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Video Capsule Endoscopy in the Evaluation of Celiac Patients with Persistent or Recurrent Symptoms. Who and When?

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Abstract Background: A proportion of patients with celiac disease are classified as having non-responsive celiac disease despite following a gluten free diet. This study seeks to clarify the appropriate use of video capsule endoscopy in non-responsive celiac disease patients. Methods: We retrospectively reviewed 32 patients with biopsy-proven celiac disease classified as having non-responsive celiac disease and referred for video capsule endoscopy at a single tertiary care center over 10 years. Results: 32 patients were categorized into those with ongoing gluten exposure at time of video capsule endoscopy (14), and those with strict gluten free diet compliance (18). Gluten free diet compliant patients were stratified by biopsy results: ongoing villous atrophy (3), no villous atrophy (6), or no biopsy data within 6 months (9). In patients with ongoing gluten exposure, video capsule endoscopy detected no concerning findings, and all patients ultimately improved with a gluten free diet. Among patients with recent negative biopsy, none had findings of celiac disease on their video capsule endoscopy and none developed complications related to celiac disease. However, in gluten free diet compliant patients with villous atrophy on biopsy, 2 of 3 were ultimately diagnosed with refractory celiac disease. Conclusions: Video capsule endoscopy may be useful in the evaluation of celiac disease in limited settings, namely after ongoing gluten exposure has been excluded and duodenal biopsy shows ongoing villous atrophy.

Keywords: *video capsule endoscopy, celiac disease, non-responsive celiac disease*

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1. Introduction

Celiac disease (CD) is an autoimmune disorder in which the ingestion of gluten triggers small intestinal inflammation in genetically susceptible individuals [1]. The current treatment of CD is a strict, life-long gluten free diet (GFD), however, approximately 30% of patients with CD have symptoms that persist despite a GFD or relapse after an initial response [2]. These patients are classified as having non-responsive celiac disease (NRCD) [1]. The most common etiology of NRCD is ongoing gluten exposure, which has been found to be the cause in just over a third of cases2. Other etiologies include, but are not limited to, irritable bowel syndrome (IBS), carbohydrate malabsorption, small intestinal bacterial overgrowth (SIBO), microscopic colitis, and refractory celiac disease (RCD). RCD is a rare cause of NRCD and involves persistent villous atrophy (VA) and malabsorptive symptoms despite strict adherence to a GFD for at least 12 months and exclusion of other etiologies [3]. Of the two types of RCD, (Type I and Type II), Type II carries a poor prognosis and a high risk of lymphoma [4].

There are several modalities for imaging the small intestine, and Video Capsule Endoscopy (VCE) stands as a noninvasive and reliable technology which may have use in the evaluation of NRCD. Prior studies have shown that VCE is able to detect findings consistent with a diagnosis of CD, such as scalloping of folds, villous blunting, mucosal fold loss, mosaic pattern, and mucosal fissures [5,6,7]. VCE can also detect lesions which imply complications of CD, such as ulcerative jejunitis (UJ), strictures, or malignancies. Currently, limited information is available to advise providers on how to manage the clinical evaluation of NRCD, when to refer CD patients appropriately for VCE, or what to expect with respect to diagnostic yield of VCE in CD patients. This study was undertaken to clarify the appropriate use of VCE in patients with NRCD who require further diagnostics to evaluate the cause of persistent or recurrent symptoms.

2. Material and Methods

We reviewed data from the University of Michigan capsule endoscopy database over a 10 year period (2004-2013), analyzing patients with known biopsy-proven CD who were referred for VCE. All patients were classified as NRCD and considered at risk for complications of CD.

