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Retraction of Studies on Potential Drug Therapies for COVID-19: A Call for Reliability and Scientific Integrity



The author of this paper recently discussed the findings on cardiovascular safety of the controversial use of chloroquine and hydroxychloroquine for the treatment of COVID-19 reported in observational studies, stressing the need of high quality large randomized controlled trials in order to assess the effectiveness and safety of these drugs and other potential therapies for COVID-19.¹ One of the commented studies,² which reported a decrease in the in-hospital survival and an increased frequency of de-novo ventricular arrhythmias with the use of chloroquine or hydroxychloroquine, was recently retracted by 3 of the 4 authors, causing controversy in the scientific community and raising serious concerns on the reliability of published papers and the transparency and accountability of researchers particularly in the midst of this global health crisis. The

reasons that lead the retraction of the aforementioned study as well as the analysis of other studies with implications for cardiovascular safety that have also been retracted or subjected to an expression of concern, are worthy of consideration.

In a recent comment, Mehra et al² stated that after an unsuccessful attempt to conduct an independent peer review of the database on which their findings were based, they can no longer assure the veracity of their conclusions thus, they requested the retraction of their publication. Likewise, a different study conducted by Mehra et al³ assessed the relationship of cardiovascular disease and drug therapy with in-hospital mortality among patients with COVID-19. In this study the authors reported no increased risk of in-hospital mortality associated with the use of angiotensin-converting-enzyme inhibitors and angiotensin-receptor blockers. However, in a subsequent letter the authors argued that they were unable to access to the raw data and the database was not available to a third-party auditor validation therefore, the authors asked for retraction of the paper.³ At this time, 15 studies about COVID-19 have been retracted, 2 temporarily retracted and 1 subjected to an expression of concern.⁴

The rush for showing results and publishing papers despite its lack of validation, as health professionals and patients desperately seek treatment options, illustrate the obvious need for strengthening the review process of papers for accuracy and reliability before publication and a call to follow the standards of the International Committee of Medical Journal Editors and the Committee on Publication Ethics. Considerations regarding veracity and scientific integrity are of utmost importance. As previously stated by the author of this paper, the current findings on efficacy and safety of the potential therapies for COVID-19 require validation from high-quality large randomized controlled trials.¹

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The Era of Point-of-Care Ultrasound Has Arrived: Are Cardiologists Ready?



Dear editor,

Point-of-Care Ultrasound (POCUS) has become a vital tool for bedside diagnosis and management in patient care. Accordingly, POCUS is becoming an important educational component in medical school and residency training programs. Although POCUS protocols can be generalized and involve multiorgan assessment, the fundamental component of bedside ultrasound assessment is cardiac POCUS, or similarly termed “focused cardiac ultrasound.” A recent publication by Kirkpatrick et al defined three forms of focused cardiac ultrasound: Ultrasound-assisted physical examination, cardiac POCUS, and critical care echocardiography.¹ However, with significant overlap between these forms of focused cardiac ultrasound, distinguishing between them may be of lesser importance from a practical standpoint.

Traditionally, the providers involved in obtaining and interpreting bedside cardiac POCUS have been predominantly non-cardiologists, including specialists in critical care medicine, emergency medicine, and anesthesia. This emphasis on cardiac POCUS by non-cardiologists is reflected by the increasing number of publications and training courses on cardiac POCUS, which are almost exclusively led by various non-cardiology professional societies.^{2,3} In particular, cardiac POCUS in the setting of critical care is increasingly perceived as its own entity with a separate term “critical care echocardiography.” In fact, critical care echocardiography has been advocated as an essential component of training and is

now officially acknowledged by the National Board of Echocardiography, which started to administer its first special competence examination in this imaging protocol beginning in 2019.

Although interest and training in POCUS has surged in the past decade, cardiologists have largely been at the periphery of this development, hesitant to adopt this concept. Perhaps this hesitancy stems from the concern that growth of bedside POCUS may encroach on the principal role of comprehensive transthoracic echocardiography (TTE) in cardiology training and practice, questioning if cardiologists are ready to participate and lead this field.

