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Robotic Colonoscopy Endotics with Colon Wash: Two Performing Technologies in a Winning Combination

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ABSTRACT

BACKGROUND: Colonoscopy is the standard method for CCR prevention, diagnosis, and treatment, but it is painful and highly dependent on quality of bowel preparation. This study describes the experience of the first 150 colonoscopies performed using the Endotics System at S. Giuseppe Hospital in Milan (Italy), demonstrating the effectiveness, diagnostic quality, and lack of pain even without sedation. Moreover, at the patient's request, robotic system was combined with Colon Wash technology, able to prepare the bowel in a comfortable and effective way without use of purgatives.

METHODS: The study is observational, retrospective, comparative, on a group of 150 patients, enrolled consecutively over a year. Quality of the intestinal preparation is evaluated and then reported based on BBPS for both patients who underwent Colon Wash and those who opted for the traditional preparation. In addition, the total percentage of cecal intubation and the average time needed to achieve it, in patients who have also undergone Colon Wash, are reported.

RESULTS: 87 out of the 150 patients enrolled, (58%) chose intestinal preparation with Colon Wash technology. In this group, optimal preparation was obtained in 71.3% of cases. The percentage of optimal preparation among patients who chose the traditional method decreased 66.7%. Failure rates of procedure due to poor bowel preparation were 4.6% and 3.2% respectively. Cecum was achieved in 99.2% of cases with an average time of 22.5 minutes. In addition, in patients with a previous failed conventional colonoscopy, cecum was achieved in 92.3% of cases. 58 patients out of the 150 were eligible for the ADR calculation according to the ASGE guidelines, resulting in an overall ADR of 39.7% (ADR M of 60% and ADR F of 24.2%).

CONCLUSIONS: Endotics system confirms its ability to perform painless procedures as effectively as conventional colonoscopy (and



more effectively in difficult cases). Colon Wash technology allows intestinal preparation comparable to the standard one. The combination of these two technologies can increase acceptance of colonoscopy procedure and adherence to CCR screening programs.

KEYWORDS: Robotic colonoscopy; Painless colonoscopy; Endotics; Colon Wash; Screening; Learning curve

ABBREVIATIONS: ADR: Adenoma Detection Rate; BBPS: Boston Bowel Preparation Scale; ES: Endotics System; CC: Conventional Colonoscopy; CW: Colon Wash; PDR: Polyp Detection Rate; RC: Robotic Colonoscopy

INTRODUCTION

Colonoscopy is the gold standard method for prevention, diagnosis, and treatment of CCR [1], but it is painful and highly dependent on bowel preparation as well. Even if the bowel preparation is fair, significant pathologies may be missed [2]. Moreover, these two procedures are often associated respectively with pain and discomfort. The only solution massively proposed to date to mitigate the above stated conditions is sedoanalgesia or anesthesia, but as a not "risk-free" option it is not always recommended [3], and the rate of colonoscopic procedures performed with conscious sedation varies considerably among countries [4,5]. Sedoanalgesia is recommended by several guidelines. Without sedation patients are likely to deal with higher chances of "unacceptable discomfort" and endoscopists' chances of completing the procedure will be lower due to patients' discomfort [6], unless robotic Endotics System (ES) and Colon Wash technology (CW) are used in a combination leading to a complete, painless, drug-free procedure.

MATERIALS AND METHODS

STUDY POPULATION

An observational, retrospective, comparative study was performed on a group of 150 consecutive patients undergoing Endotics robotic colonoscopy from February 2017 to April 2018 at the S. Giuseppe hospital, Milan, Italy. The group included both patients undergoing bowel cleaning by means of Colon Wash technology and patients undergoing traditional bowel cleaning. Not only patients with indications for a colonoscopic investigation and who elected to experience the robotic colonoscopy were included, but thanks to the absence of risks of perforation, cross-contamination and risks related to sedation also patients with minor symptoms for which conventional colonoscopy was not indicated were included. Each patient was prepared with a venous access so to administer hyoscine-N-butylbromide (buscopan®) in the event of spasms, drips, and vagal seizure, if necessary.

