SENTARA HEART PROGRAM

2004

ANNUAL OUTCOMES REPORT

SENTARA HEART™

Contents

Sentara Heart Program

presents the 2004 Cardiac Outcomes Report to our physicians, colleagues, and community. While Sentara continues to deliver many of the latest breakthroughs in cardiac care to our patients, quality of care is our primary goal. We demonstrate this goal by consistently surpassing national quality benchmarks established by the American College of Cardiology and the Society for Thoracic Surgeons. While our cardiologists, cardiac surgeons, and clinical teams provide some of the nation's best quality, experience, innovation, and research, their dedication to patients and families is paramount. Take a look at the outcomes in this report and judge us for yourself.

Sentara Norfolk General Hospital (SNGH), in Norfolk, Va, has again ranked among the *U.S. News & World Report* Top 50 Best Hospitals in cardiac programs in the 2004 report issued in July 2004. Even more impressive, our mortality ratio is superior to 4 of the 5 top programs in the nation. Furthermore, SNGH has been ranked among the Top 100 Cardiovascular Hospitals by Solucient for 5 years of the survey. Also in 2004 HealthGrades®, an independent health care quality rating and advisory company, ranked SNGH the No. 1 hospital in Virginia for overall cardiac services, open heart surgery, cardiology services, and cardiac interventional procedures for the second year in a row. Today, SNGH continues to pioneer cardiac medical breakthroughs and participate in the latest cardiac research.

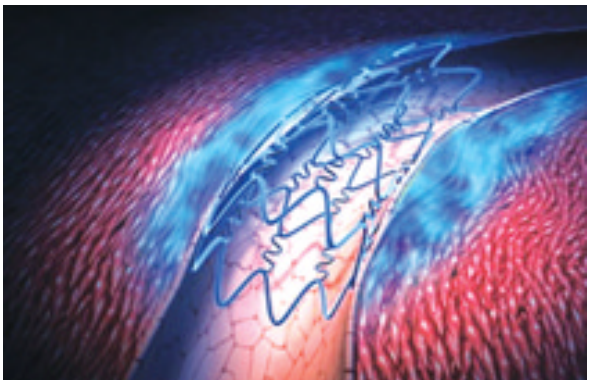
Sentara Virginia Beach General Hospital (SVBGH), in Virginia Beach, Va, continues to surpass national quality benchmarks in cardiac care. With the same team of cardiac surgeons and anesthesiologists as SNGH, the quality of this program is outstanding. SVBGH cardiac physicians continue to participate in cutting edge research and offer top quality services to cardiac patients and their families in conveniently located state-of-the-art facilities.

Interventional Technologies

Sentara's interventional technologies—including **percutaneous transluminal angioplasty, coronary artery stenting, directional coronary atherectomy, rotoblator, and laser procedures**—remain on the cutting edge, offering new options for opening occluded arteries, one of the greatest challenges in long-term management of cardiac patients.

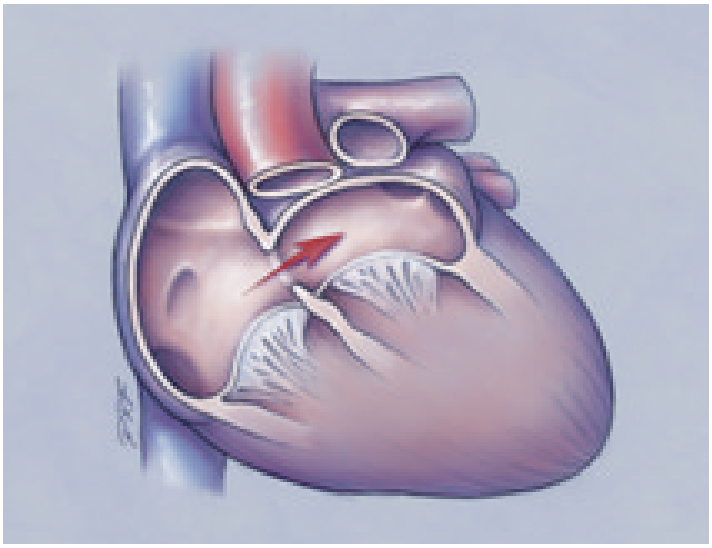
■ **Coronary artery stenting** procedures at Sentara have been performed with state-of-the-art **drug-eluting stents** since first approved by the Food and Drug Administration in April 2003. Conclusive evidence of long-term benefits of this new technology was demonstrated in the Rapamycin-Eluting Stent Evaluated at Rotterdam Cardiology Hospital (RESEARCH) registry, in which 3.7% of patients treated with drug-eluting stents experienced restenosis requiring repeat intervention vs. 10.9% of those treated with a bare-metal stent. Additional studies are being done to more clearly define long-term benefits in decreasing stent restenosis, thereby reducing requirements for repeat interventions.

Illustration 1. Coronary Artery Stent



■ **Congenital atrial septal defects (ASD)** and **patent foramen ovale (PFO)** are successfully repaired in the catheterization laboratory using a transcatheter technique that has a 1- to 2-day recovery, compared to a 4- to 6-week recovery with an open heart surgical approach.

Illustration 2. Atrial Septal Defects



■ Lumen assessment of stenotic lesions performed with **intravascular ultrasound catheters** and **pressure and flow measuring catheters** in the catheterization lab produce accurate and objective measurements of blood flow velocity and coronary flow reserve, improving the assessment of the functional status of cardiac lesions demonstrated by angiograms.

Before advanced interventional technologies are used, many patients are administered cardiac function tests. These may include **electrocardiogram (EKG), Holter Monitor, tilt table test, exercise stress test, nuclear exercise stress test, stress multiple gate acquisition scan (MUGA), echocardiogram, stress echocardiogram** or a **transesophageal echocardiogram.**

■ **Intracardiac ultrasound** provides online advanced imaging of structures within the heart chambers with instant review and analysis capabilities to support EP (electrophysiology) procedures and PFO closures.

■ The technique of **percutaneous balloon valvuloplasty** involves a transcatheter insertion of one or more large balloons into the aortic or mitral valve, or both. The balloons are then inflated across the stenotic valve to decrease the degree of obstruction within the valve.

Interventional Technology Outcomes

Figure 1. Sentara Norfolk General Hospital Interventional Procedure Volume

The volume of interventional procedures (ie, percutaneous transluminal angioplasty, coronary stents, directional coronary atherectomy, rotoblator, and laser) at Sentara Norfolk General Hospital rises with continued application of cutting edge technologies.

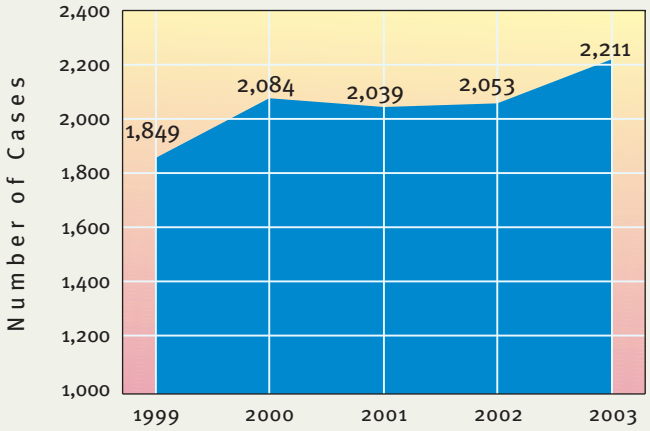


Figure 2. Sentara Norfolk General Hospital Interventional Procedure Success

The evolution of interventional cardiology now permits successful management in spite of treating more complicated lesions. Success rates remain well above the American College of Cardiology threshold.

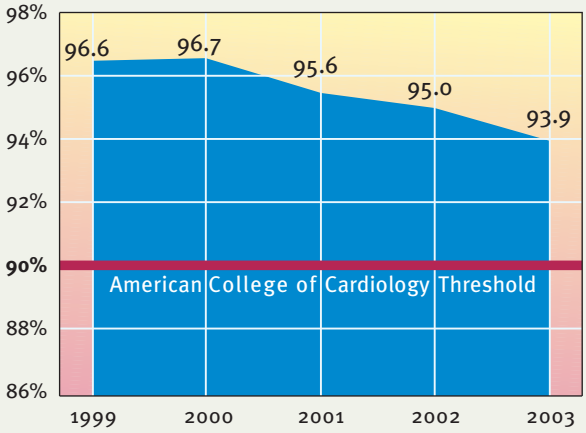


Figure 3. Sentara Norfolk General Hospital Interventional Procedure Mortality

The mortality rate for interventional procedures at Sentara Norfolk General Hospital continues to drop further below the 1% threshold established by the ACC.

