ISRCTN14537109 https://doi.org/10.1186/ISRCTN14537109

How well three surgical risk calculators can predict 30-day mortality after emergency abdominal surgery: a retrospective study from Northeastern Romania

Submission date 03/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 30/12/2025	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/12/2025	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Emergency laparotomy is a high-risk surgical procedure with significant mortality, especially in patients over 70. Risk prediction scores, such as NELA, ACS-NSQIP, and SORT, are commonly used internationally to estimate postoperative mortality, but their performance in Romania has not been evaluated. This study aims to compare the predicted 30-day mortality generated by these tools with the actual observed mortality in Romanian patients who underwent emergency laparotomy between 2022 and 2023. It also aims to assess long-term survival and identify the most common emergency procedures associated with a high mortality risk.

Who can participate?

The study includes adults aged 18 and over who underwent emergency abdominal surgery (laparotomy or laparoscopy) in one of six hospitals in Northeastern Romania between January 1, 2022, and December 31, 2023. Patients are included based on the standard eligibility criteria defined by the National Emergency Laparotomy Audit (NELA).

What does the study involve?

This is a retrospective observational study. Data will be collected from hospital records and will include patient demographics, surgical details, risk scores, and outcomes. The date of death will be ascertain by medical records scrutiny, contacting the general practitioner and as a last resort contacting the family. No intervention or treatment will be given as part of this study.

What are the possible benefits and risks of participating?

There are no direct benefits or risks for patients, as all data are collected retrospectively. However, the findings may help improve risk prediction and surgical care for future patients undergoing emergency laparotomy.

Where is the study run from?
The study is coordinated by “Grigore T. Popa” University of Medicine and Pharmacy in Iași, Romania, and involves six hospitals in the Northeastern region.

When is the study starting and how long is it expected to run for?
The study period covers surgeries performed from January 2022 to December 2023. Data collection is scheduled for September - December 2025.

Who is funding the study?
The study is funded by a doctoral grant from “Grigore T. Popa” University of Medicine and Pharmacy, Iași (Romania).

Who is the main contact?
Dr Iordache Gabriel-Andi, PhD Student
andi.iordache@umfiasi.ro

Contact information

Type(s)
Scientific, Principal investigator, Public

Contact name
Mr Andrei Moscalu

ORCID ID
https://orcid.org/0000-0002-1105-443X

Contact details
Department of General and Upper GI Surgery, Addenbrooke’s Hospital, Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0QQ
+447928927762
andrei.moscalu@nhs.net

Additional identifiers

Study information

Scientific Title
A retrospective longitudinal observational study of observed and predicted 30-day mortality after emergency laparotomy using NELA, ACS-NSQIP, and SORT risk scores in six hospitals in Northeastern Romania (Mortality In Romania: Real vs. predicted Outcomes in emeRgency laparotomy)

Acronym
MIRRoR

Study objectives

To determine the actual 30-day postoperative mortality following emergency laparotomy performed in six hospitals in Northeastern Romania and to compare it with mortality predictions generated by three preoperative risk assessment tools: NELA, ACS-NSQIP, and SORT. Analyses will be conducted for the entire cohort and stratified by age (<70 vs. ≥70 years). This is the first retrospective national initiative to evaluate the performance of these models in Romanian surgical practice.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/12/2025, Ethics Committee of the “Grigore T. Popa” University of Medicine and Pharmacy of Iași (Str. Universității nr. 16, Iași, 700115, Romania; +40 232 301 603; eticacercetarii@umfiasi.ro), ref: 691 / 22.12.2025.

Primary study design
Observational

Study design
Multicentre retrospective longitudinal cohort study

Study type(s)
Efficacy, Prevention, Other

Health condition(s) or problem(s) studied
Emergency general surgical conditions requiring laparotomy, including gastrointestinal perforation, bowel ischemia, intra-abdominal abscess, gastrointestinal bleeding, and mechanical obstruction. The study focuses on postoperative mortality following emergency laparotomy.

Interventions
This is a multicentre, retrospective, longitudinal cohort study conducted across six hospitals in Northeastern Romania, including two tertiary-level centres. The study includes adult patients (≥18 years) who underwent emergency laparotomy between January 1, 2022, and December 31, 2023. Data are collected retrospectively from medical records, and the primary outcome is 30-day postoperative mortality. The observed mortality will be compared with that predicted by three risk assessment tools: NELA, ACS-NSQIP, and SORT.

