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Intraluminal flexible sheath for the protection of low anastomosis after anterior resection: results from a First-In-Human trial on 15 patients

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Abstract

Background Defunctioning ostomy is commonly used to protect patients from anastomotic leakage complications after low anterior resection, but is fraught with its own deleterious effects. This first-in-human study examines the safety and preliminary efficacy of Colovac, an anastomosis protection device. The Colovac consists of a flexible bypass sheath, placed in the lumen of colon and anchored above the anastomosis using a vacuum stent.

Methods 15 patients underwent anterior resection (AR) with anastomosis protection by Colovac at 3 European centers. After 14 days, the anastomosis integrity was examined by CT scan and endoscopy. The device was then endoscopically removed. Data regarding demographics, surgical details, 30 day post-operative complications, and patient satisfaction were collected prospectively.

Results 15 patients (10 male) underwent laparoscopic AR with Colovac placement. Preoperative neoadjuvant therapy was administered to 54% of patients. Device placement was uneventful in all patients with a median duration of 7 min and placement was judged as easy or very easy in 93% of the cases. Patients did not report major discomfort during the 14 days. Endoscopic removal (10 min) was judged as easy or very easy in 87% of the cases. Absence of feces below the Colovac anchoring site was observed in 100% of the cases. 4 anastomotic leakages were observed (including 3 device migrations). Overall 5 patients (33%) required a planned stoma creation. At 3 months, 1 had already been closed.

Conclusion Colovac provides a minimally invasive protection of the anastomosis during the healing process by avoiding the need for a diverting ostomy for two-thirds of patients who will not experience anastomotic complications and allowing safe conversion to the standard of care for patients requiring extended anastomotic protection. A larger study is ongoing to confirm these results.

Keywords Rectal cancer · Stoma · Bypass sheath · Stent · Anastomotic leakage

Colorectal cancer represents the third most common cancer and the second most common cause for cancer mortality worldwide, with 1.8 million diagnoses and 881,000 expected deaths in 2018 [1]. Despite improvement in the perioperative management of anterior resection for rectal cancer, the rate of anastomotic leakages is still around 17% in the recent randomized studies [2, 3].

Anastomotic leakage is associated with increased morbidity and mortality, rate of definitive stoma [4, 5], and recurrence [6]. The only protective measure is the use of a diverting stoma [7]. Although the anastomosis typically heals in 10–15 days, the ostomy remains for 2–6 months. This timeframe is necessary for ostomy maturation (2 months) or the accomplishment of adjuvant therapy (3–6 months). During this period, patients are exposed to complications (up to 77%) such as dehydration, peristomal skin breakdown, skin burn, stoma prolapses, or retraction in addition to the psychological impact of carrying a stoma.

Additionally, stoma closure carries a risk of post-operative complications around 8%, including anastomotic

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leakage of the ileo-ileal anastomosis (1%) [8]. Following stoma closure, the morbidity is still high with a 10% risk of surgery for incisional hernia at the stoma site [9]. Moreover, around 20% of ostomies are not reversed [10]. This has a significant impact on the quality of life of the patients and implies life-long maintenance and associated costs.

Therefore, there is a critical need to develop a device which would protect the anastomosis temporarily to reduce the complications associated with ostomies and takedown interventions and would maintain digestive tract functionality for better recovery outcomes. Attempts to develop medical devices based on a flexible lining to protect the anastomosis proved the applicability of the concept [11], but anchoring these devices by an easily reversible mechanism proved challenging [12, 13].

The Colovac Colorectal Anastomosis Protection Device (Colovac, SafeHeal, France) is a single use, temporary intraluminal bypass device consisting of a flexible bypass sheath, which is endoscopically placed into the lumen of the colon and anchored above the anastomosis using a vacuum stent. The Colovac thus creates a functional colorectal anastomosis protection by reducing contact of fecal content with the anastomotic site. Until now, no clinical data were available to evaluate this device.

The aim of this first-in-human pilot study was to evaluate the preliminary safety and efficacy of the Colovac.

