophageal fistula; EGJOO = esophagogastric junction outflow obstruction; HM = Heller's myotomy. *These two patients had a pre-dilation distensibility index at the most narrowed site of the esophagus of 11.6 and 1.7 mm^2/mmHg. †This patient had a pre-dilation distensibility index of 2.3 mm^2/mmHg.

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n = 5), abnormal peristalsis (24%, n = 4), and esophageal stricture (18%, n = 3). There was no significant difference in the median DI between patients with normal and abnormal EGJ assessed by barium swallow (2 (1.5;6.7) mm^2/mmHg vs 2.3 (1.9;6.2) mm^2/mmHg, $P = 0.63$).

Clinical Impact

FLIP made possible to differentiate between dysphagia related to an esophageal obstruction (with low distensibility: <2.8 mm^2/mmHg) and dysphagia without major motility disorder (normal or high distensibility: >2.8 mm^2/mmHg) that guided the indication for dilation. The three patients who were not dilated had a mean DI of 9.1 (6.7;9.5) mm^2/mmHg indicating a normal or even high distensibility of the EGJ suggesting that the dysphagia was not related to an outflow obstruction. Conversely, FLIP study indicated the dilation in the patients with post-fundoplication dysphagia and confirmed the necessity of dilation in functional (EGJOO, achalasia) and anatomical obstruction (anastomotic stricture, congenital stenosis). FLIP led to a change in management in 47% of the children. Two cases of post Heller's myotomy dysphagia out of three had an elevated DI and did not undergo an esophageal dilation based on that measure (even if they have a low IRP). The last case had an esophageal dilation based on the association of manometry and FLIP results. The three post-fundoplication dysphagia cases were evaluated with both HRIM and FLIP. The decision to dilate the EGJ was taken on DI results and the three cases underwent an esophageal dilation. Four cases of suspected stenosis or strictures were evaluated with FLIP without the need of further fluoroscopy and esophageal dilation were simultaneously performed. FLIP also confirmed the indication of treatment in achalasia.

Safety

The median time of the procedure (including the esophago-gastro-duodenoscopy and the dilation) was 33 minutes and 42 seconds (31:49;39:44). Two adverse events were recorded in two patients: one mild chest pain and one transient ventilation disorder after the FLIP evaluation and the esophageal dilation. No relevant esophageal damage was recorded.

Dilation Procedures

Sixteen patients underwent a dilation with the EsoFLIP balloon (Table 2). Three patients (two with persistent dysphagia post Heller myotomy and one with dysphagia suspected to be secondary to an esophageal stricture post EA/TEF) were not dilated because of a higher DI value. Median DI was significantly higher in the patients who were not dilated than in patients who underwent a dilation (9.1 (6.7;9.5) mm^2/mmHg vs 1.7 (1.5;2.3) mm^2/mmHg, $P = 0.022$).

Post dilation, the DI increased in all patients (Table 2). The median DI was 3.8 mm^2/mmHg (3.3;4.6) and the median difference between the maximum DI before and after dilation was 1.8 mm^2/mmHg (1;2.5).

Clinical Outcome

We evaluated the effectiveness of esophageal dilation performed with esoFLIP. The indication for dilation was decided on the basis of the HRIM results and the values obtained by EndoFLIP.

Eighteen patients (95%) completed the questionnaires 8.4 months (3.5;16.3) after the procedure. Seven patients out of 15 (47%) had a therapeutic success at the time of the evaluation (achalasia (n = 2), persistent dysphagia after Heller myotomy (n = 1), anastomotic stricture after esophageal atresia repair (n = 2), EGJOO (n = 2)). In the cohort, therapeutic success was achieved post dilation for 5 of 12 patients at 3 months, for 3 of 9 patients at 6 months, and for 2 of 4 patients at 12 months.

Table 2 reports the clinical outcome according to the different diagnosis.

DISCUSSION

In the present study, we report the use of FLIP technology in children with dysphagia symptoms. We show that FLIP is feasible and safe in children. It allows to evaluate the distensibility of the lower esophageal sphincter (LES) in functional disorders (achalasia, post Heller myotomy dysphagia, post-fundoplication dysphagia and EGJOO) independently of the IRP measured by HRIM. It also allows to study the distensibility of the narrowed zone of the esophagus body in case of anastomotic stricture or congenital stenosis. In these clinical situations, FLIP 1.0 helped understand the pathophysiology of the dysphagia and guide the decision of dilatation in real-time.

