CARDIAC RESEARCH TODAY

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Trials Provide New Clinical Care Options for HF, CAD

Clinical trials give patients options they would not otherwise have, and that can change the course of disease and survival. These prospective additions to standard care are ideally available at all levels of health care. Virtua's staff of research coordinators oversee trials in a range of specialties, working to ensure that as many patients as possible have access to investigative interventions. Virtua's cardiac clinical trials in particular continue to demonstrate the benefits.

Amidst Virtua's new relationships with Rowan University and Penn Medicine, innovation and academics will increasingly mix at Virtua with cutting-edge choices for patients, as already available for those with heart conditions. This long-standing strength at Virtua Our Lady of Lourdes Hospital now reaches throughout the system, illustrated particularly by two major trials underway in interventional cardiology and electrophysiology.

Pioneering Valve and Heart Failure Treatments

- ***COMPLETE TAVR*** *(Staged Complete Revascularization for Coronary Artery Disease vs Medical Management Alone in Patients With AS Undergoing TAVR):* Coronary artery disease (CAD) often accompanies aortic stenosis. This trial will determine whether, prior to receiving transcatheter aortic valve replacement (TAVR), patients with both conditions should undergo PCI using drug-eluting stents on coronary artery lesions or be treated medically to optimally reduce subsequent cardiac events.

  "It's not unusual to see concomitant disease in these individuals," said interventional cardiologist Ibrahim Moussa, DO, FACC, FSCAI, RPVI, the trial's PI at Virtua. "However, there is no agreement on how to best treat this situation. This study may help to better identify the right path."

- ***AIM HigheR*** *(Assessment of CCM in HF With Higher Ejection Fraction):* With two leads in the heart's right ventricular septum, the Optimizer device delivers cardiac contractility modulation (CCM) that stimulates heart muscle. Myocardial cells change and gain contractile force. Ventricular function improves, decreasing heart failure scores.

  In 2020, Virtua became the first health system in South Jersey to implant the device. The current trial at Virtua now evaluates safety and effectiveness of the therapy in patients with less-severe heart failure (LVEF of 40% to 60%).

  "CCM has significantly reduced patients' symptoms, such as shortness of breath and fatigue, allowing for a better quality of life," said electrophysiologist Heath Saltzman, MD, FACC, FHRS, FACP, the trial's PI at Virtua.

Growth in Open Trials of New Advancements

Virtua research results go directly into application. Virtua pulmonologist Emilio Mazza, MD, PhD, medical director of the intensive care unit at Virtua Mount Holly Hospital, coauthored a study in the recently published in issue of *Circulation* showing that full-dose anticoagulation (except with clopidogrel) reduces thrombotic complications in critically ill patients with COVID-19.

The cardiac team at Virtua Our Lady of Lourdes Hospital also recently became the first in the nation to implant an investigational defibrillation lead designed to treat patients with ventricular tachycardia.

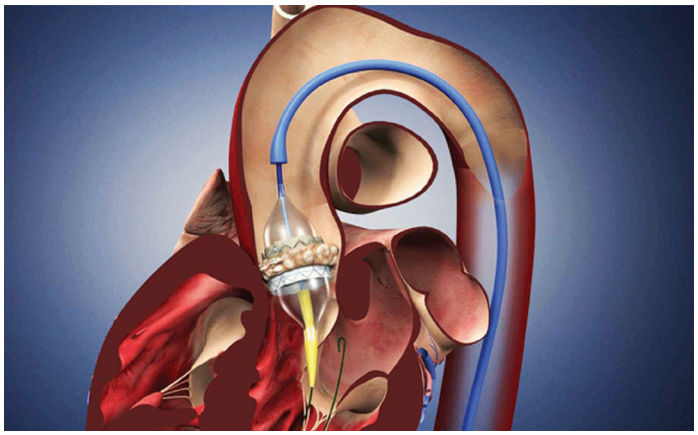

Image courtesy Edwards Lifesciences

Illustration shows a transcatheter aortic valve replacement (TAVR).