Materials and methods

Study design

This clinical study was a pilot, prospective, open-label, multi-center (Europe), single arm study which enrolled 15 subjects undergoing low anterior resection with total mesorectal excision (TME) for rectal cancer. Procedures were performed by experienced colorectal surgeons at three European tertiary centers (Hospital Saint-Antoine, Paris; IHU, Strasbourg; and UZA, Antwerp). The study protocol, its amendments, and study-associated documents were reviewed and approved by the appropriate Ethics Committee (EC) and Competent Authorities (CA). This study was registered online on the ClinicalTrials.gov website under the following identifier: NCT03352570.

It was conducted in accordance with the standard ISO 14155:2011 and the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964 and later revisions.

Objective and endpoints

The primary study objective was to demonstrate safety in using the device. It was assessed by recording all Serious Adverse Events (SAEs) in terms of type, frequency, severity, and relationship with the use of the Colovac during 3 months follow-up. Any readmission, unscheduled admission greater than 24 h, or initial hospitalization extending beyond a 14-day average length of stay due to an adverse event were considered as a serious adverse event.

The secondary objectives were to assess the clinical efficacy of bypass anastomosis protection, the overall procedural feasibility, the procedural success with placing and retrieving the device, the average procedure time, and the patient acceptance of the device.

Patients

Patients who underwent an anterior resection (AR) with TME with low anastomosis less than 20 cm from the anal verge were considered for inclusion.

Inclusion criteria were as follow: age ≥ 18 and ≤ 65 years old with an indication for colorectal resection, eligible to bear a loop ileostomy, willing to comply with protocol-specific follow-up evaluations, and having signed a written informed consent.

Exclusion criteria were the following: patient with inflammatory bowel disease, pregnant or nursing female subject (a pregnancy test should be conducted the day prior to the procedure for all women of childbearing age), known allergy to nickel or other components of the Colovac, any significant medical condition which, in the investigator's opinion, may interfere with the subject's optimal participation in the study, subject already enrolled in another investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the endpoints of this study, or patient unable to give consent.

After inclusion, subjects were studied pre- and post-procedure, with scheduled follow-up at 1, 2, 4 weeks, and 3 months, as well as a phone call at 6 weeks.

Data collection

Safety and efficacy of the Colovac were analyzed during the implantation period (0–14 days) and after 90 days follow-up. Data regarding demographics, surgical details, 90-day morbidity, and patient satisfaction were collected prospectively. All stapled anastomoses were considered as colorectal anastomoses and all hand sewn anastomoses were considered as coloanal anastomoses.

Feasibility was defined by the ability to introduce, deploy, and retrieve the Colovac to/from the desired location in the colon. Procedural success was defined by acute efficacy placing the device at the desired location. Procedure time was defined as time from insertion of the introducer to the vacuum system being ready to be connected and begin vacuum application. Migration rate was defined by the number of devices migrated over the anastomosis divided by the number of devices placed. The sheath internalization is defined as the retraction of the Colovac sheath within the colon lumen, and no more external protrusion through the anus. Patient acceptance and tolerability was analyzed using the NIH's PROMIS health measurement questionnaires to assess parameters like pain, bowel incontinence, constipation, diarrhea, or anxiety and social isolation [14].

An independent Data Safety Monitoring Board (DSMB) has been appointed by the sponsor to assess, at monthly intervals, the progress of the clinical investigation, the safety data, and the critical performance endpoints, and to recommend to the sponsor whether to continue, suspend, modify, or stop the clinical investigation. All members of the DSMB had no relationship with the sponsor or the investigators.

Investigational device

The Colovac is intended to reduce the contact of fecal content with the colorectal anastomotic site, following colorectal surgery (open or laparoscopic). It is indicated to be used in adult patients scheduled to receive a diverting loop ileostomy following colorectal surgery, who have been assessed by a multi-disciplinary team as per standard of care. The Colovac is a short-term minimally invasive device delivered and positioned through the anus. It is a sterile, single use disposable device consisting of one introducer pre-loaded with the Colovac.

The Colovac is made of two elements: an anchor made of a covered stent delimiting a vacuum chamber connected to a vacuum tube; a flexible polymer cylindrical sheath attached to the anchor, covering the anastomosis with appropriate length so that it protrudes about 5 cm outside the patient's anus (Fig. 1) in order to avoid any feces backflow in the colon at the open extremity of the sheath and to allow surveillance of the stent placement.

