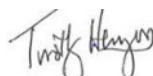


THE LINDNER RESEARCH CENTER

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May 2023

This month we review the CV Surgery trials. Drs. Geoff Answini and Rob Dowling will give a brief introduction to the amazing work they are doing at The Lindner Research Center.



It's been a very exciting and dynamic year for our Cardiothoracic surgery division!!! We added Dr. Rob Dowling to our team in July of 2022 to start a heart transplant program, and we recently added Dr. Miriam Freundt to the team in April to help run the Cardiothoracic ICU. We did our first successful Heart transplant in November 2022 and now have successfully completed 8 transplants. We have started a surgical HOCM program under the leadership of Dr. J. Michael Smith as part of a multidisciplinary effort with our cardiology colleagues and are actively getting referrals from all around the region. We are currently going through the application process to become a center of excellence. Dr. Smith has also been instrumental in the development of a multidisciplinary program for the treatment of endocarditis. We've started a surgical Afib program that offers totally endoscopic afib ablations, hybrid ablations, and minimally invasive LAA ligation. We've added Robotic CABG to our surgical offerings spearheaded by Dr. Saad Hasan in addition to our already active robotic and minimally invasive surgical valve repair and replacement programs. Dr. Griffin is actively doing minimally invasive mitral and aortic valve repairs and replacement surgeries along with Dr. Smith. We continue to offer both open and endovascular repairs of complex aortic aneurysms and dissections and are involved in many cutting edge research projects in this arena. Our Thoracic team led by Dr. Julian Guitron has successfully started a Pectus excavatum repair program and an esophagectomy program. We have enjoyed exponential growth over the last year as a division and are really becoming a one-stop shop for all things Cardiothoracic surgery. We are solidifying our status as the premiere CT surgery program in the region and have really become a quaternary referral center. We are really looking forward to continued growth and will be adding new programs this year including totally artificial heart implants, tracheal surgery, and open thoracoabdominal aneurysm repairs, with the possibility of a few other cutting edge programs. We owe much of our success to the amazing collaboration between the surgeons and our cardiology colleagues. It also goes without saying that none of this would be possible without The Lindner Center and their amazing partnership that allows us to have access to cutting edge technologies and keeps us at the forefront of CT surgery research. I extend a heartfelt thanks to everyone that has helped contribute to our success over these last few years!!! It really takes a village, and none of this is possible without the unified efforts of the Christ Heart and Vascular team, the Best team in the region!!

Best Regards
Dr. Geoff Answini

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The Division of Cardiothoracic Surgery is thrilled to be interacting with the team at the Linder Research and Education Center and we are very excited about our increased involvement in clinical and pre-clinical research.

We continue to be actively involved with the many innovative clinical trials led by our Structural Heart cardiology colleagues. Additionally, we continue to enroll patients in the Competence trial which compares the Evaheart2 LVAD to the commercially available HM3 LVAD. Our team, led by Drs. Egnaczyk and Answini, is one of the top five enrolling centers in the country. An additional study on the impact of pulsatile flow with the Evaheart2 pump is being initiated with our team and Dr. Quesada and her team. We are also enrolling patients in the Heal IST trial which is a potentially breakthrough treatment for inappropriate sinus tachycardia. We will soon start enrolling patients in the LeAAPS trial to determine if occlusion of the left arial appendage improves outcomes after heart bypass surgery. Two additional trials looking at clinical outcomes in patients supported with Impella devices are being initiated and are supported by extramural funding. Dr. Guitron is the PI on a trial of cryoanalgesia to improve pain control after thoracic procedures. Christ Hospital was one of the first three sites to enroll patients and the first to adopt a new database format. We are also excited to have Dr. Miriam Freundt, with her extensive pre-clinical and clinical trial background, join our team.

