

Welcome to *The Sanger Report*



WELCOME TO THE

inaugural issue of *The Sanger Report*, a new publication from Sanger Heart & Vascular Institute. Our goal is to provide you with quarterly updates about the activities and accomplishments of our

team of dedicated cardiovascular specialists.

The mission of SHVI is to provide comprehensive, coordinated and compassionate cardiovascular care to those in our region. To achieve this, we focus on three distinct goals:

- ▶ offering unmatched access to cardiovascular care
- ▶ providing care that is comprehensive in scope, yet innovative in delivery
- ▶ practicing with uncompromising clinical excellence

In this first edition, we introduce our efforts and progress toward these goals. To provide you with a sense of our geographic scope—the critical first step in providing access to care—you will find a regional map populated with our SHVI offices. We are able to offer patients and referring physicians access to highly specialized care in locations closer to home, and treatment is coordinated so that the quality of care remains consistent.

You will see how this integrated approach to care serves to promote clinical excellence, as exemplified by our Code STEMI program, highlighted herein. This innovative program, launched in 2007, has dramatically improved the quality of care to those patients in our region who sustain an ST-elevation myocardial infarction (STEMI). The time it takes to open the occluded artery from time of arrival in the emergency department is known as the door-to-balloon (D2B) time, and the national D2B benchmark is less than 90 minutes. Our Code STEMI program has led to superlative D2B times, averaging 45 minutes at both Carolinas Medical Center and CMC-Mercy.

To provide you with a measure of the sophistication of the care available, we highlight our Heart Failure Program. SHVI performed the first cardiac transplantation in western North Carolina in 1986, and we continue to be one of the most active and respected programs in the Southeast. The collaborative efforts of our heart surgeons and our cardiology subspecialists yield outstanding outcomes.

We also present an overview of our research efforts. These projects are diverse in their focus and include studies in the fields of interventional cardiology, electrophysiology, heart failure, cardiothoracic surgery and vascular medicine surgery.

Research efforts that merit special recognition include our ongoing work on nonsurgical mitral valve repair using a special clip device (REALISM/EVEREST trial). SHVI was one of the first 10 institutions in the world to employ this technique and remains one of the top enrolling sites in the United States. Also of note is the ADAPT-DES registry, in which we have enrolled nearly 1,000 patients through SHVI. This makes us the second highest enrolling site worldwide. Finally, SHVI is proud to have been selected as a site for the NIH-sponsored CABANA trial, which will investigate catheter-based ablation as a first-line therapy for atrial fibrillation.

Over the past two years, we have seen tremendous growth and continued innovation throughout our organization. We can evaluate patients and deliver quality care more completely and more efficiently than ever before.

I hope that you will enjoy this first issue of *The Sanger Report*. We look forward to bringing you more exciting news from Sanger Heart & Vascular Institute in the future.

Sincerely,

Paul G. Colavita, MD, FACC
President
Sanger Heart & Vascular Institute

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UPCOMING CME PROGRAM

Please join Sanger Heart & Vascular Institute in Charlotte, N.C., on Saturday, March 20, for **"EP and Device Therapy for Allied Professionals: Applying Knowledge to Clinical Practice,"** sponsored by the Heart Rhythm Society. Course directors: Robin Leahy, RN, BSN, CCDS, and Rohit Mehta, MD. To register online, visit www.hrsonline.org.



Sanger Heart & Vascular Institute

Uncompromising Excellence. Commitment to Care.



Clinical Research Programs

Michael J. Rinaldi, MD, FACC, FSCAI

Medical Director, Clinical Research, Sanger Heart & Vascular Institute

CLINICAL RESEARCH AT SANGER

Heart & Vascular Institute builds upon the proud tradition of active clinical research that brings leading-edge therapies to the “clinical” backyards of our patients. Our greatest success remains our continued strong enrollment in a large number of clinical trials with diverse participation in cardiovascular subspecialties including interventional cardiology, electrophysiology, heart failure, cardiothoracic surgery and vascular medicine and surgery.

SHVI now has more than 1,300 patients enrolled in 34 ongoing clinical trials.

