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ORIGINAL SCIENTIFIC REPORT

Impact of the COVID-19 Pandemic on Enhanced Recovery After Surgery (ERAS) Application and Outcomes: Analysis in the "Lazio Network" Database

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Abstract

Background The aim of this study was to investigate how the COVID-19 pandemic influenced ERAS program application in colorectal surgery across hospitals in the Lazio region (central district in Italy) participating in the "Lazio Network" project.

Methods A multi-institutional database was constructed. All patients included in this study underwent elective colorectal surgery for both malignant and benign disease between January 2019 and December 2020. Emergency procedures were excluded. The population was divided into 2 groups: a pre-COVID-19 group (PG) of patients operated on between February and December 2019 and a COVID-19 group (CG) of patients operated on between February and December 2020, during the first 2 waves of the pandemic in Italy.

Results The groups included 622 patients in the PG and 615 in the CG treated in 8 hospitals of the network. The mean number of items applied was higher in the PG (65.6% vs. 56.6%, $p < 0.001$) in terms of preoperative items (64.2% vs. 50.7%, $p < 0.001$), intraoperative items (65.0% vs. 53.3%, $p < 0.001$), and postoperative items (68.8% vs. 63.2%, $p < 0.001$). Postoperative recovery was faster in the PG, with a shorter time to first flatus, first stool, autonomous mobilization and discharge (6.82 days vs. 7.43 days, $p = 0.021$). Postoperative complications, mortality and reoperations were similar among the groups.

Conclusions The COVID-19 pandemic had a negative impact on the application of ERAS in the centers of the "Lazio Network" study group, with a reduction in adherence to the ERAS protocol in terms of preoperative, intraoperative and postoperative items. In addition, in the CG, the patients had worse postoperative outcomes with respect to recovery and discharge.

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Introduction

Coronavirus disease 19 (COVID-19) was declared a pandemic by the WHO on March 11, 2020 [1]. COVID-19 is characterized by flu-like symptoms that involve the upper and lower respiratory tract and can be fatal, especially in fragile patients [2]. The worldwide spread of coronavirus was unprecedented, and the initial delayed response, due to lack of preparedness, caused an overload on health care systems [3].

Italy was the first European country heavily hit by the pandemic. On March 23, 2020, the Italian government declared extraordinary measures all over the country, with a complete lockdown and implementation of hospital units dedicated to patients affected by COVID-19 [4].

Italy suffered two major outbreaks of COVID-19 in 2020: the first occurred between February 2020 and May 2020, and the second occurred between September 2020 and December 2020, with a transitional phase in that summer characterized by a slight decrease in contagions. During the first outbreak of the disease, Italy had 227,972 cases of COVID-19 infection and 34,079 deaths caused by COVID-19. Higher numbers were observed during the second outbreak, with 1,791,673 new cases and 39,927 deaths [5].

Several studies have reported how the virus became widespread, and the measures carried out to stop the contagions have caused a slowdown of colorectal cancer care and surgery worldwide [3–6]. The COVIDSurg collaborative estimated that 35.9% of colorectal cancer surgeries worldwide were cancelled during the peak of contagions [6]. Santoro et al. [3] conducted a survey about how the pandemic impacted colorectal surgery, and 97.3% of the responders suffered a reduced capacity for the procedures or a temporary suspension of elective procedures.

The ERAS (Enhanced Recovery After Surgery) program is a multimodal perioperative pathway that is applicable in various surgical fields, including colorectal surgery, and produces better clinical results in terms of patient recovery [7]. This program requires a multidisciplinary approach to the patient, involving different professional figures and many hospital facilities [8].

The aim of this study was to investigate how the COVID-19 pandemic changed application of the ERAS program to colorectal surgery in the hospitals of the Lazio region (central district in Italy) participating in the "Lazio Network" project.

Materials and methods

Population

The "Lazio Network" project is a multi-institutional, nonprofit study group including 15 institutions based in Italy's Lazio region and dedicated to the improvement and promotion of ERAS protocol application to colorectal cancer [9, 10]. The study group protocol was approved by the *"A. Gemelli"* ethics committee (Protocol: 000767418), and the ethics committees of all participating centers were consequently informed.

