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ORIGINAL ARTICLE

Impact of the novel powered circular stapler on risk of anastomotic leakage in colorectal anastomosis: a propensity score-matched study

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Abstract

Background Several risk factors for anastomotic leakage (AL) following colorectal surgery have been described. Improvement in devices for performing anastomosis is a modifiable factor that could reduce AL rates. The aim of this study was to assess the impact of technical improvements in the Echelon Circular™ powered stapler (ECPS) on the left-sided colorectal AL rate compared to current manual circular staplers (MCS).

Methods A cohort study was carried out on consecutive patients between January 2017 and February 2020 in whom left-sided stapled colorectal anastomosis above 5 cm from anal verge was performed. The primary end point was the risk of AL depending on the type of circular stapler used. The ECPS cases were matched to MCS cases by propensity score matching to obtain comparable groups of patients.

Results Two hundred seventy-nine patients met the inclusion criteria. A MCS anastomosis was performed in 218 patients and ECPS anastomosis in 61 (21.9%). Overall, AL was observed in 25 (9%) cases. Factors significantly associated with AL were American Society of Anesthesiologists score ($p=0.025$) and type of circular stapler used ($p=0.021$). After adjusting the cases with propensity score matching (119 cases MCS versus 60 ECPS), AL was observed in 14 (11.8%) patients in MCS group and in 1 (1.7%) patient in the ECPS group ($p=0.022$). AL in the MCS group required reoperation in seven cases (5.8%), the remaining seven patients were treated conservatively. The patient in the ECSP group required an urgent Hartmann's procedure

Conclusions The ECPS device could have a positive impact by reducing AL rates in left-sided colorectal anastomosis. Multicenter controlled trials are needed for stronger evidence to change practice.

Keywords Colorectal anastomosis · Anastomotic leak · Echelon circular stapler · Powered circular stapler · Surgical stapler

Introduction

Anastomotic leakage (AL) is the complication that most concerns colorectal surgeons. It leads to prolonged postoperative stay, increased costs, risk of reoperations and a permanent colostomy, together with an increase in morbidity and mortality [1]. Colorectal AL rates are associated with the anatomical location of the anastomosis. The incidence of leaks after left-sided anastomosis ranges from 1 to 23% [2]. Furthermore, it has been shown that AL in colorectal cancer patients affects long-term oncological outcomes increasing the risk of recurrence and decreasing survival [3, 4].

Identifying factors which may affect anastomotic outcomes is important in reducing the incidence and clinical impact of anastomotic complications. The causes are multifactorial. Several patient-related and surgery-related risk factors have been described [5]. An improvement in the technology of anastomotic devices is a modifiable factor and a potential target for risk reduction.

The novel Echelon Circular™ Powered Stapler (ECPS) (Ethicon, Somerville, NJ, USA), introduces design changes that could decrease the rate of technical errors and improve clinical outcomes. The powered stapler decreases the force needed on firing the device, improving stability at the

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anastomotic site. Atraumatic Gripping Surface Technology reduces the compressive forces on tissues, and along with 3D Stapling Technology allows a better compression distribution throughout the anastomosis and a better hemostasis [6].

The objective of the present study was to assess whether these technical improvements of the ECPS have an impact on left-sided colorectal AL rate compared to current manual circular staplers (MCS).

Materials and methods

A cohort study was carried out in patients consecutively included between January 2017 and February 2020, in whom a left-sided circular stapled colorectal anastomosis above 5 cm from the anal verge was performed. A retrospective analysis of a prospectively maintained database was conducted. Patients were divided into two groups depending on which circular stapler was used to perform the anastomosis (ECPS vs MCS), and the AL rate was analysed. The inclusion criteria were patients aged over 18 years who had a colorectal anastomosis after left colectomy, sigmoidectomy or anterior rectal resection, for benign or malignant pathology. Hartmann reversal cases were also included. Exclusion criteria were anastomosis < 5 cm from the anal verge, diverting stoma, preoperative radiotherapy, American Society of Anesthesiologists (ASA) score > IV and transanal total mesorectal excision.

