

The impact of SARS-CoV-2 infection on the surgical management of colorectal cancer: lessons learned from a multicenter study in Spain

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ABSTRACT

Objective: the aim of the study was to analyze the management of colorectal cancer (CRC) patients diagnosed with CRC or undergoing elective surgery during the period of the SARS-CoV-2 pandemic.

Material and methods: a multicenter ambispective analysis was performed in nine centers in Spain during a four-month period. Data were collected from every patient, including changes in treatments, referrals or delays in surgeries, changes in surgical approaches, postoperative outcomes and perioperative SARS-CoV-2 status. The hospital's response to the outbreak and available resources were categorized, and outcomes were divided into periods based on the timeline of the pandemic.

Results: a total of 301 patients were included by the study centers and 259 (86 %) underwent surgery. Five hospitals went into phase III during the peak of incidence period, one remained in phase II and three in phase I. More than 60 % of patients suffered some form of change: 48 % referrals, 39 % delays, 4 % of rectal cancer patients had a prolonged interval to surgery and 5 % underwent neoadjuvant treatment. At the time of study closure, 3 % did not undergo surgery. More than 85 % of the patients were tested preoperatively for SARS-CoV-2. A total of nine patients (3 %) developed postoperative pneumonia; three of them had confirmed SARS-CoV-2. The observed surgical complica-

tions and mortality rates were similar as expected in a usual situation.

Conclusions: the present multicenter study shows different patterns of response to the SARS-CoV-2 pandemic and collateral effects in managing CRC patients. Knowing these patterns could be useful for planning future changes in surgical departments in preparation for new outbreaks.

Keywords: Colorectal cancer. COVID-19. Pandemic. Coronavirus. Minimally invasive surgery.

INTRODUCTION

In December 2019, an outbreak of a novel coronavirus SARS-CoV-2 infection (known as COVID-19 disease) was detected in the city of Wuhan (China) (1,2). In nearly three months, SARS-CoV-2 rapidly spread worldwide, causing a massive health crisis, and was considered by the World Health Organization as a global pandemic (3,4). Cases grew rapidly across the country in Spain, leading to a peak in incidence in mid-April, making Spain the most affected European country (5). The Spanish Government declared a mandatory nationwide lockdown period for 91 days (March 14th, 2020-June 21st, 2020).

The Spanish national public and private health system were severely affected because of this pandemic, with an impor-

Declarations: all procedures performed in studies involving humans were in accordance with the ethical standards of the institutional research committee and the 1964 Declaration of Helsinki and its subsequent amendments. Informed consent was obtained from all participants included in the study.

Author's contribution: Patricia Tejedor and Carlos Pastor contributed equally in analyzing the data and writing the manuscript. The rest of the authors critically revised the paper for important intellectual content. All authors have contributed to the work and agreed on the final version.

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tant reduction in hospital resources for the treatment of other diseases beyond COVID-19. Hospital surgical activity was reduced to the minimum due to the huge demand of the intensive care units (ICU), along with a lack of hospital personnel (6). As a result, the majority of surgical societies recommended postponing non-urgent procedures and promoting non-operative treatment in order to delay the need for surgery. This was justified as there was an increased rate of mortality in patients with pre-symptomatic SARS-CoV-2 infection (7-10).

Currently, there is a lack of information regarding how CRC patients were treated during the pandemic. Therefore, the present study was designed with the aim to analyze the management of CRC patients undergoing elective surgeries during the pandemic period.

METHODS

An ambispective analysis was performed based on a prospectively maintained database from February 1st, 2020 to May 31st, 2020. Exclusion criteria were patients undergoing emergency or palliative surgery. The participating centers were: a) University Clinic of Navarre, Madrid (UCNM); b) University Clinic of Navarre, Pamplona (UCNP); c) University Hospital of Leon, Leon (UHL); d) University Hospital Gregorio Marañón, Madrid (UHGM); e) Central Defense Gomez Ulla Hospital, Madrid (CDGUH); f) M.D. Anderson Cancer Center, Madrid (MDA); g) Hospital City of Coria, Coria (HCC); h) University Hospital Rio Hortega, Valladolid (UHRH); and i) University Hospital Marques de Valdecilla, Santander (UHMV).

