Baylor St. Luke's Medical Center

CV Research Update

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The Office of Clinical Research is located in Suite O510 at
Baylor St. Luke's Medical Center on the fifth floor near the orange elevators
Our main phone number has recently changed to (713) 798-1037

First in Houston: Tack Endovascular System™

On November 30, 2016, Dr. Neil Strickman was the first in Houston, to perform a Tack optimized balloon angioplasty using the Tack Endovascluar System™ in the TOBA II trial sponsored by Intact Vascular, Inc. TOBA II is a prospective, multi-center, single-arm, non-blinded study designed to investigate the safety and efficacy of the Tack Endovascular System in subjects with post-balloon angioplasty (post-PTA)

dissection(s) type(s) A through F in the superficial femoral and proximal popliteal arteries ranging in diameter from 2.5mm to 6.0mm.

The TOBA II trial was designed to enroll 210 subjects at 30-40 sites in the United States and Europe. Subjects with advanced peripheral artery disease in one or both legs with Rutherford Class 2, 3, or 4 were considered for enrollment. Eligible subjects were treated with the Tack Endovascular System following standard balloon angioplasty or drug-coated balloon angioplasty in the superficial femoral and proximal popliteal arteries in the presence of dissection.

The Tack Endovascular System is a new technology designed to repair dissections that frequently occur as a complication of balloon angioplasty. Published literature reports up to 88% of angioplasty procedures have dissections. Promising 12- month results from the Company's European TOBA study were presented at a major vascular conference in Germany and demonstrated the potential of the Tack implant for improving arterial healing following angioplasty. Most importantly, the system allows physicians to repair dissections while leaving a minimal amount of foreign material in 2 the artery, reducing mechanical stress on the artery, and preserving future treatment options.

Dr. Strickman stated, "The earlier TOBA experience demonstrates that the long term results from angioplasty can be substantially improved if we repair arterial dissections using this new approach to minimize vessel trauma while leaving as little metal behind as possible. The Tack implant supports the dissection and allows the vessel to heal, while preserving future treatment options for patients. I am very excited that the TOBA II trial will allow us to study this technology in combination with both standard and drug coated angioplasty balloons – a first of its kind study design. No other vascular implants have been methodically studied following vessel treatment with a drug-coated balloon."

"We're very excited about our involvement in this groundbreaking clinical study," said Gay Nord, President, Baylor St. Luke's Medical Center. "TOBA II provides those in Houston suffering from PAD the latest vascular technology."

The TOBA Below the Knee (BTK) trial is expected to open at Baylor St. Luke's at the end of the second quarter 2017. Miguel Montero, MD and Jayer Chung, MD from Baylor College of Medicine Department of Surgery will also be participating in the BTK cohort.

TOBA II (H-39194) Principal Investigator: Neil E. Strickman, MD; Study Contact: Gilberto De Freitas, RN Telephone 713-798-1037

First in Class Large-bore Vascular Closure Device

Essential Medical, Inc. is sponsoring an investigational device exemption (IDE) trial for Manta, the company's large-bore vascular closure device. This pivotal trial will evaluate the safety and efficacy of vascular access closure using Manta for femoral arterial access sites in patients undergoing percutaneous procedures using sheaths ranging from 10F to 24F. Manta will be used to achieve safe, percutaneous closure in a variety of large-bore procedures including endovascular aortic repair (EVAR) of abdominal aortic aneurysms, transfemoral transcatheter aortic valve replacement (TAVR), ventricular assist devices, and balloon aortic valvuloplasty.

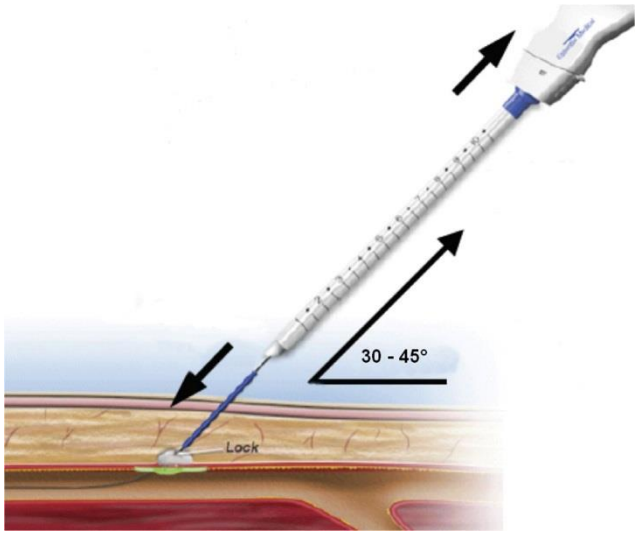

Photo JACC: Cardiovascular Interventions Jun 2016, 9 (11) 1195-1196; DOI: 10.1016/j.jcin.2016.03.010

