



Digestive Endoscopy

Use of colonoscopy in the management of patients with Crohn's disease: Appropriateness and diagnostic yield

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ABSTRACT

Introduction: Colonoscopy is a necessary tool in the management of Crohn's disease, but the benefit achieved by the procedure is a matter of debate. In the present study we evaluate the clinical impact of performing colonoscopy in Crohn's disease patients.

Methods: Consecutive patients with Crohn's disease undergoing colonoscopy were considered. The following issues were considered: appropriateness of indications; relevant findings able to change the management of the patients; the endoscopist's management decisions based on patient's clinical picture, i.e. increased, maintained or decreased treatment, compared with those selected after performing endoscopy.

Results: 204 patients (116 male/88 female, mean age 41 years) were included. Colonoscopy was judged indicated in 52.9% cases, according to current guidelines. In 54% of patients, endoscopy revealed a significant lesion, and this rate was significantly lower for non-indicated procedures (25.9%, $p < 0.0001$). The endoscopic findings were in disagreement with symptoms in about 25% of cases, but the impact of the endoscopic findings on the endoscopist's decision was likely to be very small without any differences between appropriate and inappropriate procedures.

Conclusions: Endoscopy is a potent tool in the management of Crohn's disease, if correctly used, but in the majority of cases a correct therapeutic decision may be established simply on the basis of clinical picture and non-invasive markers, whilst relevant endoscopic findings have a relatively low impact on the medical treatment.

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1. Introduction

Endoscopy plays an important role in the diagnosis, surveillance and therapeutic management of patients with inflammatory bowel disease (IBD), being useful for both Crohn's disease (CD) and ulcerative colitis (UC) [1,2].

In CD, colonoscopy identifies surface changes in the mucosa, including skip lesions, cobblestoning, aphthous ulcers, longitudinal ulceration, ileocecal involvement, and anal lesions; moreover it can check for complications such as strictures, and enables the collection of biopsy specimens for histological examination [3,4].

In spite of its wide use, the real impact of endoscopy in the management of CD has been evaluated by few studies and, as a consequence, few guidelines are today available which deal with

the correct use of endoscopy in CD, and in general in IBD [1,2,5]. The main reason for this is probably the fact that colonoscopy has been always considered of limited usefulness in the management of CD patients: only the colonic and terminal ileum involvement of CD can be assessed by means of conventional endoscopy, and symptoms may correlate poorly with endoscopic activity, as in case of overlapping irritable bowel syndrome [2,6,7]. Moreover, endoscopy has been often considered not useful to monitor medical treatment up to recent years, due to the lack of significant mucosal healing reached with first therapies like steroids and no evidence of its prognostic influence [8]. The consequence is that clinical and laboratory indices have been considered more suitable than endoscopy to monitor the disease activity and course.

When performed for specific indications colonoscopy is likely to be of particular value in the management of CD. This is the case of endoscopy performed in the initial assessment of colitis, in the differential diagnosis between UC and CD, in avoiding surgery by endoscopic interventions (such as stricture dilation) and, perhaps, in monitoring the therapeutic response to therapy or in assessing post-surgical relapse [1,4]. On the contrary, the utility of assessing

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the extent and severity of endoscopic disease in CD has remained problematic. This is largely due to interobserver variability, inability to completely visualise all involved mucosa, and because of a poor correlation between the mucosal findings and the clinical features in a disease characterised by transmural inflammation [1]. However, the recent introduction of immunomodulator and biologic therapy for CD, potentially able to obtain a complete mucosal healing and thus to change the clinical history of the disease, makes endoscopy a possibly necessary tool to assess the mucosal response to therapy [9–11].

The importance of using colonoscopy in an appropriate way is evident when we think that colonoscopy is an invasive and costly procedure and may be very unpleasant to the patients. Overuse and inappropriate use of colonoscopy would result in an unnecessary discomfort for patients with IBD; on the other hand, a correct use of colonoscopy would determine a substantial reduction of the endoscopic workload, switching off endoscopic resources into necessary care.

From a theoretical point of view, an examination can be regarded as useful when able to alter the management strategy of a disease in such a way that is not predictable before performing the procedure. How colonoscopy could alter the management of CD is a question that still remains unanswered.