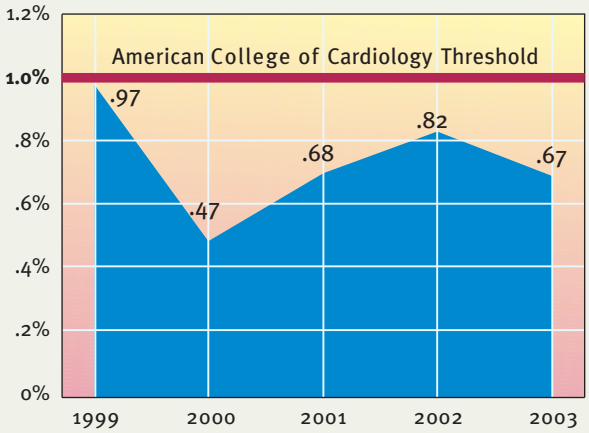


Figure 4. Sentara Virginia Beach General Hospital Interventional Procedure Volume

Interventional procedure (ie, percutaneous transluminal angioplasty, coronary stents, directional coronary atherectomy, rotoblator, and laser) volumes increased to a 3-year high in 2003, as cardiologists at Sentara Virginia Beach General Hospital continued to apply cutting edge technologies.

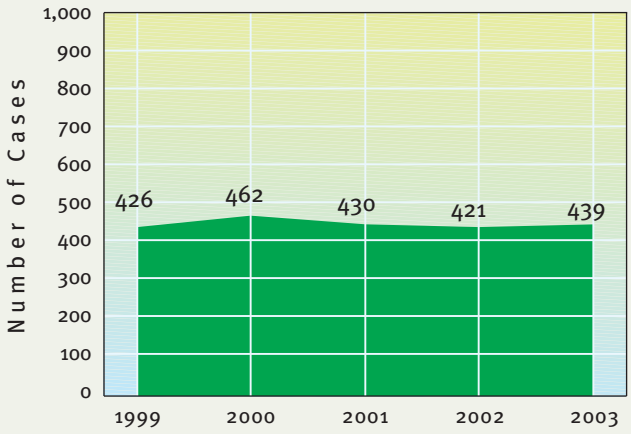


Figure 5. Sentara Virginia Beach General Hospital Interventional Procedure Success

The evolution of interventional cardiology now permits successful management of lesions that were untreatable in the past. Success rates remain well above the ACC threshold.

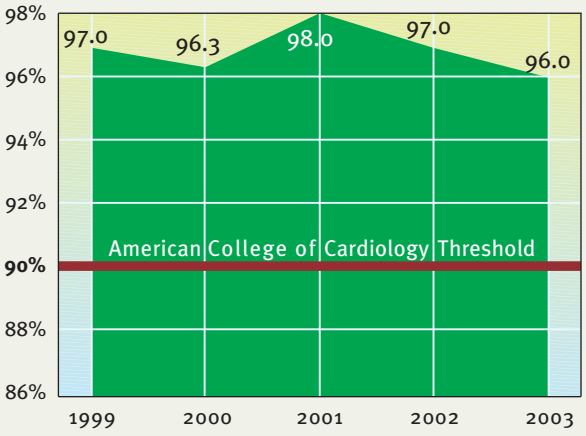
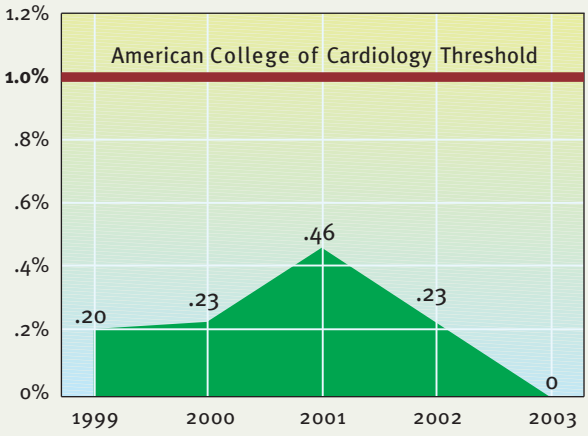


Figure 6. Sentara Virginia Beach General Hospital Interventional Procedure Mortality

The mortality rate for interventional procedures at Sentara Virginia Beach General Hospital remains well below the 1% threshold established by the ACC.



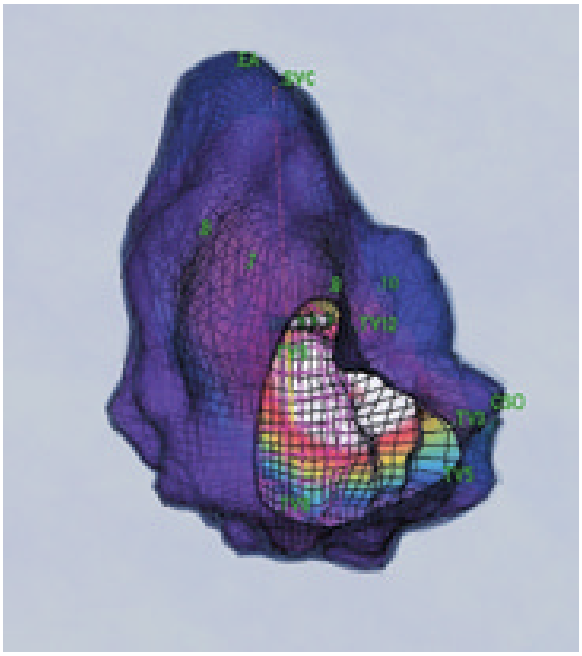
Electrophysiology Services

Until recently, therapy options for cardiac arrhythmias were limited to drugs and implantable devices, all of which would only palliate these heart rhythm disturbances. Electrophysiology services have now evolved from a cardiac rhythm identification to an interventional specialty that includes curative procedures through precise focal ablation and the destruction of abnormal cardiac electrical cells.

Ablation Therapy

Ablation is a curative approach to treatment that involves identification and elimination of cardiac arrhythmias using **radio frequency.** Techniques using radio frequency ablation are performed in the Sentara Heart catheterization labs. Accuracy is enhanced by the physician's ability to guide the catheters with **3-dimensional mapping systems** that identify structural and electrical sites in the heart. Availability of other innovative tools, such as **intracardiac ultrasound,** aid in identifying the pulmonary veins, which has led to safer, more accurate, and less time-consuming ablation procedures.

Illustration 3.
3-Dimensional Mapping for Ablation Therapy



- **Catheter Ablation** has become the first line approach for many rhythm disturbances because of low risk of complication and the great efficacy of the procedure.

- **Catheter-based 3-D mapping and ablation techniques** offer a non-operative approach to the identification and cure of a variety of arrhythmias and have become the procedure of choice for conditions ranging from concealed or manifest Wolffe-Parkinson-White syndrome bypass tracts, ventricular tachycardia, atypical atrial flutter, and focal atrial fibrillation.

- **Intracardiac ultrasound** is rapidly becoming the standard of care in electrophysiology and cardiology. It greatly facilitates imaging adjunct to all atrial fibrillation ablation therapies. Intracardiac ultrasound allows optimal viewing of the interior anatomy of the heart for identification, diagnosis, and treatment of a number of cardiac abnormalities and conditions.

Atrial ablations:

Atrial fibrillation (AF), one of the most common cardiac arrhythmias, affects 0.4% of the general population, 5% to 10% of persons aged >65 years, and 50% of patients undergoing cardiac operations. Patients with chronic AF may suffer from symptomatic tachycardia or low cardiac output, and have a 5% to 10% risk of thromboembolic complications. While cardiologists continue to struggle with the management of AF and research methods to identify an effective treatment modality, a recent study reported that survival among patients with AF after ablation is similar to that in the general population.

