

EDITORIAL

Value of Registries in ST-Segment–Elevation Myocardial Infarction Care in Both the Pre–Coronavirus Disease 2019 and the Coronavirus Disease 2019 Eras

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Expeditious coronary artery recanalization of the occluded infarct artery, either by fibrinolytic therapy or primary percutaneous coronary intervention (PCI), has been firmly established in the treatment of ST-segment–elevation myocardial infarction (STEMI) for >3 decades. The direct relationship between the paradigm of "time is muscle" with in-hospital and longitudinal mortality has been demonstrated in multiple randomized clinical trials and in observational registries, such as the NRM (National Registry of Myocardial Infarction), the ACC-NCDR (American College of Cardiology National Cardiovascular Data Registry), the CathPCI Registry, and the CP-MI (Chest Pain–Myocardial Infarction) registry, as well as in many international registries. Clinical practice guidelines for STEMI have focused on the promotion of STEMI systems of care. Both the American Heart Association and the ACC have aggressively advanced professional and patient education to minimize the "door-to-balloon (D2B)" time, the "door-to-needle" time, and the "symptom (pain) onset-to-balloon (P2B)" time to decrease myocardial necrosis occurring because of STEMI.^{1–3} "One cannot manage what one does not measure" describes the central role that MI registries have had in decreasing STEMI mortality throughout the world. Successful quality improvement initiatives, such as the Door-to-Balloon Campaign,⁴ have led to marked improvement in D2B times nationally, as demonstrated in

the NCDR CathPCI registry 2019 to 2020 report, which included data from >1750 hospitals representing >90% of PCIs performed in the United States.⁵ Greater than 94% of patients achieved D2B times of <90 minutes, with a median D2B time of 61 minutes in 121 740 patients with STEMI, representing 15.6% of the 709 494 PCIs performed in the United States. Of interest, 9% of all patients with STEMI had a documented "patient-centered" reason for delay in primary PCI, the most common being a 39% incidence of cardiac arrest or need for intubation before primary PCI. The NCDR Chest Pain–MI Registry report from the 2019 to 2020 time frame is populated with data from >780 US hospitals and offers important additional information related to STEMI care.⁶ The median time from symptom onset to hospital arrival was 96 minutes, with the median time from symptom onset to device activation of 162 minutes. Symptom onset to device activation ≤120 minutes occurred only 29% of the time.

See Article by Meisel et al.

In this issue of the *Journal of the American Heart Association (JAHA)*, Meisel and colleagues analyzed 4839 patients with STEMI, enrolled from 2004 to 2016

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in the ACSIS (Acute Coronary Syndrome in Israeli Survey) prospective biannual nationwide multicenter registry.⁷ This analysis adds important validating findings to the "time is muscle" paradigm in the already vast STEMI literature by demonstrating the relationship of P2B time with survival benefit both short-term and up to 5 years. D2B times were improved through the strategy of direct catheterization laboratory admission; bypassing the emergency department decreased the P2B time from a median of 210 to 160 minutes and decreased the D2B time from 75 to 35 minutes. Decreased ischemic time improved survival at 30 days and up to 5 years in an unadjusted analysis. The unadjusted survival advantage persisted after logistic regression and propensity matching when assessing P2B times, but not D2B times. The 5-year survivals for patients achieving P2B time <189 minutes admitted directly to the catheterization laboratory, transported to the emergency department by the emergency medical system, or self-transported to the emergency department were 87%, 85%, and 91%, respectively. When the P2B time exceeded 189 minutes, survivals decreased to 80%, 74%, and 81%, respectively ($P<0.001$). This registry report is limited by selection bias, temporal bias, and unmeasured confounders, but the conclusion that greater societal attention is needed to minimize "total ischemic time" is logical. In addition, there are inherent challenges in the measurement of P2B time. Accurate assessment of symptom onset is difficult, especially in high-risk patients with cardiogenic shock or cardiac arrest. Many patients have atypical or limited symptoms, in particular elderly, female, and patients with diabetes mellitus. We would discourage the use of the term P2B and prefer the term "symptom onset to balloon" because of these frequent atypical STEMI presentations and the inherent challenges in accurately determining time of "pain" onset. In addition, when patients recognize their ischemic symptoms, there may be reluctance to call 911 for a multitude of reasons, further delaying time to treatment.^{1,2} Finally, patients requiring transfer from non-PCI-capable hospitals clearly dramatically impact total ischemic time throughout the world.