VCEs were performed using the GIVEN Imaging PillcamSB2 system and were read with RAPID Reader software by one of three gastroenterologists with an expertise in small bowel and capsule endoscopy (L.F., M.R., M.T.). The clinical data recorded for each patient included age, gender, presenting symptoms, compliance with a GFD, celiac serologies, upper endoscopy reports and biopsy results, VCE findings, small bowel transit time (SBTT) and completion of capsule study, abdominal imaging performed within 1 year of VCE, overall clinical course, and duration of follow up. We used standard definitions of terms such as scalloping, fissures, blunting, strictures and atrophy, ulceration and erosion, with ulcers generally considered to be larger and with more depth than erosions.

Descriptive statistics (age, body mass index, sex, and race) were calculated to summarize the data as a total composite group and four sub-categorical groups. One-way analysis of variance (ANOVA) was performed to determine differences between the mean age and body mass index among the four groups compliant with a GFD. Fisher's Exact Test (FET) was performed to determine the probability of whether compliance with a GFD at the time of VCE was associated with mucosal findings consistent with CD on VCE. Odds ratios and 95% confidence intervals were calculated to determine the likelihood of negative VCE findings in patients compliant with a GFD. A p-value less than or equal to 0.05 was considered statistically significant. This study was deemed exempt from Institutional Review Board (IRB) approval after institutional IRB review.

3. Results

From a capsule data base of 3.850, we identified 32 patients with confirmed CD [71.8% female, mean age of 48.1 (range 22-82) years old], who were evaluated with VCE at our institution between 2004 and 2013 for persistent symptoms or lab abnormalities which were concerning for complications of CD [Table 1]. All had been diagnosed with CD at least 12 months prior to VCE. The reasons for testing included iron deficiency anemia (IDA) (15), abdominal pain (15), diarrhea (10), weight loss (9), nausea/vomiting (5), fatigue (2), and neurologic symptoms (1) (Figure 1). From our cohort of 32 patients we identified two initial categories. The first consisted of 14 patients (43.8%) who had ongoing gluten exposure (intentional or inadvertent) at the time of evaluation determined by physician/dietician evaluation and/or markedly positive tissue transglutaminase IgA (TTG IgA) testing. This group was classified as "non-compliant". The second category included 18 patients with dietary compliance, who were further stratified into three subgroups based on histology: Group A had duodenal biopsies showing ongoing villous atrophy (VA) (3 patients); Group B had duodenal biopsies negative for VA (6 patients); and Group C had no biopsy data within the 6 months prior to VCE (9 patients). Summary of diagnostic testing (serology, duodenal histology, and VCE findings) can be found in Table 2. More detailed VCE findings are summarized in Table 3. Follow up data are presented in Table 4.

Table 1. Demographics

	All pts	Non-Compliant pets	Compliant pets with neg bx	Compliant pets with pos bx	Compliant patients with no bx
N	32	14	6	3	9
% Female	71.8%	50.0%	100.0%	66.6%	88.9%
Mean age in year (rang)	48.1 (22-82)	51.1(33-71)	43.8(22-62)	62.0(41-82)	41.3(25-60)

Table 2. Diagnostic Summary

	Non- Compliant Pts (14)	Compliant Pts with Neg Bx (6)	Compliant Pts with Pos Bx (3)	Compliant Pts with No Bx (9)
Positive TTG IgA	11/12	0/5	1/3*	0/6
Biopsy findings of CD	14/14	0/6	3/3	0/0
VCE findings of CD	14/14	0/6	3/3	5/9

*This pt was compliant with a GFD.

Table 3. VCE Findings

	Non-compliant (14)	Compliant with neg bx (6)	Compliant with pos bx (3)	Compliant with no bx (9)
Villous atrophy	14	0	3	5
Ulceration	3	0	0	0
Erosion	5	3	0	0
Stricture	0	0	0	0
Mass	0	0	0	0
Extent of celiac findings:				
proximal SB	10	0	3	4
distal SB	3	0	0	1
unable to assess	1	0	0	0
N/A (no findings of CD)	0	6	0	4
Complete SB exam	12	5	3	8
Average SBTT (min)	292	279	299	229

Table 4. Follow- up

	Non-compliant (14)	Compliant with neg bx (6)	Compliant with pos bx (3)	Compliant with no bx (9)
Symptoms improved w/ strict GFD	11	0	0	2
Refused treatment w/ GFD	1	0	0	0
Another etiology felt to be responsible for symptoms*	0	5	0	5
Lost to follow up	2	1	1	2
Developed complications of CD:				
RCD 1	0	0	2	0
RCD2	0	0	0	0
EATL	0	0	0	0
Average follow up time (mos)	35	11	37	28

*IBS/functional pain, SIBO, CVID.