All the participating hospitals applied the maximum number of items possible, according to the facilities available (resources and staff number) and patient compliance. To standardize ERAS item application, audits and meetings were regularly scheduled in the "Lazio Network" study group, and a shared consensus protocol was developed.

A shared database, including demographic, clinical and surgical data as well as postoperative outcomes, was constructed.

All patients included in this study underwent elective colorectal surgery for both malignant and benign disease between January 2019 and December 2020. All such patients considered eligible were > 18 years of age and were enrolled regardless of sex, the presence of comorbidities or the surgical approach used. All included patients had a negative preoperative COVID-19 test.

The exclusion criteria were as follows: patients receiving emergency surgery and patients undergoing transanal procedures for resections of early cancers or polyps such as TAMIS or TEM. Multiple site resections, total colectomies and segmentary resection were categorized as other resections.

Postoperative morbidities were classified according to the Clavien–Dindo classification system [11]. Severe surgical complications were defined as Clavien–Dindo grade 3 or higher.

All medical complications were recorded. For the purpose of the present analysis, the following complications that required a specific treatment were considered severe medical complications: cardiopulmonary complications, cerebrovascular complications, pulmonary embolism or pneumonia, liver failure and nephrological complications.

Patients were considered fit for discharge if they met the following criteria: toleration of a normal oral diet, good pain control, restoration of flatus or stool passage function, absence of surgical complications, independence in normal life activities, and agreement on discharge.

The entire perioperative enhanced pathway has been evaluated following the latest edition of the ERAS Society Guidelines for Colorectal Surgery published in 2018 [8].

The Lazio Network collective database was constructed to collect data on 20 ERAS items: 9 preoperative, 6 intraoperative and 5 postoperative items. All the items are detailed in Table 1.

This study follows the STROBE Checklist for cohort study. The RECOvER checklist for ERAS Study is provided in Supplementary Table 1.

Study design and outcomes

In this cohort study, the patients were divided into 2 groups: patients operated on between February 2019 and December 2019, before the COVID-19 pandemic, called the pre-COVID-19 group (PG), and patients operated on between February 2020 and December 2020, during the first 2 waves of the COVID-19 pandemic in Italy, called the COVID-19 group (CG).

Table 1 ERAS items

Preoperative items	Preadmission information regarding the patient and counseling
	Prehabilitation
	Preoperative nutritional care (nutritional evaluation and any nutritional intervention)
	Administration of an immunonutrition drink
	Administration of preoperative carbohydeate drink
	Avoidance of mechanical bowel preparation (excluded patients undergoing rectal surgery)
	Preoperative fasting no longer than 6 h for solid food and 2 h for clear liquids
	Prevention of nausea and vomiting
	Correct antimicrobial prophylaxis
Intraoperative items	Avoidance of preanesthetic medications
	Avoidance of nasogastric intubation
	Avoidance of abdominal drains (excluding patients undergoing rectal surgery)
	The use of a standard anesthetic protocol
	Minimally invasive surgery
	Prevention of intraoperative hypothermia
Postoperative items	Use of morphine-free multimodal analgesia
	Application of standardized thromboprophylaxis protocols
	Early mobilization of the patient
	Early removal of the bladder catheter (before 3 postoperative days)
	Early oral feeding (oral feeding with fluids and light food on the first postoperative day)

The primary endpoint was the comparison of the mean number of ERAS items applied.

The secondary endpoint was the analysis of postoperative outcomes.

Statistical analysis

Quantitative data are reported as the mean ± SD (range). Normally distributed quantitative data were analyzed with the Student's *t*-test. Mann–Whitney test was used otherwise.

The qualitative data are reported as the number of patients (percentage of patients) and were compared with the Pearson χ2-test.

All tests were 2-sided with a significance level of 5%. Statistical significance was defined as a p-value < 0.05.

