

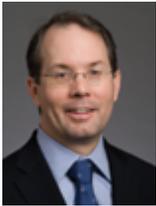


THE SANGER REPORT

A PUBLICATION OF CAROLINUS HEALTHCARE SYSTEM

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Sanger Becomes First in the Carolinas to Implant Total Artificial Heart



Eric Skipper, MD, FACS



Sanjeev Gulati, MD

Sanger Heart & Vascular Institute has a long history of bringing advanced heart care to the Carolinas and beyond, including the first heart transplant in Charlotte and the world's first stent graft specifically designed for branch vessel repair of thoracic aortic aneurysms. Sanger recently added to the list of breakthroughs by becoming the first in the Carolinas to implant the Total Artificial Heart (TAH).

The device, manufactured by SynCardia Systems, Inc., replaces both the left and right ventricles and the four native heart valves. It is connected to an external pneumatic driver by tubes (or cannulas) that run through the abdomen. Approved by the FDA as a bridge-to-transplant device, the TAH was used by Sanger's advanced heart failure and mechanical circulatory support team to support critical cardiac function in their patient, a 49-year-old man with heart failure, while he waited for a donor heart.



According to Sanjeev Gulati, MD, medical director of the advanced heart failure and mechanical circulatory support program, the TAH procedure is still relatively uncommon worldwide but provides critical

support for a subset of patients who are awaiting transplantation and cannot receive a left ventricular assistance device because they have poor right ventricular function. "The TAH is an innovative technology that has demonstrated good clinical outcomes and allows us to help patients survive until a long-term solution can be implemented for them," Dr. Gulati said. The device's availability in Charlotte means that patients no longer need to travel to hospitals in other states conducting the procedure to receive the life-saving treatment.

A Bridge to Transplant

The patient who received the TAH presented on Christmas Day with chest pain and shortness of breath and underwent right coronary artery stenting before being transferred to Carolinus Medical Center to be evaluated by the heart failure cardiologists. Over the next few weeks, he was put on IV medication to support his heart function and was subsequently placed on extracorporeal membrane oxygenation after cardiac arrest. After realizing his condition would not improve with his native heart, the heart failure cardiologists decided to conduct the TAH surgery, as this was his best chance for survival.

The eight-hour surgery was performed on January 13 at Carolinus Medical Center, conducted by Eric Skipper, MD, FACS, medical director of adult cardiovascular surgery at Sanger. To rebuild strength and improve lung function, the patient had an extended post-surgical hospitalization, which led directly to his transplantation. He has since returned home and is recovering well, Dr. Gulati said.

"This patient was a 100 percent success, as we were able to accomplish both the short-term and long-term goals of the

TAH procedure" Dr. Gulati said. "The short-term goal is to restore normal cardiac output so that all of the end organs can recover. The long-term goal is to get the patient transplanted and allow him to survive well beyond that standpoint."

Harnessing Technology for the Region

As the heart failure team's capabilities continue to evolve, its members also plan to keep working closely with primary care physicians and cardiologists throughout the region to provide specialized care. Dr. Gulati adds that a critical component of heart failure care is managing time – that transplant and mechanical circulatory support, such as the TAH, should be considered before the situation becomes an emergency.

Dr. Gulati recommends primary care doctors or cardiologists refer their patients to Sanger Heart & Vascular Institute if the patient:

- Was in the hospital within the last six months for decompensated heart failure
- Is Class III B or higher NYHA Functional Classification
- Exhibits worsening azotemia
- Has hypotension
- Does not respond to standard heart failure medical therapy ■■■

REFERENCE:

Image obtained from the SynCardia multimedia library: <http://www.syncardia.com/media/multimedia-library-dp1.html>. High-res images are also available.

For more information about our heart failure program, please call
704-512-2785

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Specialized Care Improves Lives of ACHD Patients

Supporting Afib Patients Through Stroke Research

UNICAR Celebrates 25 Years Bringing Heart Care to Guatemalans

First-Ever Robicsek Symposium

CMC-Union Now Offering Percutaneous Coronary Intervention Services

International Medical Outreach Expands to South America

Specialized Care Improves Lives of ADULT CONGENITAL HEART DISEASE PATIENTS



Jorge Alegría, MD

Despite national practice guidelines advising that patients with adult congenital heart disease (ACHD) undergo regular care at a specialized center, there has historically been no data linking this care with improved outcomes.

