


Implementing protocol-based relaparoscopy for severe complications in laparoscopic colorectal surgery

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Abstract

Background: Although laparoscopy has demonstrated growing applications for either primary colorectal resections or reoperations, no standardized criteria for implementing laparoscopy in revisional surgery have been reported. This study analyzes a single-center series of major complications after laparoscopic colorectal surgery, undergoing laparoscopic (LR), or open reoperations in compliance with a hemodynamics-based institutional management.

Methods: This study retrospectively analyzes a series of consecutive patients who primarily underwent either laparoscopic left colectomy or low anterior resection in a tertiary referral center between 2016 and 2021. Major complications requiring reoperation (MCR) were managed through an interdisciplinary protocol and submitted to reoperation according to patient hemodynamics and intra-abdominal contamination. A cohort analysis primarily assessed treatment failure rates (i.e., 90-day mortality and need for further surgery), while postoperative morbidity was secondarily examined.

Results: Out of 1137 laparoscopic colorectal resections, 497 patients met eligibility criteria, while 45 (9.1%) developed MCRs were managed according to the standardized interdisciplinary protocol. Revisional surgery was performed through either LR (66.7%) or (33.3%). Treatment failure was 13.3% overall, including additional surgery (11.1%) and 90-day mortality (6.6%) after reoperation. In both overall and anastomotic leak-specific MCRs, relaparoscopy resulted in minimized length of hospital stay, postoperative morbidity, and intensity of care.

Conclusions: Relaparoscopy for MCR preserves clinical benefits related to minimally invasive colorectal surgery. Further studies should investigate applicative determinants and impediments related to the center volume.

KEYWORDS

anastomotic complications, colorectal cancer, laparoscopic colectomy, laparoscopy, reoperation

Francesco Puccetti and Alessia Vallorani authors share the first authorship.

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1 | INTRODUCTION

Laparoscopic management of malignant and benign colorectal diseases has been globally increasing in daily clinical practice. Colorectal cancer (CRC), counting as the third most common malignancy worldwide and the second most deadly concurrently, is expected to increase globally (from 1.93 million in 2020 to 3.2 million in 2040) due to the westernization of developing countries and the subsequent spread of risk factors.^{1,2} Diverticular disease of the colon (DDC) has also been reporting a growing incidence over time, requiring surgical care more often for emergency treatment of acute inflammatory complications, recurrent prevention, and improvement of long-term quality of life.^{3–5} These epidemiological trends, combined with the establishment of minimally invasive techniques, are exponentially increasing the implementation of laparoscopic colorectal surgery (LCS). Following the initial outbreak in the early '90s, LCS demonstrated to provide multiple short- and long-term clinical benefits mediated by a significant reduction in operative stress response, such as earlier resuming of bowel functions, lower rates of intra-abdominal adhesions, reduced analgesic requirements, decreased length of hospital stay (LOS), and earlier return to daily activities.^{6–8} These findings have encouraged high-volume centers to extend laparoscopy to the most delicate patient subgroups, such as elderly or frail subjects,^{9–11} locally advanced tumors,^{12,13} and acutely presenting conditions.^{14–16} Eventually, minimally invasive surgery has been acknowledged within the array of available treatments for LCS complications.^{17–20} Also, technological advances associated with laparoscopy (e.g., energy devices and magnified video systems) have provided the potential to treat anastomotic leakage (AL) by maintaining all beneficial effects of a limited-impact approach.^{21,22} However, specific benchmarks of technical feasibility or indications for relaparoscopy have never been conceptualized and agreed upon in the literature, and applications remain depending on the surgical practice of individual institutions.

The hypothesis underlying this analysis was that major complications requiring reoperation (MCR) could be treated through a laparoscopic or open approach according to the presenting characteristics of surgical complications, such as the extent of intra-abdominal infection/contamination and the level of sepsis-related hemodynamic instability. Therefore, the present study analyzes a high-volume single-center series of major complications after LCS, which underwent laparoscopic (LR) or open reoperations (OR) performed in compliance with an institutional management based on clinical findings and vital signs of the systemic inflammatory response syndrome.

