



Research Article

Can We Set Quality Standards for the Centers: Minimally Invasive Surgery vs. Open Surgery in Colorectal Cancer Resection

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Abstract

Background: Minimally invasive surgery (MIS) is the standard method for resection of colorectal cancer, but its indications have limitations that are constantly debated. In our study, the center had to meet the following four factors: surgeons should have considerable experience, there should be a high percentage of MIS, a low conversion rate, and good results in the intervention.

Methods: Retrospective observational study of a cohort of 948 patients with colorectal cancer who underwent scheduled open surgery (OS) and MIS between 2011-2016.

Results: There were no differences based on sex, body mass index, or location of the tumor, but OS was related to older age, higher ASA, a higher stage, previous surgery, and operative adverse events. The location of the primary tumor and the existence of synchronous

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tumors were related to variability in the technique. The implementation of MIS increased from 36.2% in 2011 to 89.6% in 2016. The surgeon's experience decreased the conversion rate from 6.5% in 2011 to 3.1% in 2016, with 2% in T0-2 tumors. In logistic regression, the factor that most increased the possibility of choosing MIS was the pT grade of the tumor, and the factors that most contraindicated MIS were stages 2-4, ASA 4, stage 1, previous surgery, and advanced age.

Conclusions: In hospitals where surgeons have long experience, minimally invasive surgery could be implemented in up to 90% of cases, with low conversion rates (3-4%) and good results for patients.

Keywords: Minimally Invasive Surgery; Open Surgery; Surgeon Experience; Conversion; Surgical Outcomes

1. Introduction

Minimally invasive surgery (MIS) in colorectal cancer resection (CRC) is currently the standard method due to faster patient recovery and an oncological outcome similar to that of open surgery (OS) [1, 2]. However, its indication may be a cause for discussion in patients with a high body mass index (BMI), ASA IV, previous OS, age over 80 years, pT4 tumors, and other factors, because of risk of a high conversion rate [3-5]. In randomized studies of MIS and OS in CRC resection, the conversion rates reach up to 30% [6]. Higher conversion rates are reported in T4 tumors, and studies have examined whether they will pose a greater risk of long-term local recurrence [4]. Other studies conclude that it is necessary to reduce the conversion rate through adequate patient selection for CRC resection with MIS by expert surgeons [7, 8]. The years of experience of the surgeons and the number of MIS performed by the team may be factors in obtaining good results. This study is designed to provide information to obtain more accurate knowledge about the limits of the indication of MIS performed in 2016 in a hospital center that meets three conditions: Its surgeons are experts (minimum 25 years in MIS), and there is a high percentage of MIS in CRC (90%) and a low conversion rate (3.1%).

2. Material and Methods

The study period ranged from January 2011 to December 2016. The information about the patients was collected prospectively in a database. This research project was approved by the Research Committee. Preoperative, operative, and postoperative data were collected at ninety days from all patients operated on consecutively using CRC resection. The hospital is a university tertiary public center that serves a population of 380, 000 people. A total of 1, 126 cases were recorded during that period, of which 948 corresponded to scheduled surgery and 178 to urgent surgery. Data collection was performed by one of the authors. We have conducted a retrospective observational study of the cohort of 948 patients undergoing scheduled surgery. The indication of the approach was considered in each case by the Clinical Expert Committee, using the preoperative extension study (colonoscopy, biopsy, and tattoo of carbon lesions, computed tomography in all cases, and magnetic resonance imaging in case of rectal involvement) and the preoperative review performed by the anesthetist with staging to grade I-IV using the classification of the American Society of Anesthesiology (ASA).

The data considered for the analysis were:

-MIS or OS and patient characteristics: sex, age, body mass index (BMI), ASA grade I-IV, tumor location (colon, rectum, or synchronous tumors included in the location of the most advanced tumor), TNM-AJCC classification (stage 0-IV), previous OS (except appendectomy and cholecystectomy), and adverse operative event.

-Surgical resection procedures performed in the colon and rectum with MIS and OS. Histological result of tumor resection (pT) and nodes obtained. In the rectum, neoadjuvant chemo-radiotherapy and complete mesorectum were considered. In the postoperative period, mortality, hospital stay, and readmissions were considered.

-Conversion from MIS to OS, including strategic or preventive conversion due to the impossibility of progressing with the intervention due to adhesions, and reactive conversion due to an adverse operative event.

