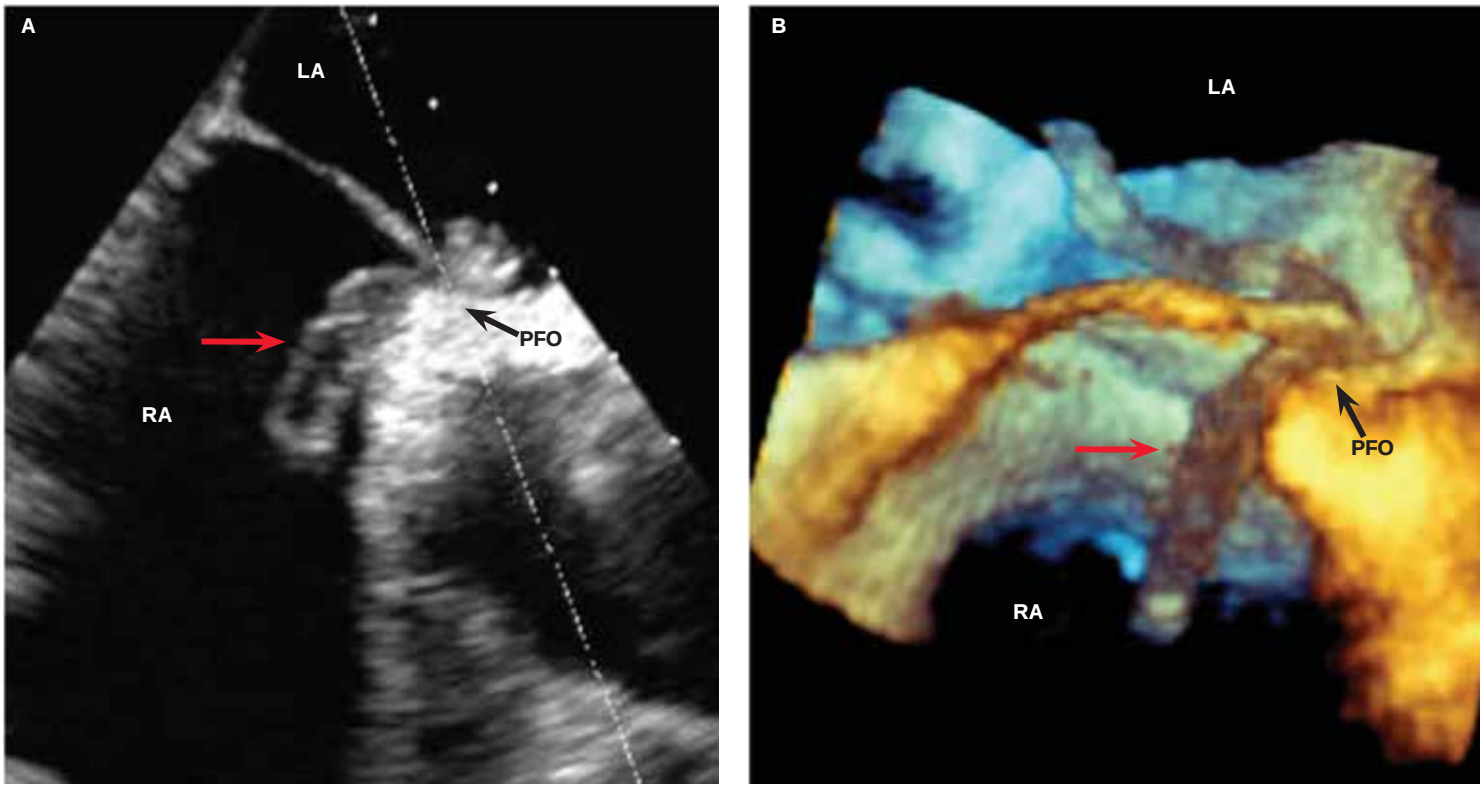

PFO with thrombus in transit. A 58-year-old male presented with pulmonary embolism and stroke. (A) A 2-dimensional (2D) TEE demonstrated a mobile mass (red arrow) traversing a patent foramen ovale (PFO). (B) Live 3D TEE revealed near equal distribution of the mass within the right atrium (RA) and left atrium (LA). The patient underwent surgical removal of a large thrombus in transit and closure of the PFO without further complication.

Images submitted by Karla Kurrelmeyer, M.D., and Stephen H. Little, M.D.

Methodist Selected as Study Site for Medtronic CoreValve® U.S. Pivotal Trial

The Methodist DeBakey Heart & Vascular Center has been selected to participate in a clinical trial investigating the use of transcatheter aortic valve implantation (TAVI) to treat patients with severe symptomatic aortic stenosis. The trial, called the Medtronic CoreValve® U.S. Pivotal Trial, will have two arms: an extreme-risk arm for patients who are not candidates for surgery under any circumstances, and a high-risk arm for patients who are surgical candidates but considered very high risk. All patients accepted as extreme risk will receive TAVI, and patients accepted as high risk will be randomized 1:1 between TAVI and open surgical aortic valve replacement. Patients eligible for this trial include those with severe aortic stenosis who are experiencing symptoms, including difficulty breathing, chest pain or pressure, or fainting.

