The Heartbeat

4th Quarter 2011

A NOTE FROM... Dr. Peter Wassmer

Peter Wassmer, MD
Medical Director, Tampa Bay Heart Institute at Northside Hospital

A lot of new exciting and innovative protocols have occurred this past quarter at the Tampa Bay Heart Institute (TBHI) at Northside Hospital. In this issue you will read about our new state of the art Cardiac Electrophysiology and Arrythmia Center from Dr. Robert Sheppard. Not only does it allow us to provide cutting edge technology and therapies for cardiac arrhythmias, but it also has dramatically allowed us to provide the least amount of radiation exposure to our patients and staff, while providing those therapies – compared to all other facilities in the area.

Our affiliation with the Sarah Cannon Research Institute is in full stride and we are now actively recruiting patients for the BOSS and ION stent trials with the ISCHEMIA Trial on the horizon as described further in this issue.

We have also actively started several protocols which we feel will improve the way we provide cardiac care to our patients and will hopefully improve cardiac outcomes. We have instituted a formal hypothermia program for cardiac arrest patients. So far, we have treated 5 patients and they have had better than previously reported historical outcomes. We have also instituted a direct to cath lab protocol for STEMI patients, bypassing the ER and so far have average door to balloon times of less than 30 minutes with a door to balloon times approaching 20 minutes!

Also in this issue, Dr. Minor writes about a pilot protocol of same day discharge for patients with elective PCI via the radial approach with excellent results and no adverse events. This not only enhances patient comfort but also decreases cost and length of stay.

Finally, Dr. Sanchez writes about the newer genomic testing available at the TBHI to better understand our true risk for CAD and coronary events and fine tunes the necessary therapies to truly reduce our patients' overall risk.

I know you will benefit from reading this issue and stay tuned for future developments as we strive to better our care of patients and improve their outcomes.

New Cardiac Electrophysiology Center at Northside Hospital

Robert Sheppard, MD
Director of Electrophysiology Lab, Tampa Bay Heart Institute at Northside Hospital

On October 6, Northside Hospital unveiled its new Cardiac Electrophysiology Center. Housed in the previous outpatient cath lab wing, the center includes a new and enlarged Electrophysiology (EP) Lab with a new state of the art GE cineflouroscopy system that minimizes radiation exposure to patients; a separate control room allowing protection of staff from radiation exposure without having to don lead drapes; the latest generation GE/Prucka Cardiac Electrophysiology Recording System; a GE Vivid Phased Array intracardiac ECHO system and both, the Endocardial Solutions Inc., as well as Biosense Webster Corp. CARTO III 3-dimensional intracardiac mapping systems making Northside's EP laboratory one of the most current and sophisticated labs in our region. The lab is also outfitted with sophisticated surgical lighting and real-time photography to assist device implantation. The large display screen (Carrot, Inc.) allows physicians to view multiple computer screens and images at once or enlarge a specific view to facilitate their procedure. *(continued on page 4)*

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Radial Catheterization Shortens Hospital Stays

Stephen Minor, MD
Director of Cath Lab, Tampa Bay Heart Institute at Northside Hospital

Since its inception in 1977, Percutaneous Coronary Intervention (PCI) has become a cornerstone in the treatment of coronary artery disease. Traditionally, PCI was performed as an inpatient procedure followed by a hospital stay up to several days, this prolonged hospital stay was influenced by multiple factors including higher dose anticoagulation regimen, larger sheath size, restriction to femoral access, lack of closure devices, and high risk of acute closure due to angioplasty without stent placement. Short- and long-term outcomes after PCI have improved dramatically in that time due to the evolution in device technology and pharmacotherapy. Despite this improvement, patients are usually still observed overnight in the hospital after elective PCI to monitor for PCI-related complications.

