



# Preliminary results of a program for the implementation of laparoscopic colorectal surgery in an Italian comprehensive cancer center during the COVID-19 pandemic

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## Abstract

Despite operative benefit and oncological non-inferiority, videolaparoscopic (VLS) colorectal surgery is still relatively underutilized. This study analyzes the results of a program for the implementation of VLS colorectal surgery started in an Italian comprehensive cancer center shortly before COVID-19 outbreak. A prospective database was reviewed. The study period was divided in four phases: Phase-1 (Open surgery), Phase-2 (Discretionary phase), Phase-3 (VLS implementation phase), and Phase-4 (VLS consolidation phase). Formal surgical and perioperative protocols were adopted from Phase-3. Postoperative complications were scored by the Clavien–Dindo classification. 414 surgical procedures were performed during Phase-1, 348 during Phase-2, 360 during Phase-3, and 325 during Phase-4. In the four phases, VLS primary colorectal resections increased from 11/214 (5.1%), to 55/163 (33.7%), 85/151 (57.0%), and 109/147 (74.1%), respectively. The difference was statistically significant ( $P < 0.001$ ). All-type VLS procedures were 16 (3.5%), 61 (16.2%), 103 (27.0%), and 126 (38.6%) ( $P < 0.001$ ). Conversions to open surgery of attempted laparoscopic colorectal resections were 17/278 in the overall series (6.1%), and 12/207 during Phase-3 and Phase-4 (4.3%). Severe (grades IIIb-to-V) postoperative complications of VLS colorectal resections were 9.1% in Phase-1, 12.7% in Phase-2, 12.8% in Phase-3, and 5.3% in Phase-4 ( $P = 0.677$ ), with no significant differences with open resections in each of the four phases: 9.4% ( $P = 0.976$ ), 11.1% ( $P = 0.799$ ), 13.8% ( $P = 1.000$ ), and 8.3% ( $P = 0.729$ ). Despite the difficulties deriving from the COVID-19 outbreak, our experience suggests that volume of laparoscopic colorectal surgery can be significantly and safely increased in a specialized surgical unit by means of strict operative protocols.

**Keywords** Colorectal cancer · Laparoscopy · COVID-19 · Treatment-related complications

## Introduction

The first laparoscopically assisted colectomy was reported by Jacobs [1]. Since then, a number of controlled studies and meta-analyses have shown that videolaparoscopic (VLS) colorectal resections are associated with lesser pain, earlier recovery, and non-inferior oncological outcomes, as compared with open surgery [2–12]. Although in recent years laparoscopic colorectal surgery has become increasingly popular, several Italian and international surveys have shown

that it is still relatively underused, with substantial differences among centers [13–19].

The Fondazione IRCCS Istituto Nazionale dei Tumori di Milano (Italy) is one of the oldest and most important European comprehensive cancer centers. Before November 2018, open surgery was considered as default for colorectal cancer (CRC), except for patients affected by familial adenomatous polyposis (FAP) [20]. After that date, the choice between open and laparoscopic surgery was left at the discretion of surgeons of the Colorectal Surgery Unit (CSU). Finally, a formal program for the implementation of minimally invasive colorectal surgery was started in September 2019.

Shortly after the opening of our program, we had to face the sudden outbreak of Coronavirus disease 19 (COVID-19) [21]. Our institution was designed by Lombardy region health authorities as a COVID-19-free center to manage

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cancer patients from the surrounding hospitals overloaded by the pandemic. Furthermore, the use of VLS was reduced until data suggesting a negligible risk of COVID-19 transmission during laparoscopic surgery were reported [22].

As monitoring outcomes is a crucial part of health-care innovation, this study was performed to analyze the volume and safety of VLS procedures during the implementation process, and the impact of COVID-19 on our program.

## Patients and methods

Data for the current study were retrieved from a prospective electronic database collecting the surgical procedures performed in our institution (<http://10.4.0.102:8098/SaleOperatoire/>). Accordingly, all the analyses were conducted on a per-procedure basis (one record per procedure). This study was approved by our Institutional Review Board and Ethics Committee (Protocol Number INT149/19), and was conducted in agreement with the principles of Helsinki Declaration. All patients gave informed consent.

