

THE LINDNER RESEARCH CENTER

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November 2022

This month we review the Womens Heart Center research and education portfolio which has seen tremendous growth over the past 2 years. Both TCH & AHA went extremely well highlighted by a presentation and simultaneous publication in JAMA by Dr. Jamie Jollis.



Michelle and Dr. Quesada share some highlights:

This month we are focusing on the Women’s Heart Center, which as you will see has experienced tremendous growth and received well-deserved recognition in the past year. Odayme Quesada, MD, MHS was honored to receive the Ginger Warner Endowed Chair in Women’s Cardiovascular Health and the 2022 HealthCare Hero Award for Innovation and was also named to the Business Courier’s 40 Under 40 Class. From a clinical perspective, Dr. Mariana Canoniero joined the practice this summer, which was very much welcomed given WHC volumes have surpassed 2100 patients. And the search continues for a full-time cardiologist to support continued expansion of services along with the innovative and specialized care for which the WHC has become known. Research and academic productivity within Women’s Heart has been robust as well with grant support from the NIH, DoD, AHA, industry and now the ACC as well; 8 active clinical studies; 20 published manuscripts; and abstracts/presentations at the AHA, ACC, ESC and JSCAI. Building capacity within the WHC Research Registry continues to be a focus of effort to further expand and support our research infrastructure. The WHC also supports mentees at all levels from high school through fellowship. In the realm of education, the WHC was excited to host the inaugural Women’s Cardiovascular symposium in partnership with ZOLL Medical this past May and is actively planning next year’s symposium scheduled for October 6, 2023 – so save the date! Community outreach partnerships have also expanded in the past year. Dr. Quesada is serving as the Co-chair of the AHA Go Red for Women campaign, providing the keynote and breakout sessions for the STEM Goes Red for Girls, and has participated in three very successful *Just for Us* events with the Black Women’s Health Movement to increase awareness of cardiovascular disease in women. More details about these and other happenings within the Women’s Heart Center can be found in the second edition of Matters of Her Heart. <https://7937075a.flowpaper.com/TCHMattersofHerHeartAUTUMN22/>

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Women’s Heart Trials

Trial/ Databases	PI	Status	# Months Active	# Consented	# Enrolled	Last Patient Enrolled	Brief Description
Hypertensive Disorders of Pregnancy	Quesada	Enrolling	25	51	51	11/3/22	Determine the extent to which measures of

Funding: NIH							coronary microvascular dysfunction or biochemical stress are related to abnormalities in cardiac structure and function that persist in women with prior preeclampsia.
Warrior Funding: Department of defense	Quesada	Enrolling	18	101	101	10/26/22 Highest Enroller	The purpose of this study is to determine whether aggressive medication treatment to modify risk factors in women with coronary arteries showing no severe obstruction but with cardiac symptoms (i.e., chest pain) will reduce their likelihood of dying, having a heart attack, stroke or being hospitalized. Randomized to IMT or SOC.
Women's Heart Clinic Long-term Follow-up Registry	Quesada	Enrolling	All patients presenting to Dr. Quesada's clinic are enrolled	NA	NA	NA	To determine the predictors of adverse outcomes (mortality, myocardial infarction, subsequent revascularization, and angina class) in women with CVD.
HARP Sponsor: Sarah Ross Soter Center of the AHA Go Red for Women Research Network At NYU.	Quesada	IRB Approved	12	3	3	5/6/22	Diagnostic observational study in patients with MINOCA to determine the prevalence and composition of disrupted plaque and location of myocardial abnormalities. Will enroll patients who present with acute ischemic symptoms, OCT will be performed in the cath lab and CMRI within 7 days after the angiogram.
Midwest STEMI Consortium Funding: ACC	Henry	Multi-center Consortium (Minneapolis Heart, Christ Hospital,	NA	NA	NA	NA	Dr. Quesada has had 6 abstracts accepted by the AHA and 3

