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HOW-I-DO-IT ARTICLE

"Virtual ileostomy" combined with early endoscopy to avoid a diversion ileostomy in low or ultralow colorectal anastomoses. A preliminary report

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Abstract

Purpose Despite the benefits of a loop ileostomy after total mesorectal excision (TME), it carries a significant associated morbidity. A "virtual ileostomy" (VI) has been proposed to avoid ileostomies in low-risk patients, which could then be converted into a real ileostomy (RI) in the event of anastomotic leak (AL). The aim of the present study is to evaluate safety and efficacy of VI associated with early endoscopy in patients undergoing rectal surgery with anastomosis to detect subclinical AL prior to the onset of clinical symptoms for sepsis.

Methods This is a single-center, retrospective study of a consecutive series of patients undergoing elective or emergent colorectal surgery with low or ultralow colorectal or ileorectal anastomosis between September 2015 and September 2016.

Results We included 44 consecutive, unselected patients. Eight patients (18.2%) required conversion into RI and one required terminal colostomy because of AL, of whom 44.4% were asymptomatic and AL was detected with early endoscopy. Fashioning of RI was not associated with further morbidity. All patients with AL converted into RI ($n = 8/9$) (88.9%), had adequate healed anastomosis, and later underwent stoma closure with no complications. A stoma was avoided in 79.6% of VI. Endoscopy was associated with 55% sensitivity and 100% specificity, with a global accuracy of 88%.

Conclusions The combination of VI with early postoperative endoscopy could avoid unnecessary ileostomies in patients with low or ultralow anastomoses and reveal AL before the onset of symptoms, thus reducing associated morbidity.

Keywords Virtual ileostomy · Colorectal anastomosis · Anastomotic leak · Complication · Early postoperative endoscopy · Ghost ileostomy

Introduction

A protective ileostomy after total mesorectal excision (TME) for rectal cancer seems to be well-supported by literature [1, 2]. Loop ileostomies do not significantly reduce the anastomotic leak (AL) rate but decrease the severity of associated symptoms [1–6]. Nonetheless, acceptable morbidity and mortality rates have been reported in series from specialized centers when performing a TME without protective stomas in selected patients [7, 8].

Loop ileostomies and their closure are not complication-free, and several studies found that associated morbidity can be significant [9–11]. Therefore, the initial benefits could be downplayed by potential subsequent complications [9, 10],

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and this adds to the negative physical and psychological impact until the stoma is eventually closed [12]. Given the importance of stoma-related morbidity and mortality, and the impact on quality of life, its systematic use might be questionable.

Predictive scores for AL after rectal surgery have been proposed [13]. It has been suggested that those patients with an estimated low risk of AL could be considered for a "virtual ileostomy" (VI). Should AL occur, VI could easily be converted into a real loop ileostomy (RI) more easily [14]. This strategy has been associated with a decrease in the expected number of ileostomies (up to 87%), with no increase in the rate of complications or mortality [15–19]. However, the use of AL prediction scores is not supported by strong evidence [13]. Endoscopy in the early postoperative phase could hence be useful to identify AL before the onset of clinical symptoms.

The aim of this study is to assess whether the combination of VI and early postoperative endoscopy could result in a safe reduction of protective ileostomy rates in patients who might require a temporary diverting ileostomy after colorectal or ileorectal anastomosis.

Methods

This is a retrospective, single-centre study on a prospectively maintained database of patients who underwent stapled colorectal or ileorectal low or ultralow anastomosis with VI from September 2015 to September 2016. The study adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies [20].

In this pilot study, all cases were performed by five staff colorectal surgeons from a specialized colorectal unit following a standard operating procedure and perioperative protocol.

Inclusion and exclusion criteria

All consecutive patients aged ≥ 18 years with complete anastomotic doughnuts, negative intraoperative air leak test, and no intraoperative technical complications (bleeding, tension stress, or ischemia of the stapled anastomosis) were considered for VI during elective or emergent procedures. Only patients with low or ultralow anastomoses were analyzed.

