Risk Factors for Postoperative Complications After Surgical Treatment of Colorectal Cancer in Argentina. Results of a Prospective National Multicenter Registry

Collaborative Consortium on Colorectal Cancer in Argentina
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ABSTRACT
Background: Surgery is a fundamental part of the treatment of patients with colorectal cancer (CRC). Currently, there is a lack of information regarding risk factors for complications following this type of procedure in Latin America.
Methods: Data from the national prospective registry of CRC in Argentina were used. Patients included were divided into 2 groups depending on whether they had complications after the procedure (PCO) or not (NPCO). A comparative analysis of clinical and operative characteristics between both groups was performed.
Results: 823 patients with a mean age of 48 years were included. The incidence of complications after surgery was 34.5%. The PCO group had more patients with a high Charlson Comorbidity Index score (51.8 vs. 33.8%; p < 0.001), higher rates of anemia (64.8 vs. 52.9%; p = 0.001), and greater exposure to neoadjuvant therapy (17.2 vs. 11.2%; p = 0.015). Rectal tumors were more frequent in the PCO group (29. 6 vs. 23%; p = 0.041), which also had more emergency surgeries. The PCO group had more requirements for prolonged surgery (34.6 vs. 17.1%; p < 0.001) and higher rates of conversion from laparoscopic to conventional surgery. In the multivariate analysis, age (OR: 1.02, p = 0.012), male sex (OR: 0.54, p < 0.001), anemia (OR: 1.61, p = 0.006), emergency surgery (OR: 2.29, p = 0.001), high-volume center (OR: 0.52, p = 0.002), and rectal vs. colon surgery (OR: 1.65, p = 0.030) were independent predictors of postoperative complications, considering the total cohort. In a multivariate analysis adjusted only to the cohort of patients undergoing rectal cancer surgery, the only protective factor associated with postoperative complications was surgery performed at high-volume centers (OR: 0.035, p = 0.004).
Conclusion: The present study shows an association between clinical and surgical factors and the development of postoperative complications. Future efforts should be devoted to optimizing patients and resources to improve the outcomes of these procedures.

Keywords: Colorectal cancer; Surgery; Complications

INTRODUCTION

Colorectal cancer (CRC) is a major health problem worldwide and surgical resection remains the cornerstone of treatment for patients with localized disease.[1] Although numerous studies worldwide have evaluated the results of surgical treatment of this type of neoplasia,[2-4] most come from developed countries. On the other hand, the information available on the results of surgical treatment of CRC and the risk factors for complications after surgery is scarce in Latin America, which makes it difficult to establish evidence-based treatment guidelines and optimize the care of these patients. The fact that it is a region mostly made up of low- and middle-income countries, with differences in environmental factors and access to medical care, among other circumstances, could lead to differences in the approach to patients compared to countries with greater resources.

Currently, some published studies have reported surgical results related to the treatment of CRC,[1,2] however, they have small sample sizes and methodological limitations, especially their retrospective nature.

Recently, some multicenter studies have been published with information from different countries in the region, on the approach to patients with colorectal neoplasia and inflammatory bowel disease.[5-9] Also, a Collaborative Consortium was created to promote these initiatives in the region.[10] However, despite having information from a significant number of patients, these studies also have important limitations that prevent having a definitive notion of what happens in Latin America with patients treated for colorectal pathology. In 2020, the prospective national registry of patients operated on for CRC in Argentina (National Database of Colorectal Cancer Argentina) was created, a project designed to obtain quality information regarding the surgical treatment of patients affected by colorectal neoplasia to use said data to implement improvements in care.

In 2022, a pilot test was carried out in 8 academic hospitals in Buenos Aires, involving 317 prospectively recruited patients. The results, as well as the process of creating the national registry, were previously published.[11] After this pilot test, new centers were recruited, currently counting 28 distributed in the Federal Capital and the provinces of Buenos Aires, Córdoba, Corrientes, Entre Ríos, Formosa, Mendoza, Misiones, Neuquén, San Juan, and Santa Fe.

This study aims to evaluate the risk factors for postoperative complications in a cohort of patients undergoing surgery for CRC, prospectively recruited nationwide in Argentina.

MATERIAL AND METHODS

Data prospectively recorded in the National Colorectal Cancer Database of Argentina were retrospectively reviewed to analyze risk factors associated with postoperative complications within 30 days after a surgical procedure for CRC.

