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Dilation of Pediatric Eosinophilic Esophagitis: Adverse Events and Short-term Outcomes

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Abstract

Objectives: Although several studies report on the experience with adult eosinophilic esophagitis (EoE)–related stricture, outcomes for pediatric patients with EoE–associated fibrostenosis and stricture is more limited. To address this, we aim to identify the adverse event (AE) rate and short-term outcomes of the largest reported cohort of children with EoE to undergo esophageal dilation for management of symptomatic esophageal narrowing.

Methods: A retrospective assessment of all children, 18 years and younger, who underwent esophageal dilation at an academic children's hospital during a 5-year period was conducted. Clinical, endoscopic, histologic, and outcomes of dilation were extracted from the medical record. AEs were captured within a standardized endoscopic AE database. Grade 2 AEs (requiring unanticipated medical intervention) were termed significant. Dilation-related events were compared between patients with EoE, without EoE, and those undergoing standard upper endoscopy.

Results: Of the 451 total dilations, 68 dilations were performed in 40 EoE patients (mean age 13.8 years, standard deviation 3.3 years [4.6–18.9 years]). Forty-three percent (17/40) had repeat dilation during the study period. Dilation-related grade 2 AE rates in EoE and in non-EoE patients were 2.9% and 3.1%, respectively ($P > 0.5$). Chest pain (any grade AE) was reported in 14.7% of EoE dilations. No significant associations were found between postprocedural pain and dilation method, final dilator size, medical therapy, or esophageal eosinophilia. No perforations or significant hemorrhage were reported.

Conclusions: We conclude that dilation can be performed safely in children with EoE. In the appropriate clinical setting, cautious dilation may be considered in the management of fibrostenotic EoE.

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Keywords

adverse event; children; dilation; eosinophilic esophagitis; stricture

Eosinophilic esophagitis (EoE) is a chronic allergen-immunemediated disease characterized by esophageal dysfunction and dense esophageal eosinophilia (1). In children, common symptoms include abdominal pain, vomiting, feeding avoidance, and dysphagia. Adult studies demonstrate chronic esophageal inflammation can increase the risk of developing fibrosis, esophageal strictures, and long-segment narrowing (2,3).

Chronic treatment with dietary restrictions or topical steroids can reduce inflammation and prevent complications(4). When complications from fibrostenosis do occur, adult studies, however, demonstrate that esophageal dilation can provide relief from partial obstruction (5,6). Early case series reported high rates of perforations in adult patients with EoE treated with dilations and cautioned against its use (7–11), whereas more recent studies examining larger numbers of adult patients with EoE demonstrate the risk of serious complications (including perforation, bleeding requiring transfusion, or hospitalization for any reason) is low (6,12–20). In contrast, reports describing outcomes of dilation in pediatric EoE have been limited (21,22), and thus leaving knowledge gaps surrounding the safety, tolerance, and role for dilation in the management of children with EoE-associated stricture. We hypothesize that complications from dilations performed in children with EoE are uncommon.

METHODS

Patient Population

The present study was approved by the Colorado Multi-Institutional Review Board. Using an electronic medical record (EMR)-based search, we identified and reviewed records of all children undergoing esophageal dilations by pediatric gastroenterologists between July 2010 and March 2015 in children 18 years of age or younger at Children's Hospital Colorado. Subjects included for detailed review were diagnosed with EoE based on consensus guidelines (1,23). Included EoE subjects did not have additional known esophageal disease (eg, tracheoesophageal fistula, caustic stricture).

Data were extracted from EMR regarding the endoscopy, histological findings, and clinical history. Indication, endoscopic appearance, dilation method, dilator size, and procedure result (including presence of mucosal rent) were recorded. Symptom, disease duration, age at diagnosis, treatment history, duration of follow-up, need for repeat dilation, and esophagram findings were also extracted. An esophageal stricture was defined as a luminal narrowing detected either by fluoroscopic esophagram or endoscopy (24). Moderate to severe stricture was defined by the inability to pass a standard endoscope (diameter of 8.8 mm). Response to dilation was recorded when available within 2 months of dilation.

