

Single-incision laparoscopic surgery for locally advanced colorectal cancer : feasibility, short-term and oncologic outcomes

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Abstract

Background and study aims : Data about single-incision laparoscopic surgery (SILS) in locally advanced colorectal cancers are scarce. This study aimed to evaluate perioperative and short-term oncologic outcomes of SILS in pT3-T4 colorectal cancer.

Patients and methods : From 2011 to 2015 data from 249 SILS performed in our Colorectal Unit were entered into a prospective database. Data regarding patients with a pT3-T4 colorectal adenocarcinoma were compared to those with pTis-pT2. Factors influencing conversion were assessed by multivariate analysis.

Results : There were 100 consecutive patients (T3-T4 = 70, Tis-T2 = 30). Demographics were similar. Tumor size was significantly larger in the T3-T4 group [3.9cm vs 2cm; $p < 0.001$]. In T3-T4 patients we found a significant higher number of lymph nodes harvested [20 vs 13 ; $p < 0.001$]. Early (<30 days) severe (Clavien-Dindo classification >2) postoperative complication rate was similar between groups (8.6% vs 10% ; $p = 0.999$), as well as conversion rate (18.6% vs 6.7% ; $p = 0.220$). Finally, there were no differences in terms of hospital stay and mortality rate. On multivariate analysis, age (OR = 1.06, 95%CI: 1.012-1.113 ; $p = 0.015$) and stage IV (OR = 5.372, 95%CI: 1.320-21.862, $p = 0.019$) were independently associated with conversion.

Conclusions : SILS for locally advanced colorectal cancer did not affect the short-term outcomes in this series and oncological clearance remained satisfactory. Age and stage IV disease are independent risk factors for conversion. (*Acta Gastroenterol. belg.*, 2018, 81, 23-28).

Key words : colorectal cancer, single incision laparoscopic surgery, laparoscopy, locally advanced colorectal cancer, conversion, lymphadenectomy.

Introduction

Laparoscopic surgery for locally advanced colorectal cancers (LACC) is still controversial. Because of concerns about prolonged operative time, increased conversion and morbidity rates, and suboptimal oncologic clearance, several authors suggested that patients with large or invasive colon cancers would be better treated by open surgery (1). Data from the North Central Cancer Treatment Group trial N0147 confirms this attitude, reporting that a locally advanced colon cancer (T3-T4) is a significant predictor of open surgery (2). On the other hand, several data in literature showed that a laparoscopic approach might be proposed safely to these patients when performed by experienced laparoscopic surgeons (3-5).

Recently, single-incision laparoscopic surgery (SILS) is gaining popularity and its safety has been reported by

several series and meta-analysis (6). However, given its recent introduction, current evidence on SILS for colorectal cancer is based mainly on retrospective studies and specific outcomes from patients with LACC are unknown (7,8).

The aim of this study was to evaluate short-term and oncologic outcomes of SILS for patients with pT3-pT4 colorectal cancer. Our hypothesis was that a SILS approach for LACC is technically feasible, does not affect perioperative outcomes and does not compromise oncologic clearance compared with SILS for early-stage colorectal cancer. In addition, we analyzed specific risk factors for conversion to open surgery.

Material and methods

Patient Selection and Data Collection

From May 2011 to February 2015 data from 249 consecutive SILS performed in our Colorectal Surgery Unit were registered into a prospective database. Among them, 111 patients underwent SILS for colorectal cancer. Exclusion criteria for a SILS approach to malignancies were body mass index (BMI) greater than 35 kg/m², tumors directly invading or adherent to other organs or structures at preoperative investigations, contraindications to pneumoperitoneum and acute bowel obstruction. The first 100 consecutive patients who underwent a radical resection for a colorectal adenocarcinoma confirmed at postoperative pathology were analyzed. Out of these patients, 70 affected by pT3-pT4 colorectal adenocarcinoma were compared to 30 patients with pTis to pT2 lesions. We excluded 3 patients with high-grade dysplasia, 1 exploratory laparoscopy, 1 palliative resection without lymphadenectomy and 6 patients operated on for neuroendocrine tumors. The study was approved by the ethic committee of Cliniques universitaires Saint-Luc, Comité de Bio-

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éthique Hospitalo-Facultaire (CBEHF). All the following variables were recorded for each patient: demographics [age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) score, history of abdominal surgery], surgery related details (type of surgery, conversion to open surgery, need for additional trocars, operative time), intraoperative complications, postoperative morbidity (defined as any local or systemic complication occurring within 30 days of operation and graded according to the Clavien-Dindo classification), postoperative mortality (defined as any death occurred within 30 days of operation) and pathology data [American Joint Committee on Cancer (AJCC) tumor-node-metastasis (TNM) stage 7th edition, tumor size as recorded from histological examination, lymph node harvest, lymph node ratio (LNR) and resection margin involvement] (9,10).