Hospital phases during the pandemic period

In order to standardize each hospital status during the SARS-CoV-2 outbreak, the classification system proposed by the American College of Surgeons (ACS) was used (10):

- Phase I. Semi-urgent setting: only a few COVID-19 patients diagnosed, the hospital resources are not yet exhausted and there are still ICU beds available. In this scenario, asymptomatic colon or rectal cancer after neoadjuvant treatment should be performed as soon as feasible.
- Phase II. Urgent setting: there are many COVID-19 patients diagnosed. The ICU capacity and the theatre's supplies are limited. Elective surgery should be re-scheduled or referred.
- Phase III. All hospital resources are for COVID-19 patients. There is no ICU capacity and the theatre's supplies are exhausted. Only emergency cases should be performed.

Objectives

The primary outcome was the management chosen for each patient diagnosed with CRC during the study period, in accordance with the hospital's phase.

Data analysis

The baseline characteristics of the study population included variables related to the patient's preoperative characteristics and the baseline features of the tumor. The

management of each patient during the study period was documented, in accordance with the hospital's phase. A delay in treatment was considered when patients were operated on beyond 30 days from diagnosis. Other management variables were also obtained for each patient (changes in indications, referrals, changes in planned surgery, delays, etc.). Perioperative complications were also recorded (Clavien-Dindo classification) (11) and specific COVID-19 postoperative complications were searched.

For data analyses purposes, the study outcomes were divided into three periods based on the observed timeline of the SARS-CoV-2 outbreak in Spain: an initial period (February 1st-March 14th), a peak period (March 15th-April 30th) and a recovery period (May 1st-May 31st). All centers obtained their Institutional Review Board (IRB) approval before participating in the study.

Statistical analysis

Descriptive statistics are presented as the mean and standard deviation (SD) or median and lower quartile range or upper quartile range (LQ-UQ) for quantitative variables. All statistical analyses were performed using the SPSS® version 22 software (SPSS, Inc., Chicago, IL) and p-values of < 0.05 were considered as statistically significant.

RESULTS

A total of 301 patients were diagnosed with CRC and 259 (86 %) underwent elective surgery during the study period. Demographics, patient's baseline characteristics and surgical procedures for the entire study population (n = 301) and performed surgeries (n = 259) are presented in table 1. The remaining 42 patients that did not undergo surgery are presented in table 2. There were 27 referrals to other non-participating centers, five cases had an expected delay due to neoadjuvant chemoradiotherapy (nCRT), seven patients did not undergo surgery due to different reasons and there were three missing cases.

Surgical activity and hospital phases

Five out of the nine included hospitals (UHGM, UCNM, CDGUH, UHL and UHRH) decreased their surgical activity to a phase III level during the peak incidence period. Another hospital remained in phase II (UCNP) and three (MDA, UHMV, HCC) were able to remain in phase I during the entire study period. Figure 1A shows the number of procedures performed during the three periods of the study of the hospital phases. During the peak period, hospitals in phase III decreased their activity to a minimum (n = 27 interventions within five hospitals). The number of procedures performed in each of the hospitals are shown in figure 1B; one (UCNM) was completely collapsed during the peak period and did not perform any elective interventions during this time.

