HEART CARE NEWS

We lead with heart

NORTHSIDE HOSPITAL HEART INSTITUTE

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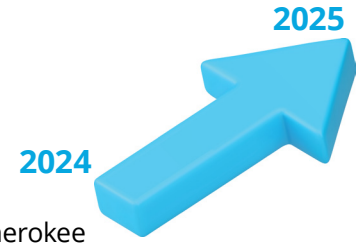
Phone: 404.845.8200 | Website: northside.com/heart

Successful 2024, Moving Forward to 2025 and Beyond

In 2024, Northside Hospital Heart Institute (NHHI) expanded its services, now boasting over 55 locations. These include five hospital campuses and three cardiovascular diagnostic centers. NHHI's ongoing investment in technology and a dedicated team of over 100 expert cardiovascular providers ensures patients receive world-class care close to home.

A few highlights from 2024 include:



- Added 15 new talented physicians in the following specialties: cardiac surgery, cardiac anesthesiology, cardiac electrophysiology, cardiology and vascular surgery
- Opened new cardiovascular diagnostic centers in Buford, Forsyth, and Gwinnett, and several new clinic locations
- Opened new heart failure clinics in Holy Springs and Gwinnett
- Expanded electrophysiology services to include transseptal procedures at Northside Cherokee
- Received Emergency Cardiac Care Center redesignation for Northside Hospital Gwinnett and Northside Hospital Duluth
- Certified as a Primary Heart Attack Center by the Joint Commission at Northside Hospital Atlanta
- Utilized new atrial fibrillation technology, Medtronic PulseSelect™ Pulsed Field Ablation (PFA) System
- Performed the state's first cardiac ablation using Boston Scientific FARAPULSE™ Pulsed Field Ablation System
- Added new Siemens Biograph Vision™ 600 PET/CT scanner dedicated to cardiac patients at Northside Hospital Gwinnett
- Received the Silver Level ELSO Award of Excellence in Life Support from the Extracorporeal Life Support Organization (ELSO) and is on the path to Excellence, which recognizes Northside Hospital for providing remarkable care in extracorporeal membrane oxygenation (ECMO)
- Received a HeartFlow CT Quality Award at Northside Hospital Gwinnett
- Received the American Heart Association Gold and Gold Plus Recognitions for all five hospitals
- Received the American Association of Critical Care Nurses Beacon Award for Excellence–Intensive Care Unit at Northside Hospital Gwinnett Medical ICU
- Received the Intersocietal Commission Accreditation for Echocardiography, Vascular Testing and Nuclear Cardiology
- The Northside Hospital Research Program participated in seven cardiology studies in 2024

We celebrate all our successes in 2024 and look forward to continued growth and innovation to best serve patients in the Atlanta region in 2025.

In This Issue

Clinical Trials and Research

Sponsor	Study/Protocol Number and Study Title	NCT Identifier
Ancora Heart, Inc.	**C-543; 5019 (CORCINCH-HF) ||** Randomized Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients who Present with Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF) (CORCINCH-HF)	NCT04331769

Study Design
- Patients are randomized in a 1:1 ratio to:
  a) Treatment group: AccuCinch Ventricular Restoration System plus GDMT
  b) Control group: GDMT

Key Eligibility Criteria
- Ejection Fraction: ≥20% and ≤40% measured by TTE and assessed by an ECHO core lab
- LV end-diastolic diameter ≥55 mm measured by TTE and assessed by an ECHO core lab
- Symptom Status:
  a. NYHA III,
  b. NYHA ambulatory IV, or
  c. NYHA II with a heart failure hospitalization† within the prior 12 months (of signing the consent form)
- Able to complete six-minute walk test with distance between 100 m and 450 m
- Diagnosis and treatment for heart failure should be established at least 90 days before consent.
- Prior to randomization, patients should be on stable, optimally titrated medical therapy for at least 30 days.

Sponsor	Study/Protocol Number and Study Title	NCT Identifier
Corvia	**C-569; RESPONDER-HF (2201) ||** Re-Evaluation of the Corvia Atrial Shunt Device in a Precision Medicine Trial to Determine Efficacy in Mildly Reduced or Preserved Ejection Fraction Heart Failure	NCT05425459

Study Design
- Eligible patients are scheduled for a right-heart catheterization at rest and during supine bicycle exercise on the day of the planned index procedure to assess hemodynamic criteria.
- If hemodynamic criteria are met, patients are blinded, sedated and undergo placement of a femoral venous access sheath and ICE or TEE exam for device implant suitability.
- Once all criteria are confirmed, eligible patients are randomized to the treatment or control group.
- Randomized participants undergo fluoroscopy and intracardiac echocardiography from the femoral vein or transesophageal echocardiography, for examination of the atrial septum and left atrial appendage.
  - If this examination is initiated and an exclusion is discovered, the excluded patient is followed for 30 days, and then exits the study.
  - This examination ends the index procedure for patients randomized to the control arm.
  - Patients randomized to the treatment arm continue in the index procedure to receive a transseptal puncture and Corvia Atrial Shunt implant.
  - An exam is performed at discharge for all randomized patients.