Definitions

A low anastomosis was performed in patients who received low anterior resection, below the peritoneal reflection, with partial mesorectal excision (PME), while an ultra-low anastomosis was performed after an ultra-low resection with TME (resection of the lower 2 cm of the rectum) according to the International Study Group of Rectal Cancer [21].

AL was defined as either (1) a clear communication between intraluminal and extraluminal compartments due to a defect in the integrity of the intestinal wall at the level of the anastomosis, or (2) as pelvic collection (even in the absence of a communication with the bowel). AL was graded according to the International Study Group of Rectal Cancer table of definition and severity grading of anastomotic leakage after anterior rectal resection and to subsequent treatment [21].

Surgical technique, and intraoperative and perioperative pathways have been previously described [22]. A brief description is provided in the following paragraphs.

Pre-operative and intra-operative stage

All patients who underwent elective rectal surgery received bowel preparation with a soft clear liquid regimen and osmotic agents (Citrafleet®), and a specialized stoma nurse marked the stoma site preoperatively. A perioperartive dose of intravenous antibiotics and thromboembolic prophylaxis with LMWH was used following the perioperative policy at our Centre. A pelvic drainage was used systematically. In patients operated on in emergency, an intraoperative "wash-out" technique was carried out if necessary.

VI was created with the terminal ileum, 20–30 cm proximal to the ileocecal valve. The loop was hooked up with a vessel–loop, and the efferent limb was marked with a stitch. Then, the vessel–loop was exteriorized through the site marked for the stoma, usually where a 5-mm trocar was placed, and it was stitched to the skin (Fig. 1) [19]. Attention was paid to gently pull the bowel loop close to the abdominal wall, in order to avoid obstructing the lumen.

Post-operative stage

According to the colorectal surgery protocol at our Centre, C-reactive protein (CRP) and procalcitonin (PCT) were measured on postoperative day (POD) 1 and POD 4. Patients underwent routine endoscopy on POD 3, which was repeated on POD 5 in doubtful cases. Endoscopy was performed at the endoscopy unit using a flexible endoscope without insufflation, and the anastomosis was washed with water to achieve adequate visualization and removal of clots (Fig. 2, Suppl. Fig. 1). Additional imaging tests were performed in patients with clinical or analytical signs of sepsis in order to exclude intrabdominal collections.

In case of AL, conversion of VI into RI was indicated, irrespective of clinical symptoms. Conversion consisted of a circular incision around the vessel–loop and exteriorization of the ileal loop that was suspended with the vessel–loop at the time of surgery, fashioning a loop-ileostomy under local anesthesia (Fig. 3).

If no signs of AL were seen at endoscopy and an uneventful clinical evolution occurred, the vessel–loop was removed at discharge. A decisional algorithm is provided in Fig. 4.

