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### The Impact of Capsule Endoscopy on Management of Inflammatory Bowel Disease: A Single Tertiary Care Center Experience

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#### Abstract

**Background**—Capsule endoscopy (CE) is performed to assess inflammatory bowel disease (IBD). We aimed to define results of CE in subtypes of IBD and to determine whether CE results in management changes.

**Methods**—A retrospective cohort study was performed of all CEs for IBD at a tertiary care center from 2003-2009. Descriptive statistics were used to compare IBD specific medications, surgeries and imaging studies in the 3 months prior and 3 months after CE.

**Results**—Of 907 CEs performed from 2003-2009, 128 were for an indication of symptomatic IBD and 124 capsules left the stomach (86 for Crohn's disease (CD), 15 for indeterminate colitis (IC), 23 for pouchitis). Only 22.1% of CEs done for CD were normal, as compared to 53.3% for IC and 34.8% for pouchitis. Severe findings in CD consisted of multiple aphthae/ulcers (22.1%), stenosis (8.1%) and stenosis with <u>immediate</u> retention (17.4%). In CD, 61.6% had a change in medication in the 3 months after the CE, with 39.5% initiating a new IBD medication; most commonly budesonide or corticosteroids. In the 3 months following CE, 12.8% of patients with CD underwent surgery. Severe findings on CE in patients with CD, as compared to no/minimal findings, resulted in significant differences in medication changes (73.2% vs. 51.1%, p=0.04), addition of medications (58.5% vs. 22.2%, p<0.01), and surgeries (21.9% vs. 4.4%, p=0.01).

**Conclusions**—<u>CE results in management changes</u> in the majority of cases of symptomatic IBD, regardless of the specific CE findings or the subtype of IBD.

#### Keywords

inflammatory bowel disease; Crohn's disease; capsule endoscopy; health care utilization

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Dr. Long contributed to study design, confirmed chart review, determined the analysis plan, performed analyses, wrote and revised the manuscript. Dr. Barnes contributed to study design, performed all data collection and chart review, and participated in critical review of the manuscript. Dr. Isaacs participated in study design, read capsule endoscopies for patient care, and participated in critical review of the manuscript. Dr. Morgan participated in study design, read capsule endoscopies for patient care, and participated in critical review of the manuscript. Dr. Herfarth contributed to study design, oversaw the analysis plan and participated in critical review of the manuscript.

#### Introduction

Capsule endoscopy (CE) (Given, Yoqnem, Israel; Pill-Cam SB) has been in use in the United States since 2001, as an important tool to evaluate the entire small bowel (1,2). Since this time, several reports of the use of CE in single centers have been published. Nearly two-thirds of CE studies are performed for the assessment of gastrointestinal bleeding, with a high diagnostic yield (45-70%) in this setting (2-6). The impact of CE on clinical management has also been studied and found to lead to improved outcomes in these cases (2). A recent randomized controlled trial of CE compared to dedicated small bowel radiography in the assessment of obscure gastrointestinal bleeding did not demonstrate improved outcomes with CE, despite a significant improvement in diagnostic yield (7).

CE also has an important role in the assessment of inflammatory bowel disease (IBD) activity, particularly Crohn's disease (CD). In some series, the diagnosis or assessment of activity of CD has been reported to be the second leading indication for CE (8). The diagnostic value of CE in unsuspected or established IBD has been compared to radiologic and endoscopic modalities including small bowel follow through (SBFT), cross-sectional imaging such as computerized tomographic (CT) enterography, colonoscopy with ileoscopy and push enteroscopy. In one recent meta-analysis, CE was found to be superior to these other modalities for diagnosing non-stricturing small bowel CD (9). The sensitivity and specificity of CE in suspected small bowel CD have been reported to be 83% and 53% respectively. When used as a third diagnostic test after ileocolonoscopy and negative CT enterography or SBFT, CE was not found to be cost effective (10). CE can also be used to revise a diagnosis to CD in patients previously thought to have indeterminate colitis (IC) or in those with previous colectomy who have an ileal pouch anal anastamosis (IPAA) and continued symptoms (symptomatic pouchitis) (11-13). However, the clinical utility of CE in the specific management of any of these subtypes of previously diagnosed IBD is not currently known (1).