Dr. Rob Dowling

CV Surgery Trials

Trial	PI	Status	# Months Active	# Screened	# Enrolled	Last Patient Enrolled	Brief Description
Foldax TRIA Aortic Heart Valve Replacement Sponsor: Foldax, Inc.	Answini	On Hold	36	18	9 (2 nd highest enroller)	8/13/21	The Foldax TRIA Aortic Valve has offers a flexible valve alternative with the perceived advantage of both the bio prosthetics and mechanical valves without the disadvantages. Patients only require 3 months of anticoagulation It is a prosthetic heart valve with a flexible polymer stent and annular base. Three flexible polymer leaflets are bonded to the frame using a casting process. Polymeric leaflet material surrounds the apertures, leaving a central opening in each aperture. The base of the valve is covered with

							ePTFE to create a sewing ring.
Foldax TRIA Mitral Heart Valve Replacement Sponsor: Foldax, Inc	Answini	On Hold	20	1	1	6/15/21	The same composition as above for patients with mitral stenosis or MR.
Apollo Sponsor: Medtronic	Answini	Enrolling	60	77	9	4/2023	Transcatheter Mitral Valve Replacement with the Medtronic Intrepid™ TMVR System in patients with severe symptomatic mitral regurgitation via transfemoral or transapical approach.
Xylocor Sponsor: Xylocor Therapeutics	Henry	Follow-up	36	10	5	4/18/22	A Phase 1/2 trial of direct administration via intracoronary infusion of AdVEGF-All6A+, a replication deficient adenovirus vector expressing a cDNA/Genomic hybrid of human vascular endothelial growth factor, to the ischemic myocardium of subjects with angina secondary to CAD that is refractory to drug therapy and unsuitable for revascularization. Sponsor: Xylocor Therapeutics
LeAAPS Sponsor: Atricure	J Michael Smith	Starting mid-May	NA	NA	NA	NA	To demonstrate the effectiveness of LAA exclusion with AtriClip for the prevention of ischemic stroke or systemic arterial embolism in subjects undergoing cardiac surgery who have risk factors for atrial fibrillation and ischemic stroke.
Heal IST Sponsor: Atricure	J Michael Smith	Enrolling	1	First patient scheduled for screening	NA	NA	Atricure Isolator Synergy Surgical Ablation System for treatment of symptomatic IST in patients who are refractory to or intolerant to rate control drugs.
Competence Sponsor:	Egnaczyk/Answini	Enrolling	12	13	5	5/4/23	Study of the EVAHEART left ventricular assist

Evaheart, Inc							system. The system is a continuous flow centrifugal pump that employs a hydrodynamic impeller levitation system designed to preserve arterial pulsatility, minimize red cell trauma and blood stagnation and lower risk of ventricular septal suction.
Reduce Sponsor: Atricure	Guitron	Enrolling	9	38	38	5/2023	A prospective national database of patients undergoing cryoanalgesia or nerve block by freezing for thoracic procedures
LOQI Sponsor; Abiomed	Dowling	Waiting for IT to build EPIC interface					Long-Term Outcomes and Quality Indicator Impella Registry
Microvascular endothelial function in continuous flow LVADS- Eva2 & HM3 Sponsor: Abiomed	Dowling	Waiting for database build					Evaluate the endothelial function pre and post LVAD implant
Coming Soon							
BiVACOR TAH Early Feasibility Study Sponsor: BiVACOR	Dowling						Total artificial heart for use in bridge to transplant.
Extend Impella	Dowling						Examining multi center outcomes and explants with Impella 5.5. THIS IS UNDER REVIEW BY ABIOMED AND NOT YET APPROVED/ FUNDED

Highlighted Trials

LeAAPS

PI: Dr. J. Michael Smith

Study coordinator: Katherine Gloria

This trial is a prospective, randomized, multicenter, multinational, blinded, superiority trial. The objective of this trial is to evaluate the effectiveness of left atrial appendage exclusion (LAAE) for the prevention of ischemic stroke or systemic arterial embolism in subjects undergoing cardiac surgery who have risk factors for atrial fibrillation and ischemic stroke.