The following ablation procedures are part of our electrophysiology program:

- **Atrial tachycardia**
- **Atrial flutter**
- **AV junction and AV node re-entry**
- **Accessory pathways**
- **Atrial fibrillation**

Ventricular ablations:

- **Ventricular tachycardia**
- **Cardiac Resynchronization Therapy (CRT)**

The incidence of heart failure (HF) in the United States is increasing, and while medications play a critical role in the management of heart failure, patient functional capabilities have improved with the evolution of cardiac devices to resynchronize the ventricle contractions. Simultaneously stimulating the left and right ventricles restores the synchronous pumping action of the heart and improves cardiac output. CRT has been implemented with implantable defibrillators to provide patient protection from the risk of sudden death.

- **Biventricular pacing**
- **Implantable cardioverter-defibrillators**

Electrophysiology Volumes

Figure 7. Sentara Norfolk General Hospital Pacemaker and Automatic Internal Cardiac Defibrillator (AICD) Volume
In 2003, the pacemaker volume and AICD volume at Sentara Norfolk General Hospital continued to increase because of the technological advancements for rate and rhythm management.

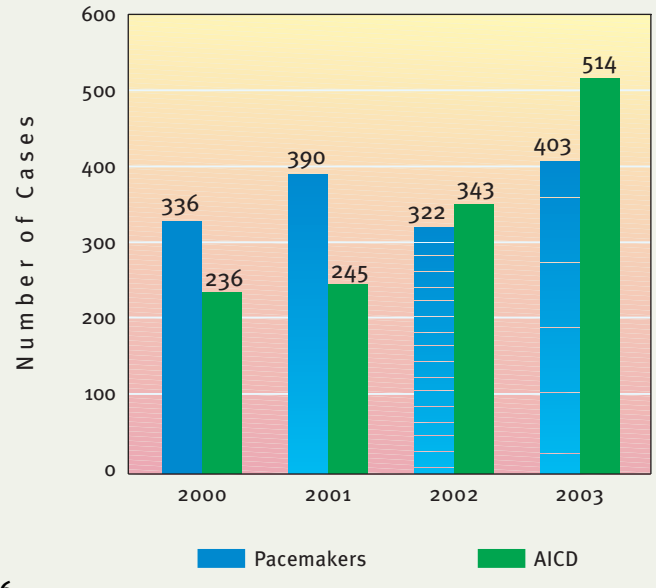
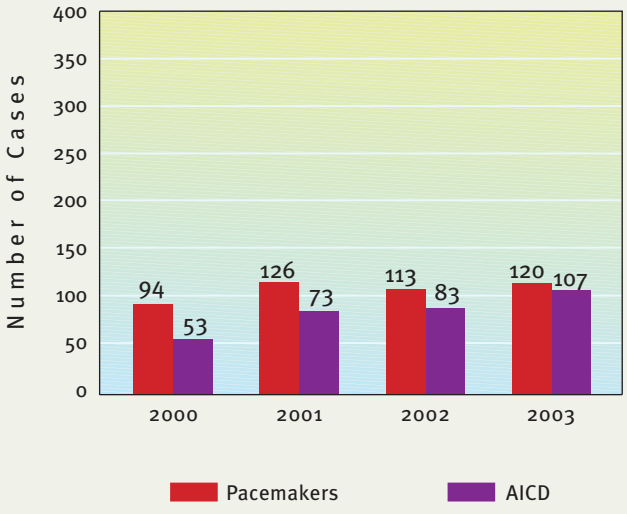


Figure 8. Sentara Virginia Beach General Hospital Pacemaker and Automatic Internal Cardiac Defibrillator (AICD) Volume
Both pacemaker and AICD volumes increased in 2003 at Sentara Virginia Beach General Hospital, with pacemaker insertions outnumbering AICDs.



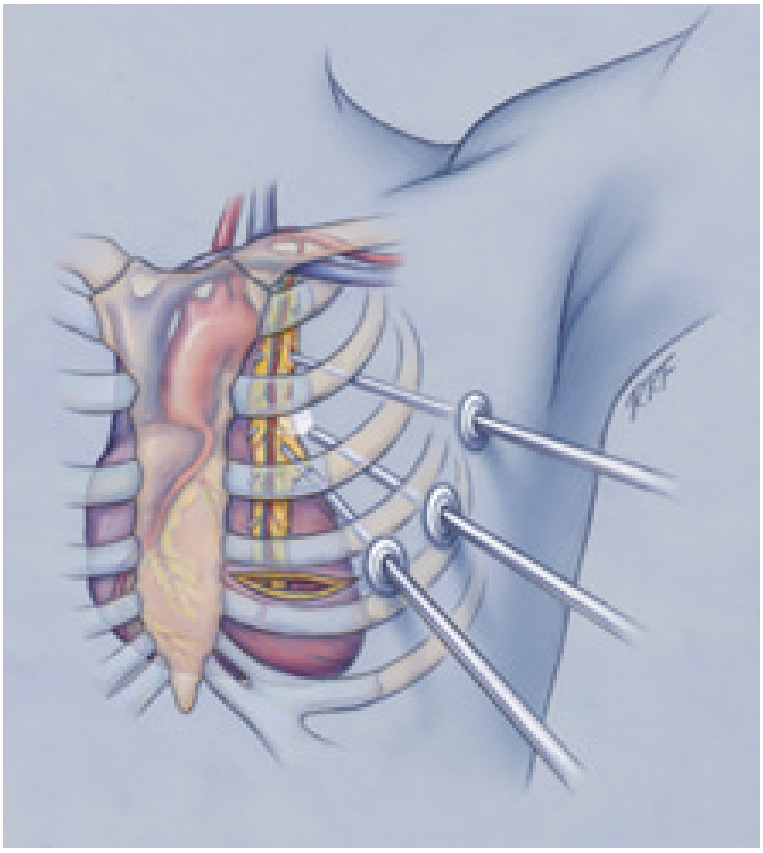
Cardiac Surgery

Cardiac surgery continues to be the appropriate therapy for patients with progressive heart disease even as catheterization therapies develop. Often cardiac surgery patients are older and with more comorbidities, presenting a greater challenge for surgeons and stimulating the need to be less invasive while maintaining excellent outcomes.

The following advanced cardiothoracic procedures are performed at Sentara Heart:

- **Internal mammary artery for bypass**
- **Valve repair and replacement procedures**
- **Transmyocardial revascularization (TMR)**
- **Maze procedure**
- The **Modified Endoventricular Circular Plasty Procedure** is available to patients who have progressive worsening of cardiac function associated with heart failure. This innovative procedure involves removing the scar in the heart muscle, thus decreasing the size of the dialated ventricle to help improve cardiac output and symptoms of heart failure.

Illustration 4. Minimally Invasive Cardiac Surgery



- **Minimally invasive cardiac surgery**—performed without the use of the heart lung machine or without a sternotomy—greatly reduces surgical morbidity by decreasing recovery time, pain, and infections and improves outcomes for selected patients. Examples of procedures offered at Sentara Heart include **off-pump coronary artery bypass (OP CAB), minimally invasive valve surgery,** and the use of **minimally invasive techniques for vein harvesting.**

Cardiac Surgery Outcomes

Figure 9. Sentara Norfolk General Hospital Cardiac Surgery Volume

The volume of open heart surgery at Sentara Norfolk General Hospital continues to be among the highest in the state of Virginia. Decreasing open heart surgery volumes are consistent with the volume trends for the United States and are indicative of broadening interventional technology success.

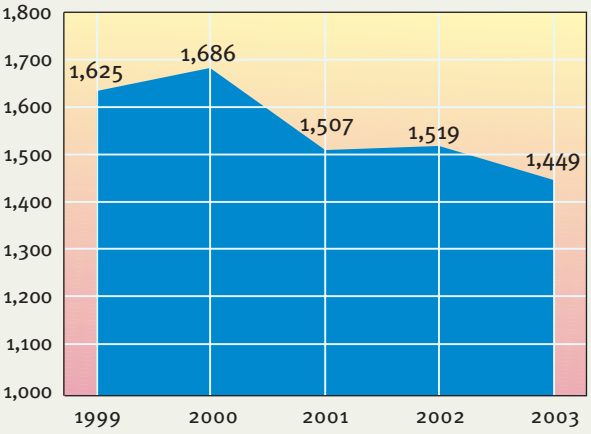


Figure 10. Sentara Norfolk General Hospital Primary Coronary Artery Bypass Graft (CABG) Mortality

Primary, defined as first time revascularization operation, CABG mortality at Sentara Norfolk General Hospital remains below the 2.4% national threshold established by the Society of Thoracic Surgeons.