Within the discipline of interventional cardiology, the **ADAPT-DES registry** has enrolled nearly 1,000 patients at Carolinas Medical Center and has positioned SHVI as the second-highest enrolling site worldwide. This study investigates stent thrombosis and whether routine platelet reactivity testing and intravascular ultrasound can reduce its incidence. The Dickson Institute at CMC serves as the study data coordination

“Our greatest success remains our continued strong enrollment in a large number of clinical trials with diverse participation in cardiovascular subspecialties.”

and analysis center for the study, managing data for more than 5,000 of a planned 11,000 enrolled patients. CMC serves as one of the founding sites, and I serve as a national

co-principal investigator (PI) with Gregg Stone, MD, of CRF/Columbia Presbyterian.

The EVEREST and REALISM study series is our ongoing investigation of the Evalve MitraClip for the nonsurgical repair of mitral insufficiency. CMC was one of the first 10 institutions in the world to employ this technique and remains one of the top enrolling sites in the world. We are one of only two sites in the Carolinas and one of a few sites in the Southeast to have experience in the exciting field of new percutaneous valve therapies.

The Dickson Institute also serves as the data coordinating and analysis center for the landmark **STENT Registry**, in which CMC enrolled a remarkable 6,892 patients and managed data from more than 35,000 patients from a dozen centers throughout the Southeast. The STENT Registry, founded and managed by our former partner Charles Simonton, MD, continues to assist in data collection to further expand our knowledge about the risks and benefits of drug-eluting stent technology.

A growing synergy between the subsections of cardiac electrophysiology and heart failure/transplantation has led to a robust increase in national study participation. SHVI has been formally invited to participate in the **NIH-sponsored CABANA trial**, which will evaluate the comparative efficacy of catheter ablation versus anti-arrhythmic medications in the treatment of atrial fibrillation.

The IMPEDE-HF study, for which we were the national leader in enrollment,

investigates markers of heart failure in comparison to cardiac device-based fluid monitoring, which can be monitored remotely.

SHVI was only the second center in the world to enroll a patient in the **EchoCRT trial**, which examines the utility of resynchronization therapy in patients with narrow QRS. Our center was one of only 15 centers invited to participate in the early phase of the trial and remains North Carolina’s only participating center.

The zLAP trial—an IDE phase I study investigating placement of a left atrial pressure-sensing lead in heart failure patients receiving CRT device therapy—is actively recruiting patients. The trial places an investigational pressure-sensing lead in the left atrium via a novel approach and allows patients a direct-feedback-based approach to the management of their congestive heart failure via the utilization of a handheld (Palm-type) computer, which can extract data from the device and guide patients with respect to the medical management of their congestive heart failure.

The PROTECT II trial—led by B. Hadley Wilson, MD, as site PI—is investigating the role of the Impella® percutaneous left ventricular assist device to facilitate high-risk coronary intervention. SHVI was the first site in the United States to utilize this device for non-investigational clinical use in patients, and Dr. Wilson has served on the steering committee for Impella. Participation in this study further solidifies our position as the regional leader in PCI.

The Gore TAG study, led by Jeremiah Holleman Jr., MD, is investigating the role of stent grafting for traumatic descending thoracic aortic transection. The treatment of aortic pathology continues to move toward a less invasive route, and we are advancing this field with the

ability to offer and study these therapies within the Charlotte-Mecklenburg and surrounding areas.

SHVI clinical research continues to focus on the offering of leading-edge clinical techniques within our community. We believe that these trials and

ongoing research strengthen our clinical mission of uncompromising excellence and commitment to care. For questions about our research department or the trials mentioned, or to refer patients for these trials, call our Charlotte office at **704-373-0212**. ■