Inclusion Criteria

Patients over 18 years of age who had signed informed consent for admission (in Argentina, most hospitals have a consent form that includes permission to use admission information for observational research) and who underwent curative surgery for adenocarcinoma located in the colon or rectum between April 2022 and May 2023 were included. Patients with appendiceal tumors, colorectal tumors with a histological subtype different from adenocarcinoma, extracolonic tumors that required colorectal resection due to invasion or metastasis, and surgical procedures with palliative intent were excluded.

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The patient cohort was divided into 2 groups:

– NPCO group: Patients who did not present postoperative complications.
– POC group: Patients who presented postoperative complications during the 30 days following the initial surgical procedure.

Variables

Demographic, preoperative, operative, and postoperative variables were analyzed. The presence of complications within 30 days after surgery was considered as the main outcome variable.

- Demographic and Comorbidity Variables: Age, sex, body mass index (BMI), smoking, comorbidity according to the Charlson Comorbidity Index, anemia at the time of surgery (defined by the Argentine Society of Hematology),[12] previous abdominal surgery. Type of participating institution (public or private), surgical volume (low volume is defined as a center that operates below the average percentile 25% of all procedures, established in 6 procedures for the present study).

- Variables Related to CRC: Synchronous tumor, tumor location (right, transverse or left colon, rectum). Neoadjuvant therapy, preoperative colonoscopy, preoperative computed tomography.

- Operative Variables: American Society of Anesthesiologists (ASA) score, nature of surgery (urgent or elective), type of specialization of the surgeon in charge of the procedure (colorectal or general), operative time (including the need for a prolonged procedure defined as one above the 75th percentile of operative time), type of approach, conversion and its cause in laparoscopic procedures, intraoperative complication and its classification,[13] types of anastomosis (stapled or handsewn), protective ostomy.

- ***Postoperative Variables:*** Length of stay, postoperative complications, Dindo-Clavien classification,[14] reoperations, readmission, and death. Surgeries for advanced tumors (those > T2 according to the TNM classification of the pathology report) were also recorded.[15]

- ***Primary Outcome Variable:*** The primary outcome variable was the presence of complications within 30 days after surgery.

Ethical Considerations

This observational study did not involve any modifications to the patient's usual treatment. This observational study did not involve any modifications to the patient's usual treatment. In turn, the data loading into the database was carried out anonymously. The study was approved by the institutional review boards of the included centers, under the standards of good research practices.

Statistical Analysis

Statistical analysis was performed using Stata software (v17, Statacorp, College Station, Texas, USA). Categorical data were described as percentages. Continuous data were tested for normal distribution using a Kolmogorov-Smirnov test. For parametric data, the mean and standard deviation were reported. For nonparametric data, the median and interquartile range were presented.

For the comparison of categorical variables, the Chi-square test or Fisher's exact test was used, and for quantitative variables, the Student t test or Mann-Whitney U test, as appropriate.

Odds ratios (OR) with 95% CI were calculated for all preoperative, intraoperative, and postoperative variables.

A logistic regression model was used for multivariate analysis, including all preoperative variables considered clinically relevant by the authors and using postoperative complications as the dependent variable. This analysis was performed on the total cohort of patients, and a second sub-analysis was performed only on patients who underwent surgery for rectal cancer. A p-value < 0.05 was considered significant.

RESULTS

During the period under review, 823 patients underwent surgery for colorectal adenocarcinoma, of whom 396 (48.1%) were female. The mean age was 65 ± 14.1 years. Eighty-nine percent (732) were operated on in private hospitals and the rest in public hospitals. Fig. 1 shows the number of patients included by each hospital.

