ORIGINAL ARTICLE

Application of colon leakage score in the left-sided colorectal surgery

Aplicación de la puntuación de fuga del colon en la cirugía colorrectal del lado izquierdo

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Abstract

Objective: *The study aims to apply the CLS in patients undergoing left-sided colorectal surgery.* **Method:** *Retrospective study in patients with the left-sided colorectal surgery and primary anastomosis without diverting stoma. CLS was calculated in patients, who were classified in AL and NO-AL groups. Predictive value of CLS was evaluated by receiver operator characteristic. Correlation between CLS and AL was determined. 208 patients (55% male, mean age 59 years) were included in the study.* **Results:** *Overall, AL was 7.2%. Mean CLS of all patients was 7.2 ± 3.2 (0-17). Patients with AL had a higher CLS (11.8 ± 2.3) than NO-AL patients (6.8 ± 3) (p = 0.0001). The area under the curve for the prediction of AL by CLS was 0.898 ([CI] 0.829-0.968, p = 0.0001). A CLS of 8.5 had 93% sensitivity and 72% specificity. There was a statistically significant odds ratio for CLS and AL (0.58: [CI] 0.46-0.73, p = 0.0001).* **Conclusions:** *CLS is a useful tool to predict AL in the left-sided colorectal surgery.*

Keywords: *Colorectal surgery. Anastomosis leak. Colon leakage score. Outcomes. Risk prediction.*

Resumen

Objetivo: *Este estudio tiene el objetivo de aplicar el CLS en pacientes con cirugía colorrectal de lado izquierdo.* **Método:** *Estudio retrospectivo en pacientes con cirugía colorrectal izquierda y anastomosis primaria sin estoma de derivación. Se calculó el CLS en los pacientes, los cuales fueron clasificados en los grupos con AL y sin AL.* **Resultados:** *La media del CLS de todos los pacientes fue de 7.2 ± 3.2 (0-17). Los pacientes con AL tenían un CLS más alto (11.8 ± 2.3) que los pacientes sin AL (6.8 ± 3) (p = 0.0001). El área bajo la curva para la predicción de la AL mediante el CLS fue de 0.898 (intervalo de confianza (CI) 0.829-0.968; p = 0.0001). Un CLS de 8.5 tuvo una sensibilidad del 93% y una especificidad del 72%. Además, se obtuvo un Odds Ratio con una diferencia estadísticamente significativa para el CLS y AL (0.58; CI 0.46-0.73; p = 0.0001).* **Conclusiones:** *La CLS es una herramienta útil para predecir la AL en la cirugía colorrectal del lado izquierdo.*

Palabras clave**:** *Cirugía colorrectal. Fuga de anastomosis. Puntuación de fuga de colon. Resultados. Predicción de riesgo.*

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Introduction

Anastomotic leak (AL) is one of the most detrimental complications following colorectal surgery[1]. The incidence rate of AL has been widely reported from 3% to 27% in different series[2-5]. Risk factors for AL have been categorized as preoperative (patient/disease-specific) and intraoperative[6-8]. Significant pre-operative risk factors related to AL are male sex, high American Society of Anesthesiologists (ASA) grades, renal disease, comorbidity, smoking history, obesity, poor nutrition, and radiotherapy. Disease-specific factors may include site, size, metastatic disease, and emergency surgery. Intraoperative factors associated with AL include significant blood loss, surgery duration (> 4 h), adequate blood supply for the remaining bowel, and a tension-free anastomosis[6-8].

Despite all published data on AL risk factors and the general acceptance of these by the surgical community, accurate prediction of AL is still a difficult task[9,10]. Clinical risk assessment for AL by the operating surgeon might have a low predictive value and underestimate leakage rate[11]. In addition, the surgeon has to decide to perform a protective stoma to counteract the problem of AL. Even though a diversion stoma cannot diminish AL incidence, it can reduce the severity of AL-related morbidity[6,12,13]. Despite this, a diverting stoma can cause morbidity, discomfort, and increased health costs which cannot be ignored. Therefore, the decision to create a protective stoma should be judiciously evaluated.