A Canadian study published recently in *Circulation*, however, has changed that. In this population-based analysis, researchers examining referral and mortality rates found that referral was associated with a significant reduction in mortality, especially in those with severe ACHD.

Key information:

- An examination of the Quebec Congenital Heart Disease database, including 71,467 individuals from 1990 to 2005
- A significant increase in referral rates to specialized centers seen in 1997 (rate ratio, +7.4%; 95% confidence interval [CI], +6.6% to +8.2%)
- A parallel significant reduction in mortality seen after 2000 (rate ratio, -5.0%; 95% CI, -10.8% to -0.8%)
- In post hoc cohort and case-control analyses, specialized care was independently associated with reduced mortality (hazard ratio, 0.78; 95% CI, 0.65–0.94) (*Circulation*. 2014; 129:1804-1812.)

The new data confirms what the physicians at Sanger Heart & Vascular Institute have long known – specialized treatment helps patients live longer and fuller lives. The study also confirms, however, that (even with the observed referral increase) only 5–10% of ACHD patients receive this kind of care.

Committed to improving ACHD treatment throughout the region, Sanger physicians are eager to team with referring cardiologists and internists, working collaboratively to provide comprehensive care that is individualized for each patient's specific presentation of ACHD.

Physician Collaboration a Key Component of Success

Sanger's ACHD team is a multi-disciplinary group that includes congenital heart surgeons, an adult congenital heart disease specialist, pediatric cardiologists, interventional cardiologists, cardiac anesthesiologists,

electrophysiologists, imaging specialists, high-risk OB practitioners and other staff. The team is led by Jorge Alegría, MD, who trained at the Mayo Clinic and joined Sanger in 2013.

Dr. Alegría emphasizes the importance of forming partnerships with referring physicians, especially when creating and maintaining the patient's care plan, which addresses any interventional or surgical needs, as well as medication, follow-up care, imaging studies, exercise, nutrition, contraception and pregnancy, psychosocial support/counseling, and other lifestyle issues that are relevant for adults with CHD.

“Patients with ACHD are unique because they have already undergone major health events in their first year, first month, or even first day of life,” Dr. Alegría said. “More than half of these patients have had multiple complex cardiac surgeries, and while they have proven to be survivors, they also subsequently experience their own set of challenges. We know that they have higher rates of depression and anxiety, and that many face systemic issues, such as liver damage in patients with a single functioning ventricle.

Providing specialized care that addresses these issues while working together with the patient's established internist or cardiologist can thus be significantly beneficial.”

Noting that the transition from pediatric to adult care is the point where treatment lapses often begin for congenital heart disease patients, Dr. Alegría cites Sanger's close work with Levine Children's Hospital as another key partnership that supports ACHD patients' success. For example, physicians from both facilities meet weekly to discuss each surgical case and other complex patients to leverage a deep knowledge base. Further, as members of the broad Carolinas HealthCare System network, Sanger staff has a vast amount of resources at their fingertips to provide the very best care that is comprehensive and collaborative. ■■■

For information about a free Adult Congenital support group for your patients, visit CarolinasHealthCare.org/ACHDarticle



Dr. Jorge Alegría consulting with adult congenital patient Chris Carlson

Supporting Afib Patients Through **STROKE RESEARCH**



Michael Rinaldi,
MD, FACC, FSCAI

As the most common cardiac arrhythmia in the adult cardiology population, atrial fibrillation (AF) has garnered significant attention from researchers looking to mitigate its associated stroke risk. Device therapy for AF-related stroke is a promising treatment avenue that Sanger Heart & Vascular Institute is involved in investigating as part of the PREVAIL trial.

PREVAIL compares chronic warfarin with the WATCHMAN™ device, Boston Scientific's left atrial appendage (LAA) closure technology. Comprised of three parts – a transeptal access sheath, a delivery catheter and an umbrella-shaped device – the WATCHMAN is permanently implanted at the LAA to trap blood clots before they exit.



“This is a completely new therapy that will have a significant impact on stroke prevention,” stated Michael J. Rinaldi, MD, Sanger's medical director of clinical research. “Currently, about one-third of patients who have a significant risk of stroke aren't receiving therapy because they have an unacceptable bleeding risk, so they can't take oral anticoagulants. These patients would be ideal for mechanical stroke prevention.”