This report does raise important questions. Are the ACSIS registry findings fully applicable in the United States when 80% of the ACSIS registry patients versus 64% of US patients were men, the average age was relatively young at 61.7 years compared with a median age of 66 years in US patients, and diabetes mellitus was present in 26% versus 36% of US patients? Have we reached the limit in lowering mortality rates with further reductions in D2B times? When patient risk is considered, most other analyses still support the association of lower mortality rates with lower D2B times.⁸ It is not clear whether patients with STEMI presenting with cardiogenic shock or out-of-hospital cardiac arrest are included in the ACSIS registry,

as they are in the CathPCI and CP-MI registries, and whether they were adjusted for in this analysis.

STEMI IN THE CORONAVIRUS DISEASE 2019 ERA

The timely management of STEMI in the coronavirus disease 2019 (COVID-19) era has led to new challenges for all STEMI systems of care. Recent reports demonstrate a decrease in STEMI admissions in Spain, Italy, and the United States.^{9–12} Hypotheses include the following: patients ignoring symptoms because they are afraid to seek care and risk potential hospital COVID-19 exposure; patients being less physically active during pandemic sheltering; less tobacco use; lower air pollution levels; and possibly even patient altruism ("I'm not as sick as those in hospital"). Substantial challenges also exist in our STEMI systems of care during the pandemic. These include atypical STEMI presentations and STEMI mimics, leading to misdiagnosis or poor triage decisions, delays in the timely assessment of patient's COVID-19 status, catheterization laboratory personnel availability, and other systems issues.^{12,13} These challenges all impede our ability in minimizing both D2B, and even more so, P2B times.

The NACMI (North American COVID-19 ST-Segment–Elevation Myocardial Infarction) registry has recently offered a snapshot of STEMI care in selected hospitals in Canada and the United States.¹⁴ Early findings from nearly 600 patients demonstrated higher in-hospital mortality with patients who are positive for COVID-19 compared with patients under investigation for COVID-19 (32% versus 12%). Both were substantially higher than propensity-matched patients with STEMI without COVID-19 from the Midwest STEMI Consortium (6%). Patients who are positive for COVID-19 were more likely to present with atypical symptoms and cardiogenic shock. Although initial evaluation from the NACMI registry showed similar D2B times, data from around the world suggest P2B times are prolonged in both patients with and without COVID-19, almost certainly contributing to the increase in both cardiogenic shock and mortality. The International study on acute coronary syndromes - ST-segment elevation myocardial infarction (ISACS-STEMI) COVID-19 registry recently reported on 6609 patients who underwent primary PCI in 77 centers, located in 18 countries.¹² Patients with STEMI who were treated in 2020 compared with patients in 2019 had significantly longer total ischemic times (median, 200 versus 180 minutes) and a slightly greater percentage of D2B times >30 minutes (57% in 2020 versus 52.9% in 2019). A significantly higher in-hospital mortality was observed in 2020 compared with 2019 (6.8% versus 4.9%). The association of longer delay to treatment and higher mortality, observed

during the pandemic, persisted after correction for major patient demographic and clinical factors and additional adjustment for COVID-19 positivity.

The NCDR CathPCI registry and its accompanying CP-MI registry now have in place an optional module focusing on COVID-19 data elements with the goal to understand the impact of COVID-19 presentation on urgent cardiovascular care. This COVID-19 module is now being used by >10% of CathPCI/CP-MI registry hospitals and will soon yield important findings related to US STEMI care during the pandemic. In addition, important monitoring of US STEMI process and performance measures will be instructive to guard against negative unintended consequences affecting STEMI care during the pandemic. The American Heart Association has also recently launched the COVID-19 CVD (Cardiovascular Disease) Registry through its Get With The Guidelines program. The American Heart Association's quality improvement registry focuses on cardiovascular outcomes in US hospitalized patients with COVID-19, offering real-time, granular data from short-term care hospitals to better help clinicians and researchers learn how to best treat patients with COVID-19 through the collection of multiple COVID-19-related descriptive and reporting measures. The ACC-NCDR recently suggested that payers using NCDR risk-adjusted performance measures, such as PCI mortality, should suspend pay-for-performance programs during the COVID-19 pandemic and appreciate that NCDR PCI mortality risk adjustment is based on pre-COVID-19 risk models. The NCDR continues to emphasize the collection and accountability of process measures, such as D2B and symptom onset-to-device times, although the NCDR acknowledges there will be additional reasons for "patient-centered delays" in calculating these process measures during the pandemic. The gold standard of "time is muscle" persists, yet the importance of achieving excellent P2B times and decreasing STEMI mortality, as demonstrated by our Israeli colleagues, may now become even more elusive in the COVID-19 era. Therefore, we must recommit to decreasing total ischemic time through patient education and continue to promote excellent prehospital and hospital systems of care.¹⁵

ARTICLE INFORMATION

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Disclosures

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