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original article

Operative start time may impact the quality of mesorectal excision in minimally invasive rectal surgery: retrospective analysis of 137 patients

A. VALVERDE[1], I. AKKARI[2], A. SEZEUR[1,3], N. GOASGUEN[1], J. CAHAIS[1], O. OBERLIN[1], J.F. FLEJOU[3,4], R.M. LUPINACCI[1]

SUMMARY: **Operative start time may impact the quality of mesorectal excision in minimally invasive rectal surgery: retrospective analysis of 137 patient .**

A. VALVERDE, I. AKKARI, A. SEZEUR, N. GOASGUEN, J. CAHAIS, O. OBERLIN, J.F. FLEJOU, R.M. LUPINACCI

Introduction. *Timing of major elective operations is a potentially important outcome variable. This study examined the impact of operative start time (OST) on pathologic and short-term outcomes of minimally invasive rectal surgery (MIRS).*

Methods. *All rectal tumors patients who underwent MIRS from May 2012 to April 2016 were identified. Peroperative outcomes and the oncological quality of surgical excision were compared between patients with OST before 13.00h and after.*

Results. *A total of 137 patients were included in the study (71 robot-assisted and 66 conventional laparoscopic). Ninety-nine (72%) patients were operated before 13.00h and 38 after 13.00h. The majority of cases were low/middle rectal tumors (69%). Patient's baseline characteristics were quite similar in both groups. The rate of severe complication (p=0.460) or reoperation (p=0.614) was the same. Pathologic criteria (T or N stage, number of harvested lymph nodes, and presence of any positive margin) were the same between groups except for the quality of mesorectal excision (ME) that was significantly poorer for cases beginning after 13.00h (complete 91% vs 74%; p=0.016). The OST was found to be the only parameter associated with a poor quality of ME [OR 2.55 (1.08 – 6.36)].*

Conclusion. *Perioperative outcome after MIRS does not appear to be influenced by OST. Poorer quality of ME was observed and may thus raise important questions about the timing and sequence of case scheduling.*

KEY WORDS: Rectal cancer - Minimally invasive surgical procedures - Outcome study - Organisation and administration - Surgery.

Introduction

Laparoscopic colorectal surgery is considered to be as safe and effective as open surgery and is consistently associated to better early postoperative outcomes (1, 2). Mesorectal excision (ME) has long been established as the standard surgical technique. Total ME (TME) refers to complete excision of the mesorectum down to the pelvic floor and is indicated for carcinoma of the middle and lower third of the rectum, whereas partial ME (PME) is sufficient for treatment of carcinomas of the upper third of the rectum (3). Of utmost importance, dissection within the anatomic planes leads to excision of an intact mesorectum which is important for reducing local recurrence and improving survival (4).

Minimally invasive rectal resection (MIRS) is a challenging procedure associated to a steep learning curve (5). As any long and difficult procedure, it is strenuous both physically and mentally. When these procedures begin late in the day, the influence of surgeon fatigue on the success of these procedures is possibly increased.

[1] Groupe Hospitalier Diaconesses, Croix Saint-Simon, Service de Chirurgie Digestive, Paris, France
[2] Fondation Ophtalmologique Adolphe de Rothschild, Service de Recherche Clinique, Paris, France
[3] Sorbonne Université, Université Pierre et Marie Curie, Paris, France
[4] Service d'Anatomie et Cytologie Pathologiques, Hôpital Saint-Antoine, Assistance Publique Hôpitaux de Paris, Paris, France

Corresponding authors: Renato Micelli Lupinacci,
e-mail: rlupinacci@hopital-dcss.org
Alain Valverde, e-mail: avalverde@hopital-dcss.org

Several studies have explored the potential negative influence of both surgeon fatigue (6, 7) and late operative start time (OST) (8-10) on complications and survival in patients undergoing complex surgical procedures, but few were focused in the oncologic quality of the procedure (9, 11). The objective of this study was to specific analyzing the impact of OST on perioperative outcomes and oncologic quality of resection in a single-institution analysis of consecutive patients undergoing MIRS.