		Iowa Heart, Prairie Heart Institute) database for STEMI patients.					abstracts presented to ACC. MINOCA Project Multiple Gender Related Projects
Freedom Sponsor: Caladrius Biosciences	Henry	Closed	NA	28	21	Highest enrolling site	Evaluation of the efficacy and safety of autologous CD34+ cells (CLBS16) in subjects with coronary microvascular dysfunction and without obstructive coronary artery disease.
COSIRA II Sponsor: Neovasc	Henry	Enrolling	8	10	10-randomized 2-compassionate use	10/31/22 Highest Enrolling site	To demonstrate the safety and effectiveness of the Reducer system for treatment of patients with refractory angina pectoris treated with maximally tolerated guideline-directed medical therapy who demonstrate objective evidence of reversible myocardial ischemia in the distribution of the left coronary artery and who are deemed unsuitable for revascularization.
DISCOVER INOCA Sponsor: Yale Cardiovascular Research Group	Quesada	IRB approved CTA in negotiation	NA	NA	NA	NA	A prospective, multicenter, registry of stable patients with ischemia and no obstructive coronary artery disease (INOCA) evaluated by coronary angiography, intravascular imaging, and physiologic measurements obtained on the Coroventis Coroflow Cardiovascular System
Upcoming Trials							

COSIRA II to COSIRA III Registry	Registry will allow microvascular disease	NA	NA	NA	NA	NA	
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Highlighted Trials

ION-682884-CS2 Trial

PI: Dr. Timothy Raymond

Study Coordinator: Susan Reilly

A Phase 3 Global, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ION-682884 in Patients with Transthyretin-Mediated Amyloid Cardiomyopathy

Inclusion: Amyloid deposits in cardiac or non-cardiac tissue confirmed by Congo Red (or equivalent) staining OR technetium scintigraphy, 99m Tc-pyrophosphate, or 99mTc-hydroxymethylene-diphosphonate) with Grade 2 or 3 cardiac uptake in the absence of abnormal light chains ratio, centrally confirmed : End-diastolic interventricular septum thickness of > 12 mm on Screening echocardiogram, Medical history of HF secondary to hereditary or wild-type ATTR-CM with at least: A) 1 prior hospitalization for HF, which may include hospitalization for arrhythmia or pacemaker/ICD placement, OR B) symptoms and signs of volume overload or elevated intracardiac pressure that requires treatment with diuretics other than mineralocorticoid receptor antagonists for clinical stabilization, Screening NT-proBNP \geq 600 pg/mL by central lab. For patients in atrial fibrillation at Screening the eligibility NT-proBNP value is \geq 1200 pg/mL, NYHA class I-III

Exclusion: GFR <30, Acute coronary syndrome, unstable angina, stroke, TIA, coronary revascularization, cardiac device implantation, cardiac valve repair, or major surgery within 3 months of Screening, Cardiomyopathy not primarily caused by ATTR-CM

Evaheart or Competence Trial

PI: Dr. Robert Dowling

Study Coordinator: Katherine Gloria

A prospective, randomized study comparing the EVA2 LVAS to the HM3 LVAS. The EVAHEART2 LVAS is a continuous flow centrifugal pump that employs a hydrodynamic impeller levitation system that has been designed to Preserve arterial pulsatility, minimize blood trauma, minimize blood stagnation and clot formation around the impeller shaft, lower risk of ventricular septal suction and minimize blood stagnation and clot formation at the left ventricular apex.

Inclusion: NYHA Class III with dyspnea upon mild physical activity or Class IV, Left Ventricular Ejection Fraction < 30%, Cardiac Index < 2.2 L/min/m²

Exclusion: Etiology of heart failure due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, or restrictive cardiomyopathy, Creatinine >2.5, Hx severe COPD

IMPACTFUL (Improving Medication Management and Abating Cost of Treatment, Follow-Up Longitudinal study)

PI: Dr. Blaxall Burns

Study Coordinator: Monica Seitz

To evaluate the impact of prospective pharmacogenomic intervention on patient outcomes, including: 30-day readmission, hospitalization, ER visit and mortality.

Inclusion: Patients prospectively randomized based on pharmacogenetic interaction probability (PIP) score.

Exclusion: Previous pharmacogenomic testing, Diagnosis of current malabsorption syndrome or history of organ transplantation during pre-index period, gastric bypass, Currently hospitalized (at time of enrollment), receiving IV antibiotics, taking immunosuppressant drugs, treatment of cancer, invasive solid tumor or hematologic malignancies, Current diagnosis of malnourishment, Occurrence of major spontaneous event that leads to a hospitalization (e.g., vehicle accident, injuries, burns, trauma, other accidents) in past 12 months, Nursing home admission, Life expectancy estimated to be less than three months by treating clinical team, Existing impaired hepatic MELD score ≥ 10 or renal function for which a lower dose or alternate drug selection are already part of current routine care. This would not apply to any drugs specifically given to manage liver/renal impairment/transplantation. Estimated glomerular filtration rate (MDRD) of less than 45 ml/min per 1.73m². Viral hepatitis, hepatic disease, Pregnancy or lactation. Duration of index drug total treatment length is planned to be less than seven consecutive days. A drug for which route of administration changes during the first seven days (e.g. intravenous to oral moxifloxacin) but for which total treatment duration is seven days or longer, is still eligible.