## Setting

Our CSU is a high volume unit in an oncological tertiary referral center. It includes the Peritoneal Surface Malignancy (PSM) Unit, and Hereditary Tumor Unit. The CSU is run by a team of eleven staff surgeons and two residents. Seven staff members have more than 20 years of experience from their board certification in general surgery. Three surgeons mainly perform cytoreductive surgery with hyperthermic intraperitoneal chemotherapy (CRS/HIPEC), and complex surgery for advanced/metastatic CRC; one surgeon performs both CRS/HIPEC and colorectal surgery; one surgeon treats both CRC and FAP patients; the remaining six mainly treat CRC. Two surgeons have a broad experience in VLS colorectal surgery, one performed regularly VLS as he was working in a general hospital previously, and four received formal VLS training during their residency. Two of them have also visited specialized centers abroad for additional training.

## Study design

The study period extends from 2017.11.01 to 2021.09.15, and was divided into four equal duration phases:

- Phase-1 (“Open surgery phase”): from 2017.11.01 to 2018.09.15.
- Phase-2 (“Discretionary phase”): from 2018.11.01 to 2019.09.15.
- Phase-3 (“VLS implementation”): from 2019.11.01 to 2020.09.15.

- Phase-4 (“VLS consolidation”): from 2020.11.01 to 2021.09.15.

The duration of Phase-2 (“Discretionary phase”) was necessarily defined by the time period between the retirement of the former CSU director, and the taking office of the new director. During Phase-2, the CSU was held ad interim by the Surgical Department Chair, and surgeons were free to choose between open and VLS surgery, mainly based on their own judgment. Consequently, the same time span was chosen for the remaining three phases, to ensure equal length for each phase. During Phase-3 and Phase-4, VLS was considered for all patients, according to surgical and perioperative management protocols. Contraindications included previous extensive abdominal surgery, large tumors directly invading surrounding organs, obesity, severe abnormalities of cardiac output and/or gas exchange.

The surgical procedures were categorized as follows:

1. Colorectal resections for primary CRC; as the present study is focused on surgical procedures, total colectomy/proctocolectomy for FAP, and surgery for anal spinocellular carcinoma relapsing after chemoradiotherapy were included.
2. Transanal resections: transanal minimally invasive surgery (TAMIS), or transanal endoscopic microsurgery (TEM).
3. CRS/HIPEC.
4. Surgery for disease recurrences, such as CRC abdominal/pelvic relapses, peritoneal metastases, and PSM recurrences.
5. Ostomy creation.
6. Ostomy closure.
7. Abdominal explorations, mainly to provide pathological diagnosis, or stage PSM patients before CRS/HIPEC.
8. Emergency procedures, mostly performed to manage postoperative complications, because our center has no emergency department.
9. Other surgical procedures.

Postoperative complications scored as grade IIIb (requiring intervention under general anesthesia), IV (life-threatening complications requiring intermediate/intensive care unit management), or V (death), according to the Clavien–Dindo classification, were considered as severe morbidity [23].

## Preoperative procedures

Each patient had an intensive clinical/radiological work-up consisting of clinical history, physical examination, endoscopy, lung and abdominal–pelvic contrast-enhanced computed tomography, carcinoembryonic antigen, and CA-19.9. Patients with rectal tumors underwent pelvic magnetic

resonance imaging, and endoscopic ultrasound. Additional studies were performed as needed. All patients were discussed during multidisciplinary meetings involving surgical, medical and radiation oncologists, radiologists, pathologists, and research nurses.

Preoperative radiotherapy was given to patients with cT3, cT4a/b, and/or cN+ primary rectal tumors below the peritoneal reflection, at a dose of 45/50 Gy in 25 days, with concurrent oral capecitabine or 5-fluorouracil-based chemotherapy, or as short-term course (25 Gy in 5 consecutive days).

Patients were admitted the day before surgery. On admission, subcutaneous nadroparin (3800 units once daily) was started. Mechanical bowel preparation was given. Cefazolin 2000 mg and metronidazole 500 mg were administered 30 min before skin incision and repeated every 6 h during surgery. Starting from Phase-3, oral metronidazole 2000 mg, neomycin 25,000 UI, and bacitracin 2500 UI were administered twelve hours before surgery.

### Operative treatment

Both open and VLS resections for primary CRC were performed according to the oncologic principles of complete mesocolic excision with central vascular ligation. Total mesorectal excision was performed in rectal tumors, and a distal margin  $\geq 2$  cm was ensured for upper-third rectal cancer, along with appropriate circumferential resection margins. Any care was taken to preserve the mesorectal fascia. After neoadjuvant chemoradiation, a clear distal resection margin was guaranteed.