Procedure

Patients received fiber-free dietary regimen 2–3 days before surgery and mechanical bowel preparation (PEG based) the day before surgery (3–4 L). After the creation of the anastomosis, Colovac was inserted endoluminally through the anus under direct laparoscopic or laparotomic vision, using a dedicated flexible introducer (external diameter 17 mm) pre-loaded with Colovac. Once positioned at the correct location, approximatively 20 cm above the anastomosis, the stent was delivered and expanded. Upon removal of the introducer, the sheath and the vacuum tube were self-deployed distally past the anastomosis and the anus. After a vacuum efficacy test, the vacuum tube was then connected to a vacuum system (Redon vial of 600 ml), fixating the mucosa against the stent during the implantation period. Redon vacuum sets are meant for post-operative wound drainage. It consists of a high vacuum drainage system. The set is connected to the Colovac device via the aspiration tube, using a specific connector. The device was left in situ up to 14 days post-implantation. Use of a pelvic drain was left at the discretion of the investigator.

The surgeon was asked to grade the ease of introducer introduction and removal using a 5-point Lickert scale ranked from very easy to impossible.

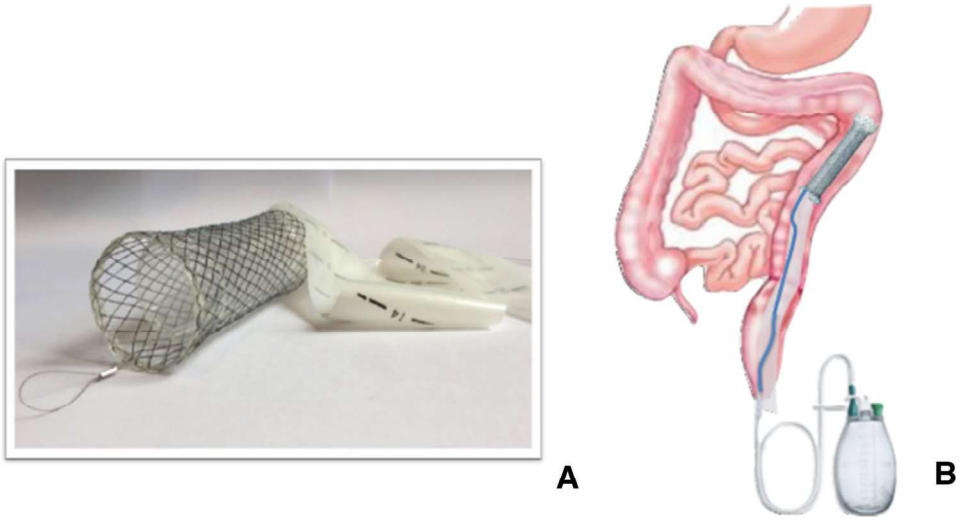

Fig. 1 **A** Colovac Device. **B** Colovac Device anchored in the colon with the high vacuum drainage system

A low fiber diet was given while the stent was in place. For the purpose of the study, all patients remained hospitalized for the entire duration of the Colovac implantation. Follow-up included daily clinical examination of the abdomen and the sheath length and CRP levels at post-operative day 1, 3, and 5 [15, 16]. After 12 to 13 days, the anastomosis integrity was examined by a CT scan with IV contrast agent and/or transanal-injected contrast CT scan before taking the patient to the OR for retrieval. The Colovac was retrieved at day 14 in the OR. An endoscopy was performed between the sheath and the colonic mucosa to verify the anchoring site and the absence of stool between the sheath and the colonic wall. Then the device was removed endoscopically through the anus by pulling on the retrieval loops located at the distal and proximal ends of the stent.

Results

Subjects demographics and surgical procedures

Fifteen patients were enrolled between November 2017 and June 2018 at three sites in Europe (Hôpital Saint-Antoine, Paris, France $n=8$—CHU Strasbourg, $n=3$—UZA, Antwerp, Belgium, $n=4$). One patient was screened but not included in this study as he declined participation in a clinical trial. Patient characteristics and surgical procedures details are summarized in Table 1.

