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A Visual Analogue Scale and a Likert Scale are Simple and Responsive Tools for Assessing Dysphagia in Eosinophilic Esophagitis

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Abstract

Background—While symptom scores have been developed to evaluate dysphagia in eosinophilic esophagitis (EoE), their complexity may limit clinical use.

Aim—We aimed to evaluate a visual analogue scale (VAS) and a 10 point Likert scale (LS) for assessment of dysphagia severity before and after EoE treatment.

Methods—We conducted a prospective cohort study enrolling consecutive adults undergoing outpatient endoscopy. Incident cases of EoE were diagnosed per consensus guidelines. At diagnosis and after 8 weeks of treatment, symptoms were measured using the VAS, LS, and the Mayo Dysphagia Questionnaire (MDQ). The percentage change in scores before and after treatment were compared overall, in treatment responders (<15 eos/hpf) and non-responders, and in patients without baseline dilation.

Results—In 51 EoE cases, the median VAS decreased from 3.6 at baseline to 1.4 post-treatment (71% decrease), the LS decreased from 6 to 2 (67%), and the MDQ decreased from 20 to 10 (49%). The VAS correlated with both the LS ($R=0.77$; $p<0.0001$) and MDQ ($R=0.46$, $p=0.001$). After stratification by histologic response, the LS decreased 70% in responders vs. 13% in non-responders ($p=0.02$). In patients who did not receive baseline dilation, both the VAS and LS decreased significantly more in the histologic responders.

Conclusions—Both the VAS and LS were responsive to successful histologic treatment. Because the VAS and LS are simple to administer and are responsive to treatment, they can

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provide an efficient and objective method for assessing dysphagia severity in EoE in clinical practice.

Keywords

Eosinophilic esophagitis; dysphagia; symptom score; treatment response

Introduction

Eosinophilic oesophagitis (EoE) is a chronic immune/antigen-mediated clinicopathologic condition typified by symptoms related to oesophageal dysfunction and eosinophilic-predominant oesophageal inflammation.¹ The diagnosis of EoE requires the presence of at least 15 eosinophils per high-power field in oesophageal biopsies as well as exclusion of other etiologies of eosinophilia.^{2,3} Children can present with vomiting, regurgitation, nausea, epigastric and abdominal pain.^{4,5} Adolescents and adults commonly present with solid food dysphagia^{6,7} and food impaction.^{8–11} EoE represents a growing health problem and a substantial disease burden.¹²

Treatment modalities for EoE include medications, diet elimination, and oesophageal dilation.¹ Assessing response to these treatments, however, is not straightforward. While the oesophageal eosinophil count has traditionally been the primary measure assessed for treatment response, a number of other outcomes may be viable including symptoms, endoscopic findings, oesophageal compliance, quality of life, other histologic findings, and biomarkers.^{1,13–19} Measurement of symptoms has been particularly challenging given the variety of symptoms and the poor correlation between eosinophil counts and some measures of symptoms.²⁰ To address this, validated instruments have been created over the last several years to measure symptoms in EoE. In adults, these include the eosinophilic oesophagitis symptom activity index and the dysphagia symptom questionnaire and in children the pediatric EoE symptom score.¹⁵ The Mayo Dysphagia Questionnaire (MDQ), though not validated in EoE, has also been used.^{21,22} However, these measures are primarily research tools that are not used in routine clinical practice. It is possible that a simpler symptom assessment tool could provide similar information but have greater clinical utility outside of the research setting.

The aim of this study was to evaluate the performance of a visual analogue scale (VAS), Mayo Dysphagia Questionnaire (MDQ) and a 10 point Likert scale (LS) in the assessment of dysphagia severity before and after initial treatment of EoE. A goal was to determine whether the VAS and LS could provide an efficient means for quantifying dysphagia, and whether they would be responsive to treatment.

Materials and Methods

We conducted an analysis of a prospective cohort study at the University of North Carolina at Chapel Hill from 2009–2014 enrolling consecutive adults undergoing outpatient EGD. The University of North Carolina institutional review board approved this study. Full details of the study design and conduct have been previously reported.^{19,23–25} Incident cases of EoE were diagnosed per consensus guidelines.^{2,3} Specifically, they were required to have

symptoms of dysphagia and at least 15 eosinophils per high-powered field (hpf area = 0.24mm^2) on oesophageal biopsy after a high-dose, eight week proton-pump inhibitor (PPI) trial to exclude PPI-responsive oesophageal eosinophilia; other local and systemic causes of eosinophilia also had to be excluded.

