# Standardizing Elective Surgery in Diverticular Disease

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AIM: Diverticular disease (DD) is one of the most common benign gastrointestinal conditions in the Western world, with a range of clinical manifestations from uncomplicated symptoms to acute complications requiring surgery. Elective sigmoidectomy is indicated in cases of Complicated Diverticular Disease (CDD) after recovery, Symptomatic Uncomplicated Diverticular Disease (SUDD), and Recurrent Diverticulitis (RD). This study aims to assess the short- and long-term outcomes of a standardized surgical approach for DD. METHODS: A retrospective analysis was conducted on 442 patients who underwent elective sigmoidectomy or left hemicolectomy for DD disease between January 2012 and March 2020. Different DD scenarios were included: 128 patients with SUDD (29%), 170 with RD (38.5%), 144 with CDD (34.0%). All patients had nearly 5 years of follow-up. Preoperative evaluations included computed tomography (CT) scans and colonoscopy. Surgical procedures followed a standardized protocol, including medial to lateral approach, inferior mesenteric artery preservation, distal resection at the level of the upper rectum with a 60 mm blue Endo Gia cartridge, an end-to-end Knight-Griffen anastomosis with a 29 mm circular stapler and Indocyanine Green (ICG) testing. Demographic data, type of DD, surgical technique, and postoperative outcomes were recorded. The primary outcome measures included intraoperative details, complication rates, recurrence rates, and quality of life (GastroIntestinal Quality of Life Index [GIQLI] scores) at 1 and 5 years post-surgery.

RESULTS: The cohort included 240 males and 202 females with a median age of 50 years. The surgical procedure was standardized across all patients. The mean operative time was  $121\pm28$  minutes, with a conversion rate of 5.2% and an overall complication rate of 16.1%. Major complications, including anastomotic leaks, were observed in 4.9% of patients. The mean hospital stay was 4 days. Diverticulitis recurrence occurred in 5.2% of patients, more frequently in those with a disease duration of more than 5 years (p=0.028). Cox regression analysis revealed that the duration of DD greater than 5 years was the only significant risk factor for diverticulitis recurrence (Hazard Ratio [HR] 2.42, 95% CI 1.12 to 4.62, p=0.028). GIQLI scores significantly improved 1 year after surgery ( $92.7\pm9.5$  vs  $97.8\pm8.5$ , p<0.001) and continued to improve at 5 years ( $92.7\pm9.5$  vs  $118.1\pm10.6$ , p<0.001).

CONCLUSIONS: Elective sigmoidectomy for DD, using a standardized laparoscopic technique, is safe and effective, with low complication rates and significant long-term improvement in quality of life. The recurrence rate of diverticulitis is low, and surgery provides lasting relief, especially for patients with recurrent or complicated forms of the disease. Standardization appears essential to optimize safety and efficacy in DD management.

Keywords: diverticular disease; SUDD; GIQLI; sigmoidectomy

#### Introduction

Diverticular disease (DD) is one of the most common benign gastrointestinal pathologies in the Western world.

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Correspondence to: Francesca Roufael, Laparoscopic and Oncological General Surgery Department, Desio Hospital, ASST Brianza, 20832 Desio, Italy (e-mail: francesca.roufael@unimi.it) However, the absence of standardized management protocols makes it one of the least understood conditions [1–3]. Some patients develop acute complicated diverticulitis requiring surgery, while others experience a chronic but uncomplicated form of the disease [4–6].

The indication for elective sigmoidectomy is given for Complicated Diverticular Disease (CDD) after recovering from the acute phase, Symptomatic Uncomplicated Diverticular Disease (SUDD), and Recurrent Diverticulitis (RD). These clinical scenarios affect millions of patients globally, with increasing incidence linked to aging populations and dietary changes. Patients with any of these presentations

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often report recurrent abdominal pain, altered bowel habits, and impaired quality-of-life, leading to numerous hospital admissions, emergency room (ER) visits, and medical treatments, all of which place a significant burden on healthcare systems until surgical intervention is performed [7–11]. Recent data has shown that surgery is effective in providing symptoms relief and improving quality of life. Therefore, surgical indications should be individualized and based on the frequency of recurrences, symptom severity and comorbidities [12,13]. When surgery is indicated, a minimally invasive approach offers superior outcomes [14].

This study presents a large series of patients who underwent elective surgery for DD using a standardized technique, focusing on both short- and long- term outcomes.