No changes were made during the study period in perioperative care or surgical principles. The splenic flexure was mobilized in all cases. The same group of dedicated colorectal surgeons performed all surgeries. ECPS was introduced in our hospital in June 2019 and used preferentially unless otherwise unavailable. The 30-day AL rate was recorded and cases were diagnosed according to the International Study Group of Rectal Cancer AL definition, as a defect of the intestinal wall at the anastomotic site leading to a communication between the intra- and extraluminal compartments, or as an abscess adjacent to the anastomosis [7]. Computed tomography (CT) scan with rectal contrast was performed in patients with suspected AL in the absence of unquestionable clinical signs of peritonitis, which would indicate urgent surgery. On postoperative day 4, C-reactive protein (CRP) levels were determined in all cases. Those patients with a CRP > 200 mg/L, went on to have a CT scan. The CT findings suggestive of anastomotic failure were: contrast leakage from inside the bowel to the pelvis and/or abdominal cavity, abscess and/or perianastomotic collection associated or not with localized pneumoperitoneum.

The study variables were age, sex, Charlson index, preoperative hemoglobin (Hb), ASA score, body mass index (BMI), type of pathology, surgical technique, open or laparoscopic approach, location of anastomosis, operative time and circular stapler device (ECPS vs MCS). The outcome variables were AL and degree of morbidity according to the Clavien-Dindo classification. The ECPS cases were matched to MCS cases by propensity score matching to obtain comparable groups of patients.

Statistical analysis

Descriptive statistics were provided for all variables. Absolute values and frequencies for qualitative variables were calculated. Quantitative variables normality was assessed with the Shapiro–Wilk test, expressing data as median and range. Subsequently, the possible relationship between the quantitative variables and the objective variables was investigated using parametric or non-parametric tests depending on the variable distribution. The relationship between the qualitative variables was established using the χ^2 test. MCS and ECPS AL risk were presented as odd ratios (OR) with 95% confidence intervals (95% CI).

Propensity score matching was used with the aim of obtaining homogeneous and comparable groups; 1:2 pairing was performed according to the device (ECPS vs MCS). Confounding variables used to compute the propensity score were age, sex, BMI, ASA, Charlson index, preoperative Hb, type of pathology and surgical approach. Logistic regression without substitution as an estimation and nearest-neighbour pairing algorithm was performed. Caliber of 0.2 was used. Relative multivariate imbalance was calculated: 0.197 before matching and 0.167 after matching. Significance was set at $p < 0.05$. The statistical software used was SPSS® v25 (SPSS Inc. Chicago, IL, USA, 2017) and R Core Team (3.2.0) for statistical analyses (R Foundation for Statistical Computing, Vienna, Austria, 2013). Propensity score matching was carried out using the *PsMatching* script of R integrated into SPSS.

Results

Two hundred seventy-nine patients met the inclusion criteria. Baseline clinical and demographic characteristics are outlined in Table 1. A MCS anastomosis was performed in 218 patients and an ECPS anastomosis in 61 (21.9%). Overall, AL was observed in 25 (9%) cases, 18 patients (6.4%) were reoperated on. The remaining seven AL were diagnosed as minor leaks (abscess or perianastomotic collection) and treated conservatively. Factors significantly associated with AL were ASA score ($p = 0.025$) and the type of circular stapler device used ($p = 0.021$). The following variables were not related to AL: age ($p = 0.882$), sex ($p = 0.513$), BMI ($p = 0.757$), preoperative Hb ($p = 0.061$), preoperative albumin ($p = 0.315$), Charlson's index ($p = 0.486$), operating

Table 1 Baseline demographic and outcome characteristics of the overall series

Age (years)[a]	66.5 (60)
Sex: male	178 (64)
BMI[a]	26.62 (29.6)
Preoperative Hg[a]	13.8 (14)
Charlson index[a]	4 (13)
ASA score	
I	9 (3.2)
II	152 (54.7)
III	114 (41)
IV	3 (1.1)
Malignant disease	190 (68.3)
Diagnosis	
Hartmann procedure	53 (19.1)
Rectal prolapse	3 (1.1)
Diverticular disease	27 (9.71)
Sigmoid cancer	81 (29.14)
Left colon cancer	22 (8)
Rectal cancer	92 (33.09)
Laparoscopic approach	179 (64.4)
Conversion to open surgery	12 (6.7)
Surgical technique	
Hartmann's reversal	53 (19.1)
Left colectomy	22 (8)
Sigmoidectomy	111 (39.9)
Anterior rectal resection	92 (33.09)
ECPS	61 (21.9)
Anastomosis level	
Middle rectum (5–10 cm)	143 (51.4)
Upper rectum (10–15 cm)	136 (49.6)
Operative time[a]	160 (371)
Morbidity (Clavien-Dindo)	
None	182 (65.5)
I	20 (7.2)
II	38 (13.7)
IIIa	4 (1.4)
IIIb	17 (6.1)
IVa	7 (2.5)
IVb	7 (2.5)
V	3 (1.1)
Anastomotic leakage	25 (9)
Minor	7 (2.5)
Major	18 (6.4)