Intervention Type
Not Specified

Primary outcome(s)
1. 30-day postoperative mortality is measured using hospital records at 30 days after surgery
2. Predicted mortality using NELA score is measured using NELA risk calculator at preoperative baseline
3. Predicted mortality using ACS-NSQIP score is measured using ACS-NSQIP risk calculator at preoperative baseline
4. Predicted mortality using SORT score is measured using SORT risk calculator at preoperative baseline

Key secondary outcome(s)

Survival status is measured using Kaplan-Meier survival analysis at 3, 6, 12, 24, and 36 months postoperatively

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years and older
2. Open, laparoscopic, or laparoscopically-assisted abdominal procedures performed in an expedited, urgent, or emergency setting (as defined by NCEPOD)
3. Procedures involving the stomach, small bowel, colon, or rectum
4. Cases involving: gastrointestinal perforation, intestinal ischaemia, intra-abdominal abscess, gastrointestinal haemorrhage, or mechanical obstruction
5. All procedures where appendicitis is the primary diagnosis, regardless of severity or extent
6. Laparotomy or enterotomy for gallstone ileus
7. Any laparotomy or laparoscopy undertaken for primary oesophageal pathology
8. Emergency laparotomy/laparoscopy for gastric pathologies, including haemorrhage, hiatal hernia repair, and removal of foreign bodies or gastric bands
9. Emergency procedures for bleeding duodenal ulcers, gallstone ileus, or foreign body removal from the small intestine
10. Emergency surgery for colorectal pathology, including iatrogenic perforations post-endoscopy
11. Emergency formation of a colostomy or ileostomy as a primary procedure via midline laparotomy
12. Return to theatre for major abdominal wound dehiscence (“burst abdomen”)
13. Emergency laparotomy for bowel ischaemia not preceded by primary vascular or endovascular intervention
14. Return to theatre requiring general surgical assistance following gynaecology-oncology surgery
15. Washout or drainage of peritoneal abscess or haematoma
16. Emergency repair of inguinal, femoral, incisional, or parastomal hernias involving adhesiolysis or bowel resection/repair
17. Laparotomy or laparoscopy undertaken exclusively for adhesiolysis
18. Any abdominal procedure performed for blunt or penetrating trauma, including laparotomy for foreign body removal from the sigmoid or rectum
19. All procedures related to organ transplantation, including reoperations
20. Any reoperation for complications following elective upper gastrointestinal or colorectal procedures meeting NELA criteria, and returns to theatre involving general surgical assistance following gynaecology-oncology surgery or interventional radiology procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
1512

Key exclusion criteria
1. Children under 18 years
2. Elective (non-emergency) surgical procedures
3. Diagnostic laparotomy/laparoscopy where no therapeutic procedure is performed due to inoperable findings (e.g., peritoneal or hepatic metastases, non-viable ischaemic bowel)
4. Surgeries targeting the oesophagus, spleen, kidneys, liver, gallbladder, biliary tract, pancreas, or urinary tract
5. Any primary surgery of the gallbladder or biliary tract, unless incidental to a major gastrointestinal procedure
6. Iatrogenic gastric perforation following endoscopic procedures
7. Foreign body removal from the colon or rectum (considered trauma cases)
8. Emergency stoma formation via trephine incision or laparoscopic approach
9. Minor or superficial wound dehiscence unless it results in bowel pathology necessitating resection
10. Laparotomies for primary vascular pathologies or complications following vascular procedures, regardless of whether bowel resection was performed
11. Laparotomies for primary gynaecological pathology, including ruptured ectopic pregnancy or pelvic abscess due to pelvic inflammatory disease
12. Returns to theatre for complications of gynaecological surgery unless involving gastrointestinal complications secondary to gynaecology-oncology procedures
13. Any procedure related to pancreatitis, removal of peritoneal dialysis catheters, or washout /drainage procedures related to appendicectomy, cholecystectomy, or vascular/urological /gynaecological surgery
14. Emergency hernia repairs not involving adhesiolysis or bowel resection/repair
15. All procedures related to organ transplantation, including reoperations
16. Returns to theatre for complications following non-gastrointestinal surgery (e.g., renal, urological, vascular, hepatic, pancreatic, oesophageal, or splenic surgery), except where complications follow gynaecology-oncology surgery or interventional radiology and require general surgical intervention

Date of first enrolment
23/12/2025

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
Romania

Study participating centre
Spitalul Clinic Judeţean de Urgenţă "Sf. Spiridon" Iaşi
Bld. Independenței nr. 1
Iași
Romania
700111

Study participating centre
Spitalul Clinic Judeţean de Urgenţă "Sf. Ioan Cel Nou" Suceava
Bld. 1 Mai nr.21
Suceava
Romania
720237

Study participating centre
Spitalul Clinic Judeţean de Urgenţă "Sf. Apostol Andrei" Galaţi
Str. Brăilei, Nr. 177
Galați
Romania
800578

Study participating centre
Spitalul Municipal Fălticeni
Strada Cuza Vodă, nr.1
Fălticeni
Romania
725200

Study participating centre
Spitalul Municipal de Urgenţă Paşcani
Str.Gradinitei nr.5
Pașcani
Romania
705200

Study participating centre

Spitalul Municipal de Urgenţă "Elena Beldiman" Bârlad
Str. Republicii nr.300
Bârlad
Romania
731054

Sponsor information

Organisation
Universitatea de Medicina și Farmacie Grigore T. Popa - Iași

Funder(s)

Funder type
Not defined

Funder Name
Universitatea de Medicina și Farmacie Grigore T. Popa - Iasi

Alternative Name(s)
Universitatea Grigore T. Popa - Iasi, Grigore T. Popa University of Medicine and Pharmacy, UMF Iasi

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Romania

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	29/12/2025	No	No