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Ancora Heart sees positive early results with Accucinch in systolic heart failure

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Ancora Heart Inc., a Santa Clara, Calif.-based company looking to help those with heart failure, is heralding results from an interim analysis of patients treated in a U.S. early feasibility study evaluating the safety of the investigational Accucinch ventricular repair system.

The multicenter, nonrandomized, prospective study is assessing the system in patients with symptomatic heart failure and concomitant functional mitral regurgitation (FMR) who have stable symptoms on guideline-directed medical therapy.

“Early safety and efficacy data on the transcatheter Accucinch system is impressive and suggests the therapy has the potential to repair the left ventricle, improve heart function, and restore the quality of life for heart failure patients,” said Satya Shreenivas, interventional cardiologist at The Christ Hospital Heart and Vascular Center and The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital.

The results were presented last week at the Transcatheter Cardiovascular Therapeutics 2019 conference in San Francisco.

Endpoints, results

Enrollment in the Corcinch FMR study recently wrapped up, with 35 patients being treated with the Accucinch at 15 heart centers. The primary safety endpoint of the study is device- related or procedure-related major adverse events through 30 days. Other endpoints included technical success, device and procedural success, as well as other observational endpoints measuring heart function, heart failure symptoms and changes in quality of life.

When looking deeper at the data, there was a 97% freedom from device-related major adverse events at 30 days. In addition, efficacy data from the first nine patients treated with the latest implantation technique and with adjudicated core lab data available through six months demonstrated a reduction in left ventricular volume by an average of 23%.

In addition, ejection fraction improved, on average, from 31% to 39% over the same period. Additionally, Kansas City Cardiomyopathy Questionnaire scores rose by an average of about 30%, suggesting reducing the left ventricular volume resulted in improved quality of life and reduced heart failure symptoms.

A different approach

Earlier this year, the FDA granted approval to Abbott Laboratories for its Mitraclip device used to repair a leaky mitral valve without open-heart surgery. It was the first transcatheter mitral valve intervention therapy approved to treat select heart failure patients with clinically significant FMR.

The Mitraclip system initially was indicated to reduce mitral regurgitation in certain patients whose significant mitral regurgitation and heart failure symptoms result from abnormalities of the mitral valve and whose risks for mitral valve surgery are prohibitive.

So what differentiates Ancora Heart's offering from Mitraclip?

"I think . . . the differentiation is Mitraclip is focused on the actual valve and the FMR problem," Jeff Closs, president and CEO of the company, told BioWorld MedTech. "But, fundamentally, all of those patients have heart failure – they have systolic reduced ejection fraction heart failure. And what happens is the ventricle dilates . . . [meaning] the patients obviously develop symptoms of heart failure, but then they can also develop FMR . . . because of that."

He noted that his company's approach is different in that it is targeting the heart failure component. "We think about FMR as just one indication. Our broader, larger indication is actually patients who have significant heart failure symptoms [who] have been treated with drugs . . . and been optimized under medical management but yet still have significant heart failure symptoms and a declining quality of life. That's really the patient population that our technology is targeted at."

He noted that the market and clinical opportunities for reduced ejection fraction heart failure patients – the company's overall target – is 10 times bigger.

Closing the gap

When asked if anything surprised him or stood out from the study, Closs noted that as far as he knew, his company is the only one to have percutaneous technology that is a direct left ventricular therapy in clinical studies addressing this clinical gap.

He also was struck by the company's capability to reduce the size and the volumes of the ventricle post-procedure. "But what's really interesting and exciting for us is that when we follow [the patients] over time, the ventricles continue to improve over the follow-up period." That means there is a "biological kickstart and a biological remodeling that putting our device in actually enables to happen." That leads to a boost in contractility and function of the heart.

In terms of being able to go to the FDA, Closs noted that his company has three early feasibility studies in the U.S. The company is assessing its technology in patients with symptomatic heart failure, those who have gone on to develop FMR, as well as those who have had a Mitraclip or surgical annuloplasty repair of the valve but continue to experience significant heart failure symptoms. The company just completed enrollment of the FMR cohort. The company expects to file in the first quarter of next year for its pivotal study.

Ancora also has a pivotal study for a CE mark, with it seeing the first few patients enrolled. "What's exciting for us is the enrollment volume both in the U.S. and Europe has really taken off," with an average of about eight to 10 patients worldwide a month.

Edwards, others

Other companies are looking to help heart failure patients, and, in particular, FMR. For its part, Edwards Lifesciences Corp., of Irvine, Calif., reported in May that the FDA had given its blessing to CLASP IIF. (See BioWorld MedTech, May 28, 2019.) It is a prospective, multicenter, randomized, controlled pivotal trial to evaluate transcatheter mitral valve repair with the Edwards Pascal Transcatheter Valve Repair System vs. Mitraclip in certain patients with degenerative mitral regurgitation and in those with FMR on guideline directed medical therapy.

Earlier this month, Kirkland, Wash.-based Cardiac Dimensions Inc. reported the publication of the REDUCE FMR clinical study of its Carillon mitral contour system. That system is a right heart transcatheter mitral valve repair device that aims to treat the primary cause of FMR in patients with MR grades 2+, 3+ and 4+.

The study, which enrolled 120 patients at 31 sites in the EU, Australia and New Zealand, met its primary endpoint, while enrolling a less severe patient population, and was published in the Journal of the American College of Cardiology: Heart Failure.

Last year, Mardil Medical Inc., of Minneapolis, completed first- in-human implants of its combination therapy Ventouch Triad device at Sanitorio Italiano in Asunción, Paraguay, among patients with type IIIb FMR. (See BioWorld MedTech, March 21, 2018.)

In 2017, Santa Rosa, Calif.-based Millipede Inc. implanted its 50 mm Iris annuloplasty ring with a transfemoral, transseptal delivery catheter in a patient with FMR. (See BioWorld MedTech, July 25, 2017.)

Late last year, Boston Scientific Corp., of Marlborough, Mass., reported that it exercised its option to acquire the remaining shares of Millipede after its successful completion of a first-in-human clinical study. (See BioWorld MedTech, Dec. 28, 2018.)