Adverse Events

Adverse events (AEs) were captured 1 of the 3 ways. First, they were identified through the use of our standardized division quality care program, a part of the Organizational Research Risk and Quality Improvement Panel at Children's Hospital of Colorado. Within this program, AEs were captured and recorded during follow-up postprocedure calls or during patient/family initiated calls to nurses/on call providers. Second, providers reported any AEs encountered during or after an endoscopy case to one of the authors (R.E.K.). Finally, quarterly queries of the hospital EMR were performed to identify patients who underwent endoscopic procedures at any of the 3 procedure sites at our institution who subsequently had an encounter in any of the Emergency Departments within the Children's Hospital Colorado network or admission within 72 hours of their procedure.

Each event was reviewed in detail and categorized by the type of procedure(s) performed, type of AE (eg, pain, fever), and grade. Grade was determined by level of medical intervention required/recommended and scaled 1–5 based on severity (25); grade 1: events requiring telephone management, reassurance, or supportive care only (eg, patient-reported pain that necessitates reassurance but does not require follow-up intervention); grade 2: events resulting in a referral to the Emergency Department or an unanticipated evaluation by a physician; grade 3: events resulting in hospital admission and/or significant intervention, such as blood transfusion or repeat endoscopy; grade 4: events resulting in significant morbidity or mortality, such as unplanned surgery or ICU admission; and grade 5: events that result in death. Grade 2 or greater was chosen as the primary outcome because it is at this point when increased intervention and costs of care are incurred (25). Mucosal rents were not included as an AE as they are considered a therapeutic endpoint for esophageal dilation in patients with EoE.

Data Analysis

Categorical data were expressed as frequencies and percentages. Continuous data were expressed as means and standard deviations (SDs). Comparison between groups was made by one-way analysis of variance or *t* test. Fisher exact test was used to calculate differences between procedure-related outcomes. A probability value of $P < 0.05$ was considered statistically significant. All analyses were done using Statistical Software SPSS version 22 (SPSS Inc., Chicago, IL).

RESULTS

Study Population

During the 5-year study period, 7092 upper endoscopies and 451 dilations were performed. Of these, 68 dilations in 40 patients with EoE and 1378 standard endoscopies without dilation in 781 patients with EoE were performed. Approximately 5% of EoE subjects undergoing endoscopy had an esophageal dilation. All subjects identified as having at least 1 dilation and EoE were included for further analysis.

Patients with EoE undergoing dilation were on average older than the mean age of patients with EoE who did not undergo dilation (13.8 years, SD 3.3 years vs 8.2 years, SD 5.1 years,

$P < 0.0001$), were 73% boys and 97% Caucasian (Table 1). The primary indication for esophageal dilation was the symptom of dysphagia and the finding of an esophageal stricture identified either with fluoroscopy ($n = 18$) or at the time of endoscopy ($n = 22$).

Subjects were followed at our institution for a mean of 17.6 months (SD 18.4, range 0–63.5 months) after first dilation. Treatment for EoE included swallowed steroids (62%), dietary therapy (12%), or both (24%). A single patient was lost to follow-up and did not receive EoE-directed treatment after initial dilation. He represented 42 months later with a food impaction.

Dilation Method

Local practice patterns determined that focal strictures of <5 cm in length were dilated with balloon dilators and nontortuous narrowings of >5 cm in length were treated with Maloney dilators both of which are defined below.

Balloon dilations: (Boston Scientific, Marlborough, MA) If strictures precluded passage of the endoscope, dilation, started at 8 mm or less. If the endoscope was able to pass the stricture but resistance was met with passage of the endoscope, dilation often started at 10 mm. Inflation was maintained at pressure for 60 seconds before advancing to the next size balloon, increasing by 1 mm in diameter. Fluoroscopy was used in 12 out of 19 (63%) balloon dilations. Fluoroscopy was not routinely used in subsequent repeat dilations.

