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A simple breath test to predict surgical outcomes

Submission date 18/05/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/05/2026	**Overall study status** Ongoing	
Last Edited 19/05/2026	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims

Heart surgery, such as coronary bypass surgery (to improve blood supply to the heart) and heart valve surgery, is a major operation that carries significant risks. Before surgery, doctors carry out various tests to estimate each patient's risk of complications and to plan their care. One of these tests is breathing function testing, but there is disagreement among experts about how useful these tests are for predicting how well a patient will recover from heart surgery. A simple bedside breathing test called peak expiratory flow (PEF) measures how fast a person can blow air out of their lungs. It is quick, inexpensive, and can be repeated at the bedside, but it has not been well studied in patients undergoing heart surgery. This study aims to find out whether a patient's PEF measured before surgery can help predict their recovery, including how long they stay in intensive care and in hospital, how long they need breathing support, and their chance of survival in the months after surgery.

Who can participate?

Adults aged 18 to 75 years who are scheduled for a planned (non-emergency) coronary bypass operation or heart valve operation, who have had a routine lung assessment before surgery, and who have been confirmed by their cardiologist to be in a stable condition.

What does the study involve?

Participants will have their breathing function measured with a small handheld device before their surgery. They will be asked to take a deep breath in and blow out as hard and as fast as they can into the device. This will be done three times, and the best result will be recorded. The measurement takes only a few minutes and is performed while the patient is connected to a heart monitor for safety. The patient's normal heart surgery and recovery care will not be changed in any way by the study. After surgery, the study team will record information from the hospital records about the patient's recovery, including time spent in intensive care, time spent on breathing support, time spent in hospital, and any complications. Patients will also be contacted by telephone or seen at a clinic visit to check on their health at 30 and 90 days after surgery.

What are the possible benefits and risks of participating?

There is no direct medical benefit to individual participants, as the breathing test is being

studied for research purposes and will not change their treatment. The results may, however, help future patients undergoing heart surgery by identifying a simple, low-cost test that can improve risk prediction before surgery. The risks of taking part are very small. The breathing test involves a strong, forced exhalation, which can occasionally cause brief lightheadedness or coughing. To minimise any risk, patients with conditions that could make the test less safe (such as a recent heart attack, unstable chest pain, severe narrowing of the aortic valve, or an aortic aneurysm) are excluded from the study, and all measurements are carried out under heart monitoring.

Where is the study run from?
University of Health Sciences Gülhane Training and Research Hospital, Department of Anesthesiology and Reanimation, Ankara, Turkey.

When is the study starting and how long is it expected to run for?
April 2026 to November 2026.

Who is funding the study?
The study is investigator-initiated and receives no external funding. All measurements and follow-up are carried out as part of routine clinical practice at the host hospital.

Who is the main contact?
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Study information

Scientific Title
The role of peak expiratory flow value in predicting clinical outcomes in cardiothoracic surgery

Study objectives
Primary objective
To investigate whether preoperative peak expiratory flow (PEF) independently predicts postoperative clinical outcomes in adult patients undergoing coronary artery bypass grafting and /or cardiac valve surgery.
Secondary objectives
To evaluate the association between preoperative PEF and each of the following outcomes: total hospital length of stay, intensive care unit length of stay, duration of invasive mechanical ventilation, duration of non-invasive mechanical ventilation, postoperative oxygen support requirement and duration, postoperative pulmonary complications, and 30-day and 90-day all-cause mortality.
To assess whether the predictive value of preoperative PEF varies by surgical subgroup
To determine, where applicable, a clinically useful preoperative PEF threshold for predicting adverse postoperative outcomes using ROC analysis with Youden index–based cut-off identification.
To examine the predictive performance of preoperative PEF after adjustment for relevant covariates

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 05/03/2026, Ankara Gulhane Training and Research Hospital Non-Interventional Clinical Research Ethics Committee (Gulhane Training and Research Hospital, General Dr. Tevfik Sağlam Street No: 1; Keçiören, Ankara, 06010, Türkiye; +903123041288; geahbilimseletikkurul@gmail.com), ref: 2026/29

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Prediction of postoperative pulmonary and clinical outcomes in adult patients undergoing coronary artery bypass grafting or cardiac valve surgery.