All patients who underwent Colon Wash were on a low fiber regime in the previous days. In addition, on the preceding evening they were required to limit liquids and to take a stool softner. Patients who did not choose Colon Wash, however, were required to follow a low fiber diet and to take a purgative in 2 liters of water. Some patients were excluded from data analysis for the following reasons:

Presence of stenosis;

•

• Very poor preparation, especially when faecal impaction was found.

As general indication, biopsies, both into the left and right colon and even into the cecum, and small pedunculated polyps (smaller than 20mm in diameter) must be operated by Endotics robotic colonoscope while remaining type of lesions (not pedunculated or larger than 20mm in diameter) must be operated by standard colonoscope. In this study the colonoscopic procedure was a 4-hand one, with the medical doctor who drove the robot through the colon by means of a console, and a nurse who inserted the robot and oversaw its tail management in the following phases. The team of nurses was composed of 6 members, who alternated to support the procedures as per working shifts. The above stated framework had a massive impact on learning curve definition, and consequently on cecum reaching time calculation, as detailed afterwards. Initially, the trainees, both endoscopist and nurses, acquired Endotics robotic colonoscopy skills through practicing in vitro trials. Then, robotic colonoscopy training began on patients with the technical assistance of Endotics personnel for 50 cases. After the training period, the GI staff started performing robotic colonoscopies without the assistance of the technical staff. At the beginning an endoscopist and two nurses were trained. The trained team then trained four other nurses in turn. For all patients, the adopted method of preparation, Colon Wash or standard (2L split dose polyethylene glycol-electrolyte solution), was recorded. Patients who chose the Colon Wash, followed a low-fibre diet for three days and received colon washing with Colon Wash technology prior to the colonoscopy procedure. In both cases the level of cleanliness was recorded following the Boston bowel preparation scale [7] and compared to each other. All the data related to the percentage of cecal intubation and cecum reaching time were also reported. Cases of robotic pan colonoscopy on patients with conventional colonoscopy failed, and vice versa, were extrapolated. Finally, the average of cecum reaching time in "standard" patients who underwent Colon Wash is reported. Standard patients mean patients who have not had a previous failed conventional colonoscopy.

THE ENDOTICS SYSTEM

The Endotics system is composed of a sterile, disposable probe and of a workstation. The probe can be steered 180 degrees in each direction without need to torque the thin and high flexible tail (7.5 mm in diameter). The probe is also equipped with a 3 mm diameter working channel that allows the passage of commercial tools such as biopsy forceps, needles, and snares and with two more other channels for air and water jet. The probe is fully controlled



by the endoscopist by means of a handheld console connected to the workstation. Besides the well-known risks of the standard colonoscopic procedure, such as perforation, risks related to sedation/anesthesia and risks of cross-infection, factors related to pain/ discomfort associated with the procedure itself and the intestinal preparation phase must also be taken into consideration. Thanks to its high flexibility and to the smooth propulsion with few air, the disposable and single use robotic system travels along the colon walls without changing the geometry of the colon, therefore without stretching the mesenteries. This combination of factors results in a risk-free and pain-free procedure, that allows both the patient and the endoscopist to deal with the procedure in a relaxed way. The extreme flexibility of the Endotics robotic device, on the other hand, makes it impossible to "force" any narrowing of the lumen due to stenosis or temporary bowel spasms. These characteristics have made it possible to broaden the indications to the colonoscopy in order to meet, sometimes, also the needs of the patient. Compared to the official guidelines regarding indications for colonoscopy, the Endotics robotic colonoscopy may also include minor symptoms such as mild abdominal pain or meteorism.

THE COLON WASH SYSTEM

The term Colon Wash, coined by the author (FC) in 2008, refers to retrograde colon washing with no prior use of several liters (in the range of 2 to 4L) of Polyethylene Glycol (PEG) solutions [8, 9].