All analyses were performed using IBM-SPSS, v.23 (IBM-Co., USA).

Results

Study population

Out of a collective database of 3110 patients treated between 2016 and 2020 in 15 hospitals of the network, 1237 met the inclusion criteria: 622 patients in the PG and 615 in the CG. The patients included in the study were treated in 8 hospitals of the "Lazio Network".

The groups were homogeneous in terms of sex, age, type of disease, stage of malignant disease and surgical procedure. There was a statistically significant difference in terms of BMI ($p = 0.029$) and ASA classification score ($p < 0.001$).

It must be noted that some data regarding the ASA score and stage of malignant disease were missing in the database.

All the population details are in Table 2.

ERAS item application

Regarding the ERAS protocol application, in the PG, a mean of 18.58 items per patient were collected in the database, and 13.12 items were applied. In the CG, a mean of 17.23 items per patient were collected in the database, and 10.92 items were applied ($p < 0.001$ for both).

In the PG, a mean of 5.78 preoperative ERAS items were applied; on the other hand, a mean of 4.56 preoperative items were applied in the CG ($p < 0.001$). Concerning the intraoperative items, the mean application was 3.90 for the PG and 3.20 for the CG ($p < 0.001$).

The mean postoperative item application was 3.44 for the PG and 3.16 for the CG ($p < 0.001$).

All these data are summarized in Table 3.

Table 2 Demographics and clinical features

	PG (n = 622)	CG (n = 615)	p value
Sex (n, %)			0.417*
Male	340 (54.7%)	322 (52.4%)	
Female	282 (45.3%)	293 (47.6%)	
Age, years (mean ± SD, range)	68.52 ± 11.82 (15–98)	69.86 ± 13.07 (21–98)	0.060**
BMI, kg/m^2 (mean ± SD, range)	25.69 ± 3.91 (15.82–43.11)	25.08 ± 3.92 (16.60–46.80)	0.029**
ASA classification (n, %)[a]			< 0.001*
ASA I	54 (9.0%)	27 (5.6%)	
ASA II	386 (63.9%)	259 (53.7%)	
ASA III	156 (25.8%)	188 (39.0%)	
ASA IV	8 (1.3%)	8 (1.7%)	
Disease (n, %)			0.316*
Malignant	508 (81.7%)	507 (82.5%)	
Benign	100 (16.1%)	101 (16.4%)	
IBD	14 (2.2%)	7 (1.1%)	
Stage of malignant disease (n, %)[b]			0.339*
Stage I	154 (31.0%)	111 (27.7%)	
Stage II	143 (28.7%)	117 (29.2%)	
Stage III	149 (29.9%)	128 (31.9%)	
Stage IV	42 (8.4%)	42 (10.5%)	
Complete response post neo-adjuvant	10 (2.0%)	3 (0.7%)	
Procedure (n, %)			0.719*
Right colectomy	224 (36.0%)	200 (32.5%)	
Transverse colectomy	31 (5.0%)	37 (6.0%)	
Left colectomy	208 (33.5%)	214 (34.8%)	
Rectal resection	132 (21.2%)	138 (22.4%)	
Other	27 (4.3%)	26 (4.3%)	

*χ^2 test

**Student's t test

[a]Missing data: n = 604 for PG, n = 482 for CG

[b]Missing data: n = 498 out of 508 malignant disease for PG, n = 401 out of 507 malignant disease for CG

Operative data

In Table 4, all the operative data are detailed. The minimally invasive approach rate was 86.3% in the PG and in 80.8% in the CG (p = 0.021). The rate of conversion to open surgery was 5.2% in the PG and 8.5% in the CG (p = 0.038). The mean operative time was 183.92 min in the PG and 196.71 in the CG (p = 0.005).

Short-term outcomes

All the postoperative outcomes are detailed in Table 5.

The difference between the groups did not reach statistical significance for the mean time to oral feeding, overall postoperative complications, severe medical complications, severe surgical complications, or reoperation rate.

