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Combined repeat laparoscopy and transanal endolumenal repair (hybrid approach) in the early management of postoperative colorectal anastomotic leaks: technique and outcomes

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Abstract

Background Few clear recommendations exist for the management of colorectal anastomotic leaks, often based on surgeon preferences or institutional protocols. The primary goal was to evaluate the feasibility and safety of the combined laparoscopic and transanal (hybrid) approach to treat postoperative colorectal anastomotic leaks. The secondary goals included comparison of outcomes following early (< 5 days after initial resection) versus late (≥ 5 days) detection of leaks.

Materials and methods Sixteen hemodynamically stable patients, with anastomotic dehiscence < 50% of the circumference after laparoscopic anterior resection underwent repeat laparoscopy (lavage/drainage) and transanal endolumenal repair (7 low (< 5 cm from the anal verge) with an ordinary anoscope and 9 high (≥ 5 cm from the anal verge) with a transanal endoscopic operations (TEO®) platform).

Results The median delay to detection and management was 4.5 days. The procedure was feasible in 13/16 patients (3 patients required conversion to laparotomy). Primary healing of the anastomosis was obtained in 14 patients (13 with the combined procedure, one after conversion). Two patients (1 early, 1 late) sustained persistent purulent discharge via their drain, but the repair healed secondarily. All patients requiring conversion to laparotomy ($n = 3$) or sustaining intra-operative complications ($n = 3$) were in the delayed group. No patients required further intervention or died. Protective stomas, created either at index surgery ($n = 7$) or at re-operation ($n = 9$), were closed in 14/16 patients within 6 months and no anastomotic sinus, persistent or recurrent fistula, was noted at 1-year follow-up.

Limitations This is a single-center study consisting of small sample size.

Conclusions Combined repeat laparoscopy and transanal endolumenal repair is feasible and safe, potentially reducing postoperative morbidity associated with repeat laparotomy and anastomotic leaks. Early detection and re-intervention are fundamental to success. Currently missing from the International Study Group of Rectal Cancer recommendations, laparoscopy and endolumenal repair could be added as a therapeutic option in Grade B.

Keywords Laparoscopy · Anastomotic leak · Endolumenal repair · Early detection · Morbidity

Colorectal anastomotic leaks are among the most dreaded early postoperative complications in elective colorectal surgery [1]. Leaks are associated with high morbidity, persistent stomas, high costs, and mortality (6–22%) [1, 2]. Notwithstanding various techniques and preventive measures, the leak rate after colorectal anastomosis remains between 1 and 22%, with a relatively higher incidence of leaks in low colorectal anastomosis or coloanal anastomosis [1, 3–5]. Anastomotic leaks have been found to be associated with poor oncological outcomes (higher local recurrence, more distant metastases, and reduced survival rates) [6–8].

Management of anastomotic leaks can lead to considerable morbidity originating from serial percutaneous drainage procedures, re-operations, and stoma creation, resulting in permanent stomas in 12–56% of patients [9–11]. Further morbidity stems from prolonged stay in intensive care, sepsis, and abdominal wall complications [12] as well as stoma

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or other leak-related complications, all of which affect the quality of life [13].

Recently, the International Study Group of Rectal Cancer (ISREC) [14] proposed a classification of colorectal anastomotic leaks, validated later by Kulu et al. [15], as a guide for subsequent management: Grade A, anastomotic leakage requiring no active therapeutic intervention; Grade B, anastomotic leakage requiring active therapeutic intervention but manageable without repeat laparotomy; and Grade C, anastomotic leakage requiring repeat laparotomy, usually associated with takedown of anastomosis followed by end stoma or salvage of anastomosis with ileostomy [14, 15].

Repeat laparoscopy or transanal endolumenal repair or both (hybrid technique) constitute newer tactics that have been reported infrequently [16–24], but these modalities are not mentioned in the ISREC classification.

This study aims to evaluate this hybrid approach to treat colorectal anastomotic leaks in the acute setting and to propose that it be integrated into the ISREC classification.

Materials and methods

Goals

The primary goal was to evaluate the feasibility and safety of the hybrid technique to treat acute colorectal anastomotic leaks.