Data Supports Safety, Efficacy

The WATCHMAN's first prospective randomized trial – Protect AF – showed non-inferiority (in the shorter-term data) and superiority (in the 4-year data) to warfarin for stroke, cardiovascular death and systemic embolism. Because of procedure-related safety issues, however, Boston Scientific launched the PREVAIL trial to obtain additional safety data with new operators.

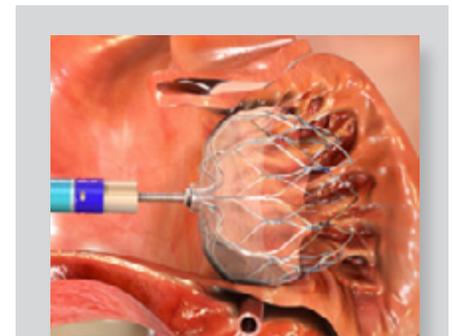
PREVAIL enrolled 407 patients, with 12 of those participants receiving treatment at Sanger. In addition to Dr. Rinaldi, Sanger cardiologist J. Warren Holshouser, MD, FACC, was also a primary investigator, and the trial further utilized talent from additional departments.

“Sanger's integration of expertise from various specialties was ideal for this trial,” Dr. Rinaldi said. “The implant is done with both fluoroscopy and continuous transesophageal echocardiographic imaging, so there is a team-based approach to the procedure in which electrophysiology, interventional cardiology and advanced imaging cardiologists work together.”

The PREVAIL trial met its primary short-term safety endpoint, and the full 18-month data for the two other primary endpoints has not yet been reported by Boston Scientific. The FDA's Circulatory System Devices Panel voted last December to approve the device, but the FDA recently announced they will convene another panel to review before making an approval decision.

Satisfying an Unmet Need

Although the PREVAIL trial enrollment is complete, Sanger is involved with the Continued Access Registry, which lets eligible patients receive the device without randomization. The registry's continuation in the coming months will be dictated by the FDA's timeline for the panel review and potential approval. Dr. Rinaldi notes that, if approved, the device will be regularly used at Sanger.



WATCHMAN
Left Atrial Appendage Closure Device

“There is a clinically significant subset of patients who aren't great anticoagulation candidates and thus don't have many options. These people are having strokes, and we see it every day,” Dr. Rinaldi said. “By utilizing this device, if approved, we will be able to have the whole toolbox of stroke prevention: warfarin for appropriate patients, novel oral anticoagulants for other patients and a mechanical solution.” ■■■

REFERENCE:
Images obtained from <http://www.whichmedicaldevice.com> and <http://www.bostonscientific.com>

First-Ever **ROBICSEK SYMPOSIUM**

The first Francis Robicsek Symposium was held March 7 at Carolinas Medical Center in Charlotte, NC. The symposium honors Francis Robicsek, MD, PhD, for his contributions to cardiovascular surgery and international health. The symposium included several speakers, including Joseph Coselli, MD, a world-renowned cardiothoracic surgeon at Baylor College of Medicine in Houston, Texas, who received the first Francis Robicsek Award for contributions to vascular and cardiothoracic surgery. ■■■



Joseph Coselli, MD, and Francis Robicsek, MD, PhD

UNICAR Celebrates 25 YEARS

Bringing Heart Care to Guatemalans

This year marks the 25th anniversary of the opening of UNICAR, the Guatemalan Heart Institute located in Guatemala City. UNICAR is a training hub for cardiologists and surgeons in Central America and is the first heart institute in the region.

The program was started as a result of a 20-year collaboration with Carolinas HealthCare System's Francis Robicsek, MD, and the Heineman Foundation. In 1971, on one of his many visits to study Mayan ruins, Dr. Robicsek befriended the president of Guatemala. A conversation soon turned into common cause, and the two men set out to provide heart surgery services to the people of Guatemala and beyond.