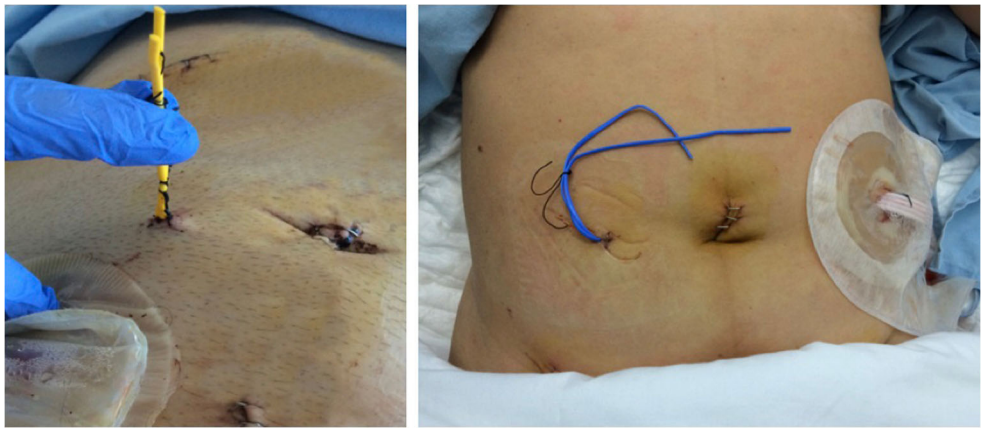

Fig. 1 Vessel–loop fixed to skin through the 5-mm trocar placed trans-rectally marked preoperatively. The vessel–loop references terminal ileum at 20–30 cm from the ileocecal valve for the creation of real ileostomy in the event of anastomotic leak. A pelvic drainage was used systematically

The study was approved by the Clinical Research Ethics Committee of the hospital.

Statistical analysis

Continuous variables are reported as median and interquartile ranges (IQR), whereas categorical variables are reported as absolute number and percentage (%). Differences in length of hospital stay (LOS) between the different complication groups were assessed by means of the Kruskal-Wallis test.

The statistical package for social sciences SPSS version 22.0.0 (IBM SPSS, IBM Corporation, Armonk, NY) was used for the analyses.

Sensitivity and specificity of early endoscopy were determined following agreed defintions [6], detailed in Supplementary Table 1.

Results

Forty-four consecutive patients were included in this study. Surgery was performed as an elective procedure in 90.9% of the cases, and half of them were performed with laparoscopy. Median age was 59 (range 28–84) years, with a male/female ratio of 2:3. Demographic and surgical data are described in Tables 1 and 2.

Thirty-day mortality was nil. A VI ($n = 44$) was converted into an RI in eight patients (18.2%) avoiding the need of a stoma in 77.2% of the patients (one patient required anastomotic disconnection and terminal colostomy). Three patients were excluded due to either medical complications not related to surgery or for declining early postoperative endoscopy. Postoperative endoscopy was performed in 41 patients on POD 3 and achieved 55.56% sensitivity (95% CI 21.2–86.3%), 100% specificity (95% CI 89.11–100%), and 90.24% global accuracy (95% CI 76.87–97.28%) (Suppl.