October Publications

1. Thaler C, Witt DR, **Henry TD**, Grey EZ, Baechler CJ, Lohese O, Okeson BK, Schmidt CW, Sharkey SW. Revascularization and long-term outcomes in high-acuity spontaneous coronary artery dissection. *Catheter Cardiovasc Interv.* 2022 Oct 23. doi: 10.1002/ccd.30448. Epub ahead of print. PMID: 36273416.
2. Damluji AA, Tehrani B, Sinha SS, Samsky MD, **Henry TD**, Thiele H, West NEJ, Senatore FF, Truesdell AG, Dangas GD, Smilowitz NR, Amin AP, deVore AD, Moazami N, Cigarroa JE, Rao SV, Krucoff MW, Morrow DA, Gilchrist IC. Position Statement on Vascular Access Safety for Percutaneous Devices in AMI Complicated by Cardiogenic Shock. *JACC Cardiovasc Interv.* 2022 Oct 24;15(20):2003-2019. doi: 10.1016/j.jcin.2022.08.041. PMID: 36265932.
3. Kunadian V, Baber U, Pivato CA, Cao D, Dangas G, Sartori S, Zhang Z, Angiolillo DJ, Briguori C, Cohen DJ, Collier T, Dudek D, Gibson M, Gil R, Huber K, Kaul U, Kornowski R, Krucoff MW, Dehghani P, Mehta S, Moliterno DJ, Ohman EM, Escaned J, Sardella G, Sharma SK, Shlofmitz R, Weisz G, Witzenbichler B,

Džavík V, Gurbel P, Hamm CW, **Henry TD**, Kastrati A, Marx SO, Oldroyd K, Steg PG, Pocock S, Mehran R. Bleeding and Ischemic Outcomes With Ticagrelor Monotherapy According to Body Mass Index. *JACC Cardiovasc Interv.* 2022 Oct 10;15(19):1948-1960. doi: 10.1016/j.jcin.2022.07.039. PMID: 36202563.

4. **Henry TD, Quesada O**, Wilson RF. Time Course of Microvascular Stunning in ST-Segment-Elevation Myocardial Infarction. *Circ Cardiovasc Interv.* 2022 Oct 28:e012528. doi: 10.1161/CIRCINTERVENTIONS.122.012528. Epub ahead of print. PMID: 36305317.
5. Rymer JA, Kaltenbach LA, Peterson ED, Cohen DJ, Fonarow GC, Choudhry NK, **Henry TD**, Cannon CP, Wang TY. Does the Effectiveness of a Medicine Copay Voucher Vary by Baseline Medication Out-Of-Pocket Expenses? Insights From ARTEMIS. *J Am Heart Assoc.* 2022 Oct 18;11(20):e026421. doi: 10.1161/JAHA.122.026421. Epub 2022 Oct 17. PMID: 36250667.
6. Simsek B, Kostantinis S, Karacsonyi J, Alaswad K, Megaly M, Karpaliotis D, Masoumi A, Jaber WA, Nicholson W, Rinfret S, Mashayekhi K, Werner GS, McEntegart M, Lee SW, Khatri JJ, Harding SA, Avran A, Jaffer FA, Doshi D, Kao HL, Sianos G, Yamane M, Milkas A, Azzalini L, Garbo R, Tammam K, Abi Rafeh N, Nikolakopoulos I, Vemmou E, Rangan BV, Burke MN, **Garcia S**, Croce KJ, Wu EB, Tsuchikane E, Di Mario C, Galassi AR, Gagnor A, Knaepen P, Jang Y, Kim BK, Poommipanit PB, Brilakis ES. A Systematic Review and Meta-Analysis of Clinical Outcomes of Patients Undergoing Chronic Total Occlusion Percutaneous Coronary Intervention. *J Invasive Cardiol.* 2022 Nov;34(11):E763-E775. Epub 2022 Oct 13. PMID: 36227013.
7. Sterns LD, Auricchio A, **Schloss EJ**, Lexcen D, Jacobsen L, DeGroot P, Molan A, Kurita T. Anti-tachycardia pacing success in implantable cardioverter defibrillators by patient, device, and programming characteristics. *Heart Rhythm.* 2022 Oct 19:S1547-5271(22)02517-6. doi: 10.1016/j.hrthm.2022.10.015. Epub ahead of print. PMID: 36272710.
8. Wick JA, Schmidlen T, Grande K, Moretz C, Ashcraft K, Green J, Moyer N, **Blaxall BC**. Implementing comprehensive pharmacogenomics in a community hospital-associated primary care setting. *J Am Pharm Assoc (2003).* 2022 Sep 9:S1544-3191(22)00303-X. doi: 10.1016/j.japh.2022.09.002. Epub ahead of print. PMID: 36243653.
9. **Quesada O, Henry TD**. Invited Article: Coronary Microvascular Disease in Patients with Obstructive Coronary Artery Disease. *Cardiology.* 2022 October 28. American College of Cardiology Magazine Spotlight Series.
<https://www.acc.org/Latest-in-Cardiology/Articles/2022/10/01/01/42/Spotlight-Series-Microvascular-Dysfunction-Coronary-Microvascular-Disease-in-Patients-With-Obstructive-CAD>
10. Zahid S, Harrington C, Michos E, Baker V, **Quesada O**, Shufelt C, Aggarwal N, Hashem A, Minhas A. Cardiovascular Complications During Delivery Admissions Associated with Assisted Reproductive Technology (From a National Inpatient Sample Analysis 2008-2019). *Am J Cardiol.* 2022 Oct 22;S0002-9149(22):00953-5. PMID: 36283885
11. Rizik DG, Rajagopal V, Makkar RR, Bajwa T, Kleinman NS, Linke A, **Kereiakes DJ**, Waksman R, Thourani VH, Stoler RC, Mishkel GJ, Iyer VS, Buchbinder M, Götberg M, Bjursten H, Allocco DJ, Reardon MJ. Long-term Outcomes after Transcatheter Aortic Valve Replacement with the Lotus Valve Versus CoreValve/EvolutR: A Secondary Analysis of the REPRISE III Randomized Clinical Trial. *JAMA Cardiol.* 2022 Oct 3;5(10):e2238792. PMID: 36301543
12. **Kereiakes DJ**, Ali ZA, Riley RF, **Smith TD**, Shlofmitz RA. Intravascular Lithotripsy for Treatment of Calcified Coronary Artery Disease. *Interv Cardiol Clinics.* 2022 Oct;11(4):393-404. PMID: 36243485