It is important to note that cardiac POCUS as a diagnostic modality is different than standard TTE. Although typical cardiac POCUS does not provide the advanced imaging features and hemodynamic data of TTE, it provides rapid evaluation and allows for rapid decision making, especially when standard TTE cannot be obtained or is not immediately available (Figure 1).^{1,4} This is particularly useful in the care of critically ill patients, including those in the cardiac intensive care unit, where cardiovascular specialists and trainees are pivotal providers of care. The role of cardiac POCUS has been more evident with the recent COVID-19 pandemic, given concerns for provider and equipment exposure.⁵ The potential for cardiac POCUS

can extend even beyond the acute care setting. In ambulatory cardiology practice, cardiac POCUS can augment the physical examination and inform cardiologists of critical information (e.g., left ventricular function, severity of valvular disease, and volume status) in a timely manner. With the advancement in technology allowing for more portable and intelligent devices, the logistics of performing cardiac POCUS is becoming even more feasible.

Increased adoption of cardiac POCUS by cardiologists will require a significant change in perception, as well as improved understanding of its practical applications and limitations. The performance of cardiac POCUS using newer devices adds minimal time to the patient encounter and provides instantaneous diagnostic information of high clinical value. However, a crucial issue is that the integration of cardiac POCUS into clinical practice would require cardiologists to become more hands-on with scanning and reduce reliance on sonographers and other support staff.

Despite the exciting opportunities that cardiac POCUS provides as a diagnostic tool, a number of challenges exist regarding this technology. One concern is that image misinterpretation may lead to omission of definitive testing or necessary procedures. The converse is also possible wherein misinterpretation of findings leads to unnecessary procedures, exposing

patients to excessive risk and increasing healthcare costs. In addition, while we believe that the responsible use of cardiac POCUS can be beneficial in cardiology practice, more research is necessary to study the impact on safety, quality of clinical care, and clinical outcomes. Another issue is that the healthcare economics associated with widespread adoption of cardiac POCUS remains unclear. However, it is encouraging that recent evidence from emergency medicine suggests that cardiac POCUS has the potential to provide substantial cost savings.⁶ Finally, the utilization of cardiac POCUS by various medical subspecialties has the potential to generate conflicts related to ownership, certification, and credentialing. These issues may prove incredibly challenging as providers and medical centers move toward reimbursement for performing cardiac POCUS in various settings.

Although we acknowledge that philosophical differences within cardiology has limited the widespread adoption of cardiac POCUS by cardiologists, it appears clear that the increasing clinical application of POCUS in medicine is reshaping the practice of cardiac imaging. We believe it is time for cardiologists play a more active role in leading cardiac POCUS education, certification, research, and clinical implementation, as well as in collaborating with other medical subspecialties in a concerted effort to improve quality of care.

Cardiac POCUS Domains

- **Structural** visualization and evaluation (assessment of chamber size, mass, pericardial effusion, obvious valvular abnormality)
 - **Functional** evaluation (estimation of ventricular function)
 - **Hemodynamic** measurement both static and dynamic after intervention (Estimation of atrial pressures, stroke volume, pulmonary artery pressure)*
- * If spectral doppler available

Cardiac POCUS Settings

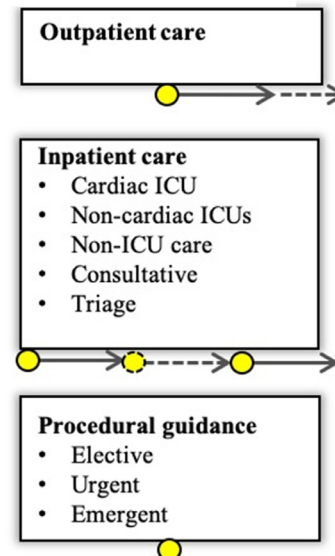


Figure 1. Cardiologist's application of cardiac POCUS. Yellow circle depicts potential timing of cardiac POCUS. Gray arrow highlights repeating nature of cardiac POCUS.

