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Pi-Cardia's Leaflex treatment improves aortic stenosis more than balloon valvuloplasty

By Annette Boyle, Staff Writer

Pi-Cardia Ltd.'s Leaflex Performer catheter increased aortic valve area and showed hemodynamic improvement post treatment that was "significant and substantially greater than has been previously reported with balloon

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valvuloplasty," according to the company. Results of the Rehovot, Israel-based company's first-in-human trials for the Leaflex Performer, a transfemoral catheter designed to treat aortic stenosis, were presented at the European Association of Percutaneous Cardiovascular Interventions in Paris on Wednesday.

The study included 16 patients, all of whom planned to proceed to transcatheter aortic valve replacement (TAVR). Imaging showed a mean increase in aortic valve area from 0.7cm^2 to 1.2cm^2, a change which took patients from severe to moderate aortic stenosis, according to Pi-Cardia CEO and Founder
Erez Golan. Previous studies have shown that balloon aortic valvuloplasty or valvotomy (BAV) increased aortic valve area from 0.5 cm^2 to 0.8 cm^2.

Trans-esophageal and trans-thoracic echo imaging taken before and after the procedure also demonstrated "clear improvement in leaflet mobility," Golan told *BioWorld MedTech*. Hemodynamics improved substantially following treatment, with a reduction in mean pressure gradient from 34 mmHg to 18 mmHg based on trans-esophageal and trans-thoracic echo imaging.

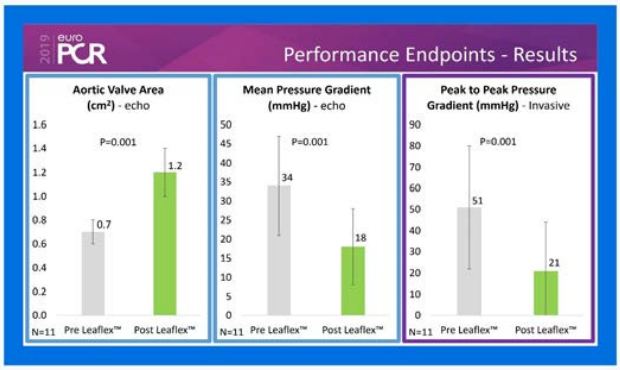
"We were really happy to learn that a safe and simple procedure that takes less than 20 minutes can produce such a dramatic effect on valve function without leaving an implant behind," said Peter Andreka, co-principal investigator and head of the department of Adult Cardiology at Gottsegen Hungarian Institute of Cardiology.

Of the 16 patients, one died within 30 days of non-cardiac causes unrelated to the procedure and two had strokes within 30 days, one a result of a prolonged procedure and the other following emergency surgery for left ventricle perforation. One patient experienced aortic regurgitation and two had conduction disturbances.

Before surgery or standalone procedure

The Leaflex Performer uses two mechanical structures that score valve calcifications at multiple locations to restore leaflet flexibility and improve valve hemodynamics. The catheter is

Leaflex Performer Catheter, Pi-Cardia Ltd.



designed to be used in patients with heavily calcified aortic valves prior to surgical aortic valve replacement (SAVR) or TAVR or in a standalone procedure.

Golan told *BioWorld MedTech* that the "most obvious group of patients" to benefit from the procedure are those "where TAVR is either excluded or of questionable benefit for the patient, patients with short life expectancy or significant comorbidities, patients who need a bridge to a future TAVR or SAVR and patients where the reason for symptoms needs to be verified."

In the study presented at EuroPCI, patients received TAVR immediately after Leaflex treatment. Pi-Cardia will report results of another study later this year where Leaflex was used prior to SAVR and plans to begin studies of the treatment as a standalone procedure "in a few months," Golan said.

Expanding patient base

"We plan to expand the patient population into younger patients with severe aortic stenosis as a means to defer the need for TAVR or SAVR," he noted. "Deferring valve implantation can be beneficial for young patients since they may not need a second or third valve in the course of their lifetime."

Further in the future, the company may study use of the catheter in an even broader group of patients for whom treatment is not currently available.

"We may think about intervening earlier in patients with asymptomatic disease, so they may never progress to become symptomatic. If we really want to be provocative, this can lead to a paradigm shift of first offering a more conservative, less invasive, non-implant-based approach," Golan added.

That potential paradigm shift could change who receives TAVR or SAVR and outcomes for those procedures. If aortic valve replacement is performed "only in cases where valve replacement is the only option, it can be performed on the most suitable patients," he noted.

On a standalone basis, the Leaflex procedure, which is planned to be a lower cost alternative to SAVR, could find a significant market.

"There are many countries, including countries in Western Europe, Eastern Europe, Canada, China, India, South America and elsewhere, where the health care system defines a limit to the TAVR budget, or where TAVR is not reimbursed at all,"

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Golan said. “In these countries, we see waiting lists for TAVR, or patients receiving suboptimal treatment. Leaflex may offer health care systems in these countries an immediate means to treat patients at a lower cost.”

TAVR market

Pi-Cardia’s plans put the company in line to benefit from expected rapid growth in the TAVR market – and from potential pushback from surgeons wary of expanding the procedure to non-high-risk patients.

Valued at $3.13 billion to $3.67 billion in 2018, the market for TAVR is expected to exceed $10 billion and potentially reach more than $12 billion by 2025, with much of the growth driven by procedures in lower-risk patients.

Despite the rosy projections, several SVB Leerink surveys have found surgeons more concerned about the durability of the procedure in intermediate-risk patients and less of a backlog of patients than expected. As all bioprosthetic valves eventually fail, Pi-Cardia hopes to step in to offer an option for younger, lower-risk patients to delay TAVR and avoid subsequent valve replacement. ♦