**EMBARGOED UNTIL**

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**First Time in Humans: Novel Venous Route Enables CoreValve Procedure
in Patients with Severely Clogged Arteries**

*Technique Provides New Options in Minimally Invasive Aortic Valve Replacement*

**Las Vegas, Nev. (May 26, 2014) —** By taking advantage of the size and elasticity of the body’s major veins, a novel procedure is making it possible to use minimally invasive techniques to replace diseased aortic valves in patients whose arteries are too clogged with plaque to allow passage of large catheters, according to a study reported this week in a Best of the Best Oral Abstracts session at the SCAI 2014 Scientific Sessions.

Generally, arteries are used to provide access for left heart procedures, like angioplasty and transcatheter aortic valve replacement (TAVR), whereas veins are used as access for right heart procedures, such as ablations for arrhythmias and closure of septal defects.

The study describes the first experience in humans using this new technique to use veins to gain access to the aorta to perform TAVR using the CoreValve system system as a replacement for a calcified, poorly functioning aortic valve in patients with no other treatment options. The study was presented by Vikas Singh, M.D., a cardiology fellow at the University of Miami in Florida.

“We have initially performed these procedures in patients with no other access options, but we believe this approach will gain popularity in the future,” Dr. Singh said. “Since it does not involve surgery, it could be a good choice whenever the femoral artery cannot be used because of extensive peripheral vascular disease.”

In what is called the transcaval technique, the sheaths (flexible tubes and devices) used in performing transcatheter aortic valve replacement (TAVR) are threaded through a puncture in the femoral vein in the groin, instead of through the usual access point, the femoral artery.

“Veins are very distensible and compliant,” Dr. Singh said. “That means we are able to use the large delivery sheaths without much difficulty.”

Dr. Singh and his colleagues performed transcaval TAVR in three patients with severe obstruction of the aortic valve. The patients were 80 years old on average and had extensive plaque build-up throughout their arteries. Such patients are often offered alternative transaortic or transapical options to perform TAVR, but these patients were not candidates for any of these. In addition, the patients were considered too high-risk for open-chest surgery to replace the aortic valve.

To begin the procedure, a guidewire with a cautery device on its tip was threaded from the femoral vein in the groin into the inferior vena cava (IVC), a large vein that carries blood from the lower part of the body back to the heart. In the abdomen, where the IVC runs right next to the aorta, the cautery device was used to burn a hole through both blood vessels, creating a connection between the venous and arterial systems to allow passage of a guidewire. A snare slender enough to fit through the plaque-filled femoral artery into the aorta was used to capture the guidewire and pull it into the aorta. All of the other tools, including the CoreValve, were then threaded through the femoral vein to the IVC, and across the new passageway into the aorta. At that point, the CoreValve was advanced to the diseased aortic valve and deployed, as in any other TAVR procedure.

Once TAVR was complete, the interventional cardiologists sealed the connection created in the IVC and abdominal aorta using a device designed to seal a specific type of congenital heart defect. Using the Amplatzer VSD Muscular Device—which is composed of two nitinol wire discs with a neck in between—they positioned one disc in the aorta and the other disc in the IVC, then sandwiched them together, sealing the connection created between the two blood vessels.

The transcaval TAVR procedure was successful in all three patients, resulting in marked improvement in the size of the aortic valve opening, and no serious complications. Equally important, patients enjoyed substantial improvement in their day-to-day physical abilities, increasing their New York Heart Association Functional Class score from an average of 3.3 to 1.3.

“The difference the patients experienced from before the procedure to after it can be likened to that between being short of breath with minimal activity and nearly bedbound to being able to go grocery shopping and do other daily errands,” said Dr. Singh. “Nevertheless, interventional cardiologists should be mindful of this approach, especially for patients with no arterial access. So far these procedures have been performed by a group of highly skilled operators, but as the technique gets more refined, there will be more widespread use of this approach.”

Dr. Singh reports no potential conflicts of interest.

Dr. Singh will present the study “Corevalve Transcatheter Aortic Valve Implantation Using The Novel Transcaval Approach: First in Man Experience” in the Best of the Best Oral Abstracts session on Thursday, May 29, 2014, 1:00 p.m. to 3:00 p.m. (Pacific Time).

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