Our aim was to determine whether CE results in management changes in patients with previously diagnosed IBD. Change in management could consist of changes in IBD specific medications, further radiologic or endoscopic studies or surgical interventions. We also sought to describe findings on capsule endoscopy in a cohort of patients with symptomatic CD, IC and pouchitis, whose disease severity and/or revised diagnosis to CD had not previously been determined by prior testing.

#### **Materials and Methods**

We performed a retrospective cohort study of patients undergoing CE from July 2003 to December 2009 at the University of North Carolina Hospitals (UNCH). This population was limited to patients with a prior diagnosis of IBD (at least 3 months prior to CE) and to those capsules that left the stomach and visualized small bowel mucosa. A patient was classified as CD based on diagnosis in the medical record with appropriate endoscopic, radiologic or pathology reports (14), as IC if there were clinical features of both CD and UC present (15), and as pouchitis if the patient was status post IPAA with inflammation in the pouch on previous pouch exam or previous clinical diagnosis of pouchitis with response to antibiotics (16). A patient could have more than one CE during the time period of the study, and each of these CE's was included in the analysis as each had the potential to change management.

All referrals for CE in IBD patients were made by gastroenterologists from the gastroenterology and IBD clinics at UNCH or by specialized IBD gastrointestinal surgeons at UNCH. All capsule endoscopies were read by one of two gastroenterologists at UNCH (K.I. or D.M.), one with a specialty in IBD and the other with a specialty in small bowel

endoscopic procedures and obscure gastrointestinal bleeding. All patients underwent the CE after a 10 hour fast. Per standard protocol at UNCH, patients were allowed to drink clear liquids 2 hours after ingestion of the capsule and eat 4 hours after ingestion of the capsule. Standard observation time for each CE was 8 hours. If patients had not passed the capsule 2 weeks after the CE, an abdominal x-ray was performed to assess for retention of the capsule.

Of those CE's done in patients with previously diagnosed IBD, information on IBD-specific medication use, endoscopic studies and radiologic examinations in the 3 months prior to CE was abstracted from the electronic medical record at UNCH. IBD-specific medications included: 5-aminosalicylates (5-ASA), antibiotics (ciprofloxacin or metronidazole), biologics (infliximab, adalimumab, certolizumab, or natalizumab), thiopurines (6-mercaptopurine or azathiaprine), methotrexate, corticosteroids, or budesonide. Additional data abstracted included type of IBD (symptomatic CD, IC, pouchitis), age, gender, duration of IBD, body mass index (BMI), and prior IBD related surgery (excluding perianal surgery). The results of the CE were also documented, and whether there was <u>immediate</u> or <u>delayed</u> retention of the capsule. Immediate retention was defined as the capsule not leaving the small bowel during the digital recording. Delayed retention was defined as the capsule remaining in the digestive tract for at least 2 weeks (as documented by radiographic image) or those cases where therapy (endoscopic or surgical) was required for removal. Finally, IBD-specific medication use, endoscopic studies, radiologic examinations and surgeries (excluding perianal surgery) in the 3 months after CE were also recorded.

Results of the CE were documented in 6 categories: normal, erythema only, few aphthae/ ulcers, multiple aphthae/ulcers, stenosis and stenosis with retention of the capsule (Figure 1). CE findings of retention referred to immediate retention on the digital recording. Capsule findings were also dichotomized as minimal (normal, erythema and few aphthae/ulcers) versus severe (multiple aphthae/ulcers, stenosis or stenosis with retention). The general characterization of capsule endoscopy findings followed usual practice and the literature during the study period, 2003-2009. As is standard practice, the CD scoring systems were not formally incorporated, but the principles were used for guidance (17-18). It is noted that the concepts and initial results for the Lewis Scoring system (17) were presented at the 5th International Conference on Capsule Endoscopy (ICCE 2006) and were incorporated after this time. This literature emphasizes extensive (multiple) aphthous ulcers, medium to large ulcers, and stenosis as indicators of more significant disease.

Results were summarized with descriptive statistics. Comparisons of changes in management by CE findings were performed via Pearson's chi squared statistic or Fisher's exact test as appropriate. Stata 9.0, College Station, TX, was used to perform all analyses. For all analyses, a p-value of 0.05 was considered significant. The study protocol was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill.

