DRIVERS OF VARIATION AMONG PEDIATRIC GASTROENTEROLOGISTS IN DIAGNOSIS AND MANAGEMENT OF EOSINOPHILIC ESOPHAGITIS

Talya Lepow Miller

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Committee:

Michelle Garrison

Casey Lion

Arti Desai

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Abstract

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Talya Lepow Miller

Chair of the supervisory committee:

Michelle Garrison, PhD, MPH

Department of Health Services

Background and aims: Widespread variation in the diagnosis and treatment of eosinophilic esophagitis (EoE) has previously been reported among adult gastroenterologists; however, variation in EoE practice in pediatric populations is unknown. The study objective was to describe and understand reasons for variation in diagnosis and management of EoE among pediatric gastroenterologists following publication of the updated 2018 EoE guidelines.

Methods: We developed and administered a 28-item survey to pediatric gastroenterologists via email using the PEDGI Bulletin Board from 03/2019-04/2019. The survey was developed using evidence-based review, expert validation, and cognitive interviews. Survey domains included respondent knowledge of and adherence to published guidelines, diagnostic and management approach and rationale, and participant demographics. Analysis included descriptive statistics and tests for association.

Results: A total of 288 pediatric gastroenterologists completed the survey, most of whom practiced in an academic center (73%). More than half (63%) reported knowledge of the 2018 updated guidelines; however, only 52% agreed with them, and only 50% of the total respondents reported adherence. Participants who reported not agreeing with updated guidelines cited

concerns regarding insufficient data (23%) increasing number of endoscopies (71%), and misdiagnosing eosinophilia from reflux (56%). Physicians cited that the most common drivers of decision-making with respect to therapy choice were patient/family preference, evidence/guidelines, and symptom burden.

Conclusions: Many physicians are not adherent to current guidelines for reasons which include lack of knowledge of updated guidelines and concern regarding the strength of the supporting evidence. This study elucidates several areas to enhance education regarding these guidelines to promote widespread adherence.

Introduction:

Eosinophilic esophagitis (EoE) is a chronic immune-mediated condition with epidemiologic techniques estimating an increasing incidence and estimated pediatric prevalence approaching 1 per 1000 in the U.S. pediatric population.[1–5] Children often present with dysphagia, food impaction, food refusal, vomiting and abdominal pain, and there is a growing awareness and diagnosis of the disease. [6,7] Diagnosis of EoE is determined by symptoms of esophageal dysfunction and esophageal mucosal biopsies showing ≥ 15 eosinophils per high power field. Previous guidelines recommending endoscopic evaluation should occur with concurrent proton pump inhibition (PPI) as a way of eliminating the contribution of reflux on endoscopic evaluation. [8] However, new evidence has shown that proton pump inhibition can be used as a treatment for eosinophilic esophagitis; therefore the updated guidelines published in 2018 now recommend performing a diagnostic endoscopy off of PPI therapy in order to avoid missing a diagnosis of EoE treated by the medication. [9]

Previous studies have shown variability in adult gastroenterologist practice patterns for both diagnosis and treatment of EoE in the United States and have compared variation in practice between adult and pediatric gastroenterologists outside of the US. [10,11] However, no studies have focused specifically on pediatric gastroenterologist behavior or captured the reasons driving variation in practice. Additionally, studies of treatment efficacy that directly compare therapy options for EoE are lacking. Furthermore, there is limited knowledge of long-term outcomes associated with specific therapies. Given these gaps in the literature, it is unclear how physicians make treatment decisions for EoE.

The aim of this study was to understand the reasons for variability in physician knowledge of and agreement with the new 2018 EoE guidelines. Secondarily, we aimed to identify how pediatric gastroenterologists address decision-making surrounding treatment options. We hypothesized that physicians would be less familiar with the evidence surrounding the 2018 guidelines; therefore, their current practice patterns would reflect older recommendations. Additionally, we hypothesized that physician decision-making surrounding therapy would be largely driven by family preference given a possible perception of clinical equipoise.

