SIMPLIFIED PREDICTIVE MODEL FOR ANASTOMOTIC LEAKAGE AFTER COLORECTAL CANCER SURGERY: A PILOT RETROSPECTIVE STUDY

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Declarations

Ethics approval and consent to participate: The study was approved by the institutional ethics committee of Policlinico Riuniti (DDG no. 363, 25/10/2016, as amended by DDG no. 318, 14/06/2019). All research procedures were conducted in accordance with relevant guidelines and regulations. Written informed consent was obtained from all participants.

Patient consent statement: All patients included in the study provided written informed consent.

Availability of data and materials: The datasets generated and/or analysed during the current study are available from the corresponding author upon reasonable request, in accordance with institutional and ethical regulations.

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Abstract

Background

Anastomotic leakage (AL) is one of the most severe complications after colorectal cancer surgery and is associated with increased morbidity, mortality, and length of hospital stay. This pilot study aimed to develop a simplified early postoperative model for AL risk stratification using readily available clinical and laboratory variables.

Methods

This retrospective single-centre cohort included 117 patients who underwent colorectal cancer resection with primary anastomosis between January 2024 and December 2025. Patients with protective stomas or incomplete data were excluded. Demographic, clinical, surgical, and first-postoperative-day laboratory variables were analysed. Multivariable logistic regression was used to evaluate factors associated with AL and to assess model performance.

Results

Nine patients (7.7%) developed AL requiring surgical reintervention. In the multivariable model, postoperative international normalized ratio (INR) showed the strongest association with AL (OR 6.40; 95% CI 0.96-42.57; $p = 0.055$), although statistical significance was not reached. The model showed acceptable discrimination for an exploratory pilot model (AUC-ROC 0.71), with balanced sensitivity and specificity.

Conclusions

This simplified pilot model suggests that early postoperative variables, particularly INR, may contribute to AL risk stratification after colorectal cancer surgery. Larger prospective studies with external validation are required before clinical implementation.

Keywords: colorectal surgery; anastomotic leakage; colorectal cancer; logistic regression; predictive model; minimally invasive surgery

Background

Anastomotic leakage (AL) is defined as a defect of the intestinal wall integrity at the anastomotic site, leading to communication between the intra- and extraluminal compartments. It remains one of the most feared complications after colorectal surgery because of its association with postoperative sepsis, reoperation, prolonged hospitalization, impaired oncological outcomes, and increased mortality [1-5]. Reported AL rates vary widely, generally ranging from 6% to 30%, depending on the definition used, tumour location, type of anastomosis, surgical approach, and patient-related risk factors [1-5].

Several clinical and technical factors have been associated with AL, including male sex, obesity, smoking, diabetes mellitus, renal insufficiency, chronic pulmonary disease, immunosuppression, steroid therapy, hypoalbuminaemia, sepsis, bowel obstruction, intraoperative blood loss, transfusion, prolonged operative time, anastomotic tension, and impaired tissue perfusion [8-13]. Despite the availability of these data, individual risk estimation remains challenging in daily practice and often relies on empirical clinical judgement.

Risk calculators such as the ACS NSQIP calculator and dedicated web-based tools have improved individualized risk estimation, but their routine use may be limited by the number of required variables and workflow complexity [14]. A simplified model based on readily available early postoperative parameters could therefore be clinically useful as a screening or triage tool, particularly in settings where rapid bedside assessment is needed.

Artificial intelligence (AI) and large language models (LLMs) are increasingly being explored as tools to support literature screening, data organization, and hypothesis generation in surgical research [15]. In the present study, AI-assisted literature exploration was used only to support the identification of candidate variables previously reported in the literature. Statistical modelling and interpretation were performed using conventional analytical methods.

The aim of this pilot retrospective study was to develop a simplified logistic regression model for early postoperative risk stratification of AL in patients undergoing colorectal cancer surgery with primary anastomosis.

Materials and Methods

Study design and population

This was a retrospective single-centre cohort study conducted at the General Surgery Department of Policlinico Ospedali Riuniti, Foggia, Italy. Consecutive patients who underwent curative-intent colorectal cancer resection with primary anastomosis between January 1, 2024, and December 31, 2025, were considered eligible.

Inclusion criteria were colorectal cancer resection, construction of a primary anastomosis, and availability of clinical and laboratory data from the first postoperative day. Exclusion criteria were staged procedures without primary anastomosis, Hartmann's procedure, protective stoma at the index operation, and incomplete data for the variables required for model construction.

Variables and outcome

The variables collected included age, sex, comorbidities, type of surgical procedure, surgical approach (open or laparoscopic), first-postoperative-day albumin, INR, neutrophil percentage, haemoglobin, fever, and length of hospital stay. The primary outcome was clinically significant AL requiring surgical reintervention and/or stoma creation. AL was considered present when clinical, radiological, intraoperative, or postoperative findings were consistent with an anastomotic defect requiring active treatment.

Role of AI-assisted support

An LLM-based tool was used as an auxiliary support for literature exploration and preliminary identification of candidate predictors reported in previous studies. The tool was not used to generate patient-level data, perform statistical inference, or replace conventional statistical analysis. Final variable selection, model fitting, and interpretation were performed by the investigators using standard statistical methods.

