

Use of robotic colonoscopy in patients with previous incomplete colonoscopy

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Abstract. – OBJECTIVE: Conventional colonoscopy (CC) is the gold standard to diagnostic and therapeutic approach to colon. However, in few cases, cecal intubation could fail due to colon anatomy, patient compliance and physician expertise. Endotics robotic colonoscopy is a novel, safe, mini-invasive modality to explore the entire colon. Our aim was to assess, in a retrospective study, Endotics ability of cecal intubation in all cases in which CC failed.

PATIENTS AND METHODS: Between January 2008 and December 2012, 276 Endotics robotic colonoscopy examinations were performed at the Gastroenterology and Metabolic Diseases Unit of Pisa University Hospital, Pisa, Italy, in a series of consecutive patients who had undergone CC and failed cecal intubation.

RESULTS: We assessed the cecal intubation rate in 102 patients addressed to Endotics after previous incomplete CC. Overall, endotics system was successful in 93.1% of the incomplete conventional colonoscopy cases (95% performance).

CONCLUSIONS: Whenever the intended exploration of the entire colon with CC failed, the endotics robotic endoscopy represented a useful tool as it helped examine the entire colon in almost all cases.

Key Words

Colonoscopy, Endotics, Robotic colonoscopy.

Introduction

Colorectal cancer is the third most common malignancy worldwide and is the second cause of all cancer-related deaths in the United States¹, even though it could be easily prevented with appropriate screening techniques².

Conventional colonoscopy is the gold standard for colorectal cancer screening methods, thanks to its ability in exploring the entire colon and in detecting/removing small or mid-size polyps during the same procedure^{3,4}. However, it is an invasive procedure and may cause pain and discomfort to patients: as matter of fact, the main reason for subjects to refuse a screening colonoscopy is the fear of pain associated with the examination.

Cecal intubation is one of the main goals of colonoscopy and, at the same time, represents an indicator of colonoscopy quality⁵. International guidelines recommend cecal intubation rates $\geq 90\%$ for all colonoscopies in daily clinical practice and $\geq 95\%$ in screening programs⁶. Nevertheless, cecal intubation fails in 5-10% of cases, even when performed by experienced endoscopists⁷.

Most authors refer to difficult colonoscopy when reaching of the cecum proves challenging or impossible to gain⁸. In addition to poor bowel cleanliness, there are several factors – including narrow-angle loopings, obstructive pathologies and patient discomfort – that may contribute to the inability to intubate the caecum^{6,9-11}. These studies reveal that a redundant colon and evoked pain represent the main causes of colonoscopy failure.

A number of studies examining patient discomfort and colon anatomical difficulties documented a correlation between pain and anatomical colon configuration. In particular, 90% of all pain episodes in colonoscopy coincided with looping colon¹²⁻¹⁴, whereas 9% matched with presumed over-insufflation of air¹².

Actually, abdominal pain is mainly due to the traction on the mesenteries exerted by the colonoscope with the intent to solve eventual loops. Moreover, such maneuvers enhance the risk of colon perforation, discomfort, undue pain and longer recovery time¹³.

In the event of incomplete colonoscopy, colon inspection could be completed either by radiological examination – as barium enema, virtual colonoscopy and magnetic resonance imaging⁹ – or by a subsequent pediatric colonoscope or a gastroscope^{5,15}.

Endotics (Era Endoscopy S.r.l, Peccioli, Pisa, Italy) is a new alternative diagnostic instrument which combines high quality performance with an extremely high level of patient acceptance¹⁶.

The aim of this study was to evaluate the performance of the endotics system in achieving total colonic examination in cases of failed cecal intubation by standard, conventional colonoscopy.

Patients and Methods

The Endotics System

Endotics (Era Endoscopy S.r.l, Peccioli, Pisa, Italy) is a new self-propelled robotic colonoscope, consisting of a workstation, a disposable probe and a console.

