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Cardiac Registries During the COVID-19 Pandemic: Lessons Learned

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Abstract

Purpose of this Review We discuss the role of observational studies and cardiac registries during the COVID-19 pandemic. We focus on published cardiac registries and highlight contributions to the field that have had clinical implications.

Recent Findings We included observational studies of COVID-19 patients published in peer-reviewed medical journals with defined inclusion and exclusion criteria, defined study design, and primary outcomes. A PubMed and MEDLINE literature review results in 437 articles, of which 52 include patients with COVID-19 with cardiac endpoints. From July 2020 to December 2021, the average time from last data collected to publication was 8.9 ± 4.1 months, with an increasing trend over time ($R = 0.9444$, $p < 0.0001$). Of the 52 articles that met our inclusion criteria, we summarize main findings of 4 manuscripts on stroke, 14 on acute coronary syndrome, 4 on cardiac arrest, 7 on heart failure, 7 on venous thromboembolism, 5 on dysrhythmia, and 11 on different populations at risk for cardiovascular.

Summary Registries are cost effective, not disruptive to essential health services, and can be rapidly disseminated with short intervals between last data point collected and publication. In less than 2 years, cardiac registries have filled important gaps in knowledge and informed the care of COVID-19 patients with cardiovascular conditions.

Keywords Registry · Cardiac · COVID-19 · Collaboration

Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) causes the coronavirus disease 2019 (COVID-19) which has rapidly resulted in a global pandemic. Cardiovascular complications of COVID-19 cause significant morbidity and mortality. Given the infectious nature of this disease, rapid responses from health care workers are required, and as such, there is a need to develop methods which can help analyze a high volume of reliable, accurate, patient-level data with avenues for rapid dissemination of information [1••]. We discuss characteristics of this pandemic that illustrate the advantages of conducting research using observational studies rather than interventional trials. Secondly, we will focus on the impact of cardiac registries during the pandemic and highlight lessons learnt that have helped us navigate cardiac care during this challenging period.

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Registries as the Ideal Vehicle of Research During COVID-19 Pandemic

The National Committee on Vital and Health Statistics defines registries as systems for "the collection, storage, retrieval, analysis, and dissemination of information on individuals who have either a particular disease or a risk factor(s) known or suspected to cause adverse health effects, to be useful for specific public health purposes" [2•, 3•]. Table 1 summarizes characteristics of the COVID-19 pandemic that made registries valuable for the rapid collection and dissemination of knowledge ideal for conducting research.

Given that multiple mutations have created an evolving myriad of complications and patterns of transmission, data

Table 1 Advantages of registries to accommodate characteristics of a pandemic

Characteristics of a pandemic	Advantages of using a registry for research
Evolving	Dynamic nature ensures up to date research Can be retrospective and observational Easily adjustable data infrastructure with minimal financial input Allows for a mechanistic understanding of the pandemic over time
Multiple patient populations	Adjustable data capture methods Large sample sizes per group Potential to provide multiple generalized results from single registries
Need for rapid dissemination	Rapid ethics approval Potential for waiver of consent Rapid data abstraction Granular analyses can allow for many sub studies
Collaboration	Rapid communication and collaboration between countries Open avenues for development of further studies
Limited patient interactions	Assessment of medical charts limits patient interaction Remote data acquisition and entry can be completed Waiver of consent can entirely limit interactions
Limited resources	Observational data abstraction completed without extra resources Cost effective, multi-center studies in comparison to RCTs

obtained from registries can provide health care workers with rapid real-time information to inform clinical decision making. Much like the disease itself, registries have a capacity to change over time to enhance efficiency. Indeed, vital information can be added to registries in a dynamic manner, thereby providing registries with the flexibility to adjust according to changes during the pandemic. Observational data can be valuable in helping to accelerate the dissemination of information and provide real-world evidence in a time and cost-effective manner to manage this challenging disease.

The initial COVID-19 research came from single center or regional collaborators with small sample sizes, and this evolved over time [4•] to multinational collaborators that resulted in an increase in global article production from 3.6 to 4.9% [4•]. With an emphasis on collaboration, there have been dynamic changes in the structure of scientific activity [4•], which includes the flexibility to provide funding to address urgent needs, overcoming the potentially elevated costs associated with extensive international collaboration. Registries are more cost effective than RCTs, and depending on study characteristics, can result in savings of up to USD 600,000 on data-associated costs alone [5].

The COVID-19 pandemic has caused significant strain on research infrastructure [6]. Specifically, the dynamic nature of the pandemic requires the availability of appropriate resources for allocation to the most severe patients. Indeed, hospitals were stressed financially, and in combination with an elevated fear of infection, this resulted in national and international lockdowns. A large number of investigators and sponsors stopped clinical trial enrollment, a practice which has been commonplace during the pandemic. Registries allowed real-time, observational research with limited burden on the health care system by allowing waiver of consents, minimizing patient contact, and flexible abstraction of information during the pandemic [7•].