Key Eligibility Criteria

Chronic symptomatic HF documented by the following:
- Symptoms of HF requiring current treatment with diuretics if tolerated for ≥ 30 days AND
- NYHA class II with prior history of > class II or prior year heart failure hospitalization; OR NYHA class III, or ambulatory NYHA class IV symptoms; AND
- ≥ 1 HF hospital admission (with HF as the primary or secondary diagnosis); or treatment with IV diuretics; or intensification of oral diuresis within the 12 months prior to study entry; OR an NT-pro BNP value > 150 pg/ml in normal sinus rhythm, > 450 pg/ml in atrial fibrillation, or a BNP value > 50 pg/ml in normal sinus rhythm, > 150 pg/ml in atrial fibrillation within the past six months.

Ongoing stable GDMT HF management and management of comorbidities according to the 2022 ACC/AHA/HFSA Guidelines for the Management of Heart Failure:
- Stable management includes a minimum period of four weeks post-hospitalization for any cause, including treatment with IV diuretics.
- Site-determined echocardiographic LV ejection fraction ≥ 40% within the past six months, without documented ejection fraction < 30% in the five years prior
- Site-determined echocardiographic evidence of diastolic dysfunction documented by one or more of the following:
  - LA diameter > 4 cm; or
  - Diastolic LA volume > 50 or LA volume index > 28 ml/m2
  - Lateral e' < 10 cm/s;
  - Septal e' < 8 cm/s;
  - Lateral E/e' > 10;
  - Septal E/e' > 15
- Site-determined elevated PCWP, a gradient compared to RAP documented by end-expiratory PCWP during supine ergometer exercise ≥ 25 mmHg, and greater than RAP by ≥ 5 mmHg
- Resting RAP ≤ 14 mmHg
- Site-determined hemodynamic evidence of peak exercise PVR < 1.75 Wood units (new inclusion criterion)
- Age ≥ 40 years old

Sponsor	Study/Protocol Number and Study Title	NCT Identifier
Endovascular Engineering	**C-558; CLN01001 (ENGULF) ||** A Safety and Feasibility Single-Arm Study of a Novel Catheter Thrombectomy Device For the Treatment of Pulmonary Embolism	NCT05597891

Study Design
- Eligible patients are enrolled into pre-pivotal and pivotal cohorts to be treated with the Hēlo™ PE Thrombectomy System.

Key Eligibility Criteria
- Clinical signs and symptoms consistent with acute submassive PE with duration ≤ 14 days, as determined by the investigator
- CTA evidence of proximal PE (filling defect in at least one main or lobar pulmonary artery)
- RV/LV ratio of ≥ 0.9
- Systolic blood pressure ≥ 90 mmHg
- Heart rate < 130 BPM prior to procedure

ACC=American College of Cardiology; AHA=American Heart Association; BPM=beats per minute; BNP= b-type natriuretic peptide; CTA=computed tomography angiography; ECHO=echocardiogram; GDMT=guideline-directed medical therapy; HF=heart failure; HFSA=Heart Failure Society of America; ICE=intracardiac echocardiography; IV=intravenous; LA=left artium; LV=left ventricle; m=meters; mmHg=millimeters of mercury; NT-pro=N-terminal pro; NYHA=New York Heart Association; PCWP= pulmonary capillary wedge pressure; PE=pulmonary embolism; PVR= Pulmonary vascular resistance; RAP=right atrial pressure; RV=right ventricle; TEE=transesophageal echocardiography; TTE=transthoracic echocardiogram.

To learn more about Clinical Trials at Northside Hospital, visit our Clinical Research page or call 404.303.3355.

In the News: Updates for Clinicians

Highlights from the 2024 Georgia Chapter of the American College of Cardiology (ACC) Meeting

Post-Ross Procedure

By Alan Wolfe, MD

Reoperations for adult patients having undergone a Ross procedure are generally indicated either for pulmonary homograft stenosis or pulmonary autograft insufficiency.

Many patients from the early period of the Ross procedure (i.e., prior to 2000) have developed varying degrees of pulmonary homograft stenosis, which is usually well tolerated. Reoperation is only indicated in the presence of a systolic gradient approaching 40 millimeters of mercury (mmHg), which is often associated with significant right ventricular enlargement manifested by echocardiographic dysfunction and/or arrhythmias. Pulmonary homograft replacement and/or transcatheter techniques have been successfully utilized in this population. Decellularization techniques utilized in current homograft preparation have largely mitigated this complication.