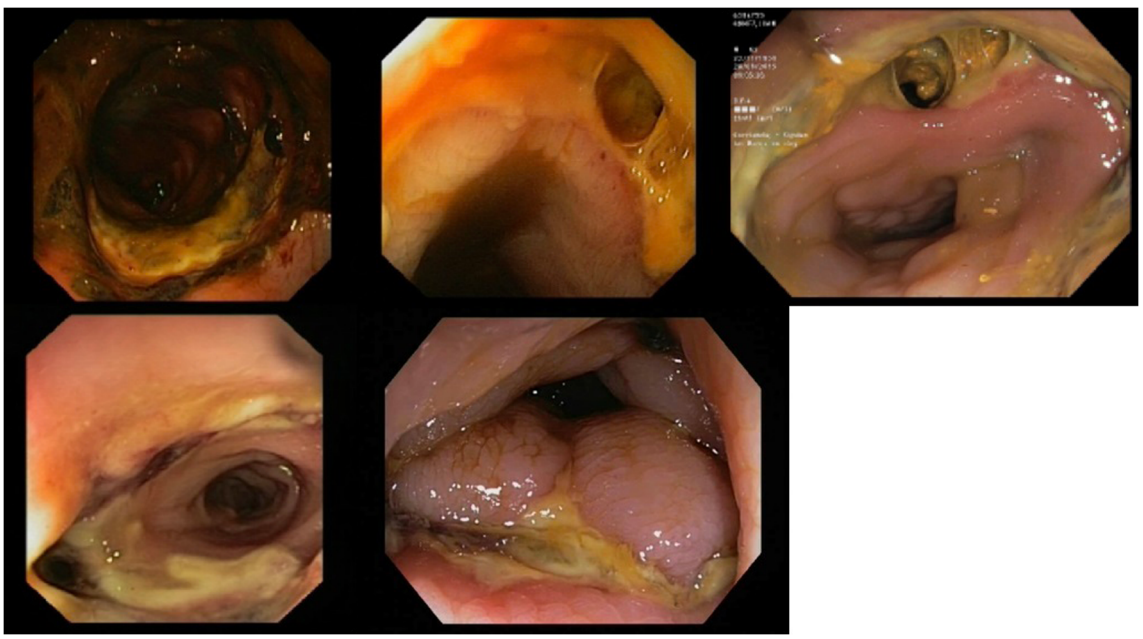

Fig. 2 Images show an anastomotic leak diagnosed by postoperative early endoscopy with a flexible scope without insufflation. In all endoscopically detected leaks, conversion of virtual ileostomy into real ileostomy was indicated, irrespective of clinical symptoms