With the advent of newer therapies, PCI in the current era is routinely requiring less hospital stay following the procedure. Indeed, participating cardiologists at Northside Hospital are increasingly opting to perform PCI as an outpatient procedure for qualified patients. Cardiovascular Angiography and Intervention (SCAI) proposed guidelines for safety regarding the same day discharge after PCI. These guidelines emphasized factors that would preclude patients from same day discharge including comorbidites, type of the procedure, number of vessels involved and anticoagulation therapy. Patients discharged same-day reported significantly higher rates of overall satisfaction and incurred lower costs for the PCI procedure.

Researchers note that despite the apparent safety of same-day discharge for selected patients, the present day analysis demonstrates that this approach is rarely practiced among sites represented in the National Cardiovascular Data Registry. This may reflect reluctance on the part of clinicians to discharge patients the same day as the PCI procedure because of concerns over early post-PCI complications. Bleeding complications after PCI are most commonly related to the vascular access site, and the predominant vascular access site for PCI in this country is the femoral artery. Vascular bleeding and blood transfusions not only increase patient discomfort, length of stay, and hospital costs but have also been associated with an increased risk of mortality. Using a transradial catheterization approach can reduce major bleeding by 95%.

With the current focus on quality in health care, the goal is not only to reduce morbidity and mortality rates, but to do so while maximizing patient satisfaction and minimizing cost. Approximately 1 million PCIs are performed annually, with related costs approaching $10 billion.

Strategies to decrease expenditures are needed and are increasingly being forced upon hospitals and physicians by insurers who are reimbursing less. Transradial procedures reduce costs by lowering procedural costs, nursing care costs, length of stay, and costs related to complications. Most elective PCIs are reimbursed as outpatient procedures. Although there remains a profit margin for hospitals with outpatient PCI, it is less than in-patient PCI and is slowly dwindling. Same-day PCI is already financially attractive for the health care system as a whole and is becoming increasingly attractive for hospitals. Same-day PCI, made truly possible by the transradial approach, has major health care cost implications and will likely result in a significant paradigm shift regarding how we approach PCI in the coming decade.

In this day and age, when we keep patients overnight, it is rarely because we fear a coronary issue; it is because of the groin bleeding complications. In this situation, a nurse or physician will apply forceful manual pressure while the patient lies there uncomfortably. Ask any patient about the worst part of his or her procedure, and the most common answer will be "lying flat afterward". For patients who have experienced both radial and femoral access, there is a strong preference for the transradial approach due to increased comfort and ability to function autonomously.

Instead, imagine your patient getting a bracelet around her wrist after having completed her PCI. She gets off the table, into a wheelchair, and is wheeled into a holding area. There, she gets dressed and sits in an chair. She grabs a snack from the counter, and perhaps takes it with her to a chair where she talks with other patients afterward. After a few hours, she goes home, spending the night in the comfort of her own bed. This is not a futuristic fantasy. Northside Hospital has already implemented a strategy to identify eligible patients for same day discharge after uncomplicated PCI. Patients who qualify for same day discharge via a transradial catheterization approach are currently going home with close followup the next day. There has been an overwhelming positive feedback from these patients and no post-procedural complications noted to date.

Same-day discharge after transradial PCI has been shown to be safe and effective. It has shown itself to be an approach that offers lower complications, increased patient satisfaction, and reduced costs and is finding a perfect fit in a transforming health care system that is demanding such outcomes. Transradial approach for cardiac catheterization is expected to be increasingly recommended by clinical practice guidelines and to become a *(continued on page 4)*

Genetics and Atherosclerotic Cardiovascular Disease

Robert Sanchez, MD
Director of Non-Invasive Cardiology, Tampa Bay Heart Institute at Northside Hospital

"Entire families sometimes show this tendency to early arteriosclerosis. A tendency which cannot be explained in any other way than that in the make-up of the machine bad material was used for the tubing."

(Osler W. The Principles and Practice of Medicine. New York: D. Appleton & Co.; 1892:664.)