As the measurements of DI were performed during the same operating time than the upper endoscopy and possible dilation, they were done under general anesthesia. General anesthesia has not been shown to affect DI in adults. (27)

Since we included a wide range of age (and weight) of patients, the distension volume of the balloon adjusted for weight was, as expected, significantly different between the patients; however, we also report that there was no correlation between the balloon inflation volume adjusted for body weight and DI suggesting that the physical properties and characteristics of the EGJ responsible of EGJ-DI are not dependent on weight or age of the children. We therefore propose to inflate the FLIP balloon with a volume of 20 and 30 mL routinely. It can be inflated up to 40 or 50 mL in adolescents with a close monitoring during inflation to verify that pressure balloon does not reach a value >50 mmHg. We acknowledge that no control children were included and that we cannot exclude an insufficient balloon inflation to measure DI. Nevertheless, we believe that the wide range of DI values measured in our study suggests that this inflation protocol is valid in children as previously used in other pediatric studies. (18–22)

The DI values according to balloon volume remained stable. This is in keeping with previous adult (26,28), and pediatric (21,22) reports; however, they were found variable in post-fundoplication patients with a lower DI value (<3 mm^2/mmHg) with volumes up to 30 mL and a sudden increase with higher volumes. Rosen et al similarly showed that DI increases with the balloon size in the fundoplication group but not in achalasia cases (21). In the Ng et al (22) study, FLIP measurements taken at different balloon sizes were comparable. Adult control participants have been described with a DI curve similar to our post-fundoplication patients (28). To the best of our knowledge, there is no published normal values of DI in children (18–22) except the eight *symptomatic* subjects ages 13.5 ± 3.6 years in the Rosen et al (21) study who were considered as controls based on a DI > 2.8 mm^2/mmHg.

In achalasia, FLIP parameters confirmed the diagnosis and the dilation led to an increase of the DI as reported in adults (26). Data suggest that the highest DI after therapy (cut-off 2.9 mm^2/mmHg) correlate with therapeutic success. DI seems to be the most useful metric for assessing the effect of treatment on EGJ opening (29).

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In post Heller's myotomy dysphagia, FLIP parameters helped to distinguish situations where symptoms are caused by myotomy failure from those wherein symptoms are associated with the absence of major motility disorder. Furthermore, post Heller's myotomy DI is strongly correlated with symptomatic outcomes (26,28) and patients with a low DI ($<2.9\,mm^2$/mmHg) were 12-fold more likely to have persistent symptoms (30).

In EGJOO, FLIP results confirmed the diagnosis suspected in HRIM in three children and indicated the dilation procedure (median DI $< 2\,mm^2$/mmHg). Currently, FLIP is increasingly used to adjudicate the severity and clinical relevance of this diagnosis and has been approved to be a valuable metric that identifies EGJOO patients who were likely to benefit from achalasia-type therapies (5).

In post-Fundoplication dysphagia, FLIP has been proven useful in assessing EGJ obstruction in patients with esophageal symptoms post-fundoplication (31). In our experience FLIP identified EGJ obstruction with a low DI ($<2.8\,mm^2$/mmHg).

In EA-TEF and other anatomical obstruction such as congenital stenosis, FLIP has been proved as an alternative to fluoroscopy in providing accurate diameter assessments during endoscopy (3). In our experience, median DI was $<2\,mm^2$/mmHg in the congenital esophageal stenosis cases. It should be noted that an important limitation of FLIP utilization in pediatrics is the size of the device precluding any use in small children and infants (<10 kg) who are the most affected by anastomotic strictures post EA-TEF repair.

FLIP led to a change in management in 47% of the patients studied. This is higher than in a previous adult study which found a change in management 39.7% (2) and suggests that FLIP measurement is useful in selected indications in pediatrics.

The strengths of this study are that we were able to report the DI in various clinical situations. Patients, when dilated, were assessed before and after the dilation procedure allowing to evaluate the effectiveness of dilation with the help of validated questionnaires; however, this study is prone to weaknesses related to the low number of patients and to its retrospective nature. For the same reasons, our study could not explore the possible prognostic value of the DI on the efficiency of the dilation. As previously acknowledged, we were not able to recruit normal control children for ethical reasons that are inherent to the pediatric studies with invasive tools.

In conclusion, we report here that knowledge of crucial luminal parameters such as distensibility can better guide endoscopic decisions in children with dysphagia. FLIP can provide real-time measurements before, during, and at the end of the dilation without radiation. Further prospective studies are needed to determine the prognostic value and the cost effectiveness of FLIP in pediatrics.

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