



Anterograde colonic irrigations by percutaneous endoscopic caecostomy in refractory colorectal functional disorders

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Abstract

Purpose In case reports or small studies, percutaneous endoscopic caecostomy (PEC) has been proposed as an alternative to the Malone intervention to perform antegrade colonic enemas. Our goal was to assess the feasibility, efficacy, and tolerance of PEC in a large group of patients with refractory colorectal functional disorders.

Methods From September 2006 to April 2014, all patients undergoing PEC for constipation, fecal incontinence, and incontinence after rectal resection in two expert centers were studied. The PEC procedure consisted in anchoring the caecum to the abdominal wall (caecopexy) and placing a specifically designed tube in the colonic lumen to perform antegrade enemas. The quality of life (GIQLI), constipation (Kess), and incontinence (Cleveland) scores were assessed before PEC and at 3, 6, 12, and 24 months.

Results A total of 69 patients were included. GIQLI scores were significantly improved in constipation group ($n = 43$), incontinence group ($n = 19$), and rectal resection group ($n = 10$). In the constipation group, Kess score decreased from 25.9 before PEC to 20.6 at 2 years ($p = 0.01$). In the incontinence and post-rectal resection groups, Cleveland scores decreased from 14.3 before PEC to 2.7 at 6 months ($p = 0.01$) and to 10.4 at 2 years ($p = 0.04$). Overall, PEC was considered successful by patients in 58%, 74%, and 90% of cases, in constipation, incontinence, and rectal resection groups, respectively. Chronic pain (52%) at the catheter site was the most frequent complication.

Conclusions Percutaneous endoscopic caecostomy for antegrade colonic enemas improves significantly the quality of life of patients with colorectal disorder refractory to medical treatment.

Keywords Colorectal functional disorders · Endoscopic treatment · Constipation · Fecal incontinence

Introduction

Chronic constipation and fecal incontinence are common gastrointestinal (GI) disorders in clinical practice, with most patients being satisfied by alimentary measures or pharmaceutical treatments. However, the management of patients who remain refractory to standard therapies and experience a significant impairment of their quality of life [1, 2] can be very challenging. Therefore, surgical techniques such as colectomy for constipation or colostomy for fecal incontinence have been developed but are still draconian approaches with potential postoperative morbidity and mortality [3]. The Malone procedure is a less invasive surgical procedure developed in children, which consists in using the appendix as a route to perform antegrade colonic enemas (ACE) [4, 5]. For patients who have had an appendectomy or whose appendix is unusable,

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surgical alternatives have been described using a tunneled caecum [6] or ileum [7, 8], providing satisfactory results in approximately 50% of patients. However, as for the Malone procedure, such surgical techniques are burdened by the need for surgical revisions, up to 88% at 36 months [9] due to stenosis [10] or stoma leakage [11].

To overcome such limitations, novel mini-invasive techniques have been developed using radiological or endoscopic approaches. These techniques consist in fixing the colon with anchors and placing a catheter dedicated to ACE into the caecum. In particular, feasibility of percutaneous endoscopic caecostomy (PEC) has been established in pilot studies [12, 13]. However, these monocenter studies are limited by their small sample size and the heterogeneity of underlying GI diseases.

Therefore, our main objective was to evaluate the efficacy of PEC for ACE in a larger group of patients with refractory constipation, refractory passive fecal incontinence, and fecal incontinence after rectal resection in two tertiary referral centers.

Materials and methods

Study design

All patients undergoing PEC for refractory functional GI disorders, i.e., intractable constipation or fecal incontinence from September 2006 to April 2014 in two French academic centers (Bordeaux, Nantes), were included consecutively. Each patient was followed by a gastroenterologist with an expertise in severe functional GI disorders and was labeled as refractory to standard therapies following failure of improvement by adequate diets combined with different lines of drugs. The indication of PEC was discussed in multidisciplinary meetings including gastroenterologists, surgeons, and the referring endoscopist of the hospital. Collected data included patient history and use of previous treatments (laxatives, enemas, perianal rehabilitation, neurostimulation devices, prucalopride, bisacodyl, neostigmin, botulinum toxin, Peristeen® artificial anal sphincter). According to the French legislation, no IRB approval was necessary for this retrospective study.

