

Feasibility, Safety, and Efficacy of 3-mm Instruments in Laparoscopic Right Hemicolectomy for Cancer: Preliminary Experience

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Abstract

Background: Nowadays, the evolution of technology has made available instruments of very small caliber without affecting the surgical technique. Mini-laparoscopy (m-Lap) right hemicolectomy is an evolution of classic laparoscopy (c-Lap), consisting of three-port laparoscopic surgery using a 3-mm trocar.

Methods: A retrospective analysis of a prospectively constructed database was performed to assess the feasibility, safety, and efficacy of 3-mm instruments. We included patients undergoing a right hemicolectomy with c-Lap or m-Lap for cancer. Patients undergoing emergency, palliative, or open surgery were excluded. Primary outcomes were the rate of anastomotic leakage (AL), surgical site infection (iSSI), organ/space infection (OSI), and disease-free and overall survival. Secondary outcomes were the length of surgery and length of stay (LOS).

Results: Between January 2015 and December 2020, seventy-five patients met the inclusion and exclusion criteria. Among them, 20 (26,67%) underwent m-Lap and 55 (73,33%) underwent c-Lap. The two groups had homogeneous baseline characteristics. There were no differences in AL (P=0.905), iSSI or OSI (P=0.831), disease-free survival (P=0.340), overall survival (P=0.351), length of surgery (P=0.742), or length of hospital stay (P=0.053).

Conclusion: A 3-mm trocar for right hemicolectomy is feasible, safe, and effective. It does not affect the quality of surgery or the short and long-term outcomes. We hope this study will stimulate further research on less invasive surgical instruments.

Keywords: Colorectal cancer, Mini-laparoscopy, Reduced port, Minimally invasive surgery, Right hemicolectomy

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Introduction

Laparoscopic surgery for colorectal cancer is worldwide accepted as the preferred approach because it reduces surgical stress, postoperative morbidity, and postoperative pain. Hence, it improves patients' comfort, minimizes the need for analgesics,

accelerates the return to normal activities, and reduces healthcare-related costs.

Nowadays, it is already possible to use instruments of very small caliber without affecting the surgical technique. Mini-Laparoscopy (m-Lap) is an evolution of conventional laparoscopy (c-Lap), involving the use of a 3 mm trocar. Its advantages are related to

the small incision sites, with less impact on the abdominal wall resulting in a lower incidence of incision-related complications like hernia, infection, or pain (1). The m-Lap was shown to be safe and feasible in cholecystectomy (2-4) as well as in urologic (5, 6) and gynecologic procedures (7, 8).

To our knowledge, no one has addressed the issues of feasibility, safety, and efficacy of the m-Lap approach in colorectal cancer treatment. This study aimed to demonstrate this approach's feasibility, safety, and efficacy and compare the results with c-Lap in the right hemicolectomy for treating cancer.

Methods

A retrospective analysis of a prospectively constructed database was performed. Informed consent was obtained from all individual participants included in the study. The database included patients' baseline characteristics, length of surgery, histology, postoperative course (with complications graded according to Clavien-Dindo) (9), blood tests, length of stay, oncologic follow-up, and therapy.

A postoperative complication was defined as any deviation from the normal postoperative course during the hospitalization or in the first 30 days after dismissal.

Between January 2015 and December 2020, 324 patients affected by colorectal cancer underwent surgery at Policlinico San Pietro (Ponte San Pietro, Bergamo, Italy). All data were collected in a prospectively constructed database. The inclusion criterion for this study was a right hemicolectomy for cancer, while patients undergoing emergency surgery, palliative surgery, or open surgery were excluded. These criteria were the same for both m-Lap and c-Lap patients.

Surgical Technique

All patients underwent standard antibiotic prophylaxis with metronidazole 500 mg and cefoxitin 2 g 30 minutes before surgery, and thromboembolic prophylaxis with nadroparin calcium 4000 U.I. started the night before surgery. All patients were operated on by two expert laparoscopic surgeons (MZ, MCV). In both c-Lap and m-Lap, the pneumoperitoneum was induced with a Veress needle in the left hypochondrium.

In c-Lap right hemicolectomy, a 10-mm camera trocar was placed 3-4 centimeter to the left of the umbilicus, a 5-mm trocar on the midline 4 cm under the umbilicus, a 12 mm in the right hypochondrium, and a 5-mm trocar was positioned in the epigastrium. Specimen extraction was made through a Pfannenstiel incision.