All VLS resections were performed under the direct supervision of an experienced surgeon, who gave side-by-side intraoperative teaching until the trainees gained proficiency in technical skills. The abdominal cavity was entered through an open access method (Hasson technique). The laparoscopic approach was used to explore the abdomen, mobilize the colon, identify critical structures, and divide vascular pedicles. A medial-to-lateral and from-top-to-bottom approach was followed to preserve mesocolic fascia integrity, and get complete clearance of mesocolic fat together with local–regional lymph nodes. In rectal cancer, inferior mesenteric artery and vein were divided proximally or, in selected cases, just above the emergence of the left colic artery.

The bowel was exteriorized through a small incision for resection and anastomosis. The same incision was used for specimen extraction. Conversion from laparoscopic to open surgery was allowed at the surgeon's discretion because of patient's safety, technical difficulties, advanced disease, or inadequate oncologic margins.

In all patients, a “fast-track” recovery protocol was adopted. The nasogastric tube was removed at the end of

the operation. Ambulation and oral fluid intake were started from the day after surgery.

### Statistics

Categorical variables were described in terms of frequency and percentages. Continuous variables were described with mean, and standard error. Differences between groups were assessed by 1-way ANOVA test, Chi-square test, or Fisher's exact test, as appropriate. *P* values  $< 0.05$  were considered significant. For primary colorectal resections, the learning curve was analyzed by the cumulative sum (CUSUM) methods, using severe complications and conversions to open surgery as indicators [24]. All statistical analyses were conducted by SPSS, version 20.0.0 for Windows (SPSS, Chicago, IL).

### Results

The main characteristics of the surgical procedures performed during each phase of the study are shown in Table 1; 414 procedures were performed during Phase-1, 348 during Phase-2, 360 during Phase-3, and 325 during Phase-4. With respect to the total number of procedures, the proportion of primary colorectal resections decreased over the four phases, although non-significantly ( $P = 0.053$ ).

### Laparoscopic procedures

The number and types of VLS vs. open procedures performed during the four phases of the study are shown in Table 2. The number of VLS colorectal primary resections increased from 11 (5.2%) in Phase-1, to 55 (33.7%) in Phase-2, 86 (57.0%) in Phase-3, and 109 (74.1%) in Phase-4. The difference was highly significant ( $P < 0.001$ ). In the four phases, the number of all-type laparoscopic procedures was 16 (3.5%), 61 (17.5%), 103 (28.6%), and 126 (38.8%), respectively ( $P < 0.001$ ). The difference was statistically significant also in the subset of elective procedures potentially eligible to VLS, excluding ostomy closures and transanal resections ( $P < 0.001$ ).

Concerning the different primary colorectal resections, the percentage of laparoscopic procedures increased over the four study phases for right/transverse colectomies ( $P < 0.001$ ), left/sigmoid colectomies ( $P < 0.001$ ), rectal anterior resections ( $P < 0.001$ ), and abdominal–perineal resections ( $P = 0.036$ ). Interestingly, the proportion of primary rectal tumors operated by VLS increased more than fourfold from Phase-2 (12/66; 18.2%) to Phase-4 (43/56; 76.8%).

VLS procedures were performed by four surgeons in Phase-1, six surgeons in Phase-2, 11 surgeons in Phase-3

