

PERISCOPE

Prospective Evaluation of a Risk Score for postoperative pulmonary COMplications in Europe

A 7-day data collection, prospective, observational study

Steering Committee:

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What is the medical problem?

Postoperative pulmonary complications (PPCs) account for a substantial proportion of risk related to surgery and anaesthesia and are a major cause of postoperative morbidity and mortality and longer hospital stays. The incidence rates range between 2% and 40%, depending on the type of patients and surgery. The factors affecting the development of PPC are related to the prior health status of the patient and the effects of anaesthesia and surgical trauma. The synergy between these factors determines risk.

What is the interest for studying prediction of PPC?

Until now, there exists no definitive study providing a simple score for predicting PPC useful in any clinical setting. Identifying patients at risk of PPC is an important step toward improving surgical safety, because we can establish a perioperative strategy to reduce the risk individually.

What is the hypothesis?

It is possible to generalize the preoperative use of a simple score, built up from a clinical set of variables, to predict PPC.

What is the objective?

In 2006, in Catalonia, a prospective study on postoperative outcome in a representative general surgical population (ARISCAT study) found a 5% incidence of PPC. The 30-day mortality of patients with PPC was 20%. The ARISCAT also identified 9 independent risk factors for PPC (age, male sex, low preoperative SpO₂, acute respiratory infection during the previous month, preoperative anaemia, positive cough test, upper abdominal or intrathoracic surgery, surgical duration ≥2 hours and emergency surgery). A simplified risk score was derived for each variable.

The main objective is to validate a risk index based on nine objective and easily assessed factors, described in the ARISCAT study, in a general unrestricted surgical population across Europe, to accurately predict PPC in any clinical setting.

Secondarily, this multinational prospective study will allow knowing the variability of the PPC rate among the different countries in Europe.

JOIN THE CLINICAL TRIAL NETWORK !

Patients:

Patients undergoing a non-obstetric in-hospital surgical procedure, elective or emergent, under general or regional (neuraxial or plexus) anaesthesia.

Exclusions: a) age <18 years; b) obstetric procedures or any procedure during pregnancy; c) procedures in which only local or peripheral nerve anaesthesia was used; d) procedures outside the operating room; e) procedures related to a previous postoperative complication; f) transplantation; g) patients with preoperatively intubated trachea; and h) outpatient procedures.

What will the outcomes be?

The main outcome, defined as a PPC, will be a composite of the in-hospital fatal or non-fatal postoperative events. This composite will include: respiratory infection, respiratory failure, bronchospasm, atelectasis, pleural effusion, pneumothorax or aspiration pneumonitis. The investigators will identify them by consulting medical records and looking for events that fulfilled any PPC definition.

The secondary outcomes will be postoperative length of stay and in-hospital mortality rate.

Data collection

A centralized database and applications for remote data recording must be developed incorporating quality control algorithms to validate online data entry and identify missing data. A data manager will check entries and asked local teams to confirm completeness of records. A questionnaire of variables and definitions will be developed. The following information will be collected and the ARISCAT score calculated for each patient:

Administrative: Date of surgery and date and status (alive or dead) at hospital discharge.

Demographic: Gender and birth date.

Preoperative: Preoperative SpO₂ breathing air in supine position, respiratory infection in the last month, preoperative haemoglobin and cough test (the patient is told to take a deep breath and cough once. A positive test is defined by repeated coughing after the first cough).

Intraoperative: Surgical incision: intrathoracic, upper abdominal or peripheral, surgical duration and type of surgery (scheduled or emergency).

Postoperative outcome: Postoperative pulmonary complications, according to the definitions previously stated.

Other additional information: ASA class, height and weight, smoking status, chronic pulmonary disease, description of the surgical procedure, surgical specialty and anaesthetic technique.

Sample size

According to the ARISCAT study, the PPC incidence was 5%. We need at least 100 PPC for a decrease in c-statistics of 0.1. Then, the minimum sample size required will be around 2000 individuals. To find differences among countries or geographical areas we need 2000 individuals for each one.

Centres

All centres in Europe will be welcome to participate in the study. **Each applicant centre must recruit for a week** (7 days) all patients meeting inclusion and exclusion criteria. The week assigned will be previously randomized.

At least a responsible local investigator must be designated and a national coordinator will be the leader maintaining continuous contact with the centres and the steering committee.

Ethical Considerations

Due to the nature of the study, no ethical concerns exist. All patients will receive routine care; no research-related intervention will be introduced. Institutional approval will be required to each participating centre in order to get permission for collecting observational clinical information.

How do you get involved?

Please contact Jaume Canet (chief investigator) by e-mail (jcanet.germanstrias@gencat.cat) or telephone (+34 93 497 89 04) or through the ESA Secretariat (research@euroanaesthesia.org).

**Further information: www.euroanaesthesia.org and
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