Pulsatile left ventricular assistance in high-risk percutaneous coronary interventions: short-term outcomes

Josko Bulum, MD PhD [1§], Marcelo B. Bastos MD MHSc [2*§], Ota Hlinomaz MD, PhD, FESC [3], Oren Malkin [4], Tomasz Pawlowski, MD, PhD [5], Milan Dragula MD [6] and Robert Gil MD PhD [7]

1. University Hospital Center Zagreb, Zagreb, Croatia
2. Thoraxcentrum, Erasmus Medical Center, Rotterdam, The Netherlands
3. International Clinical Research Center, Dpt. of Cardiology, St. Anne University Hospital and Masaryk, University School of Medicine, Brno, Czech Republic
4. PulseCath BV, Arnhem, The Netherlands
5. Department of Cardiology, National Institute of Medicine, Warsaw, Poland
6. Department of Cardiology, University hospital in Martin, Martin, Slovakia
7. Department of Cardiology, National Medical Institute of the Internal Affairs and Administration Ministry, Warsaw, Poland

* Correspondence: author；Phone: +31 10 7035260

§ Shared First Authorship

Abstract: Objectives: To document the real-world experience with the use of pneumatic-pulsatile mechanical circulatory support (MCS) with the PulseCath iVAC2L during high-risk percutaneous coronary interventions (HR-PCI).

Background: The use of MCS in HR-PCI may reduce the rate of major adverse cardiovascular events (MACE) at 90 days. The PulseCath iVAC2L is a short-term pulsatile transaortic left ventricular (LV) assist device that has been in use since 2014. The iVAC2L Registry tracks its safety and efficacy in a variety of hospitals worldwide.

Methods: The iVAC2L Registry is a multicenter, observational registry that aggregates clinical data from patients treated with the iVAC2L worldwide. 293 consecutive cases were retrospectively collected and analyzed. Estimated rates of in-hospital clinical endpoints are described. All-cause mortality was used as the primary endpoint and other outcomes of interest were used as secondary endpoints. The rates obtained are reported and contextualized.

Results: The in-hospital rate of all-cause mortality was 1.0%, MACE was 3.1%. Severe hypotension occurred in 8.9% of patients. Major bleeding and major vascular complications occurred in 1.0% and 2.1%, respectively. Acute myocardial infarction occurred in 0.7% of patients. Cerebrovascular events occurred in 1.4% of patients. Cardiac arrest occurred in 1.7% of patients. A statistically significant improvement in blood pressure was observed with iVAC2L activation.

Conclusions: The results of the present study suggest that the iVAC2L is capable of improving hemodynamics with a low rate of adverse events. However, confirmatory studies are needed to validate these findings.