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DYNAMIC MANUSCRIPT

A randomized clinical trial comparing the initial vascular approach to the inferior mesenteric vein versus the inferior mesenteric artery in laparoscopic surgery of rectal cancer and sigmoid colon cancer

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Abstract

Background The inferior mesenteric artery approach with a selective lateral splenic flexure mobilization is the most widely used initial step in laparoscopic rectal and left colon surgery. Surgery started through the inferior mesenteric vein (IMV) with systematic medial mobilization (MM) has some theoretical advantages that have never been analyzed in a clinical trial. The aim of this study was to compare the two techniques with regards to surgical technique variables (conversion, surgical time, bleeding, morbidity, and mortality) and pathological outcomes.

Methods A single-blinded, randomized, controlled trial of patients operated electively by laparoscopic with curative intention for rectal or sigmoid cancer was performed at a single, specialized colorectal surgery department from April 2016 to October 2017.

Results 49 patients were included in each group. There were no statistical differences in patient demographics between the two approaches. Pathological outcomes did not differ between the two groups. Intra-operative characteristics showed a higher conversion rate in patients in which the inferior mesenteric artery was dissected first ($p=0.031$). The artery approach also increased intra-operative bleeding ($p=0.049$), but there were no differences regarding operative time. On multivariate analysis, the artery approach was associated with a higher risk of conversion (OR 8.68; $p=0.050$). Post-operatory complications did not differ between artery and vein dissection.

Conclusions In our study, the initial approach by the IMV with a systematic MM of the splenic flexure has allowed us to reduce the conversion rate without increasing complications or the surgical time. No differences were observed in the pathological results. Both approaches seem to be safe and effective and well-trained laparoscopic surgeons should have the two techniques available to them for use as needed.

Keywords Colorectal cancer · Vascular approach · Inferior mesenteric vein · Splenic colon flexure · Rectal cancer

Colorectal cancer (CRC) is the third most prevalent malignancy and the fourth leading cause of cancer mortality worldwide [1]. Surgery is currently the basis for the curative treatment of CRC [2–4]. CRC surgery can be performed through laparoscopy or open surgery. In terms of cancer outcome, there is no difference in overall survival, disease-free survival, and wound recurrences in patients treated using laparoscopic techniques compared with conventional operation. In addition, there are short-term benefits associated with the use of these techniques [3–5].

Laparoscopic sigmoidectomy and laparoscopic rectal resection can initially be approached through the inferior mesenteric artery (IMA) or the inferior mesenteric vein (IMV) depending on the surgeon's criteria. Until now, there has been no randomized prospective study based comparing the two techniques. The main objective of the two approaches is to achieve a safe and reproducible

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liberation of the surgical piece to obtain optimal oncologic results and good anastomosis perfusion without tension.

In the early years of laparoscopic surgery, the steps of open surgery were reproduced with an initial dissection through the lateral plane and the posterior medial dissection of the IMA. Afterwards, the medial approach through the IMA with a lateral decline of the splenic flexure of the colon (SFC) was favored [6].

Nowadays, the most common approach starts with the dissection through the IMA and the section of the IMV in the root is performed only in selected cases to release anastomotic tension. The IMA approach is usually associated with a selective decline of the SFC, which may be medial, anterior or lateral. It has been demonstrated that SFC mobilization is one of the more complex steps during rectal and colon surgery [7, 8]. The lateral mobilization (LM) is the most common technique but is associated with more complications in bleeding and conversion to open surgery than medial and anterior decline [5].

Among the potential benefits of starting the dissection at the IMV is that it is an easier way of finding the embryologic plane, which can lead to a major nodal resection [9, 10]. Another benefit is that the initial approach by the IMV allows a complete and medial mobilization (MM) of the SFC at the beginning of surgery [5, 11, 12].

Our hypothesis is that by beginning the surgery at the IMV with a systematic MM of the SFC presents a greater oncological radicality and a lower rate of complications in comparison with the technique that begins with the dissection of the IMA.

The aim of this study was to compare surgical technique variables (conversion, surgical time, bleeding, morbidity, and mortality) and pathological outcomes in rectal and sigmoid cancer in patients who underwent laparoscopic surgery with different initial approaches: starting by the IMV with systematic MM vs. starting by the IMA with selective LM.