Statistical analysis

Continuous variables were summarized as mean and standard deviation or median and interquartile range, as appropriate. Categorical variables were reported as frequencies and percentages. A binary logistic regression model was developed to evaluate the association between selected postoperative variables and AL. Given the limited number of events, the model was interpreted as exploratory

and hypothesis-generating. Odds ratios (ORs), 95% confidence intervals (CIs), and p-values were reported.

Model discrimination was assessed using the area under the receiver operating characteristic curve (AUC-ROC). Calibration was evaluated using the Brier score and the Hosmer-Lemeshow goodness-of-fit test. Sensitivity and specificity were calculated to describe the classification performance of the model. A two-sided p-value <0.05 was considered statistically significant, while near-threshold values were interpreted cautiously as trends.

Results

Overall, 117 patients undergoing colorectal cancer resection with primary anastomosis were included. Nine patients (7.7%) developed clinically significant AL requiring surgical reintervention. This incidence is consistent with rates reported in the colorectal surgery literature.

Multivariable logistic regression identified postoperative INR as the variable most strongly associated with AL (OR 6.40; 95% CI 0.96-42.57; p = 0.055), although it did not reach conventional statistical significance. Age showed a positive but non-significant association with AL. Albumin and neutrophil percentage were not independently associated with AL in the multivariable model. The results of the regression analysis are shown in Table 1.

Table 1. Multivariable logistic regression analysis of factors associated with anastomotic leakage after colorectal surgery.

Variable	Odds ratio (OR)	95% CI	p-value
Age	3.72	0.31-45.02	0.302
Albumin	3.01	0.48-18.70	0.238
INR	6.40	0.96-42.57	0.055
Neutrophil percentage	1.09	0.37-3.23	0.880

The predictive model showed acceptable discrimination for a pilot exploratory model, with an AUC-ROC of 0.71. Sensitivity was 67% and specificity was 65%. The Brier score was 0.18, suggesting acceptable calibration, and the Hosmer-Lemeshow test did not indicate a significant lack of fit (p = 0.30).

Discussion

In this pilot retrospective cohort, the incidence of clinically significant AL was 7.7%, in line with previously reported rates after colorectal surgery [1-5,16-18]. The proposed model demonstrated acceptable discrimination, although its findings should be interpreted cautiously because of the limited number of events and the exploratory nature of the analysis.

Postoperative INR emerged as the most clinically relevant variable associated with AL risk. Although the p-value was near the conventional threshold for statistical significance, the magnitude of the OR suggests that early postoperative coagulation abnormalities may reflect systemic derangement, impaired haemostasis, bleeding tendency, or inflammatory stress that could contribute to impaired anastomotic healing. Previous studies have reported associations between coagulation abnormalities and adverse postoperative outcomes, although the specific relationship between INR and AL remains less consistently established [30,31].

Age showed a positive but non-significant association with AL. The role of age in AL risk remains debated: some studies have linked advanced age to impaired tissue repair and reduced physiological reserve, whereas others have not identified age as an independent predictor after adjustment for comorbidities and operative factors [8,10,19-23]. In the present cohort, age may represent a marker of frailty or comorbidity burden rather than a direct causal factor.

Albumin and neutrophil percentage did not show independent associations with AL in the multivariable model. This finding should not be interpreted as evidence against their clinical relevance. Hypoalbuminaemia has been widely reported as a marker of malnutrition, systemic inflammation, and poor surgical outcomes [8,12,24,25]. Similarly, neutrophil-based inflammatory indices have been associated with postoperative infectious complications and AL in colorectal surgery [26-29]. The lack of statistical significance in this cohort is likely related to the small number of leakage events and limited statistical power.

The model achieved an AUC-ROC of 0.71, suggesting fair discrimination in an exploratory setting. However, the wide confidence intervals around the regression estimates indicate substantial uncertainty. Therefore, the model should not be considered ready for clinical implementation but rather as a preliminary risk-stratification framework to be refined and validated in larger cohorts.

The role of AI in this study was intentionally limited. LLM-assisted support was used to facilitate literature exploration and candidate-variable identification, while statistical modelling was performed through conventional regression analysis. This distinction is important because AI-generated outputs should not be considered a substitute for validated statistical methods or independent clinical judgement.

Limitations

This study has several limitations. First, it was retrospective and single-centre in design, which may limit generalizability. Second, although the total sample included 117 patients, only nine AL events were observed. This low event rate increases the risk of model instability, wide confidence intervals, and overfitting. Third, no external validation cohort was available. Fourth, some potentially relevant variables, including intraoperative blood loss, anastomotic height, perfusion assessment, operative time, neoadjuvant therapy, and inflammatory markers such as C-reactive protein or neutrophil-to-lymphocyte ratio, were not included in the final model. Finally, the model was developed for hypothesis generation and should not be used as a stand-alone clinical decision tool until externally validated.

Future studies should include larger multicentre cohorts, prospective data collection, internal validation with bootstrap or cross-validation, and external validation. Penalized regression methods or machine-learning approaches may also be considered, provided that adequate event numbers are available.

Conclusions

This pilot retrospective study developed a simplified early postoperative model for AL risk stratification after colorectal cancer surgery. Postoperative INR showed the strongest association with AL, with a clinically relevant trend despite limited statistical power. The model demonstrated acceptable discrimination but requires further refinement and external validation before clinical use.

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