Postoperative COVID-19 infection was observed in only 3 patients in the CG. Postoperative deaths occurred in 5 patients in the PG and 10 patients in the CG (p = 0.186).

Time to first flatus and stool was faster in the PG than in the CG ($p < 0.001$ for both), and even the time to discharge was faster in the PG with a mean of 6.82 days (p = 0.021). The readmission rate was 2.7% in the PG and 1.0% in the CG (p = 0.022).

Table 3 ERAS protocol application

	PG (n = 622)	CG (n = 615)	p value
ERAS item collected (mean ± SD, range)	18.58 ± 1.50 (14–20)	17.23 ± 3.06 (12–20)	< 0.001*
Percentage of ERAS item collected	92.9%	86.1%	
ERAS item applied (mean ± SD, range)	13.12 ± 2.75 (5–18)	10.92 ± 3.45 (3–19)	< 0.001*
Percentage of ERAS item applied	65.6%	54.6%	
Preoperative ERAS items applied (mean ± SD, range)	5.78 ± 1.85 (1–9)	4.56 ± 1.90 (0–9)	< 0.001*
Percentage of Properative ERAS item applied	64.2%	50.7%	
Preadmission information and counseling	79.4%	68.8%	
Prehabilitation	73.0%	67.5%	
Preoperative nutritional care	29.9%	16.6%	
No mechanical bowel preparation[a]	57.8%	58.5%	
Immunonutrition drink	23.6%	7.6%	
Preoperative carbohydrate drink	66.9%	37.2%	
No preoperative fasting	71.4%	36.1%	
Prevention of nausea and vomiting	87.9%	77.2%	
Antimicrobial prophylaxis	100%	99.8%	
Intraoperative ERAS items applied (mean ± SD, range)	3.90 ± 0.93 (2–6)	3.20 ± 0.90 (0–6)	< 0.001*
Percentage of Intraoperative ERAS item applied	65.0%	53.3%	
No preanesthetic medications	80.7%	45.5%	
No nasogastric intubation	34.2%	43.4%	
Standard anesthetic protocol	86.8%	42.1%	
Prevention of intraoperative hypothermia	100.0%	91.5%	
Minimally invasive surgery	86.3%	80,8%	
No abdominal drain[a]	41.0%	21.0%	
Postoperative ERAS items applied (mean ± SD, range)	3.44 ± 1.14 (1–5)	3.16 ± 1.33 (0–5)	< 0.001*
Percentage of postoperative ERAS item applied	68.8%	63.2%	
Morphine-free multimodal pain control	58.2%	66.3%	
Thromboprophylaxis	99.8%	91.4%	
Early mobilization	43.1%	42.4%	
Early removal of the bladder catheter	84.7%	67.6%	
Early oral feeding	57.9%	48.5%	

*Student's t test

[a]Rectal resection excluded

Discussion

The best treatment of CRC is a multimodal approach, and surgery plays a key role in its management. A minimally invasive approach causes faster recovery after surgery and benefits patients in terms of a lower rate of postoperative complications, reoperations, mortality and readmission [12–15]. In this context, the ERAS protocol contributes to increasing these advantages, and adherence to its principles leads to better outcomes even in open surgical procedures [7, 10, 16, 17].

The ERAS Society provides guidelines for many types of surgery, and all these pathways include items for a complete perioperative management of patients, including fragile ones [8, 18–22].

The emergence of coronavirus disease 2019 was an unexpected event that required a massive deployment of resources from the health systems of all countries involved worldwide. In Italy, the first European region hit by the pandemic, the rapid spread of this disease quickly saturated the health care system, especially intensive-care units. Many hospitals became dedicated COVID-19 hospitals during 2020, and their internal organization was sometimes reorganized [23].

