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Laparoscopic colorectal surgery in learning curve: Role of implementation of a standardized technique and recovery protocol. A cohort study

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HIGHLIGHTS

- Benefits from laparoscopic colorectal surgery have been widely demonstrated.
- A steep learning curve is considered the main limitation to its adoption.
- We present short-term outcomes in a learning curve prospective series.
- A modular, stepwise approach leads to excellent results.
- Even trainees can safely learn both laparoscopic and open surgery, when strictly supervised.

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ABSTRACT

Background: Despite the proven benefits, laparoscopic colorectal surgery is still under utilized among surgeons. A steep learning is one of the causes of its limited adoption. Aim of the study is to determine the feasibility and morbidity rate after laparoscopic colorectal surgery in a single institution, "learning curve" experience, implementing a well standardized operative technique and recovery protocol.

Methods: The first 50 patients treated laparoscopically were included. All the procedures were performed by a trainee surgeon, supervised by a consultant surgeon, according to the principle of complete mesocolic excision with central vascular ligation or TME. Patients underwent a fast track recovery programme. Recovery parameters, short-term outcomes, morbidity and mortality have been assessed.

Results: Type of resections: 20 left side resections, 8 right side resections, 14 low anterior resection/TME, 5 total colectomy and IRA, 3 total panproctocolectomy and pouch. Mean operative time: 227 min; mean number of lymph-nodes: 18.7. Conversion rate: 8%. Mean time to flatus: 1.3 days; Mean time to solid stool: 2.3 days. Mean length of hospital stay: 7.2 days. Overall morbidity: 24%; major morbidity (Dindo–Clavien III): 4%. No anastomotic leak, no mortality, no 30-days readmission.

Conclusion: Proper laparoscopic colorectal surgery is safe and leads to excellent results in terms of recovery and short term outcomes, even in a learning curve setting. Key factors for better outcomes and shortening the learning curve seem to be the adoption of a standardized technique and training model along with the strict supervision of an expert colorectal surgeon.

1. Introduction

Laparoscopic surgery is now a well established treatment and often considered as the default option for several malignant and benign colon and rectal diseases. Even though laparoscopic surgery, particularly in the field of gallbladder surgery, has very soon

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demonstrated the possibility to achieve significant advantages in recovery, it took several years and many clinical trials in order to establish the role of laparoscopy in colorectal surgery. The oncologic outcomes were certainly perceived as the main issue to face in the early stage of lap colorectal surgery and this formed the basis of several international clinical trials, which were designed to rigorously investigate the feasibility of laparoscopic colectomy, the cancer risk, morbidity and recovery benefits. At least four large prospective, randomized controlled trials, from North America, Canada and Europe, have been completed and have reported on both short and long term outcomes, confirming the feasibility and the oncological safety of colorectal lap surgery [1–9].

Despite the proven benefits of laparoscopic colorectal surgery and low morbidity rates, we are still far from considering it as the gold standard procedure, as it is still under utilized among general and colorectal surgeons: the steep learning curve might be probably considered the main cause of the limited adoption of the procedure. Nevertheless a trend towards a larger adoption of laparoscopic colorectal surgery has been observed in the last years [10], but the implementation of this technique among general and colorectal departments is still progressing slowly: the study from Schwab et al. [11] shows how only one quarter of all the procedures are being undertaken laparoscopically by consultant colorectal surgeons in Great Britain. One of the main reasons for consultants not performing laparoscopic procedures is the lack of training.

The aim of the present study is to determine the feasibility and safety of laparoscopic colon and rectal surgery in a learning curve setting. A well structured training model has been adopted as long as a standardized postoperative recovery protocol. All the procedures have been undertaken following meticulous oncological criteria, according to the principle of the Complete Mesocolic Excision (CME) with Central Vascular Ligation (CVL) [12,13]. Short-term outcomes have been reported, including operative data, recovery parameters and 30-days morbidity and mortality. Complications were also graded according to the Dindo–Clavien Classification [14,15], which has been recognized and validated as a standardized and reliable tool for assessment of postoperative complications, and where grade I represents minor deviations from the normal postoperative course without the need for interventions, and grade V represents death as a result of complications.

