Transapical sutureless aortic valve implantation under magnetic resonance imaging guidance: Acute and short-term results

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Objectives: Despite the increasing success and applicability of transcatheter aortic valve replacement, 2 critical issues remain: the durability of the valves, and the ideal imaging to aid implantation. This study was designed to investigate the transapical implantation of a device of known durability using real-time magnetic resonance imaging (MRI) guidance.

Methods: A sutureless aortic valve was used that employs a self-expanding nitinol stent and is amenable to transapical delivery. MRI (1.5-T) was used to identify the anatomic landmarks in 60-kg Yucatan swine. Prostheses were loaded into an MRI-compatible delivery device with an active guidewire to enhance visualization. A series of acute feasibility experiments were conducted (n = 10). Additional animals (n = 6) were allowed to survive and had follow-up MRI scans and echocardiography at 90 days postoperatively. Postmortem gross examination was performed.

Results: The valve was MRI compatible and created no significant MRI artifacts. The 3 commissural struts were visible on short-axis view; therefore, coronary ostia obstruction was easily avoided. The average implantation time was 65 seconds. Final results demonstrated stability of the implants with preservation of myocardial perfusion and function over 90 days: the ejection fraction was 48% ± 15%; the peak gradient was 17.3 ± 11.3 mm Hg; the mean gradient was 9.8 ± 7.2 mm Hg. Mild aortic regurgitation was seen in 4 cases, trace in 1 case, and a severe central jet in 1 case. Prosthesis positioning was evaluated during gross examination.

Conclusions: We demonstrated that a sutureless aortic valve can be safely and expeditiously implanted through a transapical approach under real-time MRI guidance. Postimplantation results showed a well-functioning prosthesis, with minimal regurgitation, and stability over time. (J Thorac Cardiovasc Surg 2015;149:1067-72)

See related commentary on pages 1072-3.

Surgical aortic valve replacement is the standard treatment for patients with aortic stenosis. Recently, transcatheter aortic valve replacement (TAVR) has been considered as an alternative treatment to reduce mortality in patients who are at high risk or are considered inoperable.[1-3] This intervention utilizes bioprosthetic valves, which are delivered and implanted within the diseased aortic valve through catheters, using either a transarterial or transapical approach.[4,5]

Fluoroscopy and transesophageal echocardiography as imaging modalities for TAVR have limitations, including poor anatomic visualization and lack of soft-tissue contrast; landmark loss; a requirement for rapid ventricular pacing; intravenous contrast toxicity; and substantial radiation exposure to both the patient and the operative team.[6,7] Magnetic resonance imaging (MRI) offers an alternative means of imaging and overcomes many of the limitations of fluoroscopy. Specifically, MRI provides excellent anatomic visualization, particularly in its ability to provide high-resolution images of blood-filled structures. Vascular, as well as soft-tissue, visualization can easily be performed simultaneously with MRI. The development of real-time MRI (rtMRI) allows this imaging modality to provide intraoperative guidance for delivery of prosthetic aortic valves. Moreover, MRI-guided surgery allows direct functional assessments to be made before, during, and immediately after an intervention that are not obtainable by conventional imaging alone.

Our group has successfully performed transapical aortic valve replacements using rtMRI guidance.[8,9] We have reported the implantation of both balloon-expandable and self-expanding prostheses with midterm follow-up.[10,11] Our experience showed that rtMRI-guided TAVR is a novel and reproducible method that achieves accurate positioning of the bioprosthesis.

The Perceval S valve (Sorin Group, Saluggia, Italy) is CE (Conformité Européene) mark approved and is indicated for

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Abbreviations and Acronyms
MRI = magnetic resonance imaging
rtMRI = real-time MRI
TAVR = transcatheter aortic valve replacement

both standard and minimally invasive surgical replacement of the aortic valve in patients suffering from aortic stenosis and aortic insufficiency. The valve's functional component is made of bovine pericardium and is mounted on a super-elastic nitinol alloy frame. The self-anchoring configuration eliminates the need to suture the prosthesis into place, thereby reducing procedure time for aortic valve replacement. The preliminary results of a European multicenter pilot trial confirmed the safety and efficacy of the valve in a high-risk cohort of patients.[12] Use of this valve for sutureless aortic valve replacement showed outcomes in propensity-scored analysis that are similar to those in sutured surgical aortic valve replacement.[13] The nitinol alloy frame displays no significant artifacts in MRI, and its self-expanding mechanism allows the valve to be delivered through a transcatheter approach.

In this study, we sought to prove the safety and efficiency of rtMRI guidance for TAVR, and test the hypothesis that a sutureless aortic valve can be properly implanted under rtMRI guidance. We report the preclinical feasibility of valve implantation via an off-label transapical approach under rtMRI guidance, including acute feasibility and 90-day results.