Methods

For this review, cardiac registries were defined as outlined by the National Committee on Vital and Health Statistics and recent research by Dawson et al. [8•], and were only included if they had the following characteristics:

1. Well-defined inclusion and exclusion criteria
2. Defined study design
3. Primary outcome measures
4. Results published in a peer-reviewed medical journal
5. Defined patient population with confirmed COVID-19 infection

We searched PubMed (including MEDLINE) from May 2020 to December 31, 2021, using the search terms "COVID" AND "Cardiac" AND "Registry" for peer-reviewed studies published in English. This search yielded 437 studies. After removal of retractions, RCTs, non-English articles, reviews, protocols, and brief reports, 320 articles remained. From these 320, 99 were removed as they did not focus on patients with COVID-19, and from the remaining 221 articles, 52 manuscripts met our inclusion guidelines (Fig. 1). The 52 manuscripts included 14 related to myocardial injury/acute coronary syndrome (ACS), 11 to at-risk populations, 7 to venous thromboembolism (VTE), 7 to heart failure (HF), 5 to dysrhythmia, 4 to stroke, and 4 to cardiac arrest (CA). Supplementary Table 1 summarizes populations studied and results from the above studies.

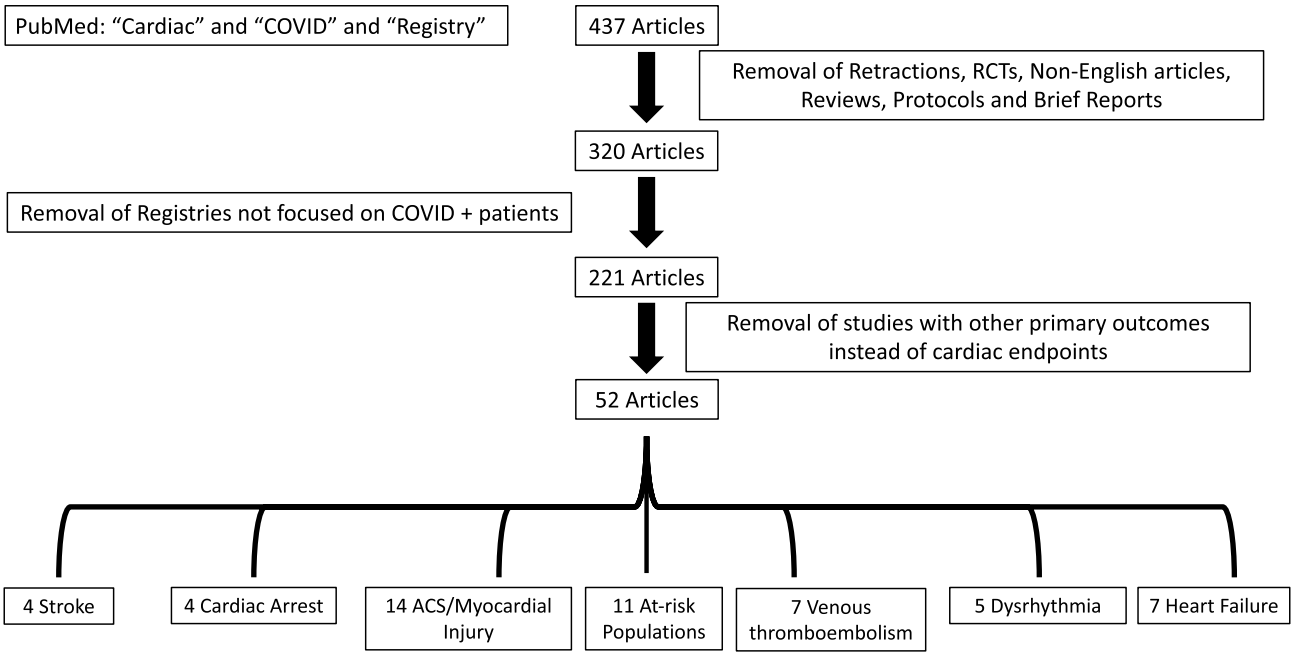

Fig. 1 Process of article selection and elimination. Of 437 identified manuscripts, 52 included manuscripts, 11 related to at-risk populations, 4 related to stroke, 5 to dysrhythmia, 4 to cardiac arrest, 14 to myocardial injury/acute coronary syndrome, 7 to venous thromboembolism, and 7 to heart failure

Rapid Dissemination of Information

From July 2020 to December 2021, the average time from last data point included to publication was 8.9 ± 4.1 months, with an increase in publication time towards December 2021 (R = 0.9444, $p < 0.0001$) (Fig. 2). The average number of months between the last data point collected and publication in the months of July to September 2020 was 2.8 ± 1.6 months, compared to 13.6 ± 4.2 months in October to December of 2021. These intervals are significantly shorter than typical intervals in standard registry publications in pre-pandemic times with examples from STEMI registries ranging from 54 to 186 months [9, 10].