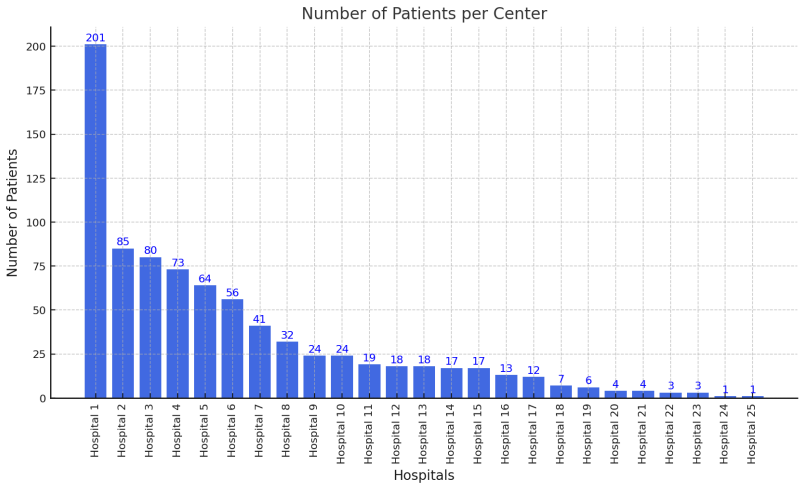

Figure 1. *Number of patients included per institution*

Primary Outcome

Overall, 284 patients (35%) experienced complications within 30 days of initial surgery. Of this group, 152 patients (53.5%) presented minor complications (Clavien-Dindo I and II) and 132 patients (46.5%) presented major complications (Clavien-Dindo > II).

Preoperative Variables

The PCO group had a higher mean age than the NPCO group (67 vs. 64 years; p = 0.006). On the other hand, there were no differences between the groups regarding BMI or the percentage of patients who were smokers at the time of surgery.

Patients in the PCO group had a high Charlson Comorbidity Index score (>3) significantly more frequently than those in the NPCO group (51.8 vs. 33.8%, p < 0.001; OR: 2.10). In addition, the PCO group had more anemia at the time of surgery (64.8 vs. 52.9%; p = 0.001; OR: 1.20), and greater exposure to neoadjuvant therapy (17.2 vs. 11.2; p = 0.015; OR: 1.66).

Finally, the PCO group presented a higher percentage of rectal tumors (29.6 vs. 23; p = 0.041; OR: 1.40). Tables 1 and 2 include information on the preoperative variables of both groups.

Table 1. Preoperative variables: Demographic characteristics and type of treating center.

Variable	Patients n (%) 823 (100)	NPCO n (%) 539 (65.5)	PCO n (%) 284 (34.5)	p-value	OR/MWD (CI 95%)	Missing values
Sex F, n (%)	396 (48.1)	279 (51.9)	117 (41.2)	0.004	0.65 (0.48–0.87)	1
Age (mean ± SD)	65 ± 14.1	64 ± 13.9	67 ± 14.3	0.006		1
Young people < 45 years	85 (10.3)	59 (11)	26 (9.1)	0.417	0.82 (0.50–1.33)	
Adults 45-75 years	534 (65)	363 (67.5)	171 (60.2)	0.038	0.73 (0.55–0.98)	
Adults > 75 years	203 (24.7)	116 (21.6)	87 (30.6)	0.004	1.65 (1.15–2.23)	
Smoking	233 (28.4)	145 (27)	88 (31)	0.228	1.21 (0.88–1.66)	2
BMI (mean ± SD)	26.4 ± 5.2	26.3 ± 5	26.7 ± 5.5	0.34		10
BMI > 30	155 ± 19.1	95 ± 17.9	60 ± 21.2	0.257	1.23 (0.86–1.77)	
Charlson score				< 0.001		0
< 2	199 (24.1)	140 (26)	57 (20.1)			
2-3	297 (36)	217 (40.3)	80 (28.2)			
> 3	327 (39.9)	181 (33.8)	146 (51.8)	< 0.001	2.10 (1.56–2.84)	
Anemia	468 (57)	284 (52.9)	184 (64.8)	0.001	1.64 (1.22–2.21)	2
Previous abdominal surgery	346 (42.2)	215 (40.7)	128 (45.1)	0.225	1.20 (0.89–1.60)	3
Type of center				0.029	0.57 (0.33–0.95)	4
Public	87 (10.6)	66 (75.9)	21 (24.1)			
Private	732 (89.4)	469 (64.1)	263 (35.9)			

NPCO: Group without postoperative complications. PCO: Group with postoperative complications. BMI: Body mass index.

Intraoperative Variables

The PCO group had a higher incidence of ASA III/IV than the NPCO group (48.9 vs. 40.9%; p = 0.026; OR: 1.39). In addition, there was a higher rate of emergency surgeries (20 vs. 11%; p < 0.001; OR: 2.04). There were no differences between the groups in the specialization of the surgeon operating.