There were 10 men (67%) with a median age of 60 (46–70) years. All patients were diagnosed with rectal cancer. Majority of the patients were staged cT3 (53%). 67% of patients received neoadjuvant radiotherapy and/or chemotherapy.

All anterior resections were performed through a laparoscopic approach, 26.7% of patients underwent a coloanal anastomosis and 60% of cases received a side-to-end anastomosis.

Two patients (14%) had associated procedures (right hepatectomy and two wedge resections for synchronous metastatic lesions). Details of surgical procedures are given in Table 1.

Table 1 Patients' characteristics and surgical procedures

	n (%)
Number of patients	15 (100)
Male gender	10 (67)
Median age (years (IQR))	60 (46–70)
Median BMI (kg/m^2 (IQR))	24 (22–28)
Active smoking	0 (0)
Diabetes	3 (20)
Arterial hypertension	3 (20)
Clinical cancer staging	
T1	4 (27)
T2	2 (13)
T3	8 (53)
T4	1 (7)
Tumor size	
< 2.5 cm	6 (40)
> 2.5 cm	9 (60)
Median tumor height (distance from anal verge, cm (IQR))	5.14 (0–6)
Median time from diagnosis to surgery (months (IQR))	3.7 (1.5–4.6)
Neoadjuvant treatment	
Chemotherapy only	1 (7)
Radiotherapy only	1 (7)
Radio chemotherapy	8 (53)
No neoadjuvant treatment	5 (33)
Surgical approach	
Laparoscopy	15 (100)
Median duration of surgery (min (IQR))	260 (218–360)
Type of anastomosis	
Coloanal Handsewn	4 (26.7)
Colorectal Stapled	11 (73.3)
End to end	5 (33.3)
Side-to-end	9 (60)
J-pouch	1 (6.7)
Median anastomosis height from anal margin (cm (IQR))	2 (1–4)
Use of pelvic drain	13 (87)
Concomitant surgery	
Right Hepatectomy	1 (7)
Hepatic wedge resection	1 (7)

Colovac procedure

Colovac placement and anchoring

The Colovac placement was scored as very easy or easy by the surgeon in 93% of cases. The median duration of placement was 7 (3–10) min. In 1 out of the 15 cases (7%), the Colovac was accidently pulled down during introducer removal. The device was then removed and replaced by a second one, without additional difficulties. Details about Colovac placement are summarized in Table 2.

One (7%) patient experienced a Colovac sheath internalization (retraction from anus) at Day 1. As the patient was asymptomatic, he was closely monitored but nothing was done to reverse the sheath internalization. The device was removed according to the protocol on Day 14.

Of the 15 devices implanted, 3 (20%) migrated before the end of the implantation period (2 device malfunctions related to a vacuum defect and 1 device misplacement (stent component of the Colovac device placed in immediate proximity (i.e., 4 cm) of the distal end of the J-pouch)). These

Table 2 Colovac placement and removal

Items	*N* (%)
Colovac placement	
Median duration	7 (3–10)
Technical ease of introducer introduction[a]	
Very easy	5 (33)
Easy	9 (60)
Moderate	1 (7)
Difficult	0 (0)
Impossible	0 (0)
Technical ease of introducer removal[a]	
Very easy	6 (40)
Easy	6 (40)
Moderate	3 (20)
Difficult	0 (0)
Impossible	0 (0)
Implantation site reached	
Yes	14 (93)
No	0 (0)
Accidental Colovac pullout during introducer removal—replaced by another device	1 (7)
Colovac anchoring	
14 days of implantation	12 (80)
Device migration	3 (20)
Colovac retrieval	
Median duration	10 (5–20)
Technical ease of Colovac retrieval	
Very easy	6 (33)
Easy	7 (54)
Moderate	0 (0)
Difficult	2 (13)
Impossible	0 (0)
Absence of feces below the anchoring site	15 (100)
Mucosal appearance[b]	
At the anchoring site	
Normal	2 (13)
Inflammatory	6 (40)
Bleeding	4 (27)
vUlcer	2 (13)
Perforation	0 (0)
Above the anchoring site	
Normal	11 (73)
Inflammatory	1 (7)
Bleeding	2 (13)
Ulcer	0 (0)
Perforation	0 (0)
At the anastomotic level	
Normal	12 (80)
Inflammatory	0 (0)
Bleeding	2 (13)
Ulcer	0 (0)
Perforation	0 (0)

