Real-time magnetic resonance imaging–guided transcatheter aortic valve replacement

Justin G. Miller, MD, Ming Li, PhD, Dumitru Mazilu, PhD, Tim Hunt, BS, and Keith A. Horvath, MD

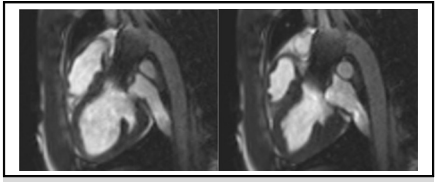
ABSTRACT

Objectives: To demonstrate the feasibility of Real-time magnetic resonance imaging (rtMRI) guided transcatheter aortic valve replacement (TAVR) with an active guidewire and an MRI compatible valve delivery catheter system in a swine model.

Methods: The CoreValve system was minimally modified to be MRI-compatible by replacing the stainless steel components with fluoroplastic resin and high-density polyethylene components. Eight swine weighing 60-90 kg underwent rtMRI-guided TAVR with an active guidewire through a left subclavian approach.

Results: Two imaging planes (long-axis view and short-axis view) were used simultaneously for real-time imaging during implantation. Successful deployment was performed without rapid ventricular pacing or cardiopulmonary bypass. Postdeployment images were acquired to evaluate the final valve position in addition to valvular and cardiac function.

Conclusions: Our results show that the CoreValve can be easily and effectively deployed through a left subclavian approach using rtMRI guidance, a minimally modified valve delivery catheter system, and an active guidewire. This method allows superior visualization before deployment, thereby allowing placement of the valve with pinpoint accuracy. rtMRI has the added benefit of the ability to perform immediate postprocedural functional assessment, while eliminating the morbidity associated with radiation exposure, rapid ventricular pacing, contrast media renal toxicity, and a more invasive procedure. Use of a commercially available device brings this rtMRI-guided approach closer to clinical reality. (J Thorac Cardiovasc Surg 2016;151:1269-77)



Postdeployment cine MRI to confirm valve position. Left, diastole; right, systole.

Central Message

We demonstrate the feasibility of rtMRI-guided TAVR, which has benefits over current imaging technologies.

Perspective

Real-time MRI-guided TAVR overcomes the limitations of the current imaging modalities. This method provides superior visualization and deployment with pinpoint accuracy while eliminating the morbidity of radiation exposure, rapid ventricular pacing, and contrast media renal toxicity.

See Editorial Commentary page 1278.

Aortic stenosis is the most common type of valvular heart disease in the United States.[1-4] While the disease process has a long latency period, patients rapidly decline after they become symptomatic unless they undergo valve replacement.[5-7] Unfortunately, some of these patients are not suitable surgical candidates or are at high risk.[8] Without valve replacement, the mortality for these patients after onset of symptoms approaches 50% after 2 years and 80% after 5 years.[9,10] The advent of transcatheter aortic valve replacement (TAVR) has become a viable treatment option for patients with aortic stenosis patients who are considered otherwise inoperable or at high risk.[8,11] Two devices are currently available for use in the United States: the CoreValve System (Medtronic, Minneapolis, Minn) and the SAPIEN Transcatheter Heart Valve (Edwards Lifesciences, Irvine, Calif).[12-14]

Although there have been multiple advances in valve design and valve delivery technology, imaging modalities have remained largely unchanged. TAVR is currently an intricate procedure that requires multimodality imaging including preprocedural imaging for planning, intraprocedural imaging for guidance, and postprocedural imaging for confirmation of placement.[15,16] Currently, the preprocedural evaluation usually includes echocardiography in combination with multidetector computed tomography (CT) or CT angiography. The TAVR procedure is most commonly performed using a combination of fluoroscopy and transesophageal echocardiography (TEE). Postprocedural

From the Cardiothoracic Surgery Research Program, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, Md.

This research was funded by the National Heart, Lung and Blood Institute, Division of Intramural Research.

Read at the 41st Annual Meeting of The Western Thoracic Surgical Association, Whistler, British Columbia, Canada, June 24-27, 2015.

Received for publication July 23, 2015; revisions received Oct 8, 2015; accepted for publication Nov 15, 2015; available ahead of print Dec 24, 2015.

Address for reprints: Keith A. Horvath, MD, 10 Center Dr, Bldg 10, Rm B1D47, Bethesda, MD 20892 (E-mail: horvathka@mail.nih.gov).

0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2015.11.024

Scanning this QR code will take you to the article title page.

Abbreviations and Acronyms

CT = Computed tomography
Gd-DTPA = Gadolinium with diethylenetriamine penta-acetic acid
RF = Radiofrequency
rtMRI = Real-time magnetic resonance imaging
TAVR = Transcatheter aortic valve replacement
TEE = Transesophageal echocardiography

imaging also routinely uses a combination of fluoroscopy and TEE to confirm valve placement and cardiac function.[15,17-19] Fluoroscopy has multiple limitations, including poor soft tissue contrast, a requirement for rapid ventricular pacing, radiation exposure to the patient and surgical team, and contrast-induced nephropathy.[14,20-22] Real-time magnetic resonance imaging (rtMRI) guidance overcomes these limitations with improved 3-dimensional visualization of the anatomic structures, guidewires, delivery catheter system, and bioprosthetic valve while allowing delivery of the valve with pinpoint accuracy. In addition, the use of rtMRI allows for immediate postprocedural functional assessment.[22-24]

Our group has successfully performed TAVR procedures through a transapical approach under rtMRI guidance. We have proven that this is a reproducible method with a high accuracy of device delivery.[14,22,25]

In the present study, we have demonstrated that the CoreValve system can be easily and effectively deployed with a left subclavian approach using rtMRI guidance, a minimally modified valve delivery catheter system, and an active guidewire. We report results indicating preclinical feasibility in an acute, nonsurvival swine model. To date, no device clinically available in the United States has been used for rtMRI TAVR.