Materials and methods

Study design

This was a single-blinded, randomized, controlled trial of patients operated electively by laparoscopic with curative intention for rectal or sigmoid cancer (Fig. 1). Patients were randomly assigned 1:1 to the IMA approach or the IMV with a sample generated by computer. Randomization

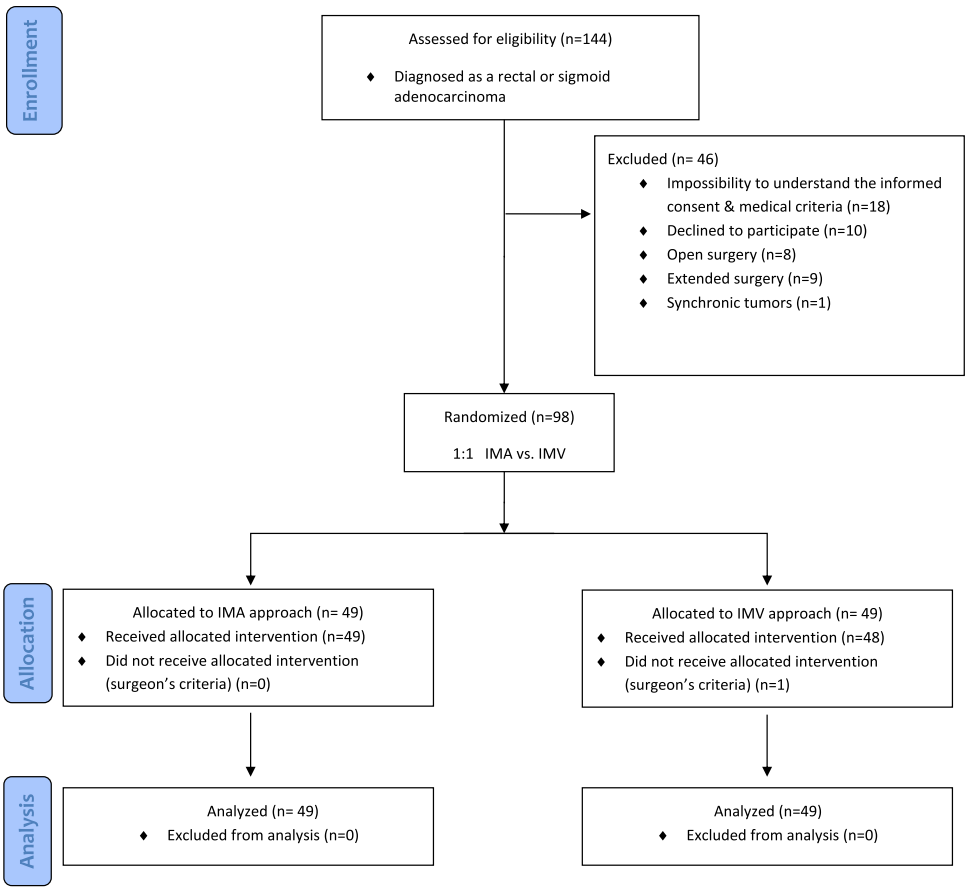

Fig. 1 Study population including inclusion and exclusion criteria. *IMA* inferior mesenteric artery, *IMV* inferior mesenteric vein

was performed using sealed envelopes. Patients and pathologists were blinded to the assigned group. The trial was conducted at a single specialized colorectal surgery department.

Primary and secondary endpoints

The primary endpoint of the present study was to compare the number of harvested nodes and the distance to/status of surgical margins between the two surgical approaches available for laparoscopically low anterior resection and left colectomy: starting by the IMV with systematic MM or starting by IMA with selective LM. Secondary objectives were to explore the differences between these two approaches in the intra-operative outcomes and post-operative morbidity.

Study population

Eligible participants were all adults aged 18 or over with rectal or left colon cancer who were to undergo radical laparoscopic resection and met the following criteria: adenocarcinoma tumor, any tumoral stage (included patients with resectable synchronous metastasis) and attempt at R0 resection.