Types of surgeries and outcomes

The median time to surgery during the study period was 22 (13-39) days. All the procedures performed are present-

Table 1. Demographic characteristics of the patients included in the study

	n = 301
Age (mean, SD)	68.2 ± 16 years
Sex (M:F) (%)	58:42
ASA	
I-II	151 (50.2 %)
III-IV	83 (27.5 %)
Missing	67 (22.3 %)
BMI (kg/m ²)	26.1 ± 4
<i>Comorbidities</i>	
Hypertension	51.5 %
Diabetes	20.6 %
Renal dysfunction	3.8 %
Pulmonary disease	17.4 %
<i>Procedure</i>	n = 259
Right colectomy	75 (28.9 %)
Sigmoidectomy	63 (24.3 %)
Low anterior resection and TaTME	61 (23.6 %)
Left colectomy	22 (8.5 %)
Abdominoperineal excision	12 (4.6 %)
TAMIS	11 (4.2 %)
Subtotal colectomy	11 (4.2 %)
Hartmann's	2 (0.8 %)
Pelvic exenteration	2 (0.8 %)
<i>TNM stage</i>	n = 259
T0	17 (6.6 %)
T1	30 (11.6 %)
T2	56 (21.6 %)
T3	99 (38.2 %)
T4	27 (11.6 %)
Missing	30 (21.2 %)
N0*	143 (57.7 %)
N1*	44 (17.7 %)
N2*	21 (8.5 %)
Missing*	40 (16.1 %)

BMI: body mass index; TaTME: transanal total mesorectal excision; TAMIS: transanal minimally invasive surgery. *Excluding TAMIS.

ed in table 1. Overall, there was a 22.2 % (n = 49) rate of minor complications (Dindo-Clavien I-II) and 7.7 % (n = 17) of major complications (Dindo-Clavien III-IV), including 3 % of anastomotic leaks (n = 6). Fourteen required a reintervention (n = 5.7 %). Nine patients (3.5 %) developed postoperative pneumonia: three in the initial period, five during the peak period and one in the recovery period. Only three

Table 2. Changes in the management of colorectal cancer patients observed during the SARS-CoV-2 pandemic

Type of change		n = 187
Referrals n = 89	Phase I (MDA)	62 (33.1 %)
	Other hospitals	27 (14.4 %)
Delay (> 30 days) n = 72	Deferred	65 (34.8 %)
	Patient's choice	4 (2.1 %)
	Prolonged interval after nCRT (12 weeks)	3 (1.6 %)
nCRT n = 5	Expected delay	5 (2.7 %)
Change in the approach n = 11	Open surgery	11 (5.9 %)
	Patient's choice	4 (2.1 %)
No surgery n = 7	MDT decision	2 (1.1 %)
	Death	1 (0.5 %)
Missing n = 3		3 (1.6 %)

nCRT: neoadjuvant chemoradiotherapy; MDT: multidisciplinary team.

patients tested positive for a SARS-CoV-2 infection and were readmitted with pneumonia, but none required ICU admission. One patient with pneumonia also developed an anastomotic leak, underwent a reintervention and subsequently died.

Two patients that underwent transanal total mesorectal excision (TaTME) procedures developed major postoperative complications (Dindo-Clavien IV) that required ICU admission. One of the transanal resection (TAMIS) patients suffered minor complications (Dindo-Clavien II) and none of the patients presented postoperative complications related to COVID-19.

The median length of hospital stay (LOS) was six (4-8) days for the entire cohort. Four patients died during the study period (1.3 %). Two underwent surgery and a reintervention due to an anastomotic leak (one was SARS-CoV-2 positive) and another patient died due to medical complications (SARS-CoV-2 negative). The remaining patient was SARS-CoV-2 positive and surgery was deferred during the peak period. This patient died from a SARS-CoV-2 respiratory infection.

Changes in the management of patients

Table 2 shows that 187/301 (61.1 %) patients encountered some sort of change in their treatment management during the pandemic period. Of them, 89/187 (48 %) had to be referred to other hospitals for surgery; 27 were referred to centers not included in the study and are considered as missing data regarding intra and postoperative outcomes. Another 72/187 (38.5 %) patients had their surgery delayed