2 | MATERIALS AND METHODS

The present analysis and findings were reported in accordance with the Strengthening the Reporting of Observational studies in Epidemiology guidelines.²³

2.1 | Study design

This study retrospectively analyzes a single-center series of consecutive patients who underwent elective LCS from January 2016 to August 2021 at a high-volume center and presented MCR postoperatively. The inclusion criteria were as follows:

1. Diagnosis of CRC (histologically confirmed) or DDC;
2. Indications of primary operations of either left colectomy or low anterior resection through laparoscopic approach;
3. Elective surgery, in a non-emergency setting, allowing a management including preoperative multidisciplinary assessment and enhanced recovery after surgery (ERAS)-based perioperative protocol.

All considered patients underwent primary surgery, including a mechanical Knight–Griffen colorectal anastomosis, with the additional fashioning of temporary ileostomy in cases of low rectal cancer, previous neoadjuvant chemo-radiotherapy, or intraoperative findings of high anastomotic risk. These characteristics also determined the placement of perianastomotic drainage during surgery, which was routinely removed after resuming bowel functioning within postoperative day 4. According to the ERAS-based protocol, only lower anterior resections were administered with standardized bowel preparation within 24 h before surgery. Both colonic resections and underlying diseases other than those stated among the inclusion criteria were excluded to maintain a homogenous and comparable population. Within the study population, all MCRs managed in accordance with the institutional standardized protocol were selected and analyzed. Revision surgery was routinely performed by trained senior laparoscopic surgeons, while the choice of specific approach was based on the degree of intra-abdominal contamination (i.e., according to the involvement of peritoneal quadrants) and the patient's hemodynamic balance at the moment of the complication onset (Figure 1).

On the other hand, exclusion criteria involved patients presenting with acute mesenteric/intestinal ischemia or requiring laparostomy. Primary outcomes included all cases of treatment failure defined as postoperative mortality or the need for additional surgery after reoperation. Other clinical details concerning the recovery after reoperation were secondarily