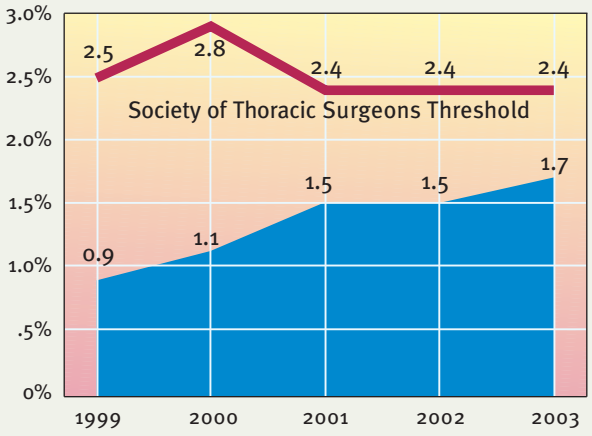


Figure 11. Sentara Norfolk General Hospital Redo Coronary Artery Bypass Graft (CABG) Mortality

Redo, defined as second time revascularization operation, CABG mortality at Sentara Norfolk General Hospital dropped to 3.3%, which is well below the 4.7% national threshold established by the Society of Thoracic Surgeons.

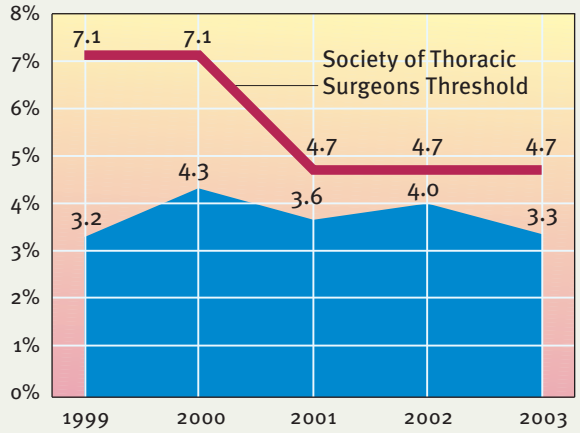


Figure 12. Sentara Norfolk General Hospital Transplant Survival

Sentara Norfolk General Hospital heart transplant patients experience 100% 1-month and 1-year survival rates, which are superior to those experienced by transplant recipients across the United States as reported by the Scientific Registry of Transplant Recipients adjusted for recipient and donor characteristics.

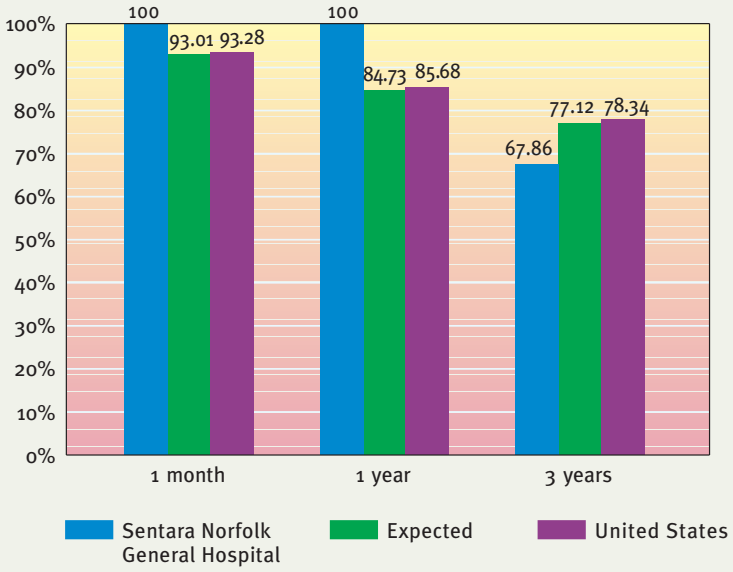


Figure 13. Sentara Virginia Beach General Hospital Cardiac Surgery Volume
The volume of open heart surgery at Sentara Virginia Beach General Hospital remains consistent.

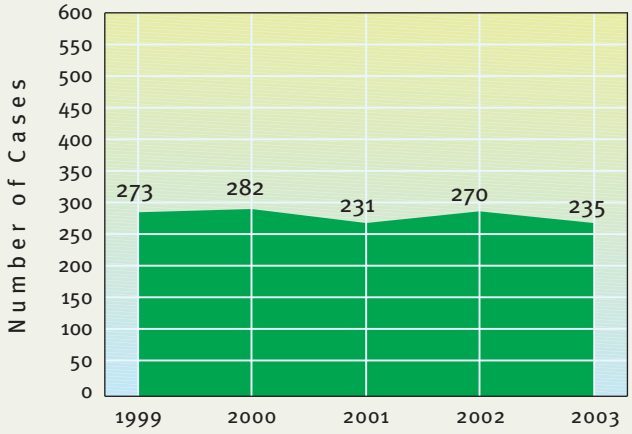


Figure 14. Sentara Virginia Beach General Hospital Primary Coronary Artery Bypass Graft (CABG) Mortality
Primary CABG mortality at Sentara Virginia Beach General Hospital continues to decline, staying well below the 2.4% national threshold established by the Society of Thoracic Surgeons.

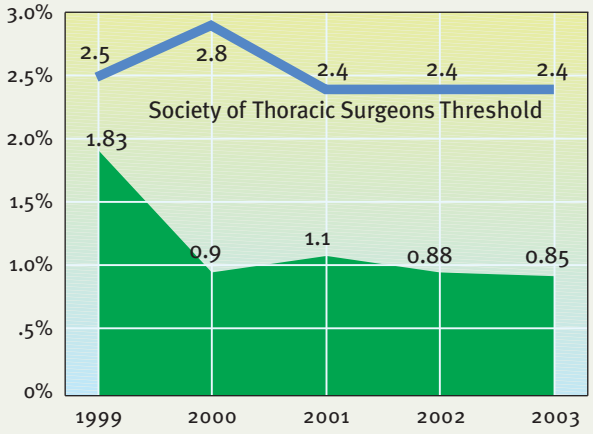
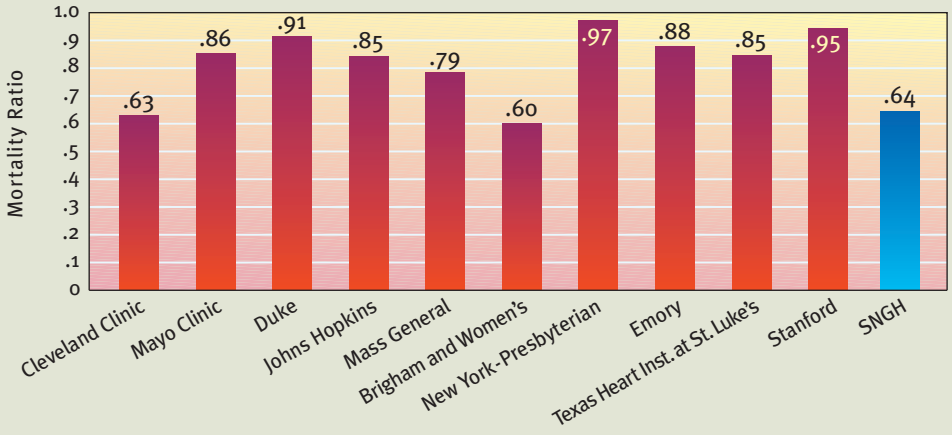


Figure 15. Sentara Norfolk General Hospital Heart Program Mortality Ratio Compared to *U.S.News & World Report* Data from Other Top U.S. Programs – 2004
A comparison of the top 10 U.S. cardiac programs reveals the adjusted mortality ratio at Sentara Norfolk General Hospital is superior to 4 of the 5 top programs in the nation.