Values in parentheses are percentages

BMI body mass index, *Hb* haemoglobin, *ASA* American Society of Anesthesiologists, *ECPS* Echelon circular powered stapler

[a]Median (range)

time ($p=0.136$), laparoscopic approach ($p=0.828$), diagnosis ($p=0.310$) or surgical technique ($p=0.224$). AL was observed in 24 (11.1%) patients in the MCS group and in 1 (1.6%) patient in the ECPS group ($p=0.021$). The anastomosis was performed in the mid rectum (between 5–10 cm from the anal verge) in 144 patients Table 2.

Outcomes after propensity score matching

After adjusting the cases with propensity score matching, two new groups of patients were generated: 119 MCS cases versus 60 ECPS cases (Fig. 1). Both groups were totally comparable after case matching (Table 2). AL was observed in 14 (11.8%) patients in the MCS group and in 1 (1.7%) patient in the ECPS group ($p=0.022$). ALs in the MCS group required reoperation in seven cases (5.8%) and the remaining seven patients with minor leaks were treated conservatively. The MCS group had higher AL risk (OR 1.258, 95% CI 1.132–1.398) than the ECPS group (OR 0.169, 95% CI 0.024–1.166). Postoperative morbidity according to the Clavien-Dindo classification was less frequent in the ECPS group ($p=0.054$).

Discussion

This cohort study showed that the left-sided colorectal AL rate significantly decreased from 11.8% (MSC) to 1.7% (ECPS) ($p=0.021$) when a different circular stapler was used. Cases were diagnosed according to the International Study Group of Rectal Cancer AL definition [7], including patients with abscess or perianastomotic collection that were managed conservatively. Surgery was required in 5.8% of cases of AL in the MCS group and 1.7% in the EPCS group. Circular stapling devices have the advantage of a shorter anastomosis time and greater reproducibility compared with hand-sewn anastomosis with similar safety and efficacy [8]. There is no scientific evidence to support either anastomotic technique [9, 10]. An end-to-end anastomosis was performed in all patients included in the present study.

The circular stapler has evolved over time, and a powered variant was introduced in 2019. The novel ECPS provides some design improvements in circular stapling technology: powered firing, 3D stapler configuration and Gripping Surface Technology. One of the potential problems with manual circular staplers is the force required to perform the anastomosis causing unwanted movements at the anastomotic site that could cause microvascular trauma and therefore compromise anastomotic healing [11]. The powered firing process improves stapling head stability and, along with the ergonomic design of the device, allows the firing to be carried out comfortably regardless of the size or the strength of the surgeon's hand. Gripping Surface Technology provides precise compression only where it is needed, to prepare tissue for staple formation facilitating smoother handling reduction in tissue compression forces.

Table 2 Demographic characteristics and outcomes of the MCS group compared to the EPCS group, pre- and post-Propensity Score Matching