Operative time was significantly longer in the PCO group, with a significantly higher percentage of patients requiring prolonged surgeries (34.6 vs. 17.1%; p < 0.001, OR: 2.56).

Although there were no differences between the groups in the type of initial approach (laparoscopic or conventional), the PCO group had a significantly higher rate of conversion from minimally invasive to conventional surgery (19 vs. 11.5%; p = 0.008; OR: 1.80). This group also had more intraoperative complications (7 vs. 2%; p < 0.001; OR: 3.62).

The PCO group had a lower percentage of patients with primary anastomosis and a higher rate of protective ostomy (25.6 vs. 12.7%; p < 0.001; OR: 2;36). No significant differences were found between the groups in the type of anastomosis performed. Table 3 summarizes the intraoperative data.

Table 2. Preoperative variables: Diagnostic procedures, tumor location, and neoadjuvant therapy.

Variable	Patients n (%) 823 (100)	NPCO n (%) 539 (65.5)	PCO n (%) 284 (34.5)	p-value	OR/MWD (CI 95%)	Missing values
Preoperative colonoscopy	721 (87.7)	483 (89.8)	238 (83.8)	0.013	0.59 (0.39–0.90)	1
Preoperative CT scan	781 (95.4)	507 (94.6)	274 (96.8)	0.149	1.74 (0.81–3.73)	34
Location of the tumor *				0.002	1.40 (1.01–1.94)	1
Right colon	283 (34.4)	202 (37.5)	81 (34.4)			
Transverse colon	97 (11.8)	52 (9.7)	45 (15.8)			
Left colon	234 (28.5)	160 (29.7)	74 (26.1)			
Rectum	208 (25.3)	124 (23)	84 (29.6)	0.041		
Synchronous tumor	37 (4.5)	24 (4.5)	13 (4.6)	0.943	1.03 (0.51–2.05)	2
Neoadjuvant therapy	109 (13.3)	60 (11.2)	49 (17.2)	0.015	1.66 (1.10–2.50)	2

NPCO: Group without postoperative complications. PCO: Group with postoperative complications.
* A comparative analysis was performed according to tumor location in the different segments of the colon and then between tumors of the colon and rectum.

Postoperative Variables

The complications presented by the patients according to the Clavien-Dindo classification were: 16.9% type I, 36.6% type II, 7.8% type IIIa, 24.3% type IIIb, 8.8% type IVa and 5.6% type IVb. The incidence of anastomotic dehiscence was 9.1%. The PCO group had more days of hospitalization (13 vs. 5 days; $p < 0.001$) and a higher percentage of prolonged hospitalization (52.3 vs. 6.8%; $p < 0.001$; OR: 15).

In the PCO group, 21.8% of patients required readmission, and 33.8% underwent reoperation. Twenty-three (8.1%) patients in this group died within 30 days of the initial procedure. Finally, patients in this group had more advanced-stage tumors (>pT2) (65.8 vs. 57.5%; p 0.023; OR: 1.42). The rest of the postoperative data are detailed in Table 4.

Multivariate Analysis

In the multivariate analysis, age (OR: 1.02; $p = 0.012$), male sex (OR: 0.54; $p < 0.001$), anemia (OR: 1.61; $p = 0.006$), emergency surgery (OR: 2.29; $p = 0.001$) and rectal surgery (OR: 1.65; $p = 0.03$) were independent predictors of postoperative complications in the total cohort. Having been operated on in a high-volume center was a protective factor (OR: 0.52; $p = 0.002$) (Table 5).

In the subgroup analysis of patients operated on for rectal cancer, the only protective factor associated with postoperative complications was having been operated on in high-volume centers (OR: 0.035; $p = 0.004$) (Table 6).

Table 3. Intraoperative variables.

