Expanding the Horizons of Transcatheter Aortic Valve Replacement (TAVR)

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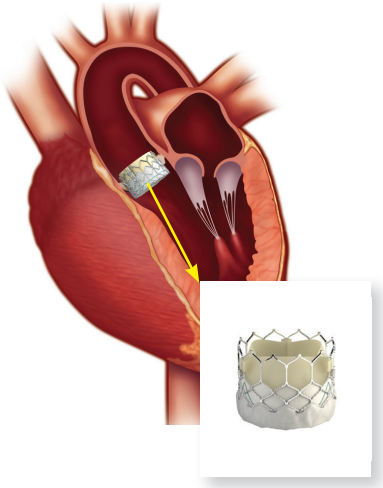
In multiple trials of transcatheter aortic valve replacement (TAVR) in various surgical risk (STS Score) patients have shown that it is an important therapeutic option for patients with severe, symptomatic calcific aortic stenosis (AS) who are extreme or high risk for cardiac surgery due to serious comorbidities.

The Mount Sinai Hospital continues to participate in clinical research to improve TAVR outcomes in patients with severe aortic stenosis. Recently, the PARTNER IIA Trial—comparing TAVR in more than 2,000 AS patients who are randomized to receive the SAPIEN XT or SAPIEN-3 device TAVR with current surgical aortic valve replacement (SAVR) technique in intermediate risk AS patients—showed that TAVR outcomes are similar to SAVR with reduced hospital stay, low morbidity, and even lower mortality in transfemoral cases.

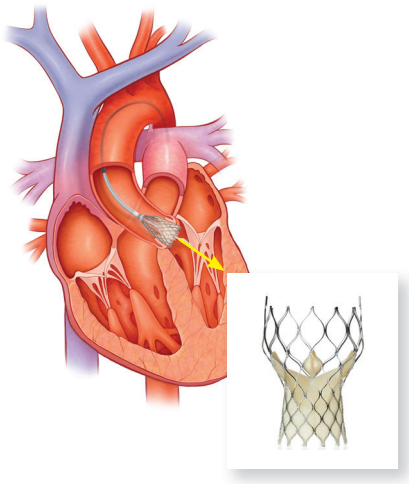
The Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) Trial is a multicenter clinical trial comparing percutaneous implantation of a self-expanding EVOLUT-R CoreValve® System with surgical valve replacement in patients with severe aortic stenosis and intermediate risk for surgery. The results will be presented in ACC 2017.

Edwards SAPIEN® Valve



Balloon Expandable, Bovine Valve

Medtronic CoreValve®



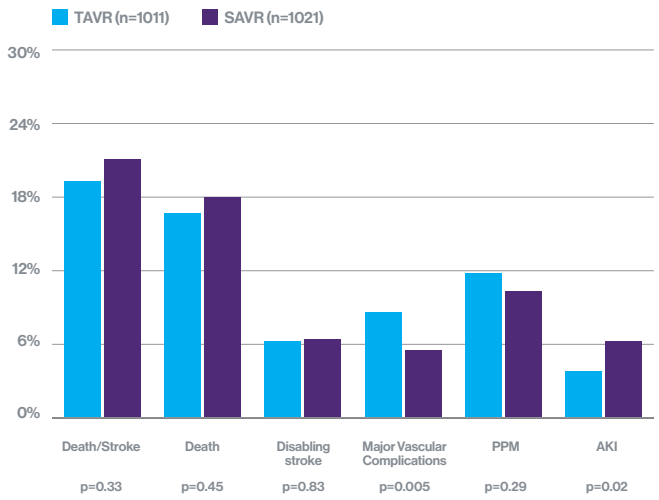
Self-Expanding, Porcine Valve

Key Points

- Mount Sinai Heart was an early pioneer in TAVR therapy for patients with severe aortic stenosis (AS).
- The Mount Sinai Hospital has participated in trials including the CoreValve, SURTAVI and Low-Risk Evolut-R trials, and continues to participate in clinical research to improve TAVR outcomes in patients with severe AS.
- We are always evaluating new imaging techniques to ensure ideal placement and enhance the success rates of TAVR devices in our patients.
- Although TAVR is associated with faster recovery and fewer complications, appropriate discharge planning is vital to ensuring that success.
- Patient education, medication adherence, follow-up, and coordination with the patient's cardiologist and PCP are vital to optimal outcomes.