Interventions
This is a single-center prospective observational cohort study to be conducted at the Department of Anesthesiology and Reanimation, University of Health Sciences Gülhane Training and Research Hospital, Ankara, Turkey. Consecutive adult patients (aged 18–75 years) scheduled for elective coronary artery bypass grafting and/or cardiac valve surgery who meet eligibility criteria will be enrolled following written informed consent.

The exposure of interest is preoperative peak expiratory flow (PEF). PEF will be measured at the bedside during the preoperative pulmonary evaluation using a handheld peak flow meter, with the patient in a seated position, under continuous ECG monitoring. Three consecutive measurements will be obtained according to standard technique, and the highest of the three values will be recorded in milliliters per minute as the participant's PEF value. No therapeutic intervention will be administered as part of the study; all clinical care, surgical management, anesthesia, and postoperative care will follow institutional standards and will not be modified by the protocol.

Baseline data collected at enrollment will include demographic information (age, sex), comorbidities, diagnosed pulmonary disease and its current control status (chronic obstructive pulmonary disease, asthma, pulmonary thromboembolism, interstitial lung disease, and other restrictive lung diseases), history of pulmonary treatment and inhaler regimen (short- and long-acting beta-agonists, muscarinic antagonists, and inhaled corticosteroids), preoperative PEF, and planned surgical type stratified by pump requirement (on-pump CABG, off-pump CABG, conventional cardiac valve surgery, and minimally invasive cardiac valve surgery).

Participants will be followed throughout their hospital stay. Outcome data collected will include intensive care unit length of stay, requirement and duration of invasive mechanical ventilation, requirement and duration of non-invasive mechanical ventilation, requirement and duration of supplemental oxygen, postoperative pulmonary complications, total hospital length of stay, and all-cause mortality at 30 and 90 days following surgery. Mortality follow-up after hospital discharge will be ascertained through outpatient records and, where necessary, telephone follow-up.

All data will be recorded in a de-identified case report form with an assigned study ID. Statistical analysis will be performed using IBM SPSS Statistics (Premium Gradpack, v30). Distribution of continuous variables will be assessed using histograms and the Kolmogorov–Smirnov test. Associations between preoperative PEF and continuous outcomes (length of stay, ventilation duration) will be assessed using Pearson or Spearman correlation as appropriate. Categorical outcomes will be compared between groups using independent-samples t-test or non-parametric equivalents. Multivariable binomial logistic and/or linear regression will be performed to adjust for comorbidities, treatment regimens, and surgical type. Where applicable, ROC analysis with Youden index–based cut-off identification will be used to derive a clinically useful preoperative PEF threshold. Prespecified subgroup analyses will be performed by surgical type.

Intervention Type
Other

Primary outcome(s)
1. 30 Days all-cause mortality measured using data collected from hospital electronic medical records and post-discharge telephone follow-up at 30 days

2. 90 Days all-cause mortality measured using data collected from hospital electronic medical records and post-discharge telephone follow-up at 90 days

Key secondary outcome(s))
1. Invasive mechanical ventilation from intubation to extubation following surgery measured using data collected from intensive care unit ventilator records on the duration of invasive mechanical ventilation, collected at one time point

2. data collected from non-invasive mechanical ventilation from intubation to extubation following surgery measured using data collected from intensive care unit ventilator records, collected at one time point

3. Admission duration, total hospital length of stay in days from hospital admission to hospital discharge measured using data from hospital electronic medical records collected at one timepoint

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Age 18–75 years
2. Scheduled for coronary artery bypass grafting and/or cardiac valve surgery
3. Preoperative pulmonary (chest diseases) evaluation available
4. Cardiologically stable as confirmed by the cardiology department
5. ECG monitoring available during peak expiratory flow measurement

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Total final enrolment
100

Key exclusion criteria
1. Emergency surgery
2. Emergency preoperative evaluation or evaluation performed at an external center
3. Postoperative transfer to another center

4. History of prior thoracic surgery
5. Significant thoracic deformity
6. Unstable angina
7. Severe and/or advanced aortic stenosis
8. History of myocardial infarction within the past 1 month
9. Presence of aortic aneurysm

Date of first enrolment
01/06/2026

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Gülhane Askerî Tıp Akademisi

ROR
https://ror.org/00c8t7d47

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available