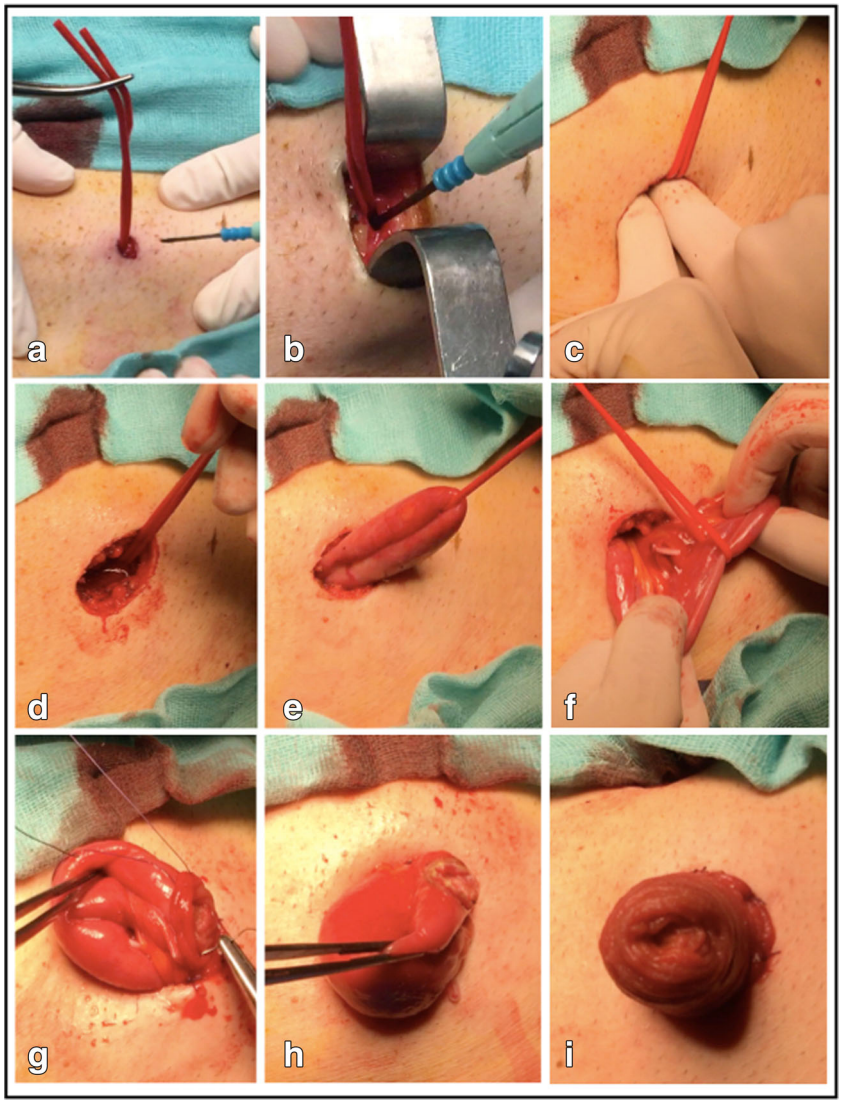

Fig. 3 Conversion of a virtual ileostomy into a real ileostomy. **a** A vessel–loop tutoring the terminal ileum is externalized during surgery. **b** The skin and subcutaneous and aponeurosis around the vessel–loop is opened with aponeurosis hole calibration (**c**). **d** Once the incision is made, the ileum is gently pulled through the incision (**e**), exposing the distal side marked in the first surgery. **g** The loop is cut open, and the distal side is stitched to the abdomen. **h** The proximal portion of the ileum is flipped open to expose the interior surface, and the opposite side is stitched in place (**i**)

Table 1). In a sub-group of five patients, endoscopy was repeated on POD 5 in order to confirm integrity of the anastomosis and resulted in 100% sensitivity and specificity. The endoscopic procedure lasted less than 10 min in all patients, and it was not associated with any complications.

All AL were diagnosed between POD 3 and POD 12.

Four (44.4%) of the nine candidates to an RI were asymptomatic and were diagnosed at POD 3 with endoscopy. In the other five cases (55.6%), signs or symptoms of pelvic sepsis were detected and confirmed by CT scan in four cases. In 66.6% of patients with AL, there was no need for a re-laparotomy or laparoscopy to convert the VI into an RI. In two patients (22.2%), a laparoscopic RI was performed because of preference of the operating surgeon, as this allowed for washing the abdominal cavity. As an adjunct to the pelvic drain placed during the surgery in all cases, in two patients, an endoanal trans-anastomotic mushroom catheter was used for drainage, with no need for other percutaneous or endoscopic therapeutic approaches for AL. No additional complications occurred after formation of the RI. All patients who required formation of an RI ($n = 8/9$) (88.9%) had adequately healed anastomosis and underwent stoma closure with no complications. The patient who needed laparotomy and anastomotic disconnection did not have the stoma reversed because of associated comorbidities (Table 3). The median height of the anastomosis from the anal verge was significantly lower in patients who needed conversion into RI (5 [4–6] cm vs 7 [5–8] cm, $p = 0.017$).

In patients with AL, the LOS was 12 days versus 8 days in those without AL ($p = 0.003$).

Discussion

We found that a combination of VI with scheduled early endoscopy is safe and could effectively avoid the need for