#### Results

A total of 907 CE's were performed over the study period, of which 128 were for an indication of symptomatic IBD. A total of 5 patients underwent repeat CE for disease assessment, and each of these CE's was included in the analyses. A total of 4 CE's were excluded because the capsule was retained in the stomach for the entire recording. The analysis therefore consisted of 124 CE's (86 for CD, 15 for IC, 23 for pouchitis). The overall median age of study patients was 37 years old, and was similar across IBD-subtypes. The majority of CE's were performed in women, and a higher percentage of women had CE for the indication of symptomatic IC or symptomatic pouchitis as compared to CD. Median

duration of CD and IC prior to CE was 6 years and median duration of IBD diagnosis in those with IPAA was 13.5 years (Table 1).

Medications, surgeries, endoscopic studies and radiologic examinations in the 3 months prior to CE are also outlined in Table 1. The highest corticosteroid utilization was observed in symptomatic IC patients, as was the highest utilization of 5-ASA medications. Distributions of other medications were similar for both CD and IC. Nearly 50% of CD patients had previous surgery. Less than 50% of patients with CD underwent a small bowel radiologic examination in the 3 months prior to CE.

The CE findings are shown in Table 2. For patients with CD, only 22.1% of CE's were normal. The majority of findings consisted of few or multiple aphthae or ulcerations. A total of 15 capsules in the CD patients (17.4%) were immediately retained on digital recording. The capsule results were normal or only had erythema for the majority of patients with IC (80.0%). A total of 2 patients <u>with IC</u> (13.3%) had few aphthae/ulcerations on the CE. In patients with previous IPAA with continued symptoms, 43.5% had normal CE's or only erythema visualized. A total of 10 patients (43.8%) had few aphthae seen in the small bowel. The remaining 3 patients with symptoms post IPAA (13.1%) had severe findings on CE and diagnoses were revised to CD, with additional therapies and/or surgeries initiated. The one patient with pouchitis who had immediate retention of the capsule was found to have a stenosis <u>of the afferent limb of the pouch</u>. CE findings in those with pouchitis were in the proximal or mid portion of the small bowel, beyond the reach of an endoscope during pouch exam, in 5/13 of these cases (38.4%).

Of the total of 16 patients who had stenosis with immediate retention, only 7 had delayed retention at 2 weeks on abdominal imaging or required surgical intervention for capsule removal prior to 2 weeks (5.6% of all CEs performed). The outcome of each immediately retained capsule is shown in figure 2. We evaluated whether small bowel imaging was performed in the 3 months prior to CE in this group of patients with immediate retention of the capsule. A total of 6/16 (37.5%) had small bowel imaging prior to the test. We were not able to determine what percentage of patients had a patency capsule prior to CE, as this information is not included in our electronic medical record, nor is it contained in our electronic endoscopy database. We did review each of these 6 cases where imaging was performed prior to CE. Two of these CEs were performed with the intention of capsule retention in order to guide surgical management. The remaining 4 cases had a SBFT prior to CE which described inflammatory changes, irregular mucosa, or mild dilation. None of these demonstrated a high grade stricture prior to the CE.

A high percentage of IBD patients had medication changes in the 3 months after CE. In all patients with CD, 61.6% had a change in medication management (defined as initiation or discontinuation of any IBD specific medication) in the 3 months after the capsule endoscopy, with 39.5% initiating a new IBD medication. The most commonly initiated medication was budesonide. A similar percentage of IC patients (66.7%) had a change in medication management, with 6 (40.0%) initiating a new IBD-specific medication. A total of 13 (56.5%) of those with symptomatic pouchitis initiated a new IBD-specific medication. Specific medication classes initiated by sub-type of IBD are shown in table 3. The precise number of IBD patients not started on a biologic or other immunosuppressive therapy due to CE results is unknown.

Surgery in the 3 months after CE is described in Table 4. A total of 12.8 % of CD patients underwent small bowel resection or stricturoplasty after CE. All of the surgeries in patients with IC (n=5) consisted of planned colectomies after CE was performed to rule out findings

consistent with CD. One patient (4.4%) with pouchitis whose diagnosis was revised to CD due to the CE findings underwent small bowel resection.