CURRENT CLINICAL RESEARCH PROGRAMS

SPONSOR	NAME OF STUDY	STUDY DESCRIPTION	CATEGORY	STATUS	PRINCIPAL INVESTIGATOR	TOTAL PATIENTS	RANKING
Cardiovascular Research Foundation	ADAPT-DES	To determine frequency, timing and correlates of DES stent thrombosis and to determine relationship of ASA and/or Plavix® hyporesponsiveness and general platelet reactivity to early and late stent thrombosis	Interventional	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	Nearly 1,000	2nd of 8 USA sites
Evalve	REALISM	Pivotal study of a percutaneous mitral valve repair system	Interventional	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	13	
Abbott Vascular	CHOICE	Carotid stenting for high-risk surgical patients: Evaluating outcomes through the collection of clinical evidence	Vascular	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	34	
Biotronik	EchoCRT	Echocardiography-Guided Cardiac Resynchronization Therapy	Electrophysiology	Enrolling	Rohit Mehta, MD, FACC	5	
Invatec	INTENSE	Iliac artery treatment with the Invatec Scuba™ Cobalt Chromium Stent	Interventional	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	2	
Abiomed	PROTECT II	A prospective, multi-center, randomized controlled trial of the Impella® LP 2.5 system versus Intra-Aortic Balloon Pump in patients undergoing nonemergent high-risk PCI	Interventional	Enrolling	B. Hadley Wilson, MD, FACC	3	
Medtronic	RESOLUTE	A clinical evaluation of the Medtronic Endeavor® Resolute Zotarolimus-Eluting Coronary Stent System in the treatment of de novo lesions in native coronary arteries with a reference vessel diameter of 2.25 mm to 4.2 mm	Interventional	Enrolling	B. Hadley Wilson, MD, FACC	5	
F. Hoffman-La Roche	Roche	A phase III, double-blind, randomized, placebo-controlled study to evaluate the effects of RO4607381 on cardiovascular risk in stable CHD patients with a documented recent acute coronary syndrome	Pharmaceutical	Enrolling	William M. Herndon Jr., MD, FACC, FAHA, FASE, FASNC	8	
Cordis	Sapphire Worldwide	Stenting and angioplasty with protection in patients at high risk for endarterectomy	Vascular	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	55	
Abbott Vascular	Spirit Prime	A clinical evaluation of the 2.25 mm XIENCE V® Everolimus-Eluting Coronary Stent System	Interventional	Enrolling	William E. Downey, MD	0	
Cordis	STROLL	S.M.A.R.T.™ Nitinol Self-Expandable Stent in the treatment of obstructive superficial femoral artery disease	Interventional	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	3	
Abbott Vascular	XIENCE V USA	Evaluate XIENCE V® EECSS for continued safety and efficacy	Interventional	Enrolling	Michael J. Rinaldi, MD, FACC, FSCAI	25	
St. Jude	zLAP	CRT-D-based heart failure monitoring study	Electrophysiology	Enrolling	Rohit Mehta, MD, FACC	0	



Integrated Programs Improve Heart Attack Mortality Rates

B. Hadley Wilson, MD, FACC

Chief, Cardiology, Sanger Heart & Vascular Institute

OVER THE PAST FIVE YEARS, SANGER Heart & Vascular Institute's integrated system-wide rapid transport program for acute heart attack patients, called Code STEMI (ST-elevation myocardial infarction), has been regularly included as one of the top 10 programs in the country. In 2009, there were 633 Code STEMI activations at SHVI.

Our door-to-balloon (D2B) times to open blocked arteries in heart attack patients average less than 45 minutes and have greatly reduced the usual 6 percent mortality in these high-risk patients. Additionally, the 90 minute national goal for heart attack care was achieved in 96 percent of our Code STEMI activations. Carolinas Medical Center and CMC-Mercy actively participate in the statewide RACE and RACE-ER rapid-transport programs for STEMI patients, making North Carolina one of the national leaders in revolutionizing efficient STEMI care (see Figures 1 and 2).

These results were shared at the 2009 Transcatheter Therapeutics conference in San Francisco, where we taught others about this efficient patient-care mechanism. We also presented a new metric: EMS activation-to-reperfusion time. In 2009, our EMS activation-to-reperfusion time for STEMI patients (median value) was 89 minutes.