Bougie dilations: Maloney dilators (Teleflex Medical, Wayne, PA) were used, ranging in size from 24 to 54 French. If a stricture precluded standard endoscope passage, dilations typically were initiated at 24 French. If the endoscope was able to be passed, the first dilation was started at 30 French. Bougies were well-lubricated and passed sequentially, advancing by 2 French with each dilation. Each dilator was examined after passage for the presence of blood streaking along the shaft. Once blood was observed on the endoscope or if tactile resistance was felt to be significant, the endoscope was reinserted and the mucosa examined for presence of a rent. Following the last bougie dilation, the scope was reinserted and the mucosa again examined. Fluoroscopy was not used with bougie dilations.

For both methods, dilation was considered complete after either reaching a diameter of 15 mm (45 French) or if a deep rent in the mucosa appeared with fibrous tissue at the base. The presence of small (<0.5 cm), shallow rents with oozing blood was not considered criteria for cessation of dilation. For older patients undergoing subsequent dilations, larger diameters were reached at the discretion of the endoscopist but generally did not exceed 18 mm (54 French).

Dilation Results

Sixty-eight dilations occurred. Bougie non-wire-guided Maloney dilators were used in the majority of dilations (72%) (Table 2). Mucosal rents were achieved in 82% of dilations and were estimated to be >4 cm in 13 (19%).

Indication for dilation included moderate to severe stricture (unable to pass standard endoscope), frequent dysphagia and luminal narrowing on endoscopy and/or fluoroscopy, or

severe dysphagia nonresponsive to medical treatment. Eleven dilations occurred in moderate to severe strictures with a starting and final dilator size of 8.3 mm (SD 0.8, range 6.7–9.3) and 11.1 mm (SD 2.1, range 8.7–15), respectively.

First dilation occurred in the setting of persistent dysphagia and evidence of narrowing despite EoE-directed treatment in half of subjects (20/40). Prior treatment of these 20 subjects included dietary elimination (n = 9) and/or swallowed topical steroids (n = 18). First dilation occurred at diagnostic endoscopy in the other half. In this setting, dilations were performed in subjects with identified narrowing and history of food impaction and/or with severe stricture that precluded passage of the endoscope. Fourteen of these subjects (70%) were on proton pump inhibitor for EoE diagnostic evaluation based on current guidelines (1). Six were not on any medication (15% of total) and clinical evaluations confirmed the diagnosis of EoE at a subsequent endoscopy. No dilation was performed at the time of a food impaction.

Twenty-three patients with EoE (58%) had a single dilation during the study period. The remaining 17 patients underwent more than 1 dilation (2–5 total). Repeat dilations were performed if there were persistence or relapse of symptoms and/or if the subject was considered at risk for food impaction and final dilation size was not reached (15 mm). Dilations occurred a mean of 8.7 months (SD 5.1 months) apart. There were a total of 28 repeat dilations. A stricture was appreciated on endoscopy in 21 (75%) and a rent occurred as a result of dilation in 27 (96%) of repeat dilations.

Having repeat dilation was not associated with use of EoE-directed treatment or mucosal eosinophilia at initial dilation, type of dilation, and initial or final dilator size. Patients undergoing a single dilation were slightly older than those who required multiple dilations ($P = 0.05$) (Table 3).

Symptoms response was available within 2 months in 43 dilations (67%). Symptoms were reported to have improved in 86% (37/43).