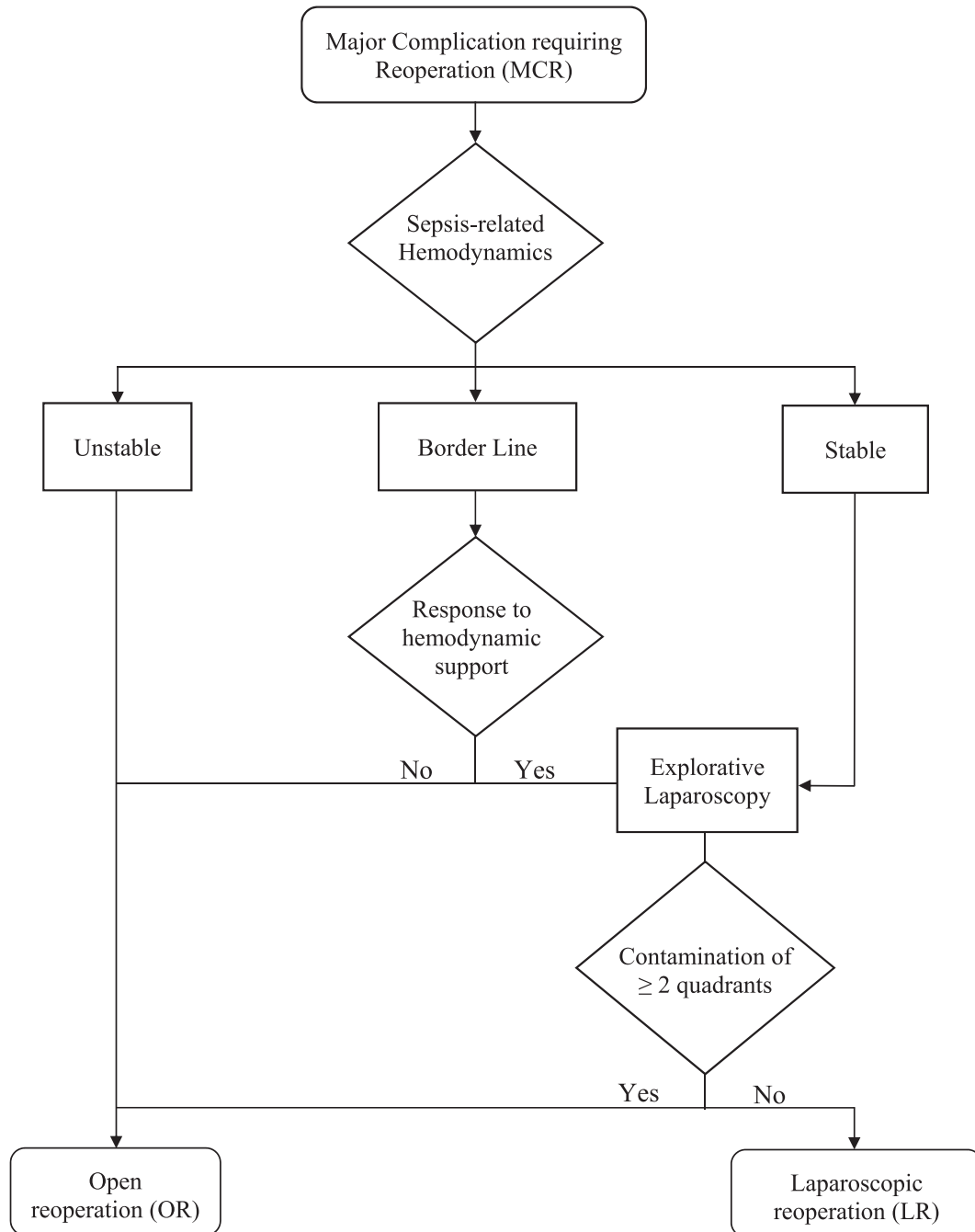


FIGURE 1 Flow chart of the standardized treatment for MCR.

assessed, such as overall morbidity, increase in the level of care (i.e., admission to the intensive care unit [ICU]), and LOS.

2.2 | Standardized protocol for MCR

The following clinical protocol was institutionally established in 2014 based on the collaboration between the units of gastrointestinal surgery and anesthesiology (Figure 1). All complicated patients were routinely

examined with an abdomen CT scan and blood test to confirm the indication of reoperation. The initial assessment comes after the diagnosis of MCR and aims to determine whether or not sepsis-related hemodynamic instability has occurred. According to specific criteria, patients' hemodynamic status can be defined as follows:

1. unstable: mean arterial pressure (MAP) < 65 mmHg, heart rate (HR) > 100 bpm, and despite supportive care (crystalloids administration up to 30 mL/kg in 3 h and use of vasoactive drugs)

2. borderline: MAP >65 mmHg with HR < 100 bpm after supportive care
3. stable: MAP >65 mmHg with HR < 100 bpm regardless supportive care

Depending on the level of hemodynamic instability, patients can be submitted to emergency reoperation through different settings and techniques. Unstable patients require an expedited and determined treatment making OR the most effective choice. For these patients, resuscitation and i.v. infusion therapy is immediately initiated at the bedside, and the anesthesiology rescue team is enabled. Borderline patients presented with initial signs of a septic shock, although a certain level of hemodynamic stability can be maintained by anesthesiological support therapy. Under these circumstances, patients can undergo a minimally invasive approach if responding (MAP >65 mmHg) to the following measures: infusion load of crystalloids and, if necessary, administration of vasoactive drugs.

Borderline (responders) and stable patients are likely to be successfully submitted to an exploratory laparoscopy. At this stage, a laparoscopic examination assesses the feasibility of LR based on the enteric contamination of the peritoneal cavity. Traditionally, the extension of more than two abdominal quadrants is a mandatory indication for OR to provide a more accurate inspection and extensive peritoneal washing. Of course, conversion to laparotomy may be performed at any time when hemodynamic instability occurs.