2. Patients and methods

A prospective database has been maintained since the beginning of laparoscopic colorectal surgery in our Colorectal Unit (University of Naples Federico II, tertiary referral university hospital). Data from the first consecutive 50 laparoscopic colon and rectal resections, performed between January 2012 to July 2013, have been analyzed. Patients were "selected" in order to get cases which were considered adequate for a learning curve setting. Exclusion criteria were: T4 and bulky tumors, previous operations with a midline incision, BMI >35, radiated rectal cancer and rectal cancer below 4 cm from the dentate line. For total colectomy, patients with BMI > 26 were also excluded. The adoption of the procedure, specially in the first 30 cases, was also limited sometimes by operating room availability, due to longer operative time required for laparoscopic resections. We also performed only one Crohn's disease laparoscopically, cause of our institutional attitude to perform ileocecal resection for Crohn's disease via a minilaparotomic transverse incision (6–8 cm); a new trial is ongoing to establish if laparoscopic resection may add additional benefits to these patients.

Short term outcomes, including operative data, recovery parameters and 30-days morbidity and mortality have been analyzed. Surgical data include operative time, number of lymph-nodes retrieved, which might be considered as a surrogate of proper oncologic resection, conversion rate and reasons for conversion. The following recovery endpoints have been considered: mean time to flatus, mean time to solid stool, time to oral feeding, mean time to quit intravenous analgesics, length of hospital stay. As this latter parameter may be affected by organizational problems (lack of a home care network or a guest house close to the hospital), we have also evaluated an additional parameter: time to fulfill discharge criteria. Discharge was considered feasible when each of the following criteria was met: eat and walk independently, bowel opened to solid stool, independence from i.v. analgesics, absence of any other complication. Results have been expressed as "mean" ± standard error (SE) and range. Statistic has been performed with STATA/SE 12.00 Stata Corp software.

The overall morbidity, reoperation and readmission rates were also identified. Both surgical and medical complications were included and were graded using Clavien–Dindo staging system [14,15]. The overall morbidity was calculated considering the number of patients who had at least 1 complication; in other words, patients who had at least 1 complication were counted only once and only their highest grade complication was counted. Major complications were considered as Clavien–Dindo grade III or higher (at least requiring endoscopic, radiological or surgical intervention).

2.1. Surgical notes

All the operation were performed by a trainee surgeon (GL), assisted by junior trainees, always under the strict supervision of an expert open colorectal surgeon, who usually took part in the open part of the procedure (after specimen extraction through the minilaparotomy) or if special challenges occurred during the lap phase and in conversion cases. A really well structured training model and surgical scheme was implemented and imported from highly specialized international colorectal departments, where laparoscopic surgery is routinely applied. Particularly, the starting of laparoscopic colorectal surgery at our Institution followed an observship and a fellowship in two highly specialized Colorectal Unit in US and UK, where the trainee surgeon spent 1 year overall, being engaged as observer or camera operator. Key factor of this part of the training was the modular approach: each operation was analyzed in a stepwise scheme, from patient positioning to more complex parts of the procedure (bowel positioning, plane dissection, vessels skeletonization etc). Even the role of nurse staff and surgical assistants needs to be precisely define in order to make everything correctly working.