	Pre-Propensity Score Matching			Post-Propensity Score Matching		
	MCS 217 (78.1)	ECPS 61 (21.9)	*p* value	MCS 119 (66.5)	ECPS 60 (33.5)	*p* value
Age (years)[a]	67 (60)	64 (52)	0.607	67 (60)	64 (52)	0.788
Sex:male	140 (64.5)	38 (62.3)	0.764	76 (63.9)	37 (61.7)	0.870
BMI[a]	26.61 (40.89)	26.37 (27.86)	0.792	26.7 (23.89)	26.39 (27.86)	0.849
Preoperative Hb[a]	13.85 (14)	13.4 (6.3)	0.721	13.6 (10.1)	13.62 (6.3)	0.975
Charlson index[a]	4 (13)	4 (10)	0.500	4 (9)	4 (10)	0.951
ASA			0.089			0.078
I	9 (4.1)	0		4 (3.4)	0	
II	116 (53.5)	36 (59)		61 (51.3)	35 (58.3)	
III	91 (41.9)	23 (37.7)		54 (45.4)	23 (38.3)	
IV	1 (0.5)	2 (3.3)		0	2 (3.3)	
Malignant disease	154 (71)	36 (59)	0.087	79 (66.4)	38 (60)	0.413
Laparoscopic approach	138 (63.6)	41 (67.2)	0.652	76 (63.9)	40 (66.7)	0.743
Conversion rate	9 (6.5)	3 (7.3)	1.000	5 (6.6)	3 (7.5)	1.000
Middle rectum anastomosis (5–10 cm)	113 (52.1)	30 (49.2)	0.772	66 (55.5)	30 (50)	0.528
Operative time[a] (min)	158 (360)	165 (222)	0.819	165 (435)	165 (222)	0.681
Morbidity (Clavien-Dindo)			0.091			0.054
None	134 (61.8)	48 (78.7)		73 (61.3)	47 (78.3)	
I	18 (8.3)	2 (3.3)		10 (8.4)	2 (3.3)	
II	31 (14.3)	7 (11.5)		17 (14.3)	7 (11.7)	
IIIa	4 (1.8)	0		4 (3.4)	0	
IIIb	16 (7.4)	1 (1.6)		5 (4.2)	1 (1.7)	
IVa	4 (1.8)	3 (4.9)		1 (0.8)	3 (5)	
IVb	7 (3.2)	0		6 (5)	0	
V	3 (1.4)	0		3 (2.5)	0	
Anastomotic leakage	24 (11.1)	1 (1.6)	0.021	14 (11.8)	1 (1.7)	0.022
Minor	7 (3.2)	0		7 (5.8)	0	
Major	17 (7.8)	1 (1.6)		7 (5.8)	1 (1.7)	

Values in parentheses are percentages

BMI body mass index, *Hb* haemoglobin, *ASA* American Society of Anesthesiologists, *ECPS* Echelon circular powered stapler, *MCS* manual circular stapler

[a]Median (range)

Furthermore, the 3D stapling technology equally distributes the compression throughout the anastomosis. Both technological innovations contribute to promoting optimal conditions for anastomotic healing. In a study by Rojatkar et al., ex vivo testing of the powered stapler was compared to a manual circular stapler, concluding that ECPS required 97% lower force-to-fire, showed 33% lower compressive forces and reduced 37% anastomotic site movement during device firing. Anastomotic pressure testing by insufflating the bowel lumen, showed that ECPS had 61% less leaks at pressures of 30 mmHg or lower than the non-powered circular stapler [6].

Athalah et al. have recently published the first clinical validation series (17 patients) on the use of the ECPS. No device failures were reported, demonstrating its safety and efficacy in the clinical setting. Surgeon perception of anastomotic quality and device ease-of-use was rated to be above average [12]. To our knowledge, this is the first study comparing the clinical results of ECPS and MCS in a consecutive series of patients. Since the introduction of ECPS in our clinical practice, a significant decrease in AL rate was observed. Only one AL was observed in the ECPS group, a 75-year-old male patient, with BMI 35.9 kg/m2, diagnosed with metastatic sigmoid cancer that was managed with a "liver first" strategy. The patient required an urgent Hartmann´s procedure, is currently disease-free and pending restoration of intestinal continuity.

A wide variety of patient-related factors has been suggested to contribute to the development of AL: ASA score > 3, smoking, excessive alcohol consumption, diabetes mellitus, anemia, hypoproteinemia, obesity, age, sex, tumor stage, the use of steroids and neoadjuvant chemoradiotherapy, heart and lung failure, blood transfusion,

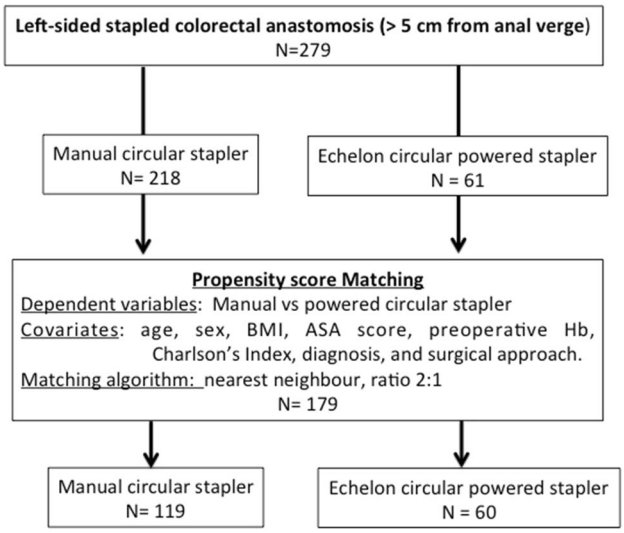

Fig. 1 Flow chart of population selection and matching by propensity score. *BMI* body mass index, *Hb* haemoglobin, *ASA* American Society of Anesthesiologists

the patient's microbiome and many others [2, 13, 14]. In our series, ASA score was the only factor predictive of AL amongst all the patient-related risk factors analysed. Some risk factors are modifiable aspects in the management of colorectal surgery that might reduce the anastomotic complications. Implementing a structural change in clinical practice can significantly reduce the AL rate after colorectal resections [15]. Multimodal prehabilitation programs enhancing nutritional status and functional capacity prior to surgery are being studied. The preoperative period might be the ideal moment for improvements that reduce the risk of postoperative complications [16].