Abbreviations for tables: Pts=patients, bx= biopsy, neg= negative, pos= positive, GFD= gluten free diet, CD= celiac disease, VCE= video capsule endoscopy, TTG IgA= tissue transglutaminase immunoglobulin A, SB= small bowel, SBTT= small bowel transit time, IBS= irritable bowel syndrome, SIBO= small intestinal bacterial overgrowth, CVID= common variable immunodeficiency, RCD= refractory celiac disease, EATL= enteropathy associated T-cell lymphoma

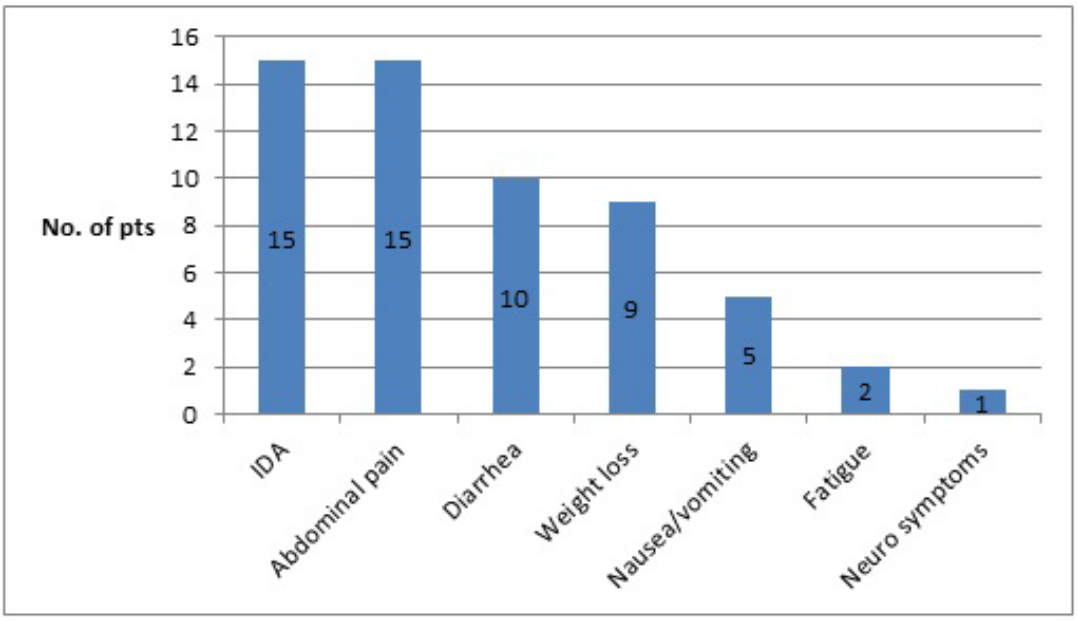

Figure 1. Presenting signs/symptoms that prompted VCE evaluation for NRCD

3.1. Non-Compliant Patients (14)

The mean age was 51.14 years old (range 33-71) and 7/14 (50%) were female. 11 out of 12 patients tested for TTG IgA at the time of evaluation were positive. With regard to the TTG negative patient, her ability to have mounted an antibody response in the past is unknown. All 14 patients underwent endoscopic evaluation with duodenal biopsy within 4 months (average 1.75 months) prior to VCE, and all had villous atrophy on intestinal biopsy. Three patients underwent CT Enterography (CTE) prior to VCE with negative results. All 14 patients had VCE showing features consistent with CD [Table 2, Table 3]. Three patients had one to few shallow ulcerations and 5 had erosions. None had findings of ulcerative jejunitis or malignancy. The average time of follow up was 35 months. 11 patients improved on a GFD, 1 patient refused to comply with a GFD because he was asymptomatic (he presented with persistent IDA), and 2 patients were lost to follow up shortly after VCE. No patients on whom there was follow up data went on to develop RCD/malignancy.