PEC technique (Fig. 1)

Colonic cleansing prior to the PEC procedure included 7 days of fiber-free diet and 3 days of oral polyethylene glycol (PEG). Antibiotic prophylaxis (either amoxicillin-clavulanic acid 1 g or ofloxacin 200 mg with metronidazole 500 mg) was administered intravenously 1 h before the PEC. In both centers, the colonoscopy was performed under general anesthesia (propofol) and CO₂ insufflation, in left lateral or supine position. Caecal position of the endoscope was confirmed using digital pressure and transillumination, and then, caecum was insufflated. The puncture site was disinfected with an

antiseptic solution. Then, three to four anchors (Chait trapdoor suture set™, Cook medical, USA or Harpoon T-fasteners™, Balt extrusion, Montmorency, France) were placed under endoscopic guidance to fix the caecum to the abdominal wall. In the center of the anchors, an 80-cm-long guide wire was introduced through a trocar from the outside and was used to introduce several dilators from 6 to 10 F and create the ministoma. Then, the final catheter (Chait trapdoor catheter™, Cook medical, USA) was introduced into the caecum over the guide wire and a rigid introducer and released as to place the external button in contact with the skin and the curved pigtail into the caecum. All previous steps were performed under endoscopic guidance, and the colonoscope was then retrieved with gradual exsufflation. After the procedure, patients received on-demand painkillers according to the intensity of pain as well as antibiotics for 72 h. They were discharged 1 to 7 days after the procedure, i.e., when they were able to eat normally and perform minimal physical activity. Two to three weeks after the procedure, patients spent 1 day in the ambulatory care unit to remove anchors, perform the first ACE with nurse assistance, and receive educational advice and material to facilitate the autonomous use of the Chait catheter at home. They were asked to use 1 l of standard tap water every day, then to adapt the pace and volume of water infusion according to the efficacy and tolerance of enemas.

Follow-up and outcomes

Quality of life and GI symptoms were assessed using standardized questionnaires before and at each visit, i.e., 1, 3, 6, and 12 months after the procedure and then annually. The physician evaluated overall patient's satisfaction regarding the device and noted adverse events during the visit. ACE volume and frequency were reported, and then adjusted according to their efficacy and individual patient's tolerance. The Chait catheter was changed for the first time at the 12-month outpatient visit, then annually. This procedure was performed without anesthesia, using a guide wire or not (at the discretion of the physician).

At each visit, patients were invited to complete standardized questionnaires about the quality of life and GI symptoms. The quality of life of patients (primary endpoint) was assessed using the French version of the previously validated Gastrointestinal Quality of Life Index (GIQLI) score, ranging from 0 to 144 (excellent) [14, 15]. This score includes 36 items including GI symptoms, physical status, emotions, social integration, and the effect of medical treatment. Constipation was evaluated using the Kess score ranging from 0 to 45 (severe constipation) [16]. Refractory fecal incontinence was assessed by the Cleveland score ranging from 0 to 20 (maximum fecal incontinence) [17].

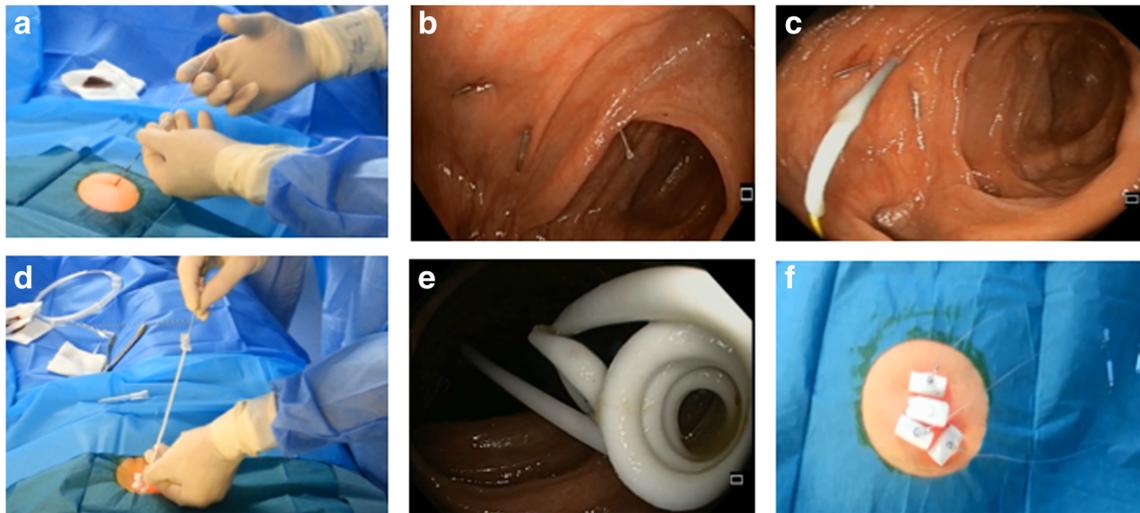


Fig. 1 Percutaneous endoscopic caecostomy procedure. **a** External view of the first anchor, **b** internal view of the caecopexy performed using three anchors, **c** dilation of the mini-stomy tract using 6, 8, and 10 French

bougies, **d** external view of Chait device during placement, **e** Internal view of the Chait device, **f** Aspect at the end of the procedure