Major Inclusion criteria: 1. Subjects ≥ 18 years of age 2. Documentation of any of the following clinical criteria: A. CHA₂DS₂-VASc ≥ 4 with age ≥ 65 B. CHA₂DS₂-VASc ≥ 4 with significant left atrium enlargement or elevated NT-proBNP C. CHA₂DS₂-VASc = 3 with age ≥ 75 D. CHA₂DS₂-VASc = 3 with significant left atrium enlargement or elevated NT-proBNP E. CHA₂DS₂-VASc score = 2 with age ≥ 65 and significant left atrium enlargement or elevated NT-proBNP

Major Exclusion Criteria: 1. Clinically significant atrial fibrillation or atrial flutter: Anytime in the past, documented by an electrocardiographic recording and episode lasting 6 minutes or longer. 2. Prior procedure involving opening the pericardium or entering the pericardial space 3. Prior LAA occlusion, exclusion, or removal (surgical or percutaneous) 4. Planned cardiac surgical procedure using non-sternotomy approaches : Partial sternotomies will be allowed. 5. Patients whose planned procedure is a heart transplant or implantation of any ventricular assist devices 6. Active endocarditis 7. Active systemic infection at the time of cardiac surgery requiring antibiotics, including known SARS-CoV2 infections regardless of symptoms 8. Known allergy to Nitinol or nickel sensitivity 9. Known medical condition with expected survival of less than 1 year 10. Other comorbidities that in the investigator's opinion make the subject unsuitable candidate to complete the protocol required visits. 11. Current enrollment in an investigation or trial or an investigational devices or investigational drug that would interfere with this trial. 12. Mental impairment or other psychiatric conditions which may not allow the patient to understand the nature, significance, and scope of the trial. 13. Pregnancy 14. Known severe symptomatic carotid disease

STOP ADHF

PI: Dr. Eugene Chung

Study coordinator: Wendy Parker

STOP-ADHF Study: An evaluation of the safety and performance of the Cardionomic Cardiac Pulmonary Nerve Stimulation (CPNS) system in patients with acute decompensated heart failure.

Major Inclusion criteria: 1. Admitted to hospital with a principal diagnosis of ADHF 2. BMI adjusted BNP ≥ 500 pg/mL or NT-proBNP ≥ 2000 pg/MI 3. LVEF $\leq 50\%$ 4. At least one sign or symptom of fluid overload despite the administration of IV furosemide (or equivalent) (at least 40 mg or equivalent)

Major Exclusion Criteria: 1. Received a high dose inotrope or Levosimendan during current hospitalization or treatment with a low dose inotrope within 24 hours before enrollment 2. Requires mechanical support 3. Cardiogenic shock or impending cardiogenic shock 4. Systolic blood pressure < 80 mmHg or > 140 mmHg 5. Symptomatic hypotension 6. eGFR < 25 mL/min/1.732