For more information call 856-355-1203 or email research@virtua.org.

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Expanding List of Cardiac Care Trials Underway at Virtua

Other key active Virtua cardiac clinical trials include:

- **Heart Failure (HF)**

  Dapagliflozin and Effect on Cardiovascular Events in Acute Heart Failure — Thrombolysis in Myocardial Infarction 68 (DAPA ACT HF-TIMI 68): Effect on clinical outcomes (cardiovascular death or worsening HF) of the sodium-glucose co-transporter 2 inhibitor (SGLT2i) Farixiga (dapagliflozin) in patients who have been stabilized during hospitalization for acute HF.

  Algorithm Using LINQ Sensors for Evaluation And Treatment of Heart Failure (ALLEVIATE-HF): Evaluation of the Reveal LINQ™ insertable Cardiac Monitor for monitoring HF patients with NYHA class II or III HF.

  Cardiovascular and Renal Treatment in Heart Failure Patients With Hyperkalaemia or at High Risk of Hyperkalaemia (CARE-HK in HF Registry): Registry evaluation of the use of renin-angiotensin-aldosterone system inhibitor (RAASi) treatments in HF patients at high risk of hyperkalemia, with the goal of assessing the impact of patiromer (which binds potassium in the GI tract) in routine clinical practice.

  Tosho Bioscience: Evaluation of the CL (chemi-luminescent) AIA-PACK assay for B-type natriuretic peptide (BNP, a biological marker for heart failure) on K2EDTA (anticoagulant used to store blood for complete blood counts) plasma specimens from non-emergency department sites using the Tosoh AIA-2000 Analyzer.

- **Acute Coronary Syndromes**

  A Randomized Trial Assessing the Effects of Inclisiran on Clinical Outcomes Among People With Cardiovascular Disease (ORION-4): Effects on atherosclerotic cardiovascular disease and events of a proprotein convertase subtilisin kexin type 9 (PCSK9)-interfering mRNA drug (synthesis inhibitor) that acts primarily in the liver to lower LDL, versus placebo.

  IMPact on Revascularization Outcomes of IVUS Guided Treatment of Complex Lesions and Economic Impact (IMPROVE): Effect on revascularization outcomes of intravascular ultrasound-guided treatment of complex lesions.

  Safe and Timely Antithrombotic Removal — Ticagrelor (STAR-T): A randomized, controlled study to evaluate reduction in postoperative bleeding by removal of ticagrelor with the intraoperative use of the DrugSorb™-ATR device in patients undergoing on-pump cardiothoracic surgery, within two days of ticagrelor discontinuation.

- **Electrophysiology**

  SyncAV Post-Market Trial (SyncAV): Impact, via left ventricular reverse remodeling, of programming cardiac resynchronization therapy devices using SyncAV (adjusts pacing automatically based on real-time changes in a patient's cardiac condition) compared with programming using conventional CRT settings with a fixed atrioventricular (AV) delay.

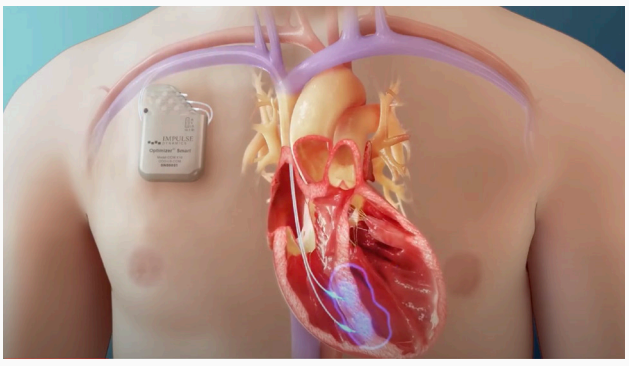

Image courtesy Impulse Dynamics

In addition to its participation in the AIM HigheR study, the Virtua EP team is also a center for the Optimizer PAS trial, a study continuing to gather data on use of the Optimizer as a standard of care for HF patients with more severe heart failure (EF of 25% to 45%).