Success or failure of PEC

In addition to standardized questionnaires, success or failure of the PEC technique for each patient was determined. The success was defined by the combination of the three following items: (1) absence of removal of the catheter or colonic surgery during follow-up, (2) improvement of the quality of life and digestive symptoms, and (3) patient answering ‘yes’ to the question: ‘would you recommend the PEC technique to someone suffering from the same condition?’. In contrast, failure was defined by the definitive removal of the catheter or a decision to perform colectomy or colostomy, or the absence of significant improvement regarding quality of life and GI symptoms, or a patient responding ‘no’ to the previously mentioned question.

Complications and adverse events

Adverse events were collected at each visit including intensity of local pain and use of painkillers at short and long terms, presence or absence of hypertrophic granulations at the PEC entry site, serous leakage, minor or major wound infection around the Chait catheter. Any catheter removal was collected and considered as a failure of the technique, even if the patient reported improved quality of life and symptom scores.

Statistics

The primary endpoint was the evolution of quality of life (GIQLI score) in each group. The secondary endpoints were evolution of the Kess score in constipated patients, evolution of the Cleveland score in incontinent patients, failure and success of PEC in each group. Statistics on scores were

performed using a Mann-Whitney test and Kruskal-Wallis test. A *p* value of less than 0.05 was considered significant.

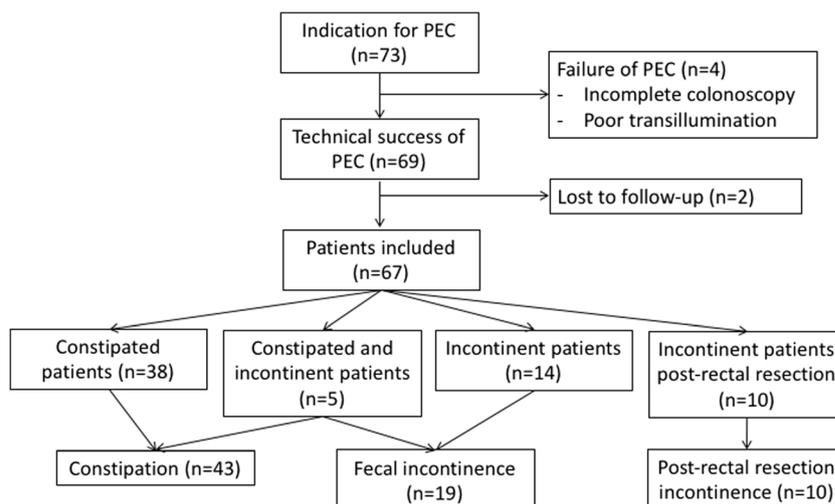
Results

Seventy-three patients with refractory functional digestive disorders were included (Fig. 2). In four patients, the PEC procedure failed due to incomplete colonoscopy *or* poor bowel preparation. Therefore, 69 patients completed the PEC procedure and underwent placement of the Chait catheter. Two patients were lost to follow-up at 3 months; consequently, results were analyzed in the 67 patients with at least 3 months of follow-up. Patients’ characteristics are reported in Table 1. Stratification according to symptoms and underlying disorders resulted in three groups of patients: constipation ($n = 43$, mean age 49 years), incontinence ($n = 19$, mean age 44 years), and incontinence following rectal resection ($n = 10$, mean age 52 years) (Table 2). Five patients had both refractory constipation and refractory incontinence.

Primary endpoint

The mean GIQLI score (Fig. 3) improved at 6 months from 69 ± 29 to 87 ± 24 ($p = 0.02$) in the constipation group, from 77 ± 21 to 110 ± 31 ($p = 0.04$) in the incontinence group, and from 71 ± 21 to 118 ± 10 ($p = 0.01$) in the incontinence following rectal resection group. The improvement of GIQLI score was still statistically significant at 12 months but not at 24 months in the constipation group ($p = 0.04$ and $p = 0.32$, respectively) as well as in the incontinence group ($p = 0.01$ and $p = 0.39$, respectively). No data were available after 6 months for the incontinence after rectal resection group.