Preoperative workup

All patients underwent a complete preoperative oncologic workup including physical examination, total colonoscopy, thoraco-abdominal computed tomography (CT) and tumor marker blood test for carcinoembryonic antigen (CEA). For rectal cancer, a pelvic magnetic resonance imaging (MRI) was also performed. In case of suspected liver metastasis, a liver MRI was performed. A fluorodeoxyglucose-positron emission tomography/computed tomography (FDG-PET/CT) was added to the workup when the CEA was higher than 15 µg/L or when distant metastases were suspected on CT or MRI. Finally, every case was discussed during our department's oncologic multidisciplinary team meetings (MDT) to establish the most appropriate management.

Surgical procedures

In case of early-stage tumors, preoperative endoscopic metallic clips were placed proximally and distally to the lesion and tumor location was confirmed intraoperatively by fluoroscopy. In case of LACC, tumor presence was confirmed by visual and instrumental tactile examination. The GelPOINT® (Applied Medical Resources Corporation, Rancho Santa Margarita, CA, USA) single-incision device was used in all procedures and placed with a 4 cm incision at the umbilicus in most of patients. In case of total mesorectal excision the port was placed at the future ileostomy site. In all cases, the specimen was retrieved through this mini-laparotomy. For right hemicolectomy and transverse colectomy, an extracorporeal handsewn anastomosis was performed. For left hemicolectomy and anterior resection, the anastomosis was performed by laparoscopic transanal intracorporeal double stapled technique.

Follow up

Every patient case was discussed during the postoperative MDT meeting and adjuvant treatments were

proposed to patients regarding the final histopathological results of the surgical specimen or presence of distant metastases. All patients were followed up prospectively with clinical examination, serum CEA blood test and thoraco-abdominal CT scan every 6 months. A first colonoscopy was performed at 12 months. Thereafter frequency of colonoscopy depends on the removal of polyps.

Statistical analysis

Normality assumptions were checked. Quantitative data are expressed as mean and standard deviation for age, BMI and LNR, or median and minimum-maximum for tumor size, operating time and hospitalization duration, while categorical data are expressed as percentages. Null hypothesis is that the group difference (early vs advance stage cancer) is equal to zero. Continuous variables were compared with the Student *t* test, or Wilcoxon rank-test as appropriate; the Fisher Exact-test was used to compare categorical data. Univariate and multivariate logistic regression analyses were performed to identify specific risk factors for conversion to open surgery. The following variables as risk factors: sex (male *versus* female), age, history of surgery, BMI, ASA score (I *versus* II, and I *versus* III), intraoperative complication, early experience (first 50 cases *versus* late 50 cases), tumor size, T-stage (pT3-T4 *versus* pTis-T2), stage IV disease (M1 *versus* M0). Higher bound for inclusion in the multivariate model was set to 20%. Backward stepwise selection was used to select optimal multivariate model. Results are reported as odds ratio (OR) with 95% confidence intervals (CI). All *p* values were 2-tailed, and *p* values of less than 0.05 were considered statistically significant. The data was collected in an Excel spreadsheet. Analysis was performed using SAS software (version 9.4 ; SAS Institute Inc, Cary, NC, USA).