The disposable device has an active part, with a head, a steerable tip, a flexible body and a passive part, including a thin tail and a special tank with an electro-pneumatic connector. The head hosts a vision system, consisting of a camera with Light Emitting Device (LED) light sources, a channel for water jet and one for air streaming, in order to provide rinsing and suction/insufflation, respectively.

The workstation gives the operator a full control of the probe by means of a hand-held console, and allows the visualization of real-time images on a screen. The endoscopist can steer 180 degrees the head of the colonoscope in any direction, can elongate the central body of the probe – allowing it to move forward following the shape of the colon – and can control rinsing, air insufflation and suction.

The system is highly flexible, as the probe adapts its shape to the complex curves of the colon, thereby exerting low straightening forces during its movement. A semi-automatic sequence of actions allows the probe to advance like an inchworm. This particular locomotion is achieved by means of two clampers located in the proximal and in the distal part of the probe, respectively. They adhere to the intestinal mucosa by means of a vacuum technique and a mechanical grasping action. The semi-automatic sequence can be described as follows:

1. The clamber located in the proximal part of the probe adheres to the mucosa (automatic phase);
2. The central part of the probe body is elongated by the endoscopist under visual control (manual phase);
3. The distal clamber adheres to the mucosa (automatic phase);
4. The proximal clamber is released (automatic phase);
5. The central part of the body is shortened (automatic phase);
6. The proximal clamber adheres to the mucosa (automatic phase);
7. The distal clamber is released (automatic phase);

Such sequence is repeated several times in order to advance the probe through the colonic lumen.

Recent reports¹⁷⁻¹⁹ have confirmed that Endotics system proves high diagnostic accuracy in absence of evoked pain.

Study Protocol

This is a retrospective study. 276 Endotics examination were performed between January 2008 and December 2012 at the Gastroenterology Department of Pisa University Hospital, Pisa, Italy. Patients underwent endotics system after they had undergone a complete or an incomplete conventional colonoscopy. The study mainly describes the technical success of Endotics in patients who failed conventional colonoscopy. Thus, there is no direct comparison between these two techniques and there are no data that require ROC curve analysis.

Senior gastroenterologists performed both traditional colonoscopy and endotics system colonoscopy without use of sedative agents.

Bowel preparation was the same for both procedures: a fiber-free diet in the seven days preceding the examination and oral administration of phosphate sodium lavage solution (80 mL in 2000 mL of water until evacuation of clear yellowish fluid) on the day before the examination.

All conventional colonoscopies were performed with a standard colonoscope (Olympus, Tokyo, Japan).

From this initial population the following exclusion criteria were applied:

1. Procedures performed in patients who underwent endotics system after they had undergone a complete conventional colonoscopy (81 procedures);

2. Procedures performed in patients who had undergone incomplete conventional colonoscopy and incomplete endotics system due to poor bowel preparation (20 conventional colonoscopic procedures and 49 endotics system procedures);
3. Incomplete endotics colonoscopies due to stenosis (5 procedures);
4. Incomplete endotics colonoscopies due to device malfunctioning (11 procedures);
5. Incomplete endotics colonoscopies with missing data (8 procedures).

After applying such exclusion criteria, 102 endotics procedures were compared with their respective previous incomplete conventional colonoscopy.

Results

102 out of 276 endotic examination were considered in patients who failed to inspect the entire colon with standard colonoscopy. In these 102 patients, we assessed the cecal intubation rate.

Patient's characteristics and standard colonoscopy results are shown in Table I. Colon segment at which standard colonoscopy stopped were sigmoid in 28.43%, splenic flexure in 58.82% and hepatic flexure in 12.74%.

Colonoscopy was defined as complete, therefore successful, when the operator succeeded in visualizing and recognizing the caecum. The colonoscopy performed with endotics system was successful in 95 (93.1%) patients.

Table I. Patients' baseline characteristic and results of incomplete conventional colonoscopy.

