CovidSurg

Outcomes of surgery in COVID-19 infection:
international cohort study (CovidSurg)

GlobalSurg Collaborative

The GlobalSurg Collaborative was established to allow individuals from around the world to lead and participate in global research aimed at improving outcomes after surgery. The ethos of GlobalSurg is inclusive and collaborative – our international studies are open to all collaborators from anywhere in the world.

There is an urgent need to understand the outcomes of COVID-19 infected patients who undergo surgery. Capturing real-world data and sharing international experience will inform the management of this complex group of patients who undergo surgery throughout the COVID-19 pandemic, improving their clinical care.

Message from the coordinator:
In order to contribute to CovidSurg you must first secure research/audit approval, according to local regulations. This short protocol has been written to support that process. The global community has recognised that rapid dissemination and completion of studies in COVID-19 infected patients is a high priority, so we encourage all stakeholders (local investigators, ethics committees, IRBs) to work as quickly as possible to approve this project. **This investigator-led, non-commercial, non-interventional study is extremely low risk, or even zero risk.** This study does not collect any patient identifiable information (including no dates) and data will not be analysed at hospital-level.

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Primary objective

To determine 30-day mortality in patients with COVID-19 infection who undergo surgery. This will inform future risk stratification, decision making, and patient consent.

Inclusion criteria

The inclusion criteria are:

- Patients undergoing **ANY** type of surgery in an operating theatre, this includes obstetrics.

AND

- The patient had COVID-19 infection diagnosed within 7 days before or 30 days after surgery, based on

  (i) positive COVID-19 lab test **or** computed tomography (CT) chest scan.

  OR

  (ii) clinical diagnosis (no COVID-19 lab test or CT chest performed).

  If COVID-19 infection is diagnosed >30 days after surgery, the patient should not be included.

Therefore this study should capture:

- emergency surgery patients with clinical diagnosis or lab confirmation of COVID-19 infection **before** surgery.
- emergency surgery patients with clinical diagnosis or lab confirmation of COVID-19 infection **after** surgery.
- elective surgery patients with clinical diagnosis or lab confirmation of COVID-19 infection **after** surgery.

'Individual participating centres have the option whether to apply an age cut-off to the inclusion criteria locally. According to local circumstances, centres can choose to include children only, adults only, or both children and adults. We encourage centres to include children if possible, but this is not mandatory

Patients who meet the inclusion criteria should be included regardless of surgical indication (benign surgery, cancer surgery, trauma surgery, obstetric), anaesthetic type (local, regional, general), procedure type, or surgical approach (minimally invasive, open surgery).

At most sites it is anticipated that the number of eligible patients is likely to be low. **If possible** all consecutive patients fulfilling inclusion criteria should be entered. Ideally all eligible patients across **all surgical specialties** should be entered, however it is recognised that in some hospitals it may only be possible to identify and enter data from specific specialties.

Study period
Overall, we plan to close data entry on 30 September 2020, however individual centres may select their own study windows, depending on the timing of COVID-19 epidemic in their community.

Patient enrolment
Ideally patients should be identified prospectively:
- At the time of surgery (patients who had test proven or clinically diagnosed COVID-19 infection up to 7 days before surgery)
- At the time of COVID-19 diagnosis (patients in whom COVID-19 is first suspected during the index admission, within the 30 days following surgery).

However, given the rapid progression of the global pandemic, there may be no further new cases of COVID-19 infection in some hospitals that treated large numbers of COVID-19 earlier in the pandemic. It is important to capture the experience of these centres, therefore **retrospective patient identification and data entry is permitted**.

Primary outcome
- 30-day mortality

Secondary outcome
- 7-day mortality
- 30-day reoperation
- Postoperative ICU admission
- Postoperative respiratory failure
- Postoperative acute respiratory distress syndrome (ARDS)
- Postoperative sepsis

Data collection

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. A designated collaborator at each participating site will be provided with REDCap project server login details, allowing them to securely submit data on to the REDCap system. REDCap has previously been successfully used for a range of other international cohort studies led by the central unit, including the GlobalSurg and ESCP Cohort studies. The REDCap server is managed by the University of Birmingham, UK.

Only anonymised data will be uploaded to the database. **No patient identifiable data will be collected.** Data collected will be on comorbidities, physiological state, treatment/operation, and outcome. No dates (e.g. date of surgery) will be collected. The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to current legislation.

qSOFA and CURB-65 will be calculated based on the individual data points entered.

Local approvals

The principal investigator at each participating site is responsible for obtaining necessary local approvals in line with their hospitals regulations. Collaborators will be required to confirm that a local approval is in place at the time of uploading each patient record to the study database.

Analysis

A detailed statistical analysis plan will be written. Analyses will be overseen by the independent data monitoring committee (DMC). Reports will include description of the primary and secondary outcomes in the cohort. Multivariable modelling will be undertaken to identify risk factors for 30-days mortality. Analyses will be stratified according to whether or not diagnosis of COVID-19 was confirmed by a lab test.

Interim analyses will be performed as guided by the independent DMC. The first analysis will be performed once 50 patients have been entered on to the database, and the frequency of subsequent analyses will be agreed with the DMC. The decision to submit data for publication will be agreed by the steering committee with the DMC. Hospital-level data will

not be released or published. Country-level analyses will only be conducted with permission of lead investigators from each participating country. Local investigators may access their local data at any time directly from the REDCap database. Investigators may choose to pool data across their country to perform country-level analyses (all participating hospitals should consent to their data being used in this way).

Authorship

Collaborators from each site who contribute patients will be recognised on any resulting publications as PubMed-citable co-authors. A corporate authorship model will be used (example: https://pubmed.ncbi.nlm.nih.gov/29452941).