After diagnosis, EoE patients were treated at the discretion of their gastroenterologist with swallowed topical steroids (either fluticasone 880 mcg twice daily or oral viscous budesonide 1 mg twice daily) or dietary elimination (six food elimination diet) for 8 weeks and had repeat endoscopy with biopsy. During both the baseline and post-treatment endoscopies, a total of 5 research protocol biopsies were obtained from the distal, mid, and proximal oesophagus (3, 8, and 13 cm, respectively, above the gastro-oesophageal junction) for determination of eosinophil counts. Eosinophil counts were quantified using a previously validated protocol.²⁶

At baseline and follow-up, clinical and endoscopic data were collected using standardized case report forms. Symptoms were measured using three instruments: VAS, LS, and MDQ. For the VAS, patients were asked to place a mark on a 10 cm line to answer the question, “How bad, on average, has your swallowing difficulty been over the past 30 days”. The VAS was anchored at 0 with “no trouble swallowing” and at 10 with “unable to even swallow saliva”. The mark was then measured in mm to provide the VAS score. For the LS, patients were asked, “In the past 30 days, how would you rate the severity of your trouble swallowing” on a 10 point scale. The LS was anchored at 0 with “not at all severe” and at 10 with “very severe.” The MDQ is a 28 item instrument with 17 questions focused on dysphagia which has been validated to measure dysphagia severity in patients with peptic strictures; we used the 30 day recall version.^{21,22} We selected the MDQ because we needed a measure of dysphagia and at the time this study was designed and started (2008-2009) there were no validated EoE symptom metrics for adults with EoE; the MDQ was felt to add content validity to the study. The score is calculated with a subset of 5 questions specifically assessing dysphagia severity and eating behavior modification to a number of foods and consistencies. The score ranges from 0 to 100, with higher scores representing more severe dysphagia.

For analysis, the primary outcome was the percentage change of the three symptom scores between baseline and post-treatment measurements. Spearman correlation coefficients were used to test the association between symptom scores. The Wilcoxon sign-rank test was used to compare baseline and follow-up eosinophil counts and symptom scores. Wilcoxon rank sums were used to assess the relationship in symptom scores between treatment responders (<15 eos/hpf) and non-responders (≥ 15 eos/hpf). We also performed a sub-analysis restricting the population to those who did not undergo esophageal dilation at baseline, as this could contribute to discordance between histologic and symptom response.^{27–29} Specifically, if patients were dilated and their stricture was improved, they may have had a symptom response regardless of whether they have a histologic response. Normally distributed continuous variables are presented as mean ± standard deviation; non-normal continuous variables are presented as median with associated intra-quartile range (IQR). Analysis was performed with Stata 14.1.

Results

A total of 51 adult patients newly diagnosed with EoE met eligibility criteria. The mean age was 37 years old, 53% were male, and the majority (92%) was white (Table 1). An associated atopic condition was reported in 89% of patients, and endoscopic features of EoE were common. Of note, a total of 17 (33%) patients underwent oesophageal dilation at baseline.

At baseline, the median peak eosinophil count was 93 eos/hpf (IQR: 38 - 183). The baseline median VAS, LS, and MDQ scores were 3.6, 6.0, and 20, respectively (Table 2). Following treatment with either swallowed topical steroids or dietary elimination for 8 weeks, the median peak eosinophil count was 2 eos/hpf (Table 1). The follow-up median VAS score was 1.4 (71% decrease; $p < 0.001$ compared with baseline). The post-treatment median LS and MDQ scores were 2.0 and 10 (67% and 49% decreases, respectively; $p < 0.001$ and $p = 0.001$ compared with baseline, respectively) (Table 2)

A total of 31 patients (67%) were histologic responders at the < 15 eos/hpf level. After stratification by histologic response, larger percent decreases in symptom scores were noted in responders compared to non-responders (Table 3). The VAS decreased 72% in histologic responders and 64% in non-responders ($p = 0.43$). This decrease was more prominent for the LS between histologic responders and non-responders (70% vs 14%; $p = 0.03$) than for the MDQ (64% and 33%; $p = 0.33$).

