**UK-REVASC Registry**

**Background**

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the cause of the ongoing global pandemic of coronavirus disease 2019 (COVID-19) that was designated a Public Health Emergency of International Concern on 11th March 2020 by the World Health Organisation.

This pandemic will place enormous resource burden on intensive care unit (ICU) beds and staff. Invasive ventilatory support remains the mainstay of therapy in those who are critically unwell with COVID-19. Publicly available data from Italy indicate that ICU admissions (n = 556) represented 16% of all patients (n = 3420) who tested positive for COVID-19 within the first 2 weeks of the pandemic (1). Patients that survive the infection are spending an average of 15 days in ICU and a minimum of 10 days in each case.

In the UK the NHS has 3,700-4,000 adult intensive care beds. At the start of March about eight in 10 were occupied. The NHS is aiming to increase capacity to 12,000 intensive care beds in total by sourcing extra ventilators and assembling field hospitals. The latest figures provided by the government this week suggests there are now 8,000 ventilators available to the NHS. Clearly attempts are being made to expand resources to accommodate COVID-19 patients. Regardless of these measures there is going to be extreme pressure on ICU beds and many routine surgical procedures will be cancelled.

In patients with more complex coronary anatomy there is general acceptance that some patients may be better treated with CABG rather than with PCI. In the latest British Cardiovascular Intervention Society (BCIS) audit (2017-2018) approximately 15,000 patients were treated with coronary artery bypass grafting (CABG) for revascularisation of coronary disease. Whilst we do not have a breakdown of the patient characteristics nor coronary anatomy, many of these will be patients with left main stem disease, complex multi-vessel disease, and a high SYNTAX score (>32). Some may even be single left internal mammary artery (LIMA) optional patients.

Many will have been discussed at local multi-disciplinary team (MDT) meetings. Sometimes decisions about CABG versus PCI revolve around which is the better option for the patient in terms of longer-term outcomes rather than an absolute, with it being rare that PCI is an absolute non-option. The same cannot be said for surgery as significant lung disease, poor ejection fraction, or poor vessel graft targets may preclude surgical intervention. Indeed, it is not uncommon for patients with multi-morbidities (previous stroke, renal failure, significant lung disease) who would otherwise be regarded as having “surgical” disease being treated with PCI because of poor surgical risk.

In the current scenario it is likely (indeed there are many reports of this taking place already) that patients who in “normal” pre-COVID times would be regarded as being best treated with CABG are now, because of the lack of optimal surgical logistic support, being referred for PCI. Whether this is right or wrong is unknown, but PCI may be the least worst option if a patient with severe symptoms presents with LMS disease or complex multi-vessel disease and cannot receive what is regarded as the optimal therapy.

If this is taking place, it is essential that we capture the data. In retrospect it will be critical to understand this patient cohort, their demographics, anatomy and risk factors, how they were treated (staged or procedurally complete revascularisation) and what the clinical outcomes are.

Interventionists in the UK have been canvassed and are keen to contribute to entering anonymised patient data into a clinical audit web-based database. This has been created in collaboration with University of Glasgow Clinical Trials Unit. The data will be robust and analysable.

**NOTE THESE ARE NOT COVID +ve PATIENTS BUT REVASCULARISATION OPTIONS IN THE COVID ERA**

**Aims**

1. Determine how many patients originally considered as requiring CABG are now treated with PCI
2. Define patient characteristics (stable severe, unstable angina, N-STEMI with complex disease), demographics, and coronary anatomy (SYNTAX score, SYNTAX II score, residual SYNTAX score) of patients with “surgical disease” undergoing PCI
3. Define the treatment strategies of this patient group (complete versus incomplete revascularisation, DES versus DEB, CTO PCI yes/no)
4. Define PCI success (“significant” lesions treated resulting in less 30% residual stenosis, TIMI 3 flow)
5. Incidence of acute (in-hospital) clinical events

**Inclusion criteria**

1. >= 18 years of age
2. Patients either on a surgical waiting list who “need” revascularisation (as documented by the clinician filling in the audit) or who deemed to be “surgical” (reasons outlined) who then go on to be treated with PCI

**Methods**

An online, user-friendly, web-based, remote data entry system has been developed in collaboration with the University of Glasgow Clinical Trials Unit. Participating sites will be asked to record anonymised data for consecutive COVID-19 positive patients that meet the above inclusion criteria.

**Research Governance**

Assurances regarding governance have been sought from University Hospitals of Leicester NHS Trust Caldicott Guardian, Head of Research Operations, Head of Privacy, and Clinical Audit Manager who have confirmed that this is a service evaluation / audit registry. The study will not be collecting any patient identifiable data and submissions will be pseudonymised. Ethics committee approval is not required for health surveys but you may wish to inform your clinical audit team (or equivalent) you are taking part. This also therefore explains why the study is being run outside of the UK National Institute for Health Research (NIHR) priority system. We will share the relevant IG documents including our Information Sharing Agreement as soon as it available.

We hope that large numbers of patient data being entered into the registry to ensure robust data. The proposed study has been disseminated on social media platforms and discussed amongst colleagues. There appears to be a global interest in collecting these data.

You will access to your own data on request to Glasgow CTU at study end.

The data will be held securely by the Clinical Trials Unit at the University of Glasgow (Dr Sharon Kean).

The data will be analysed by statisticians at the University of Leicester.

We will appoint a standard National Project Steering Committee to help define the parameters around the data analysis, the specific scientific questions that require answering, and to help define which data needs extracting. This group will follow the usual appropriate study guidelines to ensure independent, robust and transparent conclusions can be drawn.

Final data analysis will be shared with the cardiovascular community at large through publications if deemed appropriate.

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**References**

1. Grasselli G, Pesenti A, Cecconi M. Critical Care Utilization for the COVID-19 Outbreak in Lombardy, Italy: Early Experience and Forecast During an Emergency Response. JAMA. 2020.