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Novel Percutaneous LVAD Wins CRT 2024 Best Innovations Competition

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A novel mechanical circulatory support device that is delivered through a 10-French sheath that is expanded once implanted in the left ventricle won CRT 2024's Best Innovations Competition on Monday.

David Israeli, MD, the CEO of Magenta Medical Ltd., the company that is developing the device, gave the winning presentation.

He said the pump can be delivered through a commercially available 10-French introducer sheath using the femoral artery. Once the 9-French pump head is placed in the left ventricle and unsheathed, it is self-expandable to its full 30-French size.

Israeli emphasized the safety of the lower-profile delivery of the pump. The diameter of a typical human femoral artery is 9.2 mm. A 10-French introducer sheath takes up a small fraction, leaving plenty of room in the vessel, as compared to a 14-French introducer, which takes up about a quarter of the artery diameter, or a 23-French introducer, which takes up most of the artery diameter.

The pump's core technology, he said, is a helical nitinol frame, which allows for complete folding, enabling the low profile when it is being implanted.

Once implanted, the Elevate pump allows for a peak flow of 8.4 L/min, which is higher than the commercially available Impella 5.5 (Abiomed), which has a peak flow of 5.2 L/min. Elevate also has a higher mean flow (5.4 L/min) than Impella 5.5 (4.6 L/min), Israeli said.

He added that the Impella 5.5 is implanted with a 23-French introducer sheath.

Percutaneous left ventricular assist devices such as the Impella devices currently have two approved indications in the U.S.:

- High-risk percutaneous coronary intervention (PCI) for up to 6 hours in the presence of triple-vessel disease, the last patent conduit and unprotected left main, or when there is risk of hemodynamic instability during or immediately following PCI; and
- Cardiogenic shock, for 4-14 days, depending on the model, in almost any low cardiac output state.

The device has been evaluated in a first-in-human study, in 15 patients undergoing high-risk PCI in Tblisi, Georgia, and a U.S. early feasibility study in 18 patients in the New York metropolitan area.

In these two studies, Israeli said, there were no hypotensive episodes, no device-related adverse events, no clinically meaningful hemolysis, and no device stoppage or need for replacement. He added that all patients were alive and well and completed 30-day follow-up, with no major adverse cerebrovascular or cardiovascular events.

When he was asked what comments he has received from the U.S. Food and Drug Administration so far, he declined to elaborate for competitive reasons.

"I can tell you that they are extremely supportive of the effort and are providing very specific feedback about what they want to see, and it's also very consistent with what we would like to deliver," Israeli said.

Two studies are planned: a U.S. pivotal study in patients undergoing high-risk PCI, and a first-in-human study in patients experiencing cardiogenic shock.

The Best Innovations Competition featured 12 entries. The top three were recognized.

Elena Amin, MD, a pediatric interventional cardiologist and assistant professor of pediatrics at the University of California, San Francisco, won second place for her presentation, “Intellistent Pioneering Innovation Transforming Treatment Strategies for Pediatric Pulmonary Arterial Hypertension and Dilated Cardiomyopathy.”

Eyal Baror, the CEO of Innovalve, won third place for his presentation, “Innovalve TMVR: Clinical and Anatomic Outcomes.”

Photo Credit: Michael Kress

Photo Caption: David Israeli, MD, the CEO of Magenta Medical Ltd., (center) stands with CRT 2024 Course Chairman Ron Waksman, MD, of MedStar Washington Hospital Center (left) and Steven R. Bailey, MD, of LSU Health Shreveport, Louisiana. Dr. Israeli won the Best Innovations Competition on Monday with his entry, “Magenta Elevate™: High-Output, Low French Size Percutaneous Mechanical Circulatory Support.”

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