Letter by O'Neill and Burkhoff Regarding Article, "The Evolving Landscape of Impella Use in the United States Among Patients Undergoing Percutaneous Coronary Intervention With Mechanical Circulatory Support"

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To the Editor:
Amin and colleagues\(^1\) accessed administrative claims data from the Premier Healthcare Database and used statistical tools to assess clinical outcomes in patients treated with mechanical circulatory support on the day of percutaneous coronary intervention. They concluded, after propensity score adjustment, that outcomes (death, stroke, and bleeding) were worse in patients treated with Impella than those treated with intra-aortic balloon pump (IABP). The topic of this article is of critical importance. However, we believe that detailed analysis illustrates important limitations of using claims data for this purpose. Most assuredly, analyses based on large claim databases can be useful for tracking treatment trends over time and assess variability of treatment practices. However, claims data that rely solely on administrative International Classification of Diseases (ICD) codes to characterize patient factors and clinical outcomes have obvious limitations and are prone to misclassification. For example, the authors’ claim of Impella use in less sick patients was based on a designation of “critically ill” defined as the presence of cardiogenic shock (CS) or mechanical ventilation, or post-cardiac arrest, without any supportive data. CS, which accounted for much of the difference between groups, is a broad category\(^2\) in which mortality varies dramatically according to The Society for Cardiovascular Angiography and Interventions subgroup, ranging from 3% in Stage A to 67% in Stage E.\(^3\) Thus, it seems inappropriate to apply the single diagnosis of CS to all patients, without adjudication, to classifying disease severity.\(^4\) Similarly, mortality rates after cardiac arrest and with mechanical ventilation also depend on many factors not available in the database. Sole reliance on ICD-9 and ICD-10 codes to compare acuity of illness in CS has not been validated, to our knowledge. Moreover, based on the baseline descriptors provided, there are many more high-risk features in the patients with Impella versus IABP, including age, diabetes mellitus, hypertension, heart failure, chronic renal failure, multivessel disease, bifurcation lesions, chronic total occlusions, and calcified lesions requiring atherectomy. The use of a statistical propensity adjustment strategy cannot overcome the lack of required granular hemodynamic and clinical data in comparing populations. Further to this point, how can a 33% use of bare metal stents in patients with IABP (Table 1) be accounted for, unless there was a high frequency of low-risk type A lesions in the IABP cohort? Exclusion of patients who received IABP first and transitioned to Impella could have also introduced bias into the analysis.

The inability to properly account for differences in baseline characteristics using an inadequate, unvalidated propensity scoring system raises questions as to the validity of comparing outcomes between groups. Given the challenges in performing high-quality studies in the settings of CS or assisted percutaneous coronary intervention in high-risk patients, wherein accurate conclusions can only be derived from granular accounting of patient, hemodynamic, laboratory, and anatomic variables, we should require a level of data scrutiny beyond retrospective

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administrative codes. Although the use of retrospective analysis of “big” claims data may be appealing, we believe that this study lacks the required data and adjudication needed to advance our understanding of mechanical circulatory support in CS or in the setting of percutaneous coronary intervention.

ARTICLE INFORMATION

Affiliations


Disclosures

Dr O’Neill is a consultant to Edwards Life Sciences and Abiomed. Dr Burkhoff reports an institutional grant and travel reimbursement from Abiomed, consulting with BackBeat Medical and Convia Medical, and equity interest in Impulse Dynamics.

REFERENCES