Results

The total cohort included 70 patients who underwent SILS for pT3-T4 and 30 who underwent SILS for pTis-T2. Patient characteristics are summarized in Table 1. Demographics were similar between the groups with no difference regarding age, gender, BMI or ASA status. Sixteen patients had metastatic disease in pT3-T4 group : for 13 patients, metastases were demonstrated at preoperative workup (12 with liver and 1 with lung metastases), while 3 patients had an intraoperative finding of peritoneal carcinomatosis. One patient with known liver metastasis had an intraoperative diagnosis of peritoneal carcinomatosis. The only patient with a stage IV disease in pTis-T2 group had a liver metastasis diagnosed preoperatively. The most common procedures were right colectomy, left colectomy and anterior resection, performed in 39, 31 and 20 patients respectively. Segmental splenic flexure resection, transverse colectomy and total colectomy

Table 1. — Patient characteristics

	TOTAL (100)	pTis-2 (30)	pT3-4 (70)	P
Age (years)	66.9 ± 14.3	65.0 ± 9.7	67.7 ± 15.8	0.309 ^a
Male (%)	50.0	60.0	45.7	0.275 ^b
BMI (Kg/m ²)	24.4 ± 3.5	24.8 ± 3.2	24.2 ± 3.6	0.420 ^a
ASA score > 2 (%)	25.0	23.3	25.7	0.999 ^b
Previous surgery (%)	46.0	40.0	48.6	0.514 ^b
Stage IV (%)	17.0	3.3	22.9	0.019 ^b

Data are expressed as means and standard deviations ; p-values from Student t-test^a or Fisher Exact test^b. BMI, Body Mass Index ; ASA, American Society of Anesthesiologists.

Table 2. — Perioperative short-term outcomes

	TOTAL (100)	pTis-2 (30)	pT3-4 (70)	P
Conversion to open surgery (%)	15.0	6.7	18.6	0.220 ^b
Need for additional trocar (%)	3.0	3.3	2.9	0.999 ^b
I.o. complications (%)	8.0	6.7	8.6	0.999 ^b
P.o. complication (Dindo > 2) (%)	9.0	10.0	8.6	0.999 ^b
Hospital stay (days)	6.0 (2-49)	6.0 (3-49)	6.0 (2-37)	0.961 ^a
30-days mortality (%)	1.0	0.0	1.4	0.999 ^b

Data are expressed as median and minimum-maximum. P-values from Wilcoxon sign-rank test^a or Fisher Exact test^b

Table 3. — Univariate and multivariate analyses of factors associated with conversion to open surgery

VARIABLE	UNIVARIATE ANALYSIS		MULTIVARIATE ANALYSIS	
	ODDS RATIO (95% CI)	P	ODDS RATIO (95% CI)	P
Sex (F vs M)	0.621 (0.203-1.899)	0.404		
Age	1.058 (1.009-1.108)	0.019	1.061 (1.012-1.113)	0.015
ASA (2 vs 1)	0.589 (0.105-3.310)	0.548		
ASA (3 vs 1)	2.139 (0.375-12.202)	0.392		
Previous surgery (Yes vs No)	3.928 (1.156-13.35)	0.028		
BMI	1.114 (0.941-1.317)	0.209		
I.o. complications (Yes vs No)	4.000 (0.845-18.93)	0.081		
Early experience (Yes vs No)	1.170 (0.390-3.515)	0.780		
Tumor size (cm)	1.090 (0.849-1.400)	0.4998		
Stage IV (Yes vs No)	3.042 (0.885-10.46)	0.027	5.372 (1.320-21.862)	0.019
pT3-T4 vs pTis-2	3.192 (0.674-15.13)	0.144		

CI, confidence interval.

were performed in 4, 2 and 2 patients respectively. A total mesorectal excision was needed only in 2 cases. There were no statistical differences between groups in terms of type of surgical procedure ($p = 0.311$).

Peroperative results

Intra- and postoperative outcomes are shown in Table 2. Intraoperative complication rate was 5.7% (4/70) in pT3-T4 group and 6.7% (2/30) in pTis-T2 group ($p = 0.999$). Overall, we had 1 intraoperative bleeding, 1 superficial spleen injury, 2 colonic ischemia, 1 rectal perforation and 1 thermal bowel injury. In 3 cases the complication was effectively managed by SILS without any additional trocar. Conversion to open surgery was needed in 2 cases: in 1 case due to an intraoperative retropancreatic bleeding associated with a large T4 tumor and in 1 case due to a rectal perforation during distal

dissection. In 1 case an intraoperative colonic ischemia took place after the conversion due to adhesions.