MATERIALS AND METHODS

Delivery Device

A device designed for delivery of self-expanding bioprosthetic aortic valves[14] was created for deploying the Perceval S valve via the transapical approach. As described elsewhere,[14] the delivery device is made of plastic materials and is fully compatible with MR. The computer-aided design drawing of the delivery device is shown in Figure 1. Pushing the inner rod will advance the crimped prosthesis out of the sheath for deployment. To allow for hemostatic passage of a central guidewire, a modified Check-Flo Introducer Set (French size 14) (Cook, Bloomington, Ind) is used (5). To improve visibility of the device during the rtMRI-guided procedure, a loop coil antenna (6) was embedded into the exterior tube of the delivery system. An additional wire insulator (7) is used to protect the antenna wire. The antenna (6) is then connected to the matching/decoupling circuit box by a radio frequency connector (8).

The entire delivery system can be inserted through a 5-12 mm VersaStep Plus trocar (Tyco Healthcare Group LP, North Haven, Conn). The valve was crimped and placed inside the outer sheath at the distal end of the delivery system (Figure 2). Upon release of the valve by retraction of the outer sheath, the prosthesis expands to its original dimensions.

Procedure

All experiments were performed by a single operator under protocols approved by the National Institutes of Health Animal Care and Use Committee. A total of 16 Yucatan swine (weight, 60-65 kg) were used—10 for the acute feasibility study, and 6 for the survival protocol. With the use of general endotracheal anesthesia, the animals underwent a preprocedure MRI scan. A 1.5-T MRI system (MAGNETOM Aera; Siemens Medical Solutions, Munich, Germany) was used to identify the anatomic landmarks of the aortic annulus, the coronary artery ostia, and the mitral valve leaflets. Based on the aortic annulus, the sino-tubular junction diameter, and the aortic root height, an appropriately sized valve was selected. The valve was crimped and loaded into the delivery device. One of the valve commissures was aligned with the active guide wire (MR loop coil antenna) that was embedded in the delivery device.

Interactive Front End navigation software (Siemens Corporate Research, Munich, Germany), along with an interactive real-time pulse sequence (BEAT_IRTTT), was used as real-time navigation for valve deployment. Via a small subxyphoid incision, the pericardium was opened, and the apex of the heart was exposed. Two concentric purse-string sutures were placed around the apex, through which the12-mm trocar was inserted into the left ventricle to create direct access to the aortic valve. The animals then underwent rtMRI-guided transapical aortic valve replacement without unloading by rapid ventricular pacing or cardiopulmonary bypass.

During the procedure, the animals were heparinized and monitored with electrocardiography, oxygen saturation, end-tidal CO_2, systemic and left ventricular blood pressure, and arterial blood gas analysis. We recorded the time of the procedures and observed any interference of the devices with the surrounding environment during the procedures.

After placement of the valve, the trocar was removed and the apex closed via the purse-string sutures. Postplacement images were acquired to confirm the correct positioning of the prostheses, as well as the valvular and heart function. Gated cine MRI was used to assess mitral valve function and myocardial function. Phase-contrast cine MRI was used to identify flow through the new valve, as well as intravalvular or paravalvular regurgitation. An MR first-pass perfusion scan was performed during intravenous injection of gadolinium–diethylene triamine pentacetic acid (Gd-DTPA) contrast agent to confirm that myocardial blood flow was intact to all segments of the myocardium.

A series of short-term feasibility experiments were conducted (n = 10), in which the animals were sacrificed after valve placement and MRI assessment. Six additional animals were allowed to survive for short-term follow-up. At 1 month postoperatively, follow-up MRI scans and transthoracic echocardiograms were acquired; at 3 months postoperatively, MRI scans and confirmatory 2- and 3-dimensional transesophageal echocardiograms were acquired. Gated cine MRI, phase-contrast cine MRI, and MR first-pass perfusion scanning during intravenous injection of the contrast agent were repeated at those time points to confirm the position of the prostheses, and valvular and heart function.

RESULTS

The valve is MRI safe and compatible. It appears as a dark cylindrical cage in the MRI images, without significant artifacts (Figure 3). The 3, thick, commissural struts are visible as dark dots in the short-axis view. The dark cylindrical cage image was used to determine correct positioning and whether the valve had migrated over time; the dark commissural dots were used to determine whether the prosthesis was fully deployed and properly oriented.

The valve can be crimped and easily loaded into the delivery device (Figure 2). The average time that elapsed from crimping to loading of the valve onto the delivery device to deployment was approximately 6 minutes. In the acute feasibility study, 5 animals had an improperly deployed valve, as confirmed by gross examination. We noticed that in these animals, the anatomy of the ascending aorta was not ideal, most likely causing the stent to remain