METHODS

Medtronic CoreValve System

The Medtronic CoreValve is an aortic bioprosthetic transcatheter heart valve consisting of 3 porcine pericardial leaflets sutured to a self-expanding, multilevel, radiopaque nitinol frame (Figure 1).[21,26] The porcine pericardial leaflets are processed with alpha-amino oleic acid, an antimineralization treatment derived from a naturally occurring long-chain fatty acid.[26] The nitinol stent is manufactured by laser cutting a nitinol tube.[27] The stent is designed with 3 sections. The lower section has a high radial force, to anchor the valve and displace the calcified leaflets. The middle section holds the 3 porcine pericardial leaflets and is of smaller diameter than the lower and upper sections, to avoid occluding the coronary arteries, which largely eliminates the need to adjust the rotational position on deployment. The upper section has the largest diameter and exerts a lower radial force. The design of this section allows the stent to self-center during placement.[21,27] The commercially available version of the CoreValve is available in several different sizes (23, 26, 29, and 31 mm), which correlates with annulus diameters from 18 to 29 mm and ascending aorta diameters up to 43 mm. The device is MRI conditional, and nonclinical testing to date has confirmed that it is safe to use in MRI.[21,26]

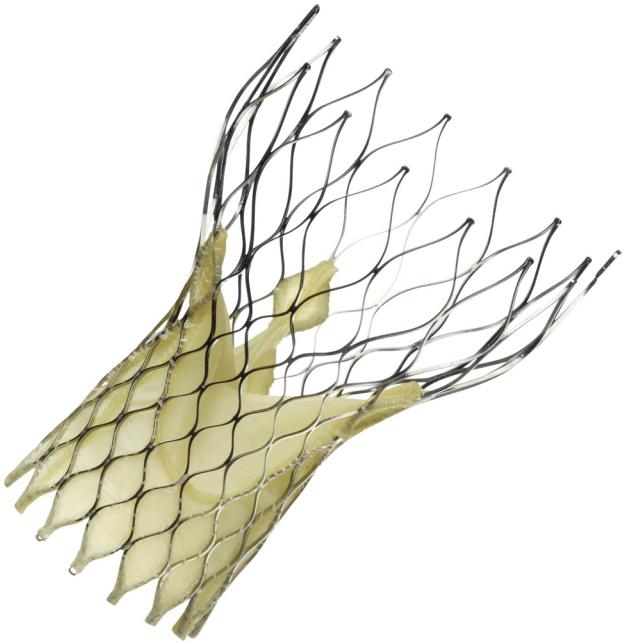


FIGURE 1. Medtronic CoreValve.

Medtronic CoreValve Delivery Catheter System

The CoreValve delivery catheter system is compatible with a 0.035″ guidewire. The distal end of the delivery catheter system has an atraumatic, radiopaque tip and a capsule that covers and maintains the valve in a crimped position. The handle is located on the proximal end of the delivery catheter system and is used to load and deploy the valve. The handle consists of a slider to open and close the capsule, with a knob to facilitate slow opening of the slider to allow precise placement. The device also has an outer tube, the AccuTrak stability layer. This outer tube covers the catheter sheath to protect the retractable delivery catheter system, introducer sheath, and vessel walls, and allows the catheter to retract freely and provides a more stable platform for deployment. The first generation model of this delivery catheter system was a 24 Fr sheath; however, the device is currently in its third generation and is 18 Fr. Now the outer diameter of the catheter is 15 Fr and the outer diameter of the valve capsule is 18 Fr. The delivery catheter system is approved for femoral, subclavian, axillary, and ascending aortic access sites, and is not MRI-compatible.[21,26]

Delivery Catheter System Modification

The Medtronic CoreValve delivery catheter system was modified to be MRI-compatible. The delivery catheter system sheath has an inner and outer flexible polymer tube embedded with braided stainless steel. The sheath also contains an inner shaft that has metallic components. To make the delivery catheter system MRI-compatible, the inner tube and capsule were replaced with tubes made of fluoroplastic resin. The outer tube was replaced with a tube from a 14 Fr Check-Flo Performer Introducer (Cook Medical, Bloomington, Ind). The metallic components in the delivery catheter system handle were replaced with corresponding parts composed of plastic materials. In addition, the handle was redesigned with a thumb slider to open and close the capsule instead of the original design composed of a slider and knob.

The delivery catheter system modifications were implemented to maintain device performance, including rigidity and flexibility, while achieving MRI compatibility. With the replacement of the non–MRI-compatible components with MRI-compatible components, the outer diameter of the catheter was increased from 15 Fr to 18 Fr and the outer