Decreasing unwanted practice variation among physicians utilizing clinical practice guidelines is known to translate to an improvement in quality of care. However, implementation of guidelines can be difficult both to initiate and sustain. Implementation strategies vary in their effectiveness and include interventions at the professional and organizational levels and can include techniques such as distribution of educational materials, educational meetings, auditing and feedback as well as marketing and mass media.[12] In related fields, successful implementation of clinical practice guidelines is influenced by professional attitude toward the credibility of the guideline, accessibility and dissemination of the information and effective techniques targeting sustained implementation of the guideline.[13–17]

Methods:

Study Design and Participants: We developed a web-based survey using rigorous survey methodology and administered this survey in a cross-sectional, observational sample of practicing pediatric gastroenterologists. Participants were identified using the PEDGI email listserv, which is supported by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) and had more than 3342 subscribers as of February 2019. Subscribers of the PEDGI listserv are primarily pediatric gastroenterologists from around the world.[18] As of 2017, there have been 1844 pediatric gastroenterologists certified in the United States as of 2017[19], with 650 practicing pediatric gastroenterologists identified in 2004, 83% of which identified having an academic appointment.[20]

Survey Development: We created a 28-item multiple-choice questionnaire through a multi-step process. We performed an extensive literature review to identify all relevant content areas regarding the diagnosis and management of EoE. We then conducted 8 key informant interviews with pediatric gastroenterologists with EoE expertise to expand and refine the list of content areas. These content areas included knowledge of and adherence to published guidelines, diagnostic approach and rationale, management approach and rationale, and participant demographics. Authors Lion and Miller then drafted survey items for each content area including questions eliciting self-reported diagnosis and management practices as well as scenarios to elicit clinical decision-making. Importantly, a key area of interest based on the evidence review and key informant interview was the variation in guideline adherence related to performing a diagnostic endoscopy on or off of proton pump inhibition. Participants who reported preferring to have a patient off of PPI therapy at the time for their first endoscopy were considered "guideline adherent".

Survey items were then tested and refined through cognitive interviews with pediatric gastroenterologists to establish the face validity of the survey and each item. Participants were asked to assess the relevance, importance, and understandability of each survey item. Five rounds of cognitive interviews were conducted, and the research team revised the survey item in between rounds. We continued cognitive interviews until the research team deemed that we captured the majority of problem items and respondents noted minimal issues with completing the survey. We then pre-tested the survey on a sample of ten pediatric gastroenterologists and other physicians. Supplementary File 1 includes the final survey instrument.

Survey Administration: We invited pediatric gastroenterologists via email over the PEDGI Bulletin Board. Respondents completed the survey anonymously via REDcap. Participation was voluntary and respondents were eligible to enter a raffle for a $100 gift card. A reminder email was sent one month after the first email.

Analysis: Descriptive statistics were calculated and we evaluated potential predictors of guideline adherence using multivariate logistic regression. Based on prior research and our stakeholder discussions during survey development, the potential predictors included in our model were whether a participant was associated with an academic practice setting, how many years they had been in practice, their geographic location and their perception of the 2018 updated guidelines. All data analysis was conducted using Stata 14 and a two-tailed P-value of less than 0.05 was considered statistically significant.

The Institutional Review Board for Seattle Children's Hospital deemed this research as exempt from review.

Results:

Respondent Characteristics: A total of 288 pediatric gastroenterologists from 6 continents completed the survey, for a response rate of 9%. The majority respondents were from North America (85%), identified practicing in an academic center (73%) and had been in practice less than 15 years (79%). (Table 1)

Guideline Agreement and Adherence: Sixty-three percent of participants reported knowledge of the 2018 updated guidelines; however, only 52% of those responders reported agreeing with them. Half (50%) of the total survey participants reported preferring to have a patient off of PPI therapy at the time of their first endoscopy, and are therefore considered "guideline adherent" in this analysis. Neither practice setting (academic versus non-academic), years of experience, or geographic location were significant predictors of guidelines agreement or adherence in bivariate analyses. Among respondents disagreeing with guidelines, they cited concerns regarding insufficient data (23%) increasing numbers of endoscopies (71%), and misdiagnosing eosinophilia from reflux as EoE (56%) as reasons for their disagreement. Interestingly, 27% of participants not adherent to the updated guidelines (i.e., performing initial endoscopies on PPI therapy) reported that they were doing so because they were following guidelines, suggesting a misinformation problem (Table 2). Our multivariate logistic regression model showed significantly increased odds (OR = 10.9, 95% CI 5.9-19.8) of guidelines adherence for respondents reporting agreement with guidelines, as would be expected. No significant effects on guidelines adherence were observed in this analysis for practice setting, years in practice, or geographic location.