The secondary goals included evaluation of the rate of successful control of the leak and outcomes, and a comparison of patients presenting with early (defined as < 5 days after the initial laparoscopic resection) versus late (≥ 5 days after operation) detection of leaks.

Study population

Forty-three patients with anastomotic leakage after laparoscopic total mesorectal excision (TME) for malignant disease followed by colorectal or coloanal anastomosis were seen between June 2013 and June 2015 at China Medical University Hospital, Taichung, Taiwan (Fig. 1). Of these, 17 were treated with antibiotics alone and six were treated by percutaneous or transanal drainage. These leaks are grades A and B according to the ISREC definition. Four patients presented with septic shock, anastomotic dehiscence $> 50\%$ of bowel circumference, or colonic ischemia and underwent re-exploration via laparotomy and therefore are classified as Grade C.

Our study group included 16 patients: five patients who were either amenable to percutaneous drainage but were not treated successfully or in whom transanal drainage failed and 11 patients who would have required laparotomy according to the ISREC recommendations [14, 15], but were hemodynamically stable and in whom anastomotic dehiscence was $< 50\%$ of the circumference.

The study was approved by the departmental and institutional ethical committees of the University Hospital of China, Taichung, Taiwan.

Pre-operative and intra-operative evaluation

Once leaks were suspected clinically or identified during endoscopic/radiologic examination, abdominal computed tomographic (CT) scan was performed to evaluate the location and the size of the collections.

Intra-operative endoscopic endolumenal examination enabling direct visualization, confirmed the leak, provided an estimation of the size of the dehiscence and the distance from the anal verge, and assessed the vascularity of the mucosa of the adjacent colorectal segments.

Data evaluation

Baseline characteristics (age, gender, American Society of Anesthesiologists (ASA) score, body mass index (BMI), stage of tumor, tumor site, neo-adjuvant chemoradiation, type of surgery, and basic laboratory values) are illustrated in Table 1.

Leak-related characteristics (time to detection of leak, day of reoperative intervention, presence of stoma at 1st operation, conversion to open procedure, failure of transanal repair, control of anastomotic leak after intervention, intra-operative and postoperative complications, duration of stay in hospital, rate of stoma reversal, and in-hospital mortality) (Table 2) were collected and analyzed.