Adverse Events

During the study period, endoscopy AE rate for grade 2 were 1.35% for all patients, 0.7% for patients with EoE, 3.1% for dilation in non-EoE patients and 2.9% for dilation in EoE. AE rates were higher for patients undergoing dilation than for those undergoing diagnostic upper endoscopy alone ($P = 0.01$). No significant differences were measured in the event rate for dilations between EoE and non-EoE subject groups. The most common indications for non-EoE dilations were caustic ingestion, epidermolysis bullosa, esophageal atresia, or tracheoesophageal fistula. AE grade 2 that occurred in association with dilation in EoE included; 1 patient with postoperative chest pain in the recovery area who had a normal chest x-ray (grade 2 event) and 1 patient with chest pain who was observed overnight for pain control who did not have evidence of perforation as evidenced by normal imaging (grade 3 event).

Patient reported postdilation pain required reassurance only (grade 1) in 15% of dilations (Table 2). Pain was reported more frequently in those patients who had mucosal rents >4 cm

(5/12) compared with those with smaller rents (4/40) ($P = 0.02$; Table 3). No significant associations were detected between $\frac{1}{4}$ postprocedural pain (any grade) and dilation method, final dilator size, medication, or mucosal eosinophilia.

During the study period, there was a postendoscopy follow-up call contact response rate of 59.8% for all procedures.

DISCUSSION

Here we present the largest recorded clinical experience with esophageal dilation in children and adolescents with EoE. Our results show that AEs were uncommon and occurred at a similar frequency as compared to non-EoE controls undergoing esophageal dilation. Pain was the most commonly reported event and this required unanticipated medical evaluation in only 2 procedures (2.9%). Most importantly, no esophageal perforations or serious bleeding events occurred. We conclude that esophageal dilation can be performed safely in children with EoE-associated strictures.

We based our clinical practice for dilation of EoE-related strictures on both early and recent literature of adult patients with EoE who underwent esophageal dilations (5,13,15–17,21). In this regard, we developed a conservative approach toward dilation as described above. Traditionally there has been a teaching to not dilate beyond an increase in 3 mm within a single session; however, we have found that does not always apply to EoE. This is due, in part, to difficulty in the estimation of lumen size (24,26) and variable response to dilation, specifically the size of the desired rent, which can either occur readily or not until larger diameters are reached. We performed dilations either with the use of through-the-scope balloons that allow for direct visualization or with cautious tactile assessment for resistance and observing for blood on Maloney bougies.

The timing of esophageal dilation remains a point of discussion. In general, EoE-directed medical therapy is initiated before considering dilation. Dilation may, however, be considered necessary as an initial therapeutic intervention. For example, dilation may be performed in the setting of a stricture precluding passage of the endoscope or in a symptomatic patient with stricture and recent history of food impaction. In our series, half of the patients had dilation at their diagnostic endoscopy before starting EoE-specific treatment. In the remainder, dilation was performed when symptoms persisted despite EoE-directed therapy with swallowed steroids and/or diet restriction and the esophageal lumen was estimated to be <15 mm. We did not identify a difference in AEs in those subjects on EoE-directed treatment at their first dilation compared with those that were not; however, this finding may be limited by a relatively small sample size.

In our series, virtually all patients were started on or continued EoE-directed treatment after dilation. Symptoms improved after dilation in the majority assessed (37/43). Results suggest that dilation may be effective in reducing symptom burden in patients with moderate to severe strictures and/or persistent symptoms despite treatment. Predictive factors of who would, however, respond to dilation, such as the use of swallowed topical steroids before dilation or degree of eosinophilia (14,15), were not identified.

In contrast, in a small but randomized controlled trial of initial esophageal dilation compared with no dilation in adults with EoE and dysphagia, dilation did not result in additional improvement compared with medical treatment alone (fluticasone and proton pump inhibitor) at 30- and 60-day follow-up (27). In the present study, subjects with narrow strictures (<7 mm) or pretreatment with fluticasone were, however, excluded.

Repeat dilations were performed in symptomatic patients with persistent narrowing. Nearly half (17/40) of patients had a repeat dilation in the study period. This suggests, in some cases, that remodeling may persist despite treatment necessitating repeated dilation to obtain satisfactory symptomatic response. This is consistent with a number of adult studies that identify the need for repeated dilations to achieve symptomatic success (28). In the largest series reported to date, 58% of 164 patients required >1 dilation even when cotreated with medication, with the only predictor being a small baseline esophageal diameter (20).