**Table 1** Surgical procedures according to study phases

	Phase-1 (n=414)		Phase-2 (n=348)		Phase-3 (n=360)		Phase-4 (n=325)		P value	
Sex										
Male	233	56.3%	200	57.5%	193	53.6%	167	51.4%	0.376	
Female	181	43.7%	148	42.5%	167	43.4%	158	48.6%		
Age, mean (SD)	61.7 (12.0)		63.1 (12.9)		62.2 (13.5)		63.2 (13.5)		0.324	
ASA score										
I/II	324	78.3%	261	75.0%	251	69.7%	237	72.9%	0.050	
III/IV	90	21.7%	86	25.0%	109	31.3%	88	27.1%		
Diagnosis										
Primary colorectal carcinoma	287	69.4%	249	71.6%	239	66.4%	215	66.2%	0.353	
FAP	16	3.9%	9	2.6%	13	3.6%	8	2.5%		
Spino-cellular carcinoma	11	2.6%	1	0.3%	6	1.7%	–	–		
Peritoneal mesothelioma	20	4.8%	22	6.3%	19	5.3%	11	3.4%		
Pseudomyxoma peritonei	22	5.3%	21	6.0%	44	12.3%	41	12.6%		
SPPC	11	2.6%	4	1.2%	6	1.7%	5	1.5%		
CRC peritoneal metastases	20	4.8%	25	7.2%	37	10.3%	19	5.8%		
CRC recurrences	12	2.9%	6	1.7%	4	1.1%	8	2.5%		
Appendiceal carcinoma	9	2.2%	6	1.7%	7	1.9%	12	3.7%		
Other	6	1.5%	5	1.4%	6	1.7%	6	1.8%		
Surgical procedures										
Primary colorectal resections	214	51.7%	163	46.8%	151	41.9%	147	45.2%		0.053
Site of primary										
Right colon	50	23.4%	49	30.0%	29	19.2%	52	35.4%		
Transverse colon	6	2.8%	4	2.5%	13	8.6%	6	4.1%		
Left colon	8	3.7%	6	3.6%	12	7.9%	5	3.4%		
Sigmoid colon	28	13.1%	31	19.0%	20	13.2%	21	14.3%		
Rectum	107	50.0%	65	39.0%	68	45.1%	57	38.7%		
Multiple/FAP	15	7.0%	8	4.9%	9	6.0%	6	4.1%		
Prior RT or CT/RT	28	13.1%	29	17.8%	30	19.9%	26	17.7%		
Trans anal resections	14	3.4%	4	1.2%	6	1.7%	8	2.5%		
CRS/HIPEC	34	8.2%	38	10.9%	43	11.9%	47	14.5%		
CRC recurrences/perit. metastases	31	7.5%	26	7.5%	25	6.9%	28	8.6%		
Ostomy creation	11	2.7%	4	1.2%	7	1.9%	1	0.3%		
Ostomy closure	48	11.6%	67	19.2%	59	16.4%	43	13.2%		
Abdominal exploration	6	1.5%	2	0.6%	14	3.9%	16	4.9%		
Other surgical procedures	14	3.4%	6	1.7%	8	2.2%	5	1.5%		
Total elective procedures	372	89.9%	310	89.1%	313	82.2%	295	90.8%		
Emergency procedures	42	10.1%	38	10.9%	47	13.0%	30	9.2%		

SD standard deviation, ASA American Society of Anesthesiology, FAP familial adenomatous polyposis, SPPC serous-papillary peritoneal carcinoma, CRC colorectal carcinoma, RT radiotherapy, CT chemotherapy, CRS cytoreductive surgery, HIPEC hyperthermic intraperitoneal chemotherapy

(including one resident), and 14 surgeons in Phase-4 (including three residents). In the four phases, VLS colorectal resections were performed by one, six, nine (including one resident), and 12 surgeons (including three residents), respectively.

The number of VLS vs. open surgical procedures performed each month during Phase-3 is shown in Fig. 1. No significant variation was observed in March 2020, after the COVID outbreak. In April, the total number of procedures and colorectal resections was increased, but only one

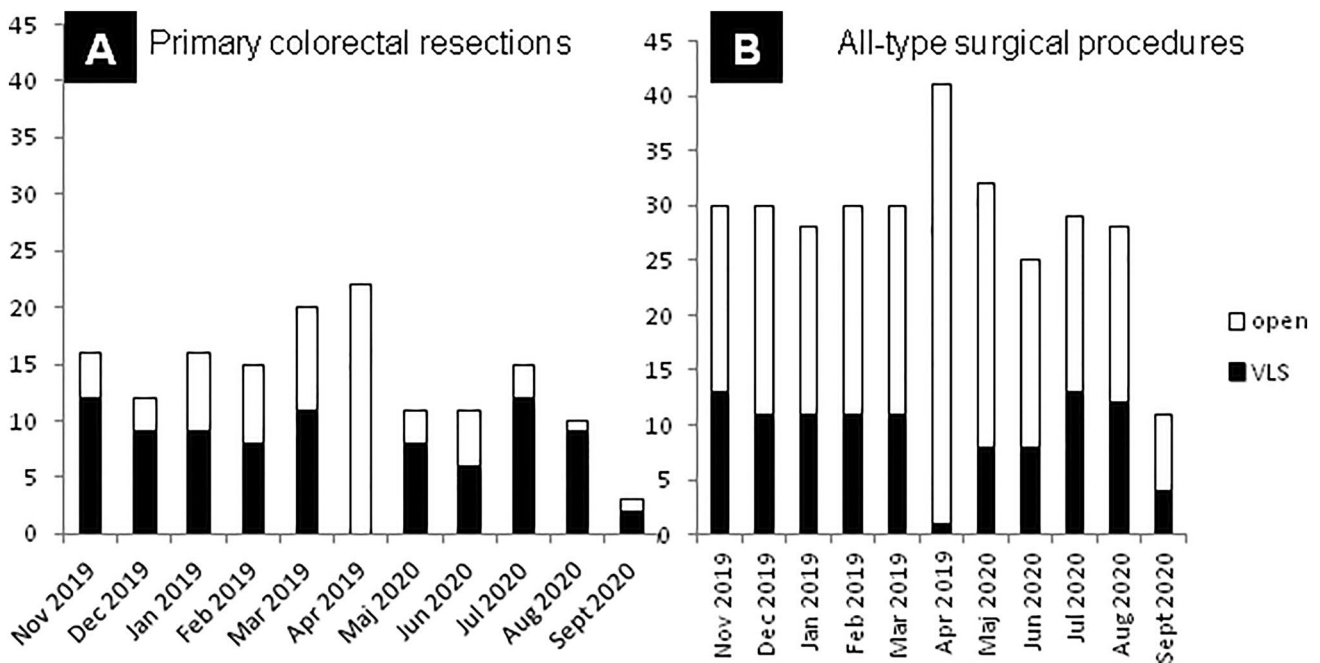
abdominal exploration was performed laparoscopically. Finally, the number of laparoscopic colorectal resections increased in May, but the proportion of all-type VLS procedures remained low.