April Publications

1. **Yildiz M, Henry TD.** Unprotected left main occlusion: Rare but deadly. *Catheter Cardiovasc Interv.* 2023 Apr;101(5):953-954. doi: 10.1002/ccd.30626. Epub 2023 Mar 15. PMID: 36922912.
2. **Henry TD, Garcia S, Bossone E.** Cardiovascular Effects of COVID-19. *Heart Fail Clin.* 2023 Apr;19(2):xi-xiii. doi: 10.1016/j.hfc.2023.02.001. Epub 2023 Feb 9. PMID: 36863819; PMCID: PMC9910013.
3. Guddeti RR, **Yildiz M**, Nayak KR, Alraies MC, Davidson L, **Henry TD, Garcia S.** Impact of COVID-19 on Acute Myocardial Infarction Care. *Heart Fail Clin.* 2023 Apr;19(2):221-229. doi: 10.1016/j.hfc.2022.08.004. PMID: 36863814; PMCID: PMC9973541.
4. **Gorder K, Young W**, Kapur NK, **Henry TD, Garcia S**, Guddeti RR, **Smith TD.** Mechanical Circulatory Support in COVID-19. *Heart Fail Clin.* 2023 Apr;19(2):205-211. doi: 10.1016/j.hfc.2022.08.003. PMID: 36863812; PMCID: PMC9973539.
5. Abraham B, Sous M, Sedhom R, Megaly M, Roman S, Sweeney J, Alkhouli M, Pollak P, El Sabbagh A, **Garcia S**, Goel SS, Saad M, Fortuin D. Meta-Analysis on Transcatheter Versus Transfemoral and Other Alternate Accesses for Transcatheter Aortic Valve Implantation. *Am J Cardiol.* 2023 Apr 1;192:196-205. doi: 10.1016/j.amjcard.2023.01.023. Epub 2023 Feb 21. PMID: 36821875.
6. Bhat AG, Verghese D, Harsha Patlolla S, Truesdell AG, Batchelor WB, **Henry TD**, Cubeddu RJ, Budoff M, Bui Q, Matthew Belford P, X Zhao D, Vallabhajosyula S. In-Hospital cardiac arrest complicating ST-elevation myocardial Infarction: Temporal trends and outcomes based on management strategy. *Resuscitation.* 2023 May;186:109747. doi: 10.1016/j.resuscitation.2023.109747. Epub 2023 Feb 22. PMID: 36822461.
7. Davidson SJ, Roncalli J, Surder D, Corti R, Chugh AR, Yang PC, **Henry TD**, Stanberry L, Lemarchand P, Beregi JP, Traverse JH. Microvascular obstruction identifies a subgroup of patients who benefit from stem cell therapy following ST-elevation myocardial infarction. *Am Heart J.* 2023 May;259:79-86. doi: 10.1016/j.ahj.2023.02.004. Epub 2023 Feb 14. PMID: 36796572.
8. **Quesada O**, Wei J, Suppogu N, Cook-Wiens G, Lauzon M, Reis S, Shaw L, Sopko G, Handberg E, Pepine C, C Bairey Merz N. Fitness attenuates long-term cardiovascular outcomes in women with ischemic heart disease and metabolic syndrome. *Am J Prev Cardiol.* 2023 April 23;14:100498.
9. Kuchtaruk AA, Sparrow RT, Azzalini L, **García S**, Villablanca PA, Jneid H, Elgendy IY, Alraies MC, Sanjoy SS, Mamas MA, Bagur R. Unplanned readmissions after Impella mechanical circulatory support. *Int J Cardiol.* 2023 May 15;379:48-59. doi: 10.1016/j.ijcard.2023.03.013. Epub 2023 Mar 7. PMID: 36893855.

11. Kim G, Sayer G, Ransom J, Keebler M, Katz J, Kilic A, Lindenfeld J, **Egnaczyk G**, Shah P, Brieke A, Walenga J, Crandall D, Farrar DJ, Sundareswaran K, Uriel N. Association of Angiopoietin-2 and TNF- α With Bleeding During Left Ventricular Assist Device Support: Analysis from the PREVENT Biorepository. ASAIO J. 2023 May 2. doi: 10.1097/MAT.0000000000001942. Epub ahead of print. PMID: 37134003.
12. Waxman A, Restrepo-Jaramillo R, Thenappan T, **Engel P**, Bajwa A, Ravichandran A, Feldman J, Hajari Case A, Tapson V, Smith P, Deng C, Shen E, Nathan SD. Long-term inhaled treprostinil for PH-ILD: INCREASE open-label extension study. Eur Respir J. 2023 Apr 20:2202414. doi: 10.1183/13993003.02414-2022. Epub ahead of print. PMID: 37080567.
13. Devich R, Neuendorff NR, Frazier OH, Eisen HJ, **Dowling R, Freundt M**. Hematopoietic Stimulation During Impella 5.5 Support to Avoid Transfusions in a Jehovah's Witness. ASAIO J. 2023 Apr 24. doi: 10.1097/MAT.0000000000001944. Epub ahead of print. PMID: 37084256.

Research and Lindner Highlights



Wednesday, May 17, 2023

Time: 2:30 PM – 6:00 PM	<u>Session:</u> SCAI Think Tank – Coronary Topic <u>Location:</u> Hyatt Regency Phoenix; 122 N 2nd St; Phoenix, AZ 85004; (Phoenix Ballroom) <u>Moderator:</u> Tim Henry
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Thursday, May 18, 2023