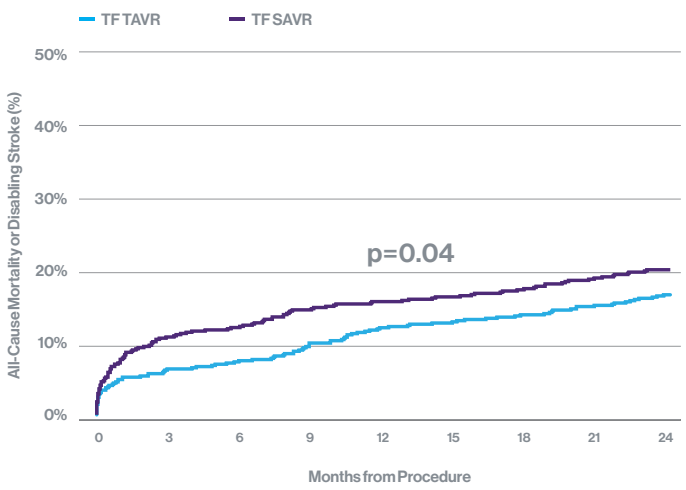
To view a prerecorded case featuring SAPIEN 3-TAVR, scan the QR code above.

PARTNER 2A Trial: 2-Year Clinical Outcomes in High Risk Aortic Stenosis



PARTNER 2A Trial: Primary Endpoint (AT)

All-Cause Mortality or Disabling Stroke



PATIENT: John O'Connor, 73-year-old male

DIAGNOSIS: Aortic stenosis and insufficiency

TREATMENT: Placement of CoreValve

"The very next day, I was already sitting up in bed with breakfast, my newspaper, and no pain or discomfort."

"In 2011, I went to a local hospital to have stents placed, but when they found that my condition was worse than expected, they rushed me in for a triple bypass. I spent a week in the hospital recovering from that invasive procedure. I remained under the care of my cardiologist, who said that I would need a new valve—while a healthy valve opens to the size of a quarter, mine was only opening to the size of a pencil eraser. He referred me to Dr. Sharma, and from the first interview with him and his team, I was at ease. My previous procedure put me at high risk for a surgical valve replacement, even though I would otherwise be at a low risk. Dr. Sharma and his team assured me that the TAVR procedure was the best option, and they were right. From then on, I didn't call him Dr. Sharma, I called him Superman. He made the procedure seem so simple, and the very next day, I was already sitting up in bed with breakfast, my newspaper, and no pain or discomfort. He made sure that I was on my way home by the end of the week. After I had my bypass, my breathing was still sluggish, and it would take me at least 35 minutes to walk one mile. Now it takes me less time, and I'm up to two miles a day. When I took a trip down to Florida, I even walked five miles, counting all the walking in the airport. It's a miracle, an absolute miracle."

PATIENT: Carol Levi, 67-year-old female

DIAGNOSIS: Aortic valve stenosis

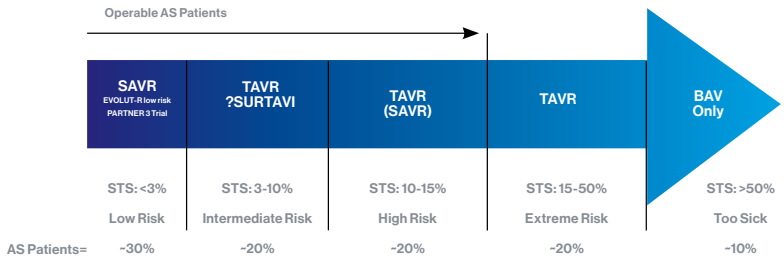
TREATMENT: TAVR using SAPIEN valve

"When Dr. Sharma told us that I was approved for this amazing new TAVR procedure and didn't need open heart surgery, I was so grateful."