2.3 | Data collection and outcomes definition

A comprehensive array of data was retrospectively retrieved from an IRB-approved, prospectively maintained institutional database. Preoperative data included demographics (i.e., age, sex, and body mass index (BMI)), age-adjusted Charlson comorbidity index (aa-CCI),²⁴ American Society of Anesthesiologists (ASA) score),²⁵ and details of presenting colorectal diseases. Other data concerning primary surgery (i.e., type of colorectal resection, operative time and blood loss, and the fashioning of temporary ileostomy), postoperative complication and reoperation (i.e., postoperative day of complication diagnosis and treatment, Clavien–Dindo severity classification type,²⁶ surgical approach, and surgical procedure), and subsequent recovery period (i.e., further morbidity or mortality after reoperation) were also collected. In particular, postoperative complications reporting a Clavien–Dindo severity score higher than IIIa were considered major among which those restrictively requiring further surgery composed the MCR group.

Eventually, study outcomes were defined as follows: the increase in the level of care was referred to the need for admission to the ICU; overall LOS consisted of days between primary surgery and the definitive hospital discharge, while 90-day mortality was the primary outcome. In particular, definitive hospital discharge was defined as the leaving day without the following readmission either after an uneventful or complicated recovery.

2.4 | Statistical analysis

Further to the selection of major postoperative complications requiring reoperation (MCR group), a comparative analysis was performed between patients submitted to LR and OR. All cases that exclusively required reoperation for AL were separately analyzed in specific types of surgical procedures. Unless differently stated, continuous variables were reported as numbers (percentages), while categorical variables were presented as mean (\pm standard deviation). According to variable types and test assumptions, continuous variables were compared with the student's *t*-test, while categorical variables were analyzed using χ^2 and Fisher's tests. A *p*-value <0.05 determined the level of statistical significance and statistics performed through IBM SPSS Statistics v27.0 (IBM Corp.).

3 | RESULTS

3.1 | Study population

From January 2016 to August 2021, 1137 patients were consecutively submitted to LCS, while 497 left colectomies or low anterior resections were laparoscopically performed for either CRC or DDC (see Figure S1). Out of the study population, 452 (90.9%) patients did not experience major complications, while 45 (9.1%) required reoperations and composed the study cohort of the present analysis (MCR group). Demographics and preoperative characteristics showed mild divergences between the MCR group and the remaining study population, demonstrating a likely association between postoperative complications and potential risk factors. In particular, the MCR group presented with significantly older median patient age ($p = 0.016$), lower BMI ($p = 0.036$), and higher proportions of preceding comorbidities ($p < 0.001$). The study population was mainly diagnosed with cancer (69.9%) and submitted to left colectomy in 55.5% and low anterior resection in 44.5%. Conversely, the MCR group showed higher proportions of malignancy (75.5%) requiring low anterior resection (53.4%) (Table 1).

TABLE 1 Study population and cohort baseline characteristics.

	Study population 497	No-MCR group (%) 452 (90.9)	MCR group (%) 45 (9.1%)	p-value
Demographics				
Age	64 [55–72]	64 [55–72]	70 [58–77]	0.016
Male sex	288 (57.9)	265 (58.6)	23 (51.1)	0.330
BMI ^a	23 (±4)	25 (±4)	23.6 (±3.6)	0.036
ASA score ≥ III	121 (24.3)	105 (23.2)	16 (35.5)	0.066
aa-CCI >5	128 (25.8)	104 (23.0)	24 (53.4)	<0.001
Pathology				
Preoperative anemia ^b	109 (21.9)	99 (21.9)	10 (22.2)	0.961
Malignant disease	346 (69.6)	312 (69.0)	34 (75.5)	0.641
Neoadjuvant therapy	100 (20.1)	93 (20.6)	7 (15.5)	0.423
Primary surgery				
Left colectomy	276 (55.5)	255 (56.4)	21 (46.6)	0.276
Low anterior resection	221 (44.5)	197 (43.6)	24 (53.4)	
Creation of stoma	123 (24.7)	114 (25.2)	9 (20.0)	0.439
Intraop. blood transfusion	13 (2.6)	11 (2.4)	2 (4.4)	0.618
Operative time ^a	182 (±64)	175 (±64)	182 (±64)	0.547

Note: Bold values would mean statistically significant p-values.

Abbreviations: aa-CCI, age-adjusted Charlson comorbidity index; ASA score, American Society of Anesthesiologists' score; BMI, body mass index.

^aMean (±SD).

^bHb cut-offs: <13 males and <12 females.

