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Real-time Magnetic Resonance Guided Aortic Valve Replacement Using Engager™ Valve

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Abstract

Purpose—New generation stented-bioprostheses coupled with better imaging modalities are expanding the clinical utility of transcatheter aortic valve replacement (TAVR). This study aimed at evaluating the feasibility of real-time cardiovascular magnetic resonance (rtCMR) guided TAVR utilizing the Medtronic Engager™ aortic valve system in a preclinical model.

Description—The Engager™ delivery device was slightly modified in order to make it CMR-compatible. Ten Yucatan swine underwent rtCMR-guided transapical TAVR. Post-placement phase contrast and first-pass perfusion CMR sequences were used to evaluate for aortic regurgitation and myocardial perfusion, respectively.

Evaluation—Real-time CMR provided excellent visualization of cardiac anatomy during TAVR. Nine out of ten animals had proper valve placement in the aortic annulus as determined by CMR and confirmed by necropsy inspection. Post-placement phase contrast scans confirmed no intra- or para-valvular leaks. Perfusion scans demonstrated sufficient coronary flow. X-ray confirmed proper placement of the prostheses.

Conclusions—The Engager™ valve can be implanted transapically under rtCMR guidance with a modified, CMR-compatible delivery device in a preclinical model. CMR allowed for accurate pre-placement evaluation, real-time guidance, and post-placement functional assessment.

Keywords

Animal Model; Aortic valve; replacement; Bioengineering (incl modeling); Heart valve replacement; transapical; percutaneous; Magnetic resonance imaging; MRI

Background

Using a catheter based approach, a minimally invasive option for aortic valve replacement was established in 2002.[1] Following *Conformité Européenne* (CE) approval in 2007 and the Food and Drug Administration (FDA) approval in 2011, transcatheter aortic valve replacement (TAVR) has been widely used in patients with severe aortic stenosis deemed inoperable or at high risk.

Currently, high-resolution fluoroscopy and adjuvant transesophageal echocardiography are used as imaging modalities for TAVR. Fluoroscopy has several shortcomings, including: misalignment of the implanted valve as a result of poor anatomic visualization and lack of soft-tissue contrast, landmark loss which can lead to improper valve placement and subsequent device embolization, requirement for rapid ventricular pacing, intravenous contrast toxicity, and substantial radiation exposure both to the patient and operative team. Our lab, along with others, have demonstrated the feasibility of using real-time cardiovascular magnetic resonance (rtCMR) as a sole imaging modality for TAVR in a porcine model.[2–4] This approach bypasses many of the limitations with the use of fluoroscopy and provides more detailed real-time imaging data for proper guidance of the implantable valve.[4] Furthermore, CMR may be used for pre-procedural planning, intraoperative guidance, and post-interventional assessment all in a single hybrid operating room suite.[5]

The Engager™ aortic valve system (Medtronic 3F Therapeutics, Inc., Santa Ana, CA, USA) was designed for over-the-wire transapical TAVR and gained *CE* mark approval in 2013. Clinical trials testing the efficacy of the Engager™ system demonstrated good outcomes with low incidence of paravalvular leakage, an independent predictor of all-cause and cardiovascular mortality,[6, 7] and proper device positioning in over 90% of procedures.[8, 9] Given the success with the Engager™ system in a clinical setting, we chose to utilize this bioprosthesis and delivery device to explore potential use with CMR as the sole imaging modality. We present our feasibility results concerning delivery device modification and implantation of the Engager™ valve in a preclinical, porcine model.

Material and Methods

Medtronic Engager™ Valve Bioprosthesis

The Engager™ aortic valve bioprosthesis consists of a self-expanding nitinol frame and bovine pericardial tissue (Figure 1). The frames are composed of a main and support frame. A polyester skirt sleeve is sewn to the main frame. The support frame has unique control arms, which are designed to be positioned in the aortic root in a predefined location, diminishing risk of coronary ostia obstruction. Furthermore, the control arms capture the native valve leaflets, minimizing any post-placement paravalvular leaks. Tissue-fixated bovine pericardium is used for the three leaflets that are mounted onto the frame. All experiments in this study utilized a 23mm sized bioprosthesis.