With regard to surgical details, each operation was performed using the same scheme and following the oncologic principles of Complete Mesocolic Excision (CME with Central Vascular Ligation) [12,13]: basically a medial to lateral approach was followed, taking the arteries at their origin, trying not to create any injuries to the mesocolic fascia layers, in order to get a complete clearance of the mesocolic fat together with all the lymph-nodes draining the tumor. Only in selected cases (e.g. diverticulitis, early cancer of sigmoid colon), we considered complete splenic flexure mobilization not mandatory and the inferior mesenteric artery was taken just below the emergence of the ascending left colic artery. In all other cases, the ligation of both inferior mesenteric artery and vein along with the clearance of mesocolic fat from the tail of the pancreas with splenic flexure mobilization was considered necessary. With regard to right side resections, after taking the ileocolic vessel at their origin, a complete dissection of the right mesocolon from the duodenum, its complete exposure together with the incision of Toldt fascia, were considered key steps of the procedure. Rectal cancer resections were performed according to the principle of

TME surgery or, in case of upper-third rectal cancer at least a two-cm distal margin was ensured along with appropriate circumferential resection margins, taking care not to disrupt the mesorectal fascia.

2.2. Recovery protocol

All the patients underwent a "fast track" recovery protocol. Patients were completely mobilized on postoperative day one and encouraged to walk or stay in chair for most of the time; they were also encouraged to drink and eat soft diet. NG tube was removed the evening of the operation and urinary catheter was removed the morning after the operation, with the exception of low rectal resection in which the catheter was maintained for at least three days. IV fluid were discontinued as soon as bowel was opened to flatus. Opioid use was restricted to i.v. tramadol, 200 mg infusion for the first 24 h. Pain was then controlled with i.v. paracetamol or NSAID. We also use a single abdominal drain, which is left in place for around three days.

Table 2
Diagnosis.

	N° (%)	Stage (n°)
Right-hepatic flexure colon cancer	7 (14%)	pT3 N0 (3) pT1 N0 (2) pTis N0 (2)
Left-sigmoid-flexure colon cancer	13 (26%)	pT3 N1 (2) pT3 N0 (4) pT2 N0 (2) pT1 N0 (1) pTis N0 (4)
Rectal cancer	14 (28%)	pT3a N1 (2) pT3a N0 (2) pT2 N1 (1) pT2 N0 (4) pT1 N0 (4) pTis (1)
Deep pelvic endometriosis	2 (4%)	–
Ulcerative colitis	5 (10%)	–
Polyposis	3 (6%)	
Crohn disease	1 (2%)	–
Diverticular disease	5 (10%)	–

3. Results

50 patients, affected from colon and rectal diseases, have been operated on laparoscopically in the study period. Demographics details are shown in Table 1. Female population was 48% of the study sample. Mean age was 57.3 ± 2.1, mean BMI was 25.9 ± 0.5.

34.7% of the patients had a previous abdominal operation, without considering the caesarean cut. The following resections were performed: 20 left-side resections, 8 right-side resections, 14 low anterior resection/TME, 5 total colectomy + ileorectal anastomosis (IRA) and three total panproctocolectomy with ileal pouch anal-anastomosis (IPAA). In four cases an associate procedure was performed: 2 cholecystectomy and 2 salpingo-oophorectomy. Diagnosis and TNM stage for cancer cases are shown in Table 2. Two patients with upper third rectal cancer resulted to be T3aN1 at pathology: they were actually understaged preoperatively and then received adjuvant radiochemotherapy. Patients with pTis lesions were either not considered suitable for endoscopic resections or received an incomplete endoscopic resection and a further radical operation was proposed and discussed with the patient.

Operative data are shown in Table 3. Mean operative time was 228 min ± 9, but it varies depending on the kind of resection. We also tried to evaluate if an improvement in operative time was registered during the learning curve; mean operative time for right and left side resections have been separately calculated depending on if they were performed during the first 25 cases or during the last 25 cases: for left side resections, mean operative time in the first 25 cases was 251 min vs 187 min registered in the last 25 cases; for right side resections, mean operative time was 200 min during the first 25 cases and 147 min in the second part of the learning curve. Regarding the left side resection group, splenic flexure was not completely mobilized in 9 patients: 5 patients had a partial mobilization, belonging to the first 25 cases and 4 patients to the latter group; that being said, we considered the two groups to be quite homogeneous. Statistical analysis was not performed due to the low number of cases considered but a clear trend toward a reduction in operative time appear to be evident.