Fig. 2 Study flowchart



Secondary endpoints

In the constipation group, mean scores of Kess (Fig. 4) were significantly decreased at every post-procedure time of the analysis ($p = 0.01$). In a similar way, mean scores of Cleveland were significantly decreased at every post-procedure time of the analysis ($p = 0.01$) in the incontinence group (Fig. 5a). In the incontinence after rectal resection group (Fig. 5b), the mean Cleveland score was dramatically reduced from 14 before procedure to 6 at 3 months and 3 at 6 months, respectively ($p = 0.02$ and $p = 0.01$).

Patients were classified as ‘success of PEC’ in 25 out of 43 (58%) in the constipation group, 14 out of 19 (74%) in the

incontinence group, and 9 out of 10 (90%) in the incontinence after rectal resection group (Fig. 6). No patient’s characteristic was predictive of success.

Among the main reported adverse effects, immediate post-procedure pain was present in 34 patients (51%), chronic pain in 34 patients (51%), hypertrophic granulations at the PEC entry site in 28 patients (42%), and minor wound infection in 13 patients (19%). At the 3-month visit, 27 out of 59 (46%) patients reported to use painkillers (level 2 or 3 in 16) in the post-procedure period.

During the follow-up, three patients died from unrelated cause, and 5 patients underwent colonic surgery (colectomy [$n = 3$], colostomy [$n = 2$]). A total of 19 devices were

Table 1 Characteristics of patients

	Constipation $n = 43$	Incontinence $n = 19$	Rectal resection $n = 10$
Mean age (range)	49 (23–75)	44 (19–69)	52 (27–69)
History			
Radiotherapy	1	Anorectal malformation	9
Anorectal malformation	2	Rectocele surgery	3
Rectocele surgery	1	Gynecological surgery	3
Gynecological tumor	2	Spina bifida	1
Gynecological surgery	6	Urinary incontinence	9
Spina bifida	1	Colo-perineal anastomosis	4
Urinary incontinence	10	Neurological patient	5
Colo-perineal anastomosis	1		
Neurological patient	12		
Previous therapy			
Medication	43	Medication	10
Enemas	41	Enemas	9
Péristeen®	10	Peristeen®	1
Botulinum toxin	1	Perineal rehabilitation	4
Perineal rehabilitation	12	Neurostimulation	4
Neurostimulation	5	Artificial anal sphincter	2
			Medication
			Enemas
			Peristeen®
			Botulinum toxin
			Perineal rehabilitation
			Neurostimulation

Table 2 Complications of PEC

Complications	Patients	%
Early pain	34	51%
Prolonged pain	34	51%
Local bud	28	42%
Infection suspected	13	20%
Catheter removal	19	29%

removed (28%) (15 constipated patients, 3 incontinent patients, and 1 constipated and incontinent patient) for confirmed local abscess ($n = 2$), inefficacy of ACE ($n = 3$), chronic local pain ($n = 7$), psychological instability ($n = 2$), inability to correctly use the Chait catheter ($n = 3$), and resolution of constipation following decrease of psychotrop drugs ($n = 2$) (Table 3). Seven patients underwent a catheter removal while showing an improvement in quality of life and in symptoms of digestive discomfort. The reasons for withdrawal among these patients were abscess [2], local pain [3], and decreased constipation by stopping neuroleptics [2].

Discussion

The results of this two-center analysis performed in routine practice show that PEC improves the quality of life and GI symptoms of patients referred for refractory colorectal functional disorders. It confirms our previous conclusions [18] regarding the feasibility and tolerance of PEC and on a larger group of patients, and it adds new information regarding the success rates of PEC according to the physicians’ perspective. In addition, it provides promising results of PEC regarding a new indication, i.e., the treatment of fecal incontinence after rectal resection.