The colon leakage score (CLS), was developed by Dekker in 2011, specifically for the assessment, and risk prediction of AL in the left-sided colorectal surgery[14]. The CLS is composed of 11 weighted patient and operative parameters and was calculated as a numeric score ranging from 0 to 43 (Table 1). A score of 11 of 43 was associated with a 3% risk of AL, which was the authors´ cutoff for a low- *versus* high-risk anastomosis[14]. Few studies have validated the efficacy of the CLS[15-18], thus, the clinical use of the CLS has been limited. This present study aims to apply the CLS in patients undergoing left-sided colorectal surgery to evaluate the use of the CLS for predicting AL in a third-level reference social security hospital in Mexico.

Material and methods

Study design and participants

A single-center retrospective study was designed and conducted, previous IRB approval (R-2020-3001-079), in patients who underwent left-sided colorectal surgery with primary anastomosis and no diverting stoma from January 2017 to July 2020. Left-sided colorectal surgery was defined if the patient underwent left colectomy, sigmoid resection, or rectal resection, and they were considered as a single group. Exclusion criteria were: recurrent disease (cancer), abdominoperineal resection, patients with sepsis caused by ITU that could have been counted as an AL, and incomplete data.

Patient data and outcome parameters

The CLS was calculated from data obtained from the medical record of each patient. AL was defined as a leak of luminal contents from a surgical join between 2 hollow viscera diagnosed by any of the following when clinical signs and symptoms (fever, pain, and sepsis) were present: Radiologically (radiographic enema or computed tomography with presence of leakage or collection adjacent to the anastomosis); clinically (evidence of bowel content or gas through a drain or wound); and intraoperatively in a second surgery. AL was classified as grade A: (no intervention), grade B: (active radiological intervention without surgical intervention), and grade C: (surgical reintervention) (7). Patients were classified into two groups: AL (patients who developed AL) and NO-AL (patients who did not develop AL).

Statistical analysis

Groups (AL and NO-AL) were compared using Student's t-test (continuous variables) and using Chi-square and Fisher's exact (categorical variables). The predictive value of CLS was evaluated by receiver operator characteristic (ROC) curve. The predicting ability of the ROC curve was determined by the area under the curve (AUC). The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the CLS were also evaluated by ROC to calculate the statistical optimal cutoff value. An AUC of 0.5-0.7 indicates a lower predictive value, 0.7-0.9 indicates moderate predictive value and 0.9 indicates a high predictive value. Binary logistic regression analysis was performed to determine the correlation between CLS and AL with Hosmer-Lemeshow goodness of fit. $p < 0.05$ was considered statistically significant. Statistical analysis was performed using IBM SPSS version 25.0.

Results

A total of 248 patients who underwent left-sided colorectal surgery were identified. Forty patients were

Table 1. Colon leakage score system

Item	Score
Age	
< 60	0
60-69	1
70-79	2
≥ 80	4
Gender	
Female	0
Male	1
American Society of Anesthesiologists	
I	0
II	1
III	3
IV	6
Body Mass Index	
19-24	0
25-30	1
> 30 / < 19 or weight loss (> 5 kg/6 mo)	3
Intoxication	
None	0
Smoking	1
Alcohol (> 3 units/d)	1
Steroids (present use excluding inhalers)	4
Neoadjuvant therapy	0
None	1
Radiotherapy	2
Chemoradiation	
Emergency surgery	
None	0
Bleeding	2
Obstruction	3
Perforation	4
Distance between anastomosis and anal verge (cm)	
> 10	0
05-10 cm	3
< 5	6
Additional Procedures	
No	0
Yes	1
Blood loss (mL) and blood transfusion	
< 500	0
500-1000	1
1001-2000	3
> 2000	6
Duration of operation (h: min)	
< 2:00	0
2:00-2:59	1
3:00-3:59	2
≥ 4:00	4

excluded from the study (10 recurrent disease, 10 abdominoperineal resection, and 10 incomplete data) leaving 208 patients (138 colons and 70 rectums) who were identified and included in the study. Baseline patient characteristics, treatment, and outcomes are shown in table 2. The mean age of all patients was 59.02 ± 14.1 years with male predominance (55%). ASA II was the most common (53.8%) pre-operative anesthetic classification. Eighty patients (38.5%) had either tobacco or alcohol intake history and 42 (20.2%) had both (alcohol and tobacco) intake history. In terms of neoadjuvant therapy, 20.2% (n = 42) patients received radiotherapy, 8.2% (n = 17) chemotherapy and 9 patients (4.3%) received radiotherapy and chemotherapy. Only one patient (0.5%) underwent emergency surgery (obstruction). Most of the anastomosis (67.3%) were 10 cm above the anal verge, and the majority of the anastomosis were stapled (88%). Eighty-seven percent (n = 182) of the surgery were performed under 3 h.