Exclusion criteria were synchronic tumors, open surgery, impossibility to understand the informed consent, prior surgery of CRC (other than local excision), extended surgeries, and emergency surgeries.

In the IMV approach, after exploring the abdominal cavity, the first step was to free the angle of Treitz. The retroperitoneal window was opened under the IMV and above Gerota's fascia. The IMV was tied and divided below the pancreas. The transcavity of the omentum was opened and the procedure was finished with complete medial SFC mobilization. The IMA was tied and divided for a high tie at 1–2 cm from its origin.

In the IMA approach the first step was a peritoneum incision at the promontory sacrum level in the right side followed by the infra-IMA dissection and the identification of the iliac left artery, gonadal vessels and left ureter. The IMA was tied and divided for a high tie at 1–2 cm from its origin, preserving the symphatic plexus. LM was performed together with the opening of Toldt's fascia. SFC mobilization was performed partially or completely depending on the surgeon. The surgeon took the decision as to whether or not to ligate the IMV depending on the mobility requirements.

Access to the presacral space in rectal cancer patients was then undertaken in both groups applying the total mesorectal excision principles. Patients in both groups received usual care (enhanced recovery program) during the post-operative period.

Definitions

Complete mobilization of the SFC is considered as mobilization until accessing the transcavity of the omentum with visualization of the gastric posterior wall. Partial mobilization of the splenic flexure is mobilization without accessing the transcavity of the omentum.

Sample size calculation

A total of 72 patients (36 per arm) would have an 80% power to estimate a difference of 10 lymph nodes between the two groups ($\alpha = 0.05, \beta = 0.2$) with a dropout rate of 0% as immediate surgical results would be analyzed.

Statistical analysis

Patient demographics, pre-operative and post-operative parameters, and pathological outcomes were compared between the IMA group and the IMV group. The analysis was by intention-to-treat.

For data analysis, continuous variables were expressed as mean and standard deviation (SD) or median and range as appropriate. Categorical variables were summarized by absolute frequency and relative frequency. To compare results between groups, *t* Student's test or the Mann–Whitney test were used in quantitative variables, whereas the Chi square or Fisher's exact test were used in qualitative ones.

p-Values < 0.05 were statically significant. All variables with $< p \leq 0.100$ were considered for multivariate analysis. On multivariate analysis, a $p \leq 0.05$ was considered statistically significant. Data analysis was performed with the SPSS statistical package SPSS v. 20.0 (SPSS Inc, Chicago, IL, USA).

Ethical considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki and "good clinical practice" guidelines. The study was approved by our hospital's ethics committee. All patients were informed before surgery and written informed consent was obtained before randomization. Patients at all time retained the right to withdraw from the study and were excluded if any exclusion criterion appeared during the follow-up. The study was registered at Clinical trials.org (No. NCT02746224).

Results

Study participants and baseline characteristics

A total of 98 patients were included in the study between April 2016 and October 2017. 49 patients were assigned

to the IMA group and 49 patients to the IMV group. The cohort presents a BMI of 27.38 kg/m^2, 78.6% of ASA III or IV patients and 79.6% of tumors staged as T3 or T4.

Demographic data are summarized in Table 1. There was no significant association between groups and sex, age, ASA classification, medical antecedents, tumor height, synchronic metastasis, and previous abdominal surgery. Furthermore, clinical T and N stratification was comparable in the two groups ($p=0.928$ and $p=0.437$, respectively).

Surgical variables

No differences were seen in the intra-operative factors between the IMA and the IMV approach except for conversion to open surgery (IMA, $n=8$, 16.3% vs. IMV, $n=1$, 2%; $p=0.031$), total splenic flexure mobilization (IMA, $n=27$, 55.1% IMV, $n=48$, 98.0%; $p<0.001$) and IMV dissection (IMA, $n=32$, 65.3% IMV, $n=46$, 93.9%; $p<0.001$) (Table 2). A patient from the IMV group underwent an