Zvonimir Krajcer, MD, is the Principal Investigator and Neil Strickman, MD is a Sub-Investigator for the MANTA trial at Baylor St. Luke's Medical Center and together have been the top enrolling team with a total of 28 subjects enrolled to date since the trial opened in December 2016. The 100th subject overall was enrolled by Dr. Krajcer earlier this month.

Dr. Krajcer, stated, "We are very excited to be a part of the MANTA vascular closure trial, as I believe it will deliver fewer complications and faster overall procedure times based on the European data. Until now for EVAR, thoracic EVAR, and TAVR we had to use the vascular closure devices that were not originally designed for this indication. Finally, for the first time with Manta we will have the opportunity to use a reliable and simple vascular closure device for large bore sheaths. This device will in a safer way advance the treatment of many patients with aortic aneurysmal and valvular heart disease."

To be considered for the trial, patients must be a candidate for elective or planned (non-emergent) percutaneous transcatheter interventional procedure via a 10-18F size retrograde common femoral artery approach. Patient vessel size should allow for Manta device access as determined by baseline CTA. Minimum vessel diameter is 5mm for the 14F device and 6mm for the 18F device. Patients with significant anemia (hemoglobin <10 g/DL, hematocrit <30%) or patients that are morbidly obese (BMI >40 kg/m2 or are cachectic (BMI <20 kg/m2) are excluded.

MANTA (H-33971) Principal Investigator: Zvonimir Krajcer, MD; Research Coordinator: Gilberto De Freitas, RN Telephone 713-798-1037

Assessing Diagnostic Value of Non-invasive FFRCT in Coronary Care (ADVANCE)

The ADVANCE Registry is a multi-center, prospective registry designed to evaluate utility, clinical outcomes and resource utilization following FFRCT-guided treatment in clinically stable, symptomatic patients diagnosed with CAD by coronary CTA. Approximately 5000 patients will be enrolled from up to 50 sites in Europe, USA, Canada and Asia. For a patient to be eligible for enrollment, atherosclerosis must be present on coronary CTA. For each enrolled patient, a clinical management review committee will use data from coronary CTA and FFRCT to determine the management plan using the following criteria: (a) optimal medical therapy, (b) percutaneous coronary intervention, (c) coronary artery bypass graft surgery, or (d) more information required. The primary endpoint of the registry is the reclassification rate between the management plan based on coronary CTA alone versus CTA plus FFRCT. The secondary endpoints of the registry include the evaluation of the rate of invasive coronary angiography (ICA), revascularization, major adverse coronary events, resource utilization, cumulative radiation dose exposure and the rate of ICA without obstructive CAD at 3-year follow-up. The ADVANCE registry is designed to assess the real-world impact of FFRCT on the clinical management of stable CAD when used along with coronary CTA.