A larger percentage of this early cohort of patients, many of whom had bicuspid aortopathy and/or annuloaortic ectasia resulting in aortic insufficiency as the original indication for surgery, developed significant late pulmonary autograft/neoaortic dilatation and insufficiency. In retrospect, this complication may have been foreseen as a result of the common embryologic derivation of both the aortic and pulmonary artery from the common truncus arteriosus.

Reoperations for this pulmonary autograft insufficiency are individualized based on surgeon experience and patient-specific factors related to the complex interaction between the sinotubular junction and the aortic annulus. The evolution and application of these surgical techniques have been dominated by the Yacoub remodeling technique as well as by various iterations of the David reimplantation technique. More recent efforts have addressed the importance of enhanced aortic annular reduction/stabilization, either from external banding or subaortic annular ring devices.

The overarching principle of all approaches is to preserve the patient's native valve tissue, which is applicable to a Ross pulmonary autograft as well as non-calcified aortic bicuspid or trileaflet insufficiency.

Share the Story to Stop the Clot

By Michele Voeltz, MD

At the 2024 Georgia ACC conference, I presented a case that, as a physician and mother, is quite near to my heart. A 17-year-old football player with a history of Factor V Leiden collapsed while at practice. He had a history of a viral infection approximately two to three months prior, followed by ongoing shortness of breath. The day before his admission, he was evaluated by pediatric cardiology and gastroenterology specialists and had undergone an upper endoscopy.

When emergency medical services arrived at the high school, they found the young man in distress. During the ride to the hospital, his heart stopped and cardiopulmonary resuscitation (CPR) was initiated. Upon arrival at the Northside Hospital Forsyth emergency department, the patient received thrombolytic therapy for a possible pulmonary embolism (PE). CPR was continued and our extracorporeal membrane oxygenation (ECMO) team was activated. We came over from Northside Hospital Gwinnett and cannulated the patient for ECMO during CPR (ECPR). He was found to have several large saddle emboli, which were treated with mechanical thrombectomy by the Northside Hospital Gwinnett team. Although the young man's hemodynamics improved, he suffered significant brain injury related to anoxia. Despite our efforts, he was declared brain dead. His family elected to donate his organs, and his heart and kidneys were transplanted successfully. The patient's mother and I remain close, and his family hopes that by telling his story, we can save another child from this terrible outcome.

It was a privilege to care for this young man and his amazing family. For details on the management of Factor V Leiden and pulmonary embolism, please see stoptheclot.org/. As of January 23, 2025, Governor Brian Kemp has proclaimed March as Blood Clot Awareness Month.

National Blood Clot Alliance
Stop The Clot®

Vulnerable Plaque Imaging in Intracoronary Cases

By Michael Yin, MD

At the 2024 Georgia ACC conference, I had the pleasure of presenting a case regarding intracoronary imaging. The patient is a 46-year-old female with no known medical history, does not smoke, exercises daily and maintains a healthy diet. She presented with 12 hours of intermittent chest pain radiating to the neck and arm. Her initial electrocardiogram (EKG) was unimpressive, but her high-sensitivity troponin (HS-troponin) was 522 ng/L.

A coronary angiogram showed 90% type A lesion at the ostial left anterior descending (LAD) involving the distal left main coronary artery (LM). Intracoronary imaging, both optical coherence tomography (OCT) and intravascular ultrasound (IVUS), was performed to better understand the lesion. We were able to rule out a localized spontaneous coronary artery dissection (SCAD) in this young female, because we

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Vulnerable Plaque Imaging in Intracoronary Cases *(continued from page 3)*

did not see a dissection or false lumen to indicate SCAD. We observed a vulnerable plaque in the form of a thin-cap fibroatheroma (TCFA), typically characterized by a thin fibrous cap, usually less than 65 micrometers, which was not well visualized on IVUS but was easily seen on OCT. Behind the TCFA was a large necrotic core, which was rich in lipid, foam cells and cholesterol crystals, homogenous and had high attenuation; hence, it appeared dark on OCT and IVUS. The high attenuation of the necrotic core made its size difficult to gauge on OCT alone. IVUS allowed full visibility, and the two tests were complementary in ascertaining more about the lesion.

Given such young age, decision was made to refer patient to a robotic coronary bypass surgery. Patient returned to the recovery area but started having recurrent chest pain. A repeat EKG showed lateral ST-segment elevation and reciprocal inferior ST-segment depression, indicating an ST-segment elevation myocardial infarction. The patient therefore underwent an emergent percutaneous coronary intervention (PCI). A repeat IVUS after stenting and post-dilation ensured the stent was well-apposed and expanded. The patient was discharged chest pain free. ST-segment elevation was resolved with aspirin, ticagrelor, a beta-blocker and a statin, and the patient was well at follow-up.