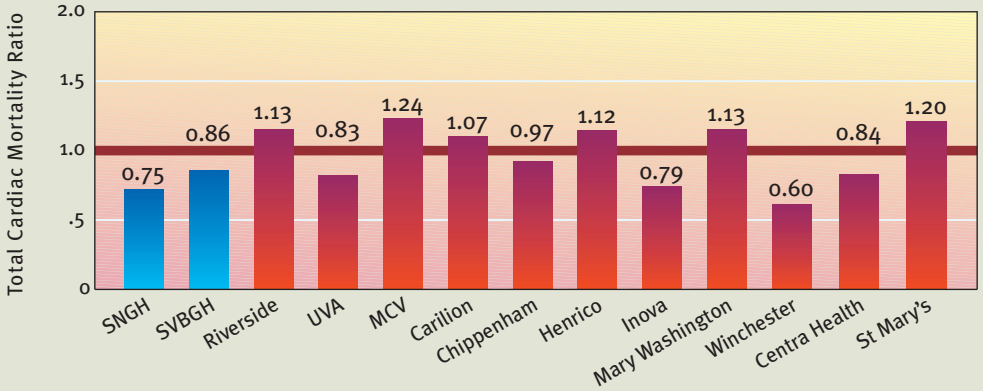


Figure 16. Sentara Norfolk General Hospital and Sentara Virginia Beach General Hospital Total Cardiac Severity Adjusted Mortality Ratio Compared to Other Programs in Virginia Based on VHI 2003 Data.
Mortality ratio associated with total cardiac procedures at Sentara hospitals is among the best of key facilities reported in Virginia.

Source: VHI 2003

Heart Failure

The latest statistics reveal over 5 million Americans have heart failure (HF), with an incidence approaching 10 per 1,000 of the population aged >65 years, and over 550,000 new cases annually. The lifetime risks double in people with blood pressure >160/90, and sudden cardiac death occurs in people diagnosed with HF at 6 to 9 times the rate of the general population.

[American Heart Association. Heart Disease and Stroke Statistics, 2004 Update.]

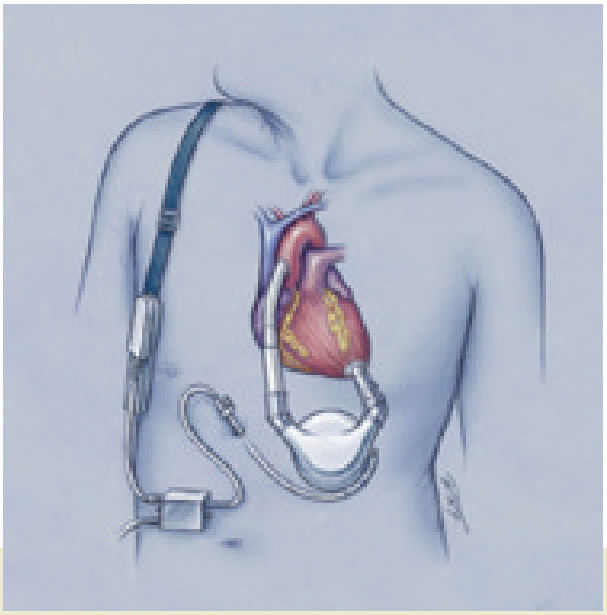
Attentive medical management is critical to reducing symptoms, lengthening the time between hospitalizations, and improving heart function, functional status, and quality of life. SNGH is the region's only comprehensive center for the treatment of advanced HF, including optimal pharmacologic management as well as evaluation for advanced HF treatments such as outpatient inotropic management, ventricular assist devices (VAD), and heart transplant.

SNGH has had a VAD program as a bridge to transplant methodology since 1992, and as of May 1, 2004, 8 patients were living with a VAD implant while awaiting a heart transplant. The Food and Drug Administration and Center for Medicare and Medicaid Services (CMS) have approved the HeartMate VAD for destination therapy in patients with stage IV heart failure who are not considered candidates for heart transplantation, and SNGH received approval from CMS to be a destination therapy center.

The heart transplant program at SNGH performed 14 transplants in 2003 and as of May 2004 more than 25 patients were listed for heart transplant. Waiting times continue to lengthen as more patients are in need of transplants and the number of suitable donor organs remains flat or slightly decreased.

Indeed, managing patients continues to be a challenge that requires the skills of a comprehensive and experienced team of cardiologists, cardiothoracic surgeons, nurse practitioners, highly specialized nurses, and other professions, all available at SNGH.

Illustration 5. LVAD (left ventricular assist device)



Peripheral Vascular Disease

The treatment of peripheral vascular disease (PVD) dominates vascular care. The advances in noninvasive screening tools have expanded the physician's ability to diagnose PVD. The variety of treatment options for the management of PVD continues to evolve. Similar to the trend seen in coronary revascularization, peripheral revascularization is shifting from surgical bypass procedures to catheter-based angioplasties and stenting. The positive results of these advances for the patient are decreased complications, decreased pain, decreased length of stay, and reduced cost.

Carotid Stent:

Advances in stent technology and other adjunctive technologies such as distal protective devices will transform carotid artery revascularization procedures to catheter based approaches. At SNGH the physicians approach carotid stenting in a collaborative manner using the expertise of the neurologist, cardiologist, interventional radiologist, and the vascular surgeon. In a unique arrangement under a research protocol, the multispecialty physicians evaluate the patient to identify and develop the treatment plan.

The peripheral procedures currently performed include the following:

- **Diagnostic Angiography**
- **Renal Artery Stenting**
- **Iliac Artery Stenting**
- **Subclavian Stenting**
- **Carotid Stenting**

Sentara Norfolk General Hospital

Cardiac Surgery Clinic: Surgical patients are evaluated 10 days after their procedure by specialized nurse practitioners trained in postoperative treatment of open heart surgery to provide rehabilitation, patient education, and ongoing cardiac monitoring.

Congestive Heart Failure (CHF) Clinic: Conveniently located at Sentara Norfolk General Hospital, the CHF clinic offers either outpatient monitoring or telemanagement for patients. Outpatients make regular visits to nurse practitioners, who work collaboratively with the patient's primary care physician. Meanwhile, telemanagement allows registered nurses familiar with CHF to monitor patient progress and drug therapy compliance by phone.

Pacemaker Clinic: Following physician's orders, expertly trained registered nurses assess and reprogram implantable pacemakers and internal cardiac defibrillators (ICDs).

Transplant Clinic: Patient education, medication monitoring, organ rejection evaluations, and myocardial biopsies are provided at the transplant clinic by transplant physicians and expertly trained clinicians, who monitor heart transplant patients before and after transplantation.

Sentara Virginia Beach General Hospital

Congestive Heart Failure (CHF) Clinic: Located at the Tidewater Cardiovascular Institute adjacent to Sentara Virginia Beach General Hospital, outpatient progress and drug therapy compliance are monitored by a registered nurse or physician's assistant specializing in CHF treatment who collaborates with the patient's physician.

Coumadin Clinic: Under the supervision of the cardiology medical director, expertly trained registered nurses manage patient medication regimens at the Coumadin Clinic.

Lipid Clinic: Located at the Tidewater Cardiovascular Institute adjacent to Sentara Virginia Beach General Hospital, the Lipid Clinic offers lipid profiles, treatment planning, and cholesterol monitoring to outpatients. Follow-up is provided by registered nurses and physician assistants, who monitor treatment efficacy to reduce risk of cardiac events.

Pacemaker Clinic: Sentara offers a Pacemaker Clinic at Sentara Virginia Beach General Hospital, where expertly trained registered nurses assess and reprogram implantable pacemakers and ICDs in accordance with physician orders.

Research: Sentara Norfolk General Hospital

Sentara Norfolk General Hospital's strong commitment to cardiac research is evidenced by the growing number of ongoing trials in the Cardiac Research Department. SNGH is nationally known for its research through the physicians presenting at various cardiology and cardiac surgery conferences throughout the United States. Table 1 summarizes the cardiac research studies in progress from January 2003 through April 2004 at Sentara Norfolk General Hospital.