Table 2 (continued)

Times are given in min (IQR)

[a]Technical ease of introducer introduction and removal have been evaluated by investigators using a Lickert scale ranked from 1 (very easy) to 5 (impossible) depending on the deployment force

[b]Missing data for one patient as Colovac was removed manually in the OR without access to endoscopic evaluation

three patients experienced moderate fever at post-operative D3 to D5 and a control CT scan was performed showing device migration. Devices were endoscopically removed in the operating room and conversion to loop ileostomies was performed without any complication in order to extend the anastomosis protection. For 2 patients, conversion to loop ileostomy was performed during the course of implantation period, while for the third patient, loop ileostomy conversion was considered at the time of scheduled removal, owing to the presence of a millimetric fistula communicating with the vaginal wall, resulting from a vaginal wall laceration during the initial surgery.

Colovac retrieval

All devices were removed endoscopically (14/15) or manually (1/15), without the need for surgery at post-operative Day 4 to 17 days. All Colovac retrievals were scored as very easy or easy by the endoscopist except the two (13%) first cases of the study, judged as difficult given the time required for removal (15 min). The median duration of the retrieval procedure was 10 (5–20) minutes. Following successful Colovac retrieval at post-operative day 14, all patients without anastomotic leakage ($n = 10$) were discharged the day after the endoscopic retrieval procedure.

The absence of feces below the Colovac anchoring site was confirmed by endoscopy performed between the colonic wall and the sheath in all the patients with the Colovac in place. The mucosal appearance was endoscopically evaluated and rated as normal or inflammatory in 80% of cases above the anchoring site and at the anastomotic level. The remaining 20% didn't require any further surveillance even if rated as ulcered or bleeding. At the device anchoring site, in 27% of patients, small bleeding lesions were experienced, not requiring any surveillance. Details about Colovac retrieval procedures are summarized in Table 2.

Post-operative course (Fig. 2)

Post-operative morbidity

The overall post-operative morbidity was 47% ($n = 9$). (Table 3). Major morbidity (Dindo III-IV) was 33%.