3.2. Compliant Patients (18)

3.2.1. Subgroup A: Compliant Patients with Positive Biopsy (3)

2 out of 3 were female, with a mean age of 62 years (range 41-82). Two of these patients had negative TTG IgA antibody testing, and one had positive titers but was deemed to be compliant with a GFD. All had VA on duodenal biopsy performed within 1 month of VCE. All had findings of CD on VCE (notably all just had proximal involvement and none had ulcers/erosions/strictures, though one had prominent nodularity). Two of these patients were diagnosed with RCD1 and one was lost to follow up. Neither of the 2 patients on which there was follow up data developed UJ or malignancy. Average follow up was 37 months.

3.2.2. Subgroup B: Compliant Patients with Negative Biopsy (6)

All 6 patients in this group were female, with a mean age of 43.8 years old (range 22-62). All of these patients

had an upper endoscopy with duodenal biopsy within 2 months of VCE and none had any degree of VA. 5 of 6 underwent serologic testing with TTG IgA and all were negative. VCE did not show findings consistent with CD in any of the cases. Three of the patients improved with treatment for IBS. Two continued to have symptoms felt to be due to another etiology other than CD. Both of these patients had an additional repeat upper endoscopy with biopsies after VCE was performed, and these were again unremarkable in both cases. One patient was lost to follow up. None of these patients went on to develop complications of CD. Average follow up was 11 months.

3.2.3. Subgroup C: Compliant Patients with no Biopsy and Either no/negative Serologies Prior to VCE (9)

Eight of nine patients were female, with a mean age of 41.3 years old (range 25-60). 3 patients had no testing (duodenal biopsy or serologies) performed prior to VCE, and thus VCE was the first test in their evaluation. 6 patients had no biopsy but negative serologies prior to VCE. 5 patients had VA on their VCE (3 that had negative TTG IgA and 2 that did not undergo serologic testing). In all but one of the patients, the extent of disease was proximal. The one patient with distal disease had negative serology, and it is unknown if he ever mounted an antibody response prior, however, he was ultimately diagnosed with Common Variable Immunodeficiency Syndrome (CVID). In those 5 patients with VA, two improved symptomatically on a continued GFD (prior studies have indicated that VA may lag behind clinical improvement), one was ultimately diagnosed with CVID and died, one improved after diagnosis and treatment of SIBO, and one was lost to follow up. Only one of the patients had a clearly documented reason for not undergoing upper endoscopy with duodenal biopsies. This patient was paraplegic and refused the procedure, but serologies still were not sent. Average follow up in this group was 28 months.

There were no statistically significant differences between the compliant and non-compliant groups in regards to mean age ($p = 0.158$), mean body mass index ($p = 0.130$), and mean small bowel transit time ($p = 0.643$) determined by one-way ANOVA. A statistically significant relationship did exist between compliance with a GFD at the time of VCE and lack of mucosal findings consistent with CD, $p = 0.001$. Additionally, a statistically significant relationship was found between compliance with a GFD and lack of VA on VCE, $p = 0.001$. Patients compliant with a GFD at the time of VCE were more likely than those who were non-compliant to have no mucosal findings consistent with CD on VCE and no VA on VCE (odds ratios of 2.857 and 2.714, respectively). No statistically significant relationship was found between compliance with a GFD and a finding of erosion or ulceration on VCE or in regards to the distal-most extent of small bowel findings on VCE.