A summary of changes in medication management, surgery or endoscopic examination in the 3 months after CE stratified by CE results is provided in Table 5. CE results were divided into no or minimal findings versus severe findings. In those patients with CD with severe findings on CE, the majority (73.2%) had changes in medication management and 21.9% had surgery after the CE. In those with minimal findings, medication changes were made to a lesser extent (51.1%), only 22.2% had the addition of an IBD-specific medication and 4.4% underwent surgery. Significant differences in medication changes, additions and surgeries in patients with CD were found based on CE results. Fewer patients had severe findings in the IC group and the pouchitis group. These findings did result in greater medication changes and surgeries in these groups as well (although non-significant).

#### Discussion

The capsule endoscopy literature to date has focused on the CE diagnostic yield and management changes in patients with occult gastrointestinal bleeding. In these studies, relatively small numbers of patients with IBD were included. For example, Chami et al describe the usefulness and impact on management of positive and negative capsule endoscopy in a total of 70 patients undergoing CE's. Of these, only 9% were performed to assess the extent of or to confirm the diagnosis of Crohn's disease. Positive studies were seen in 33% of the CE's for an indication of CD. When considering all indications, the authors concluded that both positive and negative CE's had an impact on management (19). Our study had a large sample of patients with clinically important subtypes of IBD including: symptomatic CD, symptomatic IC and symptomatic pouchitis. In our study, a higher percentage of positive studies was noted among CD patients (only 22.2% of studies were completely normal). Severe inflammatory changes, defined as multiple aphthae/ ulcerations, stenosis or stenosis with retention, were found in 47.6% of CD patients.

CE has also been used in the assessment of IC in order to determine whether CD is actually present. Mow et al published results of CE in a series of 22 patients with ulcerative colitis (UC) or IC. In this series, 40% of patients were subsequently diagnosed with CD based on CE findings of linear erosions and ulcerations (20). Mehdizadeh et all assessed the findings of CE in a larger group of 120 patients (122 CE's) with UC or IBD unclassified (IBDU). A total of 15.8% of these patients had findings (3 or more ulcerations) consistent with a diagnosis of CD. The proportion of small bowel disease was significantly higher among patients with previous colectomy (7 of 21, 33%) (12). Our study also investigated patients with IC and with previous colectomy/IPAA. We found relatively few severe findings on CE among the IC group, but similar to Mehdizadeh et al, found a higher rate of severe CE findings (13.1%) among patients with previous colectomy/IPAA. When few aphthae/ ulcerations were also included in this definition, the rate of positive findings increased to 56.9%. In our study, the colectomy/IPAA group also had longer duration of disease, which may have allowed time for the development of small bowel lesions which the IC group did not have. Nonetheless, these data support the role of CE in restaging disease previously thought to represent UC, particularly among those with prior colectomy and new symptoms.

A total of 16 patients had <u>immediate</u> retention of the capsule in our study, of these 8 (50%) <u>ultimately</u> required operative intervention. A total of 7 capsules had delayed retention. In fact, 2 of these 7 CEs were performed with the intention of capsule retention in order to guide surgical management. Surgeons have used CE to guide surgical management of stricturing and stenosing small bowel CD with previously inconclusive small bowel imaging results or symptoms out of proportion to prior radiologic findings. Others have also argued

that the specific site of retention is often useful in guiding surgical management (21,22). Importantly, in previously reported case series and also in our study, the capsule has been retained proximal to the stricture, rather than within it. A total of only 2 patients in our study (12.5% of those with <u>immediately</u> retained capsules) developed obstructive symptoms related to the capsule, and required more urgent small bowel resection. The rate of retention of CE in patients with previously diagnosed CD has been estimated to be 13% (23) in 2006. We demonstrated a similar rate of 5.6% (7/124) in our population of patients with IBD from 2003-2009, including those who underwent CE with the intent of possible retention.

The literature on CE is limited in that there is no gold standard for the CE diagnosis of small bowel CD, and there are varying definitions of positive findings on CE. Different combinations, distributions, and numbers of aphthae, ulcers, erosions and strictures have been used to diagnose and assess CD (1,17,18) Because of the difficulties associated with using a gold-standard for the diagnosis of CD, we chose instead to study the management effects of CE on patients with previously diagnosed CD, as there was not a need to determine a cut-point for a diagnosis of CD. Instead, we studied the implications of the findings (whether regarded as positive or negative by the treating physician) on CE.