Time: 9:40 AM – 10:30 AM	<u>Session:</u> The Disrupt CAD III Post-approval Study: Real-world Safety and Effectiveness of Coronary Intravascular Lithotripsy from the ACC NCDR® CathPCI Registry® <u>Location:</u> North Hall CD (Third Floor, Phoenix Convention Center) <u>Presenter:</u> Dean Kereiakes
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Time: 12:20 PM – 12:32 PM	<u>Session:</u> Coronary IVL PAS Within Cath PCI <u>Location:</u> West 106 (First Floor, Phoenix Convention Center) <u>Presenter:</u> Dean Kereiakes
Time: 4:30 PM – 5:30 PM	<u>Session:</u> Future of PCI (Including AI, New Technology, Robotic PCI, CT Imaging, & Drug-Coated Balloons) <u>Location:</u> West 301BC (Third Floor, Phoenix Convention Center) <u>Moderator:</u> Tim Henry
Time: 6:45 PM – 6:45 PM	<u>Session:</u> Meet the Masters Networking Reception - Round Table Discussions <u>Location:</u> West 211 AB (Second Floor, Phoenix Convention Center) <u>Presenter:</u> Tim Henry

Friday, May 19, 2023

Time: 8:30 AM – 8:50 AM	<u>Session:</u> SCAI Town Hall <u>Location:</u> West 301BC (Third Floor, Phoenix Convention Center) <u>Panelist:</u> Tim Henry
Time: 11:10 AM – 12:10 PM	<u>Session:</u> SCAI Early Career Research Grant Symposium <u>Location:</u> West 103BC (First Floor, Phoenix Convention Center) <u>Moderator:</u> Tim Henry <u>Panelist:</u> Santiago Garcia
Time: 11:32 AM – 11:36 AM	<u>Session:</u> High-Risk Mechanical Aortic Valve Thrombosis Managed with Transseptal Catheter Directed Tissue Plasminogen Activator <u>Location:</u> West 212 C (Second Floor, Phoenix Convention Center) <u>Presenter:</u> Kari Gorder
Time: 11:44 AM – 11:48 AM	<u>Session:</u> Conclusion: How the Case Unfolded <u>Location:</u> West 212 C (Second Floor, Phoenix Convention Center) <u>Presenter:</u> Kari Gorder
Time: 1:30 PM – 3:00 PM	<u>Session:</u> SCAI Learning Lab: Benefits of the CCTA + FFRCT Pathway for the Cath Lab <u>Location:</u> North Hall CD LL6 (Third Floor, Phoenix Convention Center) <u>Panelist:</u> Tim Henry

Saturday, May 20, 2023

Time: 7:00 AM – 7:15 AM	<u>Session:</u> Lifetime Management of Aortic Stenosis: The Importance of Choosing the First Valve <u>Location:</u> West 101 (First Floor, Phoenix Convention Center) <u>Presenter:</u> Santiago Garcia
Time: 8:12 AM – 8:22 AM	<u>Session:</u> Don't Panic, but I Have a Perforation and Don't Have a Wire Across <u>Location:</u> West 301BC (Third Floor, Phoenix Convention Center) <u>Presenter:</u> Jarrod Frizell
Time: 10:40 AM – 11:20 AM	<u>Session:</u> Bedside Removal of Impella Devices in Cardiogenic Shock Patients is Feasible and Safe <u>Location:</u> North Hall CD (Third Floor, Phoenix Convention Center) <u>Presenter:</u> Kari Gorder
Time: 1:40 PM – 3:10 PM	<u>Session:</u> Structural Live Cases: Presented by Northwestern University Feinberg School of Medicine and Banner - University Medical Center Phoenix <u>Location:</u> West 207 Lecture Hall (Second Floor, Phoenix Convention Center) <u>Panelist:</u> Santiago Garcia
Time: 3:12 PM – 3:19 PM	<u>Session:</u> Lithotripsy-Assisted Transcatheter Mitral Valve Replacement for Severe Mitral Annular and Valve Calcification <u>Location:</u> West 212 A (Second Floor, Phoenix Convention Center) <u>Presenter:</u> Puvi Seshiah
Time: 3:28 PM – 3:35 PM	<u>Session:</u> Early Use of Novel Shockwave L6 Intravascular Lithotripsy System for Treatment of Severe Heavily Calcified Abdominal Aorta Stenosis <u>Location:</u> West 212 A (Second Floor, Phoenix Convention Center) <u>Presenter:</u> John Corl

Reminders

Research Group Meeting
June 14, 2023, 6:30-7:30am
Microsoft Teams