4. Discussion

Over the last 5-10 years we have seen an increase in the diagnosis of CD at a time when capsule endoscopy has found exceptional success in the diagnosis and management of other small bowel conditions such as GI bleeding and suspected Crohn's disease. Perhaps because of its usefulness in other diseases, VCE utilization has been transferred to CD patients, yet without reliable studies to validate appropriate use. The diagnostic criteria for CD has traditionally been based on serologies and small bowel histology, neither of which is provided by capsule endoscopy. Capsule endoscopy, however, is a reliable and noninvasive modality which has the potential to offer an optical precision not possible with current endoscopes, and provides physiologic unaltered views. Although certain endoscopic findings are associated with the diagnosis of CD including scalloping of duodenal folds, reduction in the number of folds, mucosal fissures, mosaic pattern, nodularity, and visible mucosal vessels [8], many of these findings are non-specific and VCE has a relatively low sensitivity compared with other testing (sensitivity 89%, specificity 95%) [9]. In certain limited clinical settings, visual findings alone can suggest a specific diagnosis of CD so convincingly that some experts in the field are comfortable with inspection alone, but currently, strong evidence to recommend VCE as the first line tool in the diagnosis of CD is lacking. Nevertheless, this technology has been successfully used in the initial diagnosis of patients who are unable or unwilling to undergo upper endoscopy with biopsy [1].

Despite the confirmed use of VCE in other disease states, the role of this technology in the diagnosis and management of CD is still unclear. It has been suggested that VCE may have a role in equivocal cases, where it could facilitate a diagnosis, or in the evaluation of established CD patients with ongoing symptoms concerning for RCD, malignancy, or UJ. Equivocal cases can be defined as either seronegative VA or cases with positive celiac serologies but negative duodenal biopsy. CD is patchy in nature [10], and an insufficient number of biopsy specimens can lead to a false negative result [11]. It has been hypothesized that VCE, because it is capable of imaging the entirety of the small bowel, may be able to detect patients with true CD whose diagnoses were missed because of patchy disease involvement. Current evidence, however, does not strongly support the use of VCE in this setting. A study by Adler et al. in 2006 looked at 22 patients with gastrointestinal symptoms, positive celiac serology, and normal duodenal histology. [12] VCE detected abnormalities in 55% of cases but most were minor and nonspecific (erythema, denuded villi, mucosal breaks, etc.), Findings such as these have previously been described in 10-15% of healthy controls undergoing VCE. [13] A subsequent study by Lidums et al. in 2011 looked at 8 patients with positive EMA or TTG testing and negative duodenal histology. [14] VCE did not reveal any endoscopic features of CD. In antibody-negative patients with VA on histology, VCE alone is insufficient to confirm the diagnosis of CD, as the macroscopic endoscopic features seen in CD are not specific. Rather, VCE in these situations may suggest other conditions, such as Crohn's disease, or rule out concerning etiologies such as RCD, malignancy, or UJ.

Our group queried whether the use of VCE could aid in the evaluation of CD patients with persistent symptoms. A small number of studies have looked at VCE in the evaluation of CD patients with persistent symptoms on a GFD, mainly to evaluate for malignancy/enteropathy associated T-cell lymphoma (EATL), UJ, or other

pathology to account for their symptoms, though the participants in these studies have been quite heterogenous. [5,6,10,15] The most frequent VCE finding in NRCD has been macroscopic features of villous atrophy, found in 31% of cases [6]. Erosions or ulcerations are often found in NRCD patients but have been found to be associated with ASA/NSAID use, [6] and do not predict a poor prognosis. [15] In contrast, strictures and masses tend to predict a poor prognosis (RCD/EATL). [5,10,15] Data to date have not shown a clear correlation between the length of small bowel involvement and the severity of symptoms.