We also emphasize again how all the procedure were performed by a trainee surgeon, assisted by junior trainees and supervised by a consultant surgeon, who took part in most of the open part of the procedure (after the minilaparotomy and specimen extraction was performed), in converted cases and also during the laparoscopic phase in three patients (to aid in two cases of complex splenic flexure mobilization, in one case of difficult rectal mobilization). Finally, the last 11 procedures were completely performed by the trainee surgeon.

Mean number of lymph-nodes retrived was 18.7 ± 1.6. Four cases were converted (8%) and details are shown in Table 3.

With regard to recovery data: mean time to flatus was 1.3 days (range 1–5), mean time to solid stool was 2.3 days (range 1–5); soft diet was tolerate after 1.3 days on average. Mean time to quit i.v. analgesics was 1.8 days; mean length of hospital stay was 7.2 days (range 4–16). Discharge criteria, as defined previously, were met after 4.7 days. Short-term outcomes in terms of 30-days morbidity and mortality along with Dindo–Clavien staging system definitions are shown in Table 4. Overall morbidity was 24%; nevertheless, major morbidity, defined as Dindo–Clavien III or higher, was only 4% and due to one anastomotic bleeding requiring endoscopic treatment (IIIa) and one abdominal bleeding requiring reoperation under general anesthesia (IIIB). We've also registered 12% grade I complication (6 wound infections) and 8% grade II complications (2 pulmonary infections, 1 port site bleeding, 1 pelvic hematoma), all requiring only medical treatment. No anastomotic leaks, no iatrogenic injuries, no 30-days readmission was registered.

Table 1
Demographics.

	N°	Female (%)	Age, mean ± SE (range)	BMI, mean ± SE (range)	Previous surgery (n°)
Overall	50	24 (48%)	57.3 ± 2.1 (19–77)	25.9 ± 0.5 (18.2–34)	34.7% (17)
Left-side resections	20	11 (55%)	57.6 ± 3.7 (26–79)	26.2 ± 0.92 (20–34)	35% (7)
Right-side resections	8	3 (37.5%)	62.9 ± 6.1 (22–76)	27 ± 1.1 (23–31.2)	25% (2)
Low anterior resection-TME	14	7 (50%)	61.1 ± 2.2 (45–76)	27 ± 0.7 (22.5–34)	50% (7)
Total colectomy + IRA	5	2 (40%)	42.2 ± 8.1 (19–68)	21.5 ± 1.3 (18.2–25.9)	–
Panprocto + pouch	3	–	46 ± 5 (36–52)	23.9 ± 0.7 (23–25.3)	33.3% (1)

SE: standard error.

Table 3
Operative data.

	Operative time, mean ± SE (min)	Numbers of nodes	Conversion (%)	Reasons for conversion
Overall	228 ± 9	18.7 ± 1.6	4 (8%)	
Left side resection	229 ± 17	16.5 ± 1.1	2 (4%)	
First 25 cases	251 ± 23			- Omental bleeding at splenic flexure
Last 25 cases	187 ± 20			- IMA bleeding
Right side resection	163 ± 13	16.8 ± 1.9	–	
First 25 cases	200 ± 20			
Last 25 cases	147 ± 15			
Low anterior resection – TME	218 ± 15	15.4 ± 1.6	2 (4%)	- Obesity - IMA bleeding
Total colectomy + IRA	246 ± 15	34.6 ± 10.9	–	–
Panprocto + pouch	345 ± 13	35 ± 9.8	–	–

SE: standard error; IMA: inferior mesenteric artery.

Table 4
30-Days morbidity & mortality. Dindo–Clavien scoring system.