In total, 15 patients (15.0%) required conversion to open surgery. Most of conversions occurred for adhesions ($n = 3$), difficult exposure ($n = 3$) and locally invasive tumors ($n = 3$). Other reasons for conversions were intrabdominal obesity ($n = 2$), peritoneal carcinomatosis ($n = 1$), tumor size ($n = 1$), perforated tumor ($n = 1$) and iatrogenic bowel perforation ($n = 1$). Concerning the 3 patients with locally invasive tumors, we proceed immediately to laparotomy before starting any kind of dissection. Although we had more conversions in the pT3-T4 group, the conversion rate was not statistically different between groups [13/70 (18.6%) vs 2/30 (6.7%); $p = 0.220$]. Univariable and multivariable analyses of risk factors for conversion to open surgery were carried out to investigate whether T-stage was linked to conversion (Table 3). Among the factors tested, the

Table 4. — Pathological results

	TOTAL (100)	pTis-2 (30)	pT3-4 (70)	P
Lymph nodes harvest ^a	16.0 (1-111)	13.0 (1-50)	20.0 (6-111)	<0.001
Lymph node ratio ^b	0.07 ± 0.129	0.02 ± 0.035	0.09 ± 0.148	0.028
Tumor size (cm) ^a	3.45 (0.3-12.5)	2.0 (0.3-12.0)	3.9 (1.0-12.5)	<0.001
R1 resection (n) ^a	0	0	0	NA

Data are expressed as median and minimum-maximum^a or as means and standard deviations^b. P-values from Wilcoxon sign-rank test. NA, not applicable.

following were selected for inclusion in the multivariate model (higher bound 20%): age ($p = 0.019$), history of surgery ($p = 0.028$), intra-operative complications ($p = 0.081$), stage IV ($p = 0.027$) and T-stage ($p = 0.144$). Best model selection from the multivariate analysis showed that only age (OR = 1.06, 95%CI 1.012-1.113), $p = 0.015$) and stage IV disease (OR = 5.372, 95%CI 1.320-21.862, $p = 0.019$) were independent predictors of conversion. Finally, there was no statistical difference in terms of operative time between groups ($p = 0.964$).

Postoperative results

Postoperative (Clavien-Dindo classification >2) morbidity rate was 8.6% (6/70) in pT3-T4 group and 10% (3/30) in pTis-T2 group ($p = 0.999$). In the study population we had 8 clinical anastomotic leakages and 1 postoperative small bowel obstruction. Among them, reoperation was needed in all but 1 patient who underwent interventional radiologic drainage. We had one postoperative death: an 80-years-old man with a stage IV pT4bN2 caecal cancer who experienced an anastomotic leakage on postoperative day 9. Finally, there were no statistical differences between groups in terms of hospital stay ($p = 0.961$).

Pathological results

In the pTis-T2 group there were 6 pTis, 16 pT1, 8 pT2. In the pT3-T4 group there were 52 pT3, 15 pT4a and 3 pT4b. Oncologic short-term outcomes are indicated in Table 4. Not surprisingly, patients affected by pT3-T4 lesions had larger lesions ($p < 0.001$), with a significantly higher lymph node ratio ($p = 0.028$). However, despite this more aggressive behavior, in all cases the primary malignancy was radically removed and the lymph node harvest was satisfactory.

Discussion

In our study, no significant differences were recorded between SILS for locally advanced (pT3-T4) and early-stage colorectal cancer (pTis-T2) with respect to perioperative and early oncologic outcomes. A SILS approach to LACC does not seem to increase intra- or postoperative morbidity when compared to SILS for early-stage lesions. A similar operative time and hospital stay between the two groups also reflects this finding. Conversion to standard laparoscopy was rarely

necessary. On the other hand, even if conversion from SILS to open surgery was undertaken more frequently in patients with LACC, age and metastatic disease were the only factors associated with conversion at multivariate analysis. Finally, SILS approach for LACC did not lead to increased positivity rates of surgical resection margins or to insufficient lymph node harvest.

Although SILS for LACC has already been reported in the literature, specific outcomes from these patients are unknown. To date, evidence from literature on SILS for colorectal cancer is limited. Most of the available data in literature refers to retrospective case-comparison series, with only three randomized controlled trial published so far (11-13). However, despite the relatively recent introduction of this technique and lack of strong evidence, we are witnessing an incremental shift in practice of SILS for tumoral disease, especially from Eastern countries. Several large series have been recently published on this topic (7,8,14,15). In general, when compared with conventional laparoscopy, SILS seems to decrease analgesic requirements, shorten the length of hospital stay and accelerate the postoperative recovery, without increasing morbidity (7,14,15). Oncological results were reported equally satisfactory. However, the study population in these series is variously distributed across the T classification. Therefore, although SILS for pT3-T4 lesions was performed in a consistent number of patients, with rates ranging between 39.1% to 81.4%, specific outcomes of SILS for LACC remained poorly reported (7,15).