The overall AL was 7.2% (n = 15) with 86.7% (n = 5) being grade C, 6.7% (n = 1) grade B, and 6.7% (n = 1) grade A. AL patients were older (68 years) than NO-AL patients (58.3 years) and had higher ASA grades (III and IV), and these differences were statistically significant (Table 2). No other statistically significant differences in any patient characteristics were noted between AL and NO-AL patients.

The Mean CLS of all patients was 7.2 ± 3.2 (0-17). Patients with AL had a statistically significantly higher CLS (11.8 ± 2.3) than NO-AL patients (6.8 ± 3) (p = 0.0001 by Student´s t-test). CLS values and AL data for all patients are shown in figure 1. The AUC (ROC analysis) for the prediction of AL by CLS was 0.898 (95% Confidence Interval [CI] 0.829-0.968, p = 0.0001). A CLS of 8.5 had a 93.3% sensitivity and 72% specificity. The PPV of the CLS was 20.5% (95% CI: 16.6-25.2%) and the NPV of the CLS was 99.2% (95% CI: 95.4-99.8%). A CLS of 11 (original cutoff) had a 53% sensitivity and 93% specificity. Binary logistic regression showed that the odds ratio for AL prediction by the CLS was 0.58 (CI: 0.46-0.73) (p = 0.0001). The Hosmer-Lemeshow goodness of fit for the regression analysis was 2.54 (Chi-square) (p = 0.9).

Discussion

Herein, we demonstrate that the CLS has a good discrimination capability in predicting AL in the left-sided colorectal surgery, where a CLS of 8.5 had 93% sensitivity and 72% specificity. A CLS of 8.5 had 99.2% NPV for AL appearance. Moreover, there was also a well-adjusted statistically significant odds ratio for CLS and AL.

Table 2. Patient, treatment, characteristics, and outcome

Item	Value (n = 208)	AL (n = 15)	NO-AL (n = 193)	p-value
Age (years) (mean ± SD)	59.02 ± 14.1	68 ± 11.9	58.3 ± 14.1	0.01*
Gender				
Female (n), %	(92) 44.2	(6) 40	(86) 44.6	0.7
Male (n), %	(116) 55.8	(9) 60	(107) 55.4	
ASA (n), %				
ASA I	(39) 18.8	(0) 0	(39) 20.2	0.0001†
ASA II	(112) 53.8	(5) 33.3	(107) 55.4	
ASA III	(51) 24.5	(6) 40	(45) 23.2	
ASA IV	(6) 2.9	(4) 26.7	(2) 1.2	
BMI (kg/m^2) (mean ± SD)	25.6 ± 4.05	27.2 ± 6.7	25.4 ± 3.7	0.3
Intoxication (n), %				
No	(86) 41.3	(3) 20	(83) 43	0.08
Yes	(122) 58.7	(12) 80	(110) 57	
Anatomic Site (n), %				
Colon	(138) 66.3	(9) 60	(129) 66.8	0.5
Rectum	(70) 33.7	(6) 40	(64) 33.2	
Etiology (n), %				
Cancer	(172) 82.7	(12) 80	(160) 82.9	0.7
Benign	(36) 17.3	(3) 20	(33) 17.1	
Neoadjuvant therapy (n), %				
No	(140) 67.3	(8) 53.3	(132) 68.4	0.2
Yes	(68) 32.7	(7) 46.7	(61) 31.6	
Emergency Surgery (n), %				
No	(207) 99.5	(14) 93.3	(193) 100	0.07‡
Yes	(1) 0.5	(1) 6.7	(0) 0	
Distance of anastomosis				
to anal verge (cm) (n), %				
> 10 cm	(140) 67.3	(9) 60	(131) 67.9	0.4
5-10 cm	(58) 27.9	(6) 40	(52) 26.9	
< 5 cm	(10) 4.8	(0) 0	(10) 5.2	
Additional procedures (n), %				
No	(180) 86.5	(12) 80	(168) 87	0.4
Yes	(28) 13.5	(3) 20	(25) 13	
Anastomosis type (n), %				
Hand-sewn	(25) 12	(3) 20	(22) 11.4	0.3
Stapled	(188) 88	(12) 80	(171) 88.6	
Blood loss (cc) (n), %				
< 500 cc	(185) 88.9	(11) 73.3	(174) 90.2	0.06‡
500-1000 cc	(23) 11.1	(4) 26.7	(19) 9.8	
Duration of operation (h: Min) (n), %				
< 2:00	(95) 45.7	(8) 53.3	(87) 45.1	
2:00-2:59	(87) 41.8	(5) 33.3	(82) 42.5	
3:00-3:59	(24) 11.5	(1) 6.7	(23) 11.9	
≥ 4:00	(2) 1	(1) 6.7	(1) 0.5	0.09
Colon Leakage Score (mean ± SD)	7.2 ± 3.2	11.8 ± 2.3	6.8 ± 3.03	0.0001*

