

Protocol

Title:

Risk Assessment and Predictive Model for Gastrointestinal Fistula After Gastrectomy Based on F-index Scoring System

Background and Rationale:

Gastrointestinal fistula is a serious postoperative complication that significantly increases morbidity and mortality in patients undergoing gastrectomy. There is a need for a simple and effective scoring system to predict the risk of postoperative fistulas. The F-index scoring system was developed to fill this gap by integrating easily accessible clinical variables.

Objectives:

The main objective of this study is to develop and validate the F-index scoring system for assessing the risk of postoperative gastrointestinal fistula in patients undergoing gastrectomy. Secondary objectives include identifying independent risk factors associated with the development of fistulas and evaluating the predictive accuracy of the F-index through sensitivity and subgroup analyses.

Study Design:

This study is a retrospective, multicenter cohort study that includes data from two hospitals: the Third Hospital of Jilin University and Weifang People's Hospital. Patients were divided into a training set and a validation set to assess the generalizability of the scoring system.

Participants:

Inclusion criteria:

1. Patients who underwent gastrectomy between August 2021 and December 2023.
2. Diagnosed with gastrointestinal fistula confirmed by clinical symptoms or imaging.

Exclusion criteria:

1. Patients with preoperative gastrointestinal fistula.
2. Patients who did not complete follow-up.

Interventions:

No interventions are applied in this retrospective study. Data from medical records were analyzed to assess postoperative outcomes based on the F-index scoring system.

Outcome Measures:

Primary outcome:

1. Occurrence of gastrointestinal fistula post-gastrectomy.

Secondary outcomes:

1. Time to fistula occurrence.
2. Fistula diameter.
3. Hospital stay duration.
4. Postoperative complications (e.g., reoperation rates, infection).

Sample Size Calculation:

Based on preliminary data, a sample size of 83 patients was included, with 58 in the training set and 25 in the validation set.

Data Collection Methods:

Data were extracted from patient medical records, including demographic information (age, BMI), disease characteristics, surgical details, and postoperative outcomes.

Statistical Analysis Plan

Primary Analysis:

Univariate and multivariate logistic regression analyses will be conducted to identify risk factors for postoperative gastrointestinal fistula.

Odds ratios (OR) and 95% confidence intervals (CI) will be calculated to assess the strength of association between clinical factors and fistula occurrence.

Model Development and Validation:

The F-index scoring system will be developed using logistic regression on the training set.

The area under the curve (AUC) from receiver operating characteristic (ROC) curve analysis will be calculated to evaluate the model's predictive accuracy.

Internal validation will be performed using the validation set to assess the generalizability of the model.

Subgroup and Sensitivity Analysis:

Subgroup analyses will be conducted based on age (e.g., ≤ 65 vs. > 65) and BMI thresholds (e.g., ≤ 18.5 vs. > 18.5).

Sensitivity analysis will explore the impact of varying these thresholds on model performance.

Calibration:

A calibration plot will be generated to compare predicted vs. observed fistula occurrence rates, and the Brier score will be calculated to assess model accuracy.

Software:

Data analysis will be conducted using SPSS 21.0 and Python for regression analysis and ROC curve generation.

Ethical Considerations:

The study has received approval from the Ethics Committees of China-Japan Union Hospital of Jilin University and Weifang People's Hospital.