Results from the COAPT trial reported

September 24 2018

Data presented today from the randomized COAPT trial, which have the potential to significantly change current clinical practice, found that patients with heart failure and secondary mitral regurgitation (MR) who remained symptomatic despite maximally tolerated medical therapy demonstrated reduced rates of hospitalizations and death, as well as improved quality-of-life and functional capacity after being treated with the transcatheter MitraClip device.

Findings were reported today at the 30th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium. Sponsored by the Cardiovascular Research Foundation (CRF), TCT is the world's premier educational meeting specializing in interventional cardiovascular medicine. The study was also published simultaneously in the *New England Journal of Medicine*.

"The prognosis for heart failure patients who develop severe secondary mitral regurgitation is poor with limited treatment options," said Gregg W. Stone, MD, Professor of Medicine at Columbia University Irving Medical Center, and Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian/Columbia University Irving Medical Center, who presented the results at TCT. "There is a great need to help improve outcomes for these very sick patients."

The MitraClip device is already approved in the U.S. for use in primary MR, a condition in which the mitral valve leaflets do not function properly due to a degenerative defect.

Whether the device is useful for secondary MR, in which the valve structure is normal, but the ventricle is enlarged, causing the valve leaflets to fail to prevent backward flow (known as mitral regurgitation), is unknown. In the procedure tested in COAPT for secondary MR, the MitraClip device is attached to the mitral valve leaflets via a catheter that is then removed, leaving the clipped valve in place with less regurgitation.

COAPT was a randomized, parallel-controlled, open-label multicenter trial evaluating transcatheter mitral valve repair with the MitraClip device in symptomatic heart failure patients with moderate-to-severe or severe secondary MR. A total of 614 subjects were randomized at 78 centers in the United States and Canada. A total of 302 patients were assigned to the device and guideline-directed medical therapy (GDMT) in the device group and 312 patients were assigned to GDMT alone in the control group.

The primary effectiveness endpoint was the annualized rate of all heart failure hospitalizations through 24 months and the primary safety endpoint was freedom from device-related complications at 12 months. After two years, there were 160 total heart failure hospitalizations among those who received the mitral clip versus 283 for the control group. The annualized rates of heart failure hospitalization were 35.8% per patient-year in the device group versus 67.9% per patient-year in the control group (HR 0.53, 95% CI [0.40 to 0.70]; p