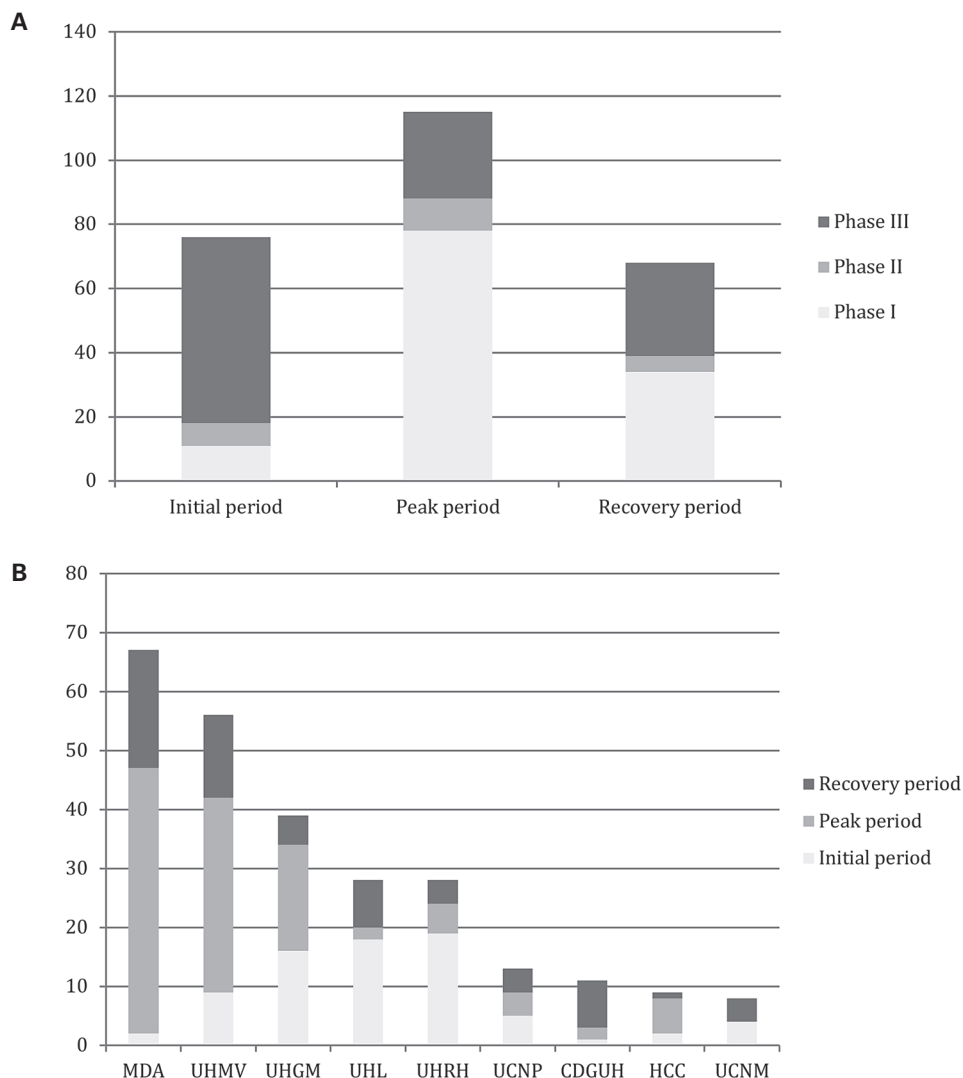


Fig. 1. Number of surgeries performed during the timeline periods of the COVID-19 outbreak in Spain. A. Divided by hospital phases. B. Divided by the hospitals included in the study.

beyond 30 days. In rectal cancer patients ($n = 98$), three (3.9 %) patients had a prolonged interval up to 12 weeks after neoadjuvant chemoradiotherapy and five were sent for neoadjuvant treatment (5.1 %). Minimally invasive surgery (MIS) was performed in 74.4 % of patients. Surgeons reported a change to open surgery in eleven cases (4.2 %), all of them during the peak period.