Family history as an independent risk factor for coronary heart disease (CHD) has been unequivocally established, however, only a fraction of the familial clustering of CHD observed can be accounted for by the familial clustering of traditional risk factors for CHD. Numerous prospective studies have shown that the risk of myocardial infarction (MI) is at least 2-fold greater if a family history of CHD is present. Retrospective studies have shown that in siblings of premature CHD patients the risk of dying from CHD was 5.2 times higher than a control population without such a family history. Furthermore, studies in twins provide strong evidence that premature death from CHD is strongly influenced by genetic factors.

The Human Genome Project (HGP) was completed in 2003. The HGP revealed that the human DNA sequence consists of 3.2 billion chemical base pairs, and approximately 20,000-25,000 genes. 99.5% of the human DNA sequence is identical across all human beings. It is estimated that over 80% of the 0.5% genetic variation difference is due to substitutions of single nucleotides (single nucleotide polymorphisms or SNPs). CHD and MI tend to be polygenic disorders in which multiple genes, each contributing only a small percentage to the disease, predispose to the disorder.

In 2007, the first common gene for coronary artery disease was identified. This polymorphism is located on the short arm (p) of chromosome 9 in the band region 2.1 and so it is referred to as 9p21. 9p21 to be very common, occurring in 75% of the Caucasian population. 50% of the population will inherit a single copy (heterozygous) and 25% will inherit 2 copies (homozygous). Individuals having 2 copies of 9p21 have an increased relative risk for CAD of about 40%. Those with a single copy have an increased relative risk for CAD of about 20%. The risk associated with 9p21 is independent of all known CHD risk factors. Studies also support that there is an association between 9p21 and CAD severity. There exists a dose response between the number of inherited copies of the risk allele and CAD severity. 9p21 seems to mediate its risk through deposition of coronary atheroma rather than plaque rupture or thrombosis. The 9p21 variant therefore predispose the individual not only to initiation of CAD but also to its progression.

Genetic testing can help differentiate population subgroups that will respond differently to the same drug therapy. Kinesin-like protein 6 (KIF6) is a protein involved in intracellular transport. The KIF6 gene is found on chromosome 6 (6p21.2). About 60% of the studied populations, predominantly consisting of Caucasians 45 years of age and older, were carriers of the KIF6 genetic variant (719Arg). Individuals with either one or two copies of 719Arg allele (e.g., Arg/Trp or Arg/Arg) have up to a 55% increased risk of CHD events as compared to noncarriers of the KIF6 719Arg allele (e.g., Trp/Trp). Studies also indicate that the presence of the KIF6 polymorphism identifies individuals that may benefit from statin therapy and is independent of LDL-C and hs-CRP reduction. Hepatic lipase (HL) is responsible for the lipolysis of both VLDL remnant particles and large, buoyant LDL, as well as the conversion of larger HDL2 to smaller HDL3 particles. A polymorphism in the promotor region of the hepatic lipase gene (HL-514T) has been linked to reduced HDL-C and reduced HDL2, but also greater HDL-C and HDL2 increase in response to combination lipid therapy. The HL-514T polymorphism has also been associated with better coronary arteriographic outcomes compared to patients without the HL-514T polymorphism.

Other genetic testing may also allow for further personalization of the individual's therapy. The apolipoprotein E (ApoE) gene was discovered in 1970 and is found on chromosome 19. The ApoE gene exists in three different forms (alleles) – e2, e3, and e4 – with e3 being the most common allele, found in 60% of the general population. ApoE e3/e3 is the most common genotype. ApoE e4 (e4/e4 and e4/e3) is found in 25% of the population and is associated with a 42% increased risk of atherosclerosis as compared to those with the ApoE e3/e3 genotype. Individuals with these e4 genotypes are predisposed to an exaggerated elevation of LDL-C and triglycerides when their diet is high in saturated fat. Individuals with the e4 genotype may respond to low fat diets with significantly greater LDL-C reduction than individuals with the normal e3/e3 genotype. Though these individuals may appropriately respond to a low fat diet, people with ApoE e4 may be less likely than those with ApoE e2 to respond to statins and may require additional adjustments to their treatment plans.