In Fig. 2, box-and-whiskers plots show the decreasing operative time across study phases according to type of primary resections. The difference was significant for rectal resections ( $P=0.032$ ), but there was only a trend toward a decreased operative time for right/transverse ( $P=0.685$ ), and left-sigmoid colectomies ( $P=0.158$ ).

**Table 2** Volume of laparoscopic surgery according to surgical procedures

	Phase-1 (n=414)			Phase-2 (n=348)			Phase-3 (n=360)			Phase-4 (n=325)			P value
	Tot	VLS	%	Tot	VLS	%	Tot	VLS	%	Tot	VLS	%	
Primary colorectal resections	214	11	5.1	163	55	33.7	151	86	57.0	147	109	74.1	<0.001
Right colectomy	55	–		54	21	38.9	40	17	42.5	56	40	71.4	<0.001
Left/sigmoid	32	–		36	15	41.7	31	22	71.0	25	19	76.0	<0.001
RAR/ACEA	86	–		54	10	18.5	60	36	60.0	49	40	81.6	<0.001
Hartmann procedure	10	–		5	1	20.0	4	1	25.0	–	–		0.152
APR	12	–		7	1	14.3	5	2	20.0	7	3	42.9	0.036
Total colectomy	19	11	57.9	7	7	100	11	8	72.7	9	7	77.8	0.197
CRS/HIPEC	34	0		38	0		43	1	2.3	47	0		0.577
Recurrences/PM	31	0		25	1	4.0	25	1	4.0	24	0		0.523
Ostomy creation	11	0		4	0		7	2	28.6	1	0		0.111
Abd. exploration	6	5	83.3	2	2	100	14	11	78.6	16	12	75.0	0.959
Other surgical proc	14	0		6	0		8	1	12.5	5	5	100	<0.001
Total elective procedures	372	16	4.3	310	61	19.7	313	102	32.6	295	126	42.7	<0.001
Emergency proc	42	0		38	0		47	1	2.1	30	0		0.850
Eligible procedures	310	16	5.2	239	61	25.5	248	102	41.1	244	126	51.6	<0.001
Trans anal resections	14	–		4	–		6	–		8	–		NA
Ostomy closure	48	–		67	–		59	–		43	–		NA
Total procedures	414	16	3.9	348	61	17.5	360	103	28.6	325	126	38.8	<0.001

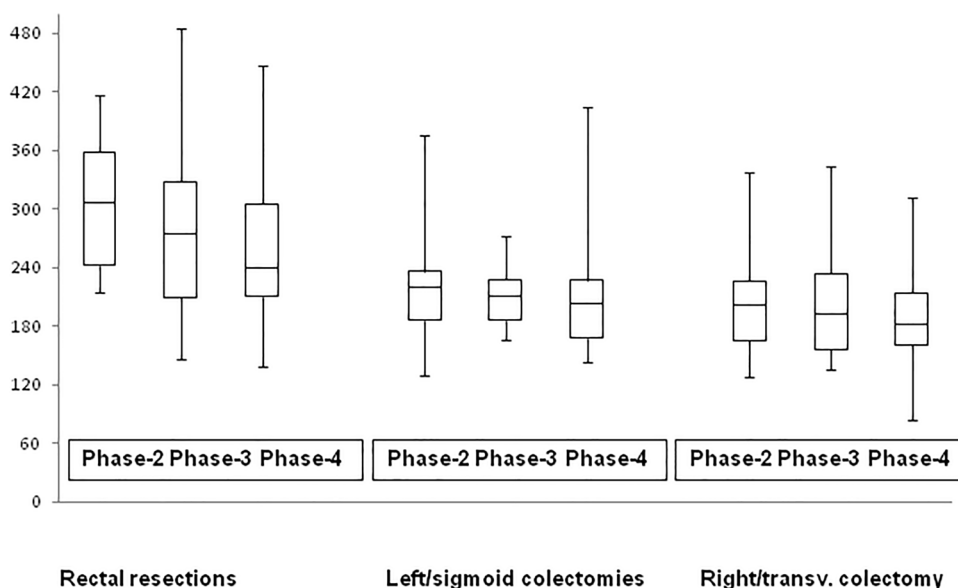
VLS video-laparoscopy, RAR rectal anterior resection, ACEA APR abdominoperitoneal resection, CRS cytoreductive surgery, HIPEC hyperthermic intraperitoneal chemotherapy, PM peritoneal metastases, NA not assessed