Diagnostic Evaluation Variation: The majority of participants (99%) sample the esophagus at multiple levels, taking two or more biopsies per level (99%) and 87% use $\geq$ 15 eosinophils per high power field as the histologic criteria for diagnosis. When we asked questions regarding physician approach to esophageal sampling during endoscopy, many physicians cited that evidence/guidelines, endoscopic appearance and their training experience influenced their overall decision to biopsy, location from where to biopsy, and number of biopsies. (Figure 1)

Treatment and Monitoring Variation: To understand how physicians choose therapies for individual patients, we asked participants which factors they weigh most heavily when deciding on first-line therapy. Physicians cited that the most common drivers of decision-making were patient/family preference, evidence/guidelines, and symptoms, while histologic severity and their training/prior experience influenced their choice of first line therapy to a lesser extent. (Table 5) Among therapy choices for first line EoE treatment, 78% of participants reported offering PPI therapy as an option, 78% offered food elimination, and 61% offered budesonide and 44% offered fluticasone. Far less common options included offering an elemental diet (17%), systemic corticosteroids (2%), and a leukotriene inhibitor (1%). Among those who offer a food elimination diet as first line treatment, 34% offer a 6-food elimination diet, 31% offer dairy only, and 18% offer a 4-food elimination diet. (Table 4)

Regarding monitoring for responses to therapy, the majority of physicians responded that they used histologic remission and symptomatic improvement together (63%) to determine when a

treatment is successful. To a lesser extent, 31% cited histologic remission and 5% symptomatic improvement separately to determine when a treatment is successful. When asked about endoscopic monitoring, 79% of physicians cited that they repeat an endoscopy when making changes to therapy, 41% cited when patients are symptomatic, and 32% reported they will repeat the endoscopy periodically when patients are asymptomatic. (Table 5)

While almost all participants cited that a pediatric gastroenterologist makes management decisions for EoE patients within their practices (98%), some reported that management decisions are also made by advanced practice practitioners (16%) and allergists (22%) within their practice. (Table 4)

Discussion:

This study is the first large-scale survey of pediatric gastroenterologists in the United States to identify widespread in management of EoE exists within the pediatric community. Despite recent updates to EoE guidelines, our study shows that half of physicians report not following guidelines, citing concerns about the strength of the evidence behind these recommendations and concern that these new guidelines may ultimately promote more endoscopies for patients with EoE. We did not see a difference in the odds of guideline adherence based on academic affiliation, clinician experience, or geographic location. Instead, the only predictor of reported guidelines adherence was whether a physician agreed with the guidelines. Behaviors surrounding esophageal sampling during endoscopy and criteria for histologic diagnosis of EoE were concordant with current literature, depicting improved adherence to older literature.[21,22]

Given that 37% of respondents were unaware of guidelines, one potential intervention that may have a high impact is the use of an educational intervention. Following education at the level of the professional, organizational implementation with clinical pathways and standardization may be a next step in implementation of these guidelines. Additionally, given that 27% of respondents cited disagreement with current guidelines, further research is necessary to identify whether more robust scientific evidence in support of the guidelines will be necessary to change physician practice among those who disagree with current guidelines.

We found that most pediatric gastroenterologists' endoscopic practice is similar, sampling multiple locations of the esophagus with multiple biopsies, and using a similar histologic cut-off for diagnosis. This diagnostic approach is reflective of older literature and guidelines and this study demonstrates that these recommendations have now been widely adopted into practice. It is important to recognize that this study demonstrates that more recently published guidelines have not yet been widely adopted.

Variability in practice emerges when new guidelines conflict with old guidelines, as with the 2018 EoE guidelines. [10,23,24] New evidence supports the use of proton pump inhibition for treatment of EoE, and therefore, a lack of standardization surrounding diagnostic endoscopic practices will have significant implications, including a heterogeneously defined population and ultimately impact our ability to study this population. It is critical to recognize that the updated guidelines reflect a difference in diagnostic criteria.

Limitations for this study include the population of physicians sampled was overall a small sample size (9% response rate) primarily from North American and predominately young physicians. [25] Despite this limitation, we still had a good representation of the number of years in practice, academic versus non-academic setting, and international physicians, with breakdowns mostly similar to those of pediatric gastroenterologists in general, although this sample may not be as representative of the general practice of mid or late career physicians, or physicians in other countries. An addition limitation here is that responses are reflective of self-reported usual practice rather than examining direct outcomes. Lastly, anonymity of the responses limits our ability to evaluate practice by center or geographic location.

Given that only limited data exist regarding long-term clinical or quality of life outcomes for individual therapies, counselling a family regarding specific treatment options can be difficult, and no evidence exists for how or if shared-decision making is used during treatment selection. Future research in these areas would generate a stronger evidence base for guidelines, which would likely lead to increased guidelines adherence in turn, as well as improving patient and family outcomes.

