Anastomotic Leakage in Colorectal Cancer Surgery in Syria: Risk Factors and Improvements Following Guideline Implementation – A Retrospective Cohort Study

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Study Protocol: Follow-Up Cohort on Anastomotic Leakage in Colorectal Cancer Surgery at Damascus Hospital, Syria

Study Title:

Official Title:

Anastomotic Leakage in Colorectal Cancer Surgery in Syria: A Retrospective Cohort Study Before and After Guideline Implementation

Brief Title:

Anastomotic Leakage in Colorectal Cancer Surgery, Syria

Study Design:

- Type: Observational, Retrospective Cohort Study
- Number of Cohorts: Two sequential cohorts
- The first cohort: Pre-guideline cohort (January 2016 – March 2024)
- The follow-up cohort: Post-guideline follow-up cohort (April 2024 – October 2025)
- Study Phase: N/A (observational)
- Number of Par•cipants: 19 (follow-up cohort)

Study Objectives:

- Primary Objective:

1. To evaluate the incidence of anastomotic leakage (AL) after implementation of updated institutional guidelines for colorectal cancer surgery.

- Secondary Objectives:

1. To assess postoperative complications, perioperative blood transfusions, ICU admissions, and postoperative mortality in the follow-up cohort.
2. To compare outcomes with the pre-guideline cohort to determine the impact of guideline implementation.
3. To evaluate the effectiveness of perioperative interventions targeting modifiable risk factors (e.g., hypoalbuminemia, transfusions, steroid use)

Study Setting:

Department of General Surgery, Damascus Hospital, Syria.

Resource-limited, conflict-affected environment with predominantly open surgery; laparoscopic surgery available for selected patients.

Eligibility Criteria:

- Inclusion Criteria:

Patients who underwent elective resection of the sigmoid colon or rectum for histologically con•rmed colorectal adenocarcinoma between April 2024 and October 2025.

Availability of complete medical records and laboratory data relevant to the study outcomes.

- Exclusion Criteria:

Emergency surgeries or non-elective resections.

Non-neoplastic (non-tumor) resections.

Incomplete or missing medical records.

Interventions / Exposure:

- No experimental interventions; retrospective observational study.
- Patients were managed under updated hospital guidelines, which included:

(Preoperative nutritional optimization) albumin Š3.5 g/dL when possible

Reduced perioperative blood transfusions

Enhanced intraoperative safety protocols

Postoperative monitoring for high-risk patients

Outcome Measures:

- Primary Outcome:

Anastomotic leakage (AL), defined according to ISREC criteria: a defect in the intestinal wall at the colorectal or colo-anal anastomosis causing communication between intra- and extraluminal compartments. Confirmed clinically or radiologically.

- Secondary Outcomes:

Postoperative complications

ICU admission

Perioperative blood transfusions

Postoperative mortality

Data Collection:

Retrospective extraction from patient charts, operative notes, laboratory results, and radiology reports.

Structured follow-up telephone interviews where applicable.

Collected variables: demographics, lifestyle factors, comorbidities, tumor characteristics, surgical details, laboratory data, and postoperative outcomes.

Statistical Analysis:

Descriptive statistics for baseline characteristics.

Comparisons with pre-guideline cohort using Chi-square or Fisher's exact test for categorical variables; t-test or Mann–Whitney U test for continuous variables.

Statistical significance: p • 0.05.

Analysis performed using SPSS version 24.

Ethical Considerations:

Ethical approval obtained from the Institutional Review Board of the Syrian Private University (IRB No. 1497/436.)

Retrospective nature: waiver of informed consent obtained where applicable.

Patient confidentiality maintained via anonymization and secure data storage.

Timeline:

- Study Start Date January 2016 (original cohort)
- Follow-up Cohort Data Collec•on Start April 2024
- Follow-up Cohort Data Collec•on End October 2025
- Study Completion Date October 2025

Study Significance:

This follow-up cohort evaluates the real-world impact of evidence-based guideline modifications on anastomotic leakage and other postoperative outcomes in a resource-limited, war-affected setting. The findings will inform future clinical practice and risk-reduction strategies for colorectal surgery in similar low-resource contexts.