The aim of the present study is to determine the impact of utilising colonoscopy in the management of CD.

2. Patients and methods

2.1. Study patients

The study has been conducted in a 1-year period (February 2005–January 2006) in a single Endoscopy Service at the “L. Sacco” University Hospital, a third level centre where about 3500 ambulatory patients with IBD are cared. All CD patients who presented during the study period to perform a colonoscopy were prospectively considered if they were older than 18 years and signed the informed consent to participate in the study. The study was approved by the local institutional review board.

The following data were recorded immediately before colonoscopy by the endoscopists (GM and VI) by interviewing the patients and analysing the patient's chart: age, sex, symptoms (characteristics, intensity and duration), extension of the disease (ileal or colonic or ileal-colonic disease), time since CD diagnosis, previous and current treatments with regard to the use of 5-aminosalicylic acid (5-ASA), steroids, immunosuppressors, and biological therapy, previous surgery, previous endoscopic and radiologic examinations, and concomitant diseases. Symptoms were scored according to the Crohn's Disease Activity Index (CDAI) [12]. Patients were considered in clinical remission if the CDAI was <150; disease activity was judged mild if the CDAI was scored between 150 and 250, moderate between 250 and 350, and severe >350 points.

2.2. Colonoscopy characteristics

Colonoscopy was conducted through the entire colon and, when possible or if not otherwise indicated, to the terminal ileum. During endoscopy, the severity and extension of lesions were recorded according to the Simple Endoscopic Score for Crohn's Disease (SES-CD), in which selected endoscopic parameters (ulcer size, ulcerated and affected surface, stenosis) are scored from 0 to 3, with lower score indicating lower endoscopic activity [13]. Presence of vascular lesions, polyps, neoplasia, strictures, and other significant lesions were also registered.

2.3. Study design

The study has been designed with the aim of assessing the following features of colonoscopies performed in patients with CD: (a) appropriateness of indication to colonoscopy; (b) rate of relevant findings achieved by colonoscopy; (c) impact of colonoscopy on the immediate therapeutic decision.

2.4. Assessment of appropriateness of colonoscopy

The appropriate indication to endoscopy was evaluated immediately before the procedure by two endoscopists (GM and VI), after having interviewed the patient and considered the clinical picture of the disease. Appropriateness was deduced by a critical analysis of the current literature and ASGE guidelines [1,2].

Endoscopy was considered indicated if performed:

1. for initial diagnosis of IBD and to distinguish between CD and UC;
2. to evaluate disease extent and activity in uninvestigated IBD patients;
3. to assess the response to biological therapy in IBD patients with acute disease;
4. to investigate a refractory disease;
5. in case of symptoms suggesting complications or malignancy;
6. to evaluate post-surgical recurrence.

Endoscopy was considered not indicated if performed:

1. in patients with stable disease;
2. to evaluate patients with mild to moderate recurrence of disease.

2.5. Relevant findings of colonoscopy

A diagnosis was regarded as relevant if able to influence the management of the disease as following:

- (a) altering the medical therapy of CD;
- (b) indicating further testing or operative procedures not otherwise hypothesised before endoscopy;
- (c) offering new findings which modified the management of the disease: a change in the initial diagnosis or in previously reported extension of the disease; a different disease activity than otherwise hypothesised; the presence of complications such as strictures or fistulas;
- (d) achieving a diagnosis of colorectal cancer, adenomatous polyp, or dysplasia.

2.6. Impact of colonoscopy on the immediate therapeutic decision

This issue deals with the question “how can colonoscopy influence the short-term therapeutic decision in CD?”. Prior to performing colonoscopy, the referring physician was asked to select a therapeutic decision based on patient's presenting symptoms and clinical history: increase, maintain, or decrease the current treatment. Adding a new medication, increasing the dosages of the current treatment, or switching from a class to another class of more potent medications (i.e. 5-ASA to steroids, steroids to immunosuppressors or to anti-TNF drugs) were all considered as an increase in the treatment. The hypothesised need for further investigations and operative procedures, dilation, surgery, etc., was also registered.

After colonoscopy, the physician was asked again to select a therapeutic decision considering also the endoscopic findings.

