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► **To cite this version:**

Flavien Vincent, Eric van Belle, Sophie Susen. Letter by Vincent et al Regarding Article, “The Evolving Landscape of Impella Use in the United States Among Patients Undergoing Percutaneous Coronary Intervention With Mechanical Circulatory Support”. *Circulation*, 2020, 142 (6), 10.1161/CIRCULATIONAHA.120.045522 . hal-04372032

HAL Id: hal-04372032

<https://hal.science/hal-04372032v1>

Submitted on 4 Jan 2024

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Letter by Vincent et al Regarding Article, “The Evolving Landscape of Impella Use in the United States Among Patients Undergoing Percutaneous Coronary Intervention With Mechanical Circulatory Support”

Flavien Vincent, Eric Van Belle and Sophie Susen

To the Editor:

We read with great interest the work of Amin et al¹ on the nationwide experience of mechanical circulatory support (MCS) with Impella in percutaneous coronary intervention in 48 306 patients at >400 hospitals in USA between 2004 and 2016.

Compared with the intra-aortic balloon pump, Impella was associated with higher adverse event rates including higher in-hospital mortality and major bleeding. These findings drawn retrospectively from the administrative Premier Healthcare Database (representing only a fraction of patients implanted with Impella in the United States) must be carefully interpreted, because the meticulous propensity-scoring analysis improved the comparability between the groups but cannot rule out potential unmeasured confounding. However, these results have been recently confirmed by a study following the same methodology exclusively in patients in cardiogenic shock and undergoing percutaneous coronary intervention for acute myocardial infarction.² Together, these studies highlight a signal that should not be ignored.

The bleeding risk observed is obviously multifactorial in such high-bleeding-risk patients requiring large bore access for MCS implantation and concomitant anticoagulant treatment. However, this study is a reminder that continuous-flow designed pumps like Impella, contrary to the intra-aortic balloon pump, rely on the continuous high-speed rotation of an impeller that has 2 major effects on the blood flow: a diminution of arterial pulsatility and the generation of high shear-stress forces. These latter produce a defect of the most potent multimers of a main primary hemostasis protein, the von Willebrand factor. Also known as acquired von Willebrand syndrome, it has been associated with an increased bleeding frequency in high shear conditions.^{3,4} These 3 phenomena (loss of pulsatility, high shear, von Willebrand factor defect) are intimately related, given that the preservation of pulsatility under Impella has been shown to mitigate the von Willebrand factor defect.⁵ This has potential important clinical consequences as observational studies have demonstrated that high-pulsatile heart-mate II recipients were less prone to bleeding events.³

The work of Amin et al did not include biological end points, which precludes further conclusions on the association between the disturbance of hemostasis and bleeding events. However, this study adds to the plethoric literature on the high number of nonsurgical bleeding events observed in patients requiring various short- and long-term MCS including

extracorporeal membrane oxygenation and Heartmate.³ These bleeding events occur in almost 50% of patients and strongly impact quality of life and survival and reduce the cost-effectiveness of these treatments.

Overall, bleeding complication appears once again as the main pitfall of MCS devices. The hemodynamic efficacy of Impella has been demonstrated, and many clinicians have experienced life-saving rescue that could have not been possible without this device. We certainly should not remove this tool from our catheterization laboratory, but we must optimize our use of this technology by adopting the best practice in large bore access management while increasing our understanding of the device's effects on blood components for hemostasis including von Willebrand factor. A win for the heart should not be lost at the groin. This study should be received as a call both for specific training before use of MCS devices and for further research on their hemocompatibility.

Disclosures

This work was supported by a grant from the French Ministry of Health and the Agence Nationale de la Recherche - 17-RHUS-0011. Dr Vincent received research grants from Fédération Française de Cardiology and from Lille University Hospital. The other authors report no conflicts.

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