3.2 | Reoperation cohorts

Depending on the clinical presentation of complications, 30 (66.7%) patients were eventually submitted to LR, while 15 (33.3%) underwent OR (Table 2). No significantly different demographics (i.e., median age, sex ratio, BMI, ASA score, and aa-CCI) were observed among the groups. Types of MCR were AL predominantly (63.3% and 53.3%, respectively), hemoperitoneum or intra-abdominal bleeding (6.7% and 20%), perforation (16.7% and 6.7%), and minimal rates of bowel obstruction, intra-abdominal collections, and segmentary intestinal ischemia. After reoperation, treatment failure was 13.3% overall, including additional surgery (11.1%) and/or 90-day mortality (6.6%). Laparoscopic and OR achieved similar LOS, although OR reported higher surgical burden (i.e., morbidity rates, increase in the level of care ($p = 0.005$), and 90-day mortality ($p = 0.011$)), consistently to the severity of clinical presentation driving the choice of the surgical approach.

A subanalysis restrictively included anastomotic complications requiring either LR or OR (Table 3). Both groups still presented similar demographics, while reoperations included leak closure through oversewn suture with temporary ileostomy fashioning (42.1% and 25%, respectively), leak closure through oversewn suture without ileostomy (10.5% and 0%), Hartmann

procedure (31.6% and 50%), redo-anastomosis with ileostomy (10.5% and 12.5%), and redo-anastomosis without ileostomy (5.3% and 12.5%). Ninety-day mortality following LCS was still significantly higher in OR ($p = 0.024$), while LR was associated with better outcomes in terms of ICU admission and LOS without reaching statistical significance.

4 | DISCUSSION

This study demonstrated the effectiveness of a clinical protocol institutionally implemented for the standardized management of MCR after LCS. This therapeutic decision process was designed to drive the application of LR based on patient and complication-specific criteria. The predominant purpose of reiterating laparoscopy was to preserve potential benefits due to the minimally invasive approach for primary surgery. The predominant finding of this analysis is the efficacy of LR, which demonstrated achievements comparable ($p = 0.991$) to OR when applied within standardized management based on the objective criteria of complication severity (i.e., recovery and discharge were achieved in 11.5 vs. 10 days, respectively). This difference appeared even larger after selecting anastomotic complications (12 vs. 19.5 days, respectively), while the increase in the level of care and mortality remained

TABLE 2 Comparative analysis of reoperations for any MCR.

	LR group (%) 30 (66.7)	OR group (%) 15 (33.3)	p-value
Demographics			
Age	70 [64–76]	64 [53–78]	0.129
Male sex	15 (50.0)	8 (53.3)	1.000
BMI ^a	23.47 (±3.7)	23.9 (±3.6)	0.825
ASA score ≥ III	11 (36.7)	5 (33.3)	1.000
aa-CCI >5	16 (53.3)	8 (53.3)	
Major complication requiring reoperation			0.490
Anastomotic leakage	19 (63.3)	8 (53.3)	
Perforation	5 (16.7)	1 (6.7)	
Intra-abdominal collection	1 (3.3)	1 (6.7)	
Hemoperitoneum	2 (6.7)	3 (20.0)	
Ischemia	0	1 (6.7)	
Bowel obstruction	3 (10.0)	1 (6.7)	
Type of surgery			0.770
Anastomotic suture w/ileostomy	8 (26.7)	2 (13.3)	
Anastomotic suture w/o ileostomy	1 (3.3)	0	
Hartmann's procedure	7 (23.3)	6 (40.0)	
Anastomosis redo w/ileostomy	2 (6.7)	1 (6.7)	
Anastomosis redo w/o ileostomy	1 (3.3)	1 (6.7)	
Other ^b	11 (36.7)	5 (33.3)	
Recovery			
Need for further reoperation	2 (6.7)	3 (20.0)	0.737
Length of stay	11.5 [8–17]	10 [7–20]	0.991
ICU admission	1 (3.3)	5 (33.3)	0.005
90-day mortality	0	3 (20.0)	0.011

Note: Bold values would mean statistically significant p-values.

