

Percutaneous MRI Guided Mitral Annuloplasty: Preliminary Results

P. Karmarkar¹, A. N. Raval², R. de Silva², C. Ozturk², R. J. Aviles², M. Guttman², E. R. McVeigh², E. Atalar^{1,3}, R. J. Lederman²

¹Radiology and Radiological Science, Johns Hopkins University, Baltimore, MD, United States, ²NHLBI, NIH, Bethesda, MD, United States, ³Electrical Engineering, Bilkent University, Ankara, Turkey

Introduction: Mitral valve regurgitation (MVR) is the backward blood flow from the left ventricle (LV) into the left atrium (LA) during systole. In dilated and ischemic cardiomyopathy this is related to annular dilation leading to the failure of mitral valve leaflets to coapt. MVR causes deleterious LV remodeling resulting in progressively reduced LV ejection fraction, increasing MVR, and congestive heart failure. Annular dilatation is surgically correctable by mitral annuloplasty, in which an annuloplasty ring is implanted along the atrial surface of the mitral annulus, reducing the annular diameter and enhancing mitral leaflets coaptation. Because surgically annuloplasty requires thoracotomy and cardiac arrest, patients are usually not treated until MVR has reached an advanced stage. However, by this time irreversible myocardial damage may have occurred.

There is growing interest in developing reliable percutaneous mitral valve repair techniques [1-3]. Kaye et al. [1] have reported a percutaneous mitral annular reduction procedure in which the dimensions of the mitral annulus is reduced by implanting a restrictive device in the coronary sinus, a vein running along the mitral annulus on the epicardial surface. This procedure is carried out under x-ray fluoroscopy and cardiac ultrasound imaging guidance. The annular restrictive device is advanced in the coronary sinus and the device is crimped to reduce the annular diameter until the mitral regurge, as monitored by ultrasound imaging was eliminated [2].

The important anatomical parameters that need to be monitored are: MVR severity, annular dimensions, LV geometry, and acute ischemic LV dysfunction related to unanticipated arterial impingement during implantation. Since MRI can successfully monitor these parameters, the safety and clinical efficacy of the procedure may be significantly improved if done with MR guidance. For example: the coronary sinus is a thin walled wide vein extending over the left atrium, also, the coronary sinus is sometimes located more toward the atrium surface than along the annulus, if the annular restricting device is implanted under x-ray fluoroscopy and ultrasound guidance, it would be difficult to monitor the "cor triatriatum physiology" induced. Thus, MRI is potentially a better guidance modality for percutaneous mitral repair compared with x-ray and ultrasound. The objective of this work is to demonstrate the feasibility of carrying out percutaneous mitral annuloplasty procedure under MR guidance.

Methods: A C-Clamp annular restrictive device with variable radius of curvature was constructed of nitinol and is shown in Figure 1. The C-clamp device comprises of two nitinol flat wires joined at the distal end and covered with PTFE tubing. The inner wire can be moved with respect to the outer wire, thus adjusting the radius of curvature. A locking mechanism held the inner wire in place and maintained the radius of curvature. The delivery catheter for the C-Clamp device is shown in Figure 2 (A). The radius of the C-clamp can be adjusted by actuating the toggle at the catheter handle, applying tension on the pull wire, which in turn is transferred to the inner wire of the C-clamp thus adjusting the C-clamp diameter. Once the C-clamp diameter is adjusted, a detachable mechanism separates the pull wire/catheter, thus leaving the C-clamp in the desired anatomy. The components of the catheter and the C-clamp are arranged to form a loopless antenna [4]. A matching tuning interface circuit as shown in Figure 2 (A) matches the output of the antenna to 50 ohms at 63.6 MHz.

The C-clamp device was tested in a porcine model on a Siemens Sonata/Artis 1.5 T XMR system. The C-clamp catheter was advanced into the right atrium from the jugular vein, and the C-clamp was placed in the coronary sinus under x-ray fluoroscopy guidance. The animal is then transferred to MR scanner and images acquired using a combination of external phased array and internal catheter coils. SSFP real time sequence (TR=3.4 ms, TE=1.2 ms, 45° flip angle, 125 KHz bandwidth, 7 mm slice thickness, 34 cm FOV 192 x 192 image matrix, NEX=0.75) was used to image the location of the C-clamp device in the coronary sinus. Images acquired in the short axis view of the location of the C-clamp and the 2 chamber long axis view showed the coronary sinus.

Results: The nitinol C-clamp has a 2 mm diameter profile and can be crimped to a minimum radius of curvature of 2.5 cm. The delivery catheter is 3 mm in diameter and functions as a loopless RF receiver antenna, which enables visualization of the catheter and the C-clamp with MRI. The entire length of the catheter (Figure 2 B, C) and the distal end of the C-clamp were visualized in the phantom and the animal images (Figure 3A). The location of the C-clamp in the coronary sinus around the mitral annulus can be seen in the short axis and long axis images (Figures 3 A and B).

Conclusions: We have developed a MR active mitral annulus reducing device and a catheter delivery system. The feasibility of performing MR guided percutaneous mitral annuloplasty is demonstrated in a porcine model.

References:

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- 3 – St. Goar F. G. et al. *Circulation*. 2003; 108:r104-r107.
- 4 - Ocali et al. *Magn Reson Med* 1997 Jan;37(1):112- 8.

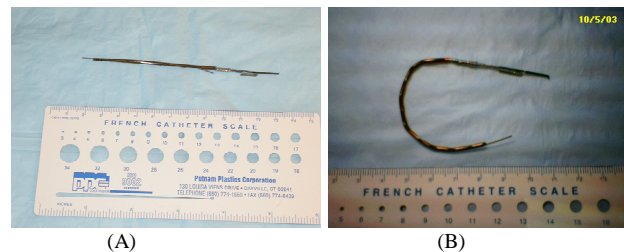


Figure 1: C-clamp when straight (A), as used during advancement into the coronary sinus, and crimped to reduce radius of curvature (B).

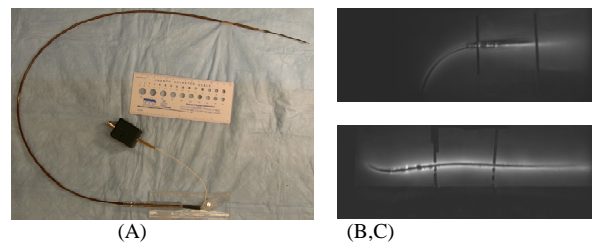


Figure 2: The C-Clamp delivery catheter with the matching tuning interface circuit (A). Sagittal and coronal view of the images acquired by the C-Clamp catheter in a saline phantom (B,C).

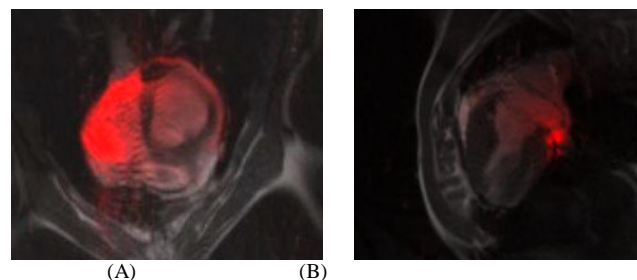


Figure 3: C-Clamp delivery catheter advanced in the right atrium and the device placed in the coronary sinus. Short axis image (A) and the two chamber long axis image (B) showing the C-clamp device in the coronary sinus