Patients baseline characteristics	
Gender M/F no.	42/60 (41.2%/58.8%)
Mean Age (\pm SD)	51 \pm 12.49
History of abdominal surgery M/F N°	13/9
Colon segment at which colonoscopy stopped n°	
Sigmoid	29 (28.43%)
Splenic flexure	60 (58.82%)
Hepatic flexure	13 (12.74%)
Reasons colonoscopy was stopped n°	
Extensive loop and or colon angulation	68 (66.7%)
Patient discomfort	34 (33.3%)

SD: Standard Deviation

In 16 cases (Table II), polyps were detected during endotics system procedure and in 7 cases these polyps were removed in a subsequent conventional colonoscopy. Conventional colonoscopy performed after endotics system procedures confirmed number and size of the polyps visualized during endotics procedures. Complete results are shown in Table II.

In only 7 (6.9%) patients, endotics system procedure resulted incomplete: in 5 cases Endotics system overcame the colon segment at which conventional colonoscopy was halted whereas in 2 cases the same colonic segment as traditional colonoscopy was reached by endotics system procedure. The mean cecal intubation time was 51 min (\pm 22.5). The reasons for incomplete endotics system colonoscopy were patient panic attack (2 cases), discomfort caused by strong abdominal adhesions (1 case), and 4 abnormal peristalsis with many prolonged spasms (4 cases).

Overall, endotics system visualized the caecum in 93.1% of the incomplete conventional colonoscopy cases (95% performance).

Discussion

Conventional colonoscopy success depends mainly on bowel characteristics of individual patients. Maneuvers to "reduce" or to "solve" the loops, together with excessive air insufflation to straighten the colon, may cause severe distress or pain during the examination. Looping of the colon also decreases the chance of cecal intubation.

Whenever a conventional colonoscopy fails, colonic examination should be completed with other procedures: to date, the most commonly-used alternative devices are barium enema, colon-Computed Tomography (TC) (e.g. virtual colonoscopy) and capsule endoscopy (Pillcam colon).

Radiological examination (Virtual colonoscopy and Barium Enema) is less painful than traditional colonoscopy, but does not allow a direct visualization of colon. The main potential drawback of a Computed Tomography Colonography (CTC) screening is the exposure to ionizing radiation. However, this is not a major issue, since low-dose protocols are now routinely implemented²⁰. As regarding to the diagnostic capability in the identification of polyps \geq 10 mm, CTC has a sensitivity of 90%, and a specificity of 86%, while for polyps \geq 6 mm the corresponding values are in the range of 78%-84%, with a negative predictive value (NPV) close to 100%, (results attainable by radiologists trained in the method)^{21,22}.

Table II. Patients' characteristics, results of conventional colonoscopy and Endotics system colonoscopy, findings of endotics system endoscopy and further evaluation.