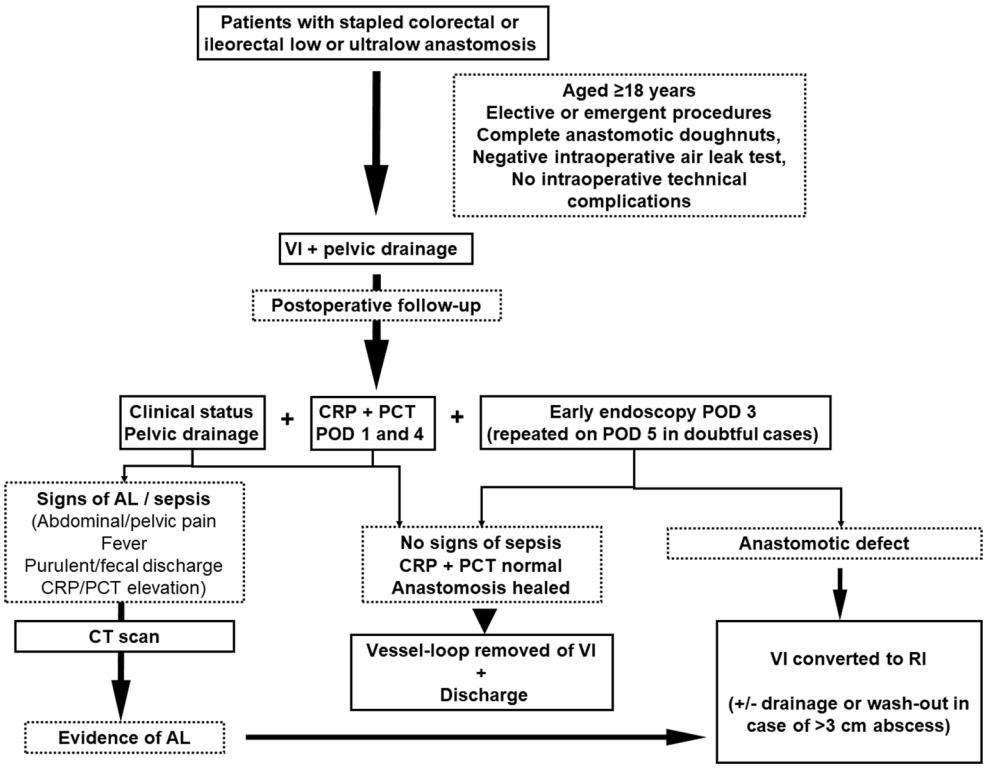

Fig. 4 Decisional algorithm for the current study. Please refer to the text for detailed explication. *VI* virtual ileostomy, *RI* real ileostomy, *CRP* C-reactive protein, *PCT* procalcitonine, *AL* anastomotic leak, *POD* postoperative day, *LOS* length of hospital stay

initially planned protective stomas in 77.2% of patients with low or ultralow colorectal and ileorectal anastomosis. This strategy resulted in a low morbidity rate in patients who needed conversion of VI into an RI, with no need for re-laparotomy or re-laparoscopy in the majority of cases.

Despite several meta-analyses published on the topic, there is no consensus concerning the need of systematically constructing a protective ileostomy after TME or PME. Protective ileostomies do not significantly reduce the AL rate, but they are believed to attenuate the severity of associated symptoms [3–6, 23].

Table 1 Demographic and surgical data

Demographic data	$n = 44$	%
Gender (*n*)		
Male	18	40.9
Female	26	59.1
Age (years) (median/range)	59	28–84
Type of procedure		
Elective	40	90.9
Urgent	4	9.1
ASA score		
I–II	34	77.3
III–IV	10	22.7
Surgical data	$n = 44$	%
Surgical time (min) (median/range)	300	215–510
Type of approach		
Laparoscopy	22	50
Laparotomy	22	50
Anastomosis height (cm) (median/range)	6	5–8

ASA American Society of Anesthesiologists

In a Cochrane review, Montedori et al. [1] included six randomized trials and found that 19.6% of all patients with TME without a protective ileostomy developed a clinical AL. Nevertheless, several authors reported acceptable rates of AL (ranging between 4 and 12%) following TME without a diversion in carefully selected patients who underwent surgery at specialized centers [3, 7, 24].

Loop ileostomies and their closure are not free from complications [7, 9], with an estimated morbidity as high as 66% [10, 11, 25]. Adverse events associated with a stoma include retraction, prolapse, necrosis, and skin damage, as well as dehydration and electrolytes imbalance in high-output stoma. In a meta-analysis with 6107 stoma closures [9], the rate of complications was 17.3%, with 0.4% mortality. Obstruction occurred in 7.2% of patients, requiring re-intervention in one third of the cases. Additional complications include surgical site infections (5%), AL (1.4%), and hernia (35%), needing further surgery in half of patients.

Besides, stomas significantly impact body-image perception and quality of life [12], and they bring about increased costs to the healthcare system.