As mentioned, many screening and diagnostic exams were delayed: the diagnosis-to-treatment interval for oncological diseases increased considerably [3]. In several

Table 4 Operative data

	PG (n = 622)	CG (n = 615)	p value
Procedure (n, %)			0.021*
Open	85 (13.7%)	118 (19.2%)	
Laparoscopic	517 (83.1%)	473 (76.9%)	
Robotic	20 (3.2%)	24 (3.9%)	
Conversion to open surgery (n, %)			0.038*
Totally minimally invasive	509 (94.8%)	455 (91.5%)	
Conversion to open surgery	28 (5.2%)	42 (8.5%)	
Operative time, min (mean ± SD, range)	183.92 ± 71.73 (55–600)	196.71 ± 79.66 (60–538)	0.005**
Stoma construction (n, %)	81 (13.0%)	65 (10.6%)	0.181*

*χ^2 test

**Student's t test

Table 5 Postoperative outcomes

	PG (n = 622)	CG (n = 615)	p value
Time to first flatus, days (Mean ± SD, range)	2.14 ± 0.99 (1–7)	2.40 ± 1.12 (1–8)	< 0.001**
Time to first stool, days (Mean ± SD, range)	3.42 ± 1.34 (1–10)	3.75 ± 1.53 (1–10)	< 0.001**
Time to oral feeding, days (Mean ± SD, range)	1.59 ± 0.97 (1–9)	1.59 ± 1.02 (1–9)	0.255**
Post-operative overall complications (n, %)	100 (16.1%)	111 (18.0%)	0.849*
ASA 1 patients[a]	8 (1.2%)	2 (0.3%)	0.454
ASA 2 patients[a]	58 (9.3%)	39 (6.3%)	0.470
ASA 3 patients[a]	31 (5.0%)	58 (9.4%)	0.071
ASA 4 patients[a]	2 (0,3%)	5 (0.8%)	0.149
Overall COVID-19 infection	0 (0.0%)	3 (0.5%)	
Post-operative severe medical complications (n, %)	8 (1.3%)	11 (1.8%)	0.472*
Post-operative severe surgical complications (n, %)	36 (5.8%)	32 (5.2%)	0.652*
Anastomotic leak	26 (4.2%)	25 (4.1%)	
Number of reoperations (n, %)	35 (5.6%)	30 (4.9%)	0.555*
Number of postoperative deaths (n, %)	5 (0.8%)	10 (1.6%)	0.186*
Time to readiness for discharge, days (Mean ± SD, range)	5.74 ± 3.76 (2–44)	6.07 ± 3.93 (2–42)	0.025**
Time to discharge, days (Mean ± SD, range)	6.82 ± 5.10 (2–63)	7.43 ± 4.84 (3–50)	0.021**
Number of readmissions within 30 days, days (n, %)	17 (2.7%)	6 (1.0%)	0.022*

*χ^2 test

**Mann–Whitney test

[a]Missing data for ASA: n = 604 for PG, n = 482 for CG

cases, tumors were diagnosed at more advanced stages or directly with the onset of their complications with the need for emergency procedures [3].

Moreover, many health workers became victims of this pandemic themselves, and a reorganization of resources was necessary with relocations of nurses and anesthesiologists [3]. In some cases, surgeons were moved to COVID-19 units due to the lack of workers.

The population analyzed in this paper was divided into 2 groups with no major differences in their clinical data. The only notable difference was in the ASA score distribution, with more patients classified as ASA II in the PG and more with ASA III in the CG. This may be related to missing data in the collective database, but the authors believe that this difference had a minimum impact on the results of this study as shown by the sub analysis of the complications.

During the COVID-19 period, only a limited number of health workers were available to deal with an important pandemic emergency; therefore, nonclinical activities, such as data collection and scientific activity, were neglected. It follows that in the COVID-19 group, there was a greater number of missing data, mostly regarding the ASA score and stage of malignant disease, as well as for the ERAS item collected.

The authors found less adherence to the ERAS protocol during the COVID-19 period, and this concerned preoperative, intraoperative and postoperative items. In the literature, there are few and discordant studies. Borghi et al. recorded a similar result in terms of reduction in the application of ERAS in Italy [23]. In the UK, on the other hand, increased adherence to the ERAS protocol was observed [24, 25].

These results can be explained by 2 main factors: a lack of facilities and workers in the hospitals and a general change of surgeons' habits to a more "conservative" approach.