No.	Age	Gender	Conventional colonoscopy reached	Reasons for incomplete conventional colonoscopy	Endotics system reached	Findings in endotics system endoscopy	Further evaluation
1	50	F	Splenic flexure	Extensive loop	Caecum		
2	58	F	Sigmoid	Patient discomfort	Splenic flexure		
3	47	M	Splenic flexure	Extensive loop	Caecum		
4	55	M	Sigmoid	Extensive loop	Caecum		
5	36	M	Splenic flexure	Extensive loop	Caecum		
6	47	F	Sigmoid	Extensive loop	Splenic flexure		
7	48	M	Splenic flexure	Patient discomfort	Caecum		
8	40	M	Hepatic flexure	Extensive loop	Caecum		
9	68	M	Splenic flexure	Extensive loop	Caecum		
10	47	F	Splenic flexure	Patient discomfort	Caecum		
11	77	M	Splenic flexure	Extensive loop	Caecum		
12	61	F	Splenic flexure	Extensive loop	Caecum		
13	56	F	Hepatic flexure	Patient discomfort	Caecum		
14	57	M	Splenic flexure	Extensive loop	Caecum		
15	81	F	Splenic flexure	Extensive loop	Caecum	1 polyp in descending colon (size 1 cm); diverticula	Conventional colonoscopy to remove the polyp
16	47	F	Hepatic flexure	Extensive loop	Caecum		
17	49	F	Splenic flexure	Extensive loop	Caecum		
18	40	F	Splenic flexure	Extensive loop	Caecum		
19	41	M	Splenic flexure	Extensive loop	Caecum		
20	38	F	Sigmoid	Extensive loop	Caecum		
21	45	M	Splenic flexure	Patient discomfort	Caecum		
22	32	F	Hepatic flexure	Patient discomfort	Caecum		
23	37	M	Sigmoid	Extensive loop	Caecum		
24	58	F	Splenic flexure	Extensive loop	Caecum		
25	56	F	Splenic flexure	Extensive loop	Caecum		
26	76	M	Splenic flexure	Extensive loop	Caecum		
27	34	F	Sigmoid	Extensive loop	Caecum		
28	40	F	Hepatic flexure	Extensive loop	Caecum		
29	43	F	Sigmoid	Extensive loop	Caecum		
30	42	F	Splenic flexure	Patient discomfort	Caecum		
31	42	F	Splenic flexure	Patient discomfort	Caecum		
32	45	F	Splenic flexure	Extensive loop	Caecum		
33	55	F	Splenic flexure	Extensive loop	Caecum	1 polyp in sigmoid colon (size 1 cm); hemorrhoid	Conventional colonoscopy to remove the poly
34	57	M	Hepatic flexure	Extensive loop	Caecum		
35	50	F	Hepatic flexure	Extensive loop	Caecum		
36	84	F	Hepatic flexure	Extensive loop	Caecum		
37	56	M	Sigmoid	Extensive loop	Caecum		

Continued

Table II (Cont.). Patients' characteristics, results of conventional colonoscopy and Endotics system colonoscopy, findings of endotics system endoscopy and further evaluation.

No.	Age	Gender	Conventional colonoscopy reached	Reasons for incomplete conventional colonoscopy	Endotics system reached	Findings in endotics system endoscopy	Further evaluation
38	55	F	Splenic flexure	Patient discomfort	Caecum		
39	49	M	Splenic flexure	Extensive loop	Caecum		
40	38	F	Sigmoid	Extensive loop	Caecum		
41	41	F	Sigmoid	Patient discomfort	Caecum		
42	50	M	Splenic flexure	Extensive loop	Caecum		
43	47	M	Splenic flexure	Extensive loop	Caecum	Diverticula and 2 polyp in sigmoid (size 3 mm)	Polyp were not been identified with successive conventional colonoscopy
44	50	F	Hepatic flexure	Extensive loop	Caecum	2 polyp in sigmoid (size 3 mm)	
45	39	M	Splenic flexure	Extensive loop	Caecum		
46	46	F	Sigmoid	Patient discomfort	Caecum		
47	58	M	Splenic flexure	Extensive loop	Caecum	1 polyp in transverse colon (3 mm); hemorrhoid	
48	43	F	Splenic flexure	Extensive loop	Caecum		
49	40	M	Splenic flexure	Extensive loop	Caecum	1 polyp in splenic flexure (size 8 mm)	Conventional colonoscopy to remove the polyp
50	44	M	Splenic flexure	Patient discomfort	Caecum		
51	63	F	Splenic flexure	Patient discomfort	Caecum		
52	46	M	Hepatic flexure	Patient discomfort	Caecum		
53	35	M	Splenic flexure	Extensive loop	Caecum		
54	65	F	Sigmoid	Extensive loop	Caecum		
55	42	M	Sigmoid	Extensive loop	Caecum	1 polyp in transverse colon (size 1 cm)	Conventional colonoscopy to remove the polyp
56	33	F	Sigmoid	Patient discomfort	Caecum		
57	40	M	Splenic flexure	Extensive loop	Caecum	2 polyp in transverse colon (size 3 mm)	
58	49	F	Splenic flexure	Patient discomfort	Caecum	1 polyp in ascending colon (size 5 mm)	Conventional colonoscopy to remove the polyp
59	73	F	Sigmoid	Patient discomfort	Caecum		
60	78	M	Sigmoid	Extensive loop	Caecum	Polyp in the transverse colon about 5 mm. In proximity of ileocecal valve there was small whitish outgrowth (3-4 mm), easily bleeding. Diverticula in the sigmoid colon and between ascending colon and caecum	
61	35	F	Splenic flexure	Extensive loop	Caecum		
62	29	F	Splenic flexure	Extensive loop	Caecum		
63	56	F	Splenic flexure	Patient discomfort	Caecum		
64	47	F	Sigmoid	Extensive loop	Hepatic flexure		
65	55	F	Sigmoid	Patient discomfort	Caecum		
66	48	F	Sigmoid	Extensive loop	Caecum		

