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Magenta Elevate: The Beginning of a New Era in Protected PCI?

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Funding: The authors received no specific funding for this work.

ABSTRACT

The Magenta Elevate (Magenta Medical Ltd.) pump—a novel transvalvular percutaneous ventricular assist device—was tested in the first-in-human study at the Israeli-Georgian Medical Research Clinic 'Helsicore' in Tbilisi, Georgia. Results on 14 patients undergoing high-risk percutaneous coronary intervention suggested a promising safety and efficacy profile. Characterized by a low profile, percutaneous insertion, and a self-expandable pump, the Magenta Elevate pump holds promising venues for the implementation of mechanical circulatory support in a wide range of patients.

For many patients in need of myocardial revascularization, impaired left ventricular function precludes safe coronary artery bypass graft surgery. Instead, these patients are referred for less-invasive strategies, such as percutaneous coronary intervention (PCI), aka stents. In high-risk patients, mechanical circulatory support can facilitate such interventions by avoiding prolonged hypotension and ultimately maintaining both adequate coronary flow and end-organ perfusion. On December 23, 2024, researchers from the Israeli-Georgian Medical Research Clinic 'Helsicore' (Tbilisi, Georgia) published results in *JACC: Cardiovascular Intervention* from the first-in-human study (i.e., ELEVATE-I) to evaluate the safety and utility of the Magenta Elevate system (Magenta Medical Ltd.) in patients undergoing high-risk PCI [1].

The Magenta Elevate system is novel because of its low profile and ability to expand after introduction. The impeller is comprised of a thin shape-memory metallic frame and soft elastic blades. When crimped for introduction, the impeller is elongated and decompressed to a 9Fr diameter. The system is deployed via standard percutaneous technique and placed over a wire into the left ventricle. Once positioned, the impeller is unsheathed and expands by nearly 3.5× to a 30Fr system. The pump is able to deliver > 5 L/min. In the ELEVATE-I study, 14 high-risk patients—defined by a left ventricle ejection fraction ≤45% and at least 1 of the following: (i) intervention on an unprotected left coronary artery; (ii) intervention on a last patent coronary vessel; or (iii) presence of three-vessel disease—underwent preprocedural implantation of the Magenta Elevate system. The pump was successfully delivered, deployed, utilized, and removed in all 14 patients, without major complications (i.e., hypotensive episodes, need for pharmacological hemodynamic support, abrupt drops in pump flow, arrhythmia occurrence and hemolytic events) [1]. This system, which is designated for high-risk PCI and hospitalized patients in cardiogenic shock, has demonstrated early safety and feasibility and may join the armor of devices utilized in "protected PCI." The concept of "protected PCI" has been extensively investigated and facilitated by several devices, including intra-aortic balloon pumps (IABP), veno-arterial extracorporeal membrane oxygenation (V-A ECMO), and microaxial pumps such as the Impella device (Abiomed, Denver, USA), to mitigate the inherent periprocedural risk associated with high-risk PCI [2].

The IABP was first described in 1967 and entails a pulse-synchronized inflating balloon positioned in the descending aorta. Balloon inflation during diastole increases mean arterial pressure, while its deflation in systole is able to allow for both unloading of the left ventricle and an increase in cardiac output. When combined, these aforementioned hemodynamic changes

result in an increase in both coronary and systemic perfusion. In 2010, the BCIS-1 trial evaluated the efficacy of IABP in preventing the occurrence of major cardiovascular and neurological adverse events during high-risk PCI [3]. However, it failed to detect a difference in these events between patients treated with IABP and those who were not—although a significant reduction in long-term mortality and intraprocedural hypotensive events was found to occur in the former group. Subsequently, a meta-analysis of 11 trials published in 2013 did not demonstrate a clear beneficial effect of a preplanned IABP use (as opposed to a bail-out strategy) in high-risk PCI. Consequently, this device is currently not recommended as a form of circulatory support in high-risk PCI. Similarly, V-A ECMO has scarce data on high-risk PCI, and the first-line use of this device is currently not recommended.

In 2008, Impella was released in the United States and in 2012 in Europe. It is a microaxial flow pump, inserted into a large artery and advanced—under fluoroscopic guidance—into the left ventricle across the aortic valve. Once in place, the pump actively transfers blood from the left ventricle into the ascending aorta, thus generating a flow of up to 5 L/min and simultaneously providing an effective unloading of the left ventricle. The PROTECT II trial compared Impella and IABP in high-risk PCI, and the findings favored the Impella device in terms of long-term major adverse events and intraprocedural hypotensive episodes.

However, the quest for the ideal mechanical circulatory support device in the field of high-risk PCI still persists as a hot and highly debated topic, given the inherent limitations of Impella devices (i.e., the surgical insertion required for Impella 5.0, hemolysis, risk of limb ischemia, arrhythmias, and embolic events). Therefore, in order to optimize patient outcomes, a low-profile, percutaneous system able to provide full circulatory support while minimizing hemolysis and vascular complications would be ideal. In this light, the Magenta Elevate pump holds promising venues.

Its ability to expand from 9 to 30Fr allows both for a smooth percutaneous insertion and to minimize hemolysis, while its inherent mechanical features make it a load-dependent device. This implies that even at full support and with a closed aortic valve, the idle left ventricle contractions are converted into usable hydraulic power, thus maintaining a certain degree of aortic pressure pulsatility. Moreover, this mechanism plays an important role in the rate of suction events, which were not observed in the ELEVATE-I trial. The load-dependency of the pump grants a self-limitation of pump flow at any given revolutions per minute during the restoration of native hemodynamics (typically, after relief of coronary obstruction), in turn preventing excessive unloading of the left ventricle and thus suction events.

While these early results are encouraging, they are just the beginning. Larger studies are already planned to confirm the device's safety and effectiveness, and we are eagerly awaiting their results. If the Magenta Elevate pump lives up to its promise, it would constitute a great addition to the existing family of mechanical circulatory support devices currently employed in protected PCI, and it also shows promise to expand its scope to the context of cardiogenic shock as well. This device may gain more traction in light of the results of the DanGer Shock trial, which demonstrated a benefit in mortality rates with Impella CP in patients with myocardial infarctions complicated by cardiogenic shock, albeit having a higher risk of limb ischemia, severe bleeding, and acute kidney injury [4]. The smaller insertion profile of the Magenta Elevate device with maintenance of comparable pump output could decrease the rate of limb ischemia and vascular adverse events, thus further expanding the benefits of mechanical circulatory support in the setting of cardiogenic shock.

Author Contributions

Jacopo D'Andria Ursoleo: conceptualization, supervision, investigation, data curation, writing – original draft and writing – review and editing. **Aakash Manish Shah:** investigation, data curation and writing – review and editing. All authors have read and approved the final version of the manuscript.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Further information is available from the corresponding author upon request.

Disclaimer

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