Table 1. Cardiac Research at Sentara Norfolk General Hospital 2003 through April 2004

Title	Research Description	Principal Investigator
	Heart Failure	
SCD-Heft	Prevention of Sudden Cardiac Death in Heart Failure Trial: Multicenter, randomized, 3-arm, primary prevention trial to identify therapy (AICD vs. amiodarone vs. placebo) that reduces death rates in patients with CHF	John Herre, MD
COMPANION	Multicenter, randomized clinical trial comparing medical therapy, biventricular pacing, and defibrillation in heart failure	Allen Ciuffo, MD
DECREAS HF	Multicenter, randomized trial comparing 3 methods of biventricular pacing with ICD	John M. Herre, MD
HRV	Heart Failure Heart Rate Variability Trial: Registry to assess the relationships among heart rate variability and NYHA class, physical activity, and quality of life	John M. Herre, MD
Block HF	Comparison of biventricular vs. right ventricular pacing in HF patients with atrioventricular block	John M. Herre, MD
ADVANCENT	National Registry to Advance Heart Health: Data from ADVANCENT will be benchmarked against controlled clinical trial data and recognized standards of care	John M. Herre, MD
	Electrophysiology/Arrhythmia	
QUIKSITE LV LEAD STUDY	Resynchronization for hemodynamic treatment for HF management; quicksite left heart lead mode 1056K	John M. Herre, MD
RHYTHM ICD	Resynchronization for Hemodynamic Treatment for Heart Failure Management	John M. Herre, MD
TRENDS	Multicenter, prospective, nonrandomized trial in subjects implanted with a commercially available Medtronic implantable pulse generator	John M. Herre, MD
HAT	Home Automatic External Defibrillator Trial	John M. Herre, MD
HOPE	Prospective, randomized, single-blind study to demonstrate safety and efficacy of the atrial overdrive feature in the Protos DR pulse generator	Robert Bernstein, MD
CONTACT CD	Randomized, controlled study evaluating improvement in functional capacity and quality of life resulting from biventricular pacing with the Ventak CHF/CONTAK CD (automatic ICD in patients with HF)	John M. Herre, MD
DAVID II	Study to evaluate the hypothesis that, in patients needing an AICD who have no overt indications for pacing, AAI pacing with maximal concomitant drug therapy will: 1) improve prognosis; 2) improve quality of life; and 3) reduce the cost of treating patients compared to VVI pacing with maximal concomitant drug therapy	John M. Herre, MD
VECTRA	Study to verify the safety and efficacy of a non-thoracotomy defibrillation lead system (ie, Vectra ACX Lead System)	Robert Bernstein, MD
CAPS	The VENTAK CHF/CONTAK CD Biventricular Pacing Study to determine the safety and efficacy of resynchronization therapy in slowing the progression of HF; trial provides a continued access study of the CONTAK CD heart failure device and EASYTRAK coronary venous pace/sense lead	John M. Herre, MD
RF-CONDUCTR	Atrial Flutter Ablation with the Medtronic RF Conductr MC/Contractr 8mm ablation catheter and the Medtronic ATAKR II Model 4803 Ablation System. A multicenter, prospective, nonrandomized trial to determine safety and efficacy of devices in treating atrial flutter	John Onufer, MD
RF-CONDUCTR Continued Access Study	Continuation of the RF CONDUCTR study to allow physicians use of the devices pending final FDA approval	John Onufer, MD

Title	Research Description	Principal Investigator
BIOTRONIK PROTOS HEART RATE DISTRIBUTION STUDY	Multicenter, prospective, randomized study to evaluate rate responsive pacemaker modes when comparing the CLS to the accelerometer mode in patients with chronotropic incompetence	John Onufer, MD
RENEWAL ACT	Multicenter, prospective, single-arm study to demonstrate safety and efficacy of atrial therapies in HF patients using the RENEWAL 3 AVT device and the EASYTRAK 2 pace/sense lead	John Onufer, MD
BREATHE	Study to evaluate impact of a higher pacing rate during rest in pacemaker patients with identified sleep apnea	John M. Herre, MD
	Acute Coronary Syndromes	
RESCUE ACS	Prospective, randomized, parallel group, open-label trial to evaluate the safety and efficacy of enoxaparin vs. unfractionated heparin in patients who present to the emergency department with acute coronary syndrome	Ramanaiah Kakani, MD
RESCUE ACS	Prospective, randomized, parallel group, open-label trial to evaluate the safety and efficacy of enoxaparin vs. unfractionated heparin in patients who present to the emergency department with acute coronary syndrome	Paul Mahoney, MD
PREMIER	Prospective registry evaluating outcomes after myocardial infarction	John Brush, MD
	Cardiac Catheterization Laboratory Device Trials	
TAXUS V	Randomized, double-blind trial to assess TAXUS™ slow-release formulation paclitaxel-eluting coronary stents in the treatment of high risk de novo coronary lesions	Ronald Stine, MD
STELLAR REGISTRY	Prospective evaluation of the impact of stent deployment techniques on clinical outcomes in patients treated with the Cypher™ Stent	Carl Hartman, MD
ZIPPER WIRE REGISTRY	Registry to assess the impact of using short wires on the time and ease of procedure	Scott Robertson, MD
SYMBIOT III	Prospective, randomized trial evaluating the Symbiot™ III covered stent system in saphenous vein grafts	Ronald Stine, MD
CAPTIVE	CAPTIVE Pivotal Trial: CardioShield™ application protects during transluminal intervention of vein grafts by reducing emboli	Paul Mahoney, MD
	Cardiac Catheterization Laboratory Drug Trials	
PFIZER "IVUS" STUDY	Multicenter, randomized, parallel group, double-blind, coronary artery intravascular ultrasound evaluation of the anti-atherosclerotic efficacy, safety, and tolerability of fixed combination CP-529,414/atorvastatin, administered orally, once daily for 24 months vs. atorvastatin alone, in subjects with angiographically documented coronary heart disease	Ronald Stine, MD
ORBIT II	Oral Rapamycin Inhibits Restenosis, Phase II: To evaluate the efficacy of oral rapamycin for reduction of stent restenosis in patients receiving bare metal stents in the coronary arteries	David Eich, MD
	Cardiac Surgery	
ON-X PROSTHETIC AORTIC and MITRAL HEART VALVES	Multicenter, prospective study evaluating the safety and efficacy of On-X prosthetic heart valves for replacement of diseased human aortic and mitral valves	Szabolcs Szentpetery, MD
CABEST	CABG/Carotid Endartectomy Staging Trial: NIH-sponsored registry study for concurrent or staged surgeries for coronary and carotid disease	Glenn Barnhart, MD
EXPEDITION	Multinational, placebo-controlled, double-blind trial to investigate the effect of IV treatment with the Na+/H+ exchange inhibitor cariporide (HOE642) on all-cause mortality and non-fatal MI in patients at risk of myocardial necrosis during and after CABG surgery	Szabolcs Szentpetery, MD
PRIMO-CABG	Study to confirm the efficacy of pexelizumab in the reduction of death or MI through 30 days post-op, in patients undergoing CPB as part of CABG surgery	Jeffrey Rich, MD