Conversions by tumor grade pT0-4a were studied separately, as well as those that required resection of other organs (small intestine, abdominal wall, ovary, uterine tube, uterus, bladder, prostate, seminal vesicles, segmental resection of iliac vessels) due to adhesion or tumor infiltration (pT4b) in ASA IV patients, previous OS, after operative adverse events, and in patients older than 80 years. The data were processed in SPSSv21-IBM. Quantitative data are presented as mean ± standard deviation, and qualitative data as frequency and / or percentage. The normality of the variables was studied. For the comparison of variables, Student's t test was used with a 95% Confidence Interval, and Pearson's Chi-square or Fisher's exact test were used when appropriate. Subsequently, a multiple logistic regression was performed to determine the factors that conditioned the performance of MIS or OS. The performance of MIS or OS was used as a dependent variable, and independent variables were factors related to both the patient and the surgery: age, sex, BMI, ASA, stage, resection of other organs, histological grade pT of the tumor, or previous surgery. Given the non-linear behavior of age, it was grouped in <60, from 60 to 69, from 70 to 79, and over 80 years. In a similar way, BMI was classified into four groups according to the World Health Organization Health guidelines [9]: normal and underweight (BMI <24.9), overweight (BMI 25.0-29.9), obesity (BMI <30.0).

3. Results

In all, 712 patients were intervened with MIS and 236 with OS. In the study of the patients in the analyzed series, there were no differences in sex, BMI, or tumor location, but the OS group had older age, higher ASA, a higher stage, previous OS, and operative adverse events (Table 1). Surgical resection procedures showed variability determined by the location of the primary tumor and the existence of a synchronous tumor (Table 2). The implementation of MIS (Table 3) increased from 36.2% in 2011 to 89.6% in 2016 (88.8% in colon and 91.9% in rectum), with a global average over the six years of 75 %. In the rectum, neoadjuvant treatment was administered in 55.9% of the OS patients and in 50.2% of the MIS (Pearson's Chi-square-Fisher's exact test: p=0.810). The results show that there is a relationship between the minimum years of experience of the surgeon and the conversion rate, which begins in the year 2011 with 6.5% and ends in the year 2016 with 3.1%. The 90-day postoperative mortality was 5.5% in OS and 0.6% in MIS (Pearson's Chi-square-Fisher's exact test: p=0.000), 21% due to tumor disease progression and 42% due to comorbidities. The average stay showed a median of 9 days in OS and 7 days in MIS (Student's t: p=0.000 95% CI 1.5 3.9), and readmissions made up 5.5% in OS and 3.1% in MIS (Pearson's Chi-square-Fisher's exact test: p=0.109).

The histological classification pT presented statistically significant differences (Table 4) because there was a greater indication of OS in pT4 tumors and a greater indication of MIS in pT0-3 tumors. There were 96 resections of other organs due to tumor adhesion or infiltration: 19 were reported histologically as T4a and 77 as T4b. The number of lymph nodes obtained in the colon in OS (13.7 \pm 8) and MIS (11.9 \pm 7) was slightly

lower in MIS (Student t: p=0.006 95% CI 0.51 3.01). In the case of the rectum, there were no significant differences between OS (8.9 \pm 7) and MIS (9.9 \pm 6) (Student's t: p=0.275 95% CI -2.91 0.83). The integral mesorecta in OS were 70.4%, and in MIS 89.4%, showing that MIS was statistically superior (Pearson's Chi-square-Fisher's exact test: p=0.001). Simultaneous resection of CRC and liver metastasis was performed in five cases in MIS and six in OS. The overall conversion was 4.3% (Table 5). In general, the conversion rate increased with the difficulty of resecting pT4 tumors, and it ranged from 2% in T0-2 to 25% in T4b. Conversion after operative adverse events occurred in 15% of OS and in 0.8% of the total in MIS. In ASA-IV, this percentage was 9.1%, but it was lower in previous OS and patients over 80 years old. There was conversion (20%) in simultaneous resection of CRC and liver metastases.