Disclosures

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Comparative Outcomes of Mitral Valve in Valve Implantation Versus Redo Mitral Valve Replacement for Degenerated Bioprostheses



Structural valve deterioration is the Achilles' heel of surgical bioprostheses.¹

It is estimated that >1/3 of patients receiving mitral valve replacement (MVR) with a bioprosthetic valve require MV re-intervention within 10 years.² Although redo-MVR has been the gold-standard strategy for degenerated bioprostheses, transcatheter mitral valve-in-valve (MViV) recently emerged as a feasible alternative to redo-MVR.³ However, comparative data of the 2 strategies are limited.⁴ We sought to compare outcomes of MViV versus redo-MVR using the National Readmission Database.

We used the International Classification of Disease 10th-Clinical Modification codes to identify patients age ≥50 years with structural valve deterioration (T82.01XA, T82.02XA, T82.03XA, T82.09XA, T82.221A, T82.222A, T82.223A, T82.228A, Z45.09, Z95.2, and T82.857) who underwent redo-MVR (02RG07Z, 02RG08Z, 02RG0KZ, and 02RG0JZ) or MViV (02RG37H, 02RG37Z, 02RG38H, 02RG38Z, 02RG3JH, 02RG3JZ, 02RG3KH, and 02RG3KZ) between January 1, 2016 and December 31, 2017. This method has been used in previous studies to identify re-interventions for degenerated bioprostheses.⁵ We excluded patients with infective endocarditis, patients with missing mortality data, and those who were transferred to another hospital to avoid duplication. The primary end point was in-hospital mortality. Secondary end points were in-hospital major adverse events (MAEs); a composite of death, vascular complications, acute kidney injury, or stroke; length of stay, cost, and 30-day readmissions.

Descriptive statistics were presented as frequencies with percentages for categorical variables. Medians and interquartile ranges (IQR) were reported for continuous variables. To account for differences in baseline characteristic, a nearest neighbor 1:3 variable ratio, parallel, balanced propensity-score matching model with a caliper of 0.01 was applied. Furthermore, we performed a sensitivity analysis by excluding patients who underwent concomitant valve surgery. Statistical analyses were performed using statistical package for social science (SPSS) version 26 (IBM Corp).

A total of 1,788 patients (MViV = 384; MVR = 1,404) were included in the current analysis. Patients who underwent MViV were older (76 years [IQR 68 to 82] vs 68 years

[IQR 61 to 75], $p < 0.01$) and had higher comorbidity burden (Table 1). After propensity-score matching, in-hospital mortality and MAEs were lower in the MViV group (5.3% vs 11.9%, $p < 0.01$), and (25.8% vs 44.1%, $p < 0.01$), respectively. Length of stay was shorter, and cost was less in the MViV group. However, 30-day readmissions were similar in the 2 groups (Table 1). In the sensitivity analysis, MViV remained associated with lower incidence of adjusted in-hospital mortality, but this did not achieve statistical significance (4.8% vs 8.0%, $p = 0.06$). However, adjusted MAEs continued to be significantly less with MViV (25.6% vs 40.0%, $p < 0.01$).

This study suggests that MViV for degenerated mitral surgical valves is associated with favorable short-term outcomes and resource utilization compared with redo-MVR. The results of this study need to be interpreted in the context of the known limitations of administrative databases which include: the potential for under- or over-coding; the lack of echocardiographic, hemodynamic, or angiographic information or details on surgical techniques; the limited ability to account for selection bias, and the lack of long-term follow-up data. Nonetheless, considering the low likelihood of randomized comparative data of MViV versus redo-MVR, this real-world observational study provides reassuring evidence supporting the short-term safety and cost-effectiveness of MViV as a primary strategy in selected patients with degenerated mitral bioprostheses.

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