Research: Sentara Norfolk General Hospital

Title	Research Description	Principal Investigator
PREVENT IV	Study to determine the safety and efficacy of graft pretreatment with the E2F Decoy (CGT003) vs. placebo on the incidence of patients experiencing vein graft failure, as defined by at least one critical graft with ≥ 75% stenosis or total occlusion	Robert Hagberg, MD
STICH TRIAL	Study to test 2 primary hypotheses: 1) improvement in myocardial perfusion by CABG combined with intensive MED improves long-term survival compared to MED alone; and 2) in patients with anterior LV akinesia, LV shape, and size optimization by SVR combined with CABG and MED improves long-term survival free of cardiac hospitalization vs. CABG and MED without SVR	Szabolcs Szentpetery, MD
TISSELL TRIAL	Study to demonstrate equivalent hemostatic efficacy and safety for Fibrin Sealant Vapor Heated Solvent/Detergent Treated (FS VH S/D) and TISSEEL VH fibrin sealant; primary efficacy end point is proportion of subjects who achieve hemostasis within 5 minutes of treatment with either FS VH S/D or TISSEEL VH fibrin sealant	Szabolcs Szentpetery, MD
PHARMACIA	Study to evaluate the safety and efficacy of parecoxib and valdecoxib in a population of patients who have undergone CABG surgery	Glenn Barnhart, MD
OMNICARBON VALVE	Prospective, nonrandomized, post-market study to follow patients with the Omnicarbon valve, specifically for evaluation of thromboembolic/hemorrhagic risks	Hormoz Azar, MD
SYNERGY PC	Multicenter, prospective, nonrandomized trial of the Synergy PC stented valve implanted in patients requiring aortic valve replacement; comparison of complication and survival rates to historical controls	Robert Hagberg, MD
ON-X VS. ST JUDE MEDICAL VALVES	Multicenter, randomized trial to investigate whether the incidence of thromboembolic-related complications is reduced with a current generation mechanical prosthesis (MCRI-On-X) vs. previous generation mechanical prostheses (St. Jude Medical Regent)	Robert Hagberg, MD
EDWARDS PRIMA PLUS™ STENTLESS BIOPROSTHESIS VALVE	Multicenter, nonrandomized trial to obtain clinical data on the full root implantation technique of the Prima Plus™ Stentless Bioprosthesis valve	Glenn Barnhart, MD
CHOOSE -OFF	Open-label, prospective, multicenter, non-randomized study of Angiomax® in patients with heparin induced thrombocytopenia type II (HIT) and thromboembolic syndrome (HITTS) undergoing OP CAB	Szabolcs Szentpetery, MD
HOME STUDY	Multicenter, prospective, non-randomized outcome study to evaluate the impact of monitoring oral anticoagulant therapy delivery for On-X valve patients through the use of PST at home	Szabolcs Szentpetery, MD
CARBOMEDICS VALVE SIZING REGISTRY	Data collection study to assess sizing and implant techniques used with Carbomedics™ aortic and mitral valve prostheses; data will be gathered to compare labeled sizes of Carbomedics™ valves vs. those of other prosthetic heart valves and actual annulus diameter measured by a universal annulus sizer, and used to create a valve sizing registry that can provide comparative sizing and implantation guidelines for improved valve selection, hemodynamics, and safety	Robert Hagberg, MD
TMR REGISTRY	Data collection on patients undergoing TMR procedure; designed to yield further definition of the clinical characteristics of the population being treated and the 30-day postoperative risk factors and monitoring use of cardiac medication post procedure	Szabolcs Szentpetery, MD
TR3ISVR REGISTRY	Registry to track clinical and functional outcomes for patients who undergo SVR	Szabolcs Szentpetery, MD

AAI = atrial inhibited pacemaker; **AICD** = automatic implantable cardioverter defibrillator; **CABG** = coronary artery bypass graft; **CHF** = congestive heart failure; **CLS** = Closed Loop Stimulation; **CPB** = cardiopulmonary bypass; **FDA** = Food and Drug Administration; **HF** = heart failure; **ICD** = implantable cardioverter defibrillator; **IV** = intravenous; **LV** = left ventricular; **MED** = medical therapy; **MI** = myocardial infarction; **NIH** = National Institutes of Health; **NYHA** = New York Hospital Association; **OP** = off-pump; **PST** = patient self-testing; **SVR** = surgical ventricular restoration; **VVI** = ventricular inhibited (pacemaker).

Research: Sentara Virginia Beach General Hospital

Sentara Virginia Beach General Hospital is nationally recognized for its initiatives in national and international clinical trials, keeping it on the cutting edge of technology and innovation in management of heart disease. Table 2 summarizes the cardiac research studies in progress from January 2003 through April 2004 at Sentara Virginia Beach General Hospital.

Table 2. Cardiac Research at Sentara Virginia Beach General Hospital January 2003 through April 2004

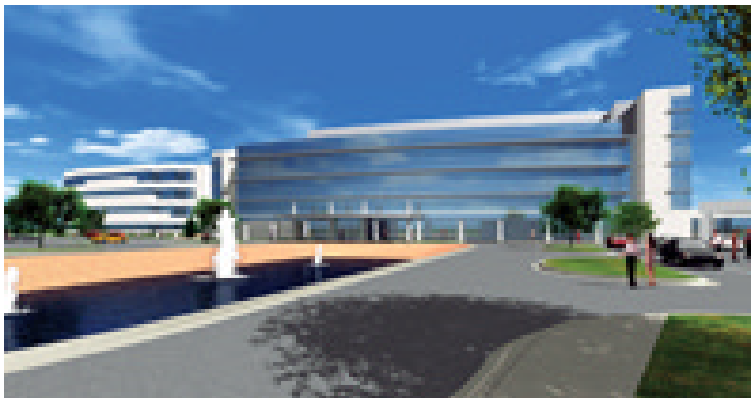
Title	Research Description	Principal Investigator
COOL-MI	Evaluation of the effects of induction of mild hypothermia in patients presenting to emergency department for MI	John Griffin, MD
COOL-MI II feasibility study	Evaluation of the effects of induction of mild hypothermia in patients presenting to emergency department for anterior MI	John Griffin, MD
ACUITY	Study to evaluate the efficacy of Angiomax vs. heparin plus IIBIIIa inhibitors in patients with unstable angina, a nearly occluded artery, and threatened MI	John Griffin, MD
CHARM	Study comparing mortality and morbidity in patients with HF treated with Candesartan vs. placebo	John Griffin, MD
PROVE-IT	Study comparing Pravachol vs. Lipitor and administration of antibiotics vs. placebo, and the effectiveness of each in preventing cardiovascular disease and events	John Griffin, MD
SYNGERY	Study comparing enoxaparin to heparin during cardiac cath interventions in patients with unstable angina	John Griffin, MD
CRUSADE	Data registry for quality indicators to comply with American College of Cardiology cardiac care guidelines concerning patients with unstable angina or NSTEMI	John Griffin, MD
EMERALD	Clinical test of device for use in acute MI (Percusurge [Medtronic]); end points are decreasing infarct size, improved outcomes, and preserving cardiac muscle	John Griffin, MD
CHARISMA	Study comparing Plavix with aspirin vs. aspirin alone for improved outcomes in cardiac disease, vascular disease (ie, cerebral, peripheral, and coronary), and stroke	John Griffin, MD
TACT	NIH-funded trial to assess the impact of chelation therapy on cardiovascular disease	John Griffin, MD
CATCH	Registry for patients with HITT	John Griffin, MD
CLOSURE I	Study comparing closure device vs. standard blood thinners in patients with cerebrovascular accidents or transient ischemic attacks with PFOs	Sidney Mallenbaum, MD, and John Griffin, MD
ASPEN	Trial to evaluate potential benefits of atrial fibrillation suppression algorithm for preventing first episode in high-risk AICDs patients without a history of atrial fibrillation	John Griffin, MD
DEFINITE	Study of defibrillators in patients with nonischemic cardiomyopathy	Harry Kanter, MD
INSYNC III	Multicenter study to assess safety and efficacy of a biventricular pacemaker	Harry Kanter, MD
INSYNC Registry	Registry to follow patients implanted with biventricular pacemakers	Harry Kanter, MD
HRV	Study of heart rate variability in congestive heart failure patients implanted with a biventricular AICD	Harry Kanter, MD

AICD = automatic implantable cardioverter defibrillator; **HF** = heart failure; **HITT** = heparin-induced thrombocytopenia and thrombosis; **MI** = myocardial infarction; **NIH** = National Institutes of Health; **PFO** = patent foramen ovale.

Sentara Heart Hospital—Opening February 2006

The new Sentara Heart Hospital, the region's only dedicated heart facility, will enable patients seeking heart care to receive comprehensive cardiac services — from diagnostics and interventional cardiology to open heart surgery and transplantation—at one location. This state-of-the-art, 6-story, 300,000 square foot, digital facility will contain 112 licensed all-private patient rooms, 45 pre- and postprocedure rooms, 6 cardiac catheterization labs, 3 electrophysiology labs, and 5 cardiac operating rooms designed to accommodate 2,000 cardiac surgery procedures annually. There are 7 key design principles centering on patient and family with a focus on accessibility, safety, efficiency, effectiveness, flexibility, and convenience for patients, family, physicians, and staff.

Sentara Virginia Beach General Hospital West Wing, Sentara Heart Center: Opening fall 2005



In late 2005, Sentara Virginia Beach General Hospital will unveil a new state-of-the-art patient tower with 108 private rooms, of which 46 are dedicated to heart care. The Sentara Heart Center is the door through which all heart patients will continue to receive high quality cardiac care—from diagnostic and interventional cardiology to open heart surgery. Patients will receive the ultimate in customer service while experiencing the latest in medical technology, including Picture Archival Communication System (PACS) radiology technology and wireless telemetry.