Medtronic Engager™ Delivery Device

The Engager™ delivery device is designed as an over-the-wire delivery system (compatible with 0.89mm wires). This delivery device is composed of an introducer (29 Fr inner diameter and 32 Fr outer diameter) and a flexible delivery catheter (13 Fr shaft). The introducer is designed to stay within the apex, allowing the shaft and crimped valve prosthesis to be advanced into position within the aortic annulus.

High Resolution CMR in vivo testing

Both the Engager™ bioprosthesis and delivery device were placed in a water basin and tested to determine imaging artifacts in the MR-scanner. A high resolution T1-weighted scan was used. The delivery device revealed significant ferromagnetic artifact on CMR imaging as a result of the metal braiding found in the catheter shaft. The Engager™ bioprosthesis is composed of nitinol, whereas the valve is composed of bioprosthetic bovine leaflets. The in vivo CMR testing showed artifact-free visualization of the nitinol, stented-prosthesis with good visualization of the control arms (Figure 2).

Device Modification

To make the delivery device CMR compatible, we replaced the original stainless steel stent retainer with one made of polyether ether ketone, a thermoplastic material (Figure 3A). Additionally, the blue outer shaft, which was composed of a fluoropolymer lined, stainless steel braided catheter, was replaced with a shaft made of polytetrafluoroethylene. A passive marker was added to the delivery catheter, which allowed for tracking of the delivery device during rtCMR. The assembled, modified delivery device is shown in Figure 3B and was tested in the MR magnet, showing no visible ferromagnetic-related artifacts (Figure 3C and D).

Animal Surgery Protocol

All animal experiments were approved under protocols by the National Institutes of Health Animal Care and Use Committee. Detailed animal surgery protocols have been previously described. [2, 3]

MRI scanner

All procedures and imaging were done in a hybrid operating room suite using the 1.5-T Magnetom Aera (Siemens Medical Solutions, Munich, Germany). The magnet design, which utilizes a short (145cm) and wide (70cm) bore, permits surgical access to the animal within the magnet. High-quality images can be obtained at 5–10 frames per second with low latency. A fully interactive rtCMR system (Interactive Front End navigation software, Siemens Corporate Research, Baltimore, MD) is connected to the scanner and permits use of the real-time interactive imaging sequencing for visualization during interventions.

Results

A total of 10 Yucatan swine underwent rtCMR-guided TAVR with the Engager™ bioprosthetic valve. Pre-intervention CMR demonstrated proper delivery device positioning (Figure 4). Anatomic landmarks, such as the locations of the coronary ostia, mitral valve leaflets and aortic annulus, were marked.

All animals received an Engager™ bioprosthetic valve. The delivery device tip and aortic annulus were clearly visualized in 3 different planes during rtCMR-guided TAVR. These 3 planes provided a virtual real time 3D reconstruction of the coronary ostia, aortic annulus and cardiac chambers. A stepwise progression of the TAVR procedure in 2 planes, parasagittal and axial, are shown in Figure 5. As a result of the good visualizations of

anatomic landmarks, rtCMR allowed for easy guidance of the stent-valve into the landing zone within the aortic annulus, without any hemodynamic compromise to the heart.

Post-placement CINE CMR showed proper prosthetic valve position, ventricular contractility, and structural and functional integrity of the mitral valve in 9 animals. One animal had high placement of the prosthetic valve and was sacrificed immediately following TAVR procedure. Phase contrast scans confirmed no intra- or para-valvular leaks (Figure 6). Perfusion scans demonstrated adequate coronary flow at tissue level (Figure 7).

High contrast radiographs of animal necropsy specimens demonstrated proper valve positioning in the aortic annulus (Figure 8). On autopsy inspection, the Engager™ bioprosthesis was properly seated in the aortic annulus and appeared to be well incorporated into the aortic wall.

Comment

This study demonstrated the feasibility of rtCMR-guided TAVR in a preclinical model using the Engager™ aortic valve system with a modified delivery device. The nitinol stent was MR-compatible, while the delivery device required modification to remove ferrous parts (Figure 3). The modified delivery device maintained its integrity and functionality.

CMR allowed for proper pre-placement planning, real-time guidance, and post-placement evaluation in a single imaging modality. For pre-placement imaging, a recent study showed that CMR measurements were in concordance with computed tomography (CT) imaging. [10] The high resolution pre-placement CMR images in our study provided detailed anatomic information along with myocardial soft tissue visualization (Figure 4). These images allowed for the accurate marking of the coronary ostia and aortic annulus, aiding in rtCMR-guidance.