SBTT has been found to be longer in RCDII than RCDI or symptomatic CD (p=0.03), and in one study a complete SB exam was performed in only half of patients with RCD versus all patients with noncomplicated symptomatic CD (p<0.005). [5] Another study found that proximal focal erythema (p=0.033) and the absence of progression of the capsule to the distal intestine (p=0.035) were independently associated with a poor prognosis (RCDII and/or EATL) and increased mortality. [15]

In this paper, we report our experience with VCE in 32 NRCD patients seen at our institution over a 10 year period. We were able to discern two distinct groups on the basis of compliance with GFD. The Non Compliant group which improved with dietary rehabilitation, and the Compliant group which was further characterized into 3 groups by the histologic presence of VA. In this cohort of NRCD patients, there appeared to be little utility in performing VCE on Non Compliant patients with ongoing gluten exposure, or on Compliant patients in subgroups B & C (patients with a recent negative duodenal biopsy and patients with no recent duodenal biopsy, respectively). In the Non Compliant group VCE detected no concerning findings, resulted in no changes in management, and ultimately all patients improved with a GFD. In the patients with recent negative biopsy and negative serologies, no patients had findings of CD on their VCE and none developed complications related to CD in follow up. In this group while VCE provided no confirmatory information about the presence or extent of CD, VCE could be used in assessing for alternative etiologies of symptoms, such as Crohn's disease (although no alternative etiologies were found on VCE in our study). In those patients who had not undergone recent endoscopy, VCE may have been obtained prematurely, as an Esophagogastroduodenoscopy (EGD) to assess for the presence or absence of VA should likely have been performed first [13].

In the Compliant subgroup A (compliant patients with positive biopsy), however, 2 out of 3 GFD compliant patients with positive biopsy and persistent symptoms, were ultimately diagnosed with RCDI, and we found that there is likely a benefit in performing VCE this population to evaluate for potential complications of CD. Although our study identified no severe complications of CD at the time of VCE in group A, other studies have detected malignancy and UJ in those with RCD. Therefore, VCE may be an important diagnostic step in this population with persistent symptoms in order to assess for these potential complications. Not surprisingly, the Compliant group in our study was significantly more likely to have no mucosal findings consistent with CD on VCE (p=0.001), including no VA (p=0.001) compared with the Non-compliant group.

