[8] Ferraresi R, Centola M, Ferlini M, et al. Long-term outcomes after angioplasty of isolated, below-the-knee arteries in diabetic patients with critical limb ischaemia. Eur J Vasc Endovasc Surg 2009;37(3):336–42.
[9] Melillo E, Ferrari M, Balbarini A, Pedrinelli R. Transcutaneous oxygen and carbon dioxide levels with iloprost administration in diabetic critical limb ischemia. Vasc Endovascular Surg 2006;40(4):303–11.

## Letter by Bilazarian et al. regarding the article, "Adverse events and modes of failure related to Impella RP: Insights from the Manufacturer and User Facility Device Experience (MAUDE) database" by Khalid et al.

We read with interest the study by Khalid N et al. [1], reporting on the most common complications and failure modes with Impella RP based on analysis of the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. In this article, 35 medical device reports on Impella RP were identified between Jan 2009 and Dec 2018. Of the 35 MAUDE reports, commonly reported complications included bleeding ($n = 15$) and vascular complications ($n = 8$). Also, failure modes with Impella RP included fracture/damage of device ($n = 12$), thrombus in the device ($n = 6$), and device detachment ($n = 3$).

We have the following concerns:

1. It should be noted that the United States FDA approved the Impella RP for providing temporary support of right ventricular function in patients with right ventricular failure on Sep 20, 2017 [2]. Thus, the intent behind the query of the MAUDE database from 8 years before the actual approval of the device seems unclear.
2. Considering that likely several hundreds of Impella RP devices were implanted since Sep 20, 2017, and the 35 reports could include duplicate reports both by the user and the manufacturer, the overall incidence of patient complications and device failure modes with Impella RP is extremely low. Moreover, the FDA clearly states that the number of MDR reports cannot be interpreted to reach conclusions about the frequency or severity of problems associated with devices [3]. The authors themselves state that the complete analysis of the failure modes of Impella RP following the procedure could not be performed as only a minority of the devices were returned to the manufacturer. Given the limitations of the MAUDE database and the inability to establish the cause-and-effect relationship, we disagree with the conclusion by Khalid et al. that "the failure modes of the Impella RP device needs to be addressed to improve device performance and clinical outcomes."
3. A recent publication from the JACC scientific expert panel highlighted the dramatic increase in the use of VA-ECMO for cardiopulmonary failure since 2009 [4]. Despite the increased used of VA-ECMO during this time period and the reported rates of bleeding complications with VA-ECMO of about 60% [5], there are no reports on the complications rates or failure modes with VA-ECMO from the MAUDE database. Which begs the question of the appropriateness and intent of this analysis of the MAUDE database for the newly approved Impella RP devices.

Given that the MAUDE database was established to aid in the identification of complications associated with a new medical device not yet reported in the published literature [6], and the lack of a noteworthy finding of this study, we question the utility and validity of this study.

Seth Bilazarian*
William Bolt
*Abiomed, Inc., Danvers, MA, United States of America*
*Corresponding author at: Abiomed, Inc., 22 Cherry Hill Drive, Danvers, MA 01923, United States of America.
*E-mail address:* sbilazarian@abiomed.com (S. Bilazarian).

https://doi.org/10.1016/j.carrev.2019.04.020

☆ Conflict of interest: All authors are employees of Abiomed, Inc.

## References

[1] Khalid N, Rogers T, Shlofmitz E, Chen Y, Musallam A, Khan JM, et al. Adverse events and modes of failure related to Impella RP: insights from the Manufacturer and User Facility Device Experience (MAUDE) database. Cardiovasc Revasc Med 2019;20(6):503–6.
[2] Impella RP® System - P170011. Available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm581165.htm. Accessed April 9, 2019.
[3] MAUDE: Manufacturer and user facility device experience. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Accessed April 9, 2019.
[4] Guglin M, Zucker MJ, Bazan VM, et al. Venoarterial ECMO for Adults. JACC Scientific Expert Panel J Am Coll Cardiol 2019;73(6):698–716.
[5] Keebler ME, Haddad EV, Choi CW, et al. Venoarterial extracorporeal membrane oxygenation in cardiogenic shock. JACC Heart Fail 2018;6(6):503–16.
[6] Gurtcheff SE. Introduction to the MAUDE database. Clin Obstet Gynecol 2008;51(1):120–3.

## Response to the letter by Bilazarian et al. regarding the article, "Adverse events and modes of failure related to Impella RP: Insights from the Manufacturer and User Facility Device Experience (MAUDE) database"

We appreciate the comments by Bilazarian and Bolt [1] regarding our manuscript analyzing the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) reports of the Impella RP published in the recent issue of *Cardiovascular Revascularization Medicine* [2]. The Impella RP (Abiomed, Danvers, Massachusetts) received FDA approval for short-term right ventricular support on September 20, 2017; however, 13 reports were submitted to the MAUDE database before that date. The Impella RP system received the CE Mark in Europe on April 4, 2014, was in limited clinical use in Canada, under Health Canada's Special Access Program, and was tested in clinical trials in the United States (US) [3]. The MAUDE database reporting is worldwide and not limited to the US; therefore, our report included the totality of the available reports inputted into the database, including those preceding the FDA approval date for marketing, as they represent the initial operator experience with the device.

In the Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health, the FDA outlined a vision for enhancing device innovation and assuring safety. Some of the key elements of this plan include to "*establish a robust medical device patient safety net in the US, explore regulatory opportunities to streamline and modernize timely implementation of postmarket mitigations and spur innovation towards safer medical devices*" [4]. The FDA depends on several mechanisms for post-marketing surveillance and monitoring of long-term safety outcomes of devices. The MAUDE database is one of these mechanisms but has well-recognized inherent limitations including underreporting, lack of event adjudication, duplicate reporting, and inability to estimate the incidence of adverse events because of the lack of a denominator. We believe that, despite these limitations and in the absence of robust post-marketing studies, the MAUDE database is a helpful source to identify the types and trends of device adverse events in real-world clinical practice. Reports from the MAUDE database have been useful in fostering awareness among physicians and patients on the myriad adverse events and malfunctions of a wide variety of devices, including drug-eluting stents, inferior vena cava filters, transcatheter aortic valves, guide extension catheters, and percutaneous left ventricular assist devices [5–10]. With the lack of systematic post-marketing studies, the MAUDE database is the only tool to inform publicly on these events related to the devices.

Bilazarian and Bolt question the utility of our study. However, as already stated in our study, the totality of the events is not reported, as there is no available denominator of the Impella RP used in the market. Therefore, our study details only proportions of reported complications and not incidence rates [2]. Interestingly, most