In the logistic regression involving OS vs. MIS (Table 6), the Omnibus test had a p-value of 0.00, the Cox and Snell test gave a value of 20.6%, and the Nagelkerke test yielded 30.7%. The independent variable set model was statistically significant, explained between 20.6% and 30.7% of the dependent variable, and correctly classified 80.2% of the cases, and so we can accept the statistical model. The factor that most increased the possibility of choosing MIS over OS was the tumor's pT grade, in order of potency: T2 (OR 11.03), T3 (OR 7.6), T1, (OR 5.3). By contrast, the factors that most decreased the possibility of choosing MIS over OS were, in order of potency: stages 2-4 (OR 0.1), ASA 4 and stage 1 with OR of 0.2, previous surgery (OR 0.4), and age over 80 years and 70-79 years with OR 0.5 and 0.6, respectively. No statistically significant differences were found for sex, BMI, location of surgery (colon/rectum), resection of synchronous tumors, or resection of other organs.

	OS		MIS				
	m	sd	m	sd	P value		
Age	71.9	11	68.6	11	0.000 (1.43-4.79) a		
Body Mass Index	27.3	5	28.6	13	0.164 (-3.23-0.55) a		
	n	%	n	%	P value		
Sex			L		0.442 b		
Male	139	58.9	440	61.8			
Female	97	41.1	272	38.2			
Total	236	100	712	100			
ASA	ASA						
I	11	4.7	41	5.8			
II	103	43.6	402	56.5			
III	105	44.5	255	35.8			
IV	17	7.2	14	2.0			
Tumor location		II.			0.213 b		
Colon	177	75.0	513	72.1			
Rectum	59	25.0	199	27.9			
Synchronous*	26	11.0	37	5.2	0.002 b		

Stage					0.000 b
0	20	8.5	100	14.0	
I	26	11.0	163	22.9	
II	63	26.7	210	29.5	
III	70	29.7	171	24.0	
IV	57	24.2	68	9.6	
Previous OS**	51	21.6	75	10.5	0.000 b
AOE***	26	11.0	40	5.6	0.005 b

^{*}They were included in the colon or rectum group considering the predominant or more advanced tumor; **Cases with previous OS (laparotomies except appendectomy and cholecystectomy); ***Adverse Operatory Event; a Student's t test (Confidence Interval 95%); b Pearson's Chi-square test - Fisher's exact test

Table 1: Characteristics of patients operated on by open surgery (OS) and minimally invasive surgery (MIS).

Procedure	OS		MIS		Total	
	n	%	n	%	n	
Right Colectomy	74	28.5	187	71.5	260	
Sigmoidectomy	54	21.4	199	78.6	252	
Anterior Resection of Rectum	45	20.5	174	79.5	219	
Enlarged Right Colectomy ^a	20	23.8	64	76.2	84	
Left colectomy	14	28.0	36	72.0	50	
Abdominal-Perineal Amputation	13	37.1	22	62.9	35	
Segmentary Colectomy ^b	8	57.1	6	42.9	14	
Total Colectomy ^c	4	30.8	9	69.2	13	
Subtotal Colectomy ^d	1	16.7	5	83.3	6	
Right Colectomy + Sigmoidectomy	1	25.0	3	75.0	4	
Right Colectomy + Anterior Resection of Rectum	0	0.0	2	100	2	
Left Colectomy + Anterior Resection of Rectum	0	0.0	2	100	2	
Total Colectomy + Anterior Resection of Rectum	1	50.0	1	50.0	2	
Right Colectomy + Left Colectomy	0	0.0	1	100	1	
Total Colectomy + Abdominal-Perineal Amputation	0	0.0	1	100	1	
TOTAL	236	24.9	712	75.1	948	

^a Resection of medium colic vessels; ^b Resection of splenic angle; ^c Resection of colon to upper rectus; ^d Preservation of sigmoid colon

Table 2: Specific surgical resection procedure in open surgery (OS) and minimally invasive surgery (MIS).

Year	2011	-	2012		2013		2014		2015		2016		Tota	l
OS	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Colon	52	59.8	48	43.6	28	22.4	22	18.0	15	10.8	12	11.2	177	25.7
Rectum	29	72.5	10	25.0	9	19.6	1	2.7	7	12.1	3	8.1	59	22.9
Adverse event	9	11.1	6	10.3	4	10.8	6	26.1	1	4.5	0	0.0	26	11.0
Number	81	63.8	58	39	37	21.6	23	14.5	22	11.2	15	10.4	236	24.9
MIS	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Colon	35	40.2	62	56.4	97	77.6	100	82.0	124	89.2	95	88.8	513	74.3
Rectum	11	27.5	30	75.0	37	80.4	36	97.3	51	87.9	34	91.9	199	77.1
Adverse event	4	8.7	3	3.3	9	6.7	11	8.1	10	5.7	3	2.3	40	5.6
Conversion	3	6.5	6	6.5	8	6	1	0.7	9	5.1	4	3.1	31	4.3
Number	46	36.2	92	61	134	78.4	136	85.5	175	88.8	129	89.6	712	75.1
Total	127	100	150	100	171	100	159	100	197	100	144	100	948	100
Minimum		ı												
years of														
experience of														
surgeon	20		21		22		23		24		25		-	