When the analysis was restricted to patients who did not undergo oesophageal dilation ($n = 34$), the results were more pronounced. The median VAS decreased by 75% in histologic responders and 16% in histologic non-responders ($p = 0.07$). The decrease in the median LS was similar (71% in responders vs 13% in non-responders; $p = 0.006$). The MDQ score decreased 80% in histologic responders versus 25% for non-responders ($p = 0.26$). Of note, in the overall study population, 8 of the 35 histologic responders were dilated at baseline and 9 of the 16 non-responders were dilated at baseline.

The VAS and LS had a strongly positive and statistically significant correlation ($R = 0.77$; $p < 0.001$). There was additionally a moderately positive statistically significant association between the VAS and MDQ ($r = 0.46$, $p = 0.001$).

Discussion

Dysphagia is the hallmark symptom of EoE in adolescents and adults, and can impact on EoE-related quality of life.³⁰ Only recently have two instruments have been validated to measure dysphagia in EoE,^{14,31} and their use is largely limited to research applications at this time. For routine clinical use, a simpler measure may be preferable. In this study, we evaluated the performance of two brief symptom scores, the VAS and LS, and the longer MDQ for assessing improvement in dysphagia severity in adult patients after initial treatment for EoE. We found that the VAS and LS significantly correlated with the MDQ score. All three measures decreased after treatment, with the largest decreases seen in the VAS and LS. In the overall study population, median percent decreases in all three measures were larger in patients who were histologic responders, but the only statistically significant

decrease was with the LS. However, to assess for the effect of baseline dilation, which could improve symptoms regardless of histologic response status, we limited the analysis to those who did not receive oesophageal dilation. In this situation, there was a correlation between histologic response and symptom scores for both the VAS and the LS, and we observed less prominent symptom improvement in the histologic non-responder group. In sum, these data show that both the VAS and LS not only measure dysphagia severity but are also reflective of symptom improvement with treatment response, particularly in patients who are not dilated at baseline. Data for the LS are stronger than for the VAS.

As the VAS and LS are easily administered and appear responsive to treatment, they may provide an efficient means of assessing dysphagia severity over time in patients with EoE, and could readily be used in clinical practice. The utility of this approach would still need to be confirmed in future prospective studies in routine clinical settings. There are currently several options for measuring symptoms of dysphagia in EoE in adults and adolescents. The Straumann Dysphagia Index is a non-validated instrument that measures dysphagia frequency and severity, and it was responsive to treatment in one randomized trial,³² but not in a second.³³ As noted above, the MDQ was initially developed to assess dysphagia severity and predict the presence of peptic strictures. While it has been used in randomized trials of topical steroids for EoE, it has not been responsive to treatment, with similar improvements seen in active and placebo arms.^{34,35} We observed similar findings in our patient cohort. The dysphagia severity score is a daily symptom diary that measures dysphagia frequency and severity with a 24 hour recall. It has been used in one trial, where it was shown to be responsive.³⁶ The eosinophilic oesophagitis activity index measures dysphagia frequency and severity as well as food avoidance and modification behavior in a single summary score,³¹ but responsiveness data have not yet been published. Both the dysphagia severity questionnaire and eosinophilic oesophagitis severity index were specifically developed in accordance with FDA guidance on patient-reported outcomes.³⁷ Because there can be discordance between symptoms and histology in EoE, with some studies reporting a poor correlation between EoE symptoms and histologic activity,^{32,34,38,39} in practice it is important to assess responses in both domains. For clinical use, a VAS or LS may provide quantitative data that can be followed over time, in an efficient, rapidly ascertainable and non-invasive manner. This point remains particularly salient given the increased cost and inconsistent results of more invasive measures to assess EoE disease activity.^{40,41}