*Statistically significant by student t test.
†Statistically significant by Chi-square.
‡Fisher's exact.
AL: anastomotic leak; ASA: American Society of Anesthesiologists; BMI: body mass index.

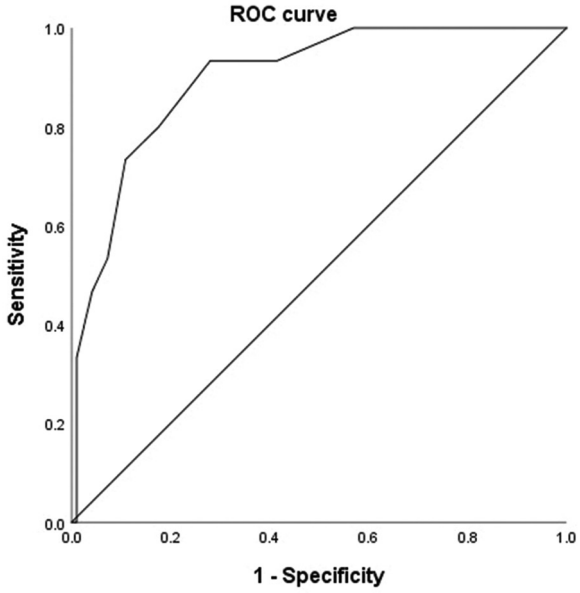

Figure 1. *Receiver operator characteristic curve for colon leakage score.*

The CLS comprises 11 variables with different weighted points. According to the score; higher ASA classification, high blood loss, and shorter anastomosis distance to the anal verge confer the most points per variable (from 0 to 6). In this sense, Dekker et al.[14] reported statistically significant differences of mean CLS and AUC when AL and NO-AL groups were compared, and an odds ratio of 1.74 (95% CI = 1.32-2.28). An in-depth examination of the results of our study reveals that the significant differences and subsequent points are given by the variables were the ASA classification and blood loss (variables with high score points) followed by age. We also had a significant difference in AL CLS versus NO-AL CLS (12 vs. 7 points) and a good AUC (close to 0.9) which was slightly lower than the results obtained in the original publication.

The purpose of a score is patient stratification. In particular, CLS might help the surgeon to define a low versus a high-risk colorectal anastomosis. This decision is critical regarding whether to perform a diverting stoma. Even though diversion stoma can reduce the severity of AL-related morbidity[6,12,13], it has been associated with perioperative mortality and longer hospitalization of patients[1,2]. Surgeons' clinical risk assessment for AL appeared to have a low predictive value in gastrointestinal surgery (< 60% both sensitivity and specificity)[11]. Therefore, it is necessary to identify an objective and accurate system that can be easily used to determine when to perform a diverting stoma. One interesting feature of the ROC analysis is the ability to choose a cutoff point, depending on the emphasis on sensitivity and specificity. The majority of the studies of CLS validation[5,14,17] have determined a cutoff value of 11 in the CLS. In this study, this cutoff (11 points) had very good specificity (> 95%) but poor sensitivity (around 50%). Our study evidences a lower cutoff value (8.5), with better sensitivity and specificity than 11 points, which might be useful to minimize the risk of AL. In addition, when regression analysis is performed, it is possible to determine risks, such as AL in this setting. Here, the odds ratio of 0.58/CLS value was statistically significant. Interestingly, the regression model had goodness of fit by Hosmer-Lemeshow test as well.