**Fig. 1** Videolaparoscopic (VLS) vs. open colorectal resections for primary tumors **a**, and VLS vs. open all-type surgical procedures, **b** performed each month during Phase-3 (2019.11.01 to 2020.09.15). In

April 2020, the total number of procedures and colorectal resections was increased, but only one abdominal exploration was performed laparoscopically

**Fig. 2** Operative times of colorectal primary resections according to study phases. The difference was significant for rectal resections ( $P=0.032$ ), but there was only a trend toward a decreased operative time for right/transverse colectomies ( $P=0.685$ ), and left-sigmoid colectomies ( $P=0.158$ )



## Safety

Seventy severe (Clavien–Dindo grades IIIb–V) complications occurred after 675 primary colorectal resections (10.4%). The most common complications were anastomotic leaks/bowel perforations ( $n=42$ ), followed by bleeding ( $n=19$ ), abdominal wall dehiscence ( $n=6$ ), postoperative ileum ( $n=2$ ), and ureter leak ( $n=1$ ). In the overall series, 114 severe complications occurred after 1289 all-type elective procedures (8.8%).

No in-hospital mortality occurred in patients undergoing primary colorectal resections during the four study phases. Conversely, one postoperative death occurred after CRS/HIPEC in Phase-4. Two additional patients died during Phase-2, but both patients underwent only emergency procedures to manage complications of elective surgery performed previously. Thus, one in-hospital mortality occurred after 1289 elective procedures included in the present analysis.

Conversion to open surgery occurred in two primary tumor resections (15.4%) during Phase-1, three (5.2%) during Phase-2, three (3.4%) during Phase-3, and nine (7.4%) during Phase-4 ( $P=0.299$ ). Concerning all-type surgical procedures, conversions were two (11.1%), three (4.9%), five (4.4%), and eleven (8.0%), respectively ( $P=0.281$ ).

Severe postoperative complications occurring during the four phases of the study are shown in Table 3, according to surgical procedure and open vs. laparoscopic approach. Morbidity rates did not change significantly for any surgical procedure over the study period. Complications of both open and VLS primary colorectal resections increased, although non-significantly, in Phase-2 and Phase-3, as compared with Phase-1, and then declined in Phase-4 to lower rates than in Phase-1. Severe morbidity was not significantly different

between open and VLS colorectal resections in Phase-1 ( $P=0.976$ ), Phase-2 ( $P=0.799$ ), Phase-3 ( $P=1.000$ ), and Phase-4 ( $P=0.729$ ).

Unfortunately, the assessment of our learning curve for primary colorectal resections provided no meaningful result, presumably because splitting our case series into rectal vs. colonic surgery resulted in insufficient sample sizes. Furthermore, severe complication and conversion rates were comparable to reference literature data since the earlier phases of our experience [2–13], and did not change significantly during the study, further hampering our analyses (see Table 3).

To better characterize the safety profile of the present series, we assessed ASA score distribution among patients who underwent primary colorectal resections. The proportion of patients with ASA score of III–IV who underwent open surgery increased significantly from 33 (16.3%) in Phase-1 to 26 (23.9%) in Phase-2, 22 (33.8%) in Phase-3, and 18 (47.4%) in Phase-4 ( $P>0.001$ ). On the contrary, the proportion of patients with ASA score of III–IV who underwent VLS surgery did not change significantly, being 0, 9 (16.4%), 15 (17.4%), and 19 (17.4%), respectively, over the four phases ( $P=0.595$ ).