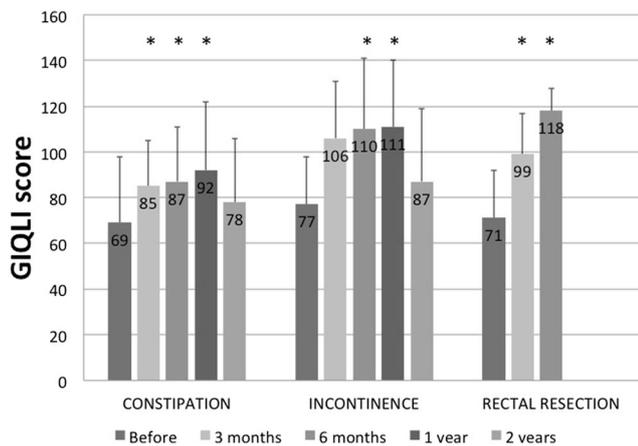


Fig. 3 GIQLI score evolution in patients from constipation, incontinence, and rectal resection groups who performed antegrade colonic enemas through a percutaneous endoscopic caecostomy before PEC, at 3, 6, 12, and 24 months ($*p < 0.05$)

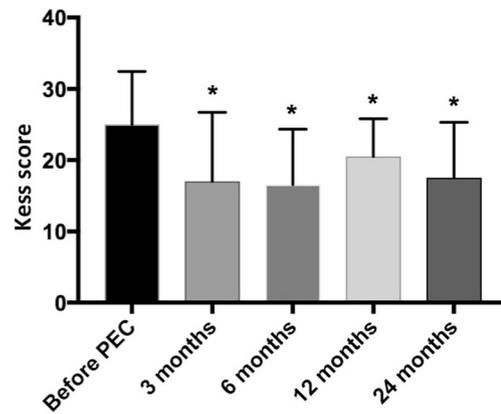


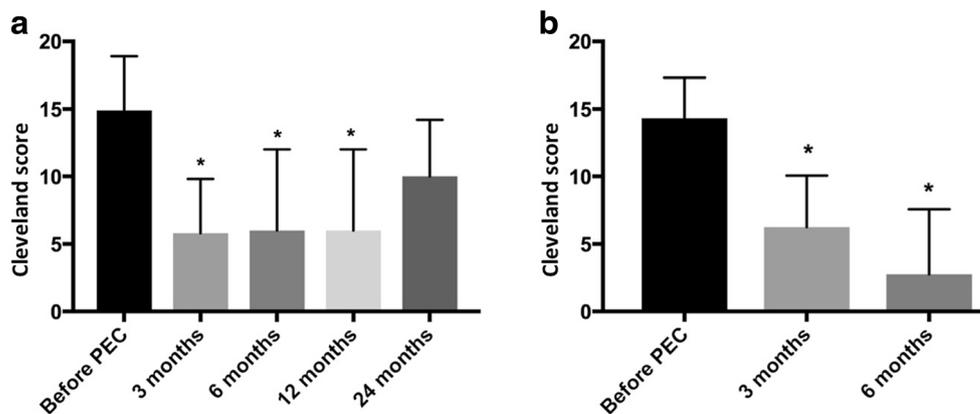
Fig. 4 Kess score evolution in the refractory constipation group before PEC ($n = 43$), at 3 ($n = 41$), 6 ($n = 29$), 12 ($n = 29$), and 24 months ($n = 19$) ($*p < 0.05$)

Indeed, it is the first study on the effectiveness of the PEC in patients undergoing resection for rectal adenocarcinoma. Little is known on these patients who have poor quality of life due to frequent soiling episodes with a highly negative social impact, despite the cancer remission. In the present study, PEC provided a 90% success rate, with a significant improvement of both quality of life and incontinence scores. However, the small number of patients in this group and the lack of mid- or long-term data are an important limitation, which warrants further evaluation on a larger cohort.

In patients with refractory constipation or severe uncontrolled incontinence as predominant symptom, this study shows a significant improvement of the GIQLI score, as well as the constipation and incontinence scores. These results obtained in 69 patients further confirm the initial results of our pilot series of 19 patients [13]. Also, apart from the patient’s perspective drawn from standardized questionnaires, the present study adds new information from the physician’s perspective regarding success or failure of PEC during follow-up. Although partly subjective, it is interesting to note that the success rates of PEC are quite high in these refractory situations where previous medical strategies failed. However, it is important to observe that the difference in terms of quality of life was no longer statistically significant at 2 years as compared to the period before PEC. This could be due either to a clear decrease in quality of life or to a lack of power due to the small sample size. So far, no long-term data regarding the efficacy of PEC are available in the literature.

A limitation regarding the refractory constipation group is that collected data did not allow us to distinguish between transit and distal constipation. It is therefore possible that, among 40% of these patients considered as ‘failure’ of PEC, a more subtle stratification might show differences among groups and predictive factors for success of PEC. Further studies should explore these patients with better characterization of the disease’s profile to help refine the PEC indications in refractory constipation.