Table 1 Demographic and pre-operative variables

	Artery approach ($N=49$)	Vein approach ($N=49$)	p-value
Sex			
Men	35 (71.4)	35 (71.4)	1.000
Women	14 (28.6)	14 (28.6)	
Age in years, median (range)	64 (27–94)	67 (46–92)	0.836
BMI in kg/m^2 median (range)	28 (18–40)	27 (15–36)	0.781
Medical antecedent			
Yes	38 (77.6)	32 (65.3)	0.180
No	11 (22.4)	17 (34.7)	
ASA			
I + II	10 (20.4)	11 (22.4)	0.806
III + IV	39 (79.6)	38 (77.6)	
Tumor location (cm)			
Sigmoid	10 (20.4)	8 (16.3)	0.655
Rectum	39 (79.6)	41 (83.7)	
0–5	9 (23.1)	12 (29.3)	
> 5–10	17 (43.6)	20 (48.8)	
> 10–15	13 (33.3)	9 (22.0)	
Previous abdominal surgery			
Yes	18 (36.7)	16 (32.7)	0.671
No	31 (63.3)	33 (67.3)	
Synchronic metastasis			
Yes	4 (8.2)	9 (18.4)	0.136
No	45 (91.8)	40 (81.6)	
RMN T			
T1	1 (2.0)	1 (2.0)	0.928
T2	6 (12.2)	6 (12.2)	
T3	30 (61.2)	32 (65.3)	
T4	3 (6.1)	1 (2.0)	
Non (sigmoid)	9 (18.4)	9 (18.4)	
RMN N			
N0	5 (10.2)	8 (16.3)	0.437
N1	19 (38.8)	12 (24.5)	
N2	16 (32.7)	20 (40.8)	
Non (sigmoid)	9 (18.4)	9 (18.4)	
Neoadjuvant treatment			
Yes	34 (69.4)	33 (67.3)	0.828
No	15 (30.6)	16 (32.7)	

Data are number (percentage), n (%), unless stated otherwise

Bold p values indicate significance

initial approach by the IMA due to difficulty in finding the dissection plane and by decision of the surgeon. Since an intention-to-treat analysis was performed, this patient is the only case in the IMV group without SFC mobilization.

Bleeding during the intervention was significantly greater in patients in which the initial approach was made by the artery (IMA, 165.41 ± 222.6 ml, IMV, 94.08 ± 114.2 ml; $p = 0.049$). Two single emergency conversions were performed during the artery approach because of bleeding (IMA, $n = 2$, 4.1% IMV, $n = 0$, 0%; $p = 0.031$). In both cases this was due to laparoscopic non-controllable splenic bleeding. The other seven cases of conversion were: four difficulty exposure for obesity and redundant mesocolon, two for narrow pelvis, one for prostate invasion.

Post-operative outcomes

As shown in Table 3, the analysis of severe complications through the Dindo Clavien classification did not show statistical differences between the two approaches (IMA, $n = 4$, 8.2% IMV, $n = 7$, 14.3%; $p = 0.627$). Re-hospitalization (IMA, $n = 6$, 12.2% IMV $n = 7$, 14.3% $p = 0.766$) and anastomosis leakage (IMA, $n = 3$, 6.1% IMV, $n = 5$, 10.2% $p = 0.715$) did not differ between groups.

No statistical association was found on evaluating length of stay (IMA, 6 (4–27), IMV, 7 (4–96), $p = 0.155$).

No patients died in either of the two groups.

Pathological outcomes

There were no differences in the number of lymph nodes included in the surgical specimens (IMA, 21.67 ± 7.03, IMV, 23.33 ± 12.02; $p = 0.408$). The affectation of the circumferential and distal margins were similar between groups; IMA, $n = 2$, 4.2% IMV, $n = 0$, 0%; $p = 0.495$ and IMA, $n = 1$, 2.1% IMV, $n = 2$, 4.1%; $p = 1.000$, respectively. Furthermore, the distal (IMA, 3.96 ± 4.28, IMV, 3.46 ± 4.24, $p = 0.567$) and proximal distances (IMA, 19.85 ± 11.52 IMV, 19.46 ± 6.89, $p = 0.840$) to the tumor were also measured without differences being found between the artery and vein approaches. The probability of obtaining an incomplete mesorectum depending on the initial approach was also evaluated but no association was found (IMA, $n = 3$, 6.1%, IMV, $n = 3$, 6.1% $p = 0.353$). Pathological results are set out in Table 4.