This case illustrates the importance of intracoronary imaging in determining the plaque morphology acute coronary syndrome especially in younger patients. Additionally, once vulnerable plaques are identified, urgent revascularization is needed, even if it means stenting of the left main. Good long-term outcomes can be achieved with favorable anatomy, careful planning using intracoronary imaging, and meticulous techniques.

2024 American College of Cardiology Cardio-Obstetrics Essentials Meeting Recap

Collaborative Care of Cardiovascular Disease and Pregnancy

By Parham Eshtehardi, MD

The American College of Cardiology Cardio-Obstetrics Essentials Team-Based Management of Cardiovascular Disease and Pregnancy meeting was held in Washington, D.C., on November 1-3, 2024. The goal of this meeting was to update and educate clinicians on data and information pertaining to the care of cardiovascular disease in patients of child-bearing age due to the continued rise in maternal morbidity and mortality rates.

I had the pleasure of being part of the planning committee and giving three presentations, including "I Am Torn, Could It Be P-SCAD?", "Secrets Leaked: Everything You Need to Know About Regurgitant Lesions in Pregnancy" and "Ablation of Supraventricular Arrhythmias During Pregnancy."

"I am Torn, Could It Be P-SCAD" reviewed the diagnosis, management and prognosis of pregnancy-associated spontaneous coronary artery dissection (P-SCAD). P-SCAD prevalence is 2-8%, is the most common cause of pregnancy-associated myocardial infarctions (43%) and typically presents early postpartum. Multiparity, first childbirth at an older age, history of fertility treatment and preeclampsia are risk factors for P-SCAD. Pharmacologic management of P-SCAD is generally safe during pregnancy and includes aspirin, clopidogrel, beta-blockers and potentially, statins (remains controversial). P-SCAD recurrence is possible (2-22%); therefore, avoidance of additional pregnancies is advised by most clinicians despite the lack of definitive evidence that previous P-SCAD increases recurrence risk.

"Secrets Leaked: Everything You Need to Know About Regurgitant Lesions in Pregnancy" focused on hemodynamic changes during pregnancy and their effect on valvular heart disease (VHD) and the management of valve regurgitation during pregnancy. Hemodynamic changes during pregnancy can result in cardiac decompensation in women with severe VHD, and women with VHD should receive counseling and a preconception risk assessment. In general, regurgitant lesions are better tolerated compared with stenotic lesions. Most women with mild/moderate regurgitation do well during pregnancy. Patients with aortic or pulmonary regurgitation are at low risk for cardiac complications during pregnancy. Mitral or tricuspid regurgitation or multivalve regurgitation are also well tolerated during pregnancy in the absence of high-risk features (e.g., left ventricular systolic dysfunction (LVSD) or cardiac events prior to pregnancy). For patients with severe symptomatic regurgitant lesions or with LVSD or dilatation, surgical intervention prior to conception is recommended. For patients with severe left-sided regurgitant lesions and severe LVSD (or significant pulmonary hypertension), pregnancy should be avoided. Centers that specialize in pregnancy and heart disease should be utilized when necessary.

"Ablation of Supraventricular Arrhythmias During Pregnancy" was part of a debate in which data and guidelines outlining the importance of ablating supraventricular arrhythmias (SVT) during pregnancy were presented. I argued that during pregnancy, paroxysmal SVT is associated with adverse maternal/fetal events, and medications are less effective with more risks. SVT ablation has shown to be reliable during pregnancy, effective and safe, and therefore should be considered as a treatment option for patients with atrioventricular nodal reentrant tachycardia, atrioventricular reentrant tachycardia, focal atrial tachycardia and typical flutter to avoid adverse events from medications.

2024 SCAI SHOCK Presentations Recap

The 2024 Society for Cardiovascular Angiography & Interventions (SCAI) SHOCK meeting was held from October 17–19 in Washington, D.C. Northside Hospital's Allison G. Dupont, MD, was Co-Chair and Jason Grady, NRP, AACC, was a program Co-Chair. Dr. Dupont will chair the upcoming SCAI SHOCK 2025 meeting in Tampa, September 18–20, and encourages attendance from Northside Hospital staff.

The Latest in ECMO

By Allison Dupont, MD

Extracorporeal membrane oxygenation (ECMO) is a team sport at Northside Hospital, and this approach to caring for ECMO patients is becoming more common worldwide as interventional cardiology, cardiology and critical care medicine take on more of a role in these complex patients. At some centers around the world, cardiothoracic surgery manages ECMO patients, but this is becoming less common globally as the number of indications for ECMO has increased well beyond post-cardiotomy patients. Thus, several centers are shifting to a model similar to what we have employed at Northside, with interventional cardiology cannulating patients and a multidisciplinary approach to post-cannulation care.