Conclusions: Our study is the first to identify drivers of physician decision-making in regard to endoscopic practices and therapy selection in pediatric EoE. We identified that pediatric gastroenterologists report making treatment decisions primarily based on evidence/guidelines, patient/family preference and symptoms. The variation seen in treatment and management approach in this study may be a reflection of the clinical equipoise in regards to therapy choice perceived by many pediatric gastroenterologists. This study highlights the need for a targeted approach to EoE management that not only takes long-term outcomes into consideration, but prioritizes acute patient-centered outcomes such as quality of life, symptom burden, and family impact. Ultimately, further evidence regarding the acute and long-term impact of individual treatment and monitoring approaches on clinical outcomes will give gastroenterologists the evidence necessary to guide patients and families toward the best options.

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Tables

Table 1: Physician Self-Reported Agreement and Adherence to 2018 EoE Guidelines

Demographics	Overall N=288	Agreement[a] N=243	Adherence[b] N=288
Total Participants	288	125 (52%)	144 (50%)
Practice Setting			
Academic setting[c]	209 (73%)	94 (51%)	104 (50%)
Non-academic setting	79 (27%)	31(53%)	40(51%)
Years in Practice			
Current Fellow	66 (23%)	31 (56%)	34 (52%)
≤ 5 years	87 (30%)	32 (44%)	44 (50%)
6-14 years	72 (25%)	32 (51%)	33 (46%)
≥ 15 years	61 (21%)	28 (55%)	32 (53%)
Geographic Location			
North American Physicians	243 (85%)	106 (51%)	121 (50%)
International Physicians	44 (15%)	18 (51%)	23 (52%)

[a]Agreement defined as reporting definitely agree or agree with 2018 guidelines. The denominator for this category reflects only participants who were aware of the guidelines.

[b]Adherence defined as reporting adherence to a key component to the 2018 guidelines, specifically performing the initial endoscopy off of PPI therapy.

[c] Self-reported practice in an academic setting.

Abbreviations: EoE, Eosinophilic Esophagitis

Table 2: Reasons for Disagreement with 2018 EoE Guidelines	
Response options to the following question: Why do you disagree with the 2018 guidelines?*	**N =117**
Concern that guideline adherence will result in an increase of total number of endoscopies	83 (71%)
Concern that eosinophilia from GERD will be inappropriately diagnosed as EoE	65 (56%)
Insufficient data to support the recommendations	27 (23%)
Other	7 (6%)

*Participants were able to choose more than one response option.

Abbreviations: GERD, Gastroesophageal Reflux Disease, EoE, Eosinophilic Esophagitis

Table 3: Association of demographic characteristics and adherence to 2018 EoE guidelines			
Predictor of interest	OR*	95%CI	P-Value
Perceptions of Guidelines			
Disagree with guidelines	Ref	--	--
Agree with guidelines	10.8	5.9-19.8	<0.005
Practice Setting			
Non-academia	Ref	--	--
Academia	1.0	0.5-2.1	0.92
Years in Practice			
Current fellow	Ref	--	--
≤ 5 years	1.2	0.5-2.9	0.67
6-15 years	0.64	0.3-1.8	0.50
≥ 15 years	0.86	0.3-2.2	0.75
Geographic Location			
International Physicians	Ref	--	--
North American Physicians	0.59	0.2-1.5	0.25
*Odds ratios represent the odds of adhering to 2018 EoE guidelines adjusted for all other variables, including perceptions of guidelines, practice setting, years of experience and geographic location. Abbreviations: EoE, Eosinophilic Esophagitis			

Table 4: Therapeutic Preferences				
Factors influencing therapy choice, ranked by importance	**N**	**1st**	**2nd**	**3rd**
Evidence/Guidelines	279	101 (36%)	64 (23%)	54 (19%)
Patient/Family Preference	275	81 (30%)	70 (26%)	53 (19%)
Patient Symptoms	278	45 (16%)	68 (25%)	80 (29%)
Histologic Severity	272	36 (13%)	57 (21%)	58 (21%)
Training/Prior Experience	268	15 (6%)	15 (6%)	29 (11%)
First line therapy options		N = 288		
PPI		225 (78%)		
Fluticasone		126 (44%)		
Budesonide		175 (61%)		
Food elimination		225 (78%)		
Elemental diet		49 (17%)		
Systemic corticosteroids		6 (2%)		
Leukotriene inhibitors		4 (1%)		
Other		3 (1%)		
Empiric food elimination		N = 288		
Dairy only		88 (31%)		
Dairy, wheat, egg		14 (5%)		
4 food elimination (dairy, wheat, egg, soy)		51 (18%)		
6 food elimination (dairy, wheat, egg, soy, nuts, seafood)		99 (34%)		
I do not offer empiric food elimination		8 (3%)		
Other*		28 (10%)		
Allergist involvement		N= 287		
Always		115 (40%)		
Sometimes		143 (50%)		
Never		29 (10%)		
Management Decisions		N = 286		
Pediatric gastroenterologist		281 (98%)		
Allergist		63 (22%)		
Advanced practice practitioner		45 (16%)		
Other		4 (1%)		