# Methods

#### Study Design and Cohort Selection

This retrospective analysis was conducted using a prospectively maintained single-institution database. We enrolled patients who underwent sigmoidectomy or left hemicolectomy for DD between January 2012 and March 2020, with a minimum follow-up of five years.

All patients underwent preoperative computed tomography (CT) scans confirming the presence of DD and full colonoscopy. The surgeries were performed by six experienced colorectal surgeons who performed more than 150 procedures. All of them attended the same theoretical and practical courses on cadavers at Advanced International Mini-Invasive Surgery (AIMS) Academy (Milan, Italy). Within the reported series, the 6 operating surgeons performed 105, 80, 72, 64, 61, and 60 procedures respectively. No specific exclusion criteria were applied.

Institutional Review Board approval was obtained by the Comitato Etico Milano Area 3 (approval number 233-22042021). Patient enrollment in the Diverticular Disease Registry (DDR) was subordinate to formal informed consent. The research was conducted in line with the Declaration of Helsinki.

#### Variables Collected

Demographic data, including age, gender, body mass index (BMI), and American Society of Anesthesiologists (ASA) classification were recorded. Clinical data were collected based on the type of DD (CDD, SUDD, or RD), number of diverticulitis episodes, type of surgery performed, and pathology reports.

CDD was defined as the presence of pericolic abscesses, colonic perforation, diverticular bleeding, colonic diverticular stenosis, or colonic fistula. Patients with CDD were electively operated on after fully recovering from the acute phase. SUDD was defined as the presence of colonic diverticulosis on both CT scan and colonoscopy, accompanied by persistent localized pain and diarrhea/constipation without evidence of inflammation in blood tests or complications. RD was defined as multiple episodes of left lower

quadrant abdominal pain, fever, leukocytosis, and evidence of inflammation on CT.

## Surgical Technique

The surgical procedures were standardized, and all operations followed a uniform technique. This included a medial-to-lateral dissection, inferior mesenteric artery (IMA) preservation, distal transection at the upper rectum below the colonic-rectum junction using a 60 mm blue Endo Gia cartridge (FELC – II Generation, Endoscopic Linear Cutter and Reloads, Touchstone®, Suzhou, China) and an end-to-end Knight-Griffen anastomosis using a 29 mm circular stapler (ECSC, Endoscopic Circular Stapler Curved, Touchstone®, Suzhou, China). Perfusion assessment with Indocyanine Green (ICG) was introduced in 2018, performed before colonic transection. The splenic flexure was mobilized only when necessary to ensure a tension-free anastomosis (Fig. 1).

All patients included underwent pre-operative bowel preparation with citric acid two days before surgery, metronidazole 500 mg 3 times/day the day before surgery, and mesalamine 800 mg 3 times/day the day before surgery.

## Follow-up Strategy

Follow-up began immediately after hospital discharge, typically within 2 weeks post-surgery, with an initial postoperative assessment to evaluate recovery and address any early complications. The end of follow-up was set at 5 years after surgery, with all patients included in the study having a minimum duration of follow-up to assess long-term outcomes. Patients were seen for clinical evaluation at 3-, 6and 12-month post-surgery, then they were followed up annually at least once every 12 months. Patients were also encouraged to contact the medical team if they experienced symptoms of diverticulitis or other gastrointestinal issues. Content of follow-up included physical examinations, assessment of postoperative complications, and review of symptoms such as abdominal pain, bowel habits, and signs of recurrence. CT scans and colonoscopies were performed if patients showed signs of recurrence or complications.

The Gastrointestinal Quality of Life Index (GIQLI) questionnaire was administered at baseline (preoperative) and at 1-year and 5-year follow-ups to evaluate changes in gastrointestinal health, functional status, and overall quality of life.

# Statistical Analysis

Continuous variables are presented as means  $\pm$  standard deviation (SD) or median (range), as appropriate. Categorical variables are presented as percentages.

The  $\chi^2$  test was used for categorical variables and the Student t tests was used for continuous variables comparing patients with and without recurrence. The normality assumption was assessed using the Shapiro-Wilk's test. When the assumptions to use a parametric test were not met,