As the volume of ECMO runs worldwide has increased over the past decade (as per data from the Extracorporeal Life Support Organization), so have the data and knowledge surrounding complications associated with ECMO. Vascular complications have decreased by taking steps upfront, at the time of cannulation, to perfuse the affected extremity in veno-arterial ECMO patients. Dual lumen veno-venous ECMO cannulas allow for patient mobility and ambulation on ECMO, which would be more cumbersome and higher risk with femoral cannulation. Minimizing sedation, mobilizing patients, and in some cases, liberating them from the ventilator are goals that the ECMO team prioritizes in every case.

If you have a patient with respiratory failure, pulmonary embolism or cardiogenic shock whom you feel may benefit from ECMO, please call the Northside Transfer Line at 855.662.6625 to speak with the ECMO team on call.

Care Complexities in Cardiogenic Shock

*By Jason Grady, NRP, AACC**

The care of patients with cardiogenic shock is inherently complex, requiring a comprehensive, multidisciplinary team approach. While treatment plans often focus on definitive care and the devices necessary for recovery, the critical roles of early recognition, timely escalation, and safe, competent transport are sometimes underappreciated.

At 2024 SCAI SHOCK, several key topics emphasized the importance of a team-centered approach in managing cardiogenic shock. One notable session, "The Role of Emergency Medical Services (EMS), Transport, and the ED in the Management of Cardiogenic Shock," explored the essential resources available to EMS and emergency medicine for diagnosing cardiogenic shock. The discussion highlighted how effective communication and coordination can guide optimal upstream destination decisions.

The "Cardiogenic Shock in the Cath Lab" presentation focused on empowering the entire care team to offer input, suggest interventions and voice concerns, fostering a collaborative decision-making environment. "ICU Models" underscored the value of hemodynamic monitoring in tailoring treatment plans, while "The Challenges and Nuances of Transporting Patients on MCS" shed light on the logistical and technical difficulties involved in transferring patients to dedicated shock centers.

Throughout the conference, Northside Hospital Heart Institute showcased many of its expert-driven and innovative processes designed to address these critical areas of care. These insights underscored the institution's commitment to advancing the management of cardiogenic shock through a multidisciplinary lens.

** Jason Grady, NRP, AACC is the Northside Hospital system manager of emergency cardiac care and the SCAI Shock program co-chair for EMS and critical care transport.*

Northside Hospital's Involvement in the American Heart Association Scientific Sessions

Dr. Parham Eshtehardi (right) moderated an abstract session at the American Heart Association (AHA) 2024 Scientific Sessions, and Dr. Marcus Brown (left) is part of the Georgia's AHA Board of Directors.

Highlights from the Transcatheter Cardiovascular Therapeutics (TCT) Conference 2024

Transcatheter Aortic-Valve Replacement (TAVR) Superior to Clinical Surveillance for Asymptomatic Severe Aortic Stenosis: Results of the EARLY TAVR Trial[1]

Guideline recommendations for patients with asymptomatic severe aortic stenosis (AS) and preserved left ventricular ejection fraction (LVEF; ≥50%) include clinical surveillance with routine follow-up every 6 to 12 months. The EARLY TAVR randomized trial explored transfemoral-TAVR early intervention compared to clinical surveillance in 901 patients with asymptomatic severe AS, ≥65 years old, LVEF ≥50% and a Society of Thoracic Surgery (STS) score of ≤10%. The primary endpoint was the composite of death, stroke or unplanned cardiovascular-induced hospitalization.

The average age of the patients was 75.8 years old, and patients had a mean STS score of 1.8%. The primary endpoint was met in 26.8% of patients in the TAVR arm and in 45.3% of patients in the clinical surveillance arm ($p < 0.001$); death occurred in 8.4% of patients assigned to TAVR and in 9.2% of patients assigned to clinical surveillance. Stroke occurred in 4.2% and 6.7%, respectively, and unplanned cardiovascular hospitalization occurred in 20.9% and 41.7%, respectively. The majority of patients in the clinical surveillance arm (87%) underwent aortic valve replacement by the median follow-up of 3.8 years.[2]

Ultimately, the EARLY TAVR trial showed that early transfemoral-TAVR significantly reduced death, stroke or unplanned hospitalization in patients with asymptomatic severe AS; and, therefore, may be preferred over clinical surveillance, especially with the added challenge of timely symptom recognition and prompt treatment in real-world settings.

References:

1. Genereux P, Schwartz A, Leon M. TAVR for Asymptomatic Severe Aortic Stenosis: Results of the EARLY TAVR Trial. Presented at: Transcatheter Cardiovascular Therapeutics Conference; October 27-30, 2024; Washington, D.C., USA.

2. Genereux P, Schwartz A, Oldemeyer JB, et al. Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis. *N Engl J Med*. 2024; 392:217-227. doi: 10.1056/NEJMoa2405880.

