Small

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Spotlight on Clinical Research

Cardiology, Cardiothoracic Surgery, and Trauma

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Editor's note: *This is the third in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describe ongoing research studies, with a focus on those actively enrolling patients. Other active studies have been described in previous issues of this Journal.*[1,2]

Physicians who wish to refer patients for any of the studies mentioned below are encouraged to contact the Lancaster General Health Research Institute at 717-544-1777.

Other members of the LGH staff who are conducting research and wish to have their studies described here, are encouraged to contact the offices of JLGH at 717-544-8004.

ELECTROPHYSIOLOGY LABORATORY

MARVEN

Clinical, Electrocardiographic, and Cardiac Magnetic Resonance Imaging Risk Factors Associated with Ventricular Tachyarrhythmias in Nonischemic Cardiomyopathy (MARVEN Study).

Principal Investigator: Matthew Bernabei, M.D.

Insertion of an implantable cardioverter defibrillator (ICD) for primary prevention of mortality is an approved therapy in ischemic and nonischemic cardiomyopathy (NICM) patients with left ventricular ejection fraction (EF) ≤35%. However, data from clinical trials leading to this indication in nonischemic cardiomyopathy (NICM) patients were limited.

A risk prediction model that utilizes Holter-detected NSVT, LBBB or Non-LBBB QRS morphology, plus left ventricular volume, provided effective risk stratification that could guide therapeutic decisions regarding implantation of CRT-D, CRT-P, or ICD devices in NICM heart failure patients with QRS ≥120ms, as per current CRT indications.

Cardiac Magnetic Resonance Imaging (CMR) offers insight into the extent of myocardial fibrosis that, if combined with electrical markers, could greatly improve identification of those patients who could benefit from an implantable defibrillator, as well as those in whom device placement might be deferred.

This study aims to prospectively evaluate NICM patients who qualify for CRT-D based on currently approved standard indications. This approach has three goals: a) to validate the MADIT-CRT-derived model that predicts fast VT/VF in NICM patients with QRS ≥120ms; b) to determine whether CMR added to the risk model validated in aim "a" will further improve risk stratification for predicting fast VT/VF; and c) to evaluate costs of risk stratification using Holter and CMR in relationship to costs of implanted devices without risk stratification.

CARDIOTHORACIC SURGERY

REVERSE VA ECMO

A Prospective **R**andomized Trial of **E**arly LV **V**enting Using Impella CP for **R**ecovery in Patients with Cardiogenic Shock Managed with VA **E**CMO (**REVERSE**)

Principal Investigator: Mark Epler, M.D.

Veno-arterial extra-corporeal membrane oxygenation (VA-ECMO) is indicated as a hemodynamic rescue strategy in decompensated acute or chronic heart failure presenting as cardiogenic shock.[3] One of the major deficiencies of peripheral VA-ECMO is its lack of left ventricular unloading, with associated pulmonary congestion, which can derail clinical improvement and hamper cardiac recovery.

The objective of this randomized study is to determine whether the addition of early direct ventricular unloading using Impella CP leads to higher rates of cardiac recovery, defined as survival free from mechanical circulatory support, heart transplantation, or inotropic support at 45 days. This study will also examine the clinical, biochemical, echocardiographic, and radiologic effects of VA ECMO with and without the addition of Impella CP.

HYPERLIPIDEMIA

CASCADE FH

Principal Investigator: Rolf Andersen, M.D.

CASCADE FH is a national registry for patients with familial hypercholesterolemia. It was initiated and funded by The FH Foundation, a California-based NPO focused on raising awareness of familial hypercholesterolemia (FH), and leading the way in

research and patient advocacy.

FH is a common genetic condition that occurs in approximately 1 in 300-500 individuals and affects all racial and ethnic groups.[4] FH is characterized by a dramatically high level of low-density lipoprotein cholesterol (LDL-C usually >190 mg/dL [5 mmol/dL]) that is not related to diet or lifestyle.

The purpose of this registry is to collect and maintain clinical information about patients with FH that will be used to track events, trends in therapy, and outcomes in individuals with FH to improve their care, quality of life, and survival, and to further our knowledge and understanding of the disease.

Lancaster General has been participating in this registry since 2015, and more than 400 patients have consented to be included in the registry.

TRAUMA

CLOTT

The Pathogenesis of Post-Traumatic Pulmonary Embolism: A Prospective Multicenter Investigation by the CLOTT Study Group: Part 1

Principal Investigator: Frederick Rogers, M.D.

Venous thromboembolism (VTE) remains a leading cause of death in trauma patients. Based on the EAST Management Guidelines for the prevention of VTE in trauma patients, a number of research questions could be addressed by a thorough review of the current literature combined with a concurrent analysis of experience at multiple centers. This proposal therefore seeks to create a data registry of trauma patients from multiple trauma centers around the United States that will serve as a platform for the study of VTE.

This study aims to compare the safety of observation versus treatment of asymptomatic peripheral pulmonary thrombi discovered on computed tomography of the chest with contrast (CTA). It will evaluate the effectiveness of various prophylactic measures in preventing PE, and determine how much surveillance bias affects the observed incidence of PE, based on the frequency with which CTA is utilized.

The CLOTT team consists of 17 investigators from 17 major trauma centers across the country.

CONGESTIVE HEART FAILURE

REDUCE LAP-HF II

A study to evaluate the Corvia Medical Inc. IASD® System II to **REDUCE** **E**levated **L**eft **A**trial **P**ressure in Patients with **H**eart **F**ailure

Principal Investigator: Amit Varma, M.D.

This multicenter, prospective, randomized, controlled, blinded trial aims to examine the safety and efficacy of creating an inter-atrial septal defect to treat patients with heart failure with preserved ejection fraction (HFpEF). Over a 12-month period, safety and efficacy will be assessed by developing a composite statistic comprised of the incidence of, and time to, cardiovascular death or first non-fatal, ischemic stroke; total rate per patient/year of heart failure (HF) admissions or health care facility visits for IV diuresis for HF through 12 months, time-to-first HF event; and change in baseline KCCQ total summary score at 12 months.

Patients randomized to the experimental arm undergo fluoroscopic and intra-cardiac echocardiography (ICE), or transesophageal echocardiography (TEE) guided trans-septal puncture, and implant of the IASD System II. The primary component of the system is an implant placed in the atrial septum that allows flow from the left atrium to the right atrium to reduce the elevated left atrial pressure.

Patients randomized to the control arm undergo ICE from the femoral vein or TEE for examination of the atrial septum and left atrium.

REFERENCES

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