Today, Carolinas HealthCare System continues its partnership with UNICAR, developing a modern record-keeping system



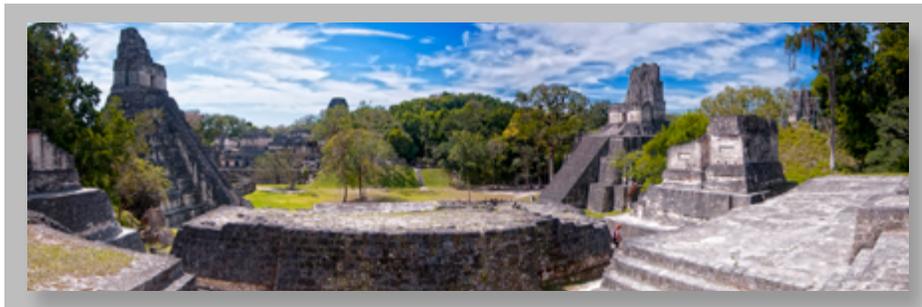
and establishing a network of echocardiographic laboratories. To date, doctors have performed more than 13,000 heart surgeries at UNICAR, and will undoubtedly save many more lives over the next 25 years. ■■■

International Medical Outreach **EXPANDS** TO SOUTH AMERICA

Since 2012, cardiologists and echocardiography technicians with Sanger Heart & Vascular Institute

have participated in virtual medical consultations with clinical staff in Central American hospitals. The virtual

network, established and facilitated by the International Medical Outreach Program, now is expanding to South America. On Aug. 1, Dr. Jorge Alegría and Dr. Gonzalo Wallis participated in a consultation with cardiologists and cardiac surgeons in Guatemala and Chile. Following a presentation by Dr. Alegría, Guatemalan clinicians shared echocardiograms of patients with complex congenital heart anomalies and received treatment recommendations from Sanger physicians. ■■■



CMC-Union Now Offering **PERCUTANEOUS CORONARY INTERVENTION SERVICES**

Sanger Heart & Vascular Institute continues to expand advanced care to its network of facilities across the Carolinas. On April 7, Sanger began offering urgent and elective percutaneous coronary intervention (PCI) services at Carolinas Medical Center (CMC)-Union in Monroe, NC. The new service eliminates the need for area residents to travel to Charlotte or Pineville for treatment.

New PCI services follow extensive renovations to the CMC-Union Cardiovascular Center, including a new patient and family waiting area, patient recovery unit, and an upgraded interventional radiology and vascular suite. The center also offers a radial lounge, a first for Carolinas HealthCare System. ■■■



RECENT NEWS

Publications and Presentations

Michael Rinaldi, MD, had an abstract entitled “The Final Result of the EVEREST II Randomized Controlled Trials Percutaneous and Surgical Reduction of Mitral Regurgitation” accepted for Oral Presentation at the American College of Cardiology 2014, National Meeting.

Joseph Mishkin, MD, was a co-author of a paper entitled “Characterization of a Novel Symptom of Advanced Heart Failure: Bendopnea,” published in the *Journal of American College of Cardiology: Heart Failure*, in February.

Geoffrey Rose, MD, authored Imaging Council Chairman’s Article, “Demystifying Imaging Laboratory Accreditation,” published in the *Journal of American College of Cardiology: Cardiovascular Imaging*, in February.

Kshitij Mistry, MD, presented “Building a Quality Framework for Success” along with others at the CHOP-sponsored 17th Annual Update on Pediatric Congenital and Cardiovascular Disease Cardiology Conference in February.

Michael Rinaldi, MD, co-authored an article entitled “Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents,” published in January in *Circulation*. He also co-authored a paper published in *Circulation* entitled “Relationship Between Intervascular Ultrasound Guidelines and Clinical Outcomes after Drug-Eluting Stents: The Assessment of Dual Antiplatelet Therapy with Drug-Eluting Stents (ADAPT-DES) Study.” **Dr. Rinaldi** was also co-author on an abstract accepted for presentation at the European Association of Percutaneous and Cardiovascular Interventions. The title of the abstract is “The EVEREST II Randomized Controlled Trial of Percutaneous and Surgical Reduction of Mitral Regurgitation: 5-Year Results Stratified by Degenerative or Functional Etiology.”

Thomas Johnson, MD, and **Geoffrey Rose, MD**, had an article accepted for publication in the *Journal of the American Society of Echocardiography* entitled, “Improving Appropriate use of Echocardiography and SPECT MPI: A Continuous Quality Improvement Initiative.” Dr. Alan Pearlman, the editor, commented, “I continue to be impressed by the strong commitment of Sanger Heart & Vascular Institute to quality improvement. This is a great model for our readers and for all ASE members.”