Expert Commentary

By Pradyumna Tummala, MD

In the USA, approximately 3% to 5% of people over the age of 65 have severe aortic stenosis (AS), which, if left untreated, is associated with only a 50% chance of survival over three to five years due to the development of heart failure and sudden death. Survival is particularly worse when patients begin having symptoms of fatigue, shortness of breath, chest discomfort, lightheadedness or syncope. Therefore, it has become standard of care to replace the aortic valve either with surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR) when symptoms develop. Replacing the severely stenotic aortic valve in symptomatic patients has proven to improve their survival as well as quality of life, with relief of symptoms. However, it is unknown whether asymptomatic patients with severe aortic stenosis would benefit from aortic valve replacement, as their prognosis is not as poor as those patients with symptoms; and procedures such as TAVR and SAVR have a small risk of major complications, including an approximate 1% chance of death and 1% chance of stroke. The EARLY TAVR trial has shown that TAVR is safe in patients with severe AS without symptoms, and furthermore, appears to reduce severe events, including the combined endpoints of hospitalization, stroke and death. It is important to note that there are different grades of asymptomatic, severe aortic stenosis. Generally, the lower the aortic valve area and the greater the pressure gradient across the aortic valve, the worse the prognosis is for the patient. In fact, patients who have very severe/critical AS or have evidence of heart failure on physical exam or worsening left ventricular function on echocardiogram are already recommended aortic valve replacement, per national guidelines. Part of the problem with basing the decision of replacing the aortic valve on symptoms alone is that many patients do not notice their symptoms, because they have adapted to the disease by slowing down, refraining from activities that cause symptoms, or may feel that they're just "getting older." Therefore, close follow-up with their cardiologist every three to six months and supplementary testing, such as exercise treadmill testing or checking the B-type natriuretic peptide (BNP) level, which increases in patients with subclinical heart failure, may lead to recommendations for aortic valve replacement sooner rather than later. Findings of the EARLY TAVR study are very encouraging in that they demonstrate the safety and efficacy of TAVR in these patients and will lead to closer monitoring of patients, with a low threshold to replace the aortic valve, even when patients do not disclose any symptoms.

Intervention with Large-Bore Mechanical Thrombectomy vs. Catheter-Directed Thrombolysis for Intermediate-Risk Pulmonary Embolism Treatment: Outcomes from PEERLESS[1,2]

PEERLESS is the first randomized controlled trial evaluating large-bore mechanical thrombectomy (LBMT) for intermediate-risk pulmonary embolism (PE) and the first to compare acute clinical outcomes from patients randomized to catheter-based interventions with various mechanisms of action. In this study, 550 intermediate-risk PE patients with right ventricular dilatation and other clinical risk factors were randomized to large-bore mechanical thrombectomy (LBMT) or catheter-directed thrombolysis (CDT) treatment.

The primary endpoint was a composite of all-cause mortality, intracranial hemorrhage, major bleeding, clinical deterioration and/or bailout and post-procedural intensive care unit (ICU) admission and length of stay, hierarchically assessed using a win ratio at hospital discharge or seven days after the procedure, whichever was shorter. LBMT was associated with a significantly lower primary endpoint versus CDT ($p < 0.001$). The LBMT patients experienced significantly less clinical deterioration and/or bailout (1.8% versus 5.4%; $p = 0.04$) and post-procedural ICU utilization (41.6% versus 98.6%; $p < 0.001$). Mortality, intracranial hemorrhage and major bleeding did not differ between the groups.

Findings of this study demonstrated the superiority of LBMT versus CDT in intermediate-risk PE patients. The LBMT

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Intervention with Large-Bore Mechanical Thrombectomy vs. Catheter-Directed Thrombolysis for Intermediate-Risk Pulmonary Embolism Treatment: Outcomes from PEERLESS *(continued from page 6)*

treatment strategy also resulted in additional benefits to the patients, including faster clinical and hemodynamic improvement at 24 hours, less clinical deterioration or escalation of treatment, fewer readmissions within 30 days, decreased ICU use and fewer hospital days.

References:

1. Jaber WA, et al. Large-Bore Mechanical Thrombectomy vs. Catheter-Directed Thrombolysis for Treatment of Intermediate-Risk Pulmonary Embolism: Primary Outcomes from the PEERLESS RCT. Presented at: Transcatheter Cardiovascular Therapeutics Conference; October 27-30, 2024; Washington, D.C., USA.

2. Jaber WA, Gonsalves CF, Stortecky S, et al. Large-bore mechanical thrombectomy versus catheter-directed thrombolysis in the management of intermediate-risk pulmonary embolism: primary results of the peerless randomized controlled trial. *Circulation*. Oct 2024. doi:10.1161/CIRCULATIONAHA.124.072364.