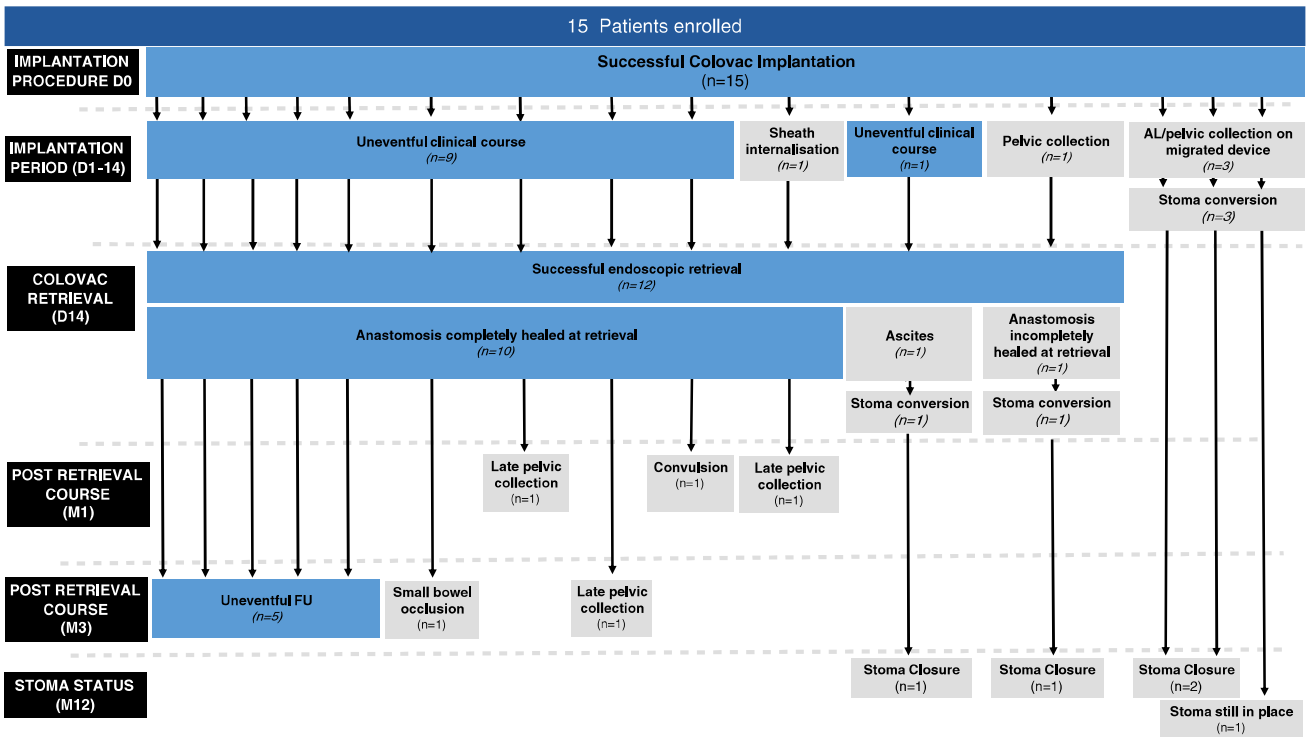

Fig. 2 Patients overview

Major post-operative complications during the Colovac implantation period were device migrations with anastomotic leakages (20%) and incomplete anastomosis healing diagnosed at the end of the Colovac implantation (13%). They were all managed by an ostomy placement for longer protection of the anastomosis. One (7%) patient with a colonic J-pouch anastomosis who experienced a Colovac migration in the first week after the implantation was operated for the removal of the device, colonic lavage, and a loop ileostomy creation. Unfortunately he presented few hours later a peritonitis requiring a second re-intervention for abdominal lavage. The recovery after the second operation was uneventful.

The other two patients who presented with Colovac migration during the implantation period were re-operated. The Colovac was removed and the loop ileostomy was created without any complications. No other patients experienced any morbidity related to the anastomosis during the implantation period. As reported in the Table 3, one patient with previous right hepatectomy developed an ascites which was medically treated. Post-operative complications during the post-Colovac retrieval period (14 days to 3 months) were dominated by pelvic collection ($n=3$) in patients who did not experience leaks during the immediate post-operative period. All pelvic collections were managed conservatively by antibiotics.

Patient acceptance and success rate

Colovac was well tolerated by patients with a full or very good acceptance of vacuum system presence for 80% of them and a NIH's PROMIS median score of 15 (8-20) at 3 months (Table 3). The Colovac device provided effective protection of the anastomosis in 12/15 (80%) subjects during the 14 day implantation period and allowed avoidance of ostomy creation in 10/15 (67%). Among the 5 patients converted to ostomy, 1 (7%) had his stoma reversed at 3 months, 2 were still under chemotherapy treatment, and the remaining two are planned to have a stoma closure at 6 months following surgery.

Discussion

The current standard of care to minimize the sequelae of anastomotic leakage is the creation of a temporary diverting ostomy in order to protect the anastomosis [7]. A recent meta-analysis by Phan et al. of 8 randomized studies with 892 anterior resections confirms that a stool diversion following rectal surgery can effectively reduce anastomotic complications [17]. The Colovac presents an alternative to ostomy by creating a functional intraluminal bypass which