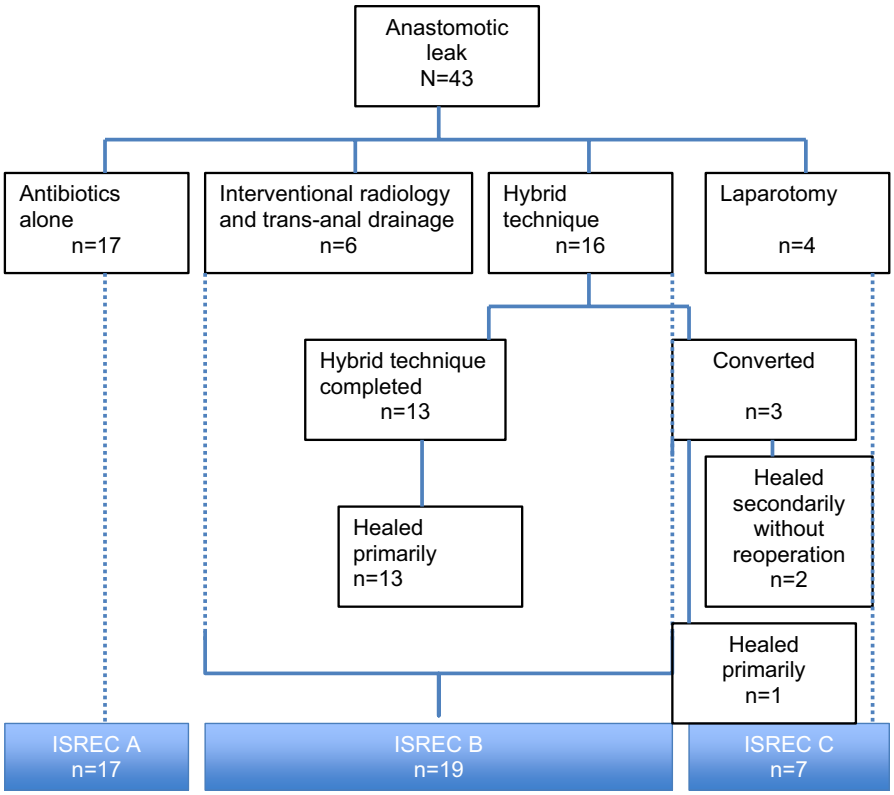
Surgical technique

Technique for repeat laparoscopy

All surgeries were performed by experienced laparoscopic colorectal surgeons. The patients were placed in a modified Trendelenburg position.

The open technique was used to insert a 10 mm port through the umbilicus (ideally through the previous umbilical port site) to create the pneumoperitoneum and then insert the camera. Intra-abdominal pressure was maintained at 12–15 mm Hg. The operation table was tilted according to the quadrant to be assessed. Subsequently, three or four 5 mm working ports were placed. Use of previous port sites was not always possible due to adhesions. Diagnostic laparoscopy was performed to assess the abdominal cavity and rule out any other iatrogenic injuries to the hollow viscera during initial surgery.

Pelvic adhesions with pus/fecal collections were observed in all patients. After evaluation, blunt adhesiolysis with



ISREC; International Study Group of Rectal Cancer
Grade A, anastomotic leakage requiring no active therapeutic intervention
Grade B anastomotic leakage requiring active therapeutic intervention but manageable without relaparotomy, and
Grade C anastomotic leakage requiring relaparotomy, usually associated with takedown of anastomosis followed by end stoma or salvage of anastomosis with ileostomy (14, 15)

Fig. 1 Patients with anastomotic leak and treatment modality. *ISREC* international study group of rectal cancer, *Grade A* anastomotic leakage requiring no active therapeutic intervention, *Grade B* anastomotic leakage requiring active therapeutic intervention but manageable without relaparotomy, and *Grade C* anastomotic leakage requiring relaparotomy, usually associated with takedown of anastomosis followed by end stoma or salvage of anastomosis with ileostomy [14, 15]

the suction irrigator and occasional sharp dissection using monopolar scissors or another energy-driven device was performed. The precise site of leak was usually difficult to identify especially when located < 5 cm from the anal verge. Copious lavage with saline was performed in all quadrants and all intra-abdominal collections were drained. Two drains were placed routinely in the pelvis, whereas additional drains were added in other quadrants as required.

Technique of transanal repair

Transanal repair of the dehiscence site was attempted in all 16 patients. Patients with low anastomotic leaks (< 5 cm from the anal verge) ($n = 7$) underwent repair under direct visualization using an ordinary anoscope, whereas a transanal endoscopic operations (TEO®) platform was used for higher anastomotic (≥ 5 cm from the anal verge) ($n = 9$) leaks. The leak site was easily identified in all cases (Fig. 2), and closed with continuous Vicryl® 2-0 sutures after debriding the mucosal edges of the defect, whenever possible (Fig. 3).

Successful outcome (anastomotic healing) was defined: (a) clinically: patient discharged without further need for care and not undergoing re-intervention, (b) radiologically: no leak or residual sinus on water-soluble contrast study performed 2 weeks after repair; (c) endoscopically: healed anastomosis as seen by flexible sigmoidoscopy performed 1 month after repair. Work-up before stoma reversal included water-soluble contrast study and flexible sigmoidoscopy at least 1 week prior to stoma closure.