Variable	Patients n (%) 823 (100)	NPCO n (%) 539 (65.5)	PCO n (%) 284 (34.5)	p-value	OR/MWD (CI 95%)	Missing values
ASA				0.051		3
I	71 (8.7)	52 (9.7)	19 (6.7)			
II	391 (47.7)	265 (49.4)	126 (44.4)			
III	350 (42.7)	216 (40.3)	134 (47.2)			
IV	8 (1)	3 (0.6)	5 (1.8)			
Emergency surgery	116 (14.1)	59 (11)	57 (20.1)	< 0.001	2.04 (1.37–3.04)	1
Specialization				0.797	0.95 (0.67–1.36)	1
Colorectal surgeon	650 (79.1)	424 (78.8)	226 (79.6)			
General surgeon	172 (20.9)	114 (21.2)	58 (20.4)			
OT, min (mean ± SD)	182 (69.8)	171 (61.8)	202 (79)	< 0.001	-31 (-41.57 – -20.43)	3
Long operation (> 220 min)	190 (23.2)	92 (17.1)	98 (34.6)	< 0.001	2.56 (1.82–3.60)	
Approach				0.134	1.33 (0.91–1.93)	3
Laparoscopic	680 (82.9)	453 (84.4)	227 (80.2)			
Conventional	140 (17.1)	84 (15.6)	56 (19.8)			
Conversion	95 (14)	52 (11.5)	43 (18.9)	0.008	1.80 (1.15–2.80)	1
Intraoperative complications	31 (3.8)	11 (2)	20 (7)	< 0.001	3.62 (1.70–7.72)	2
CLASSIC Minor	25 (81.2)	9 (81.8)	16(80.9)			
CLASSIC Major	6 (18.7)	2 (18.2)	4 (19)			
Primary anastomosis	663 (80.8)	449 (83.6)	214 (75.6)	0.006	0.61 (0.42–0.87)	3
Protective ostomy	112 (16.9)	57 (12.7)	55 (25.6)	< 0.001	2.36 (1.55–3.59)	
Type of suture				0.089	0.70 (0.47–1.06)	0
Handsewn	150 (22.6)	110 (73.3)				
Stapled	513 (77.4)	339 (65.9)				

OT: Operating time.

Table 4. Postoperative variables.

Variable	Patients n (%) 823 (100)	NPCO n (%) 539 (65.5)	PCO n (%) 284 (34.5)	p-value	OR/MWD (CI 95%)	Missing values
Hospitalization, days (mean ± SD)	8 (7.8)	5 (5.8)	13 (12.2)	< 0.001	-8 (-9.50 – -6.50)	17
Long-term hospitalization (>8 days)	182 (22.6)	36 (6.8)	146 (52.3)	< 0.001	15 (9.25–24.24)	
Locally advanced tumor (> pT2)	473 (60.4)	292 (57.5)	181 (65.8)	0.023	1.42 (1.05–1.93)	40

NPCO: Group without postoperative complications. PCO: Group with postoperative complications.

Table 5. Multivariate analysis considering postoperative complications as dependent variable, including the entire cohort.

Variables	OR	Standard error	p-value	CI 95%
Age	1.02	0.006	0.012	1.00–1.02
ASA > II	0.85	0.14	0.321	0.61–1.17
Male sex	0.54	0.09	< 0.001	0.60–1.22
Smoking	0.85	0.16	0.391	0.60–1.22
Anemia	1.61	0.28	0.006	1.14–2.26
Previous abdominal surgery	1.18	0.20	0.337	0.84–1.65
Emergency surgery	2.29	0.58	0.001	1.40–3.76
Colorectal surgeon vs. general surgeon	0.83	0.20	0.429	0.52–1.32
Laparoscopic surgery	0.90	0.21	0.674	0.57–1.44
High volume	0.52	0.11	0.002	0.35–0.78
Rectal surgery vs. colon surgery	1.65	0.38	0.030	1.05–2.59

Table 6. Multivariate analysis considers postoperative complications as dependent variable, including only patients operated on for rectal cancer.

Variables	OR	Standard error	p-value	CI 95%
Age	1.00	0.13	0.768	0.98–1.03
ASA > II	0.99	0.33	0.998	0.52–4.00
Male sex	0.52	0.18	0.062	0.26–1.03
Smoking	1.03	0.37	0.929	0.51–2.08
Anemia	1.52	0.51	0.213	0.79–2.93
Previous abdominal surgery	1.54	0.53	0.210	0.78–3.04
Neoadyuvancia	1.14	0.38	0.688	0.59–2.21
Emergency surgery	1.28	1.36	0.814	0.16–10.25
Colorectal surgeon vs. general surgeon	0.70	0.43	0.562	0.21–2.36
Laparoscopic surgery	2.22	1.06	0.093	0.87–5.64
High volume	0.35	0.13	0.004	0.17–0.72