Table 3 Patient acceptance and post-operative morbidity

Item	1 week *N* (%)	2 weeks *N* (%)	3 months *N* (%)
Overall morbidity	3 (20)	2 (13.3)	5 (33.3)
Medical complication			
Ascites		1 (7)	
Seizure			1 (7)
Surgical complication			
Incomplete anastomotic healing		2 (13.3)	
Device migration with leakage	3 (20)		
Pelvic collection			3 (20)
Bowel obstruction			1 (7)
Peritonitis	1(7)		
Patient tolerance to the presence of vacuum system			
1 (Full acceptance)	10 (66.7)	8 (53.3)	
2	5 (33.3)	4 (26.7)	
3	0 (0)	1 (7)	
4	0 (0)	0 (0)	
5 (No acceptance)	0 (0)	0 (0)	
Missing data[a]	0 (0)	2 (13.3)	
Patients tolerance to the presence of sheath protruding out of the anus			
1 (Full acceptance)	9 (60)	6 (40)	
2	5 (33.3)	4 (26.7)	
3	1 (6.7)	2 (13.3)	
4	0 (0)	1 (6.7)	
5 (No acceptance)	0 (0)	0 (0)	
Missing data[a]	0 (0)	1 (13.3)	
NIH's PROMIS health score (median IQR)	44 (38-51)	36 (15-46)	15 (8-20)
Stoma reversal			1 (20)

Some patients experienced more than one complication

[a]Questionnaires have not been fully filled by all patients

is endoscopically placed into the lumen of the colon and anchored above the anastomosis using a vacuum stent.

This first preliminary study showed that the Colovac procedure is feasible with promising initial results in terms of protection of the anastomosis: 80% of subjects were protected during the 14 days implantation period and avoidance of ostomy creation was observed in 10/15 (67%). Given the known incidence of clinical complications due to ostomy creation and ostomy reversal, avoidance of ostomy could potentially reduce morbidity in these patients. Typically, ostomy patients are exposed to a 43% post-operative complication rate (including risk of readmission, dehydration, and acute renal failure) [8]. Most patients with a temporary ileostomy will keep their ostomy at least 3 months, and it is not unusual that the ostomy is left in place much longer, and for 20% of patients, it becomes permanent [8]. Closure of the temporary ileostomy is associated with a low mortality, but the morbidity may be more than 20% [8].

Of the 15 Colovac devices placed, 3 migrated before the end of the implantation period (2 device malfunctions related to a vacuum defect, and 1 device misplacement related to the placement of stent component of the device in the immediate proximity of the distal end of J-pouch). For those 3 cases, initial device placement and introducer removal were uneventful.

The endoscopic use of stents in the gastrointestinal tract has been instrumental in the treatment of unresectable esophageal cancer, esophageal leak, and as a bridge to surgery in case of colonic obstruction. The historical use of colorectal stents for the protection of anastomotic leak has been limited due to technical issues, leading to the migration of stent in up to 58% of patients [18–20].

Regarding the Colovac migration whose associated conversion to ostomy caused a peritonitis, this case has been considered as probably related to a misplacement of the device and the lavage during the first re-operation. It was the first case of Colovac placement above a colic J-pouch. The device was placed at 13 cm above the anastomosis (3–4 cm above the distal part of the J-pouch, in front of the sacral promontory). So the distal part of the Colovac was too close

to the proximal dilated part of the pouch, leading maybe to an ease and early migration of the device. Instructions for use have been revised to recommend device anchoring above the promontory, at 20 cm above the anastomosis in order to avoid further similar complications.

The Colovac-related migration rate (13%)—related to vacuum defect—reported in the current study is much lower than the migration rate for standard colonic stents reported in the literature and confirms the efficacy of the vacuum system for anchoring the device. Additional surveillance measures have been implemented in order to identify early signs of migration (daily control of the external sheath length) and/or vacuum malfunction, enabling swift action if required (conversion to ostomy for example) and thus reducing the potential complications associated with this migration.

Regardless of the migrations, the incidence of anastomotic leakages in the SAFE-1 study population, during the Colovac implantation period (0–14 days), was 13%. This rate was within the same range as AL rate reported for similar patient populations receiving a diverting ostomy (12% to 17%) [2, 3, 21].

It is widely accepted that following rectal surgery, some patients will experience anastomotic complications such as anastomotic leakage. The process of anastomotic healing will therefore be longer for these patients.