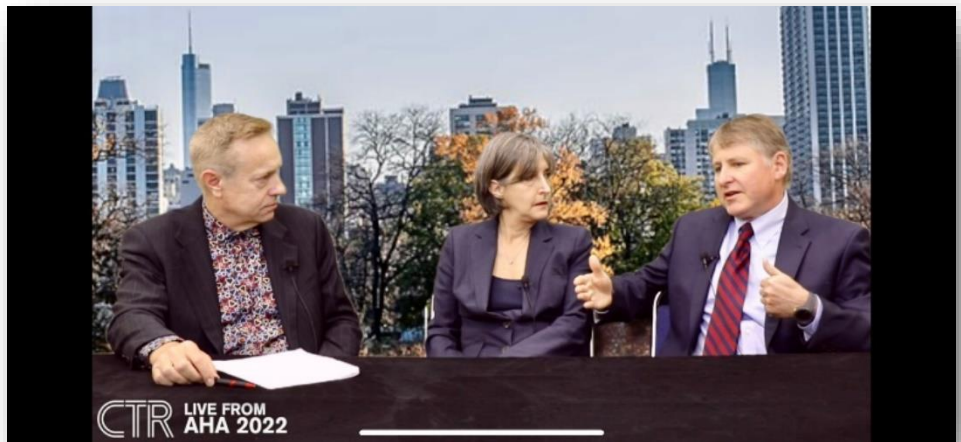
Research and Lindner Highlights

2022 American Heart Association Conference



Dr. James Jollis Presenting
“Treatment Time and In-Hospital Mortality Among Patients With ST-Segment Elevation Myocardial Infarction, 2018-2021.”

<http://clinicaltrialresults.org/dr-james-jollis-dr-jacqueline-tamis-holland-and-dr-c-michael-gibson-discuss-treatment-time-and-in-hospital-mortality-among-patients-with-st-segment-elevation-myocardial-infarction-2018-2021/>



Dr. Mehmet Yildiz (Middle) poster presentation "Trends in Clinical Characteristics and Mortality in STEMI Patients Over Two Decades: Insights From the Midwest STEMI Consortium"



Congratulations to Dr. Corl and his team!

Performing the first L6 Shockwave in the world!!



Reminders

Research Group Meeting
December 14, 2022, 6:30-7:30am
Microsoft Teams