Study aims to assess bleeding complications in patients undergoing high-risk percutaneous coronary interventions

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A new multi-center, single-arm, open-label study is the first to

exclusively assess bleeding complications in patients undergoing high-risk percutaneous coronary interventions (PCI) with Impella with independent adjudication via a clinical events adjudication committee and will gather meaningful real-world data based on contemporary practice. The design and rationale of the study was published online in the *Journal of the Society for Cardiovascular Angiography & Interventions*.

Nearly one in every five patients will experience a bleeding complication during a large-bore endovascular procedure. Periprocedural bleeding is the most common complication in patients undergoing PCI and is associated with a significantly increased risk of mortality, morbidity, and cost.

The Design and Rationale of the Safe Surveillance of PCI Under Mechanical Circulatory Support with the Saranas Early Bird Bleed Monitoring System (SAFE-MCS) study evaluates the safety of complex high-risk PCI using the Impella Heart Pump in conjunction with the Saranas Early Bird Bleed Monitoring System (EBBMS).

The study will enroll a total of 184 evaluable subjects at up to 15 U.S. centers. Evaluable subjects are defined as all participants who had EBBMS placed ipsilateral to mechanical circulatory support and had post-procedure monitoring with EBBMS for a minimum of two hours.

The Saranas EBBMS includes a bleed detection array with integrated electrodes in a fully functional vascular access sheath. It is designed to measure changes in bioimpedance to detect and monitor bleeding from vessel injury.

The primary clinical endpoint is the incidence of access site-related Bleeding Academic Research Consortium (BARC) type III or V bleeding. Secondary clinical endpoints include the incidence of each

Saranas EBBMS level 1, 2, and 3 indicators, and the incidence of all BARC type III or V bleeding.

The study authors note that in addition to the main clinical study, data from the SAFE-MCS study will also be used to perform an economic analysis of the potential economic benefit of the Saranas EBBMS.

"SAFE-MCS is the first study dedicated to evaluating bleeding events post-Impella use and will bring meaningful important insight on the rates of bleeding events during those procedures. While most of the studies on MCS devices focus on efficacy outcomes, SAFE-MCS focuses on safety and risk mitigation, and outcomes which are very important for patients, care givers, and the healthcare system in general," stated Dr. Philippe Généreux, MD, from Gagnon Cardiovascular Institute at Morristown Medical Center, New Jersey, lead author, and co-principal investigator of the study.

Généreux noted that while this study focuses on stable patients undergoing high-risk PCI, the role of early bleeding detection is even more important in an emergency such as cardiogenic shock, ST-elevated myocardial infarction, and during ECMO initiation.

"Timely identification of bleeding events is crucial in preventing adverse events that can have serious consequences for patients. The data from SAFE-MCS will provide meaningful guidance on how real-time monitoring can improve clinical outcomes through a proactive approach to managing bleeding risk," said Dr. Babar Basir, Director of Acute Mechanical Circulatory Support at Henry Ford Health System, and co-principal investigator of SAFE-MCS.

Authors note that the study is anticipated to finish enrollment by the end of 2023.

More information: Design and Rationale of the Safe Surveillance of PCI Under Mechanical Circulatory Support with the Saranas Early Bird Bleed Monitoring System (SAFE-MCS) Study, *Journal of the Society for Cardiovascular Angiography & Interventions* (2023). doi.org/10.1016/j.jscai.2023.101049