Despite the overwhelming evidence that a family history of CHD is an independent risk factor for future cardiovascular events and the association of multiple genetic polymorphisms with a significant increased risk of CHD, the routine analysis of detailed family history and genetic testing for the purpose of *(continued on page 4)*

SCRI Current Research Trials at Northside

BOSS:

Randomized, prospective, double-blind trial comparing isotonic sodium bicarbonate to reduce contrast-induced chronic kidney injury in patients with advanced chronic kidney disease who are undergoing angiography. Principal Investigator: Dr. Peter Wassmer
Sponsor: MD Scientific
Status: Open to enrollment

ION:

Paclitaxel-Eluting Platinum Chromium Coronary Stent System US Post-Approval Study
Principal Investigator: Dr. Andrew Rosenthal
Sponsor: Boston Scientific
Status: Opening November 28, 2011

CABANA:

Catheter Ablation Versus Antiarrhythmic Drug Therapy for Atrial Fibrillation Trial
Principal Investigator: Dr. Robert Sheppard
Sponsor: National Heart Lung and Blood Institute, Investigator Initiated Trial Mayo Clinic, Dr Douglas Packer
Status: Site Approved

ISCHEMIA:

International Study of Comparative Health Effectiveness with Medical and Invasive Approaches
Principal Investigator: Dr. Robert Sanchez
Sponsor: NIH
Status: Applying for Site Qualification

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If you have patients you think would be good candidates for any of the above trials, or you would like to learn more about the research program at Northside, please do not hesitate to contact any of the Investigators above, or the Research Coordinator, Heather Harteneck, RN at 521-5392 (office located in the new EP suite) or mobile 615-927-6793.

New Cardiac Electrophysiology Center at Northside Hospital *(continued from page 1)*

Although the new lab is the centerpiece of the new EP Center, the center offers more "patient-centric" care to our patients than had been available at our facility. A 5 room admission and recovery room built adjacent to the new lab is outfitted with telemetry which will allow patients to recover in the same room as they were admitted. A separate waiting area next to the recovery room allows family members to remain nearby without having to travel through the main hospital if patients are undergoing outpatient procedures. This should enhance the experience for our patients and families but also assures that the physicians, nurses, and staff that they encounter are all trained and attuned in the care of patients with cardiac arrhythmias.

We hope to use our association with the Sarah Cannon Research Institute to participate in national trials involving catheter ablation for atrial fibrillation, device trials for ventricular tachyarrhythmias and heart failure. Please stop by the new EP Center and see for yourself Northside Hospital's commitment to excellence.

Radial Catheterization shortens Hospital Stays *(continued from page 2)*

benchmark for quality of care. Participating interventional cardiologists at Northside Hospital are helping to shape the next era of percutaneous procedures, with transradial approach allowing advances in post procedural care and allowing patients to be safely discharged the same day of their percutaneous intervention.

Genetics and Atherosclerotic Cardiovascular Disease *(continued from page 3)*

identifying very high-risk individuals has not been universally accepted by the medical community. Interestingly, in the November 1989 issue of Clinical Genetics, Karl Berg from the Institute of Medical Genetics, University of Oslo, Norway wrote, "Knowledge of genetic factors in the etiology of coronary heart disease has not so far been adequately utilized in attempts to combat premature CHD. The time has now come to utilize genetic information in a setting of family-oriented preventive medicine. This approach would greatly improve the efficiency of preventive efforts, utilizing predictive genetic testing and targeting counseling on those who need it most." Given our increasing understanding of cardiovascular genetics and its clinical applications that time is well overdue. We need to apply this knowledge in routine clinical practice in order to improve CHD risk assessment, select the most appropriate therapy for our patients and provide appropriate family counseling.