## Discussion

The fundamental purpose of cancer therapy is to eradicate tumors and preserve patients' quality of life. Laparoscopic colorectal surgery is associated with less postoperative pain, shorter time to recovery, shorter hospital stay, and non-inferior oncological outcomes [2–12]. In a challenging setting, such as the dramatic COVID-19 outbreak during the spring of 2020, our institutional program for the implementation of

**Table 3** Severe (Clavien–Dindo grades IIIb–V) complications

	Phase-1 (n=414)			Phase-2 (n=348)			Phase-3 (n=360)			Phase-4 (n=325)			P value
	Tot	Compl.	%	Tot	Compl.	%	Tot	Compl.	%	Tot	Compl.	%	
Primary colorectal res	214	20	9.3	163	19	11.7	151	20	13.2	147	11	7.4	0.366
Open	203	19	9.4	108	12	11.1	65	9	13.8	38	2	8.3	0.539
VLS	11	1	9.1	55	7	12.7	86	11	12.8	109	9	5.3	0.677
CRS/HIPEC	34	4	11.8	38	6	15.8	43	10	23.3	47	4	8.5	0.261
Open	34	4	11.8	38	6	15.8	42	10	23.8	47	4	8.5	0.235
VLS	–	–	–	–	–	–	1	–	–	–	–	–	–
Recurrences/PM	31	1	3.2	25	2	8.0	25	1	4.0	24	3	12.5	0.520
Open	31	1	3.2	24	2	8.3	24	1	4.2	24	3	12.5	0.563
VLS	–	–	–	1	–	–	1	–	–	–	–	–	–
Transanal resections	14	1	7.1	4	–	–	6	–	–	8	–	–	–
Ostomy closure	48	1	2.1	67	2	3.0	59	2	3.4	43	5	11.6	0.160
Ostomy creation	11	1	9.1	4	–	–	7	–	–	1	–	–	–
Abdominal exploration	6	–	–	2	–	–	14	–	–	16	1	6.2	NA
Open	1	–	–	–	–	–	3	–	–	4	–	–	–
VLS	5	–	–	2	–	–	11	–	–	12	1	8.3	–
Other procedures	14	–	–	6	–	–	8	–	–	5	–	–	NA
Open	14	–	–	6	–	–	1	–	–	0	–	–	–
VLS	–	–	–	–	–	–	7	–	–	5	–	–	–
Tot. elective procedures	372	28	7.5	309	29	9.4	313	33	10.5	295	24	8.1	0.497
Open	356	27	7.6	251	22	8.8	205	22	10.7	126	14	11.1	0.486
VLS	16	1	6.2	58	7	12.1	108	11	10.2	169	10	5.9	0.348

VLS videolaparoscopy, CRS cytoreductive surgery, HIPEC hyperthermic intraperitoneal chemotherapy, PM peritoneal metastases, NA not assessed

minimally invasive surgery resulted in a significant increase in the volume of laparoscopic colorectal resections, without clinically and statistically significant changes in postoperative severe complications.

Our CSU was one of the first surgical teams to introduce TME and colo-anal anastomoses in Italy during the 1990s, and it is highly specialized in conservative surgery for low rectal tumors [25]. Open colorectal surgery was considered as default because of lack of training in VLS, perceived oncological limitations of laparoscopic low rectal resections, and logistic issues, such as a large number of patients in the waiting list exceeding the capacity of our operating theaters, and shorter operative times of open surgery. A change of the head of the unit provided the opportunity to start a program for the implementation of VLS.

Recent literature data about the transition to minimally invasive surgery in specialized colorectal units are scarce because many institutions shifted to VLS before the year 2000, or during the first decade of the new millennium. The learning curve of VLS colorectal surgery has been reported to range widely from 30 to 80 cases, depending on colonic vs. rectal primary, and different outcome measures, but these series began in the early 1990s [26, 27]. More recently, the state of the art of laparoscopic surgery has greatly improved [28], and we hypothesized that a “global learning curve” could have resulted in a faster and safer increase in VLS

volume. This innovative concept includes continuous technological advancement, training improvements, and standardization of surgical and perioperative protocols. Our perspective is in agreement with Luglio et al., who report the results of the first 50 laparoscopic cases performed over 18 months in an Italian University Hospital. Operative outcomes were comparable to our series, but, unlike the present study, all the operations were performed by a single surgeon [29].