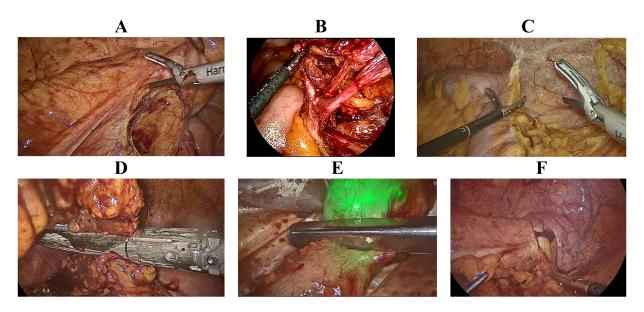


Fig. 1. Surgical steps. (A) Medial to lateral dissection with the opening of the mesosigma. (B) Ligation of the sigmoid vessels. (C) Lateral mobilization of the colon. (D) Distal transection at the level of the upper rectum with a 60 mm blue Endo Gia cartridge. (E) Colonic perfusion assessment with Indocyanine Green (ICG). (F) End to end Knight-Griffen colorectal anastomosis performed with a 29 mm circular stapler. The laparoscopic images (A-F) were captured from intraoperative video and then processed using Adobe Photoshop (version 25.2, Adobe Inc., San Jose, CA, USA) for cropping, color correction, and labeling. Additional vector-based text and graphical elements were created and arranged in Adobe Illustrator (version 29.5.1, Adobe Inc., San Jose, CA, USA).

the Mann-Whitney U test was performed. Paired t-tests were used for comparisons of pre- and postoperative GIQLI

Cox regression analysis was used to assess risk factors for diverticulitis recurrence, with a focus on the duration of DD as a potential predictor. The significance level for all statistical tests was set at p-value of <0.05. All analyses were conducted using Statistical Package for the Social Sciences (SPSS) software (version 22, SPSS Inc., Chicago, IL, USA).

#### Results

Overall, 442 patients were enrolled in the analysis. The patients' characteristics are summarized in Table 1.

The cohort had a median age of 50 (range 20–84) years. 240 patients were male and 202 were female. The mean BMI was  $25.4 \pm 5.4$  kg/m<sup>2</sup>. The mean Charlson Comorbidity Index was 1.0 (0-1.5).

Patients were asked to complete GIQLI [15] questionnaires during pre- and post-operative physical examinations. Post operative short- and long-term outcomes, including intraoperative blood loss, operative time, Clavien-Dindo [16] complication rate, conversion rate, leak rate, time to first passage of flatus and stool, length of hospital stay, diverticulitis recurrence rate and GIQLI test results at 1 year and 5 years post-surgery, were collected and reported as shown in Table 2.

The distribution of DD types was as follows: 170 patients (38.5%) had RD, 128 patients (28.9%) had SUDD, and 144 patients (34.0%) had recovered from CDD. We did not include patients who underwent emergency surgery for CDD. Mean operative time was  $121 \pm 28$  min and no ostomies were performed. Conversion rate was 5.2% and all cases occurred in patients who underwent surgery for CDD. The overall complication rate was 16.1% (n = 71), however the Clavien-Dindo  $\geq 3$  rate was only 4.9% (n = 22), with the leak rate being 3.5% (n = 17). All leaks occurred in patients who underwent surgery for CDD. Re-operated patients (n = 22, 4.9%) underwent pelvic lavage in 10 cases (2.3%), drain tube placement and loop ileostomy. 7 patients (1.6%) underwent laparoscopic Hartmann procedure. All patients underwent either subsequent ileostomy closure or laparoscopic Hartmann Reversal. The mean hospital stay was 4.0 (2.0-7.0) days. Anastomotic bleeding happened in 32 patients (7.2%) but only 5 cases required colonoscopy to achieve the bleeding control.

The mean GIQLI score was significantly improved 1 year after surgery (92.7  $\pm$  9.5 vs. 97.8  $\pm$  8.5, p-value < 0.001) showing a progressive improvement after 5 years from surgery as well (92.7  $\pm$  9.5 vs. 118.1  $\pm$  10.6, p < 0.001). Diverticulitis recurrence happened in 23 (5.2%) of 442 patients. 10 cases (2.3%) happened in the SUDD subgroup, 10 cases (2.3%) happened in the RD group and 3 cases (0.7%) happened in the CDD. A DD longer than 5 years was the only risk factor associated with diverticulitis recurrence (pvalue = 0.028) at Cox regression analysis, as shown in Tables 3,4.