In our study, perioperative outcomes of SILS in pT3-T4 patients were not statistically different compared with pTis-T2 patients and, in general, they compare favorably with those from the literature. Kim et al. reported results from a retrospective comparison between 76 SILS and 106 conventional laparoscopies for colorectal cancer (7). The percentage of LACC in the SILS group in this study was considerably high when compared with other series in the literature (81.4%), allowing a fair comparison with our cohort. The authors observed a median operative time of 274 min, an intraoperative complication rate of 5.5%, a postoperative (Clavien-Dindo classification > 2) morbidity rate of 9.6% and a mean hospital stay of 9.6 days. Our perioperative results are concordant with those from Kim et al.

Conversion rate in our pT3-T4 population is higher than that usually reported in SILS literature, but in line with those from conventional laparoscopic colectomy for locally advanced and metastatic colorectal cancer

(7,8,5,14-19). In largest series conversion rate from SILS to open surgery ranges between 0% (14,20) and 1.3% (8,21). In this context we have to point out that in previous studies T4 tumor, metastatic disease and history of major abdominal surgery were considered an exclusion criteria (7,8,13-15,22). Conversely, we believe that, unless obvious invasion of other organs or structures at preoperative investigations, most patients can benefit from a laparoscopic abdominal exploration by SILS. During SILS in fact, a complete abdominal exploration can be performed through a midline mini-laparotomy, without the need of additional and potential unnecessary trocars. In case of conversion, the 4-cm periumbilical incision can easily be enlarged according to tumor size and localization. In this regard, it must point out that our additional trocar rate was only 2.9% (2/70) in pT3-T4 group and 0% in pT4 patients (0/18). These findings reflect that with an extensive SILS experience, when a patient cannot safely be managed by SILS, rarely the addition of an additional trocar will avoid a conversion to laparotomy. This policy led us to offer SILS to a substantial number of patients with advanced tumoral stage who otherwise would not have benefited from a minimally invasive surgery. On this issue we agree with Kim et al. in saying that the limitations of SILS are just same as the limitations of conventional laparoscopy itself and that the real limitation of SILS is the surgeon's experience, rather than tumoral stage (7).

In our study, we assessed the role of the T-stage as a risk factor for conversion against several patient-, tumor-, surgery- and surgeon-related variables. Bearing in mind the low incidence of conversion in our population for the purpose of statistical risk identification, the only factors that significantly influenced the risk of conversion to open surgery in our multivariate analysis were age and metastatic disease. The literature is controversial concerning the role of age on conversion. Several authors reported age as a risk factor for conversion to open surgery after colorectal laparoscopic resection, while others have found no relation (23-27). A full explanation to this observation has not been provided. Possible explanation for this finding is that long laparoscopic procedures are less well tolerated by elderly because of coexisting morbidity. As elegantly demonstrated by Cima et al., many factors that influence outcomes of laparoscopic colorectal resections are confounding and profoundly influenced by the institution's specific patient mix, surgeon factors and system issues (28).

This study is subject to the inherent limitations of any retrospective analysis and the possibility of selection bias for patients with lower BMI. Moreover, our population study was not well balanced between the two groups in terms of metastatic disease. Finally, the relatively small sample size might explain the low statistical power for certain outcomes.

In conclusion, SILS for pT3-T4 colorectal cancer is technically feasible and can be performed safely by experienced laparoscopic surgeons. When compared

with SILS for early stage colorectal cancer, SILS for LACC has similar short-term and oncologic outcomes, except for a trend towards higher conversion rate. However, on the basis of the analysis from this study, T-stage does not seem to be a major risk factor for conversion to open surgery. Benefits from a SILS approach should be carefully evaluated in elderly and in presence of metastasis given the high risk of conversion in these patients. Long-term survival and recurrence rates analyses were beyond the scope of this study. Further studies are needed to investigate this important issue.

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