Our results revealed that AEs associated with dilation in pediatric patients with EoE appear to be comparable to that found in adult EoE studies. A recent meta-analysis of dilations in adult patients with EoE reports <1% develop serious complications (perforation, hemorrhage) (18). Although we did not identify any serious complications, we did identify that 3% of patients experienced a grade 2 or 3 AE (unanticipated medical intervention) with the use of a systematic AE reporting and classification system.

Pain after EoE dilations was common (15%), self-limited, and typically required only reassurance or minor analgesics. The frequency of reported procedural-related pain is variable and likely depends on the means of symptom identification. For instance, Schoepfer et al (13) reported 74% of adult patients felt at least mild pain when asked by postprocedure questionnaire, yet in only 7% was pain recorded in the chart. Other studies report postprocedural chest pain occurs in 2% to 5% of patients (18,20). Our data reiterate the role for anticipatory guidance and preemptive assessment of the need for short-term prescription analgesics after the procedure.

The AE reporting system used included methods of direct patient follow-up of postprocedure symptoms and systematic screening for unanticipated medical attention by use of an EMR. There is, however, still potential for not capturing all AEs. Patients may have presented to emergency centers outside our hospital system or not reported pain (AE grade 1). As all but 1 patient was, however, followed long term at our facility, we believe we were able to reliably capture all AE grade 2 or greater.

Other limitations of the present study stem from its retrospective nature. The follow-up of patients after dilation was not standardized and symptom improvement may be due to medical or dietary treatment or dilation alone. In our study, all dilations were performed by endoscopists experienced with EoE-associated strictures; this may have led to a lower than expected AEs because outcomes in dilation can be related to level of experience (29). Despite these limitations, we feel our findings provide clinically useful information to guide therapeutic use of dilation in children with EoE.

Comparative studies examining children and adults, such as those by Singla et al, will be critical to examine the natural history of complicated EoE and to see how these phenotypic

differences may affect AEs and response to dilation. For instance, although studies have demonstrated that long-term chronic inflammation increases risk of fibrotic strictures (2,3), it is still unknown whether treatments can alter the natural history of EoE. Encouraging results recently suggest treatment may in fact limit the progression to fibrosis and stricture in children (30). In contrast, in a telephone survey follow-up study, Bohm et al (31) found that more than half of the children had resolution of symptoms an average of 8 years after diagnosis with no clinical predictors identifying who would have a better outcome.

Fibrotic features are increasingly recognized in children with EoE (18,30). Commonplace symptoms thought to be primarily related to eosinophilic inflammation, may also be related to chronic remodeling and esophageal narrowing in younger patients (13,24). Although topical steroids may improve some aspects of this complicated EoE, dilation may be a necessary part of symptom management when lumen narrowing is present. Despite half of the subjects reported here to have had dilation before starting EoE-directed treatment, anti-inflammatory approaches with either diet restrictions or topical steroids should remain the first-line therapy for symptomatic pediatric patients with EoE. When symptomatic esophageal narrowing is present, our results support the cautious use of dilation as an important therapeutic adjunct in children with dysphagia and lumen narrowing. Dilation, once performed, may need to be performed repeatedly to achieve therapeutic success. Further studies are needed to determine the optimal timing, technique, and co-morbid considerations required for children, to maximize clinical benefit and minimize risks and costs.

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What Is Known

- Esophageal narrowing (stricture) occurs in children as a result of eosinophilic esophagitis and causes symptoms of dysphagia and risk of food impaction.
- Dilation can be used safely in the treatment of adults with eosinophilic esophagitis–associated strictures with report of low rates of serious adverse events in adults.