Abbreviations: aa-CCI, age-adjusted Charlson comorbidity index; ASA score, American Society of Anesthesiologists' score; BMI, body mass index.

^aMean (±SD).

^bHemostasis/drainage/peritoneal washing/atypical bowel resection.

steady and associated with the clinical severity of complications that initially drove the choice of reoperations surgical approach. Eventually, wound infection after reoperations was roughly nil after laparoscopy, representing a significant advantage in favor of this approach. Other studies previously analyzed reoperation techniques in colorectal surgery, although comparisons were never performed under the homogenous

TABLE 3 Subgroup analysis of reoperations for anastomotic leakage.

	LR group 19 (70.4%)	OR group 8 (29.6%)	p-value
Demographics			
Age	70 [62–77]	67 [54–77]	0.970
Male sex	10 (52.6)	4 (50.0)	0.901
BMI ^a	23.4 (±3.9)	24 (±4.2)	0.710
ASA score ≥ III	8 (42.1)	1 (12.5)	0.201
aa-CCI >5	11 (57.9)	3 (37.5)	0.333
Type of surgery			0.695
Anastomotic suture w/ileostomy	8 (42.1)	2 (25.0)	
Anastomotic suture w/o ileostomy	2 (10.5)	0	
Hartmann's procedure	6 (31.6)	4 (50.0)	
Anastomosis redo w/ileostomy	2 (10.5)	1 (12.5)	
Anastomosis redo w/o ileostomy	1 (5.3)	1 (12.5)	
Recovery			
Length of stay	12 [9–19]	19.5 [10–27]	0.766
ICU admission	1 (5.3)	2 (25.0)	0.201
90-day mortality	0	2 (25.0)	0.024

Note: Bold values would mean statistically significant p-values.

Abbreviations: aa-CCI, age-adjusted Charlson comorbidity index; ASA score, American Society of Anesthesiologists' score; BMI, body mass index.

^aMean (±SD).

parameters of pre-established clinical protocols.^{27–30} In our algorithm (Figure 1), the first turning point was the assessment of patient hemodynamics, a multidimensional aspect that reflects both the complication magnitude and subsequent detrimental effects on patient functions. Hemodynamic fluctuations are directly related to the septic component of complications and require to be assessed early by resuscitators during their immediate treatment. The evaluation of hemodynamic impact guides the choice of complication treatment in terms of time-to-surgery and feasibility of the laparoscopic approach.

The first ERAS guidelines for patients undergoing emergency abdominal surgery strongly recommended the early identification and prompt correction of physiological and sepsis-related derangements in accordance with the 2021 Surviving Sepsis Campaign International Guidelines.^{31,32} Previous studies have demonstrated systemic restrictions to laparoscopy, which cannot be performed under certain circumstances, such as specific comorbidities (i.e., severe COPD or congestive heart failure) or hemodynamic

instability.³³ For this reason, all cases requiring reoperations and presenting with hemodynamic instability were promptly submitted to the OR to provide immediate and reliable treatments. Conversely, stable or borderline patients showing adequate response to initial resuscitative therapy were considered fit for exploratory laparoscopy, which represented the opportunity to assess intra-abdominal involvement. A standardized examination of the anastomotic site, focusing on laparoscopic feasibility and the degree of peritoneal contamination, dictated the choice of the following reoperation approach and subsequently reduced the conversion rate due to unexpected technical limitations. Intraoperative findings of enteric contamination involving more than two peritoneal quadrants were intentionally treated through laparotomy to guarantee appropriate intra-abdominal washing. Only cases developing hemodynamic instability during reoperation were meant as technical conversion, although it did not occur in this series and was not measured as a study outcome.