Table 3: Number of interventions in open surgery (OS) and minimally invasive surgery (MIS) in the colon and rectum, specifying the complication or adverse operative event and conversion according to the years of study.

	OS		MIS		TOTAL		
	n	%	n	%	n	%	
pT0	24	10.2	100	14.0	124	13.1	
pT1	13	5.5	56	7.9	69	7.3	
pT2	24	10.2	152	21.3	176	18.6	
рТ3	85	36	338	47.5	423	44.6	
pT4a	41	17.4	38	5.3	79	8.3	
pT4b	49	20.8	28	3.9	77	8.1	
TOTAL	236	100	712	100	948	100	

Pearson's Chi-square test - Fisher's exact test: p = 0.000

Table-4: pT grade tumor in OS and MIS.

	Cases	Conversion	on	
	n	n	%	% total cases
Total	712	31	4.3	4.3
Colon	513	21	4.1	

^{*}Adverse Operatory Event

Table 5: Conversion of MIS to OS.

D., J. 4 V 11	Beta	Typical		Odds	(CI 95%	(CI 95%
Predictor Variables	Coefficient	Beta error	p	ratio	inferior)	superior)
MIS over OS	I					
Age: over <60 years	-	-	0.014	-	-	-
60-69 years	-0.066	0.287	0.818	0.936	0.534	1.643
70-79 years	-0.554	0.283	0.050	0.575	0.330	1.001
>80 years	-0.799	0.308	0.010	0.450	0.246	0.824
Sex: female over male	0.147	0.195	0.452	1.158	0.790	1.697
BMI: over normal/infra-weight	-	-	0.403	-	-	-
Overweight	0.170	0.213	0.424	1.185	0.781	1.798
Obesity	0.332	0.247	0.179	1.394	0.859	2.264

ASA: over ASA 1	-	-	0.003	-	-	-
ASA 2	0.144	0.451	0.749	1.155	0.477	2.797
ASA 3	-0.105	0.466	0822	0.901	0.362	2.243
ASA 4	-1.645	0.645	0.011	0.193	0.055	0.683
Colon-Rectum: over colon	0.104	0.213	0.626	1.109	0.731	1.684
Synchronous; over no	-0.360	0.323	0.264	0.697	0.370	1.313
Stage: over Stage 0	-	-	0.001	-	-	-
Stage 1	-1.619	0.773	0.036	0.198	0.044	0.901
Stage 2	-1.964	0.805	0.015	0.140	0.029	0.679
Stage 3	-2.338	0.792	0.003	0.097	0.020	0.456
Stage 4	-2.817	0.802	0.000	0.060	0.012	0.288
ROO*: over no	22.265	8918.370	0.998	max	0.000	max
T: over T0	-	-	0.001	-	-	-
T1	1.672	0.792	0.035	5.323	1.126	25.149
T2	2.401	0.768	0.002	11.030	2.450	49.658
T3	2.034	0.772	0.008	7.642	1.682	34.726
T4a	1.064	0.810	0.189	2.897	0.592	14.169
T4b	22.145	8918.370	0.998	max	0.000	max
Previous OS: over none	-1.004	0.236	0.000	0.366	0.231	0.581

^{*}Resection of other organs

Table 6: Factors associated with the choice of minimally invasive surgery (MIS) and/or open surgery (OS), and Conversion over No (only MIS).