As previously stated, few studies have validated the CLS[15-18]. These studies are detailed in table 3. Several aspects should be considered when examining all these results. First; all the studies included only colorectal cancer patients but this study and Dekker's CLS study. In this study, 82% of our patients underwent surgery for cancer; thus, we decided to include patients with a benign etiology of the disease to broaden the predicting capability of the score similarly to Dekker et al.[14]. In addition; there was not enough information in the studies about patients who underwent a non-diverting stoma in addition to the colorectal surgery. It was our belief that not including patients with a non-diverting stoma, created a more homogenous study population. Another aspect is that the AL rates in all the studies (including the present one) were acceptable (< 10%), which might also work as a surrogate marker for good study outcomes. Differences in scores between AL and NO-AL patients were similar (5-6 points between studies)[15-17]. Finally, it is important to notice that the results of our study had a lower cutoff value (8.5) with one of the highest sensitivity and specificity of all studies, with a good predicting capability (AUC).

Early detection of leakage at the anastomotic site helps in the early detection, treatment, and prevention of post-operative complications, sepsis, and mortality. There are different strategies for identifying AL using different markers, including C-reactive protein (CRP), white cell count (WCC), and procalcitonin (PCT)[19-21]. CRP is being studied as a specific early protein marker for postoperative complications. Acute phase reactants are produced by hepatocytes in response to inflammatory cytokines[20]. The tendency for CRP usually increases 48 h after surgery. A steady trend showing

Table 3. Studies validating the colon leakage score

Author (year) Ref	(n)	Inclusion criteria	AL rate (%)	Mean CLS		AUC (95% CI)	Sensitivity (%)	Specificity (%)	Cut-off value
				AL	NO-AL				
Dekker et al. 2011[14]	121	Left-sided colorectal surgery	8.3	15.7	7.6°	0.95 (0.89-1.000)	n/d	n/d	11
Yu et al. 2016[15]	304	Left-sided colorectal cancer	6.9	13.8	7.75°	0.96 (091-1.00)	84.6	87.2	11
Sammour et al. 2017[16]	626	Binational Colorectal Cancer Audit database	7.2	13	8	0.8 (0.61-0.98)	n/d	n/d	n/d
Muñoz et al. 2018[17]	180	Left-sided colorectal cancer	6.6	11.5	6.9°	0.82 (0.69-0.96)	67	89	11
Yang, et al; 2019[18]	566	Left-sided colorectal cancer	4.1	12.5	9.6°	0.7 (0.61-0.78)	91.3	43.3	8.5
Present study, 2021	208	Left-sided colorectal surgery	7.2	11.8	6.8°	0.89 (0.82-0.96)	93.3	72	8.5

AL: anastomotic leak, AUC: area under curve, CLS: colon leakage score, n/d: not disclose, Ref: reference.

increased inflammatory markers, such as CRP, WCC, and PCT would suggest looking out for an AL with the clinical features[19-21]. Their levels between post-operative days 3 and 7 are carefully taken into consideration as they could be the predictor of the leak[21]. The post-operative trajectories of these inflammatory markers are very useful tools to predict AL after colorectal surgery[21]. Nevertheless; despite the usefulness of these inflammatory markers, they are postoperatively determined, as opposed to the CLS items, in which most of them are pre-operative registered and the rest of them are measured during surgery.

This study has limitations that we have to acknowledge: First, the study is a retrospective single-center with a moderate sample size for prediction, and patients were operated on by different surgical departments (colorectal surgery and surgical oncology) which might bias the procedure. In addition, due to the retrospective nature of the study, there is always the possibility that the AL rate may be underestimated (localized abscesses in a computed tomography caused by a small leak may not be counted as AL). This underestimation might have created a confusing AL low prevalence, which might have influenced the low PPV (20%). However, the NPV was superior to 99%, which means that a low CLS had a very good probability of AL absence. Although the studies on CLS have been retrospective, they have confirmed that CLS is a tool to accurately identify patients at risk for AL preoperatively, assisting surgeons in the surgical procedure through a simple score calculation from 0 to 43. Thus, optimizing this score with an adaptation of standard operating procedures could change pre-operative decision-making regarding preventive measures for a favorable postoperative outcome. Finally, a prospective comparison study between pre-operative leakage scores and post-operative inflammatory markers (CRP and PCT) could enhance AL prediction and subsequent management.

Conclusion

CLS is a useful tool to predict AL in the left-sided colorectal surgery. Further larger prospective multicenter series will continue to validate this score in our institution and other hospitals.

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Conflicts of interest

The authors declare no conflicts of interest and have no relationships relevant to the contents of this paper to disclose.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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