Expert Commentary

By Michele Voeltz, MD

More than 900,000 Americans are affected by pulmonary embolism (PE) each year. The mortality associated with PE ranges from 10% to 30%. Considering this significant risk, the management of PE has become a very important topic in the world of interventional cardiology and vascular surgery. The PEERLESS trial enrolled 550 intermediate-risk patients with submassive PE, randomizing them to large-bore mechanical thrombectomy (LBMT) versus catheter-directed thrombolysis (CDT). The trial demonstrated that patients with LBMT had lower rates of the primary composite endpoint.

This very important trial demonstrates that both CDT and LBMT are effective in the treatment of submassive PE. LBMT patients were less likely to clinically deteriorate and had lower rates of post-procedural admission to the intensive care unit. Both groups of patients had equivalent rates of mortality, intracranial hemorrhage and major bleeding. LBMT, although requiring large-bore access, is superior to CDT in several important ways. The development of Pulmonary Embolism Response Teams (PERTs) has allowed medical teams to immediately treat patients with submassive PE and reduce morbidity and mortality for this critically important condition. As we expand PERTs, we hope to develop a wide-reaching approach to PE, allowing rural centers to transfer patients for life-saving procedures, including LBMT.

TRILUMINATE Pivotal Study 1-year Outcomes Continue to Support Tricuspid Transcatheter Edge-to-Edge Repair in Patients with Severe Tricuspid Regurgitation[1,2]

The TRILUMINATE Pivotal study is the first randomized controlled trial (RCT) evaluating the impact of tricuspid transcatheter edge-to-edge repair (T-TEER) with the TriClip device in patients with symptomatic, severe tricuspid regurgitation (TR). One-year outcomes of the full randomized cohort from the TRILUMINATE study were presented at the TCT meeting.

Five hundred and seventy-two patients were randomized to receive T-TEER with the TriClip device or medical therapy alone. The primary outcome was a composite of all-cause mortality or tricuspid valve surgery, heart failure hospitalizations (HFHs) and quality-of-life improvement measured by Kansas City Cardiomyopathy Questionnaire (KCCQ) at one year. Baseline characteristics included an average age of 78.1 years and comorbidities such as atrial fibrillation (87.8%) and prior HFH (23.8%).

The primary endpoint was met for the full cohort with superiority in the device group (p <0.0001), primarily driven by improvements in health status. Freedom from all-cause mortality and tricuspid valve surgery through 12 months was 90.6% for the device group and 89.9% for the control group (p=0.82); the HFH annual rate was similar between the two groups (0.17 versus 0.20 events/patient-year; p=0.40). The quality of life of device patients showed a significant change with a ≥15-point KCCQ score improvement in 49.5% of patients compared to 25.6% of control subjects (p <0.0001).

Overall, T-TEER with TriClip demonstrated promising outcomes for the treatment of severe, symptomatic TR. The device group was also associated with low rates of adverse events and significantly favorable secondary endpoint outcomes. Although, in the subsequently enrolled cohort, HFH favored the device group, more studies will be needed to fully understand the effect of TR on HFH.

References:

1. Tang GHL, et al. Tricuspid Transcatheter Edge-To-Edge Repair For Severe Tricuspid Regurgitation: 1-Year Outcomes From The Full TRILUMINATE Pivotal Randomized Cohort. Presented at: Transcatheter Cardiovascular Therapeutics Conference; October 27-30, 2024; Washington, D.C., USA.

2. Tang GHL, Hahn RT, Whisenant BK, et al. Tricuspid transcatheter edge-to-edge repair for severe tricuspid regurgitation: 1-year outcomes from the TRILUMINATE randomized cohort. J *Am Coll Cardiol*. October 2024. doi:10.1016/j.jacc.2024.10.086.

Expert Commentary

By Fredy El Sakr, MD

Severe tricuspid regurgitation is associated with significant symptoms of shortness of breath, fatigue, lower extremity edema or swelling, and can lead to liver disease. Over time, untreated tricuspid regurgitation can lead to worsening right ventricular function and progressive pulmonary hypertension. Management of significant tricuspid regurgitation has been predominantly with the use of medications, such as diuretics to relieve symptoms, but rarely affecting the actual severity of disease. Isolated tricuspid regurgitation surgery is an infrequently performed procedure due to the associated morbidity of the procedure and limited improvement in mortality observed among multiple studies.

For this reason, percutaneous therapies to treat the tricuspid valve have been explored. One of the more promising therapies is tricuspid transcatheter edge-to-edge repair (T-TEER). One device, the TriClip system (Abbott Medical Systems), was studied in the TRILUMINATE trial, which compared treatment of severe tricuspid regurgitation with T-TEER versus usual management. Findings of this trial showed a significant improvement in the primary outcome (i.e., mortality, heart failure hospitalization, quality of life; as measured by Kansas City Cardiomyopathy Questionnaire [KCCQ12]) driven by improvement in quality

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Expert Commentary *(continued from page 7)*

of life with 42% of patients having a large (>20-point increase) improvement.