"For the past five years, I experienced fatigue all the time. Even at work, I would get tired walking from one office to the next, or I would fall asleep at my desk. A week before my son's wedding, I had tests done with my cardiologist: They told me I would need open heart surgery, and I was shocked. I had no idea that my symptoms could have been related to my heart. I didn't want to say anything to my family because I didn't want to take away from the wedding, but my daughter, Randi, knew something was up. I finally told her, and then my son when he returned from his honeymoon. Randi really took charge! She researched doctors in the area and got a recommendation from a friend at Mount Sinai to go see Dr. Sharma because 'he's the best.' As soon as we met with Dr. Sharma, he knew what I needed right away. I've had diabetes for many years and I don't heal well, so Randi made a case for me not to get open heart surgery. When Dr. Sharma told us that I was approved for this amazing new TAVR procedure and didn't need open heart surgery, I was so grateful.

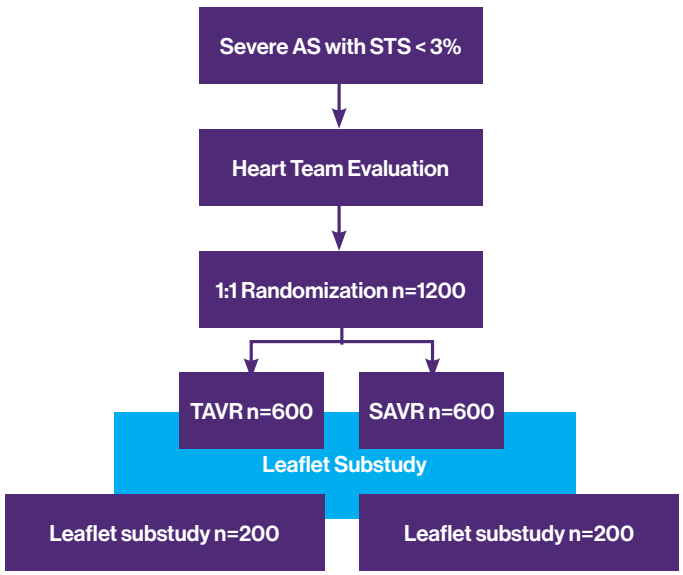
The people at Mount Sinai are incredible. Just two weeks later they did my TAVR procedure and when I was there, I always knew that I had lots of people right there taking care of me. I said that if I got through this, I was going to go on a cruise with my grandsons, Randi, and her husband. We just got back and had such a good time!"

TAVR Recommendations Based on Surgical Risk (STS): Increasingly More Patients are appropriate for TAVR Procedures as Shown Below



The Mount Sinai Hospital is enrolling patients in the EVOLUT-R Low Risk Trial which is evaluating TAVR vs. SAVR in low STS risk (<3 percent) AS patients.