Dindo–Clavien classification Definition	% of patients (n°)
Grade I – Any deviation from normal postoperative course without the need for pharmacologic treatment or surgical, endoscopic and radiologic interventions. Allowed therapeutic regimens are drugs as antiemetics, antipyretics, analgetics and diuretics, and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.	12% (6/50)
Grade II – Requiring pharmacologic treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.	8% (4/50)
Grade III – Requiring surgical, endoscopic or radiologic intervention.	4% (2/50)
IIIa – Intervention not under general anesthesia	2% (1/50)
IIIB – Intervention under general anesthesia	2% (1/50)
Grade IV – Life-threatening complication (including CNS complications) requiring IC/ICU management.	
IVa – Single organ dysfunction (including dialysis)	–
IVb – Multiorgan dysfunction	–
Grade V – Death of the patient	–
Overall	24% (12/50)

CNS: Central Nervous System; IC: Intermediate Care; ICU: Intensive Care Unit.

4. Discussion

The driver of laparoscopic colectomy in the setting of cancer was clearly the possibility of gaining patient benefits. It was presumed, but not proven, that a shorter incision would result in less pain, short duration of ileus, and shorter hospital and post hospitalization recovery. Data on recovery endpoints are now available, demonstrating the main advantages of laparoscopic approach: length of hospital stay, duration of ileus and duration of analgesic use or postoperative pain. Short-term complications, morbidity and mortality were investigated and found to be very similar between groups in all the trials [1–9]. No significant differences in the rates of intraoperative complications, rates and severity of postoperative complications at discharge, and rates of readmission or reoperation were identified by all the biggest multicenter randomized trials. Perhaps surprisingly, the Barcelona trial reports a significant reduction in postoperative complication in the laparoscopic arm. Several studies, other than the main trials we mentioned before, report on short-term outcomes and morbidity after laparoscopic and open colectomy for colon cancer, with laparoscopic surgery often favoring a lower rate of wound complication [16,17]. It has also been demonstrated that benefits from laparoscopic surgery still persist in “selected” high risk patients, with higher ASA grade, obese, elderly and even with more advanced disease [18–24].

On the other hand, Law et al. [25] also emphasize how conversion to open operation was associated with poorer outcomes, perhaps suggesting that careful selection of patients to avoid conversion should be preferred. Fear for conversions, intraoperative complications due to what is supposed to be a steep learning curve might be probably considered the main causes of the limited adoption of lap colorectal procedures. Nevertheless, a larger adoption of laparoscopy has been registered in the last years: Bardakcioglu et al. [10] analyze data from the Nationwide Inpatient Sample (NIS) and show how laparoscopic colorectal procedures improved from 5% in 2004 to 31.4% in 2009. Many surgeons admit that lack of training and operating room time are still to be considered the main causes of reduced adoption of lap procedures [26].

In a multicenter analysis of 4852 cases [27], the learning curves for conversions, complications, operating time, blood loss, and hospital stay ranged from 87 to 152 procedures, depending on which parameter is considered. In this case all surgeons in the included studies have been self-taught and did not receive structured and guided training such as a fellowship in laparoscopic colorectal surgery. Hence, numbers may be significantly lower when structured supervised training is implemented. In effect supervised fellowships provide training in LCS without compromising patient safety and careful observation of a laparoscopic procedure, such as acting as the scope operator for a certain amount of time, may help in shortening the LC of the actual procedure [28]. A modular approach is a primary element for both surgeons education and patients safety [29]. Although cadaveric or animal tissue training courses and other forms of simulation may be an initial step toward proficiency, operating on real patients in a structured, supervised setting is unavoidable [30]. The surgeon, in fact, can perform laparoscopic colectomies more independently after 50 cases, increasing professional experience [31]. Several studies also show how a decrease in operative time, conversion rate and morbidity can be achieved in laparoscopic colon and rectal surgery after 60–80 cases [32–35].