The TriClip system, a very promising and encouraging new therapy, gives patients with significant tricuspid regurgitation an option for treatment without having to undergo the risks of open-heart surgery. Moreover, patients still benefit from improvements in their overall functional capacity and quality of life.

Elevating the Patient Experience

BUILT TO QUIT: Northside Hospital's Smoking & Tobacco Cessation Program at a Glance

By Parham Eshtehardi, MD

Smoking is a major risk factor for cardiovascular disease and poses several significant hazards to heart health. Smoking accelerates the development of atherosclerosis and endothelial dysfunction, is associated with increased levels of inflammation and promotes a pro-thrombotic state. Increases in heart rate and blood pressure due to smoking can contribute to hypertension, a major contributor to cardiovascular disease. Smoking can reduce oxygen supply, worsening the effects of existing heart conditions, and it can affect lipid profiles, leading to higher levels of LDL cholesterol and lower levels of HDL cholesterol, both of which contribute to cardiovascular risk. However, smoking is a modifiable risk factor for cardiovascular disease. Smoking cessation can significantly reduce the risk of developing cardiovascular disease and offers substantial health benefits, even for long-term smokers. The cardiovascular system begins to recover soon after quitting, and the longer a person remains smoke-free, the lower their risk of cardiovascular disease. One year after quitting, the risk of coronary artery disease is decreased by half compared to a smoker. After approximately five years, the risk of stroke declines to the same level as someone who has never smoked. Similarly, the risk of myocardial infarction continues to decrease and can approach the level of a non-smoker's risk after about 10-15 years of being smoke-free.

Northside Hospital's "Built To Quit" smoking cessation program is designed to help individuals stop smoking through a comprehensive approach that includes education, support and medical guidance. This program offers group support sessions, educational resources, behavioral therapy, pharmacotherapy (advice and access to medications), personalized quit plans and follow-up support. Built To Quit is a great resource for physicians to promote the heart health of their patients. To learn more about Northside Hospital's, Built to Quit Program, please visit the Smoking & Tobacco Resources webpage.

Northside Hospital Atlanta Certified as a Primary Heart Attack Center

Northside Hospital Atlanta is a Primary Heart Attack Center, certified by The Joint Commission and American Heart Association on November 6, 2024. This certification, which demonstrates the hospital's dedication to providing high-quality and optimal patient outcomes, requires a collaborative effort with both hospital team members and pre-hospital medical services assisting patients at the first medical contact. More information can be found by visiting the Joint Commission webpage.

Around Our Campuses and Community

New Clinic Locations: Northside Cardiac Surgery

Northside Cardiac Surgery
1276 Jesse Jewell Parkway SE
Gainesville, GA 30501
Provider: Dr. Alan Daniel Winston

Northside Cardiac Surgery
2220 Wisteria Drive
Suite 209
Snellville, GA 30078
Provider: Dr. Azad S. Karim

Provider Features and Recognitions

New Providers and Recognitions

Lalitha Medepalli, MD is the new Chair of the International Medical Graduate Section at the Medical Association of Georgia (MAG).

Hussein Rayatzadeh, MD, is a non-invasive cardiologist practicing at Northside Heart – Canton. To learn more, visit: northside.com/Hussein-rayatzadeh.

Congratulations to **Sigbert "Gary" Stephenson**, who successfully passed the International Board of Heart Rhythm Examiners (IBHRE) Allied Professionals Certified Cardiac Device Specialist (CCDS) Exam.

Upcoming Education and Events

EDUCATION

The Heart of the Matter: Managing Cardiovascular Risks in Pregnancy
February 28, 2025, from 5-8 p.m. and March 1, 2025, from 7 a.m-3 p.m. @ Hyatt Regency Atlanta Perimeter at Villa Christina

Emergency Cardiovascular Care (EC3) Conference
March 14, 2025 @ Gas South District Conference Center

ACC.25: American College of Cardiology
March 29-31, 2025 @ McCormick Place Convention Center in Chicago, IL

SCREENINGS

Big Canoe Cardiovascular Screening
March 26, 2025 from 9 a.m.-1 p.m. in Big Canoe

CLASSES

Built To Quit, Smoking and Tobacco Cessation Course
Next 6-week session start date: March 4, 2025
Weekly classes include the American Lung Association Freedom from Smoking curriculum.

SPONSORED COMMUNITY EVENTS

American Heart Association Go Red for Women Luncheon
May 22, 2025 @ Marriott Buckhead in Atlanta

EC3 EMERGENCY CARDIOVASCULAR CARE CONFERENCE

BUILT TO QUIT Resources to help you stop smoking and using tobacco

American Heart Association. Go Red for women.

Sign up for Heart Care News

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