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JACC Reports on First-In-Human Transcatheter Tricuspid Repair

Mitralign Transcatheter Annuloplasty System could present a non-surgical option for both mitral and tricuspid valve regurgitation

TEWKSBURY, MA – March 12, 2015 –A detailed reporting of the first successful case of a direct transcatheter tricuspid repair (TTVR) for severe TR has been reported by Prof. Dr. med. J. Schofer of the Medicare Center and Department for Percutaneous Interventions of Structural Heart Disease, Albertinen Heart Center, Hamburg in the current issue of the peer-reviewed Journal of the American College of Cardiology (JACC). The Mitralign System is currently being evaluated in clinical trials for an indication in functional mitral regurgitation. The device is not approved for sale or distribution in the EU or US.

“We are pleased to see the development of the Mitralign System to not only treat mitral regurgitation but to potentially be the non-surgical option for patients suffering from tricuspid regurgitation,” said Prof. Dr. med. J. Schofer. “These are challenging disease states. Surgery for tricuspid regurgitation suffers from high mortality rates and for those who do undergo surgery, reoccurrence is high as well. A transcatheter option is needed for this underserved patient population.”

The patient was an 89-year-old woman who was suffering from mild to moderate mitral and aortic regurgitation and severe tricuspid regurgitation. She underwent a transcatheter bicuspidization of the tricuspid valve, successfully converting a regurgitating tri-leaflet valve into a functioning bi-leaflet valve. The patient was discharged 5 days later.

In an accompanying editorial, William W. O’Neill, MD, and Brian P. O’Neill, MD noted that “Tricuspid regurgitation (TR) remains an undertreated problem with substantial morbidity” and that for “those patients who undergo surgery, recurrence of moderate or severe TR can be as high as 60% at 5 years”. The editorial also notes that despite a 1-year mortality rate of 36.1% for patients with severe TR¹, only 16% of patients with isolated severe TR underwent surgery at 5 years.²

“This is the first experience with a transcatheter tricuspid annuloplasty device, and we were able to immediately quantify dimensional changes and see significant reduction in tricuspid regurgitation” stated Rebecca Hahn, MD, “Imaging with 2D and 3D echocardiography is feasible and essential for the advancement of this technology.”

About Functional Mitral Regurgitation (FMR)

The mitral valve controls blood flow from the left atrium to the left ventricle of the heart, allowing blood to flow in one direction through the heart and into the body. Functional Mitral Regurgitation (FMR) is the most common valve disease and occurs when the left ventricle of the heart is enlarged and stretches the valve opening. The valve leaflets are not able to come together to close, allowing blood to flow, or regurgitate, back into the atrium. Consequences can include heart failure or serious rhythm problems called arrhythmias. There are an estimated 3.2 million patients with FMR in the USA.³ If left untreated, FMR overloads the heart and can lead to or accelerate heart failure.

About Functional Tricuspid Regurgitation (FTR)

Functional tricuspid regurgitation occurs when the tricuspid valve fails to open and close properly, causing blood to flow backward into the right atrium. If left untreated, FTR can lead to heart enlargement and heart failure. In the U.S. alone, there are an estimated 1.6 million patients suffering from FTR³. It is estimated that 50% of patients with mitral regurgitation have moderate to severe tricuspid regurgitation.² FTR is currently undertreated by surgery. In the U.S. surgeons treat only 5,500 patients per year, most of them in conjunction with left heart surgeries³. When treated, surgeons choose to repair 90% of the time over replacement (10%)⁴.

About Mitralign Inc.

Mitralign Inc. is the valve repair company with the only transcatheter annuloplasty system designed to treat both functional mitral regurgitation and functional tricuspid regurgitation. The company is a venture-backed, medical innovation company located near Boston, Massachusetts, USA. For more information, visit www.mitralign.com.

1. Nath J, Foster E, Heidenreich PA. Impact of tricuspid regurgitation on long-term survival. J Am Coll Cardiol 2004;43:405–9.
2. Topilsky Y, Nkomo VT, Vatury O, et al. Clinical outcome of isolated tricuspid regurgitation. J Am Coll Cardiol Img 2014;7:1185–94.
3. Acker MA, Bolling S, Shemin R, et al., J Thorac Cardiovasc Surg 2006;132:568-77
4. Argarwal et al. Circ Cardiovasc Interv 2009;2:565-573

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Company Contact:
David Schleifer
Director of Marketing
Mitralign Inc.
+617.869.6166
dschleifer@mitralign.com