Evolution PCR testing and personal protective equipment (PPE) during the study period

In the initial period, only 13 patients were preoperatively tested for SARS-CoV-2 using the PCR test (17 %), while the majority of patients underwent testing during and after the peak period (85.2 % and 98.5 %, respectively). During the peak period, only two patients tested positive and did not undergo surgery, while three were inconclusive and surgery was deferred until a negative test was obtained. Another patient tested positive in the recovery period and the surgery was also deferred. Most patients underwent a

postoperative PCR test, especially during and after the peak period (95 % and 86 %, respectively). Only three patients tested positive after surgery and six had an inconclusive test (all during the peak period). Surgeons wore high-risk PPE in 14 cases (5.4 %); 13 tested negative preoperatively and the PCR test was not requested in one case. A low-risk PPE was used in 201 cases (77.6 %).

DISCUSSION

The present study shows the management and outcomes of elective CRC surgeries from a multicenter cohort of patients treated during the SARS-CoV-2 pandemic in Spain. In the last few months, several surgical societies have introduced specific perioperative recommendations for the SARS-CoV-2 pandemic. In our study, the majority of centers followed the national Surgical Spanish Association (AEC) guidelines (12) as well as the American College of Surgeons (ACS) recommendations (5,8,13-15). In terms of treatment strategies for CRC patients during the SARS-CoV-2 pandem-

ic, both societies proposed three main strategies with the goal to keep the effectiveness of the health systems while providing the best possible care to oncological patients (9). First, non-critical surgical elective care in phase III hospitals should be deferred. Second, selected patients (such as those with rectal cancer) can be offered neoadjuvant therapies instead of surgery as the primary treatment (13). Third, patients may be referred to other centers in order to avoid prolonged delays in further treatment and to optimize the care of regional populations (9,13).

In our study, a significant reduction was observed in the number of regular surgeries in every center except for phase I hospitals, which remained under low pressure for COVID-19 patients throughout the outbreak. These centers have some peculiarities that deserve to be mentioned. The MDA is a cancer-dedicated center that served as one of the referral hospitals for cancer surgery in the Madrid region during the peak period. The HCC is located in a region of Spain where the incidence of SARS-CoV-2 infection was very low and could continue with its normal surgical activities. Finally, the UHMV is a multi-building hospital that could preserve an entire separate building to exclusively attend to COVID-19 patients. In contrast, phase III hospitals had a high-volume COVID-19 patients and had to reduce their surgical capacities to a minimum or zero. As a consequence, one hospital in the study was completely collapsed during the peak period (UCNM).

Currently, there is a lack of information about the secondary effects that SARS-CoV-2 infection has had on particular conditions such as CRC. A recent study published by the COIDSurg Collaborative Initiative estimated that nearly 500,000 CRC interventions (36 % of the normal volume) have been cancelled globally or postponed due to the pandemic (16). We reported that 62 % of patients experienced some change to their initial planned management. Due to the capacity of referring patients to other hospitals (30 % in this study), the median time from the date of entering the waiting list to the date of surgery remained below 30 days. Even though these outcomes may be deemed notable, it should be emphasized that 24 % of patients continued to have their surgery delayed (> 30 days) and more than 3 % did not undergo surgery at all. We believe that these numbers could be multiplied in the event of suffering new waves of the SARS-CoV-2 pandemic. There is no evidence yet of the implications that cancelling or referring patients will have on the long-term follow-up of patients (6). In advanced cancers, it may imply delays in initiating adjuvant chemotherapy and may lead to worse survival rates (13,17-19) and a higher mortality (14).

Additional reported data in the study were those related to changes in the surgical technique or the approach. At the beginning of the SARS-CoV-2 outbreak, the majority of societies warned about the use of MIS, due to the potential risk for aerosol transmission (7,20-22). This advice was given based on previous reported studies of the isolation of other virus particles (hepatitis B virus) from surgical smoke (23). To the best of our knowledge, there is no evidence of the isolation of SARS-CoV-2 in aerosols from surgical smoke. As shown in our data, MIS was the most used approach. In addition, some initially considered "high risk" procedures such as TaTME or TAMIS (24) were performed during the study period in safe conditions. However, during the peak

period, a change to an open surgical approach was made in eleven (5.5 %) patients.