Concerning low and ultralow colorectal anastomoses, most authors would suggest that protecting the anastomosis with a temporary stoma would be a safer option, but there are reports showing the safety of alternative strategies. Sacchi et al. [15]

Table 2 Diagnostic and performed procedures

Diagnostic	*n* (%)	Procedure	*n* (%)
Rectal cancer	25 (56.8%)		10 (38.5%)
Superior	13 (52%)	LAR (PME)	
Medium	9 (36%)	ULAR (TME)	15 (60%)
Inferior	3 (12%)	ULAR (TME)	
Ovaries Neoplasm + peritoneal carcinomatosis	11 (25%)	Supra-PPE	
		(PME)	10 (90.9%)
		(TME)	4 (100%)
Deep pelvic endometriosis	4 (9.1%)	ULAR (TME)	
Others:			
Crohn's disease Complicated diverticulitis	4 (8.9%)	LAR (PME)	4 (100%)
Colonic polyposis			
Hartmann reconstruction			

Supra-PPE Supralevator Posterior Pelvic Exenteration, *TME* total mesorectal excision, *PME* partial mesorectal excision, *LAR* low anterior resection, *ULAR* ultralow anterior resection

suggested that a VI could be a compromise to avoid the systematic performance of ileostomies and repeated laparotomy in patients with AL. In our series, using a VI and postoperative endoscopy, we were able to avoid a stoma in almost 80% of non-selected patients with low or ultra-low colorectal or ileorectal anastomosis. All these patients would have otherwise received a derivative ileostomy with associated medical, psychological, and economic impact. We found a similar stoma-sparing rate (77.2%) than that recently published by Sacchi (80%) [15], even if lower than that reported by Mori (91%) [19].

AL rate in our series (20.5%) is slightly higher compared with current literature figures, which vary between 5 and 19%, depending on location and type of anastomosis [26]. In 2012, Wexner et al. published the COMPRES study, reporting a 14% AL rate in the available literature concerning colorectal anastomoses at 10 cm from the anal verge, with and without protective ileostomies [27]. The higher rate observed in our study could be explained by the systematic use of postoperative endoscopy, which identified 44.4% asymptomatic leaks due to small anastomotic defects. These AL would not have been detected otherwise, but they could have resulted in deleterious consequences in the long-term. Of note, most studies did not systematically use imaging to detect AL, suggesting that published AL rates do not reflect the actual incidence of this complication. This also applies to studies published on VI. Sacchi et al. included patients with VI who underwent the same type of surgery, reporting an 18% clinical AL rate. No method of early detection was used in this study, which may have underestimated sub-clinical AL [18].

In our series, eight out of nine patients with preclinical or paucisymptomatic AL (88.9%), a VI was successfully converted into an RI, and only one patient (11.1%) required disconnection of the anastomosis and terminal colostomy. These figures were in line with those reported by others (10–12.5%) [18, 19]. Conversion into RI was feasible, easy, and without complications. In 66.6% of AL, no surgical re-interventions were required. However, Mori et al. reported a 10% rate of re-laparotomies or re-laparoscopies, lower than in our series (33.4%).

The main and the most common disadvantage in most of the published studies on VI is that AL findings are based on clinical symptoms/signs and serology, which can delay the diagnosis [28–30]. Early endoscopy allows for prompt detection of AL before signs and symptoms of sepsis develop, and it allows for timely formation of a stoma, thus reducing further morbidity [18, 19].

To our knowledge, this is the first study to investigate the role of routine early endoscopy as a guide for subsequent management in patients with a VI for high-risk colorectal anastomoses. In our series, sensitivity at POD 3 was 55.56%, which may be explained because of the late onset of most of the anastomotic leaks. In the sub-group of patients who had endoscopy at POD 5, we observed 100% sensitivity and specificity for AL. We did not offer endoscopy routinely at POD 5 because many of the patients were discharged on POD 4.

Every AL detected by postoperative endoscopy was successfully managed by converting the VI into an RI. We support its routine use because it is technically easy and replicable.

Importantly, all VI converted into RI were successfully closed. No stenoses or other complications occurred after closure. Mori et al. [19] reported that 73% of VI converted into RI were eventually closed. The higher stoma reversal rate (i.e., closure of RI) in our series could be related to the early diagnosis of AL by means of endoscopy.