The machine used for the Colon Wash is the same machine used for the Hydro colon therapy (CleanColon 004RA). It is an automatic, closed-circuit electro-medical instrument that is therefore safe, hygienic, and odorless. The filling and emptying cycles are button-controlled. A cannula is inserted into the rectum when the patient is lying on their side or on their back. This cannula is equipped with two pipes, smaller one for water entry and a larger one for removing fecal material and used water. The cannula is connected to the equipment that controls water pressure and temperature. During the procedure, an abdomen massage is also performed to enhance the fragmentation and detachment of fecal materials from the mucous membrane of the colon. The session lasts about 45 minutes. Even if the same machine is used, hydro colon therapy and Colon Wash are procedures that differ. With hydro colon therapy the colon is washed with the intention of eliminating large fecal residues, while with Colon Wash the washing is more accurate as it is necessary to "cleanse" the mucosa to allow optimal endoscopy vision. Patients who underwent a session of traditional hydro colon therapy are not clean enough to be eligible for colonoscopy. The Colon Wash technology requires, in the days immediately preceding the procedure, fiber-free diet and laxatives. It is a preparation much more tolerated by patients because it does not require the ingestion of large quantities of liquids, but in any case, it must be observed because the sole mechanical washing performed by the Colon Wash system is not always sufficient.

Patients chose the Endotics robotic colonoscopy for several reasons that are shown in (Table 1).

RESULTS

In total, 150 patients (81 women mean age 59.6 years and 69 men mean age 55.5 years) with a mean age of 57.7 years, were considered in the study. In 12 cases (8%) the colonoscopic procedure was interrupted because of stenosis while in 6 cases (4%) because of very poor bowel preparation. In the 12 cases in which patients presented a stenosis, 3 were explored with a pediatric colonoscope then reaching the cecum, 2 with a gastroscope reaching once the cecum and once the hepatic flexure, 4 with the conventional colonoscope where the cecum was reached only in 2 cases while in the other 2 cases the procedure was interrupted at sigmoid colon, same as occurred using the robotic colonoscope. 3 patients refused to switch to a traditional colonoscopy out of fear of sedation. For the 6 cases of insufficient intestinal cleansing, only in 2 cases the conventional colonoscopy was used, reaching once the cecum and once the hepatic flexure same as occurred for the robotic colonoscope. In the remaining 4 cases it was decided to not revert to traditional colonoscope because of inadequate preparation. (Table 2) resumes robotic procedure failures and then converted to standard procedures. It shows that only in 2 cases of stenosis and 1 of poor bowel preparation standard colonoscope completed the procedure.

In the remaining 132 cases, cecum was reached in 131 patients (99.2%) and in 1 case cecum was not reached (interrupted on the right colon) because of extremely long bowel. 13 patients (8.7%) with an history of previously failed standard colonoscopy, underwent robotic procedure. In 12 cases (92.3%) robotic colonoscope reached the cecum (confirming the data in the literature [10]) and in 1 case reaching the cecum was not possible because of the stenosis. In 13 patients (8.6%) particularly sensitive/anxious, at their request, venous access was used to administer a minimal sedation [11] (midazolam 2mg) before the robotic procedure began. The Polyp Detection Rate, also considering the patients in whom the inspection of the colon had been interrupted, therefore out of a total of 150 patients, was reported in 38 patients (25.3%) divided into 23 (60.5%) in men and 15 (39.5%) in women and 56 lesions were identified. Out of these 23 (41.1%) were in the right colon, 6 (10.7%) in the transverse colon and 27 (48.2%) in the left part of the colon. (Table 3) shows the type of lesions found in the patients, their allocation within the colon, with which instrument they were removed and the results of the histological analysis.