Statistical analysis

Univariate analysis assessed the relationship between each factor and the outcome variables. No multivariable analysis was performed because the sample size and events were small. Comparisons were made using Fisher's exact test for all categorical variables and the Mann–Whitney U test for

Table 1 Baseline characteristics

	Patients ($n = 16$)
Age (years)	60.5 (32–89)
Male	15 (94%)
BMI (kg/m^2)	23.3 (19.3–34.1)
ASA	
II	11 (69%)
III	5 (31%)
Stage	
I	2 (13%)
II	4 (25%)
III	4 (25%)
IV	6 (38%)
Tumor site	
Rectosigmoid junction	4 (25%)
Upper rectum	3 (19%)
Middle rectum	5 (31%)
Lower rectum	4 (25%)
Neo-adjuvant therapy	9 (56%)
Hemoglobin (g/dl)	12.1 (7.5–15.2)
Glutamic pyruvate transaminase (U/l)	22 (9–55)
Creatinine (mg/dl)	0.9 (0.6–1.5)
Albumin (g/dl) ($n = 15$)	4.1 (2.6–4.9)
Carcinoembryonic antigen (ng/ml) ($n = 15$)	6.6 (0.7–4573.8)

Data are medians with interquartile ranges and ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

ASA American Society of Anesthesiologists, *BMI* body mass index, *TAMIS* transanal minimal invasive surgery

continuous variables. $p < 0.05$ was considered statistically significant, and all tests were 2-sided.

The data were tabulated on a Microsoft Excel spreadsheet (Excel for Mac; Microsoft Corporation, Redmond, WA) and then processed with R commander (version 2.1-7) (The R Foundation for Statistical Computing, Vienna, Austria, version 3.1.3).

Results and outcome

Characteristics of leaks

Fifteen of 16 leaks were detected during the same hospital stay (Table 2). One patient presented as an outpatient on postoperative day 22. Half of the leaks ($n = 8$) were detected within 5 days (median 3.5) of operation and were classified as early leaks (Table 3). The other half ($n = 8$) were detected 5 days or more after the initial operation and were classified as late. The median delay to detection of anastomotic leakage was 4.5 days (range 1–22).

In seven patients, the anastomotic site was low (< 5 cm from the anal verge) while in the other nine, the anastomotic site was high (≥ 5 cm). All seven patients had a protective ileostomy performed routinely during the primary operation. The median distance of anastomosis from the anal verge was 4.5 cm (range 2–10 cm).

The anastomotic site was located at 7 cm (median) from the anal verge in eight patients with early leaks, while it was 3 cm (median) for patients with late leaks: this difference was statistically significant ($p = 0.018$). Six of the late leaks were located less than 5 cm from the anal verge. Six of eight patients who presented late ($p < 0.001$) had a protective ileostomy at the initial operation. All patients requiring conversion to laparotomy ($n = 3$) or sustaining intra-operative complications ($n = 3$) were observed in the delayed leak group only (Table 3).

Univariate analysis found that patients with stoma ($p = 0.041$) and presence of low anastomosis ($p = 0.041$) were statistically significantly associated with late detection. Conversely, factors such as ASA status (II vs. III), early versus advanced stage of cancer, low versus high vessel ligation, or neo-adjuvant chemo-radiation did not affect the interval before detection of leak, the time before reoperative intervention, the difficulty of repair or outcomes.

Characteristics of re-operation and outcomes

Overall, the median delay between initial surgery and reoperative laparoscopy combined with transanal repair was 4.5 (range 1–22) days. In addition to the seven patients who already had a protective stoma at the initial operation, the other nine patients had a transverse loop colostomy performed during the reoperative procedure.

The median duration of the combined procedure was 176 (35–324) min with median operative blood loss of 20 (20–1650) ml. One patient in the late intervention group had significant blood loss (1650 ml) during adhesiolysis which required blood transfusion (Table 2). Three patients required conversion to an open procedure (one due to inadequate exposure and two because of dense adhesions). Two of these patients sustained intra-operative serosal tears during adhesiolysis which were repaired immediately. Transanal suture was not possible in one patient who presented late (on postoperative day 22) due to fragile and edematous tissues. This patient had undergone conversion for inadequate exposure: treatment was debridement, lavage, and placement of drains. All converted patients and the two patients with intra-operative serosal injury had an otherwise uneventful recovery.

The median duration of hospital stay for both operations was 12 days (range 5–62 days). The median hospital stay after the second intervention was 9 days (range 2–53 days) (Table 2).