Likewise perioperative care, surgical techniques and technologies have an important role in the incidence of AL. Several operative factors can influence left-sided anastomotic complications: surgical approach, anastomosis technique, anastomotic level, number of linear stapler firings during rectal transection, diverting stoma, intraoperative assessment of the anastomosis (air leak test, endoscopy, indocyanine green angiography (IGA)), intra-abdominal drainage and prophylactic transanal tube decompression [17]. The same perioperative management protocols were maintained during the entire study period. Similarly, the basic surgical principles were not modified and the same group of surgeons performed all the surgical procedures. IGA was not available to check colon and rectal perfusion in our hospital during the study period, so the anastomotic site was selected by the surgeon using typical standard of care assessment. However, intraoperative IGA has been recently introduced into our regular clinical practice. The use of the ECPS to perform the anastomosis was the only modification.

In addition to the clinical consequences suffered by the patients, AL may lead to a 65–81% increase in hospital costs [18]. Patients who had postoperative AL incurred an additional hospital cost of 34.900–54.300€ [19, 20]. The new device is around 35% more expensive than the previous manual version. Nevertheless, if the reduction in AL rate is confirmed, this increase in the cost of the stapler could be compensated by a reduction in hospital expenses.

Finally, we acknowledge the limitations in the present study. We used a retrospective and uncontrolled single-centre design with a small sample size. Patients were operated in different time frames (MCS before and EPCS after June 2019), albeit by the same surgeons with over 10 years experience in colorectal surgery. This leads to inherent bias particularly in the ECPS group, restricting the ability to draw conclusions. Propensity score matching was used to obtain homogeneous and comparable groups and address some of these limitations though other AL related variables may not have been included. This study attempts to assess the impact of the ECPS stapler on the risk of AL as a primary outcome, presents valuable data relevant to clinical practice and possible improvement of outcomes. It is a single-center preliminary experience and the results must be interpreted with caution. To assess the real impact of the novel ECPS on AL rate, we are currently planning a multicenter international controlled trial with the same inclusion and exclusion criteria as the present study (540 patients, randomized on a 1:1 basis to anastomosis performed with ECPS or MCS, alpha 0.05, beta 80%). Participating centres will be high volume accredited colorectal centers with homogeneous perioperative care protocols.

Conclusions

Our initial experience with ECPS shows that it could have a positive impact in reducing AL rates in left-sided colorectal anastomosis. Multicenter controlled trials are needed to obtain stronger evidence and justify a change in clinical practice.

Author contributions VP-M: conception and design, drafting the article and final approval of the manuscript. JM-A: acquisition of data, analysis and interpretation of data, revising critically the content and final approval of the version to be published. DM-V: design, revising the study critically for important content and final approval and final approval of the version to be published. SG-B: design, revising the manuscript critically for important intellectual content and final approval of the version to be published. IM-O: acquisition of data, revising critically the content and final approval of the version to be published. RG-M: acquisition of data, revising critically the content and final approval of the version to be published. CC-L: revising of data, analysis and interpretation and final approval of the manuscript. AE-M: conception and design, revising the manuscript critically for

important intellectual content and final approval of the version to be published.

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Availability of data and material Not applicable.

Compliance with ethical standards

Conflict of interest Pla-Martí V. reports consultancy for Johnson and Johnson and has received honorarium for speaking at symposia by Johnson and Johnson and Medtronic. Moro-Valdezate D. has received honorarium for speaking at symposia by Johnson and Johnson. The rest of the authors declare no conflict of interest.

Ethical approval All procedures performed in the study were conducted according with the ethical standards of the institution and with the 1964 Helsinki declaration and later amendments or comparable ethical standards.

Informed consent All patients signed the institution informed consent for colorectal surgery. No specific consent for this type of study is required.

Code availability Not applicable.

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