All variables were also separately analyzed in rectum and colon subgroups to evaluate any differences between them, but the results did not differ.

Table 2 Surgical variables

	Artery approach ($N = 49$)	Vein approach ($N = 49$)	p-value
Type of surgery			
High anterior resection	21 (42.9)	17 (34.7)	0.185
Low anterior resection	13 (26.5)	21 (42.9)	
Abdominoperineal resection	3 (6.1)	3 (6.1)	
Hartmann	4 (8.2)	0 (0.0)	
Sigmoidectomy	8 (16.3)	8 (16.3)	
Conversion to open surgery			
No	41 (83.7)	48 (98.0)	**0.031**
Yes	8 (16.3)	1 (2.0)	
Splenic angle decline			
No	11 (22.4)	1 (2.0)	**< 0.001**
Partial	11 (22.4)	0 (0)	
Total	27 (55.1)	48 (98.0)	
IMV dissection			
Yes	32 (65.3)	46 (93.9)	**< 0.001**
No	17 (34.7)	3 (6.1)	
Stoma			
No stoma	25 (51.0)	22 (44.9)	0.385
Colostomy	7 (14.3)	4 (8.2)	
Ileostomy	17 (34.7)	23 (46.9)	
Bleeding (ml)	165.41 ± 222.6	94.08 ± 114.2	**0.049**
Operative time in minutes, median, (range)	180 (65–360)	195 (70–330)	0.229

Data are number (percentage), n (%), unless stated otherwise

Bold p values indicate significance

Table 3 Post-operative outcomes

	Artery approach ($N=49$)	Vein approach ($N=49$)	p-value
Dindo Clavien classification			
0	36 (73.5)	34 (69.4)	0.627
I + II + 3A	9 (18.4)	8 (16.3)	
> 3A	4 (8.2)	7 (14.3)	
Re-intervention			
Yes	3 (6.1)	6 (12.2)	0.487
No	46 (93.9)	43 (87.8)	
Anastomotic leakage			
Yes	3 (6.1)	5 (10.2)	0.715
No	46 (93.9)	44 (89.8)	
Length of stay (days) median, (range)	6 (4–27)	7 (4–96)	0.155
Re-hospitalization			
Yes	6 (12.2)	7 (14.3)	0.766
No	43 (87.8)	42 (85.7)	

Data are numbers (percentage), n (%), unless stated otherwise

Bold p values indicate significance

Univariate and multivariate analysis

Explanatory variables assessed in the univariate analysis were evaluated through multivariate analysis. The model indicated that the artery initial approach was an explanatory factor for increased risk during surgery of conversion to open surgery (Table 5).

Discussion

Until now, no study has presented evidence as to which is the best initial surgical approach in sigmoid colon cancer and rectal cancer. Our study randomized patients to two different approaches: starting by the IMV with a complete MM of the SFC and starting by the IMA with a selective LM of the SFC depending on the surgeon's criteria. A high tie of the IMA was performed in all patients.

In a cadaver study, it was shown that the combination of the high tie of the IMV and the IMA achieves greater mobilization of the colon (17.98 ± 6.80 cm), compared to the low tie (2.08 ± 4.39 cm) or to the high tie of the IMA with the mobilization of the SFC (8.20 ± 5.95 cm) [13]. On the other hand, the high tie has been associated with a greater risk of nerve injury and an increase in the risk of vascular commitment of the colon [14, 15].

In our study, the initial approach was not a factor that influenced the number of resected nodes or the length of the surgical specimen. Our surgery has the main objective of performing a mobilization leading to oncologic surgery and anastomosis without tension. Given this, the dissection of the IMV and the complete mobilization of the SFC were performed on all patients treated with low or middle rectum surgery in which the initial approach was the IMA, despite this being selective and based on the surgeon's criteria. This could explain the lack of statistical differences between the two approaches with regards to the length of the surgical piece, surgical margins and anastomosis leakages due to colon tension.

We found favorable results in the IMV group because of a low conversion rate and less bleeding. No differences in operative time, length of stay, anastomosis leakage, complications, re-hospitalizations, and deaths were found.