Fig. 5 a Cleveland score evolution in the incontinence ($n = 19$) group before PEC ($n = 29$), at 3 ($n = 27$), 6 ($n = 15$), 12 ($n = 12$), and 24 months ($n = 5$) ($*p < 0.05$). **b** Cleveland score evolution in the post-rectal resection group before PEC ($n = 10$), at 3 ($n = 10$) and 6 months ($n = 6$)



While no severe complication was noted in our study, the adverse event rate was quite high and led to removal of the catheter in almost one third of patients, especially because of local chronic pain. This appears to be a significant limitation since almost half of patients who underwent catheter removal for local chronic pain also reported a good efficacy of ACE. There is no clear explanation for local chronic pain (25), for which we could not find predictive factors. Therefore, complete and clear information should be given to the patient before the PEC procedure. Injury during the procedure to pain-sensitive fibers from ilioinguinal and iliohypogastric nerves located in the right iliac fossa, as well as nerve irritation around anchors used for caecopexy have been proposed as potential causes [19]. In our experience, the migration of anchors in the colonic wall has also been observed in rare cases, but their surgical removal did not improve symptoms. Prophylactic measures and potential improvements of the PEC technique are important challenges to reduce post-operative pain and avoid removal of catheters when ACE are efficient.

Another issue is the number of minor wound infection, which might have been overrated in our series since we

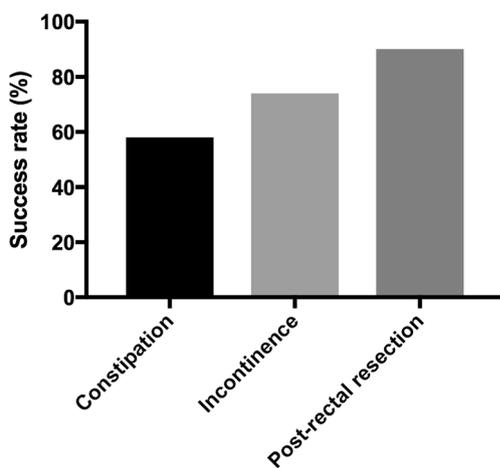


Fig. 6 Success rates of percutaneous endoscopic caecostomy according to initial presentation

considered as suspicious for infection any leakage or local redness requiring antibiotics use by the patient. Indeed, only 2 out of 67 (3%) catheters have been removed due to proven local abscesses, and most of the other ‘minor wound infections’ cases have been treated at home by oral antibiotics based on clinical examination only. Stronger collaboration between teams trained in expert centers with the management of PEC and general practitioners might help, at least in part, exploring more thoroughly any suspicion for local wound infection and avoid unnecessary antibiotic treatments.

Whether PEC should be offered in routine clinical practice to patients or limited to research programs is a relevant question. In 2013, a Canadian study compared the Malone surgical technique to PEC [20] with respect to efficacy, complications, percentage of patients switching to the other technique, and length of hospital stay. Fecal continence rates were similar (85% for the Malone surgical technique and 91% for PEC, respectively). The most frequent complications were stomal pain (23%), difficulty to catheterize the appendix (19%) following the Malone surgical technique, and difficulty to flush water through the catheter (26%) following PEC. Finally, 8.7% of PEC-first patients switched to the Malone surgical technique, while 11.5% of Malone-first patients switched to PEC. Mean length of hospital stay was similar in the two groups.

Finally, in our experience, PEC is technically easy to perform in routine practice and offers good results in terms of

Table 3 Reasons for catheter removal

Catheter removal	
Abscess	2
Inefficient device	3
Local pain	7
Difficulty of acceptance	2
Difficulty of use	1
Improved constipation	2
Missing data	2

clinical efficiency, provided the patient can be autonomous with daily antegrade colonic enemas. This multicenter study shows that PEC does not only have a positive impact on GI symptoms, but also significantly improves, at least at short- and mid-terms, the quality of life of patients with colorectal functional disorders refractory to medical treatment. Local chronic pain at the catheter site is the most important limitation and deserves further understanding in order to improve patients' pain management.

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Compliance with ethical standards

Conflict of interest E Coron has received speaker's fees from Cook medical and Fujifilm, and is member of the board of Medtronic. J Ricard, L Quénehervé, C Lefevre, M Le Rhun, E Chabrun, E Duchalais-Dassonneville, G Meurette, Y Touchefeu, S Bruley des Varannes, and F Zerbib have nothing to disclose.

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