Patients and methods

Patients and data collection

First, approval was obtained from the hospital's institutional review board. Patients who underwent MIRS for cancer were identified from surgical databases between May 2012 and April 2016. Data collected included demographic, clinical and pathological data. The study population was analyzed by age, gender, tumor size, body mass index (BMI), American Society of Anesthesiologists (ASA) physical status score, procedure performed (TME or PME), pathological margin status, ME quality (graded by the pathologist) (4), duration of operation, estimated blood loss (EBL), and postoperative length of stay (LoS). Patients were assessed for complications at 30 days postoperatively. Complications were classified by the Clavien-Dindo method (12).

Patients with concurrent or previous invasive pelvic malignant tumors within 5 years before surgery were excluded. Neoadjuvant treatment included preoperative chemoradiotherapy, short-course radiotherapy, or chemotherapy and was planned after multidisciplinary staff discussion.

In 2012 all minimally invasive procedures were laparoscopy. Since January 2013 we started progressively (AV and NG in 2013; OO in 2014; and RML in 2015) to perform all rectal resections using the robotic platform.

Surgical timing

OST was analyzed as a categorical variable (before and after 13.00h). We elected before 13.00h and after 13.00h because in our institution it usually the moment when surgeons transit from day-surgery cases (performed at the beginning of the scheduled program in order to allow patients to leave the hospital before 19.00h) to first major case and allows for comparison of fatigue, focus and mental concentration.

Statistical analysis

Continuous variables were expressed as means with their standard deviation (SD) or medians with Interquartile Range (IQR). Normally distributed variables were analyzed using the Student t test while non-parametric variables were analyzed using the Wilcoxon test. Categorical variables were expressed as percentages. The association between categorical variables was analyzed using Pearson's Chi-square test or Fisher's exact test. All variables with probability values <0.05 were considered to be statistically significant. The Wald test was used to test the association between the independent variables (predictors) and the quality of ME. All statistical analyses were performed using R software (Free Software Foundation, University of Paris-Jussieu).

Results

One hundred and thirty seven patients were included for this study (71 robot-assisted and 66 conventional laparoscopic). Ninety-nine (72%) patients were operated before 13.00h whereas 38 (28%) after 13.00h. Complete description of clinicopathological and operative characteristics are outlined in Table 1. The majority of cases were low/middle rectal tumors (69%) and TME was performed for 98 patients. Patient's baseline characteristics were mostly similar in all groups. Differences were observed for neoadjuvant treatment (57 *vs* 30% before and after 13.00h, respectively; p=0.006), type of ME (more PME performed after 13.00h; p=0.046), and operative time (shorter after 13.00h; p=0.004). The use of diverting ileostomy was considerably similar (77 *vs* 66%; p=0.22).

The median LoS was slightly shorter for cases beginning after 13.00h (10 *vs* 8 days; p=0.014). Postoperative complications occurred in 44% of patients. Table 2 summarizes surgical outcomes stratified by operative start time. Overall postoperative complications were more frequently observed in the

TABLE 1 - CLINICOPATHOLOGICAL AND OPERATIVE CHARACTERISTICS STRATIFIED BY OPERATIVE START TIME.

Characteristic	**Total**	**Before 13h00**	**After 13h00**	***P*-value**
Age, years, median (IQR)	65 [58-74]	65 [58-73]	65 [56-75]	0.754
Sex, n (%)				0.094
Female	48	30	18	
Male	89 (65%)	69 (70%)	20 (53%)	
Body mass index, Kg/m^2, median (IQR)	24 [21-28]	24 [21-27]	25 [22-29]	0.212
Obesity[a], n (%)	20 (15%)	12 (12%)	8 (21%)	0.291
ASA physical status, n (%)				0.628
Class 1 or 2	110	81	29	
Class 3 or 4	27 (20%)	18 (18%)	9 (24%)	
Prior surgical intervention, n (%)	59 (44%)	42 (43%)	17 (45%)	0.996
Neoadjuvant treatment, n (%)	67 (49%)	56 (57%)	11 (30%)	**0.006**
Location of tumor in rectum[b], n (%)				0.060
low/middle	94 (69%)	73 (73%)	21 (55%)	
high	43	26	17	
Greatest diameter of tumor, cm, median (IQR)	3 [2-4.5]	3 [2-4.8]	3 [2.5-4.5]	0.891
Mesorectal excision, n (%)				**0.046**
total	98 (73%)	76 (78%)	22 (60%)	
partial	36	21	15	
Drainage, n (%)	125 (91%)	90 (91%)	35 (92%)	1
Temporary defunctioning stoma, n (%)	102 (74%)	77 (77%)	25 (66%)	0.222
Operative time, min, median (IQR)	220 [180-255]	230 [180-262]	190 [160-230]	**0.004**