Our study demonstrated that the initial approach through the IMA is a risk factor for conversion to open surgery (odds ratio 8.68; 95% CI 1.00–75.3, $p=0.05$). The meta-analysis of Clancy et al. reports a conversion rate of 17.9% ± 10.1% and found that males, tumor height, T3/T4 and $N+$ were factors associated with a higher conversion rate. Conversion to open surgery was also associated with high mortality and worst oncologic outcomes in surveillance and recurrence [16]. The implementation of transanal total mesorectal excision (TaTME) could decrease the conversion rate [17, 18].

The only study to compare the three most common techniques of SFC is the retrospective study by Benseler et al., which included 415 patients with the main objective of comparing the lateral, anterior and medial approaches for mobilization of the SFC. All surgeries started with the dissecting and tying of the IMA. It was concluded that the LM led to a higher rate of intra-operative complications (bleeding, $p=0.032$) and conversion ($p=0.001$), without statistical differences in anastomosis leakage [5]. These findings are entirely in keeping with the results of our study.

Brennan et al. reported that the mobilization of the SFC led to an increase in the operative time of 47 min in comparison with those patients in whom the SFC was not mobilized [19]. However, the analysis of the operative time is complex due to it being determined by different factors. Furthermore, the excess of tension in the anastomosis was demonstrated as a risk factor for anastomosis leakage, a fact which is related to worse long-term oncologic outcomes. When the comparison has been made between systematic or selective splenic angle decline, the results were not found to differ: selective angle decline is not related to anastomosis leakage and worse oncologic outcomes [5, 20]. The systematic mobilization of the splenic flexure through laparoscopy, a mandatory step in open surgery, did not increase morbid mortality, although an increase in the operative time was observed [21].

With the popularization of the medial approach of the splenic flexure through the IMV, several articles have appeared warning about the risk of vascular injury and ischemia of the colon through that approach. 11% of the population have an accessory arcade-Moskovitz artery

Table 4 Pathological outcomes

	Artery approach ($N=49$)	Vein approach ($N=49$)	p-value
Tumor size (mm)	2.70 ± 2.62	2.89 ± 1.69	0.683
ypT tumor stage			
T0	15 (30.6)	10 (20.4)	0.426
T1	1 (2.0)	5 (10.2)	
T2	12 (24.5)	14 (28.6)	
T3	20 (40.8)	19 (38.8)	
T4	1 (2.0)	1 (2.0)	
ypN tumor stage			
N0	36 (73.5)	34 (69.4)	0.827
N1	11 (22.4)	11 (22.4)	
N2	2 (4.1)	4 (8.2)	
Circumferential margin			
Non-affected	46 (95.9)	49 (100)	0.495
Affected	2 (4.1)	0 (0)	
Distal margin			
Non-affected	48 (98.0)	47 (95.9)	1.000
Affected	1 (2.1)	2 (4.1)	
Distal margin (cm)	3.96 ± 4.28	3.46 ± 4.24	0.567
Proximal margin (cm)	19.85 ± 11.52	19.46 ± 6.89	0.840
Piece longitude (cm)	26.73 ± 11.2	26.20 ± 6.92	0.776
Resection type			
R0	46 (93.9)	47 (95.9)	1.000
R1	2 (4.1)	2 (4.1)	
R2	1 (2.1)	0 (0)	
Pathological complete response			
Yes	13 (26.5)	11 (22.4)	0.638
No	36 (73.5)	38 (77.6)	
Mesorectum quality			
Complete	29 (59.2)	36 (73.5)	0.353
Partial	8 (16.3)	3 (6.1)	
Incomplete	3 (6.1)	3 (6.1)	
Unreported (sigmoid)	9 (18.4)	7 (14.3)	
Lymph nodes retrieval	21.67 ± 7.03	23.33 ± 12.02	0.408
Affected lymph nodes	0.92 ± 3.22	0.73 ± 1.69	0.725

Data are numbers (percentage), n (%), unless stated otherwise

Bold p values indicate significance

and this subgroup of patients presents a high risk for this approach [22]. However, the risk is not only associated to the medial approach through the IMV but also to the tie of the IMV independently of the tie order. This procedure is usually essential in rectal cancer surgery [23]. Proper training and experience decreases the risk of the IMV approach that includes dissection posterior to pancreas, especially in obese patients.