2.7. Data analysis

Three dependent variables were considered: (1) appropriateness of colonoscopy; (2) having a significant diagnosis revealed by colonoscopy; (3) having a colonoscopy which changes the short-term management decision. Descriptive statistics consisted of *t* tests for continuous variable and χ^2 tests for categorical variables. Univariate logistic regression was used to test the significance of the characteristics with dependent variables. Multivariate logistic regression was conducted to evaluate the association among the determinants with a dependent variable whilst simultaneously controlling for the effect of other variables. A Pearson's analysis was performed to evaluate the correlation between the symptom score and the severity of mucosal lesions. Statistical significance was defined as $p < 0.05$.

3. Results

In the study period, among 562 patients with IBD who underwent colonoscopy, 257 were affected by CD. According to the inclusion and exclusion criteria, 204 patients were enrolled and agreed to participate in the study. Sixty-four (31.4%) were referred from the outpatient clinic and the remaining by the inpatient clinic. Table 1 shows the demographic and clinical characteristics of the enrolled patients.

3.1. Appropriateness of colonoscopy in CD patients

Indications to colonoscopy in patients with CD are reported in Table 1. Indication to colonoscopy was considered not appropriate in 108 patients (52.9%). Inappropriate endoscopies were performed in patients with stable disease on clinical remission (72 patients, 35.3%) and in patients with a mild/moderate clinical relapse (36 patients, 17.6%).

3.2. Relevant findings of colonoscopy

A relatively good correlation between severity of mucosal lesions as assessed by the SES-CD score and the clinical activity index as assessed by the CDAI was found ($r = 0.53$, 95% CI 0.41–0.64, $p < 0.001$). In spite of this, in a relevant number of patients a discrepancy between the symptoms score and the severity of mucosal lesion as assessed at endoscopy was found. In particular, in 34 of 71 patients with a complete clinical remission (CDAI < 150) an active disease was found at endoscopy and in 8 of them the lesions were moderate or severe; in 3 of 47 patients with a CDAI score showing a mild disease endoscopy revealed severe lesions; on the other side, in 9 of 45 patients with severe symptoms endoscopy was not able to reveal any sign of activity or showed a mild disease.

Table 2 reports the relevant findings achieved by endoscopy. A relevant lesion was revealed in 54% of examinations, but this rate was significantly lower for the not indicated procedures (25.9%, $p < 0.0001$), whilst it was not different with regard to gender, age and referral source. The likelihood of obtaining a relevant finding was 2.26 times (95% CI 1.6–3.3) higher when endoscopy was appropriate. In particular, endoscopy performed to obtain the first diagnosis or to stage the disease in naive patients achieved, as expected, 100% of relevant findings. A rate of 100% was also observed when endoscopy was performed in the suspicion of complications. In 36 patients, endoscopy was able to confirm the complication, a stenosis in 34 patients and a fistula in 2. In the remaining 6 patients endoscopy allowed to exclude the complications and this was also considered a relevant finding. In all 14

patients on infliximab therapy the endoscopic findings were considered relevant since able to influence the further treatment with the drug and to give information about the likelihood of a long-term remission in patients with complete healing of mucosal lesions.

The rate of relevant findings was lower for endoscopies performed with other indications. In patients with stable disease and with mild to moderate recurrence the few relevant findings were mainly the presence of a more severe mucosal damage then expected on the basis of the symptoms (12 patients). A polyp, a stenosis and an actively bleeding lesion were also found in two patients each. These lesions were all considered relevant since able to influence the further management of the disease. Endoscopy performed in patients with refractory disease showed in five cases the absence of any signs of endoscopic activity and in three the presence of severe colitis with deep and extended ulcers. These lesions were considered significant since able to explain refractoriness (severe inflammation) or to exclude mucosal inflammation as a cause for the symptoms.

3.3. Impact of colonoscopy on the therapeutic decision

The endoscopist's decision regarding medical therapy is provided in Table 3.

A sufficient degree of concordance (76.9%) was observed between what the endoscopist would have done before and after endoscopy, but in about 25% of patients endoscopy was not concordant to symptoms and thus potentially able to modify the immediate therapeutic decision. Interestingly, the rate of endoscopies with a significant impact on the management was not different between appropriate and inappropriate examinations (26/108, 24.1% vs. 13/70, 18.6%) suggesting that the management of patients with CD should be based mainly on the clinical evaluation. Endoscopies performed in naive patients to make the first diagnosis of CD and to evaluate the disease extent and activity were excluded from this analysis since the endoscopists did not have enough information to express their management decision prior to perform endoscopy.