Additional facilitators were both early diagnosis, timely resuscitation therapy, and the high experience of surgeons performing reoperations. Early MCR treatment is associated with better postoperative outcomes, and therefore, a variety of predictive methods have been developed in the literature. Novel laboratory and biochemical parameters may prevent delayed diagnosis, avoiding time-dependent deterioration leading to hemodynamic instability or extensive contamination.^{34–36} Addressing early diagnosed complications may entail smaller intra-abdominal collections and septic damages allowing larger proportions of patients to be submitted to LR. On the other hand, predictable requirements should be considered for increasing LR implementation, such as surgeons' experience in laparoscopic surgery or dedicated infrastructure resources. A prospective multicenter observational trial recently demonstrated that the minimally invasive approach positively impacted postoperative outcomes of patients undergoing emergency abdominal surgery in the context of an ERAS standardized program.³⁷ However, the incomplete penetrance of laparoscopy in emergency series confirms the possibility of greater benefits under specific circumstances, while open surgery still remains more reliable in case of hemodynamic instability.³⁸ According to the literature, the management of MCR does require a specific learning curve that has been advocated to be different than in primary LCS and reach a minimum reference threshold of 50 cases to observe improvements in terms of operative time and conversion.³⁹ However, the authors of the present analysis still believe that a learning curve cannot be predictable and thus, systematically planned in the field of complication treatment of colorectal surgery. At the same time, the conversion rate should be considered negligible for

reoperations when performed by experienced laparoscopic surgeons within a specifically structured clinical program. Accordingly, individual institutions should encourage the change to the minimally invasive approach for early complication treatment by allocating hospital resources and training laparoscopy-oriented anesthesiological and surgical teams. In this context, the recent introduction and spread of the perioperative ERAS program tore down several administrative impediments, facilitating management standardization and the application of minimally invasive procedures.⁴⁰

Despite the standardized protocol-driven treatment of MCR, this study also has to mention minor design and methodological limitations. The main bias is the retrospective design of the study, although the prospectively maintained database and preapproved institutional protocol for colorectal complications should contribute to the high quality of the analysis. The power of the present study cannot be adequately assessed due to the restricted number of MCRs occurring over an extensive series from a referral high-volume center that, despite its favorable meaning, also limited the current analysis. Eventually, despite the hypothetical association between surgical technique and operative stress, the authors of this analysis could not quantify patients' earnings in terms of functional recovery and postoperative satisfaction following minimally invasive surgery. Quality of life and restoration of individual functions should be prospectively investigated by a multidisciplinary research group, including nutritional and physiotherapy assessments.

In conclusion, this study demonstrated the feasibility of a protocol-based relaparoscopy for complications after elective laparoscopic colorectal resections. Under these circumstances, all benefits related to the minimally invasive approach of primary surgery can be preserved without worsening the results of MCR treatment. These results suggest more RCTs and multicenter studies validate the proposed clinical management, identify new standardized criteria, and extend their applicability to any-volume colorectal centers.

AUTHOR CONTRIBUTIONS

Francesco Puccetti: Conception and design; Provision of study materials or patients; Collection and assembly of data; Data analysis and interpretation; Manuscript writing; Final approval of manuscript. **Alessia Vallorani:** Conception and design; Provision of study materials or patients; Collection and assembly of data; Data analysis and interpretation; Manuscript writing; Final approval of manuscript. **Lorenzo Cinelli:** Conception and design; Collection and assembly of data; Data analysis and interpretation; Manuscript writing; Final approval of manuscript. **Stefano Turi:** Conception and design; Collection and assembly of data; Data analysis and interpretation; Manuscript

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CONFLICT OF INTEREST STATEMENT

Drs Puccetti Francesco, Vallorani Alessia, Cinelli Lorenzo, Turi Stefano, Gozzini Lorenzo, Barbieri Lavinia A., Cossu Andrea, Elio Treppiedi, Armienti Alessandro F., Socci Davide, Piccinali Davide, Del Prete Lidia, Rosati Riccardo, and Elmore Ugo have no conflicts of interest or financial ties to disclose.

ETHICS STATEMENT

1. This material is the authors' own original work, which has not been previously published elsewhere.
2. The paper is not currently being considered for publication elsewhere.
3. The paper reflects the authors' own research and analysis in a truthful and complete manner.
4. The paper properly credits the meaningful contributions of co-authors and co-researchers.
5. The results are appropriately placed in the context of prior and existing research.
6. All sources used are properly disclosed (correct citation). Literally copying of text must be indicated as such by using quotation marks and giving proper reference.
7. All authors have been personally and actively involved in substantial work leading to the paper and will take public responsibility for its content.

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