Physicians who have patients with possible heart attack symptoms should immediately contact CMC's emergency department at **704-355-2157** to activate this advanced rapid transport system of care and save lives. ■

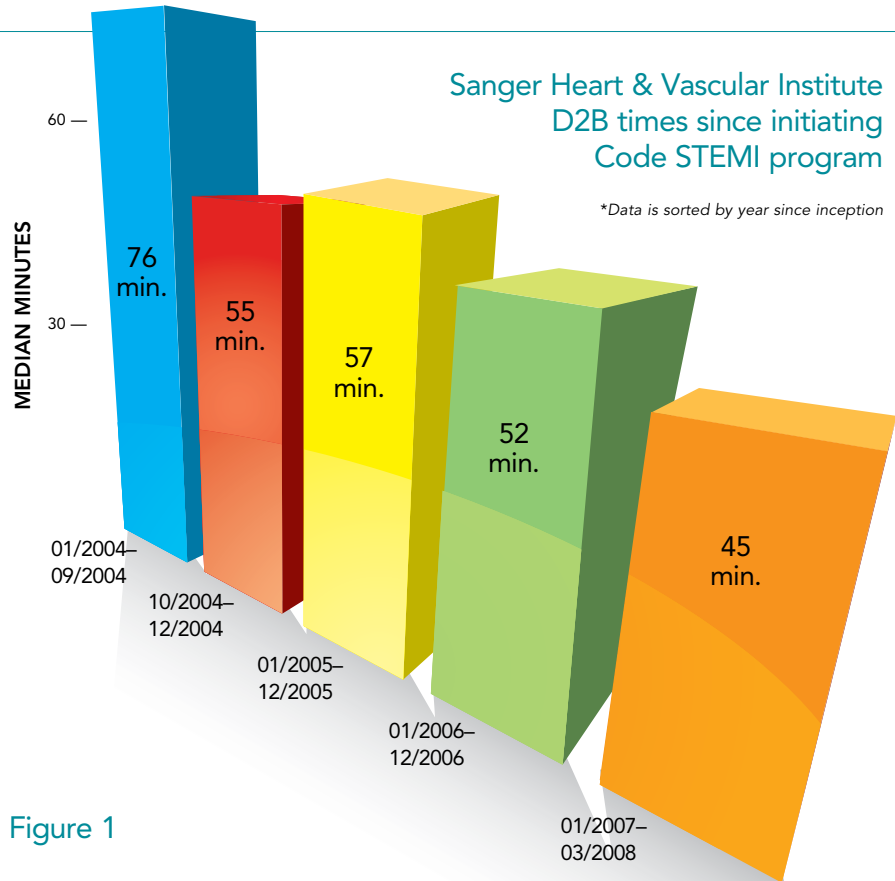


Figure 1

In-hospital mortality at Sanger Heart & Vascular Institute by D2B times

(D2B times of less than 60 minutes produced a statistically significant reduction in mortality as compared to times greater than 60 minutes.)

P = .05

P-value is comparing <=60 minutes (2.4%) to >60 minutes (6.8%)

- <=60 min. = 2.4% (n = 208)
- 61–89 min. = 6.4% (n = 88)
- >=90 min. = 7.9% (n = 35)

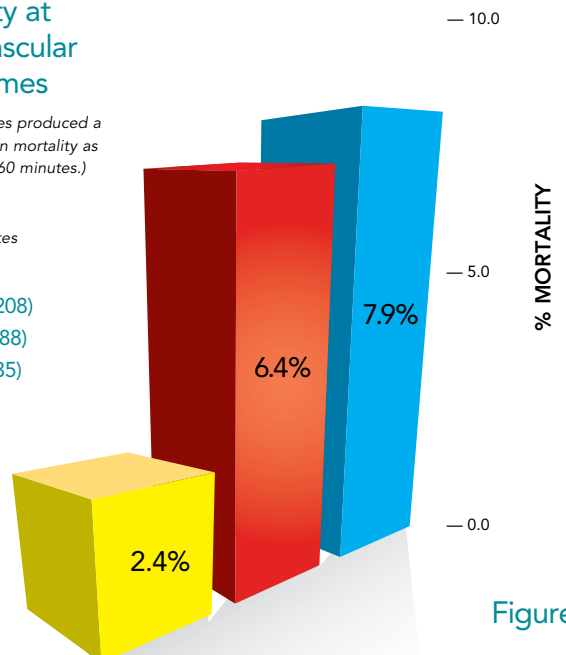


Figure 2

Heart Failure Program

Theodore A. Frank, MD, FACC [A]
Sanjeev K. Gulati, MD, FACC [B]
Alan M. Thomley, MD, FACC [C]