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared ; ASA, American society o anesthesiologists; [a] Obesity defined as BMI >30; [b] High defined as 10-15 cm from the anal verge; middle, 5-10 cm; and low, less than 5 cm.

TABLE 2 - SURGICAL OUTCOMES STRATIFIED BY OPERATIVE START TIME.

Characteristic	**Total**	**Before 13h00**	**After 13h00**	***P*-value**
Conversion, n (%)	16 (12%)	11 (11%)	5 (13%)	0.770
Estimated blood loss, ml, median (IQR)	50 [50-150]	60 [50-150]	50 [20-100]	0.102
Length of stay, days, median (IQR)	9 [7-14]	10 [7-15]	8 [6-10]	**0.014**
Highest grade complications, n (%)				
No complications	76 (55%)	48 (48%)	28 (74%)	**0.014**
Grade 1-2	36 (26%)	31 (31%)	5 (13%)	
Grade ≥3	25 (18%)	20 (20%)	5 (13%)	0.460
Reoperation, n (%)	23 (17%)	18 (18%)	5 (14%)	0.614

TABLE 3 - PATHOLOGICAL CHARACTERISTICS RELATED TO ONCOLOGIC OUTCOMES STRATIFIED BY OPERATIVE START TIME.

Characteristic	Total	Before 13h00	After 13h00	*P*-value
Quality of mesorectal excision*, n (%)				***0.016***
complete	114 (88%)	88 (91%)	26 (74%)	
near complete	15	8	7	
incomplete	2	0	2	
CRM[a] (≤ 1 mm)	14 (10%)	10 (10%)	4 (11%)	1
Distal margin (<1 mm)	3 (2%)	2 (2%)	1 (3%)	1
T stage				1
T0-2	62	35	17	
T3-4	73 (54%)	53 (54%)	20 (54%)	
Harvested lymph nodes, median (IQR)	15 [5-21]	14 [12-21]	16 [12-24]	0.345
Nodal status (N+)	41 (31%)	30 (31%)	11 (31%)	1
Any positive margin	6 (4%)	4 (4%)	2 (5%)	0.666

* Quality of mesorectal excision defined as complete; [a] CRM, circonferential resection margin

period before 13.00h (52 *vs* 26%; p=0.014) but it was no longer observed for severe complication (20 *vs* 13%; p=0.460) nor reoperation (18 *vs* 14%; p=0.614).

Pathological characteristics related to oncologic quality of the rectal excision stratified by OST are summarized in Table 3. Quality of ME specimen was significantly poorer for cases beginning after 13.00h (complete 91 *vs* 74%; p=0.016). We searched for predictors of near complete/incomplete ME (Table 4) and found the OST to be the only parameter associated with a poor quality of ME. The Wald test was then used to confirm the true value of this association [OR 2.55 (1.08 – 6.36)].

Discussion

Work hours and workers' schedules, and their impact on quality and safety in the workplace, are major societal concerns. In a study of 7577 German workers, Hänecke et al. suggested an association between work-related errors and both duration of work day and time of day (13). Also, it has been suggested that workers' performances are related not only to hours worked, but also to the circadian cycle (14).