The categories of adenomas have been defined according to the amended Vienna classification [12], in accordance with the European guidelines [13]. All lesions were removed and analyzed except for 2 that were dealt with later, 1 due to poor bowel cleansing (lesion number 17) and 1 because it was of surgical interest (lesion



number 13). Out of the 54 remaining lesions, 36 were peduncular polyps removed with the robotic colonoscope, 1 was a doubtful swelling (lesion number 12) removed with the robotic colonoscope, 4 were pedunculated polyps larger than 20 mm (lesion numbers 14, 15, 57 and 63 removed with the conventional colonoscope) and 12 were non-pedunculated polyps (removed with the conventional colonoscope). 28 biopsies were also performed in 10 (6.7%) patients. 24 (85.7%) of these were performed with the robotic colonoscopes. Biopsies with the conventional colonoscopes (also pediatrics and gastroscopes) were performed in two patients with a stenosis. In these cases, the robotic colonoscopy had to be inter-

rupted. (Table 4) shows biopsies per patient and their allocation within the bowel.

The Adenoma Detection rate is calculated based on guidelines that currently recommend a minimum target for overall ADR (male/ female population over 49 years old undergoing a screening colonoscopy) of at least 25%, with a recommended ADR target of 30% for men and 20% for women [14]. Out of the 150 patients enrolled, 80 (44 women and 36 men) underwent a screening colonoscopy and of these only 58 (33 women and 25 men) were older than 49 years. Of the remaining 58 patients, 23 had an adenoma (overall ADR 39.7%) and were divided into 8 women (ADR F 24.2%) and 15 men (ADR M 60%). Data are resumed in (Table 5).

| Reason | Percentage |
|---|------------|
| Because the patient is afraid of infections or cross-contamination | 9% |
| Because the patient is afraid of perforations | 51% |
| Because the patient does not want to be sedated mistrusting drugs or because they do not want to lose consciousness | 25% |
| Because the patient has had negative experiences with conventional colonoscopy, for example pain despite sedation, drug reactions or because they have not been completed | 15% |

Table 2: Reasons of robotic colonoscopy failures and outcome of the procedure following the use of a conventional endoscope

| Cause of procedure failure | 2nd device | Endoscope used after device | Bowel section reached after | | | |
|----------------------------|------------|-----------------------------|-----------------------------|--|--|--|
| Cause of procedure failure | used | change | conversion | | | |
| Stenosis | Yes | Pediatric colonoscope | Caecum | | | |
| Stenosis | Yes | Pediatric colonoscope | Caecum | | | |
| Stenosis | Yes | Pediatric colonoscope | Caecum | | | |
| Stenosis | Yes | Gastroscope | Caecum | | | |
| Stenosis | Yes | Gastroscope | Hepatic Flexure | | | |
| Stenosis | Yes | Conventional Colonoscope | Caecum | | | |
| Stenosis | Yes | Conventional Colonoscope | Caecum | | | |
| Stenosis | Yes | Conventional Colonoscope | Sigmoid | | | |
| Stenosis | Yes | Conventional Colonoscope | Sigmoid | | | |
| Stenosis | No | - | - | | | |
| Stenosis | No | - | - | | | |
| Stenosis | No | - | | | | |
| Poor bowel preparation | Yes | Conventional Colonoscope | Caecum | | | |
| Poor bowel preparation | Yes | Conventional Colonoscope | Hepatic Flexure | | | |
| Poor bowel preparation | No | - | - | | | |
| Poor bowel preparation | No | - | - | | | |
| Poor bowel preparation | No | - | - | | | |
| Poor bowel preparation | No | - | - | | | |

Table 3: Lesions and their localization in the bowel, type of instrument used for the treatment of the lesion and histological results

| Lesion n. | Patient n. | Description of lesion | Device in use | Results of histology |
|-----------|------------|---------------------------------------|---------------|--|
| 1 | #5 | Polyp of 7 mm in the sigmoid colon | ES | Hyperplastic polyp |
| 2 | #9 | Polyp of 6 mm in ascending colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 3 | #9 | Polyp of 12 mm in transvers colon | CC | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 4 | #13 | Polyp of 6 mm in transverse colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 5 | #13 | Polyp of 6 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 6 | #15 | Polyp of 6 mm in the sigmoid colon | ES | Hyperplastic polyp |
| 7 | #15 | Polyp of 8 mm in ascending colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 8 | #17 | Peduncular Polyp of 8 mm in the cecum | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |



| 9 | #17 | Polyp of 10 mm in transvers colon | СС | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
|----|------|---|---|---|
| 10 | #18 | Polyp of 8 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 11 | #21 | Polyp of 6 mm in ascending colon | ES | Hyperplastic polyp |
| 12 | #21 | Polyp of 7 mm in the sigmoid colon | ES | Hyperplastic polyp |
| 13 | #22 | Vegetative formation, sessile, with an adenomatous appearance of about 30 mm in the cecum | CC | Tubulo-villous adenoma with high-grade glandular epithelium dysplasia (cat. 4.1). |
| 14 | #29 | Polyp of 10 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 15 | #30 | Polyp of 8 mm in transverse colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 16 | #30 | Peduncular polyp of 5 mm in the distal sigmoid colon | ES | Hyperplastic polyp |
| 17 | #36 | Peduncular Polyp of 5 mm in the cecum | ES | Serrated adenoma |
| 18 | #40 | | ES | Hyperplastic polyp |
| 19 | #42 | Polyp of 6 mm in the hepatic flexure | ES | Polypoid fragment of mucous membrane of the large intestine with discreet edema of the lamina propria. |
| 20 | #42 | Peduncular polyp of 15 mm in the distal sigmoid colon | ES | Tubular adenoma with low dysplasia (cat. 3) and focally high- grade glandular epithelium (cat. 4.1) |
| 21 | #44 | Polyp of 7 mm in the sigmoid colon | CC | Hyperplastic polyp |
| 22 | #44 | Polyp of 10 mm in proximal ascending colon | СС | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 23 | #49 | Polyp of 12 mm with short peduncle in ascending colon | ES | Fragments of fibro-sclerotic tissue with mild chronic inflammation. |
| 24 | #49 | Polyp of 6 mm in the distal sigmoid colon | ES | Hyperplastic polyp |
| 25 | #51 | Doubtful mucosa bulge of about 15 mm in proximal ascending colon | ES | Normal mucosa |
| 26 | #56 | Peduncular polyp of 10 mm in the distal sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 27 | #57 | Peduncular polyp greater than 20 mm in distal ascending colon | СС | Tubular adenoma with high-grade glandular epithelium dysplasia (cat. 4.1). |
| 28 | #58 | Polyp of 6 mm in ampulla | ES | Hyperplastic polyp |
| 29 | #63 | Peduncular polyp greater than 20 mm in distal sigmoid colon | СС | Tubular adenoma with high-grade glandular epithelium dysplasia (cat. 4.1). |
| 30 | #64 | Cancer in the sigmoid colon | Surgical intervention | Adenocarcinoma |
| 31 | #68 | Peduncular polyp greater than 20 mm in distal ascending colon | CC | Tubulo-villous adenoma with high-grade glandular epithelium dysplasia (cat. 4.1). |
| 32 | #77 | Peduncular polyp greater than 20 mm in distal sigmoid colon | CC | Tubulo-villous adenoma with low dysplasia (cat. 3) and focal, high grade glandular epithelium (cat. 4.1) |
| 33 | #83 | Polyp of 5 mm in ampulla | ES | Hyperplastic polyp |
| 34 | #86 | Polyp of 6 mm in the rectum | ES | Hyperplastic polyp |
| 35 | #91 | Polyp of 5 mm in distal sigmoid colon | New procedure after new colon preparation | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 36 | #97 | Polyp of 6 mm in proximal ascending colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 37 | #97 | Polyp of 10 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 38 | #100 | Polyp of 6 mm in ampulla | ES | Hyperplastic polyp |
| 39 | #107 | Polyp of 10 mm with short peduncle in ascending colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 40 | #107 | Polyp of 8 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 41 | #112 | Polyp of 6 mm in the medium rectum | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 42 | #114 | Polyp of 5 mm in ascending colon | ES | Serrated adenoma |
| 43 | #114 | Polyp of 5 mm in transverse colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 44 | #114 | Polyp of 5 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 45 | #119 | Polyp of 5 mm in transverse colon | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |



| 46 | #119 | Polyp of 5 mm in the sigmoid colon | ES | Hyperplastic polyp |
|----|------|--|-----|---|
| 47 | #125 | Polyp of 10 mm in the sigmoid colon | ES | Tubular adenoma with low-grade glandular epithelium |
| 47 | #125 | I bryp of 10 min in the significateoron | 110 | dysplasia (cat. 3) |
| 48 | #132 | Peduncular Polyp of 15 mm in the cecum | ES | tubulo-villous adenoma with low dysplasia (cat. 3) and high- grade dysplasia microfocal unit of the glandular epithelium (cat. 4.1) |
| 49 | #132 | Large formation of adenomatous and tubular appearance in the cecum | СС | tubulo-villous adenoma with low dysplasia (cat. 3) and high- grade dysplasia microfocal unit of the glandular epithelium (cat. 4.1) |
| 50 | #136 | Flat lesion of 15 mm in the ascending colon | CC | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 51 | #139 | Polyp of 6 mm in the sigmoid colon | CC | Hyperplastic polyp |
| 52 | #139 | Polyp of 8 mm in ascending colon | СС | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 53 | #139 | Polyp of 8 mm in transverse colon | СС | Tubulo-villous adenoma with low dysplasia (cat. 3) and high- grade dysplasia microfocal unit of the glandular epithelium (cat. 4.1 |
| 54 | #140 | Peduncular Polyp of 6 mm in the cecum | ES | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 55 | #144 | Polyp of 5 mm in ascending colon | CC | Tubular adenoma with low-grade glandular epithelium dysplasia (cat. 3) |
| 56 | #144 | Polyp of 15 mm in transvers colon | CC | Tubular adenoma with high-grade glandular epithelium dysplasia (cat. 4.1). |

Table 4: Biopsies per patient and their allocation within the bowel.

| N. of Patient | N. of biopsies | Site | Device in use | Results of histology | | |
|---------------|----------------|------------------------------|--------------------------|---|--|--|
| #8 | 3 | Right and left colon | Robotic Colonoscope | Slight edema of the lamina propria. | | |
| #27 | 2 | Ileum | Conventional Colonoscope | # Absence of salient histopathological changes. # Low | | |
| #21 | 2 | lieulli | Conventional Colonoscope | edema of the lamina propria. | | |
| #36 | 2 | Transverse colon | Conventional Colonoscope | Adenoma | | |
| | | | | # Chronic moderate lympho-plasma cellular inflammation | | |
| #58 | 5 | Right and left colon | Robotic Colonoscope | and eosinophilic granulocyte of the lamina propria. # | | |
| #38 | 5 | Right and left colon | Kobolie Colonoscope | Morphological finding compatible with clinical suspicion | | |
| | | | | of microscopic colitis. | | |
| #59 | 5 | Right and left colon | Robotic Colonoscope | Edema of the lamina propria. | | |
| | | Sigmoid colon in addition to | | | | |
| #64 | 3 | marker with ink by means of | Robotic Colonoscope | Adenocarcinoma | | |
| | | needle | | | | |
| | | | | # Edema of the lamina propria | | |
| #81 | 4 | Right and left colon | Robotic Colonoscope | # Slight increase in lymphoplasmacellular infiltrate of the | | |
| | | | _ | lamina propria. | | |
| #106 | 4 | Right and left colon | Robotic Colonoscope | Slight edema of the lamina propria. | | |