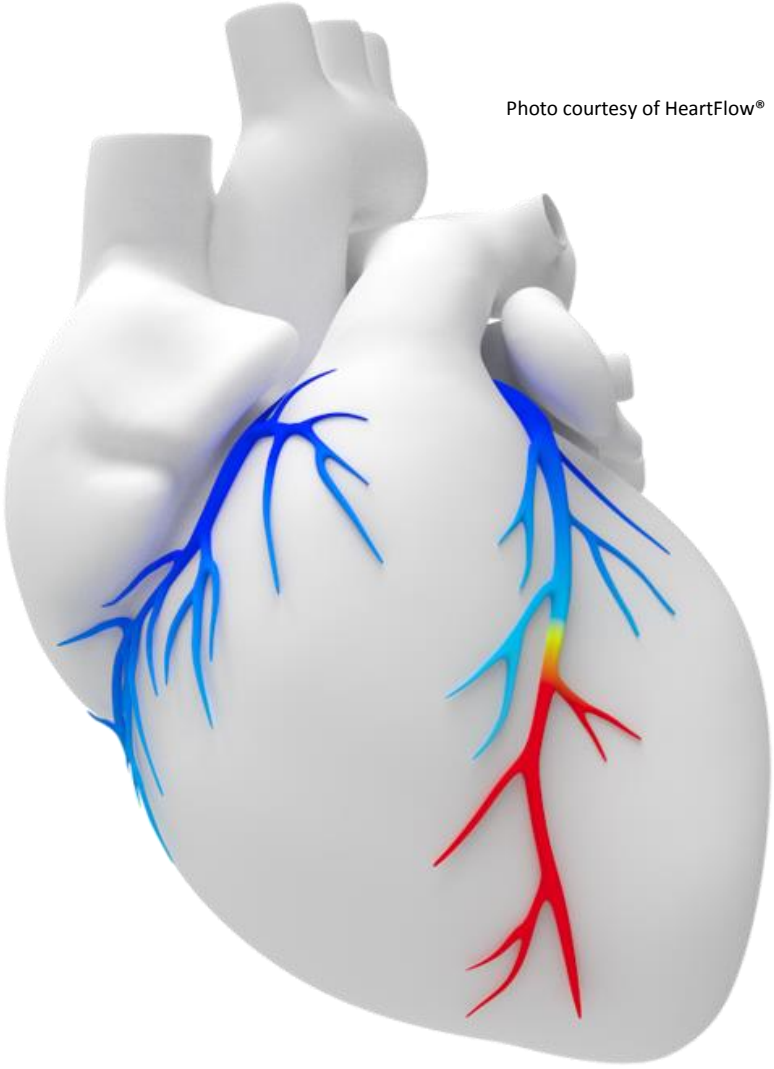

Photo courtesy of HeartFlow®

Advance Registry (H-38992) Principal Investigator: Juan Carlos Plana, MD; Research Coordinator: Erica Frankel, RN Telephone 713-798-1037

Vein of Marshall Ethanol Infusion for Persistent Atrial Fibrillation

The broad, long-term objective of this project is to evaluate the therapeutic value of vein of Marshall (VOM) ethanol infusion when added to catheter ablation of atrial fibrillation (AF). AF is the most common sustained arrhythmia in adults, and it is a leading cause of stroke, disability and increased mortality. Catheter ablation - pulmonary vein (PV) antral isolation (PVAI)- can lead to cure, but is best suited for paroxysmal AF, in which ectopic beats arising from the pulmonary veins were shown to initiate AF. PVAI success is lower in persistent AF, in which the role of the cardiac autonomic system, particularly the intrinsic cardiac ganglia, is being increasingly recognized. Expanding the ablation lesions to include greater areas the left atrial (LA) anatomy marginally improves outcomes, but also leads to increases in procedural complexity and duration, need of repeat procedures, and complications such as atrial flutters, particularly perimitral flutter (PMF). The investigators have developed a technique to perform rapid ablation of atrial tissues in AF using ethanol infusion in the vein of Marshall (VOM), and have shown: 1) Effective, rapid and safe tissue ablation of LA tissue neighboring the LA ridge and left inferior PV; 2) Regional LA vagal denervation by reaching the intrinsic cardiac ganglia; and 3) Facilitation of cure of PMF by ablating most of the mitral isthmus.

The investigators propose to evaluate outcomes differences yielded by VOM ethanol when added to conventional PVAI. The specific aims are: #1.To assesses the impact of VOM ethanol infusion in procedure success when added to de novo catheter ablation of persistent AF. The investigators will randomize patients with persistent AF undergoing a first AF ablation to standard PVAI vs. a combined VOM ethanol infusion plus PVAI (VOM-PV) #2. To assess the impact of VOM ethanol infusion added to repeat catheter ablation of recurrent AF after a failed ablation. Patients undergoing a repeat procedure for persistent AF after a failed PVAI will be randomized to either PVAI or VOM-PV as their repeat procedure. End points will include freedom from symptomatic or electrocardiographic AF after 12-15 months.

Patients must be between the ages of 21 and 85 to participate and be diagnosed with symptomatic persistent AF Documentation of history of AF for at least 6 months AF not spontaneously converting to sinus rhythm; persisting for ≥7 days Sinus rhythm after cardioversion is NOT exclusion, provided that≥2 episodes of persistent AF occurred in the previous 6 months.

Vein of Marshall (H-39358) Principal Investigator: Abdi Rasekh, MD; Research Coordinator: Stephen Harold Telephone 713-798-1037