Guidelines for treating aortic valve disease established by the American College of Cardiology and the American Heart Association list aortic valve replacement for symptomatic aortic stenosis as a Class I recommendation. Class I recommendations are for situations where it is very clear that the benefit far outweighs the risks and the treatment should be carried out. Despite having a Class I recommendation, surgery for severe symptomatic aortic stenosis is denied to a large number of patients for reasons of surgical risk based on age, frailty, other medical comorbidities, or anatomic factors such as a hostile mediastinum from prior surgeries, infection, or radiation.

Untreated symptomatic severe aortic stenosis has a high mortality, often from sudden death. While some of the symptoms of aortic stenosis can be managed through medications, the only way to treat the condition effectively and extend survival has been by repairing or replacing the valve. Traditionally, all valve replacements have been performed via open-heart surgery, in which the damaged valve is removed and replaced with an artificial valve. For the roughly one-third of aortic stenosis patients who cannot receive surgical aortic valve replacements because the severity of their condition puts them at excess risk for surgery, the TAVI procedure may offer an alternative. The TAVI procedure uses a balloon catheter to dilate the narrowed aortic valve and then place an artificial aortic valve, which is attached to a Nitinol wire frame, into the position where the diseased valve is located. Once in place, the Nitinol wire frame expands, allowing the new valve to enlarge the opening and keep it from restenosing. The difference, says principal investigator Michael Reardon, M.D., is that the catheter is generally inserted through the groin much like heart catheterization, which means there is no chest incision and no stopping of the heart as in traditional open-heart surgery.

"We are hoping to find that this procedure helps people live longer with a better quality of life than those treated medically, poses no greater mortality risk than standard surgery, and lasts long enough to benefit our patients," says Reardon, who leads the research team along with fellow principal investigator Neal Kleiman, M.D., co-investigator Stephen Little, M.D., and study coordinator Nicole C. Hakala, M.H.A. "The advantage is that TAVI is minimally invasive and therefore will heal faster."

Studies of other TAVI devices have shown such positive results that the FDA earlier this year allowed the U.S. Pivotal Trial of Medtronic's CoreValve device to drop the "best medical therapy" arm of the study, thus allowing all extreme-risk or previously "inoperable" patients in the trial to receive the device.

The Methodist DeBakey Heart & Vascular Center is one of 40 sites across the country selected to participate in the study. Long recognized as a center of excellence for valvular heart disease, the Methodist DeBakey Heart & Vascular Center treats complex valve disorders through its Valve Clinic, which provides centralized assessment, advanced diagnostic imaging, and treatment options from some of the country's most experienced surgeons.

To learn more about the Medtronic CoreValve® U.S. Pivotal Trial at the Methodist DeBakey Heart & Vascular Center, please contact Nicole Hakala, study coordinator, at 713-441-6539 or 281-615-9407, or send an email to nhakala@tmhs.org.

Adding Stem Cells to Common Bypass Surgery May Improve Heart Failure

In a new research study at the Methodist DeBakey Heart & Vascular Center, surgeons are adding a patient's own stem cells to the heart during coronary artery bypass grafting (CABG) surgery. The goal of this research is to determine whether the stem cell infusion will generate new blood vessels and improve heart function in patients with ischemic congestive heart failure more than what is typical in CABG surgery alone.

According to surgeon Brian Bruckner, M.D., the injection of stem cells may improve the effectiveness of the bypass.

"We perform a bypass to reroute blood flow around blockages in the coronary arteries," says Bruckner, the study's principal investigator. "The injection of stem cells might enhance the bypass surgery by causing the formation of new blood vessels at the site of injection."

Researchers involved in this study harvest stem cells from a patient's own bone marrow while the patient is under anesthesia. These cells are simultaneously processed during the procedure to separate stem cells from bone marrow. After performing the bypass, the surgeon completes the procedure by injecting the stem cells into the patient's heart.

The Methodist DeBakey Heart & Vascular Center is one of only three centers in the country to have this study available.

A potential benefit for study subjects is that the stem cells can be delivered during the bypass surgery rather than needing an additional procedure, says Kevin Lisman, M.D., a cardiologist at the Center and co-investigator in the study. "To be considered for this trial, patients must have an existing need for heart bypass surgery and must have an ejection fraction of 40% or less," Lisman explains. Up to 42 patients will be enrolled in this randomized study nationwide. The research team cannot guarantee individual benefits from participation in the study.

The technology that processes the stem cells was developed by Harvest Technologies and it sorts the cells quickly. This enables the procedure to be interoperative rather than having the patient come in days before surgery for the bone marrow aspiration.