In the three-port m-Lap approach, a 10-mm camera trocar was placed midline in the suprapubic region in the middle of the future Pfannenstiel incision for the specimen extraction. One 3-mm trocar (ab medica s.p.a., Cerro Maggiore, Milan, Italy) was positioned

in the right iliac fossa, and a 12-mm trocar was positioned in the left iliac fossa, allowing the insertion of the linear stapler for the intracorporeal anastomosis.

The mini-laparoscopic skin incisions did not require stitches and were closed with Steri-Strips™.

In both c-Lap and m-Lap, an intracorporeal latero-lateral isoperistaltic anastomosis was performed using a mechanical linear stapler. Enterotomies were closed in both cases with 3/0 resorbable running barbed sutures (Assut Europe, Italy). Mesenteric windows were also systematically closed. No drains were positioned in either approach.

Statistical Analysis

Data were expressed as the median and interquartile range (IQR), and number and relative percentage.

Normal distribution of continuous variables was assessed with the Kolmogorov-Smirnov test. Continuous variables were analyzed using the T-test or Mann-Whitney U test, and categorical variables by the Pearson chi-squared test and Fisher's test as appropriate. All statistics were performed using IBM SPSS Statistics version 26 (IBM corp., Armonk, NY) and two-tailed statistical significance was accepted when $P < 0.05$.

Primary outcomes were anastomotic leakage rate, superficial and deep incisional surgical site infection (iSSI), organ/space infection (OSI), and oncological radicality. Secondary outcomes were the length of surgery and length of stay.

Results

Three hundred and twenty-four patients affected by colorectal cancer underwent surgery at Policlinico San Pietro (Ponte San Pietro, Bergamo, Italy) between January 2015 and December 2020. In the period mentioned above, 75 patients met the inclusion and exclusion criteria for the study. Twenty (26,67%) underwent m-Lap and 55 (73,33%) underwent c-Lap. Forty-one were male (54.7%). The median age was 69 years (Range 40-90; IQR 65-78). The average follow-up was 14 months (range 0-60; IQR 8-30).

We performed a comparative analysis between c-Lap and m-Lap in right hemicolectomy intending to demonstrate feasibility, safety (in terms of anastomotic leakage, surgical site infection, deep infection), and efficacy evaluated as the adequacy of lymphadenectomy (at least 12 harvested nodes). No prominent differences in ergonomics were found in our experience. There was no conversion in both groups. The baseline analysis showed no differences in terms of age, sex, site of the tumor, or stage (Table 1).

Primary Outcomes

There were no differences in the overall complication rate ($P=0.428$), in complication severity according to the Clavien-Dindo classification ($P=0.210$), in the rate of iSSI or OSI ($P=0.831$), and in anastomotic leakage occurrence ($P=0.905$) (Table 2).

Table 1: Baseline characteristics of patients: conventional laparoscopy (c-Lap) versus mini-laparoscopy (m-Lap).

N	c-LAP				m-LAP				P		
	%	Median	Range	IQR	N	%	Median	Range		IQR	
Sex	Female	26	47.3%			8	40.0%			0.313	
	Male	29	52.7%			12	60.0%				
Age at surgery			69	40-90	65-78			68	54-84	64-74	0.517
Site	Right Colon	40	72.7%			15	75.0%			0.862	
	Right angle	7	12.7%			2	10.0%				
	Transverse colon	7	12.7%			2	10.0%				
	Left angle	1	1.8%			1	5.0%				
Stage	0	15	27.8%			8	40%			0.532	
	1	6	11.1%			3	15%				
	2	12	22.2%			2	10%				
	3	18	33.3%			7	35%				
	4	3	5.6%			0	0%				

Table 2: Statistical analysis of conventional laparoscopy (c-Lap) versus mini-laparoscopy (m-Lap).

		c-LAP		m-LAP		P
		N	%	N	%	
Anastomotic Leak	No	50	90.9%	17	85.0%	0.687
	Conservative treatment	1	1.8%	1	5.0%	
	Surgery	4	7.3%	2	10.0%	
Infection	No	43	78.2%	16	80.0%	0.831
	iSSI	5	9.1%	1	5.0%	
	OSI	7	12.7%	3	15.0%	
Adequacy of Lymphadenectomy (≥12 harvested nodes)	No	7	12.7%	4	20.0%	0.431
	Yes	48	87.3%	16	80.0%	

The analysis of the oncologic outcome showed no differences in the adequacy of lymphadenectomy (P=0.199). This datum was also confirmed by the Kaplan-Meier analysis for both disease-free survival (P=0.340) (Figure 1) and overall survival (P=0.351) (Figure 2), with an average follow-up of 14 months (range 0-60; IQR 8-30).

