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New scoring system to help predict risk of digestive complications after stomach surgery

Submission date 11/10/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 24/10/2024	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 12/11/2024	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Gastrointestinal fistula is a serious complication that can occur after stomach surgery (gastrectomy). It involves an abnormal connection forming between the stomach and surrounding organs, leading to severe health problems or even death. Identifying patients at high risk of developing this complication early is crucial to improve their care and reduce complications. Our study developed a scoring system called the "F-index" to predict the risk of gastrointestinal fistula after gastrectomy.

Who can participate?
Patients who had stomach surgery at two hospitals between August 2021 and December 2023 were included in the study.

What does the study involve?
Participants were divided into two groups: low-risk and high-risk, based on the F-index score. We analyzed different factors such as age, body weight, type of disease, and time until the fistula occurred to determine which factors increased the risk of developing a fistula.

What are the possible benefits and risks of participating?
None

Where is the study run from?
The study is run from The Second Hospital of Jilin University in China.

When is the study starting and how long is it expected to run for?
August 2021 to December 2023.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Yongsheng Yang, qdjnmm@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
L202412001

Study information

Scientific Title
A multicenter retrospective study on the development and validation of the f-index scoring system for predicting the risk of gastrointestinal fistula after gastrectomy

Acronym
F-GF Study

Study objectives
The F-index scoring system can effectively predict the risk of gastrointestinal fistula after gastrectomy, allowing for early identification of high-risk patients and improved postoperative management to reduce morbidity and mortality. Specifically, the hypothesis is that certain clinical factors (e.g., age ≥65 years, BMI <18.5, malignant disease, fistula size >1 cm) are significantly associated with an increased risk of postoperative gastrointestinal fistula.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/09/2024, The Ethics Committee of Weifang People's Hospital (Guangwen Street No. 151, Kuiwen District, Weifang, 261000, China; +86 0536 819 2019; daniel_zdk@163.com), ref: L202412001

Study design

Retrospective cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Gastrointestinal fistula after gastrectomy

Interventions
This study is a retrospective cohort analysis aimed at developing and validating the F-index scoring system for predicting gastrointestinal fistula risk after gastrectomy. The participants of this study are patients who underwent gastrectomy between August 2021 and December 2023. Data were collected from electronic medical records, and the study involved a total of 83 patients across multiple centers. Participants in this study did not require active recruitment or intervention, as the research was based on the retrospective analysis of existing patient records. All included patients had previously undergone surgery and were diagnosed with gastrointestinal fistula through clinical symptoms and imaging or endoscopic examinations. These symptoms included signs of systemic inflammation, respiratory issues, or abdominal discomfort, which were documented as part of routine post-operative care. The primary variables extracted from patient records included age, BMI, type of primary disease, fistula type, history of diabetes, time to fistula occurrence, and fistula size. These factors were analyzed to develop the F-index, a scoring system designed to predict the risk of postoperative fistula. Based on this scoring system, patients were divided into low-risk (0-3 points) and high-risk (4-7 points) groups. Follow-up for the purposes of this study refers to the post-surgical monitoring recorded in patient medical files, which included outcomes such as hospital stay duration, incidence of reoperation, and post-operative complications. The duration of follow-up was effectively the period from the surgery until the occurrence of a fistula or until the patient's condition was stabilized postoperatively. The length of follow-up varied depending on the individual's clinical progression, with some patients requiring longer hospitalization due to complications, while others had relatively shorter follow-up periods. Given that this is a retrospective study, participants' involvement concluded when their medical data was collected and analyzed for the purpose of this study. There was no active intervention or experimental procedure beyond the standard clinical care they received.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Risk of developing gastrointestinal fistula after gastrectomy, assessed by the F-index scoring system (measured as high-risk or low-risk classification) measured using patient records at a single time point

Key secondary outcome(s))
Predictive accuracy of the F-index scoring system, including AUC of the ROC curve, sensitivity, specificity, and calibration plot measured using patient records at a single time point

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients who underwent gastrectomy between August 2021 and December 2023.
2. Patients diagnosed with gastrointestinal fistula postoperatively, confirmed by clinical symptoms and imaging or endoscopic examination.
3. Patients who underwent laparoscopic surgery for benign or malignant gastric diseases.
4. Patients with postoperative clinical manifestations of gastrointestinal fistula, including signs of inflammation (heartbeat >100/min, hyperthermia >38), peritonitis (diffuse abdominal tenderness), respiratory symptoms (cough, expectoration), or elevated white blood cell count (WBC > 11 x 10^9/L).
5. Patients able to provide informed consent or whose consent was provided by a legal representative.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
83

Key exclusion criteria
1. Patients with a history of gastrointestinal fistula prior to laparoscopic surgery.
2. Patients who did not complete follow-up.
3. Patients who died during surgery or due to other major complications that prevented a clear diagnosis of postoperative fistula.
4. Patients who underwent non-laparoscopic surgical procedures for gastric diseases.

Date of first enrolment
01/08/2023

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
China

Study participating centre
The Second Hospital of Jilin University
No.218 Ziqiang Street, Nanguan District
Changchun
China
130000

Study participating centre
Weifang People's Hospital
Guangwen Street No.151, Kuiwen District
Weifang
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Sponsor information

Organisation
The Second Hospital of Jilin University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
At this time, there is no plan to share individual participant data publicly. However, de-identified data may be made available upon reasonable request for research purposes, subject to ethical approval and data use agreements. Any data sharing will comply with applicable privacy and confidentiality regulations to ensure participant safety and anonymity.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			24/10/2024	No	No