Concerning the lack of facilities, during the COVID-19 period, some services in Italian hospitals were less available, some outpatient clinics were closed, and patients had less access to the hospitals due to both government restrictions and fear of getting infected [4]. This finding can likely explain the smaller adherence to most of the preoperative items compared to that in the previous period. In particular, the major difference is evident for the nutritional items: the authors registered a reduction of up to 20% of application of this item because some of the "nonessential" services were completely stopped. Similar observations were made by Sica et al. in a single hospital in Rome, Italy [26].

The adherence to all postoperative items was reduced in the COVID-19 group. One of the items that was more affected by this difference was the early mobilization. This item requires dedicated time and energy by nurses, who were sometimes fewer in number. Furthermore, in some hospitals, this item is applied with the help of physiotherapists, who, as mentioned, were included in the suspended "nonessential-services". In addition, the restrictions on access to the surgical ward for relatives and caregivers, required more work for the nurses in charge.

The work overload on the surgical staff combined with a lack of surgeons, for the shifts in other services or for workers affected by COVID-19, can also explain the inferior use of a minimally invasive approach in the COVID-19 period. In the experience of the authors, during that period, it was very difficult to guarantee the presence of all the members of the colorectal team during surgeries, and sometimes surgeons dedicated to other specialties had to collaborate to maintain the activity of the colorectal units.

Moreover, during the pandemic, international recommendations for laparoscopy were published, suggesting safety measures such as the presence of CO2 filters, smoke evacuation systems and negative pressure rooms [27], so this required the reorganization of the operating theatres.

This situation can also explain why more open surgical procedures were registered in the CG than in the PG.

Regarding the change in the surgeons' habits, a major number of abdominal drains placed in the CG was registered in this experience. These data can be interpreted with a more "conservative approach" of the surgeons during the stressful period of the pandemic when even the postoperative management of the patients could have been more difficult.

Outpatient services were strongly reduced during the pandemic period, and access to first-aid had to be limited to strictly necessary cases. For these reasons, it is possible that the longer hospitalization in the CG is related to the need of the surgeons to discharge the patient with the certainty of absence of complications. The difficulty of access to the emergency unit can also explain the lower rate of readmissions in the CG.

The reduction of ERAS protocol application is evident in the comparison of postoperative outcomes: the patients of the PG had a shorter time to first flatus and stool and received a faster discharge. The time to oral feeding was the same, probably because the involved centers have an ERAS protocol, and oral feeding with solid food is administered following a precise schedule.

The incidence of reoperation and postoperative death was the same between the 2 groups. No difference in terms of postoperative medical and surgical complications was recorded between the groups.

All the patients in the present study had a negative COVID-19 swab result at admission, and all safety measures were taken during hospitalization. Nevertheless, in the CG, 3 cases of COVID-19 infection were registered. Two of these patients required medical therapies in the COVID-19 department, and one patient was admitted to the intensive care unit. None of them had a fatal outcome.

Limitations of the study can be found in its multicentric design, but it must be noted that all the centers followed a common ERAS protocol. Furthermore, there were some missing data, especially in the CG, probably related to the difficulty of data collection during the pandemic.

Conclusion

The COVID-19 pandemic had a negative impact on the application of ERAS in the centers of the Lazio Network study group, with a reduction in adherence to the ERAS protocol in terms of preoperative, intraoperative and postoperative items. In addition, in the CG, the patients had worse postoperative outcomes in terms of recovery and discharge.

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Availability of data and material The dataset generated during the current study is available from the corresponding author upon reasonable request.

Declarations

Conflict of interest The authors have no competing interests or conflicts of interest relevant to this article to disclose.

Ethical approval This research involves only human participants and no animals and was performed in accordance with the 1964 Helsinki Declaration. This study was first approved by the institutional Ethics Committee of *Fondazione Policlinico Universitario A. Gemelli IRCCS* (Protocol Number 000767418) and then approved by the institutional ethics committee of every participating center.

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

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