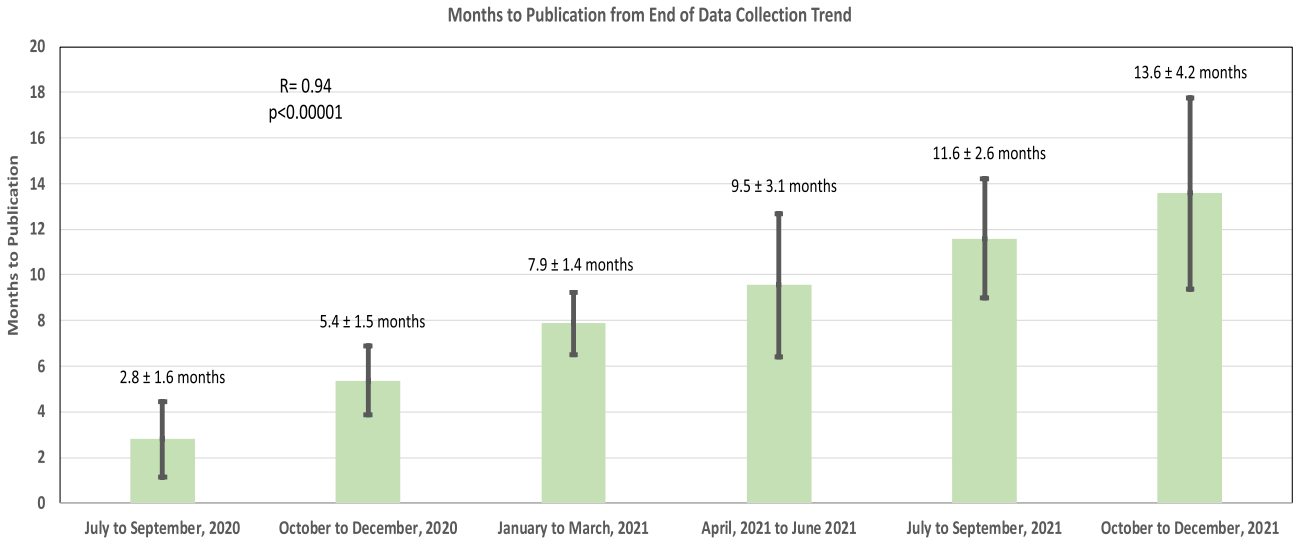

Fig. 2 Average months to publication following final data collection period. The publication rate over time increased during the course of the pandemic, although the current publication rate is still relatively rapid in comparison to pre-pandemic

ACS/Myocardial Injury

Based on 14 registries with 18–1310 patients with COVID-19 and ACS or myocardial injury, the North American COVID-19 Myocardial Infarction registry found that patients with COVID-19 and STEMI are more likely to be non-white and diabetic [11••]. Furthermore, patients with COVID-19 and STEMI have higher in-hospital mortality, have higher rates of cardiogenic shock, and are more likely to have no culprit lesions identified on invasive angiography as compared to STEMI patients without COVID-19 [11••, 12–15]. Patients with NSTEMI and COVID-19 are less likely to undergo invasive coronary angiography and PCI than patients with NSTEMI but without COVID-19, and they tend to have higher hospital admission and mortality rates than patients with COVID-19 and STEMI [14]. Finally, in contrast to increased prevalence of cardiogenic shock in patients with COVID-19 and STEMI, cardiogenic shock prevalence is not increased in patients with COVID-19 and NSTEMI [13].

Patients with severe COVID-19 admitted to the hospital have elevated C-reactive protein, D-Dimer, and troponins, which can increase risk of death or ICU admission [16]. Furthermore, elevated troponin levels appear to be associated with mortality in older and in intubated or severe patients with COVID-19 [17–19]. In hospitalized patients with COVID-19 and elevated troponin levels, 65.7% show left and/or right ventricular dysfunction by conventional and speckle tracking echocardiography [20]. Imaging studies suggest multiple mechanisms of injury to help describe the COVID-19 microthrombi pathway, including fibrosis, edema, myocarditis, elevated troponin, and elevated native T1 and T2 cardiovascular magnetic resonance imaging values [21–24].

Stroke

Four registries with 38–5761 patients with COVID-19 and stroke were included, with results showing that COVID-19-associated ischemic strokes are more severe with worse functional outcome and higher mortality than non-COVID-19 ischemic strokes [25••]. Furthermore, COVID-19 is a risk factor for ischemic stroke [26]. Those who suffer from ischemic stroke tend to be older with the median time between the onset of COVID-19 symptoms and diagnosis of stroke at 2 weeks [26, 27]. In one registry of patients with COVID-19 and stroke, intracerebral hemorrhage was common occurring in 15.2% [28].