EVOLUT-R Low Risk Trial

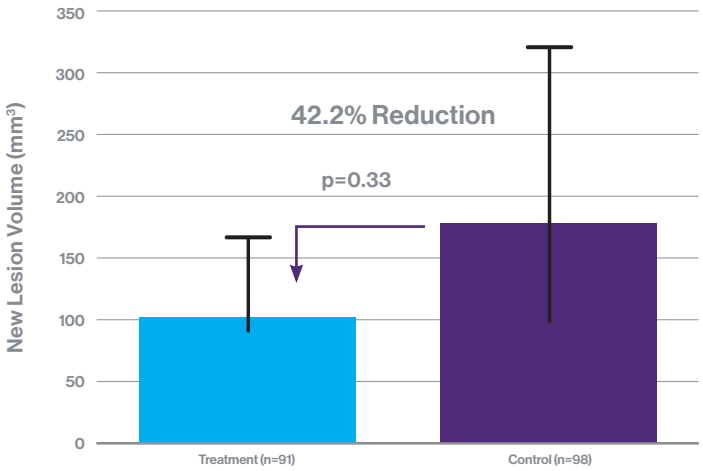


Endpoint: Death or Major Stroke at 2 Years

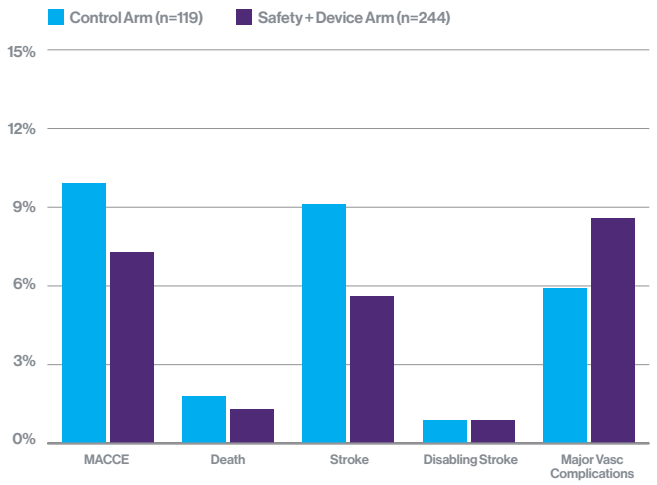
Another study (SENTINEL Trial) to assess the risk of stroke in patients who have TAVR with the Sentinel Cerebral Protection System (which is an embolic filter that is designed to trap calcified deposits that become dislodged during the TAVR procedure), showed that use of the Sentinel device is associated with lower risk of brain infarction (42 percent) with a trend toward lower stroke rates compared to a control group.

Cardiologists at The Mount Sinai Hospital routinely employ three-dimensional transesophageal echocardiography (3D TEE echo), and 4D computed tomography (CT) to better evaluate the TAVR procedure. Image quality and details are highly relevant to the

The SENTINEL Trial Primary Efficacy Endpoint



SENTINEL Trial: Primary Safety Endpoint



success of TAVR, which relies on the appropriate evaluation and measurement of the aortic annulus to prevent complications such as paravalvular leak, prosthesis migration, coronary artery occlusion, or annulus rupture.

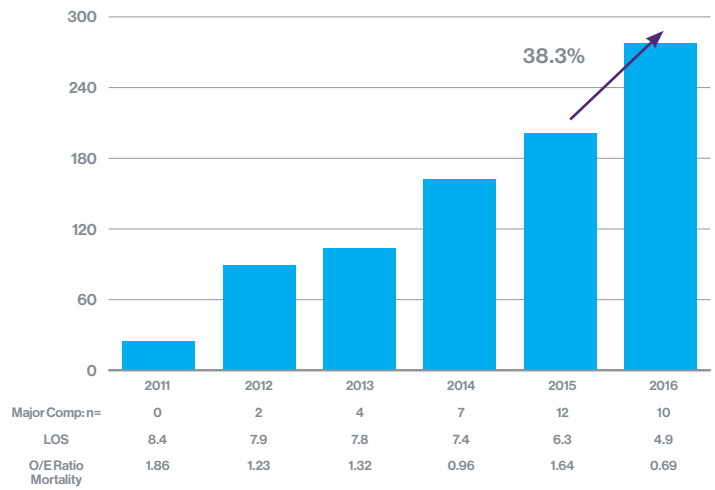
The Mount Sinai Hospital was one of the earliest centers to demonstrate the safety of TAVR with 3D transthoracic echo (3D TTE), in which patients are given conscious sedation (done in = 60 percent of cases) and avoiding general anesthesia. This approach is associated with fewer complications, faster recovery time and less procedural time than 3D TEE, which requires the patient to be intubated during general anesthesia.

The Mount Sinai Hospital was the first center in the United States to deploy the CoreValve® in December 2010. Since then, our TAVR volume and outcomes have improved significantly. Our TAVR data is regularly submitted to the national TVT registry.

References:

1. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients (PARTNER 2A trial), *N Engl J Med* 2016;374:1609.
2. Protection against cerebral embolism during transcatheter aortic valve replacement (SENTINEL trial), *J Am Coll Cardiol* 2017;69:367.

TAVR Volume and Outcomes Mount Sinai Experience



TAVR Outcomes at Mount Sinai Hospital 2016

-68% Evolut-R CoreValve, 32% SAPIEN-3
-60% Conscious Sedation; 40% General Anesthesia
-80% Perc Femoral; 10% Cutdown Iliac; 9% Subclavican; 1% Direct Aortic
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