Continued

Table II (Cont.). Patients' characteristics, results of conventional colonoscopy and Endotics system colonoscopy, findings of endotics system endoscopy and further evaluation.

No.	Age	Gender	Conventional colonoscopy reached	Reasons for incomplete conventional colonoscopy	Endotics system reached	Findings in endotics system endoscopy	Further evaluation
67	43	F	Hepatic flexure	Extensive loop	Caecum		
68	36	F	Sigmoid	Patient discomfort	Caecum		
69	37	M	Sigmoid	Extensive loop	Splenic flexure		
70	24	M	Splenic flexure	Extensive loop	Caecum		
71	57	F	Splenic flexure	Patient discomfort	Caecum		
72	37	M	Splenic flexure	Extensive loop	Caecum		
73	70	F	Splenic flexure	Extensive loop	Caecum		
74	69	F	Splenic flexure	Patient discomfort	Caecum		
75	50	M	Splenic flexure	Extensive loop	Caecum	3 polyp in sigmoid colon (size 6 mm)	Conventional colonoscopy to remove the polyp
76	48	M	Splenic flexure	Extensive loop	Caecum		
77	36	M	Sigmoid	Extensive loop	Caecum		
78	53	F	Sigmoid	Extensive loop	Caecum		
79	54	M	Splenic flexure	Patient discomfort	Caecum		
80	38	F	Sigmoid	Patient discomfort	Caecum		
81	60	M	Splenic flexure	Extensive loop	Caecum	2 polyp in caecum (size 6 mm)	Conventional colonoscopy to remove the polyp
82	70	M	Sigmoid	Patient discomfort	Splenic flexure		
83	50	F	Sigmoid	Extensive loop	Sigmoid		
84	53	F	Splenic flexure	Patient discomfort	Caecum		
85	50	F	Sigmoid	Patient discomfort	Caecum		
86	20	M	Splenic flexure	Extensive loop	Caecum		
87	54	F	Splenic flexure	Extensive loop	Caecum	2 polyp (size 3 mm) in rectal ampulla	
88	43	M	Splenic flexure	Patient discomfort	Caecum		
89	71	M	Sigmoid	Patient discomfort	Caecum		
90	60	F	Splenic flexure	Patient discomfort	Caecum	1 polyp (size 4 mm) in rectal ampulla	
91	70	M	Splenic flexure	Extensive loop	Caecum		
92	51	F	Splenic flexure	Extensive loop	Caecum		
93	73	F	Splenic flexure	Extensive loop	Caecum		
94	54	F	Splenic flexure	Patient discomfort	Caecum		
95	38	F	Splenic flexure	Extensive loop	Caecum		
96	64	F	Sigmoid	Extensive loop	Caecum		
97	70	M	Hepatic flexure	Patient discomfort	Hepatic flexure		
98	59	F	Splenic flexure	Extensive loop	Caecum		
99	62	M	Splenic flexure	Patient discomfort	Caecum		
100	39	F	Splenic flexure	Extensive loop	Caecum		
101	40	M	Splenic flexure	Extensive loop	Caecum		
102	58	F	Hepatic flexure	Patient discomfort	Caecum		

Colon capsule endoscopy does not require sedation, air inserted in the colon, or radiation; the diet is similar to the preparation for colonoscopy, but requires a major amount of laxatives²². The examination lasts several hours and requires on average 1h for reporting. It has been reported with sensitivity and specificity for the diagnosis of polyps ≥ 6 mm of 89% (95% CI 70-97) and 76% (95% CI 72-78), respectively, while for polyps ≥ 10 mm were 88% (95% CI 56-98) and 89% (95% CI 86-90) respectively²¹.

