

THE LATEST MURMURS

COAPT: MitraClip Reduces Repeat Hospitalizations, Mortality in Functional MR Patients with Severe Congestive Heart Failure (CHF)

After 8 years of a rigorous prospective randomized clinical trial the data from the COAPT study was released on September 23, 2018 at the international Transcatheter Therapies conference in San Diego, CA. The results show that transcatheter mitral valve repair using the percutaneous clip procedure in patients with heart failure and severe functional mitral regurgitation (MR) significantly reduced not only the primary endpoint of heart failure (HF) rehospitalizations, but also mortality at 2 years.

The primary efficacy endpoint—all hospitalizations over 24 months—was significantly lower in the MitraClip versus the medical care group. Annualized rates of hospitalizations were 35.8% versus 67.9%, respectively ($P < 0.001$), yielding a number needed to treat of 3.1. Results in per-protocol, intention-to-treat, and as-treated analyses were very similar to the overall findings. Freedom from device complications in the MitraClip group was 96.6%. Perhaps most strikingly, 2-year mortality, a powered, prespecified secondary endpoint, was significantly lower among MitraClip-treated patients: 29.1% versus 46.1% (HR 0.62; 95% CI 0.46-0.82), yielding a number needed to treat of 5.9.

In COAPT, death or rehospitalizations for heart failure, which was the primary endpoint in MITRA-FR (measured at 1 year in MITRA-FR and 2 years in COAPT), was 45.7% in the MitraClip group versus 67.9% in the medical therapy arm (HR 0.57; 95% CI 0.45-0.71).

Click here for the New England Journal of Medicine Coapt Trial Outline: [NEJM Coapt](#)

TRANSCATHETER MITRAL VALVE REPLACEMENT, A PERCUTANEOUS OPTION FOR MITRAL VALVE DISEASE

North Florida Regional Medical Center in conjunction with The Cardiac and Vascular Institute and The Florida Heart and Lung Institute is proud to announce the acceptance and enrollment for the Apollo Clinical Trial for Transcatheter Mitral Valve Replacement with the Medtronic Intrepid TMVR System in patients with severe symptomatic mitral regurgitation. We are one of two sites in the state of Florida that have been chosen for enrollment. Truly a transformative and revolutionary technology, transcatheter valve therapies (TVT) have provided unprecedented benefit to a group of patients with valvular heart disease (VHD) not amenable to or at high risk for surgical treatment, extending and improving their daily lives. Percutaneous therapies for the management of aortic valve disease have been in practice now for over a decade. Now there is a new frontier for the structural heart team in the approach to treating mitral valve disease. One could speculate as to why the percutaneous mitral valve technologies have been developmentally behind the aortic field but it is likely related to the technical, anatomic, and clinical limitations associated with the mitral valve. Nevertheless, the approach in the management of these intermediate to high risk mitral valve surgical candidates has changed.

The valve

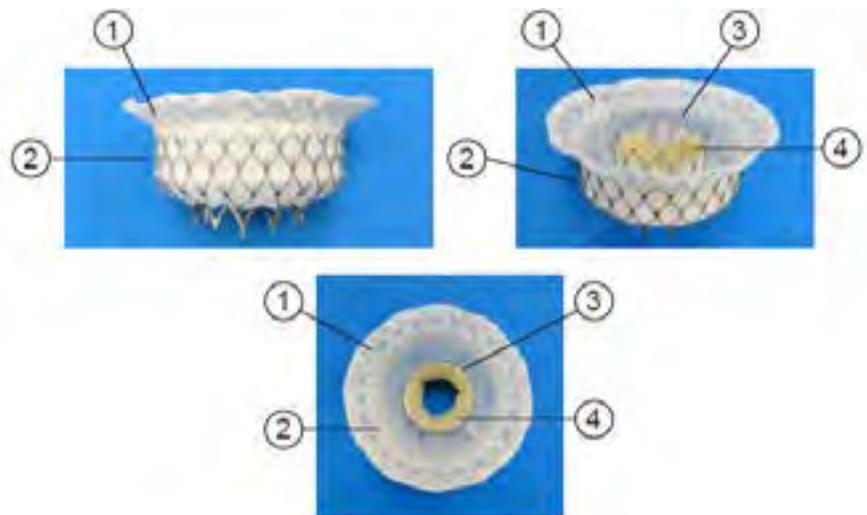


Figure 2 - Intrepid™ Implant

1. Atrial brim, 2. Outer Fixation ring, 3. Inner stent, 4. Inner valve leaflets

Continued on back



Continued from front

Medtronic Intrepid™ transcatheter heart valve has a self-expandable nitinol outer stent, which provides fixation and sealing, and a circular inner stent, which a tri-leaflet bovine pericardium valve with an effective orifice area. The valve is implanted via transapical access and a transeptal delivery approach is being developed.

Who should be considered for Transcatheter Mitral Valve Replacement (TMVR)?

Individuals who have moderate to severe or severe symptomatic mitral regurgitation should be evaluated by a heart team to determine candidacy for TMVR. Several features that would exclude candidacy are prior transcatheter mitral valve procedure with device in place, prohibitive mitral annular calcification, intracardiac mass or thrombus and/or prior mitral valve surgery. Enrollment will begin in December 2018 at North Florida Regional Medical Center.

We remain committed to providing the full spectrum of therapies available to treat valvular heart disease at North Florida Regional Medical Center. To this end we continue to invest in both research trials, and products already commercially available, to bring the best and most innovative percutaneous and minimally invasive valve treatments to our center. Our team is quite proud to deliver what we consider to be the full spectrum of commercial and research technologies with best in class performance. Stay tuned for updates on enrollment and results of this exciting mitral trial and more new technologies to follow.

Charles T. Klodell, MD

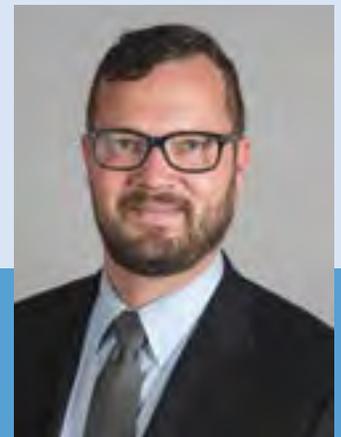
Aubrey J. Hall, ARNP



Last month, the heart team participated in a Habitat for Humanity build that will benefit a local community member.



Charles T. Klodell, MD
Cardiothoracic Surgeon



Thomas Zeyl, MD
Cardiothoracic Surgeon

For insights, answers to questions,
or to share commentary contact:
Aubrey Hall, NP and Publisher of The Practice Pulse,
at Aubrey.hall2@hcahealthcare.com