4. Discussion

Since the introduction of colon resection by MIS in the early 1990s [10], this technique has been extended, and today its worldwide implementation is being studied [11] for CRC. Large randomized controlled trials have shown short-term advantages of this approach [12-14], and long-term oncology outcomes similar to OS [15-20]. As mentioned in the introduction, of the three factors to consider in the centers, the first is the experience of the surgeons. In our center, the MIS was introduced for CRC resection in the early 1990s [21, 22] with a large group of surgeons who were experts in this technique. However, patients had always been selected from those who had a high probability that the

intervention would be completed with a minimal risk of conversion, so that in 2011 we only recommended it in 36% of the cases of CRC. We decided to expand the indications in 2012, and 90% CMI was reached in 2016 out of all the cases of CRC.

Based on the definition of Evidence-based Medicine and Surgery, which integrates clinical experience and patient values with the best available research information [23], it should be kept in mind that the first factor is clinical experience. All published works state the importance of surgeons' experience, but few studies describe it in detail. We consider that the years of experience of surgeons in MIS is the most important factor, and so in our case the number of years of

experience of the main surgeon in the group was recorded. As a proxy for this aspect, other studies talk about training. Thus, the study carried out in the Netherlands [24] establishes that they began with the training of a select group of surgeons between 2003 and 2008; however, they established 24 as the number of resections by MIS necessary to be considered an expert. Other equivalents to training would be the board-certified colorectal surgeons [25].

Other similar parameters to reflect the surgeons' experience are established according to the hospital volume of MIS, and so the study by Babberich, MP, et al. [26] refers to high-volume centers with more than 100 CRC, including more than 40 resections by MIS, although they show higher conversion rates, over 10% [27]. Other works try to measure this factor based on the number of expert surgeons who participated in the study. Here the variations are important. Thus, whereas some authors [28] talk about the same surgeon operating on all the patients, or surgeons trained by him, other authors [29] establish that there were 6 experienced surgeons who performed the MIS, and others are simply databases of all the patients who undergo resection for primary CRC in the Netherlands [26]. This audit collects information about the patient, the tumor, the treatment, and the characteristics of the short-term results of all patients.

The second factor we consider important is the percentage of MIS out of the total. The values are very different in the large number of studies that have been published on this aspect, such as those collected by Lorenzon L et al. [11]. However, some studies have obtained similar figures to those we found in our hospital, although somewhat lower for 2015 [26], 84% for colon cancer and 89% for rectal cancer. The third factor we consider is conversion. In our study, there is a relationship between the surgeon's years of experience

and conversion, although other factors may have intervened. By contrast, there are studies such as Massaroti et al. [30] that do not associate the conversion rate with the surgeon's experience. However, we think this study does not have sufficient strength to prove otherwise because it was performed with 6 surgeons and a total of 408 MIS between 2009 and 2014, classifying surgeons as experts if they had done more than 100 MIS.

When considering the results, the 90-day postoperative mortality was 5.5% in OS and 0.6% in MIS (considering that 37% of the deaths were attributable to the surgery), and the average stay presented a median of 9 days in OS and 7 days in MIS. Moreover, among the results we must consider that the priorities of the patients surveyed after colorectal surgery [31] are freedom from cancer, stoma, and surgical complications, whereas the hospital stay, the MIS, and the appearance and duration of the incision have secondary importance. In our review, the ASA IV, previous OS, and age over 80 years did not present an excessive conversion rate compared to the global rate. For tumors and advanced stages (pT4 and stage IV), OS was indicated more, as in other studies [32], but MIS was indicated in 66 cases of pT4 tumors. In the review by Bretagnol et al [33] of 39 patients with T4 tumors, there was a conversion rate of 18%, 2.5% mortality, and 33% morbidity. Adverse operative events, mortality, and hospital stay were lower in MIS. The histological results were similar, but with 19% more full mesorectum in MIS, which can be explained by case selection. Logistic regression indicates that the only unfavorable factor in indicating MIS, and the highest conversion rate, is multi-visceral resection in T4 tumors, coinciding with other published works [6, 12], although some Societies' guidelines recommend OS in these cases [34].

5. Conclusion

The review allows us to conclude that our center has better results than those published in the literature, simply because its surgeons have developed a great MIS practice over the years and, therefore, a good indication for this approach. Therefore, we believe that the experience of surgeons who practice MIS should be described more precisely. Thus, in centers where surgeons have extensive experience, MIS could be implemented for CRC resection in up to 90% of cases, with low conversion rates close to 3-4% and good results for patients. We believe that, based on the number of articles published, it is time to start establishing quality standards of the Centers that practice this type of surgery.

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Conflict of Interest

All authors declare that they have no conflict of interest.

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