Endoscopy was considered to be potentially able to change the clinical management mainly when the severity of mucosal lesions was different then expected on the basis of the symptoms. In four patients with the suspicion of an intestinal obstruction and in two with abdominal pain, for whom the endoscopist had hypothesised to perform further investigations or surgery, endoscopy altered the management excluding the complications.

4. Discussion

Colonoscopy has always been considered to have an ancillary role in the assessment of patients with CD in comparison to clinical and laboratory evaluation [1,14]. The main reasons for this are primarily the fact that endoscopy is able to evaluate only the colonic localizations of the disease and secondarily the described discrepancy existing between the clinical and endoscopic severity of disease [2,6,7]. In spite of this, assessing the correct use and the real impact of endoscopy on the management of CD patients is likely to be an important issue which has been never extensively evaluated until now.

The exact definitions of “useful endoscopy” and “appropriate endoscopy” in CD are nebulous. In the present study, we have evaluated the problem from two points of view: (1) the definition of those lesions that are able to influence the management of disease, the so-called relevant findings, those lesions who give information on the diagnosis, prognosis, and therapy of the disease; (2) the definition of those lesions that are able to affect the immediate

Table 1
Demographic and clinical characteristics of the study patients.

	All patients	Diagnosis–staging	Refractory disease	Stable disease	Symptom relapse	Biological therapy	Suspected complication	Others
Number (%)	204 (100)	26 (12.7)	12 (5.9)	72 (35.3)	36 (17.6)	14 (6.9)	42 (20.6)	2 (0.9)
Gender (M/F)	116/88	14/12	4/8	50/22	16/20	8/6	24/18	1/1
Age (mean, range)	41.1 (15–77)	31.0 (18–58)	49 (21–74)	42.7 (25–72)	41.2 (24–67)	34.9 (18–47)	42.7 (23–77)	54 (46–62)
Disease duration, years (S.D.)	7.9 (6.7)	0.7 (1.4)	11.3(10.1)	8.2 (6.1)	8.9 (5.6)	2.6 (1.3)	10.8 (5.8)	13
Disease extension (%)								
Colon	60 (29.4)	12 (46.1)	8 (66.7)	14 (19.4)	16 (44.4)	6 (42.8)	3 (7.1)	0
Ileum + colon	144 (70.6)	14 (53.9)	4 (33.3)	58 (80.6)	20 (55.6)	8 (57.2)	39 (92.9)	2
Previous surgery (%)	126/204 (61.7)	0/26 (0)	6/12 (50)	58/72 (80.5)	22/36(61.1)	6/14 (42.8)	32/42(76.2)	2/2(100)
Endoscopic exploration								
Neo-ileum	105 (51.5)	0	5 (41.7)	50 (69.4)	20 (55.5)	5 (35.7)	23 (54.8)	2 (100)
Terminal ileum	42 (20.6)	24 (92.3)	3 (25)	3 (4.2)	5 (13.8)	2 (14.3)	5 (11.9)	0
Cecum	25 (12.2)	2 (7.7)	2 (16.7)	7 (9.7)	5 (13.8)	3 (21.4)	6 (14.3)	0
Partial colonoscopy	32 (15.7)	0	2 (16.7)	12 (16.7)	6 (16.7)	4 (28.6)	8 (19)	0
Current treatment (%)								
No treatment	44 (21.6)	8 (30.7)	0	24 (33.3)	6 (16.7)	0	6 (14.3)	0
ASA	74 (36.3)	16 (61.5)	2 (16.7)	32 (44.4)	16 (44.4)	0	6 (14.3)	2
Steroids	32 (15.6)	2 (7.8)	8 (66.6)	6 (8.4)	4 (11.1)	0	12 (28.6)	0
Immunosuppressors	40 (19.6)	0	2 (16.7)	10 (13.9)	10 (27.8)	0	18 (42.8)	0
Anti-TNF	14 (6.9)	0	0	0	0	14 (100)	0	
Symptom score (%)								
No symptoms	71 (34.8)	8 (30.7)	0	56 (77.8)	0	5 (35.7)		1
Mild	47 (23)	10 (38.4)	6 (50)	16 (22.2)	10 (27.8)	1 (7.1)		1
Moderate	41 (20.1)	6 (23.1)	2 (16.7)	0	24 (66.7)	8 (57.2)		0
Severe	45 (22.1)	2 (7.8)	4 (33.3)	0	2 (5.5)	0		0
Referral clinic (%)								
Outpatient	64 (31.4)	2 (7.8)	2 (16.7)	38 (52.8)	6 (16.7)	10 (71.4)	0	2
Inpatient	140 (68.6)	24 (92.2)	10 (83.3)	34 (47.2)	30 (83.3)	4 (38.6)	42 (100)	0