VTE/Thrombosis

Seven registries with 49–2601 patients suggest that although asymptomatic patients with COVID-19 have elevated markers of thrombo-inflammatory activation (such as ferritin and D-Dimers) [29], this did not translate into higher rates of VTE in patients with COVID-19 compared to those without COVID-19 [30]. However, those with COVID-19 and prior oral anticoagulants had higher mortality than those not taking oral anticoagulants [31], with a potential benefit associated with antiplatelet use [32]. Critically ill patients with COVID-19 infection have a much more aggressive thrombotic profile. Close to 1 in 4 ICU patients with COVID-19 suffer from venous thrombotic events with up to 52% of these complications representing pulmonary embolism [30, 33–35].

Arrhythmias

Arrhythmias are more frequent in hospitalized patients who are older, male, and critically ill with COVID-19, with an incidence of 11.7 to 21.8% [36, 37]. These include sinus bradycardia, paroxysmal supraventricular tachycardia, and tachyarrhythmias—all of which have been associated with increased mortality in patients hospitalized with COVID-19 [36–40]. Repolarization abnormalities are also predictive of clinical outcomes [40]. Atrial fibrillation appears to be the most common arrhythmia, accounting for 62.5% of all reported arrhythmias [37], and is associated with an elevated in-hospital mortality as compared to patients with COVID-19 and no atrial fibrillation [36–40].

Cardiac Arrest

In-hospital CA occurs in approximately 5.9% of hospitalized COVID-19 patients. Up to 74% of these in-hospital cardiac arrests occur in ICU patients [41•]. Prior history of coronary artery disease, atrial fibrillation/flutter, cerebrovascular disease, hypertension, HF, chronic kidney disease [41•, 42, 43], and diabetes mellitus [43, 44] are major risk factors for patients with in-hospital CA. The 30-day mortality rate was lower among in-hospital CA patients than out of hospital CA patients with COVID-19 [44].

At-Risk Populations

While nearly 1 in 3 hospitalized patients with COVID-19 have a history of heart disease [45], there is heterogeneity in the strength of association between heart disease and in-hospital mortality [45–48]. Risk of mortality appears to range between 29.7 and 35.7% in hospitalized patients with COVID-19 and a history of CVD [45–47]. History of HF is independently associated with in-hospital mortality [45, 49, 50]. Patients with COVID-19 who were already on ACEIs/ARBs, β-blockers, glucocorticoids, and statins have a better survival rate compared to those not on these medications [49–54]. COVID-19 mortality in adults with congenital

heart disease was not greater than the general population and was increased in those with worsening physiologic stage as opposed to anatomic complexity alone [55•].

Heart Failure

Based on 7 registries with 40–12,226 patients hospitalized with COVID-19 and pre-existing CVD, 20% had HF [56•]. Patients with HF and COVID-19 were generally older [56•, 57–61] and had associated cardiovascular comorbidities [56•, 58–60] compared to those without COVID-19. Patients with COVID-19 and HF are more likely to require ICU admission [56•, 58, 59], more likely to require mechanical ventilation support or intubation [56•, 58–60], and have a higher in-hospital mortality than patients with COVID-19 and no heart failure [56•, 57–62].

Limitations

The majority of registry data come from hospitalized patients, with a paucity of data for outpatients with COVID-19. Observational patient data are mostly derived from the early phases of the pandemic, which can lead to selection bias as it fails to capture areas affected in subsequent waves. Some of the sample sizes in the abovementioned studies are small, with data gathered retrospectively potentially leading to bias.

Conclusion

To adequately understand and respond to this evolving COVID-19 pandemic, there is a need for a research platform that is flexible and modifiable, accommodates international collaboration, is cost effective, is not disruptive to essential health services, and has avenues for rapid dissemination. Registries can best serve this purpose. In less than 2 years, cardiac registries have taught us that patients with COVID-19 have a high chance of having underlying cardiovascular disease when hospitalized, have distinct clinical characteristics, and have worse hospital outcomes when presenting with ACS. Furthermore, these patients with COVID-19 have a high incidence of fatal stroke complications and pulmonary embolism when critically ill. Arrhythmias are not uncommon in this patient population, and along with heart failure, signalize worse outcomes compared to those without these features. We await with enthusiasm further publications from these registries as investigators seek to shed light into mechanisms and pathophysiology of disease to help us refine management.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s11886-022-01686-5.

Declarations

Conflict of Interest Dr. Garcia reports grants and personal fees from Edwards Lifesciences and Medtronic, personal fees from BSCI, and grants from Abbott Vascular, outside the submitted work. The other authors do not have anything to disclosure, including no relationship to industry pertaining to this manuscript.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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