The March 2020 COVID-19 outbreak in Lombardy region had a negative impact on our program. First, the planned attendances of staff members to training courses with animal models and simulators in international centers were canceled. Second, concerns about possible COVID-19 transmission during laparoscopy led to a reduction in the number of VLS procedures until a screening protocol was set to identify asymptomatic COVID-19 patients before admission [30]. Third, since national and international guidelines suggested to postpone all non-strictly urgent surgeries, patients referred from other hospitals were mostly advanced cases or border-line surgical candidates with relevant comorbidities, for whom there was no available intensive care beds for postoperative recovery in the referring hospitals overloaded by COVID-19 [31].

As a result of our implementation program, the percentage of laparoscopic primary resections increased to 74.1% in our center. In 2019, an Italian survey involving 184 surgeons

from 57 centers reported a 64.4% rate, but all the participating centers had an experience of  $\geq 7$  years in laparoscopic colorectal surgery [13]. Data from the UK for the year 2009, and Austria for the year 2013 revealed that only 25% and 26.1%, respectively, of colorectal procedures were performed laparoscopically [17, 18]. According to the National Surgical Quality Improvement Program (NSQIP) database, the use of laparoscopy increased in the USA from 22.7% in 2005 to 49.8% in 2014 [19]. Taken together, these data suggest that adoption rates for laparoscopy are still relatively low, compared to other fields of surgery, presumably due to the complexity of colorectal procedures.

An interesting finding of our study is the low rates of conversion to open surgery, that were required in 17/278 attempted laparoscopic operations in the overall series (6.1%), and 12/207 during Phase-3 and Phase-4 (4.3%). Completion rate is a quality indicator of VLS surgery. Conversions were 6.5% in an Italian survey [13], 17.9% in a systematic meta-analysis collecting 15 studies and 5293 patients [32], and up to 42% in the literature [4–6, 8, 32]. Furthermore, although confounding factors such as advanced tumor stage may play a role, unsuccessful laparoscopic surgery has been associated with poor perioperative and long-term outcomes [32].

Another interesting finding is that severe morbidity was not significantly higher in laparoscopic than open surgery. However, morbidity trends across study phases deserve a closer look. Complication rates of laparoscopic colorectal resections were similar between Phase-2 and Phase-3, and declined in Phase-4. This may suggest technical skill improvement, since only easier and less technically demanding cases were treated laparoscopically during Phase-2, and, indeed, there was a fourfold increase in the number of VLS rectal resections from Phase-2 to Phase-4. On the other hand, the steady (albeit non-significant) complication rate increase for open surgery in Phase-2 and Phase-3 appears to be related to the fact that the open approach was increasingly restricted to patients unfit for laparoscopic surgery. Also, the referral of patients with advanced tumors and/or border-line conditions from surrounding hospitals during the COVID-19 pandemic likely resulted in further deterioration of our surgical case-mix.

Our study suffers from the limitations of any retrospective series. However, we took advantage of our prospective clinical database to limit any potential bias. Also, our findings may be specific to our setting, given the broad experience in open colorectal surgery of our unit. Our attempts to analyze our learning curve were unsuccessful. Despite the relatively high volume of all-type VLS resections, the need to analyze separately colonic vs. rectal resections resulted in insufficient sample sizes. Furthermore, the different levels of expertise at baseline among members of our team (from experts who had presumably completed their learning curve,

to surgeons trained in standard non-oncologic procedures, and absolute beginners) likely generated additional bias. We are planning future studies, as soon as sufficient numbers are accumulated.

## Conclusions

Despite the difficulties deriving from COVID-19 outbreak, our program was successful in increasing the volume of laparoscopic colorectal surgery, and keeping complication and conversion rates to acceptable levels. Our findings strongly suggest that other colorectal units still reluctant to embrace laparoscopic surgery should no longer be scared by outdated analyses reporting overly high number of consecutive procedures needed to gain technical proficiency. On the contrary, a rigorous implementation program would result in a faster and safer transition.

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**Data availability** Baratti, Dario (2021): Preliminary results of a program for the implementation of laparoscopic colorectal surgery in an Italian comprehensive cancer center during the COVID-19 pandemic.. figshare. Collection. <https://doi.org/10.6084/m9.figshare.c.5772248>.

## Declarations

**Conflict of interest** The authors declare that they have no affiliations with or involvement in any organization or entity with any financial or non-financial interest in the subject matter or materials discussed in this manuscript.

**Ethical approval** This study was approved by the Institutional Review Board and Ethics Committee of the Fondazione IRCCS Istituto Nazionale dei Tumori, Milano (Italy) (Protocol Number INT 149/19).

**Research involving human participants and/or animals** All procedures were performed in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975 (in its most recently amended version).

**Informed consent** Informed consent was obtained from all patients included in the study.

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