SINCE THE FIRST HUMAN HEART

transplant in 1967, cardiac transplantation has dramatically reduced mortality from end-stage congestive heart failure (CHF). United Network for Organ Sharing data reveals an average survival rate of 85 percent and 75 percent at one and five years, respectively.¹

A MULTIDISCIPLINARY APPROACH TO CARE

The cardiac transplantation program at Sanger Heart & Vascular Institute began in 1985 under the leadership of cardiothoracic surgeon Francis Robicsek, MD, PhD. Carolinas Medical Center's first cardiac transplant was performed in 1986. Since that time, the CHF and transplantation program has developed into a multidisciplinary effort. The one- and three-year survival rates for cardiac transplantation at SHVI are **100 percent** and **82 percent**, respectively. Recent expansions in therapeutics include the development of a pulmonary hypertension program led by Theodore A. Frank, MD, which has rapidly expanded to the active management of more than 50 patients to date.

Our use of left ventricular assist devices (LVADs), under the leadership of cardiac surgeon Eric Skipper, MD, and cardiologist Sanjeev K. Gulati, MD, complements our cardiac transplantation program in managing patients who have advanced cardiac disease. Consistent with data from the REMATCH trial, LVADs have reduced the relative risk of death due to advanced CHF by 50 percent as compared with medical therapy.² While commonly thought to be a therapy primarily used as a bridge to transplantation, LVADs are now a source of

"destination" therapy for patients refractory to medical and advanced device therapy.

The CHF clinic, under the direction of physicians at SHVI, employs a multidisciplinary approach to the management of heart failure patients. The ADHERE registry demonstrated a 4 percent in-hospital mortality rate in patients who were admitted with decompensated heart failure independent of therapeutic approach, and thus the clinic focuses on preventing heart failure hospitalization.³

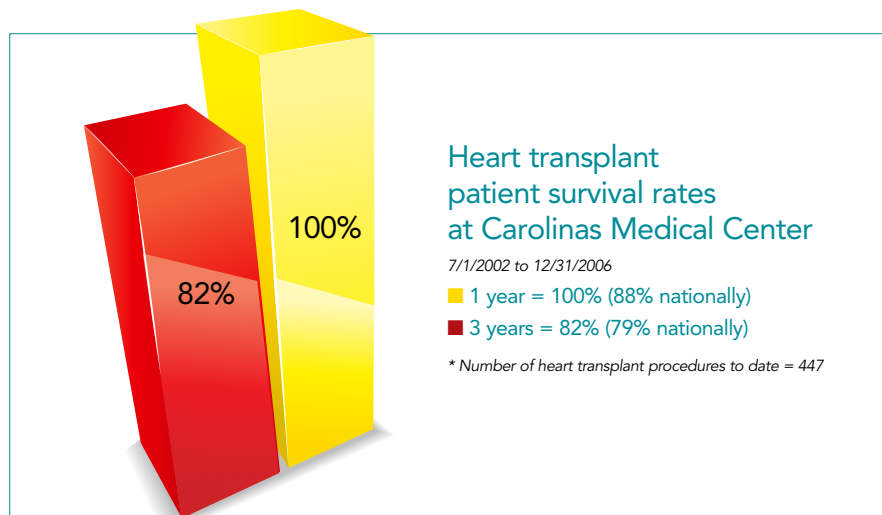
TAILORED THERAPIES

While under our care, patients' clinical visits are managed by specialty heart failure physicians, mid-level providers and pharmacists to provide medical therapy that is tailored to meet their individual needs and to complete an educational process that allows patients to partner with us for their healthcare. A new approach, which aggressively utilizes heart failure diagnostic data incorporated within implantable cardiac rhythm devices, allows for the early recognition of heart failure decompensation.⁴

