ENDOVASCULAR REPAIR OF THORACIC AORTIC ANEURYSMS SAVES LIVES

With the recent FDA approval of a new endovascular stent, the Methodist DeBakey Heart Center (MDHC) will be one of the first to offer a procedure to prevent thoracic aortic aneurysm (TAA) ruptures without the risk and complications of traditional open surgery.

The Gore TAG endovascular stent-one of four stents being tested nationwide for use in treating TAAs-underwent pivotal trials and confirmatory studies at a handful of U.S. medical centers, including the MDHC, and is the first to receive FDA approval. While TAA devices have been available outside the country for several years. no thoracic endografts had been approved for domestic use until now.

Heart Center vascular surgeon Alan B. Lumsden, who was Methodist's lead investigator for the TAG study, has been involved in trials testing three of the four different stents and was principle investigator in similar studies at Emory before joining Methodist in 2001.

"The experience for the patient is drastically better," Lumsden says. "This technology could revolutionize the treatment of aneurysms and save lives."

Thoracic aortic aneurysms reportedly affect more than 15,000 people each year, although that figure is thought to be substantially higher since three of every four individuals with aneurysms are asymptomatic. If left untreated, the two-year survival rate after diagnosis is less than 30%-with half of those deaths caused by aneurysm rupture. Open surgical procedures are particularly risky for older patients who may suffer from additional medical conditions such as diabetes or hypertension.

For the past five decades the standard treatment for TAAs has been open surgery, which was pioneered at Methodist by surgeons Stanley Crawford and Michael E. DeBakey. The procedure lasts an average of five hours and requires lateral thoracotomy. Because of its proximity to the spinal cord, the surgery is considered risky-carrying a 10% mortality rate and complications including postoperative paraplegia (25%). renal failure (20%). bleeding stroke and prolonged ventilator dependence.

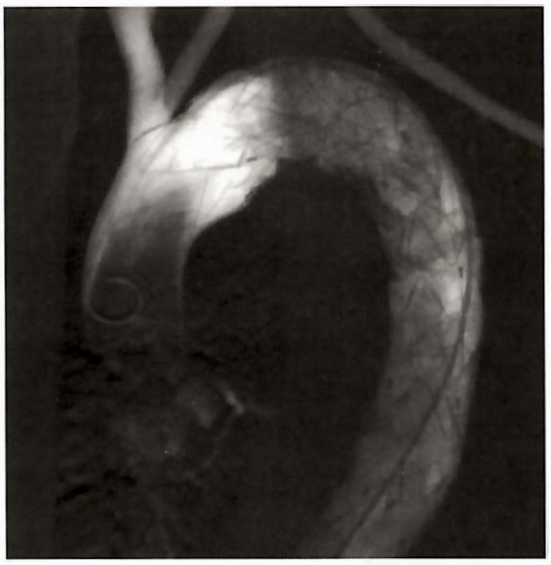
In the less-invasive endovascular method, the stent is inserted through a small incision In the patient's groin. Once a catheter delivery system is guided into position, the stent is secured inside the weakened section of the thoracic aorta, protecting it from the pressure of blood circulation and thereby reducing the risk of rupture. Since the procedure is less invasive than surgery, patients typically experience less trauma and shorter recovery times. In fact, patents treated with the stent during clinical trials had one-third the operative mortality, less than one-fourth the paraplegia rates and fewer strokes than the patients in the control group. The stent patients also had no aneurysm ruptures through two years, experienced 80% less procedural blood loss than in traditional open surgery, and had typical hospital stays of three days compared to 10 with surgery.

Anatomical Eligibility for DTAA Endovascular Repair

At the Society far Clinical Vascular Study's annual symposium held in March, Dr. Alan Lumsden and his research colleagues presented findings from a recent study that assessed the anatomical eligibility far endovascular repair in patients with descending thoracic aortic aneurysms (DTAAs) using guidelines of a current clinical investigation. The researchers reviewed imaging studies of all patients who underwent open repair of DTAAs from July 1998 to June 2004-excluding patients with ascending or thoracoabdominal aortic aneurysms-and analyzed anatomical features of each aneurysm and eligibility rates for endovascular repair. In their findings, 8 7% of patients with DTAAs met the anatomical eligibility criteria far endovascular repair, based on a current clinical trial guideline. With planned surgical bypass of the diseased artery segment, an even greater proportion of patients would become eligible far endmascular treatment.

As a Gore stent testing site, and the only Texas Medical Center location with an imaging suite specifically designed for advanced catheter-based procedures, the Methodist DeBakey Heart Center will soon offer training on endovascular TAA repair-and Lumsden plans to test the technology on a broader range of patients.

"The next frontier will determine if endovascular stents can be used to manage thoracic aortic dissection, an aortic emergency even more common than ruptures," Lumsden says. "Since Methodist has played an incredible role in the evolution of treatment for thoracic aortic disease, it's fitting that we continue to explore and develop new treatments that can benefit the most people."



M.D.H.C. AND THE HOUSTON TEXANS FUND VULNERABLE PLAQUE STUDY

How do heart specialists detect and manage "vulnerable" plaque? Physicians Juan Granada, Greg Kaluza and Albert Raizner of the Methodist Hospital Research Institute's Center for Research in Cardiovascular Intervention are hoping to find out. Through a generous grant from the Methodist DeBakey Heart Center and the Houston Texans, the physicians plan to further their studies on the development of an animal model of "vulnerable plaque," the culprit lesion responsible for most heart attacks.

"Not all plaque causes a heart attack, and there's currently no way to identify vulnerable plaque," Raizner says. An angiogram can detect irregularity in the artery lining, but about 98% of it is nothing more than routine plaque-something fairly common in men and women over age 50.

While vulnerable plaque has certain characteristics that differentiate it from other plaque, obvious characteristics such as the degree of narrowing don't necessarily provide clues.

"You may see slight irregularity in one artery compared to heavy narrowing in another, but the minor occlusion may be the potential troublemaker," Raizner says. "We stent the obvious ones, but it's the less obvious ones that may rupture, clot and cause a heart attack."

Preliminary experiments show that lesions can be created in porcine coronary arteries by injecting lipid material using a specially designed catheter. Coronary arteries in pigs look and behave the same way as human coronary arteries, which is why it is used as the standard model of coronary artery disease in most research. After a period of maturation, lesions having many of the features of human vulnerable plaque can be identified using intravascular ultrasound and histologic analyses.

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No one to date has been able to create vulnerable plaque, although a few-including the Methodist team, whose pilot experiments appeared in the peer-reviewed journal *Coronary Artery* Disease-have identified some of its components.

'The goal in this next round of research is to further develop and refine the vulnerable plaque model to one that closely simulates the human lesion," Raizner says. "Once you have that model, it opens the door to developing diagnostic tools for detection, applying the tools to human and developing methods of treating plaque where they lose the vulnerability."