There are several strengths to this study of CE in the management of IBD. First, there were a relatively large number of CE's studied, all with an indication for evaluation of IBD, and all with previously diagnosed IBD. Therefore, there was no question as to the prior diagnosis. Second, all of the CE's were read by 1 of 2 experts in small bowel imaging with vast CE experience. This reduces the risk of inter-observer variability. Third, all documentation was available within a centralized electronic medical record, and all patients included in the study had to be referred by one of the academic gastroenterologists or specialized IBD surgeons at UNCH. This allowed for near complete capture of medications, endoscopic, radiologic and surgical interventions prior to and after CE. Finally, we studied the clinically important outcomes (changes in management) associated with CE, rather than only describing results.

There are also several limitations to this single center retrospective study. The results may not be generalizable to a community practice, as the IBD patient population at a specialized IBD tertiary care center likely differs significantly from that in the community. For this reason, our CEs may be more likely to have positive or severe findings. Also, while we were able to determine differences in medical management after the CE, we were unable to determine retrospectively whether the CE findings were the specific trigger for these changes. To definitively determine this, data would need to be collected prospectively, interviewing the treating gastroenterologists at the time of CE results. Because of this, we may have attributed some changes in management to the CE that were not necessarily causal. We were also unable to determine the role of patency CE prior to CE. During the course of this study, patency CE became available, and in some cases was used instead of SBFT or other radiologic testing prior to CE when small bowel stenosis was suspected. Since this is not considered an endoscopic procedure, the results are not uniformly captured in the endoscopic electronic record database. We were therefore unable to estimate how many patients underwent patency CE. Also, while we could document changes in IBDspecific medications, several of these medications (such as natalizumab or certolizumab pegol), were not approved at the beginning of the study period. Therefore, some of these medications were only available in the final portion of the study, which could have skewed the medication changes results. However, there were very few patients with IBD actually using these particular medications in the study.

In conclusion, we demonstrated a high rate of severe findings on CE in patients with CD. In addition, patients who have undergone previous colectomy and IPAA who develop

symptoms also have a relatively high yield of positive findings on CE, many in the proximal small bowel. Our study suggests that CE results in changes in medical management in symptomatic patients with CD, IC and pouchitis with prior inconclusive work-up. Future prospective studies are needed to further assess the role of CE, specifically in the IBD population.

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#### Figure 1.

Capsule endoscopy pictures: Clockwise from top left: erythema, few aphthae/ulcerations, multiple aphthae/ulcerations, stenosis and stenosis with retention

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#### Figure 2.

Outcome of capsule endoscopies where capsule was immediately retained on the digital recording

Characteristics of patients with inflammatory bowel disease undergoing 124 capsule endoscopy studies from 2003-2009, stratified by indication of symptomatic Crohn's disease, indeterminate colitis or pouchitis

Characteristic	0	rohn's Disease n=86	Inde	sterminate Colitis n=15		Pouchitis n=23
	<b>n</b>	Median (IQR)# or %	u	Median (IQR)# or %	<b>n</b>	Median (IQR)# or %
Age, median (IQR)	86	35 (27-43)	15	40 (18-49)	23	39 (35-45)
Gender (% female)	51	59.3	12	80.0	18	78.3
Duration of IBD (years) median (IQR)	85	6 (2-12)	15	6 (2-12)	22	13.5 (6-17)
BMI (age>17), median (IQR)	76	24.8 (21.3-29.5)	12	27.0 (25.2-35.7)	22	26.0 (22.0-32.0))
Medications prior to capsule						
5-ASA	36	41.9	6	60.0	4	17.4
Antibiotics <sup>*</sup>	6	10.5	5	33.3	9	26.1
Infliximab	Ξ	12.8	3	20.0	-	4.3
Adalimumab	×	9.3	-	6.7	0	0
Certolizumab	-	1.2	0	0	0	0
Natalizumab	-	1.2	0	0	0	0
Thiopurine	25	29.1	4	26.7	7	8.7
Methotrexate	٢	8.2	5	13.3	0	0
Corticosteroids	14	16.3	9	40.0	3	13.0
Budesonide	14	16.3	-	6.7	4	17.4
Prior Surgery (% yes)**	36	41.9	б	20.0	,	
Multiple prior surgeries <sup>**</sup> (% yes)	20	23.3	1	6.7	I.	
Radiologic studies in 3 months prior to capsule						
CT abdomen	19	22.1	З	20.0	٢	30.4
SBFT	18	20.9	4	26.7	7	8.7
MRI abdomen	4	4.7	-	6.7	0	0
Endoscopic studies in 3						