Table 2 Operative characteristics

1st operation	
Low anterior resection	8 (50%)
Total mesorectal excision	8 (50%)
Stoma at 1st operation	7 (44%)
Operative time (1st) (min)	261.5 (191–439)
Blood loss (1st) (ml)	75 (20–360)
Vessel ligation low/high	9 (56%)/7 (44%)
Distance of anastomosis (cm from anal verge)	5 (2–10)
Low (< 5 cm from anal verge)/high (≥ 5 cm) anastomosis	7/9 (44%)
Interval to detection of anastomotic leak (days)	3.5 (1–22)
Early (< 5 days) detection (*n*)	8 (50%)
Detection after readmission	1 (6%)
2nd operation	
Laparoscopy + Stoma + TAMIS	9 (56%)
Laparoscopy + TAMIS	7 (44%)
Operative time (2nd) (min)	176.5 (35–324)
Blood loss (2nd) (ml)	20 (20–1650)
Postoperative (2nd) length of stay (day)	9 (2–53)
Total length of stay in days ($n = 15$)	12 (5–62)
Interval from 2nd operation to stoma closure in days ($n = 8$)	158.5 (62–531)

Data are medians with interquartile ranges and ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

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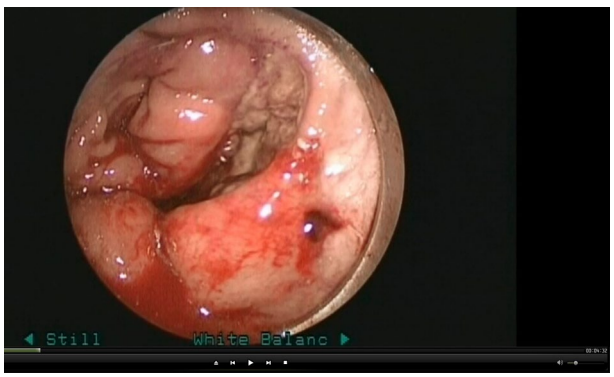

Fig. 2 Leak site was easily identified in all cases

Fig. 3 Closure of the leak site using Vicryl 2-0 continuously after debridement, when possible

Immediate success rate

The repaired anastomosis healed completely within 12 days for 14 patients (13 with the combined therapeutic modality, one after conversion) according to the above-mentioned clinical, water-soluble contrast study, and flexible endoscopy criteria. Two patients sustained persistent purulent discharge via their drain, which was managed conservatively: the anastomosis healed within 2 months without further intervention. All patients had completely recovered at 2-month follow-up. There was no in-hospital mortality (Table 3).

Follow-up characteristics

Stoma closure was achieved in 14 of 16 patients after a median of 158 (range 62–531) days. One patient refused any further operation while another patient expired during follow-up. The cause of death was unrelated to initial disease or the reoperative procedure.

One patient developed a short anastomotic stenosis 1 month after stoma closure which was managed by dilation as an outpatient. There were no other complications related to stoma closure. No anastomotic sinus, fistula, or recurrence was noted at 1-year followup.

Table 3 Comparison of outcome according to early (< 5 days) and late (≥ 5 days) detection and repeat operation

	Early (< 5 days) (*n* = 8)	Late (≥ 5 days) (n = 8)	*p*
Low anterior resection	5 (63%)	3 (37%)	
Total mesorectal excision	3 (37%)	5 (63%)	
Stoma at 1st operation	1 (15%)	6 (85%)	0.041
Operative time (1st) (min)	246 (191–379)	302 (206–439)	0.4
Blood loss (1st) (ml)	35 (20–300)	125 (20–360)	0.44
Inferior mesenteric vessel ligation low/high	4/4	5/3	1
Distance of anastomosis (cm from anal verge)	7 (2–10)	3 (2–6)	0.018
Anastomosis (< 5 cm from anal verge) (*n*)	1 (13%)	6 (75%)	0.041
Interval to detection of anastomotic leak (day)	3.5 (1–4)	7.5 (5–22)	< 0.001
Interval to 2nd operation (day)	3.5 (1–4)	7.5 (5–22)	< 0.001
Operative time (2nd) (min)	176.5 (112–211)	173 (35–324)	1
Blood loss (2nd) (ml)	20 (0–20)	20 (20–1650)	0.076
Bleeding requiring transfusion	0	1	1
Injury to other organs	0	2	0.47
Conversion to open procedure	0	3	0.2
Surgical site infection	1	1	1
Persistent purulent discharge	1	1	1
Anastomotic stenosis	0	1	1
Postoperative (2nd) length of stay (day)	8 (2–23)	11 (2–53)	0.34
Interval from 2nd operation to stoma closure	131 (107–269) (*n* = 8)	168 (62–531) (n = 6)	0.64