The endotics is in many ways more similar to traditional colonoscopy than the afore-mentioned techniques; it is the only system that allows a direct view of the mucosa in real time and has the advantage of being painless.

Endotics is a new emergent technology, with an unique locomotion system which allows the probe to self-propel through the intestine without any external pushing action, thus exerting low straightening forces on colon walls during its forward progression¹⁸ (90% lower than conventional colonoscopy).

When using the endotics system, there is no need to "solve" possible loops by means of painful torsion and push/pulling maneuvers. As matter of fact, thanks to a hand-held console, the operator can elongate and steer (by bending the tip of the probe more than 180 degrees along each axis) the very soft and flexible probe in order to move it while following the shape of the intestine, also in presence of narrow-angle loops.

As shown in literature, this probe is able to adapt its shape to the configuration of the bowel, thus minimizing the pain and/or the discomfort related to unusual conformations of the colon. In fact it is reported that 70% of patients displayed a score for pain less of 1 by using a scale from 0 to 10 (30% of patients displayed a score ranging from 1 to 2.1)¹⁸.

Endotics system is also able to remove another cause of pain evoked by conventional colonoscopy: the considerable amount of air insufflated into the colonic lumen. Indeed this device requires minimal amount of air insufflation, mainly necessary in the proximity of the head to increase the portion of bowel visualized. Moreover, during locomotion phases, clamping mechanisms remove air from the bowel in order to adhere to the colon tissue, resulting in an empty intestine at the end of the procedure.

The system requires a thorough cleaning of the bowel, greater than the conventional colonoscopy, because of the suction channel of 1 mm diameter. Previous characteristics would explain why the number of endotics exams interrupted for poor bowel preparation is higher than that of

conventional colonoscopy. The size of the suction channel does not allow cleaning of the colon, therefore, the progression of the robot is more difficult in the case of poor bowel preparation. The diagnostic accuracy was equal to colonoscopy¹¹, with high sensitivity and specificity for polyps any size (93.3% and 100% respectively), with positive predictive value (PPV) and NPV of 100% and 97.7%¹⁵.

This study demonstrates that such new robotic system is successful in most cases where conventional colonoscopy fails because of patient reported pain due to colonic anatomical challenges. In this report, endotics system reached the caecum in 93.1% of incomplete conventional colonoscopy cases, and in 98% of cases, a longer portion of colon was inspected. These data are different from those reported in previous studies, mainly because at that time operators were still in training phase^{11,14}. However, the learning curve of the product is very rapid¹¹ and, therefore, the same physicians can be considered as senior endoscopists.

Our data shows that in almost all cases in which conventional colonoscopy had to be halted to patients discomfort and/or looping colon, endotics system can complete the colon inspection, thus allowing a complete diagnosis by physicians.

Endotics system used for this study was exclusively a diagnostic tool, because it is not yet equipped with an operating channel, so it is not possible, like in radiological studies, to perform biopsies or remove small polyps. A new version of endotics probe is already available, equipped with a tool channel, which allows operators to sample colonic mucosa and to perform biopsies.

Nevertheless, and despite this is a retrospective, single center study, the high cecal intubation rate obtained allows us to state that endotics system is superior to conventional colonoscopy in examining "difficult" colons, thus enabling endoscopists to handle with relative ease even the most challenging colon.

Conclusions

It has been shown that endotics system, combining high diagnostic accuracy¹⁷ to high level of patient acceptance, is a valid option not only in colon cancer screening but also in daily clinical practice, and it can play a complementary role to conventional colonoscopy in achieving the caecum when the latter procedure fails to explore the entire colon.

Statement of Interests

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Conflict of Interest

The Authors declare that they have no conflict of interests.

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