Nightingale

With the recent addition of an intra-aortic balloon-pump to the helicopter (for stabilization of cardiac patients while in flight) and a flight crew that is among the nation's best, the Nightingale is equipped and ready to transport critically ill cardiac patients in need of immediate cardiac care, cardiac intervention or open heart surgery. The Nightingale—the region's only air ambulance—is ready to be called into service when time is critical to a patient's survival and air transportation is the best method.

Preventive Services

Sentara emphasizes heart disease prevention through several forums and events that reach a broad spectrum of consumers. Among other areas of outreach, **Sentara Community Health & Prevention Division** works with the local community on heart education. Sentara Community Health & Prevention works with the Hampton Roads Minority Health Coalition and helps churches establish health ministries to educate church members about cardiovascular disease and arrange health screenings. In addition, Sentara Community Health & Prevention responds to all community requests by providing educational material and participates in several community screening events throughout Hampton Roads.

Sentara Heart Nights are held many times throughout the year at libraries, hotels, and Sentara facilities. Each evening is a free, 2-hour program that focuses on matters of the heart for consumers throughout Hampton Roads. Sentara Heart Night includes presentations by a cardiologist and cardiac surgeon followed by questions and answers, heart-healthy cooking demonstrations, and exhibits by various organizations, including the American Heart Association, cardiac rehabilitation, YMCAs, local rescue squads, home health care providers, and LifeNet.

Mrs. Laura Bush visited the Sentara Norfolk General Hospital in 2003 to raise awareness about women and heart disease. She addressed an audience of more than 250 attendees that represented the diversity of the Hampton Roads Community including the military, physician groups, health care providers, public service employees, homemakers, teachers, mothers, and heart disease survivors. Mrs. Bush's talk focused on *The Heart Truth Campaign,* a national initiative designed to inform women of their risks of heart disease.

Guest Services for Family

Sentara Norfolk General Hospital

offers Guest Services accommodations on the 6th floor of the hospital. Family members from longer distances (ie, those living outside Norfolk, Chesapeake, Portsmouth, or Virginia Beach) can stay overnight for a low cost of $25 per night, as well as enjoy discounted cafeteria meals, free cab vouchers to area restaurants and shopping, free parking, and other amenities to help them give their full attention to their family member's needs.

Reservations for SNGH Guest Services:
(757) 668-3118 or (800) 237-4822, ext. 83118.

Sentara Virginia Beach General Hospital

offers accommodations for families from out of the area (ie, those not residing in Suffolk, Knotts Island, Williamsburg, Newport News and those living at least 75 miles from SVBGH) at the Crowne Plaza, 4453 Bonney Road, Virginia Beach, for $35 per night, with a limit of 3 nights. Families will also receive a 25% discount meal card for the SVBGH cafeteria and a free 10-minute long distance calling card.

Reservations for SVBGH Guest Services:
(757) 395-8360 or (757) 395-8134. After-hours reservations can be made through the SNGH Guest Services at (757) 668-3118 or call pager number (757) 456-6002.

Landmark Dates

1967 Performed first cardiac catheterization at Sentara Norfolk General Hospital

1967 Performed first open heart surgery at Sentara Norfolk General Hospital

1969 Opened 11-bed coronary care unit with monitored beds at Sentara Virginia Beach General Hospital

1973 Implemented treadmill testing

1973 The Virginia Beach Emergency Medical Service launched the first advanced life support team of cardiac technicians, with training provided by Sentara Virginia Beach General Hospital

1974 Introduced the Holter monitor

1975 Introduced the M-mode echocardiogram

1975-76 Launched cardiac rehabilitation

1976 Introduced thallium stress testing

1978 Introduced 2-dimensional echocardiogram

1981 Introduced percutaneous transluminal coronary angioplasty at Sentara Norfolk General Hospital

1982 Airlifted first cardiac patient via Nightingale

1985 Established cardiac ambulance transport service

1987 Started electrophysiological study program at Sentara Norfolk General Hospital and Sentara Virginia Beach General Hospital

1988 Performed first diagnostic catheterization at Sentara Virginia Beach General Hospital

1988 Implanted first cardiac defibrillator in Southeastern Virginia at Sentara Virginia Beach General Hospital

1989 Performed first heart transplant at Sentara Norfolk General Hospital

1990 Performed first open heart surgery and first interventional catheterization at Sentara Virginia Beach General Hospital

1992 Introduced left ventricular assist device at Sentara Norfolk General Hospital

1992 Established Chest Pain Unit at Sentara Virginia Beach General Hospital

1996 Performed first peripheral diagnostic and intervention in catheterization laboratory at Sentara Norfolk General Hospital

1999 Sentara Norfolk General Hospital named among the Top 100 Cardiovascular Hospitals by HCIA, Inc, and one of only 34 hospitals nationwide to be in the top 100 list for both cardiac bypass and interventional cardiology programs.

1999 Sentara Norfolk General Hospital named one of America's Best Hospitals for Heart and Heart Surgery by *U.S. News & World Report*

2000 Sentara Norfolk General Hospital named among the Top 100 Cardiovascular Hospitals by HCIA/Sachs for the second consecutive year

2001 Sentara Norfolk General Hospital named among the Top 100 Cardiovascular Hospitals by Solucient; only hospital in Virginia to be named all 3 years of survey

2001 Sentara Norfolk General Hospital named in Top 50 Heart and Heart Surgery Hospitals by *U.S. News & World Report*

2001 Performed first beta-catheterization (brachytherapy) in region at Sentara Virginia Beach General Hospital

2002 Sentara launched the system-wide Women's HeartAdvantage Program

2002 Sentara Norfolk General Hospital ranked 23rd among Top 50 Heart and Heart Surgery Hospitals by *U.S. News & World Report;* only Virginia hospital to be ranked in heart by *U.S. News & World Report*

2002 Sentara Norfolk General Hospital named among Top 100 Cardiovascular Hospitals in the United States by Solucient; only hospital in Virginia to be named all 4 years of survey

2002 Performed first adult congenital atrial septal defect (ASD) interventional repair at Sentara Norfolk General Hospital

2003 First drug-eluting stents in the region implanted at Sentara Norfolk General Hospital and Sentara Virginia Beach General Hospital

2003 Sentara Norfolk General Hospital ranked 21st among Top 50 Heart and Heart Surgery Hospitals by *U.S. News & World Report;* only Virginia hospital to be ranked in heart by *U.S. News & World Report*

2003 Sentara Norfolk General Hospital named among Top 100 Cardiovascular Hospitals in the United States by Solucient; only hospital in Virginia to be named all 5 years of survey

2003 Performed region's first minimally invasive valve surgery at Sentara Norfolk General Hospital

2004 Sentara Norfolk General Hospital ranked 40th among Top 50 Heart and Heart Surgery Hospitals by *U.S. News & World Report*

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Szabolcs Szentpetery, MD

How to Refer a Patient

Sentara Norfolk General Hospital

If you know the cardiologist or cardiac surgeon to whom you want to refer your patient, call the physician directly. For your convenience, the telephone numbers of the cardiac physicians with privileges at SNGH are listed in the back of this 2004 Sentara Heart Program Outcomes Report.

Once contact has been made between the referring physician and the cardiac physician at SNGH, the receiving cardiac physician will arrange for patient transport. Depending on the patient's condition, the cardiac physician will choose to transport by ambulance or by Nightingale. Both transport teams have been trained to manage critical cardiac patients including those with intra-aortic balloon pump (IABP) assist devices and ventilators.

Sentara Virginia Beach General Hospital

If you know the cardiologist or cardiac surgeon to whom you want to refer your patient, call the cardiac physician directly. For your convenience, the telephone numbers of cardiac physicians with privileges at SVBGH are listed in the back of this Sentara Heart 2004 Outcomes Report. If you do not know the name or telephone number of a cardiologist or cardiac surgeon at SVBGH, use the following procedures:

Weekdays: Call the SVBGH Continuing Care office at (757) 395-8144 to begin the transfer process.

Weekends: Call the SVBGH operator at (757) 395-8000 and ask for the nursing supervisor, who will contact the cardiac physician on call.

Once contact has been made between the referring physician and the cardiac physician at SVBGH, the receiving cardiac physician will contact the admissions department to coordinate your patient's care at SVBGH, with the referring physician writing the transfer orders.

SENTARA HEART™

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