Table 1. Baseline details of the cohort.

| Characteristic  | n = 442        |
|---|----------------|
| Sex, n (%)  |                |
| Male  | 240 (54.3)     |
| Female  | 202 (45.7)     |
| Age, years, median (range)                            | 50 (20-84)     |
| BMI, kg/m $^2$ , mean $\pm$ SD                        | $25.4 \pm 5.4$ |
| Diverticulitis of sigmoid colon                       | 323 (73.1)     |
| Diverticulitis of sigmoid & descending colon          | 119 (26.9)     |
| Symptomatic Uncomplicated Diverticular Disease, n (%) | 128 (29.0)     |
| Complicated Diverticular Disease, n (%)               | 144 (34.0)     |
| Perforation   | 71 (16.8)      |
| Bleeding  | 21 (5.0)       |
| Stenosis  | 52 (12.3)      |
| Recurrent Diverticulitis, n (%)                       | 170 (38.5)     |
| Episodes in recurrent diverticulitis, $n$ (%)         |                |
| 1   | 25 (5.7)       |
| 2   | 45 (10.2)      |
| 3   | 38 (8.6)       |
| 4   | 42 (9.5)       |
| >4  | 20 (4.5)       |
| ASA class, n (%)                                      |                |
| I   | 191 (43.1)     |
| II  | 193 (43.7)     |
| III   | 58 (13.2)      |
| Charlson comorbidity index, median (IQR)              | 1.0 (0-1.5)    |
| Pre-surgery GIQLI, mean $\pm$ SD                      | $92.7 \pm 9.5$ |

Note: The analysis of Complicated Diverticular Disease was on 423 patients, as 19 had a missing value. BMI, body mass index; SD, standard deviation; ASA, American Society of Anesthesiologists; GIQLI, Gastrointestinal Quality of Life Index.

# Discussion

Elective surgery for DD requires a comprehensive evaluation of several factors: the patient's general condition, the type of diverticulitis, the optimal timing for surgery, and the extent of the resection required [17]. Maximizing the standardization of the surgical approach is therefore necessary to minimize potential biases, given the wide range of anatomical and clinical scenarios that DD presents [18]. Our study reports a large series of patients who underwent laparoscopic sigmoidectomy using a standardized procedure and consistent surgical equipment.

Surgical times, complication and conversion rate align with those in other reported series [11,17]. The significant improvement in quality, as measured by GIQLI score, is consistent with findings from other studies [19,20], indicating that surgery is an effective method to improve bowel function in patients with diverticulitis, within the vast medical armamentarium available [21], while remaining safe, with a low incidence of major complications and recurrence [2]. The improvement in GIQLI score observed in this study is a notable finding, with scores significantly increasing 1 year and 5 years after surgery. The GIQLI, which mea-

Table 2. Intra- and post-operative details of the cohort.

| Characteristic                                | n = 442          |
|---|------------------|
| Operative time, minutes, mean $\pm$ SD        | $121\pm28$       |
| Conversion rate, $n$ (%)                      | 23 (5.2)         |
| Estimate blood loss, mL, mean $\pm$ SD        | $53 \pm 14$      |
| 30-days complications, $n$ (%)                | 71 (16.1)        |
| Anastomotic bleeding                          | 32 (7.2)         |
| Anastomotic leak                              | 17 (3.8)         |
| Clavien-Dindo ≥3                              | 22 (4.9)         |
| 30-day reoperation, $n$ (%)                   | 22 (4.9)         |
| First flatus, days, mean $\pm$ SD             | $2.0\pm1.0$      |
| First passage of stool, days, mean $\pm$ SD   | $3.5\pm1.2$      |
| Length of stay, days, median (IQR)            | 4.0 (2.0–7.0)    |
| Diverticulitis recurrence, $n$ (%)            | 23 (5.2)         |
| GIQLI at 1 year after surgery, mean $\pm$ SD  | $97.8 \pm 8.5$   |
| GIQLI at 5 years after surgery, mean $\pm$ SD | $118.1 \pm 10.6$ |

sures gastrointestinal quality of life, encompasses several domains such as gastrointestinal symptoms, physical functioning, emotional well-being, and social functioning [16]. A significant increase in these scores indicates a meaningful enhancement in both the physical and emotional well-being of patients who underwent elective surgery for DD.

Clinically, a 5-year postoperative improvement in GIQLI scores from  $92.7 \pm 9.5$  preoperatively to  $118.1 \pm 10.6$  highlights the durable benefit of surgery, particularly in terms of symptom relief. This improvement can be interpreted as a reduction in the severity and frequency of abdominal pain, bowel dysfunction, and other quality-of-life impairments commonly associated with DD. Given that patients with DD often experience persistent symptoms despite medical treatment, the magnitude of improvement seen in this study provides strong evidence for the clinical benefit of elective surgery in appropriate candidates.