Applicability

The initial approach by the IMV allows a complete and MMof the SFC at the beginning of surgery. This permits the surgery to be divided into a first cranial or superior period (Treitz, pancreas, IMV, SFC) and a second caudal or lower period (IMA and pelvis). This is especially useful in emerging techniques such as robotic surgery in CRC and the TaTME approach with two simultaneous teams. These techniques do not allow the patient to be mobilized easily and the procedures need to be as standardized as possible. This is the first study available evaluating this increasingly popular strategy.

Table 5 Multivariate analysis of risk factor for conversion to open surgery

	Conversion		Univariate analysis		Multivariate analysis	
	No	Yes	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
	n = 89	*n* = 9				
Initial approach						
Vein	48 (53.9%)	1 (11.1%)	1	**0.039**	1	**0.050**
Artery	41 (46.1%)	8 (88.9%)	9.36 (1.12–78.0)		8.68 (1.00–75.3)	
Sex						
Male	63 (70.8%)	7 (77.8%)	1	0.660	1	0.513
Female	26 (29.2%)	2 (22.2%)	0.69 (0.13–3.55)		0.55 (0.09–3.23)	
BMI (kg/m^2)						
< 30	66 (74.2%)	8 (88.9%)	1	0.346	1	0.411
> 30	23 (25.8%)	1 (11.1%)	0.35 (0.04–3.02)		0.39 (0.04–3.6)	
Neoadjuvant treatment						
No	26 (29.2%)	5 (55.6%)	1	0.119		
Yes	63 (70.8%)	4 (44.4%)	3.02 (0.75–12.18)			
Tumor height (cm)						
> 15	74 (83.1%)	6 (66.7%)	1	0.236		
< 15	15 (16.9%)	3 (33.3%)	0.40 (0.09–1.80)			
T3 or T4 stage						
No	16 (18.0%)	4 (44.4%)	1	0.074	1	0.070
Yes	73 (82.0%)	5 (55.6%)	0.27 (0.06–1.13)		0.24 (0.05–1.12)	
Surgery technique						
Sigmoidectomy	13 (14.6%)	3 (33.3%)	1			
High anterior resection	36 (40.4%)	2 (22.2%)	0.24 (0.03–1.60)	0.141		
Low anterior resection	32 (36.0%)	2 (22.2%)	0.27 (0.04–1.81)	0.178		
Miles	5 (5.6%)	1 (11.1%)	0.86 (0.07–10.42)	0.910		
Hartmann	3 (3.4%)	1 (11.1%)	1.44 (0.10–19.21)	0.781		

Data are number (percentage), *n* (%), unless stated otherwise

BMI body mass index, *CI* confidence interval, *OR* odds ratio

Bold *p* values indicate significance

Limitations

The two main limitations of our study were the sample size and the fact that it has been performed in one single hospital. Furthermore, the sample of patients is highly complex (79% ASA III–IV, 80% T3–T4, 68% neoadjuvant treatment), although this makes it easier to extrapolate findings to normal clinical practice.

Conclusion

In our study, the initial approach by IMV with a systematic MM of the SFC has allowed us to reduce the conversion rate without increasing complications or surgical time. No differences were observed in the pathological results.

The two different approaches seem to be safe and effective and well trained laparoscopic surgeons should have the ability to perform both techniques as needed.

Author Contributions PPG: study concept, execution, data interpretation and manuscript writing, HSR and ACC: design, analysis and final manuscript review, RFC: execution, analysis and final manuscript review, NGR, DJB, JGG, MPdP and FM: execution and analysis and LCF: design, analysis and drafting of manuscript.

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Compliance with ethical standards

Disclosures Pere Planellas Giné, Helena Salvador Rosés, Ramon Farrés Coll, Núria Gómez Romeu, David Julià Bergkvist, Júlia Gil Garcia, Marcel Pujadas de Palol, Franco Marinello, Lídia Cornejo Fernández and Antoni Codina Cazador have no conflicts of interest or financial ties to disclose.

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