Patients are grouped according to the indication for endoscopy (see also the text). The group “other” includes two patients who underwent endoscopy after surgery. The symptom scores of patients with suspected complication were not calculated and thus not reported in the table since patients’ clinical picture was dominated by the symptoms determined by the complication.

Table 2

Relevant findings achieved by colonoscopy with respect to the indications to the procedure.

	Relevant findings (%)	Type of findings (number)
All patients	110/204 (53.9)	
Diagnosis–staging	26/26 (100)	First diagnosis of CD (14) Extension of disease (12)
Refractory disease	8/12 (66.7)	No active lesions (5) Severe lesions (3)
Stable disease	14/72 (19.4)	Stenosis (2) Unexpected severe lesions (12)
Symptom relapse	14/36 (38.9)	Active bleeding (2) Polyp (2) Stenosis (10)
Biological therapy	14/14 (100)	Severity of lesions (14)
Suspected complication	42/42 (100)	Confirmed complication (36) Excluded complication (6)
Others	0/2 (0)	

therapeutic decision, i.e. whether endoscopy is able to modify the treatment in a way that is not predictable without performing the investigation.

The first important information arising from our study is the confirmation that in a group of patients with CD a substantial discrepancy may exist between the clinical severity of disease and the severity of mucosal lesion as assessed at endoscopy. The immediate consequence for this is that in about 25% of patients a therapeutic decision based on the endoscopic finding could be different to what the physician would have done simply on the basis of the clinical presentation and probably not correct. This is the case of endoscopy performed in patients with stable disease, refractory disease and mild to moderate symptom relapse where endoscopy would theoretically change the immediate therapeutic decision in about 35%, 50% and 8% of case, respectively. Actually, authors agree that in clinical practice patients with known CD who experience typical symptoms of a disease flare (eventually aid by other objective markers such as CRP or anaemia) should be treated empirically without endoscopic evaluation; this is because, as observed in a few previous studies, endoscopy seems to be not necessary for the measurement of disease activity in a patient with an established diagnosis of CD, endoscopy items contributing little additional information to indices of disease activity [1,8]. Moreover, endoscopic remission is not usually considered a purpose of therapy in CD, since not necessarily a patient in clinical remission shows also an endoscopic remission.

This point of view has changed in the last years with the introduction of biological treatments, i.e. anti-TNF drugs, in to therapy of CD. Recent reports suggest that a clinical response to a treatment with infliximab is likely to be followed within 4 weeks from the first infusion by a prompt regression of the mucosal lesions, and that endoscopic remission of colitis is likely to predict a more

sustained clinical remission and a better long-term outcome with respect to hospitalisation, surgery and relapse rate [15,16]. In our study, 5/14 (35.7%) of patients investigated with this indication became asymptomatic under infliximab treatment, but only in two of them the mucosal lesions were completely healed, whilst in the remaining patients lesions of some degree were still present. For the latter patients the risk of an early recurrence is likely to be quite high, and it would set some questions about their further management. Our study was not designed to evaluate this aspect since a post-endoscopy follow-up is lacking; however, the likelihood of under-treating these patients is high if we do not perform an endoscopic check at the end of the medical treatment.

Some indications to colonoscopy are considered appropriate by most of authors dealing with CD [1,2]: to make the initial diagnosis of CD, to distinguish CD from UC, to assess the disease extent and activity in uninvestigated patients, to exclude or confirm a complication. In our study we have confirmed that endoscopies performed with these indications are undoubtedly useful and offer in all cases relevant findings to the physician. In the case of endoscopies performed in the suspicion of complications both a positive and a negative finding were considered relevant and thus able alter the further management of the patients.