Our experience shows that one of the key factor in a successful learning curve in laparoscopic colon and rectal surgery is the implementation of a well structured method and a standardized technique; this can be only achieved in highly specialized institutions where laparoscopic surgery is routinely performed. Our experience also shows that also an accurate "observational training" may be enough to start lap surgery at your home institution, provided you have an adequate volume and all the procedures can be supervised by an expert colorectal surgeon, who can assure prompt conversion and patient safety. In our institution we perform around 150 colorectal resection per year, but it is generally believed that a specialized colorectal unit should not perform less than 30–40 cases per year. We think that at least one laparoscopic operation each couple of weeks should be performed for a successful learning curve. Our morbidity rates are comparable to our open experience or probably slightly better, with exception of significantly longer operative time that actually got better in the second part of the learning curve. The fact that all the procedures were performed by a trainee surgeon also demonstrates that open and laparoscopic colorectal surgery can be learnt at the same time and probably 50 cases are enough for considering the learning curve completed. There are not recognized and universal tools to establish when a learning curve for a surgical procedure can be considered completed; in our experience we believe that the personal feeling of confidence with the procedure, the trend in reduction in operative time are important factors; more, we also emphasize how the last eleven cases were completely performed by the trainee and this might be considered a good landmark for considering the learning curve completed.

We also focus on our operative technique and accurate oncological resection (complete mesocolic and mesorectal excision and central vascular ligation) [36]; in fact, we think that completion of the operation laparoscopically is important but performing a correct oncological resection is even more important; basically, we think that an inappropriate resection is not justifiable even in a learning curve setting and oncological outcomes should not be compromised, as it might happen in self-taught experience. One might argues that our results are limited by a small sample size and selection bias; we actually decided to stop our analysis to 50 patients as results really had to reflect learning curve outcomes; moreover, we also think that appropriate patients selection should be pursed in all learning curve experience both for patients safety and to avoid surgeon's frustration. We also talk about "fast track" recovery protocol instead that "enhanced recovery protocol" [37–41]; we actually think that enhanced recovery protocol might be too complex in a learning curve setting, due to its multimodal nature which includes preoperative, intraoperative and postoperative measures; this requires the involvement of an expert anesthetist staff, nurse staff other than a dedicated equipment: this is really difficult to achieve in an early experience and might be a further cause of frustration and failure.

Despite the results from the present series are probably similar to those already demonstrated by previous studies, we believe that the limited adoption of laparoscopic colorectal surgery still reflects the presence of significant challenges in the early stage of the adoption of this technique. This report aims to be a further proof to show how a stepwise and modular approach can be the key factor to overcome the learning curve, even by trainee surgeons which are learning both open and laparoscopic surgery at the same time.

5. Conclusions

Proper laparoscopic colorectal surgery is safe and leads to excellent results in terms of recovery and short term outcomes, even in a learning curve setting. Key factors for better outcomes and shortening the learning curve seem to be the adoption of a well standardized technique and training model along with the strict supervision of an expert colorectal surgeon and adequate volume.

Disclosures

Drs Gaetano Luglio, Rachele Tarquini, Mariano Cesare Giglio, Viviana Sollazzo, Emanuela Esposito, Emanuela Spadarella, Roberto Peltrini, Filomena Liccardo, Giovanni Domenico De Palma and Luigi Bucci have no conflicts of interest or financial ties to disclose.

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Author contribution

Gaetano Luglio: study design, data collections, data analysis, writing.

Giovanni Domenico De Palma: study design, data analysis.

Rachele Tarquini: study design, data collections.

Mariano Cesare Giglio: study design, data analysis, writing.

Viviana Sollazzo: data collection, data analysis, writing.

Emanuela Esposito: data collections, writing.

Emanuela Spadarella: data collections, writing.

Roberto Peltrini: data collection, reviewing draft.

Filomena Liccardo: data collection, reviewing draft.

Luigi Bucci: study design, data collections, data analysis, writing.

Conflicts of interest

None.

Guarantor

Gaetano Luglio, MD.

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