Data are medians with interquartile ranges and ranges in parentheses for continuous variables. Data are numbers with percentages in parentheses for categorical variables

ASA American Society of Anesthesiologists, *BMI* body mass index, *TAMIS* transanal minimal invasive surgery

Discussion

Our study showed that the combined laparoscopic and transanal endoluminal approach was a viable option for diagnosis and repair of colorectal or coloanal anastomotic leaks, performed successfully in 13 of 16 patients. Combined laparoscopic and transanal endolumenal repair of anastomotic leakage seems safe and effective if performed early after the initial operation since 14 of these repairs healed primarily without further complications; the other two patients sustained persistent purulent discharge that healed secondarily with conservative management. All postoperative complications but one occurred in patients treated late (≥ 5 days after initial surgery). There was no in-hospital mortality.

As laparoscopy has gained in popularity in the current era of elective colorectal surgery, several reports have highlighted the safety and success of diagnostic and therapeutic laparoscopy in the emergency management of septic situations, notably colonic diverticular perforation [19, 20]. The next logical step was to extend its role to the management of complications after colorectal surgery [16–18, 21, 23, 24].

Our study emphasizes that repeat laparoscopy can be an important diagnostic tool in this setting: it provides a complete view of the abdominal cavity, allows to assess and treat the intra-peritoneal consequences of the leak, offers the possibility of checking the vascularization of the proximal loop, and potentially adding information that might not always be obtained through imaging. Moreover, laparoscopy has therapeutic potential, enabling the surgeon to take appropriate management decisions such as suture repair of intra-peritoneal leaks, aspiration of infected fluid, peritoneal lavage, stoma formation, and placement of drains.

The role of repeat laparoscopy after colorectal anastomotic leak has been highlighted in several reports [16–18, 21, 23, 24]: all have suggested that repeat laparoscopy was feasible and safe while avoiding the need for a midline laparotomy incision [17, 18].

Of note, however, timing of re-intervention is of critical importance. As observed in our study, there was no intraoperative or postoperative morbidity or conversion to open surgery needed in patients undergoing early re-operation (< 5 days) when compared to late intervention (≥ 5 days) (morbidity = 37%). One of the possible explanations is that early anastomotic failure is usually due to mechanical failure rather than ischemia [25] and therefore primary healing can still occur after re-suturing the anastomotic dehiscence. Moreover, patients presenting late usually have dilated bowel, dense adhesions, and considerable contamination. Adequate visualization and navigation in the intra-abdominal cavity is difficult, increasing the risk of hollow viscera

injury and the need to convert. Indeed, all three conversions were necessary only in patients who were seen late (≥ 5 days), two because of dense adhesions and one because of dilated intestinal loops, most likely a consequence of the uncontained anastomotic leak. This conversion rate for adhesions is in agreement with Agresta et al. who treat peritonitis via the laparoscopic route [26] where conversion was necessary in 23.2% of patients with peritonitis and was mainly due to the presence of dense intra-abdominal adhesions.

Special attention is warranted in patients with previous protective stoma, and the possibility of leak should not be eliminated just because the patient has a stoma. Anastomotic leakage was detected late in six of seven patients with low anastomosis and protective stoma in our series. The stoma may have contributed to substantial delay in detection and management and consequently to further morbidity.

Most anastomotic leaks heal after proximal diverting stoma but some persist as discrete sinuses (1–5%) or ultimately cause rectovaginal/rectourethral fistula [27, 28] and can further delay stoma closure [24, 27]. Intestinal healing after anastomotic leak can be associated with intense fibrosis and eventually some degree of postoperative stenosis [29, 30]. Persistent complications sometimes require complex surgery (delayed transanal repair using an advancement flap associated with marsupialization of the tract) with limited success rates [31, 32]. We believe that early repair could possibly avoid these complications or at least reduce the inflammatory response associated with their persistence.