Another apparently appropriate indication to perform endoscopy is the occurrence of refractoriness, i.e. unresponsiveness to the ongoing therapy. In about 40% of patients (5/12) with refractory disease, endoscopy was unable to demonstrate any signs of mucosal activity, suggesting another pathogenetical mechanism for the symptoms (irritable bowel syndrome for example); in 3 of them endoscopy revealed severe mucosal lesions with extended and deep ulcers; in all 12 patients histology was able to exclude a cytomegalovirus infection as a cause for the symptoms.

About 50% of endoscopies performed in our study were considered to be not indicated according to the current literature [1,2], for instance in patients with stable disease and with mild–moderate recurrence of symptoms. Inappropriate endoscopies achieve a very low rate of relevant findings so that their impact on the management of disease is likely to be very low. The discrepancy existing between symptoms and endoscopy that we have observed also in these two groups does not seem to have any clinical consequences. Our study thus confirms that patients with stable disease should not undergo an endoscopic follow-up and that in case of a clinical recurrence of disease a change in the treatment can be established simply on the basis of symptoms and non-invasive disease markers.

Our study design has some limitations and deserves some considerations. First, we tried to evaluate how endoscopy could improve the management of CD, but we have not included a proper follow-up to evaluate the impact of treatments and of different endoscopic findings on the clinical course of disease. Second, the endoscopists were not blinded to the study hypotheses, and this

Table 3

The endoscopist's decision regarding medical therapy before and after colonoscopy.

	Increase (%)		Maintain (%)		Decrease (%)		Concordance (%)
	Before	After	Before	After	Before	After	
All patients	197 (41.8)	224 (47.5)	264 (55.9)	236 (50)	11 (2.3)	12 (2.5)	137/178 (76.9)
Diagnosis–staging (26)	–	18 (69.2)	–	8 (30.8)	–	0 (0)	Not considered
Refractory disease (12)	10 (83.3)	6 (50)	2 (16.7)	4 (33.3)	0 (0)	2 (16.7)	6/12 (50)
Stable disease (72)	14 (19.4)	39 (53.2)	56 (77.8)	31 (43)	2 (2.8)	2 (2.8)	47/72 (65.3)
Symptom relapse (36)	32 (88.9)	33 (91.7)	4 (11.1)	3 (8.3)	0 (0)	0 (0)	35/36 (92.1)
Biological therapy (14)	9 (64.3)	12 (85.7)	5 (35.7)	2 (14.3)	0 (0)	0 (0)	11/14 (78.6)
Suspected complication (42)	42 (100)	38 (90.5)	0 (0)	4 (9.5)	0 (0)	0 (0)	38/42 (90.5)
Others (2)	0 (0)	2 (0)	2 (100)	0 (0)	0 (0)	0 (0)	0/2 (0)

Endoscopies performed in naive patients to make the first diagnosis of IBD and to evaluate the disease extent and activity were excluded from this analysis since the endoscopists did not have enough information to express their management decision prior to perform endoscopy.

could represent a potential bias. Third, about half of our procedures were judged as inappropriate according to the current guidelines and this is likely to make our series not representative of the endoscopic series of other tertiary IBD centres. We believe, however, that even this high rate of inappropriateness could be of particular value for the study: due to the discrepancy existing between symptoms and mucosal appearance, at least from a theoretical point of view, even inappropriate endoscopies are potentially able to offer to the physician valuable information in the management of the disease and our series of patients includes patients comprising the whole clinical spectrum of CD.

In conclusion, endoscopy is potentially a useful tool in the management of patients with CD, but, with the exception of naive patients and of patients with suspected complications, it seems to have a marginal role in the clinical assessment of disease. In particular, in the majority of patients with CD a correct therapeutic decision may be established simply on the basis of clinical symptoms and laboratory indices, whilst endoscopy is able to add further information only in a limited number of cases. After the recent introduction of the biological therapies endoscopy is likely to have gained new importance since able to offer information on the degree of mucosal healing and thus in the prognostic assessment of patients with CD.

Conflict of interest statement

None declared.

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