*Other options respondents cited were offering multiple dietary eliminations and allowing patient/family to choose.

Table 5: Endoscopic and Diagnostic Practices	N=288
Levels of the esophagus sampled during diagnostic endoscopy	
1	1 (0.3%)
2	166 (58%)
3	120 (42%)
Other	1 (0.3%)
Number of esophageal biopsies per level of esophagus sampled	
0-1	4 (1%)
2-4	258 (90%)
5-6	21 (7%)
>6	5 (2%)
Histologic criteria for diagnosis of EoE	
≥ 10 eos/hpf	6 (2%)
≥ 15 eos/hpf	251 (87%)
≥ 20 eos/hpf	23 (8%)
Other	8 (3%)
Techniques to exclude GERD*	
PPI therapy	169 (64%)
pH/impedance probe study*	33 (12%)
Endoscopic appearance	59 (22%)
Clinical assessment	132 (50%)
Other	12 (5%)
Determination of Treatment Success	
Histologic remission AND symptomatic improvement	182 (63%)
Histologic remission	90 (31%)
Symptomatic improvement	15 (5%)
Other	1 (0.3%)
Endoscopic monitoring	
When making changes to therapy	226 (79%)
When symptomatic	117 (41%)
Periodically when asymptomatic	91 (32%)
Other	9 (3%)
No endoscopy, only clinical monitoring	3 (1%)

*Total participant response number was 266, with 22 participants not selecting an option or choosing to respond.
*pH/impedance probe refers to any pH testing or impedance testing.
Abbreviations GERD, Gastroesophageal Reflux Disease, EoE, Eosinophilic Esophagitis

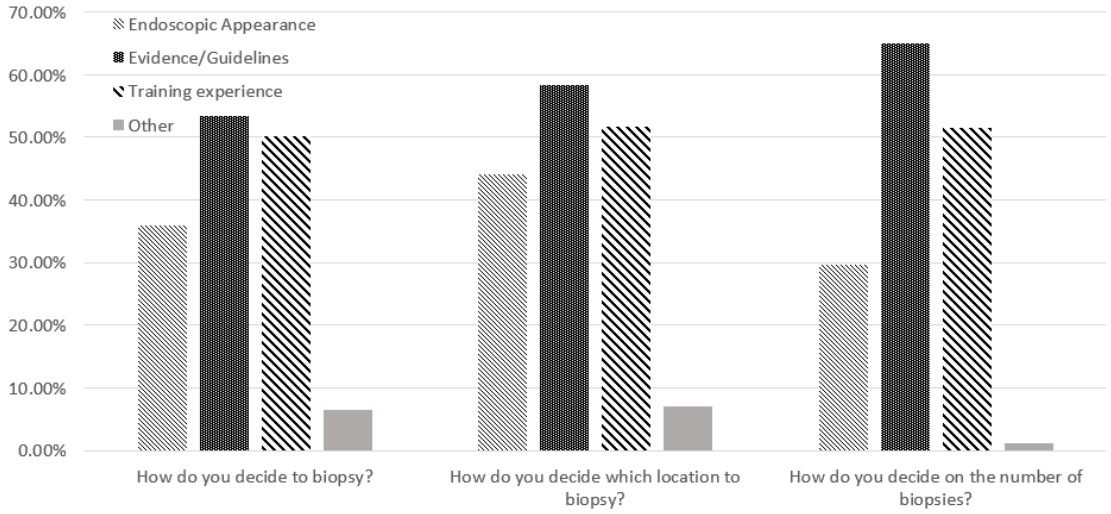

FIG. Physician-reported factors affecting decision around esophageal sampling during endoscopy.

Endoscopic appearance refers to gross findings during endoscopy. Evidence/Guidelines refers to participants citing using either evidence and/or guidelines to support their decision making. Training experience refers to participants relying on their experience during training to guide their decision-making.