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Real Time MRI Guided Cardiac Cryo-Ablation : A Feasibility Study

Eugene G. Kholmovski, PhD^{1,2}, Nicolas Coulombe, MS³, Joshua Silvernagel, MS^{1,4}, Nathan Angel, MS^{1,4}, Dennis Parker, PhD^{1,2}, Rob MacLeod, PhD^{1,4}, Nassir Marrouche, MD¹, and Ravi Ranjan, MD, PhD^{1,4}

¹CARMA Center, Division of Cardiology, University of Utah

²UCAIR, Department of Radiology, University of Utah

³Medtronic CryoCath LP, Pointe-Claire, Canada

⁴Bioengineering, University of Utah, Salt Lake City, UT

Abstract

Introduction—MRI based ablation provides an attractive capability of seeing ablation related tissue changes in real-time. Here we describe a real time MRI based cardiac cryo-ablation system.

Methods—Studies were performed in canine model (n=4) using MR-compatible cryo-ablation devices built for animal use: focal cryo-catheter with 8 mm tip and 28 mm diameter cryo-balloon. The main steps of MRI guided cardiac cryo-ablation procedure (real-time navigation, confirmation of tip–tissue contact, confirmation of vessel occlusion, real-time monitoring of a freeze zone formation, and intra-procedural assessment of lesions) were validated in a 3 Tesla clinical MRI scanner.

Results—The MRI compatible cryo devices were advanced to the right atrium (RA) and right ventricle (RV) and their position was confirmed by real-time MRI. Specifically, contact between catheter tip and myocardium and occlusion of superior vena cava (SVC) by the balloon was visually validated. Focal cryo lesions were created in the RV septum. Circumferential ablation of SVC-RA junction with no gaps was achieved using the cryo-balloon. Real-time visualization of freeze zone formation was achieved in all studies when lesions were successfully created. The ablations and presence of collateral damage were confirmed by T1-weighted and late gadolinium enhancement MRI and gross pathological examination.

Conclusion—This study confirms the feasibility of a MRI based cryo-ablation system in performing cardiac ablation procedures. The system allows real-time catheter navigation, confirmation of catheter tip–tissue contact, validation of vessel occlusion by cryo-balloon, real-time monitoring of a freeze zone formation, and intra-procedural assessment of ablations including collateral damage.

Address for correspondence: Ravi Ranjan, MD, PhD, Division of Cardiology, University of Utah, Salt Lake City, UT 84132, ravi.ranjan@hsc.utah.edu, 801-213-2273.

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Keywords

Real-Time MRI; Cryo-ablation; Cryo-balloon

Introduction

Ablation is routinely used to treat numerous arrhythmias.¹ Pulmonary vein isolation is the cornerstone of atrial fibrillation ablation and is achieved by using point-by-point ablation using radiofrequency or using a cryo-ablation balloon.¹ The appeal of using a cryo-balloon is that with good occlusion of the pulmonary vein one can achieve complete circumferential ablation lesion set in a shorter period of time.² Despite this attraction one still relies on confirming electrical isolation using a functional assay, namely a lasso catheter placed in the pulmonary veins, as one cannot visualize ablation related tissue changes. The duration of freeze required to achieve durable lesion creation is also still evolving.³

Previously, MRI based cardiac ablations in animal models and humans have been done only using a radiofrequency (RF) based system.⁴⁻⁶ For such studies in the MRI environment special RF catheters were designed. Initially, these catheters only allowed for passive tracking of the catheter; later, tracking coils were added for active tracking and for better visualization.⁷⁻⁹

MRI provides excellent monitoring of non-cardiac cryo-ablations with accurate depiction of freeze zone boundaries.¹⁰⁻¹³ MRI guided cardiac cryo-ablation has not been previously demonstrated. Our study is the first study showing it is feasible to perform cardiac ablations with MRI based cryo-system. MRI based cryo-ablation may increase the success rate and reduce complications by real-time monitoring of the exact location of ablation, monitoring the freeze zone, validating tissue changes during the procedure, and allowing clinicians to perform targeted re-ablation in acute settings if required. In this study, we examined the feasibility of an MRI guided cardiac cryo-ablation procedure.