DISCUSSION

This study presents prospective information from the National Colorectal Cancer Database of Argentina on 823 patients who underwent surgical procedures in various medical centers throughout the country. The study evaluated risk factors for complications after the surgical procedure. The first result to highlight is the heterogeneity in the surgical volume of the participating centers, with 7 centers representing more than 70% of the recruited patients and another 7 centers with less than 6 patients (below the 25th percentile for recruitment). A large body of research has examined the link between higher surgical volume and better outcomes in CRC surgery, especially postoperative complications and long-term survival.[16,17]

These results have also been demonstrated in the present study, where high-volume centers were independently associated with a lower risk of postoperative complications, both at a general level (OR: 0.52; p = 0.002) and specifically in surgery for rectal cancer (OR: 0.35; p = 0.004).

Another notable fact is that 10% of the cohort was made up of patients under 45 years of age, following a current global trend that shows an increase in the incidence of colorectal tumors in the younger population.[18,20] Although other publications in the region have associated this factor with worse surgical results,[21] in this study the younger age of presentation was not associated with greater short-term complications, both in the univariate and multivariate analysis.

Seventy-nine percent of patients were operated on by surgeons specializing in the treatment of colorectal pathology, while the rest were operated on by general surgeons. This factor in itself was not associated with a lower incidence of complications after surgery, even though publications from other regions have associated specialization with better results.[22,23] A plausible explanation for this phenomenon is a possible selection bias, since the most complex surgeries are probably performed in referral centers and/or by surgeons with greater exposure to this type of pathology, which in itself could imply a higher risk of complications in the postoperative period. However, this is only a hypothesis, since Argentina does not have precise information regarding the referral flow of more complex patients to high-volume centers, something that might be corrected in the future through the prospective registry used for this study.

Some of the factors independently related to postoperative complications in multivariate analysis also deserve to be included in this discussion.

Emergency surgery was directly associated with the development of postoperative complications, in agreement with previous publications.[24,25] It is known that urgent CRC surgeries are generally due to advanced tumors complicated by perforation or obstruction. Since the data on CRC screening in Argentina are imprecise, we must again formulate a hypothesis about the possibility of improving postoperative results through early detection of these neoplasms, as described with the implementation of this strategy in other countries.[26]

In this study, no independent relationship was found between patients with more comorbidities and the risk of postoperative complications, although in the univariate analysis the group of patients with complications presented a significantly higher Charlson score. This association has been previously described in the literature[27] and we must remember that there are currently programs specifically designed to optimize this type of patients to reduce the risk of adverse outcomes. Specifically, the Enhanced Recovery After Surgery (ERAS) program has among its objectives to reduce the stress to which the body is subjected during surgery, which has been associated with better surgical outcomes. Therefore, the possible implementation of this program in Argentina could correct this fundamental factor associated with worse outcomes. ERAS program has already been successfully incorporated in some hospitals in Latin America.[28-30]

There is a marked discrepancy between the overall complication rate presented in this cohort (35%) compared to previous publications from different centers in Argentina.[21,31,32] This divergence can be explained by the fact that this registry includes not only academic centers, but also other medium and low volume centers. In turn, the difference in the definition and stratification of complications in the different publications makes the comparison even more difficult and represents a call to unify definitions when recording the operative results of colorectal surgery.

This study has limitations, starting with the aforementioned heterogeneity of patients, which is due to the different volumes treated at each center. In turn, although the study has included information provided by a significant number of centers located in different parts of Argentina, there are still many provinces that are underrepresented and many institutions that treat patients with CRC have not yet been incorporated into the national registry, so this sample may not be representative of the entire country.

Finally, for the reasons explained in previous publications, the number of variables included in the registry is limited, since its purpose is to obtain data from the general population and not related to a particular object of study. This explains why some factors that could influence the results of surgery have not been included in the analysis.

However, this study is the first to include prospective information from a large number of centers treating patients with CRC and represents a reliable source of data that begins to show aspects that can be worked on in the future to improve the postoperative results of these patients.

CONCLUSION

The present study indicates that male gender, anemia, urgent surgery, and prolonged procedures are factors associated with increased risk of developing early postoperative complications following colorectal surgery at various centers in Argentina. Furthermore, patients treated at high-volume colorectal surgery centers tend to experience fewer postoperative complications when compared to those treated at low-volume centers.

Future efforts should focus on evaluating modifiable surgical factors to improve treatment outcomes for these patients.

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