What Is New

- Adverse events related to esophageal dilation in pediatric eosinophilic esophagitis occur with the same frequency as non-EoE patients.
- Dilation of eosinophilic esophagitis–related strictures can be performed safely.
- Pain is a commonly reported postprocedure complaint in the setting of mucosal rent; postprocedure pain management needs should be considered.

Table 1.

Eosinophilic esophagitis subject characteristics undergoing dilation

Subjects characteristics (n = 40)	
Demographic	Mean or no., %
Age at first dilation, yr (SD; range)	13.8 (3.3, 4.6–18.9)
Male	30 (73)
Caucasian	39 (97)
Age at symptom onset, yr (SD; range)	8.7 (3.4, 1–15)
Presenting symptom	
Dysphagia	27 (68)
Food impaction	8 (20)
Feeding dysfunction	5 (12)
Treatment	
Diet elimination	9 (23)
Swallowed topical steroids	18 (45)
Proton pump inhibitor	25 (63)
No medication	6 (15)
Dilations per patient	
Single	23 (57)
Multiple	17 (43)
Dilations per patient (range)	1.7 (2–5)
Starting dilation size, mm (SD; range)	10.1 (1.4, 6.7–13.5)
Final dilation size, mm (SD; range)	14.9 (2.7, 9–20)

SD = standard deviation.

Table 2.**Dilations in pediatric eosinophilic esophagitis**

Dilation characteristics (n = 68)	
Characteristic	No., %
Endoscopic appearance	
Stricture	
Mild >9 mm	57 (83)
Moderate to severe <9 mm	11 (17)
Dilation method	
Non-wire-guided Maloney	49 (72)
Through the scope balloon	19 (28)
Starting dilator size (mean mm) (SD; range)	10.4 (1.7; 6.7–15)
Final dilator size (mean mm) (SD; range)	14.9 (2.8; 8.7–20)
Increase in dilator size/dilation, mm (SD)	4.5 (2.3, 1–9)
Dilation outcome	
Mucosal split	56 (82)
Improved symptoms *	37 (86)
Adverse event	
Pain	10 (15)
Fever	1 (1)
Grade >2	2 (3)
Perforation, bleeding, infection	0 (0)

SD = standard deviation.

* Follow-up assessment of symptoms available in 43 dilations.

Table 3.

Predictors of number of dilations performed and adverse events

	Dilations		OR	CI	P
	Single (n=23)	Multiple (n=17)			
	Mean or no., %				
EoE Treatment	11 (48)	9 (53)	0.8	0.23–2.9	1.0
Eosinophilia (>14 eos/hpf)	18 (78)	13 (76)	3.6	0.2–4.9	1.0
Maloney	19 (83)	9 (53)	4.2	1.0–17.8	0.08
Final dilator size, mm (SD)	14.7 (2.9)	13.9 (3.2)			0.4
Duration of follow up, yr (SD)	1.2 (1.4)	2.1 (1.6)			0.09
Age, yr (SD)	14.7 (3.2)	12.7 (3.2)			0.05
	AE (n=11)	No AE (n=57)			
Adverse events	Mean or no., (%)		OR	CI	P
Maloney	9 (82)	40 (70)	1.9	0.4–9.8	0.5
Rent—any	9 (82)	47 (82)	1.0	0.2–5.6	1.0
Rent—> 4 cm	5 (45)	8(14)	5.1	1.3–20.7	0.02
Final dilator size, mm (SD)	16.3 (2.8)	14.7 (2.7)			0.07
Steroid	6 (55)	35 (61)	0.8	0.2–2.8	0.7
PPI	8 (73)	32 (56)	2.1	0.5–8.7	0.3
Eosinophilia	9 (82)	44 (77)	1.3	0.3–6.9	1.0
Age, yr (SD)	13.5 (3.5)	15.2 (1.9)			0.2

AE = adverse event; CI = confidence interval; EoE = eosinophilic esophagitis; OR = odds ratio; PPI = proton pump inhibitor; SD = standard deviation.