Our study demonstrates that OST had no impact on the rate of severe complications and reoperations in patients who underwent MIRS. Some differences between the two start time subgroups concerning tumor location, neoadjuvant treatment, and the number of PME could influence results and must be highlighted. Concerning the quality of the surgical specimen, all parameters were equivalent except for the quality of the ME, with significantly less frequent complete mesorectum in the group of patients who underwent surgery after 13.00h.

Our study has the limitations associated with all retrospective studies. Also, the single center nature of this analysis potentially limits its generalizability. Nevertheless, it raises important questions about the timing and sequence of case scheduling and may hopefully stimulate an honest assessment from individual surgeons as well as surgical departments. The ambition of the development of outpatient surgery is based on two expectations: one medical, the other economic (15). The goal of the public health all over the world is to improve the rate of outpatient sur-

TABLE 4 - PREDICTORS OF NEAR COMPLETE/INCOMPLETE MESORECTUM.

Characteristic	near complete/incomplete	complete	*P*-value
Age, years, median (IQR)	72 [60-77]	65 [58-72]	**0.196**
Sex, n (%)			0.788
Female	5	39	
Male	12 (71%)	75 (66%)	
Body mass index, Kg/m^2, median (IQR)	24 [21-27]	25 [21-28]	0.831
Obesity[a], n (%)	3 (18%)	17 (15%)	0.724
ASA physical status, n (%)			0.343
Class 1 or 2	12	92	
Class 3 or 4	5 (29%)	22 (19%)	
Prior surgical intervention, n (%)	5 (29%)	49 (43%)	0.306
Neoadjuvant treatment, n (%)	7 (41%)	59 (52%)	0.556
Location of tumor in rectum[b], n (%)			0.584
low/middle	13 (76%)	78 (68%)	
high	4	36	
Greatest diameter of tumor, cm, median (IQR)	2.7 [1.8-4.0]	3.0 [2.0-4.8]	0.360
T stage			0.934
T0-2	4	52	
T3-4	10 (59%)	62 (54%)	
Mesorectal excision, n (%)			1
total	13 (76%)	81 (73%)	
partial	4	30	
Nodal status (N+)	5 (29%)	35 (31%)	1
CRM (≤ 1mm)	2 (12%)	12 (11%)	1
Operative time, min, median (IQR)	240 [177-285]	220 [180-255]	0.432
Conversion, n (%)	3 (18%)	13 (11%)	0.436
Estimated blood loss, ml, median (IQR)	100 [50-250]	50 [50-120]	0.148
Time of the day			**0.016**
before 13h00	8	88	
after 13h00	9 (53%)	26 (23%)	

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; ASA, American society of anesthesiologists; [a] Obesity defined as BMI >30; [b] High defined as 10-15 cm from the anal verge; middle, 5-10 cm; and low, less than 5 cm; [c] the period between 07.00-11.00 was chosen as reference for statistical analysis.

gery considerably. Thereby, surgeons and surgical departments will be compelled to reorganize their work organization.

Conclusion

Operating room scheduling can possibly affect perioperative and/or oncologic outcomes following major gastrointestinal surgery. The results of our single center cohort warrants further evaluation, nevertheless it underscores the need for continued assessment and for efforts to identify and implement practices that ensure the safest possible operation.

Declarations

Ethics approval

Approval to conduct this study was obtained from The Groupe Hospitalier Diaconesses Saint Simon (GHDCSS) Institutional Review Board.

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding Author on reasonable request.

Competing interests

Renato Micelli Lupinacci (RML), Olivier Oberlin (OO), Nicolas Goasguen (NG) and Alain Valverde (AV) have acted as a consultant or advisory roles for Intuitive Surgery. NG and AV have acted as a consultant or advisory roles for Medtronic.

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Authors' contributions

(I) Conception and design: RML, IA, AS, AV; (II) Administrative support: AV; (III) Provision of study materials or patients: RML, AS, NG, JC, OO, JFF, AV; (IV) Collection and assembly of data: RML, IA; (V) Data analysis and interpretation: RML, IA, AS, NG, AV; (VI) Manuscript writing: All Authors; (VII) Final approval of manuscript: All Authors.

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