In this preliminary series, the patients were not selected according to their associated risk factors for AL. There is a need for more solid evidence concerning predictive tools for

Table 3 Demographic, preoperative, surgical, pathological and postoperative details for the patients with anastomotic leak

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9
Age	72	69	76	53	72	79	53	58	65
Gender	M	M	M	M	M	F	M	M	M
DM	No	No	No	No	No	No	Yes	No	No
BMI	22	26	28	31	22	23	28	28	35
AHT	No	No	No	Yes	Yes	No	Yes	No	Yes
ASA Score	I-II	I-II	I-II	I-II	III-IV	I-II	I-II	I-II	I-II
Disease	Rectal cancer	Rectal cancer	Rectal cancer	Rectal cancer	Rectal cancer	Rectal cancer	Rectal cancer	Rectal cancer	Rectal cancer
Neoadjuvant treatment	No	No	Yes	No	No	No	No	No	No
Approach	LAP	LAP CONV	LAP	OPEN	LAP	LAP	LAP	LAP	LAP
Type of ME	TME	TME	TME	TME	PME	TME	TME	TME	PME
Height of anastomosis (cm)	5	6	4	4	6	6	4	2	7
AL DIAGNOS	END	END	END	END	CLINIC + CT SCAN	CLINIC + CT SCAN	CLINIC	CLINIC + CT SCAN	CLINIC + CT SCAN
POD VI EXTERIORIZED	3	3	3	3	10	12	7	4	7
Anal drain	No	No	No	No	No	No	No	Yes	Yes
Relaparotomy/relaparoscopy	No	No	Laparoscopy	No	Laparoscopy	Laparotomy	No	No	No
LOS (days)	8	10	10	14	19	6	16	5	20
Stoma closure	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes

DM diabetes mellitus, *BMI* body mass index, *AHT* arterial hypertension, *ASA* American Society of Anesthesiologists, *ME* mesorectal excision, *TME* total mesorectal excision, *PME* partial mesorectal excision, *AL DIAGNOS* type of anastomotic leak diagnosis, *END* endoscopy, *CLINIC* clinical, *CT SCAN* computed tomography scan, *POD VI EXTERIORIZED* postoperative day virtual ileostomy exteriorized, *LOS* length of hospital stay

AL after rectal surgery, because they would be useful in the decision-making process of performing a derivative stoma [10].

In 2011, Dekker et al. published the Colon Leakage Score, which might predict AL risk after colorectal anastomosis and help surgeons in the decision-making process [13]. However, some aspects remain to be addressed, such as the validation of a wider series of patients. Future studies could aim to validate predictive scores for AL and select patients with a low to moderate risk for VI. Therefore, only those patients with a validated high risk of AL would benefit from an RI.

Study limitations

This study has several limitations, including its retrospective fashion and the heterogeneous sample of patients included in the analysis. It should be noted that several surgeons were involved in the study, and this could have been a source of bias and variability. On the other hand, procedures were carried out at a single center, following agreed perioperative pathways. Of note, the fact that several surgeons were involved in the procedures confirms applicability in different scenarios and replicability on a global scale. Furthermore, endoscopy has never been routinely advocated to guide the fate of VI. Our findings offer original perspectives which warrant further investigation.

Conclusions

A combination of VI and postoperative endoscopy allowed us to avoid unnecessary ileostomies in patients with high-risk colorectal anastomoses and early detection of AL. In case of AL, their related complications can be safely avoided converting the VI into an RI.

Further multicentric studies are warranted in order to establish the role of the herein proposed strategy.

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Authors contributions Study conception and design BFL, LSG, MF, SDDP, EGG. Acquisition of data BFL, LSG, MF, AGG, MPR, SDDP, VPA. Analysis and interpretation of data BFL, LSG, MF, GP, AGG, MPR, SDDP, VPA. Drafting of manuscript BFL, LSG, MF, GP, EGG. Critical revision of manuscript BF, LSG, MF, GP, AGG, MPR, SDDP, VPA, EGG.

Compliance with ethical standards The study was approved by the Clinical Research Ethics Committee of the hospital.

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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