**COVID-ACS Global 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.

It is increasingly recognised that SARS-CoV-2 infection is associated with multiple direct or indirect cardiovascular complications including acute myocardial injury, myocarditis, arrhythmias and thromboembolic disease. It is unclear to what extent these presentations may be mimicked by COVID-19. Clinical evaluation of the underlying disease process in the context of COVID-19 is challenging; myocarditis and Type 2 Myocardial Infarction causing ischaemic ECG changes mimicking ST elevation myocardial infarction have been documented. Incident rates of true Type 1 Myocardial Infarction have yet to be published, but the profound inflammatory response and haemodynamic changes associated with SARS-CoV-2 may theoretically confer risk for atherosclerotic plaque rupture in susceptible patients.

This combined with concerns regarding the importance in reducing healthcare worker exposure to SARS-CoV-2, availability of personal protective equipment (PPE), and huge volume of patients unwell because of the viral illness itself has resulted in a challenging period for healthcare systems and providers.

Observational data of presentation, management and outcomes of acute coronary syndrome (ACS) in COVID-19 positive patients, may help to inform future clinical decision-making. It may help in the understanding of Type 2 MI and the role of biomarkers. Not least, we are facing a completely novel clinical experience and as much pertinent data that can be collected could provide, as yet unknown future insights.

**Aims**

* Define the presentation of COVID-19 patients with apparent ACS as defined by normal criteria
* Understand their clinical and angiographic characteristics and clinical outcomes
* Understand if the patients with a combination of COVID-19 and ACS present differently, as for example, patient presentation delay and the impact of this on outcomes
* Understand the effect of COVID-19 on hard endpoint in-hospital outcomes in ACS
* Differentiate the obstructive versus non-obstructive ACS disease patterns and their outcomes in the context of COVID-19
* Provide insights into the latter as compared to other Type 2 MI
* Understand the thrombotic nature of any lesions
* Evaluate global practice of COVID-19 patients with suspected acute coronary syndrome (ACS) undergoing an invasive coronary strategy (use of PPE etc)

**Inclusion criteria**

1. Age ≥ 18 years of age
2. COVID-19 positive
3. Underwent coronary angiography

**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.

* 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 International Trial Project Committee (independent co-chair Gregg Stone) 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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Dr Jonathan Gibb

Dr Carl Walker

Professor Gregg Stone

Professor Tony Gershlick