The worldwide recommendation is to not perform surgery on patients who are SARS-CoV-2 positive or who have symptoms of this disease (15,25). Due to the high rate of morbidity and mortality seen in surgical patients with SARS-CoV-2 (26), only true emergency surgeries should be performed. Coccolini et al. recently published the Italian clinical pathways for operating on SARS-CoV-2 positive patients, including PPE recommendations (25). During the peak period, societies highly recommended a preoperative PCR test 24 hours prior to surgery (27). As shown in this study, more than 85 % of the patients underwent testing prior to surgery. For positive or highly suspicious patients in whom a procedure needs to be performed, physicians should wear high-risk PPE (28,29). However, for confirmed negative patients, the equipment can be a low-risk PPE (taking into consideration possible false negative PCR test results) (30). High-risk gear consists of wearing double gloves, booties, surgical gowns, FFP3 mask and face shield or goggles (30).

An initial report from China by Lei et al. that focused on surgical complications reported a high percentage of complications and mortality due to SARS-CoV-2 pre-symptomatic patients who developed postoperative pneumonia (10). In contrast, our experience was different, and there were the same expected rates of surgical complications, anastomotic leakage and mortality during the study period. The median LOS was six (4-8) days for the entire cohort. A total of eight patients (3.1 %) developed postoperative pneumonia and three tested positive for SARS-CoV-2. Of these, eight recovered well from their respiratory symptoms without ICU support, whereas one died due to an anastomotic leakage, who was positive for SARS-CoV-2. Another patient died from SARS-CoV-2 pneumonia while on the waiting list. We believe that the progressive implementation of preoperative PCR-testing, especially during the peak and recovery period, may have had an influence on lowering the reported surgical complications during the SARS-CoV-2 pandemic. In this study, only three patients tested positive for SARS-CoV-2 preoperatively (two during the peak period and another afterwards) and surgery was deferred in all cases.

There are two ongoing trials collecting patients that have undergone curative cancer surgery during the pandemic, the CRC COVID Collaborative (31) and the COIDSurg (32). Similar to this study, the former aims to describe changes in cancer care in response to the pandemic and proposes a standardized model of delivering CRC services based on the impact of COVID-19 on the NHS and USA model of healthcare, whereas the latter is more focused on postoperative COVID-19 related outcomes. In the meantime, prior to having the results of these studies, there is a lack of knowledge regarding the impact of the SARS-CoV-2 pandemic on the management of CRC patients. To the best of our knowledge, this is the first multicenter study showing the real management of a cohort of patients diagnosed with CRC during the SARS-CoV-2 pandemic in Spain. As shown in our data, the pandemic also had huge collateral effects on the management of CRC patients causing delays, referrals or changes in the treatment strategies. The results from this study suggest that in the case of new global waves, maintaining COVID-19-free centers where patients may

be referred for surgery will ensure the delivery of quality oncological care. We believe that knowing the patterns of response to COVID-19 for each center will be useful for planning future reorganizations of surgical departments in the event of suffering new outbreaks.

This study has some limitations that should be mentioned. Firstly, this is an ambispective non-randomized study, so there are some inevitable biases. However, consecutive patients were included in order to avoid a selection bias. Besides, this is a multicenter trial, including centers that are representative of the public and private practice in Spain and some hospitals with an excessive overload of COVID-19 patients throughout the outbreak. A longer follow-up is needed in order to investigate the real impact of delaying elective cancer surgery on survival. Nonetheless, this is the first study showing the collateral effect of the SARS-CoV-2 pandemic on the management of a large cohort of CRC patients.

CONCLUSIONS

The SARS-CoV-2 pandemic is having an unprecedented effect on health-care systems around the world, with a collateral effect in the appropriate delivery of oncological care. The present multicenter study shows the patterns of response for different centers in Spain to COVID-19 and their outcomes in managing patients with colorectal cancer. We believe that knowing these experiences is useful for planning future changes and modifications concerning surgical and medical services in preparation for further SARS-CoV-2 outbreaks.

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Appendix 1

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