It was possible to visualize and manage the anastomotic defect transanally in all patients. The anastomotic dehiscence was sutured in 15 while one patient had local debridement only. This was possible with an anoscope for seven patients with a low anastomosis (< 5 cm) while a TEO port was used in the remaining nine patients. In our series, transanal endolumenal repair was possible in anastomotic defects up to 10 cm from the anal verge, avoiding, once again, the need for trans-abdominal repair. Another potential advantage of the endolumenal approach is the possibility of assessing the mucosal vascularity and the size of defect at the anastomotic site. On the whole, 14 anastomotic defects healed primarily and two healed after chronic discharge for several weeks but without further intervention.

The theoretical advantages to the hybrid approach are to reduce the morbidity associated with re-operation by laparotomy (reduced abdominal trauma leading to early recovery) as well as early and late morbidity associated with anastomotic leaks.

The possible benefits of adding a stoma for the secondary procedure would be to allow early enteral nutrition, prevent further contamination of the abdominal cavity and promote healing of the repaired leak site. Stoma creation should be performed judiciously as underscored by various authors [33, 34].

Recently, Brunner et al. [35] reported a similar combined technique with successful outcome in two patients. Of note, the authors did not perform any protective stoma in both patients who were kept under careful observation. In our study, a protective stoma was created in all patients who did not have one during initial surgery. This did not have any adverse consequences as the median duration of stay was 12 days in our series, comparable to that of repeat laparoscopy alone performed for postoperative complications without protective stoma (12–21 days) [16–18]. In our series, the stoma was closed in 14 of 16 patients: one patient died of unrelated cause before the stoma could be reversed, the other refused any further surgery. This closure rate compares favorably with the rates reported in the literature (52–80%), especially when compared to patients undergoing repeat laparotomy (41–60%) [16–18].

Presently, neither repeat laparoscopy nor endolumenal repair appears in the ISREC scheme [14, 15]. Based on our experience and the favorable outcome and acceptable morbidity with the hybrid approach, we believe that repeat laparoscopy and endolumenal repair should be included in type B (anastomotic leakage requiring active therapeutic intervention but manageable without relaparotomy) according to the ISREC recommendations [14, 15]. Accordingly, we have set up the following clinical pathway and selection criteria to manage colorectal leaks at our institution: all hemodynamically stable patients with early (< 5 days of the initial operation) detected leaks, located within 15 cm from the anal verge, where the dehiscence is less than 50% of the anastomotic circumference, are offered this hybrid approach of laparoscopic exploration followed by endolumenal transanal repair.

Our study has several limitations: this was a single-center study, and the series was small.

Further studies with larger numbers of patients could help highlight the pros and cons involved with this technique. Whether early transanal endoluminal repair of anastomotic leak can provide oncological benefits to the patient by reducing the risk of local recurrence remains undetermined at present; this requires studies with long-term follow-up.

Conclusion

Combined repeat laparoscopy and transanal endoluminal repair (hybrid approach) is feasible and safe in the management of early postoperative colorectal anastomotic leaks. It could possibly reduce early and late postoperative morbidity associated with anastomotic leaks or their repair. According to our experience, early detection and early re-intervention remain the key issues for success. A protective stoma was always added when the patient did not have one initially, as there is currently no evidence that this technique could

preclude the need for a protective stoma. Healing was ultimately satisfactory in all 16 patients, and stoma closure could be proposed to all living patients. Once this modality has been well established in the surgical literature, laparoscopy combined with endolumenal repair could be added to the therapeutic recommendations of the ISREC [14, 15]. We propose to add it to Grade B.

Compliance with ethical standards

Disclosures William Tzu-Liang Chen, Saurabh Bansal, Tao-Wei Ke, Sheng-Chi Chang, Yu-Chun Huang, Takashi Kato, Hwei-Ming Wang, and Abe Fingerhut have no conflicts of interest or financial ties to disclose.

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