CovidSurgCancer - Gynaecological Oncology: a global observational cohort study investigating the impact of COVID-19 on the care of patients with gynaecological malignancies requiring surgery

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A corporate authorship model will be used under CovidSurg Collaborative group, for example: https://pubmed.ncbi.nlm.nih.gov/29452941

COVIDSurg - Gynaecological Oncology is part of a collaborative across all solid cancer sites. (https://globalsurg.org/cancercovidsurg/). Each specialty (e.g. gynaecological oncology) will produce specialty specific publications. In addition, each specialty also contributes to one manuscript pooled across all solid cancers. This manuscript on approximately 1000 solid cancer patients, including 27 gynaecological cancers, is being submitted to the NEJM shortly.

The COVIDSurg-Cancer suite of studies has received financial contributions from specialist societies (Bowel and Cancer Research, European Society of Coloproctology, Sarcoma UK, Association of Upper Gastrointestinal Surgery of Great Britain and Ireland, Bowel Disease Research Foundation, Association of Coloproctology of Great Britain and Ireland) to enable optimization of costs across all solid cancer sites and timely set up. Funders are acknowledged in the manuscripts.

The COVIDSurg – Gynaecological cancer study steering committee forms the writing group and comprises Professor Jalid Sehouli (Germany), Dr Luis Chiva (Spain), Dr Murat Gutelkin (Turkey), Professor Keiiji Fujiwara (Japan), Dr Joe Ng (Singapore), Dr TS Shylasree and Dr Rajkumar Seenivasagam (India), Dr Rahel Ghebre (Ethiopia), Dr Tom Konney (Ghana), Dr Sean Dowdy and Dr Rob Bristow (US), Dr Rene Pareja (Columbia). Dr Elaine Leung and Dr Tabassum Khan from the UK are trainee representatives on the steering committee.

All contributors to COVIDSurg-Gynaecological Cancer study are included as collaborating authors – thus far, we have 80 collaborators already contributing, including 15 from the UK and another 50 waiting for local IRB approval to start. The COVIDSurg-Gynaecological Cancer study commenced in April 2020 by adapting the ongoing COVIDSurg – Cancer study platform to collect gynaecological cancer specific data.

Introduction

Challenging decisions on gynaecological cancer surgery have been needed during the COVID-19 pandemic; cancer surgical treatments put patients at higher risk of post-operative complications, but delay in treatments can lead to poorer outcomes. There is an urgent need to understand the impact of COVID-19 on cancer surgery. The COVIDSurg study established outcomes from COVID in non-oncological surgical procedures; overall mortality was 25% with ITU requirements in 67% (Lancet, accepted). The COVIDSurg Cancer paper across all solid tumour sites demonstrates the safety of 'cold' COVID operating sites over 'hot' operating sites (submitted to NEJM). The present study investigates the outcomes of gynaecological cancer patients with a decision for surgery.

Methodology
Eligible hospitals/centers: Any hospitals/centers performing elective gynaecological cancer surgery.

Inclusion criteria:

- Patients who are undergoing surgery for gynaecological cancers with curative intent or life-prolonging intent during the COVID-19 pandemic.
- Patients with gynaecological cancers that would have been planned for curative or life-prolonging cancer surgery in the pre-COVID-era, who have surgery delayed or cancelled during the COVID-19 pandemic.
- Patients who are undergoing surgery for gynaecological cancers with curative intent or life-prolonging intent during the COVID-19 pandemic with/who develop COVID-19.

Key study outcomes:

- Primary: 30-day postoperative COVID-19 infection rate.
- Secondary: 30-day postoperative mortality and critical care admission; delay in surgery >4 weeks; progression to inoperable or incurable disease at 3 months.

Data collection period: 3 months from the time of emergence of COVID-19 in the enrolled hospitals (as identified by local investigators). Both retrospective and prospective data collection are permissible. Data on background hospital CRITCON levels will be collected (https://www.londonccn.nhs.uk/media/1485/critcon-2013-14.pdf)

Follow up: 3 months from the time of study entry (when care decision was made) for each participant.

Data storage: Anonymised data is collected and stored in a secure online platform (REDCap). No sample size has been calculated, given current trajectory, we anticipate around 2000 study patients

Research Ethics Committee Approval: In the UK, this is considered an audit. International contributors seek local permissions as appropriate. The study is NCRI badged and supported by the RCS and RCOG.

Discussion
This is the only ongoing international study investigating outcomes from planned cancer surgery and will provide valuable data for health systems, clinicians and patients to manage gynaecological cancer. As the study is across countries, at different points during the pandemic, this will give insight into anticipated outcomes across different transmission rates. Finally, the study will help in benchmarking outcomes and reinforce the BGCS as a leader in gynaecological cancer care.

Update since grant award

BGCS has been acknowledged as funder in the following Outputs

1.

Elective surgery cancellations due to the COVID -19 pandemic: global predictive modelling to inform surgical recovery plans
COVIDSurg Collaborative
First published: 12 May 2020
British Journal of Surgery

https://doi.org/10.1002/bjs.11746

2. Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-COV2 infection: an international cohort study
COVIDSurg Collaborative
Lancet (The Lancet; doi.org/10.1016/S0140-6736(20)31182-X)