Michael Rinaldi, MD, Markus Scherer, MD, William Downey, MD, and Geoffrey Rose, MD, had a paper published in *Cardiac Interventions Today* entitled “Site-Specific Transseptal Puncture for Emerging Structural Heart Interventions.”

Kevin Lobdell, MD, co-authored an article, “Effects of Hemodynamic Instability on Early Outcomes and Late Survival Following Repair of Acute Type A Aortic Dissection,” in the journal *Aorta*.

Hadley Wilson MD, led a panel “How Healthcare Reform will Affect Cardiovascular Medicine” at Cardiology 2014: Advances in Science and Practice at Vanderbilt Heart in April. He was also appointed to the North Carolina Hospital Association Committee on PCI Regulation and to the Interventional Council of the American College of Cardiology.

The Heart Failure Team had four abstracts accepted by the American Association of Heart Failure Nurses:

- a. *Specialized Exercise Prescription Program on Quality of Life and Functional Capacity in Heart Failure*
- b. *Quality of Life in Heart Failure Patients Following a Multidisciplinary Four Week Program*
- c. *Palliative Care, Quality of Life and Depression in Persons with Heart Failure*
- d. *Reducing Heart Failure Readmissions through Care Coordination*

The Heart Failure Team also had an abstract entitled “Reducing Heart Failure Admissions through Heart Success Transitional Care Model” accepted to be presented at the 18th annual Scientific Meeting of the Heart Failure Society of America in Las Vegas this fall.

Michael Rinaldi, MD, presented two talks at the Society of Angiography and Intervention. One talk was entitled “TAVR Related Stroke: Will the Risk Ever Be <3%?,” the other was entitled “The Patient is Ready: Medical Therapy for Claudication.”

Rachel Keever, MD, participated in the development of the “Accountable Care Guide for Cardiologists,” part of the Toward Accountable Care (TAC) Consortium, presented at the North Carolina Bar Association’s annual meeting in April.

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If you’re interested in learning more about the programs or physicians featured in this issue of the Sanger Report, please call Aaron Fisher, physician liaison manager, at 704-607-8518.

RECENT NEWS continued

Honors and Recognition

Carolinas Medical Center, Carolinas Medical Center-Pineville and Carolinas Medical Center-NorthEast have all received the Mission: Life Line Receiving Center Recognition Award. This award is based upon the Mission: Lifeline Achievements through the ACTION Registry – GWTG data submitted for the 2013 calendar year. Both CMC and CMC-NorthEast received Gold Plus Awards. CMC-Pineville received the Silver Plus award, the highest possible award for the facility.

Hadley Wilson, MD, Michael Rinaldi, MD, and Glen Kowalchuk, MD, were cited at the American College of Cardiology Conference as subject-matter experts in *The Wall Street Journal*, *Bloomberg* and the *Associated Press*, which was picked up in *The New York Times*, *U.S. News & World Report*, and ABC News.

The Department of Pediatric Cardiology and Congenital Heart Surgery was ranked for the third consecutive year in the *U.S. News and World Report* Children's Hospital rankings for cardiology and heart surgery. This year they rose to #36.

Geoffrey Rose, MD, was nominated by the American Society of Echocardiography and reappointed by the ACC to serve on the Revascularization and Medical Therapy Appropriateness Task Force.

For the first time ever, Sanger's **Pediatric Heart Transplant Program** has been accepted into the "Blue Distinction Centers for Transplants." This is the Blue Cross/Blue Shield Centers of Excellence Program and is the largest and most difficult network to gain access to.

Sherry Saxonhouse, MD, was designated faculty for the maintenance of certification of cardiovascular disease and for the maintenance of certification of cardiac electrophysiology by the American College of Cardiology. She will also serve on the Certification and Accreditation, Anticoagulation Task Force and Emerging Faculty Committees.

Rohit Mehta, MD, has been appointed Governor for the North Carolina Walk with a Doc Program.

Michael Rinaldi, MD, and Hadley Wilson, MD, were named to the *Charlotte Business Journal's* list of the "Best Doctors 2014."

Congratulations to **Drs. Hadley Wilson, Geoffrey Rose, Warren Holshouser, Theodore Frank, Benjamin Peeler, Eric Skipper, Mark Reames, and Timothy Roush** for being chosen "Top Doctors in Charlotte," listed in *Charlotte Magazine*.

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