As was the case in our prior experiments,[2, 3] rtCMR proved to be successful as a sole imaging modality with excellent visualization of the delivery device and stented bioprosthesis during the TAVR procedure (Figure 5). Nine out of ten pigs had successful placement of the 23mm Engager™ bioprosthesis within the aortic annulus. Quick detection of any procedural complications was possible with rtCMR. One of the pigs had high placement of the stented-bioprosthesis. This was immediately detected by CMR and the pig was euthanized following TAVR. In human procedures, rapid detection of complications is pivotal, as it allows for the option of retrieving and repositioning the bioprosthesis using a stent retrieving device or deploying another prosthesis into the correct position.

Immediate post-placement CMR evaluation allows for quick functional and positional determination. Our post-placement phase contrast CMR sequences demonstrated no para- or intra- valvular regurgitation (Figure 6). Using first-pass perfusion scans, we demonstrated that the myocardium was well perfused without evidence of coronary ostia obstruction (Figure 7).

Necropsy specimens confirmed the findings on CMR of proper valve positioning without blockage of the coronary ostia (Figure 8). High contrast x-rays showed an intact stented

prosthesis within the aortic annulus without evidence of stent strut fractures. These findings confirmed the reliability of post-placement CMR imaging.

Conclusions

This in vivo feasibility study showed that transapical rtCMR-guided TAVR can be accomplished using the *CE* mark approved Engager™ aortic valve system with a modified delivery device. CMR was successfully used for pre-placement imaging, real-time guidance, and post-placement scanning. Pre-placement imaging allowed for accurate determination of anatomic landmarks. The TAVR procedure using rtCMR guidance provided detailed soft tissue visualization. Immediate post-implantation imaging results showed a well-functioning bioprostheses with no regurgitation and complete myocardial perfusion. Future studies using new generation aortic bioprostheses for rtCMR-guided TAVR should be conducted to identify the ideal valve for translation into patients.

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Figure 1.

Picture of the Medtronic Engager™ Valve showing the self-expanding nitinol frame, control arm, commissural posts and bioprosthetic leaflets composed of bovine pericardial tissue.

Figure 2. MR-imaging of Medtronic Engager™ stented-bioprostheses. Left, photograph shows a single coronal slice of the stented-prosthesis with good visualization of markers. Middle, photograph shows a different orientation coronal slice of the stented-prosthesis with visualization of the control arm. Right, photograph shows axial slice of the stented-prosthesis.

Figure 3. Medtronic Engager™ delivery device modification. (A) shows picture of modified delivery device with specific modifications. (B) shows assembled delivery device, as it was used for rtCMR experiments. (C) and (D) show MR-images of modified delivery device without any indication of ferromagnetic artifact.

Figure 4.

Pre-intervention representative CMR snapshots. These snapshots are taken in 3 different planes and show the location of coronary arteries, aortic annulus and implanted delivery device within the apex. Left, long-axis view showing right coronary artery and delivery device. Middle, long-axis view showing left coronary artery and delivery device. Right, short-axis view with delivery device visible.

Figure 5. Transapical TAVR using rtCMR guidance. (A) and (B) show a stepwise deployment of the Medtronic Engager™ valve in a parasagittal and axial orientation, respectively. Tip of the delivery device is clearly visible (double arrow) along with the implanted valve within the aortic annulus (asterisk).

Figure 6. Snapshots of parasagittal and axial CMR following rtCMR TAVR procedure. (A) and (D), shows proper valve placement in the aortic annulus in parasagittal and axial views, respectively. (B) and (C) are parasagittal and (E) and (F) are axial views showing phase contrast flow demonstrating proper flow through the prosthetic valve without any evidence of intravalvular or paravalvular regurgitation.

Figure 7.

A representative first-pass perfusion scan. This perfusion scan is seen in three heart slices (from apical to basal position of the heart) following the rtCMR-guided TAVR procedure. Each image row represents a different time after venous injection of Gd-DTPA. The heart appears well perfused, indicating proper valve placement with respect to the coronary ostia.

Figure 8. X-ray and Macroscopic Pathology of Medtronic Engager™ *in situ*. Left, X-ray confirmation of the valve position after valve implantation. Right, autopsy confirmation of proper valve position within aortic annulus.