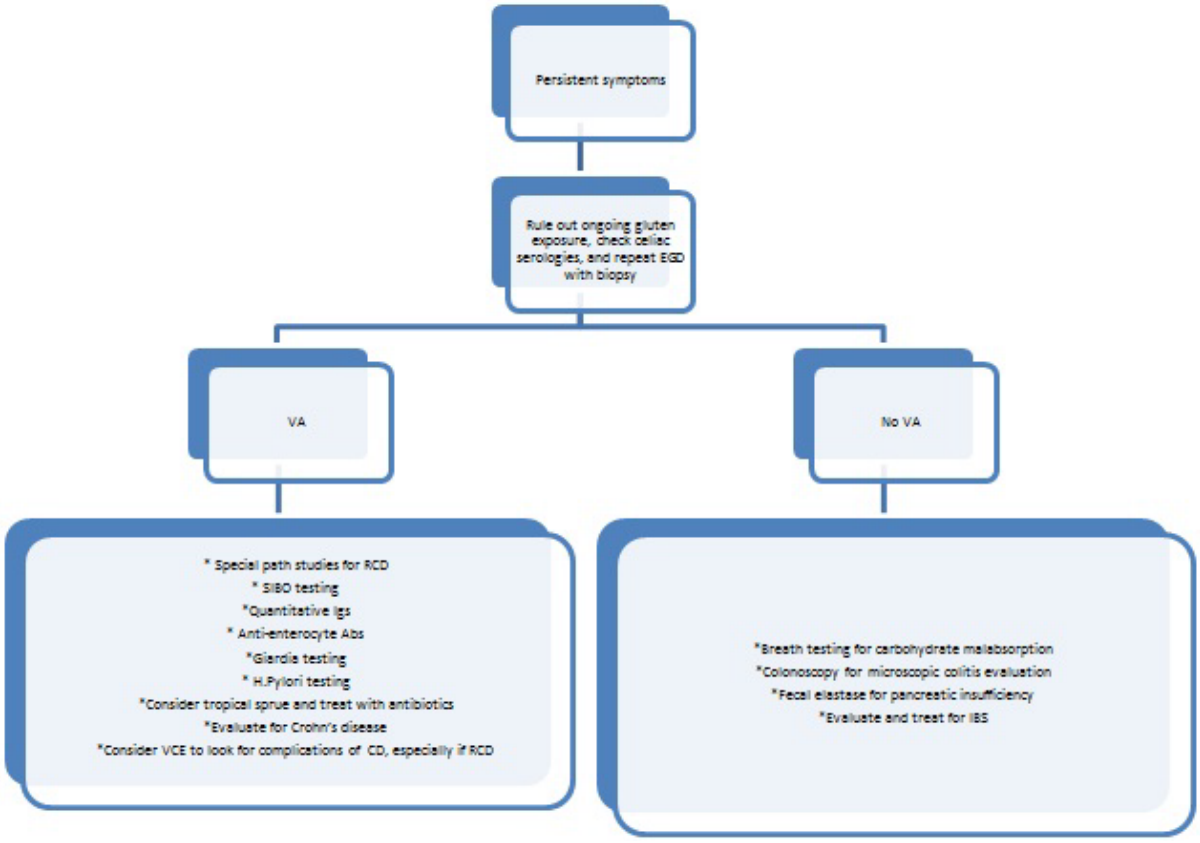

Figure 2. Proposed diagnostic algorithm for evaluation of NRCD

Abbreviations for figures: Pts=patients, No.=number, IDA = iron deficiency anemia, GFD= gluten free diet, VA= villous atrophy, RCD= refractory celiac disease, SIBO= small intestinal bacterial overgrowth, Abs = antibodies, VCE= video capsule endoscopy, CD= celiac disease, IBS = irritable bowel syndrome

Based on the findings in our study and the literature to date, we suggest that VCE may be useful in the evaluation of CD in limited settings. We have proposed a diagnostic algorithm for the work up of NRCD (Figure 2). We recommend that in most cases VCE be done only after ongoing gluten exposure has been excluded and duodenal biopsy shows ongoing VA. The highest yield for detecting the complications of CD with VCE is in those who are diagnosed with RCD. Like most studies addressing the role of VCE in evaluation of CD, a primary limitation of our study was cohort size, as well as a lack of an existing algorithm for the workup of NRCD, and a heterogeneous referred population. We found that approximately 90% of VCEs done at our center for celiac patients with ongoing symptoms were either performed with equivocal indications or obtained before dietary compliance and VA were assessed. While the total number of cases we saw over a 10 year period was small (n=32), the majority of these (81%) were performed within the past 5 years, suggesting that VCE use in CD assessment is increasing. VCE has become a standard diagnostic tool for the investigation of small bowel bleeding and suspected Crohn's disease, but its role in evaluation of other small bowel conditions, particularly CD, needs further scrutiny to identify appropriate use.

Better awareness is needed in the GI community about the appropriate clinical scenarios which would merit referral of celiac patients with ongoing symptoms for VCE, and this can be best addressed in future studies with larger celiac patient populations

5. Conclusions

VCE is increasingly utilized in the evaluation of patients with CD, however, the appropriate use of VCE in this population of patients is currently unclear. In our study we found that there appeared to be little utility in performing VCE on the following groups of patients: 1) celiac patients with ongoing symptoms who are non-compliant with the GFD and 2) celiac patients who are compliant with the GFD and had a recent duodenal biopsy without VA. VCE may also have been ordered prematurely in those patients who did not undergo recent EGD with duodenal biopsy. VCE may be of benefit in patients compliant with the GFD who have ongoing VA on biopsy to rule out complications of celiac disease such as malignancy or ulcerative jejunitis (though none were detected in our series).

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