The improvement in GIQLI scores not only signifies symptom relief but also correlates with better overall functional status, which can positively impact a patient's daily activities and emotional well-being. For instance, many patients suffering from recurrent diverticulitis or SUDD face chronic discomfort and a diminished quality of life, which frequently leads to hospital admissions, frequent visits to healthcare providers, and prolonged medical treatments [7,19]. By improving these scores, the data suggest that elective surgery offers a long-term solution to these persistent issues, reducing the need for ongoing medical management and improving both physical and psychological outcomes. Moreover, the progressive nature of the improvement over 5 years post-surgery further supports the idea that surgery not only offers immediate relief but also contributes to long-term well-being. While patients may experience some postoperative recovery challenges, the longterm benefits in terms of symptom resolution and quality of life are significant, especially when compared to the recurrent and debilitating symptoms that often characterize the

Table 3. Recurrence Rates based on condition and symptoms duration.

| Condition                                    | Recurrence (%) | No recurrence (%) | <i>p</i> -value | $\chi^2$ (Chi-Square) |
|--|----------------|-------------------|-----------------|-----------------------|
| Total  | 23 (5.2)       | 419 (94.8)        |                 |                       |
| Diverticulitis of sigmoid & descending colon | 15 (65.2)      | 104 (24.8)        | < 0.001         | 18.08                 |
| Time from symptoms onset >5 years            | 18 (78.3)      | 129 (30.8)        | < 0.001         | 22.14                 |

Table 4. Multivariate Cox regression analysis of risk factors for diverticulitis recurrence.

| Factors                              | HR   | (95% CI)       | <i>p</i> -value |
|--------------------------------------|------|----------------|-----------------|
| Diverticulitis of the sigmoid and of | 1.22 | (0.54 to 2.21) | 0.059           |
| the descending colon                 |      |                |                 |
| Onset of symptoms >5 years           | 2.42 | (1.12 to 4.62) | 0.028           |

HR Hazard Ratio

natural course of untreated or conservatively managed DD [22]. In clinical practice, the decision to proceed with elective surgery should be informed by these improvements in quality of life, especially for patients with persistent symptoms that interfere with daily living. The clinical relevance of these changes is clear: they reflect a substantial reduction in patient-reported burdens of disease, leading to a better functional and emotional state.

Therefore, the decision to recommend elective surgery is typically based on two main goals: improving bowel function and preventing the development of complicated disease, such as major perforation or stenosis [3].

Although similar to sigmoid resection for sigmoid cancer, surgery for diverticulitis can be more challenging, even if performed during the non-acute phase of the disease. Inflammation can still be present along the dissection planes, and fistulas or pelvic adhesions are often encountered, making dissection more difficult [18]. It is noteworthy that all reported conversions occurred in patients operated on for CDD. After recovery from an acute case of CDD, in fact, the left colon's anatomy may remain impaired due to chronic inflammation, making minimally invasive surgery more challenging. The standardization of both surgical steps and technological tools ensures greater safety and precision in the dissection.

As noted by Hawkins et al. [23], patients view the decision to undergo colectomy through three main pillars: their beliefs about surgery, their psychosocial context, and moderating factors that influence the choice to undergo surgery. Pre-operative counseling is thus a critical step [23]. Additionally, Harrison NJ et al. [22] reported that patients with self-reported diverticulitis often experience high levels of decision regret and bowel dysfunction, regardless of the management strategy, highlighting the influence of psychosocial factors on the decision between colectomy and observational management.

To the best of our knowledge, our five-year follow-up data is relatively rare in the literature. Diverticulitis recurrence occurred in 5.2% of cases. Diverticulitis affecting both the sigmoid and descending colon has the highest recurrence rate (65.2%), with recurrence being more likely in patients with long-lasting symptoms. As previously stated in a recent paper of our group, recurrent diverticulitis occurred more frequently in patients suffering from an active disease for more than 5 years. It is conceivable that other colonic segments may become more susceptible to inflammation, with the persistence of the inflammatory state correlated with diverticulitis [24].

The recurrence of diverticulitis remains a critical concern in the management of DD, and the findings of this study provide insightful evidence regarding the risk factors associated with recurrent episodes of diverticulitis. In particular, the duration of the disease was identified as a significant factor influencing the recurrence rate, with a longer duration of symptoms, specifically greater than 5 years, associated with a higher risk of recurrence.

The recurrence rate of diverticulitis in this cohort was 5.2%, which is relatively low compared to rates reported in other studies, particularly those in which patients were not treated with a standardized surgical approach. However, the subgroup analysis revealed that patients with longer durations of diverticulitis (over 5 years) were at a substantially greater risk for recurrence, with a hazard ratio of 2.42 (95% CI 1.12 to 4.62, p = 0.028). This finding is consistent with existing literature that suggests the chronicity of diverticulitis is a strong predictor of recurrence [1,2].