Our data analysis showed no significant differences in the length of surgery (P=0.742) and length of stay (P=0.053) (Table 3).

Discussion

One of the aims of the modern surgical care is the

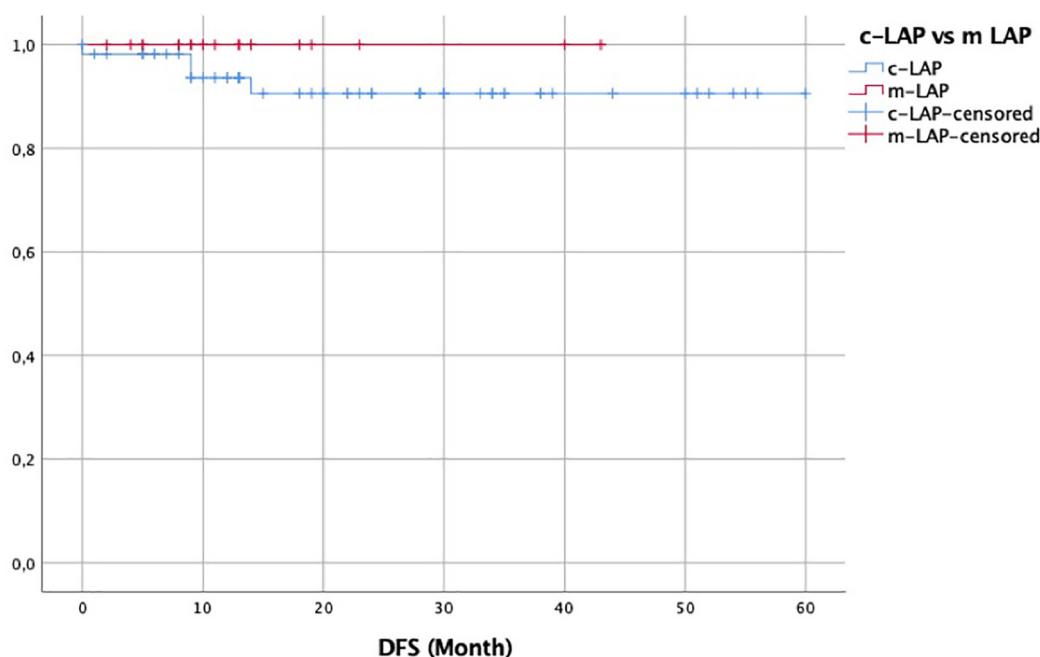


Figure 1: Kaplan-Meier, disease-free survival

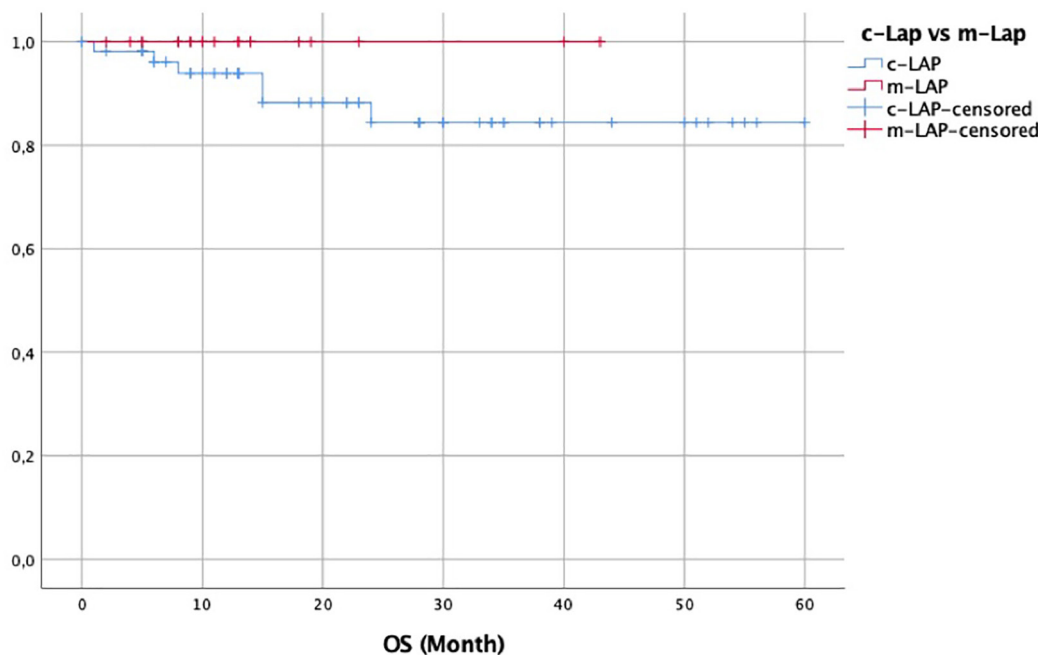


Figure 2: Kaplan-Meier, overall survival

Table 3: Length of surgery and length of stay analysis.

c-Lap versus m-Lap									
	c-Lap				m-Lap				P
	Average	Min	Max	IQR	Average	Min	Max	IQR	
Length of Surgery	165	75	255	135-205	150	100	280	130-218	0.742
Length of Stay	8	5	52	6-12	7	4	30	6-9	0.053

reduction of surgical stress. The first big step was the advent of laparoscopic surgery, with the first report on colonic surgery from Jacobs in 1991 (10). After this event, colorectal laparoscopic surgery progressively became widespread, and many techniques have emerged to reduce surgical stress.

Natural-orifice surgery and single-port surgery provide cosmetic advantages and reduce postoperative pain (11-13) at the price of higher complexity due to the more complicated triangulation and consequential instrument collision. In this setting, the natural orifice specimen extraction (NOSE) (14-16) method has emerged.

Parallel to improvements in surgical techniques, devices have evolved to reduce surgical trauma and improve cosmetic results. Accordingly, the miniaturization of surgical devices has made mini-laparoscopy (m-Lap) a possible way to perform advanced surgery by expert laparoscopic surgeons, as an evolution of classic laparoscopy (c-Lap), with reduced ports that allow less impact on the abdominal wall, preserving triangulation and ergonomics (17). Its advantages are less obvious with respect to laparoscopic surgery, but are mainly related to smaller incisions, which entail a lesser impact on the abdominal wall and a lower incidence of incision-related complications (18), like hernia (no incisional hernias have been described using the 3 mm port

yet), trocar site bleeding, infection, or pain (1).