Characteristic	0	'rohn's Disease n=86	Ind	eterminate Colitis n=15		Pouchitis n=23
	u	Median (IQR)# or %	a	Median (IQR)# or %	u	Median (IQR)# or %
months prior to capsule						
Upper endoscopy	20	23.5	9	40.0	4	17.4
Enteroscopy	-	1.2	0	0	0	0
Colonoscopy	30	34.9	6	60.0	i.	
Sigmoidoscopy	9	6.7	З	20.0		ı
Ileoscopy^	7	2.4	0	0	11	47.8

\* Antibioticsused in treatment of IBD, including ciprofloxacin ormetronidazole

\*\* All gastrointestinal surgeries excluding prior perianal surgeries

^ Including pouch exam with ileoscopy

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Findings of complete capsule endoscopies from 2003-2009 at a tertiary care center, done for an indication of inflammatory bowel disease, stratified by indication of symptomatic Crohn's disease, indeterminate colitisand pouchitis

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Finding	Cro	ın's disease n=86	Indet	cerminate colitis n=15	Ā	ouchitis n=23
	u	percent	u	percent	u	percent
Normal	19	22.1	8	53.3	~	34.8
Erythema	11	12.8	4	26.7	7	8.7
Few aphthae/ small ulcers	15	17.4	0	13.3	10	43.8
Multiple aphthae/ulcers	19	22.1	0	0	-	4.4
Stenosis	7	8.1	1	6.7	-	4.4
Stenosis with retention	15	17.4	0	0	1	4.4

Initiation of medications in the 3 months after capsule endoscopy, stratified by symptomatic Crohn's disease, indeterminate colitis, or pouchitis

Surgery in 3 months after capsule endoscopy, stratified by symptomatic Crohn's disease, indeterminate colitis or pouchitis

Surgery	Croł	ın's disease	Indete	rminate colitis	Pou	chitis
	u	percent	u	percent	a	percent
None	75	87.2	6	60.0	20	87.0
Small bowel resection	10	11.6	-	6.7	-	4.4
Stricturoplasty	1	1.2	0	0	0	0
Colectomy*	0	0	S	33.3	i.	ı

\* All 5 patients undergoing colectomy for IC had planned pre-colectomy capsule endoscopy to rule out evidence of small bowel CD prior to operation

Changes in management by capsule endoscopy findings (minimal defined as normal, erythema or few aphthae/ulcers and severe defined as multiple aphthae/ulcers, stenosis or stenosis with retention)

	Cro. caps	hn's diè ule finc	sease dings			Indecaps	termin ule fine	ate c lings	olitis		Pout	chitis ule fine	ding		
	Non Min	e/ imal	Sev	ere	P value	Non Min	e/ imal	Sev	ere	P value	Non Min	e/ imal	Set	ere	P value
Medications															
No change **	22	48.9	11	26.8	0.04	4	28.6	-	100	0.14	9	30.0	0	0	0.27
Any change	23	51.1	30	73.2		10	71.3	0	0		14	70.0	З	100	
No added med <sup>***</sup>	35	77.8	17	41.5	<0.01	8	57.1	-	100	0.40	6	45.0	-	33.3	0.70
Added med	10	22.2	24	58.5		9	42.9	0	0		Ξ	55.0	0	66.7	
Surgery															
None	43	95.6	32	78.1	0.01	6	64.3	0	0	0.21	19	95.0	-	33.3	<0.01
Any^	5	4.4	6	21.9		S	35.7	-	100		1	5.0	7	66.7	
Endoscopy															
None	39	86.7	36	87.8	0.88	10	71.4	-	100	0.53	15	75.0	0	66.7	0.76
Any	9	13.3	5	12.2		4	28.6	0	0		S	25.0	-	33.3	

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 $^{\circ}$  5 patients undergoing surgery with indeterminate colitis, who had none/minimal findings, had a scheduled colectomy after capsule findings were minimal without evidence of active CD