The pathophysiological explanation for this association could relate to the progressive nature of DD. Chronic diverticulitis is thought to cause repeated episodes of colonic inflammation, leading to more significant scarring, structural changes, and increased susceptibility to further inflammatory events. Additionally, the persistence of inflammation may result in the progressive weakening of the colonic wall, which may predispose patients to further episodes of diverticulitis, particularly in the left colon. The ongoing inflammatory state may also render the colonic wall more vulnerable to mechanical and functional impairments, such as stenosis or fistula formation, which could predispose patients to recurrent disease.

It is also important to note that the recurrence rate was more pronounced in patients with Recurrent Diverticulitis (RD), a subgroup of DD. Recurrent episodes of diverticulitis represent a more complex, ongoing inflammatory process, which may reflect an altered or dysfunctional immune response or insufficient healing of the colonic mucosa after previous episodes. The results of this study highlight the potential need for more aggressive treatment or earlier intervention in patients with RD, as these patients are more likely to experience subsequent flare-ups.

On the other hand, patients with SUDD, who did not present with acute or complicated episodes, had a relatively low recurrence rate (2.26%). This supports the concept that surgical intervention in this group may offer lasting relief, as these patients are less likely to experience significant progression of disease. In contrast, those with CDD, who often require more extensive surgical resections due to the severity of their condition, did not experience a high rate of recurrence (0.68%). This finding may be attributed to the more definitive nature of the surgical intervention in these patients, where the resection of affected areas effectively eliminates the source of recurring inflammation. However, the small sample size and low number of recurrent cases may reduce the statistical power, limiting the generalizability of the findings.

Several limitations need to be discussed. First, the retrospective nature of the study might impact the results, although the database was prospectively collected. Second, different DD scenarios (SUDD, RD, and CDD) were analyzed together without further subcategorization, as the aim of this study was not a comparative analysis but rather a technical standardization. Third, the splenic flexure was not always mobilized, but was done as needed to ensure a tension-free anastomosis.

In conclusion, while the study provides useful data on the outcomes of elective laparoscopic surgery for DD, the retrospective design, the lack of a comparative group and randomization, and surgeon experience variability must be taken into account when interpreting the results. Further prospective, randomized studies with larger, more diverse patient populations are needed to validate the findings and minimize potential biases.

Future research on laparoscopic sigmoidectomy for DD should aim to address the limitations of this study and further validate the findings. Key areas for future investigation include: randomized controlled trials (RCTs), multi-center studies, longer follow-up and comparative analyses, standardization of postoperative care, and exploration of predictive models. By addressing these research gaps, future studies can provide more conclusive evidence on the optimal management of DD and further refine surgical techniques and patient care strategies.

Finally, future research should aim to better understand the molecular and immune mechanisms that contribute to the recurrence of diverticulitis, as identifying biomarkers or genetic factors associated with a higher risk for recurrence could offer opportunities for personalized interventions. Long-term studies with larger patient populations are needed to further confirm the role of disease duration and other potential risk factors in predicting recurrence and to refine postoperative management strategies.

#### **Conclusions**

This study demonstrates that a standardized approach to laparoscopic sigmoidectomy for DD can achieve acceptable surgical outcomes and significantly improve patient quality of life, both in the short- and long-term. The findings support the value of a uniform surgical technique in improving patient outcomes while minimizing complications.

# Availability of Data and Materials

All experimental data included in this study are available upon reasonable request from the authors.

### **Author Contributions**

GM and RS: Conceptualization, Methodology, Visualization, Supervision, and Project administration. GM, RS and FR: Methodology, Software, Data curation, Visualization, and Writing—original draft. SMDC, AM, MGero, EDF, MS, MGian, BV, CL, DM: Investigation, Resources, and Supervision. All authors contributed to critical revision of the manuscript for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

# **Ethics Approval and Consent to Participate**

Institutional Review Board approval was obtained by the Comitato Etico Milano Area 3 (approval number 233-22042021). Patients were subordinate to formal informed consent. The research was conducted in line with the Declaration of Helsinki.

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#### **Conflict of Interest**

The authors declare no conflict of interest. Giulio Mari is serving as one of the Guest Editors of this journal. We declare that Giulio Mari had no involvement in the peer review of this article and has no access to information regarding its peer review.

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