Early recognition of heart failure decompensation allows for early intervention to prevent heart failure hospitalization and its inherent risks. The CHF clinic is now caring for more than 1,000 patients. Using this multidisciplinary approach has reduced the number of re-hospitalized patients. ■

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Sanger Heart & Vascular Institute Physicians by Location

ALBEMARLE

Dominique A. Falewee, MD, FACC
Matthew J. Levinsky, MD
F. Scott Valeri, MD, FACC

ASHE (MON/TUES/WED)

Peter J. Ashline, MD, FACC
Joseph W. Helak, MD, FACC

BOONE

Peter J. Ashline, MD, FACC
Leverne S. Fox Jr., MD, FACC
Joseph W. Helak, MD, FACC

CAROLINA LAKES

James C. Bower Jr., MD, FACC, FASE
E. Scott Dawson, DO, FACC

CHARLOTTE (BLYTHE BOULEVARD)

Adult Cardiologists

Richard E. Browne, MD, FACC
John C. Cedarholm, MD, FACC
Paul G. Colavita, MD, FACC
William E. Downey, MD
John M. Fedor, MD, FACC
Theodore A. Frank, MD, FACC
Sanjeev K. Gulati, MD, FACC
Robert H. Haber, MD, FACC
William M. Herndon Jr., MD, FACC,
FAHA, FASE, FASNC
J. Warren Holshouser Jr., MD
Glen J. Kowalchuk, MD, FACC
Rohit Mehta, MD, FACC
Irvin H. Naylor Jr., MD, FACC
Michael J. Rinaldi, MD, FACC
Geoffrey A. Rose, MD, FACC, FASE
Cheryl A. Russo, MD, FACC
John D. Symanski, MD, FACC, FACP, FASE
Alan M. Thomley, MD, FACC
B. Hadley Wilson, MD, FACC
Samuel H. Zimmern, MD, FACC

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Andrew S. Bensky, MD, FACC
J. Rene Herlong, MD, FAAP, FACC
Donald A. Riopel, MD, FACC
Nicholas B. Sliz Jr., MD, FACC
Richard T. Smith Jr., MD, FACC

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Larry T. Watts, MD, FACS

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Jeko M. Madjarov, MD
Mark K. Reames Sr., MD, FACS
Francis Robicsek, MD, PhD
Eric R. Skipper, MD, FACS
R. Mark Stiegel, MD, FACS

Vascular Surgeons

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Stephen G. Lalka, MD, FACS
Tzvi Nussbaum, MD
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HICKORY

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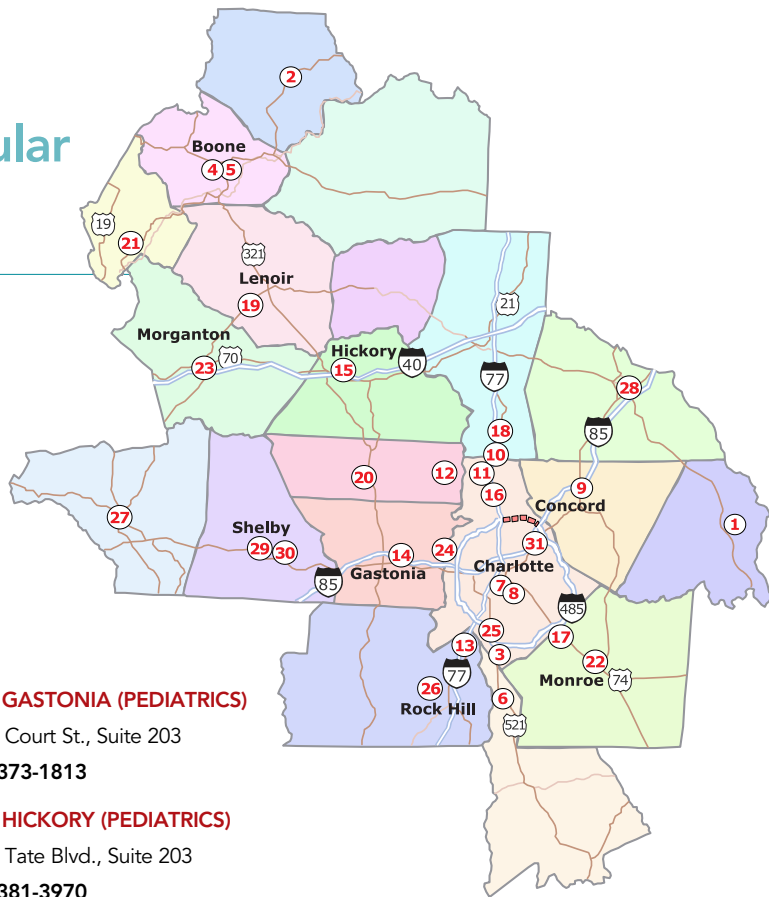
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Pioneering Cardiovascular Care for More Than 50 Years