The m-Lap approach is safe and feasible in cholecystectomy (2-4) and in urologic (5, 6) and gynecologic procedures (7, 8). Still, nobody, to date, has demonstrated its applicability in a series of oncologic colorectal surgeries. We aimed to demonstrate the feasibility, safety, and efficacy of m-Lap right hemicolectomy to reduce the impact of surgery on the patient through a less invasive procedure. This is the first report worldwide that compares m-Lap and c-Lap in this field.

The use of 3-mm instruments did not show significant differences in ergonomics and in the surgical results with respect to the c-Lap approach. In other words, no specific learning curve can be expected because both surgical technique and strategy fully reproduce that employed by the surgeon through the c-Lap approach. Moreover, it does not require suturing upon skin incision, resulting in a “scarless” incision.

This study has some limits, first of all it is retrospective and non-randomized. Furthermore, the number of patients is low, but this is a preliminary experience. The continuous use of the m-Lap approach will therefore increase the number of patients, allowing a more reliable analysis of results. Ideally, randomized trials would be needed in this context to confirm the benefits of m-Lap right

hemicolectomy.

Despite this limitation, ours is a preliminary study on a homogeneous population, and it is the first worldwide experience in right hemicolectomy for cancer with the m-Lap approach compared with c-Lap. It could be the premise for a more extensive application of this minimally invasive surgical approach not only to obtain a better aesthetic result but also to stimulate the development of an even less invasive surgical instrumentation.

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Conclusion

Mini-laparoscopic right hemicolectomy is feasible, safe, and reproducible in our experience. It does not affect the quality of surgery or the short and long-term oncologic success rate of this procedure. We hope this study will stimulate further research on less invasive surgical instruments.

Conflicts of interest: None declared.