Our study has some weaknesses. First, it was performed at a tertiary care center, but the characteristics of the study population are typical of a non-referral population, particularly because only new cases of EoE were included who were treatment naive. Second, as we evaluated an adult population, we are not certain if these symptom scores would be valid in younger subjects where dysphagia is much less commonly reported.^{5,11} Third, the VAS and LS were not developed or validated with qualitative methodology or in accordance with FDA guidance, so these could not currently be used as primary outcomes in drug development trials. Fourth, as previously detailed, the MDQ was not validated as an EoE symptom metric. However, utilization of the MDQ provided some content validity to the VAS and LS measured we used in this study. Finally, our study does not include a placebo arm, so we cannot comment on how the VAS or LS would perform in a randomized trial. This point is important, as there are multiple trials in EoE where symptoms have improved

equally in both the treatment and placebo arms when non-validated measures were used.^{33–35,42–44} However, in a non-trial clinical practice setting, use of either of these measures would provide quantitative data to follow over time, which may have added utility to a patient's overall subjective report of symptoms.

The study also has a number of strengths. It uses a prospective cohort design with rigorous methodology and data collection. The population is homogenous, with treatment naïve incident EoE cases and exclusion of PPI-responsive eosinophilia. It uses and compares multiple symptom measures, and performs analyses by histologic response and in those patients without baseline oesophageal dilation. However, future studies should be conducted to determine the degree of reduction in the VAS or LS that is deemed clinically significant.

In summary, dysphagia severity as measured by the VAS and LS were correlated with dysphagia severity measured by the MDQ. Both the VAS and the LS were responsive to successful histologic treatment, and this effect was more prominent when limiting the analysis to those without dilation at baseline. Because the VAS and LS are simple to administer and are responsive to treatment, they can provide an efficient method for assessing dysphagia severity in EoE in the clinic setting.

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Table 1

Population Characteristics, Initial Treatment History and Baseline Endoscopic Findings (n = 51)

Patient Characteristics; n (%)	
Age, mean $\pm$ SD	37 $\pm$ 11
White	47 (92)
Male	27 (53)
Atopic illness	42 (89)
Initial Treatment; n (%)	
tCS	49 (96)
Budesonide	42/49 (86)
Fluticasone	7/49 (14)
Six-Food Elimination Diet	2/51 (4)
Baseline EGD findings; n (%)	
Normal	2 (4)
Rings	45 (88)
Furrows	44 (86)
Decreased vascularity	26 (51)
Plaques	26 (51)
Crepe paper	4 (8)
Dilation	17 (33)

Table 2

Median and Interquartile Range of Baseline and Follow-up Eosinophil Count and Symptom Score

	Baseline	Follow-up	% Decrease	P Value
Eos/hpf, median [IQR]	93 [38, 182]	2 [0, 41]	97 [73, 100]	< 0.001
VAS, median [IQR]	3.6 [1.5, 6.4]	1.4 [0.2, 2.7]	71 [12, 92]	< 0.001
LS, median [IQR]	6.0 [2.0, 7.0]	2.0 [0, 3.0]	67 [33, 90]	< 0.001
MDQ, median [IQR]	20 [15, 45]	10 [0, 35]	49 [0, 91]	< 0.001

Eos, eosinophils; hpf, high-power-field; VAS, visual analogue scale; LS, Likert Scale, MDQ, Mayo Dysphagia Questionnaire.

Table 3

Percentage Decrease in Symptom Scores Before and After Treatment by Histologic Response and Oesophageal Dilation

	<15 eos/hpf	15 eos/hpf	p-value
All Patients	n = 35	n = 16	
VAS, median [IQR]	72 [17, 98]	64 [12, 75]	0.43
LS, median [IQR]	70 [50, 100]	14 [0, 83]	0.03
MDQ, median [IQR]	64 [0, 100]	33 [6, 73]	0.33
No Baseline Dilation	n = 27	n = 7	
VAS, median [IQR]	75 [34, 100]	16 [0, 73]	0.07
LS, median [IQR]	71 [50, 100]	13 [-50, 14] *	0.006
MDQ, median [IQR]	80 [0, 100]	25 [0, 56]	0.26

* Negative values represent percentage increase.

Eos, eosinophils; hpf, high-power-field; VAS, visual analogue scale; LS, Likert Scale, MDQ, Mayo Dysphagia Questionnaire.