SANGER HEART & VASCULAR

Institute links physicians with the most in-depth knowledge of cardiovascular specialties, advanced technologies and innovative programs while guiding the growth and development of cardiovascular care in the region.

SHVI is distinguished for providing outstanding care in the following disciplines:

INTERVENTIONAL CARDIOLOGY

- ▶ National center for acute heart attack care
- ▶ Complex coronary artery intervention
- ▶ Percutaneous left ventricular assist devices
- ▶ Patient access to ongoing clinical trials
- ▶ Intracoronary radiation therapy

ELECTROPHYSIOLOGY

- ▶ Ablation for atrial fibrillation and other complex arrhythmias
- ▶ Permanent pacemaker placement
- ▶ Implantable cardioverter defibrillator insertion
- ▶ Cardiac arrhythmia management
- ▶ Cardiac device lead extraction
- ▶ Pediatric and congenital heart care

CONGENITAL HEART DISEASE

- ▶ Therapeutic heart catheterization
- ▶ Hybrid surgical procedures
- ▶ Electrophysiology
- ▶ Preventive clinic
- ▶ Adult congenital clinic

CARDIOTHORACIC SURGERY

- ▶ Minimally invasive heart surgery
- ▶ Off-pump surgery
- ▶ Region's only minimally invasive lung surgery
- ▶ Region's only heart transplant center

VASCULAR MEDICINE AND SURGERY

- ▶ Endovascular and surgical aneurysm repair
- ▶ Peripheral vascular disease management
- ▶ Carotid endarterectomy and stenting
- ▶ Fully accredited vascular ultrasound laboratory
- ▶ Comprehensive management of vascular diseases

VALVULAR HEART DISEASE

- ▶ Percutaneous and minimally invasive surgical mitral valve repair
- ▶ Fully accredited transthoracic and stress echocardiography in noninvasive laboratories
- ▶ Region's highest volume aortic valve surgical center

CONGESTIVE HEART FAILURE

- ▶ Region's only heart transplant program
- ▶ Cardiac resynchronization therapy
- ▶ Left ventricular assist device implantation
- ▶ Outpatient inotropic therapy
- ▶ Cardiac device-based heart failure management ■

Patient Support Programs

SANGER HEART & VASCULAR

Institute believes that support groups and additional services play an important role in patient recovery. SHVI is proud to sponsor the following support groups and services for our patients:

▶ The **Heart of a Woman Support Group** unites women who have survived a cardiac event with women striving to prevent similar experiences. Through education and encouragement, participants are empowered to begin or maintain a heart-healthy lifestyle. For more information, visit www.heartofawoman.org.

▶ The **ICD (Implantable Cardioverter Defibrillator) Support Group** is for ICD recipients, their families and friends and offers a forum for education and a network for support.

▶ **Levine Children's Hospital's Cardiac Kids** is a group that supports children who are being treated for, or have recently been diagnosed with, congenital heart defects and their families. For more information and upcoming events, visit www.levinecardiackids.com.

▶ **Dare to C.A.R.E. Carolinas** is a cardiovascular disease early-detection program that provides free vascular ultrasound examinations and education about cardiovascular disease. For more information and upcoming events, visit www.daretocarecarolinas.org. ■