Table 5: ADR results

| Filters | Number of patients (Female, Male) | | | | | | | | | | | | |
|---------------------|-----------------------------------|----------|---------|---------|-----------|-----------|-----------|---------|-----------|----------|---------|-----------|--|
| Patients | 150 (81,69) | | | | | | | | | | | | |
| C | | No | | | | | Yes | | | | | | |
| Screening 70(73,43) | | | | | | 80(44,36) | | | | | | | |
| | | No | | Yes | | | No | | | | Yes | | |
| Age > 49 | 1 | 17(7,10) | | | 53(30,23) | | 22(11,11) | | 58(33,25) | | | | |
| DDD | No | Y | es | No | Yes | | No | Yes | | No | Yes | | |
| PDR | 52 (29,23) | 1(1 | ,0) | 13(5,8) | 4(2,2) | | 17(11,6) | 5((|),5) | 30(21,9) | 28(| 12,16) | |
| | | No | Yes | | No | Yes | | No | Yes | | No | Yes | |
| ADR | | 1 (1,0) | 0 (0,0) | | 1 (1,0) | 3 (1,2) | | 1 (0,1) | 4 (0,4) | | 5 (4,1) | 23 (8,15) | |

6/9



As for the calculation of the cecum reaching time, cases with previous failed traditonal colonoscopy were not taken into account. Moreover, only cases where an optimal cleaning level was reached (Boston preparation scale 3+3+3) with Colon Wash procedure were considered. Finally, the above stated timing is related to the performance of the best trained nurse, excluding from the calculation the learning curve period. The learning curve end can be identified as the moment when the curve stops raising. Cecum reaching time is highly impacted by the alternating of all nurses. With the above stated assumption, learning curve completion was set to 30 procedures done. The complete data set has been taken into consideration and included in all calculation except the cecum reaching time from which the learning curve data were cut off. The chart in (Figure1) shows the data related to the time needed to reach the cecum in the robotic procedures carried out by the same doctor with three different nurses. Time data is grouped and mediated every ten patients. It was observed that at most after 30 cases (in average) the curve begins to decrease, indicating that the doctor and the nurse have found the right harmony and the right coordination to better cope with the robotic procedure.

The Colon Wash preparation was used for 87 patients (58%) while the remaining 63 patients (42%) underwent standard bowel preparation with Polyethylene Glycol (PEG). According to Boston bowel preparation scale, in the first case 71.3% reached the optimal preparation (3+3+3) and in the second case 66.7%. 4 patients (4.6%) with Colon Wash bowel preparation were excluded because of poor bowel preparation versus 2 patients (3.2%) with standard preparation. In the early stages of use of Endotics robotic

colonoscopy associated with Colon Wash, patients did not follow medical indications on diet and laxatives as they mistakenly believed that washing would still be effective. Following a series of poorly effective preparations, the doctor has intensified patient's sensitization to follow the given directions. The results improved, but some patients even observing the indications still presented non-optimal colon preparation due to their peculiar intestinal characteristics, such as excessive constipation. The doctor therefore began to modulate the preparation by increasing the days of diet and laxative doses individually. Moreover, in the final time slot, the role of Colon Wash Trainer, in charge of contacting and interacting with patients during the days of intestinal preparation, was introduced.

The chart in (Figure 2) shows the level of intestinal cleansing of patients who underwent the Colon Wash according to the Boston Bowel Scale and timing of corrections to the methodology of the pre-procedure bowel preparation. Cleansing levels are mediated every 10 patients on a scale ranging from 0 to 9. The number of patients who required the Colon Wash procedure associated with the robotic colonoscopy Endotics has grown over time, far exceeding those who preferred the robotic colonoscopy with the standard preparation. The graph in (Figure 3) shows the trend of Colon Wash requests in the first 150 patients.

In this case the Colon Wash requests are indicated with the value 1, while the standard preparations are valued with a zero. The individual cases are reported to appreciate the density of events, but also a grouping of every ten patients to be able to evaluate the growth curve as a percentage.