Regardless of the efficacy of the Colovac at protecting the anastomosis during the first 14 post-operative days, it is anticipated that a proportion of patients will still demonstrate incomplete anastomotic healing as it is the case with systematic stoma diversion [2, 3]. In such cases, the Colovac should be removed and a fecal diversion is required to provide long-term anastomotic protection. Results obtained in this first 15 patient cohort are aligned with these observations. It is likely that the rate of conversion to diverting ostomy is inherent to the anastomotic healing problem.

Additionally, a trend toward delayed anastomotic healing and/or fistulisation was observed for patients with evidence of extensive local disease and/or patients for whom colorectal resection was combined with additional surgical procedures such as hepatectomy. The two patients from this cohort who underwent a hepatectomy required stoma conversion. This suggests that a 14 day protection period is likely to be insufficient for this subset of population. Mitigation measures consisting of improved patient selection criteria have been implemented to reduce the occurrence in the future. The improved patient selection criteria exclude patients for whom rectal surgery is associated with a secondary procedure such as liver resection due to a higher risk of anastomotic complications requiring prolonged protection and the population will become more homogenous.

In addition to this, we would like to highlight that patients converted to ostomy ensure a longer protection of their anastomosis and have not experienced any major complication related to this conversion surgery except for the peritonitis following the perioperative lavage that required a new intervention. All stoma creations were planned, but were not performed in an emergent situation due to the clinical symptoms of the patients.

Clinical complications during the follow-up period were dominated by late pelvic collections (20%). The occurrence of a collection more than 8 days after the Colovac retrieval is advocating for a late fistulation, as reported in the literature. The nature of the collected liquid converges along those lines. The study from Alves et al. [22] reports a leakage rate between 1 and 4% after early ostomy closure (between 7 and 14 days), and the study by Yin and al. supports the same rate [23]. Nelson et al. reported intra-abdominal collection rate at 14% after early ostomy closure (between 14 and 28 days) [24]. These late pelvic complications were managed conservatively by antibiotic treatments.

Regarding procedural feasibility, this study showed that delivery of the Colovac during colorectal surgery and endoscopic device retrieval are feasible and safe. Indeed, no anastomotic trauma was reported by the investigators.

In addition, delivery of the Colovac is likely to require less time than ostomy creation with no major differences in terms of hospital stay. The consistent delivery time signifies the simplicity of the procedure, especially when considering that three different physicians placed the devices at differing times.

Device retrievals were performed endoscopically or manually. The mean retrieval duration was 10 min except for one case which took longer due to the learning experience. The longer time (15 min) associated with the first case is attributed to the learning curve effect, since colonic stent retrieval is not routinely performed in the standard GI practice. As for the device placement, the consistent retrieval time after the first case signifies the simplicity of the procedure.

This initial study also provided the first evidence that this novel concept was well tolerated by patients. Limited discomfort related to the presence of a drain and a sheath through the anus was reported during the 14 day period, which can be counterbalanced by the discomfort associated with the ostomy for a much longer period of time. For the purpose of the study, patients were not discharged before the end of the implantation period (i.e., 14 days), but earlier patient discharge could be envisioned in the future.

There are some limitations to this study. The number of included patients is low and the study population is a convenient cohort of rectal cancer patients treated at expert centers. Results may not be generalizable to all rectal cancer patients and other centers. Second, the use of Colovac should be limited to patients undergoing rectal resections without concomitant surgery given the associated increased risk of complications.

Other attempts to replace ileostomy by intraluminal approaches confirm the clinical need for minimally invasive protection of colorectal anastomosis. Recently, Reshef et al. reported the use of an intraluminal device (CG-100), confirming the beneficial impact of this approach [25]. However, the patient population addressed in this study was different from our cohort. The mean anastomosis height was 10 cm, which demonstrated to be less prone to anastomotic complications than low to very low colorectal anastomosis, as included in our study [26].

Colovac provides a local, temporary, minimally invasive protection of the anastomosis during the healing process, avoiding the need for a diverting ostomy for patients who will not experience anastomotic complications and allowing safe conversion to the standard of care by diverting ostomy for patients requiring prolonged anastomotic protection. By optimizing conditions of use and patient selection, Colovac could become an effective patient management alternative for patients undergoing low anterior resection. This should be confirmed in a larger and randomized study.

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Compliance with ethical standards

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