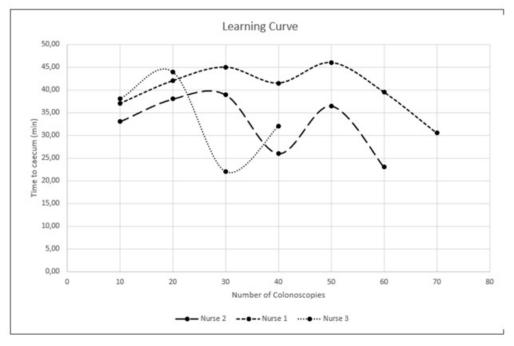


Figure 1: Learning curve



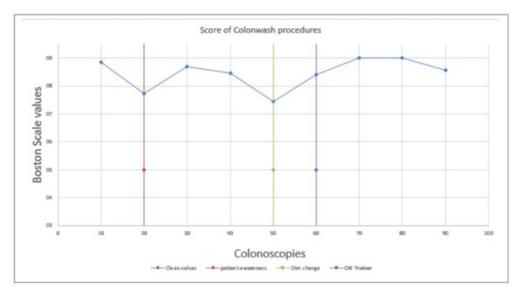


Figure 2: Bowel cleansing score with Colon Wash procedure

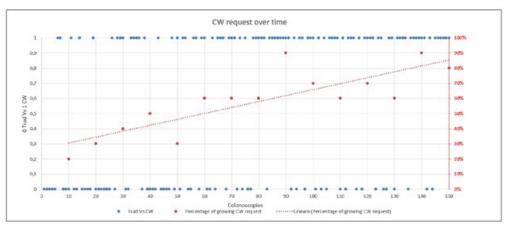


Figure 3: Colon Wash request trend

CONCLUSIONS

The combination of the two technologies presented in this paper gave unique results as alternative to standard colonoscopy preceded by standard preparation. The advantages are tangible and related to patient acceptance due to lack of pain and discomfort, and to cecum reaching time and percentage. The ADR is 39.7% (60% in men and 24.2% in women) according also to the ASGE guideline (total ADR 25%, 30% in men and 20% in women). Moreover, since the operative feature of robotic colonoscopy is relatively recent and certainly had never been used before by the doctors, they preferred to test its effectiveness gradually. Initially they started with biopsies into the left and right colon as well as into the cecum, and removal of small pedunculated polyps (smaller than 20mm), diverting to standard colonoscopy procedure for patients in whom there was a high probability of intervention. For the same reason some of the lesions diagnosed by the Endotics robotic colonoscopy were then operated with the standard colonoscope. The Endotics Robotic System also offers other advantages over conventional colonoscopy system. Being disposable, it avoids all the problems

related to cross-infection and reprocessing of colonoscopes. According to literature, the rates of post endoscopic infection per 1000 procedures within 7 days were 1.1 for screening colonoscopy, 1.6 for non-screening colonoscopy. The rates of 30-day infection-related unplanned visits per 1000 procedures were 4.0 for screening colonoscopy, 5.4 for non-screening colonoscopy [15]. Another advantage of the Endotics robotic system is that all the maneuvers necessary to perform a colonoscopic procedure with the conventional colonoscope are no longer required, with a positive impact on the work-related injuries. In conclusion, Endotics' robotic colonoscopy is a very advanced technology that allows to have a comparable or even superior diagnostic [16] quality in respect to that of the conventional colonoscopy, with an ability to reach the cecum in an extremely high percentage. Thanks to its pain free and risk-free performance, it encourages the accession of younger patients to a procedure so far considered invasive and painful, and it allows to expand the list of indications to colonoscopy even if in some cases only to meet the demands of patients in absolute safety. The operative capabilities of the Endotics robot-



ic colonoscope have not been fully evaluated because of the few operative procedures performed. To date the physician can affirm that the biopsies and polypectomies of pedunculated polyps can be safely and easily performed.

Overall, the addition of Colon Wash technology and Colon Wash trainer to the robotic procedure enhance the tolerability and comfortability throughout all the phases of colonoscopy examination.

AUTHORS CONTRIBUTIONS

- Felice Cosentino has designed and followed all the phases of the study, defining the methodology, performing colonoscopic procedures and interpreting results, also performing the critical review of the article.
- Rosa Tinelli assisted Felice Cosentino in most of the colonoscopic procedures.
- Rosanna Giuberti and Rosanna Zanardi have worked as colon hydrotherapists.
- Antonella Rigante has worked on the acquisition, analysis, and interpretation of all data set.
- Roberta Barbera has contributed substantially to the drafting and reviewing of the article.

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