Methods

Equipment

Two investigational MRI compatible cryo-ablation devices built for animal use (focal cryo-catheter and cryo-balloon) were developed and tested. A MRI compatible 28 mm cryo-balloon was developed from a clinical 28 mm Arctic Front Advance cryo-balloon (Medtronic CryoCath, Montreal, Canada) by removing or replacing ferromagnetic components. These alterations were required to drastically reduce force and torque induced by strong magnetic field on the device and to minimize the device heating by RF pulses of MRI pulse sequences. The MRI compatible cryo-catheter with an 8 mm tip was constructed in a similar manner from a clinically approved Freezor MAX cryo-catheter (Medtronic CryoCath, Montreal, Canada). The console of the cryo system was positioned outside the scanner room and was connected to the cryo-catheters by extension tubing for Nitrous Oxide circulation through the catheters. The 25 feet long coaxial umbilical extension tubing was custom made to connect the catheter and the cryo-console.

Study Protocol

A canine model was used for these studies (n=4) and the study protocol was approved by the institutional animal care and use committee. The animals were sedated using propofol and then intubated. Deep sedation was maintained using isoflurane throughout the study. Right femoral vein access was obtained and a 16Fr (Cook Medical, USA) sheath was placed in the femoral vein with tip ending in the right atrium (RA). The animal was then moved to the 3 Tesla MRI scanner (Verio, Siemens Healthcare, Erlangen, Germany).

In brief, the main steps of the MRI guided cryo-ablation procedure were as follows; The cryo-catheter was advanced into the right ventricle (RV) via femoral vein access under real time (RT) MRI guidance. The catheter was positioned on RV septal wall and catheter tip-tissue contact was visually confirmed. Cryo-ablation was performed for 4 minutes with simultaneous MRI monitoring of the freeze zone. After thawing, the catheter was withdrawn from the animal and the MRI compatible cryo-balloon was advanced into the RA. The balloon was positioned at the superior vena cava (SVC) – right atrial (RA) junction and inflated. A 10–15 ml bolus of 10% diluted solution of Gd-BOPTA (Bracco Diagnostic Inc., Princeton, NJ) was injected from the tip of the balloon to confirm SVC occlusion. In the case of partial occlusion, the balloon was deflated, re-positioned, inflated, and occlusion was re-validated. In the case of complete occlusion, ablation was initiated and the junction was frozen for 3 minutes with simultaneous MRI monitoring of the freeze zone. After thawing, the balloon was deflated and withdrawn from the heart. 3D T1-weighted (T1w) imaging was performed to assess the ablations and possible collateral damage. Contrast (0.1 mmol/kg of Gd-BOPTA) was injected and 3D LGE-MRI was acquired 15–30 minutes after the injection to validate the ablations. After imaging the animal was injected with triphenyltetrazolium chloride (TTC, 0.1 g/kg). TTC stains live tissue red in color clearly demarcating ablated areas. At the end of the study, the animal was euthanized with intravenous potassium chloride and the heart was explanted for macroscopic and histological examination.

MRI Protocol

Imaging protocol included real-time MRI, 3D T1w, and 3D LGE sequences. Typical parameters for the different scans were as follows. RT-MRI: 2D turbo-FLASH pulse sequence with in-plane resolution = 1.8x2.4 mm, slice thickness = 4 mm, repetition time (TR) = 3.5 ms, echo time (TE) = 1.5 ms, flip angle = 12 degrees. During the navigation phase of the study, the sequence was acquired without ECG-gating resulting in temporal resolution of 4 frames per second. The sequence was acquired with ECG-gating during validation of catheter tip-tissue contact or SVC occlusion by the balloon and visualization of freeze zone formation. Saturation recovery preparation with inversion time (TI) of 200 ms was used during contrast enhanced validation of SVC occlusion.

3D T1w: respiratory navigated, ECG triggered, saturation recovery prepared 3D GRE pulse sequence with spatial resolution = 1.25x1.25x2.5 mm, TR/TE=2.8/1.3 ms, flip angle=17 degrees, TI = 150 ms, and whole heart coverage.

3D LGE: respiratory navigated, ECG triggered, inversion recovery prepared 3D GRE pulse sequence with spatial resolution = 1.25x1.25x2.5 mm, TR/TE = 3.1/1.4 ms, flip angle = 14 degrees, TI = 250–330ms, and whole heart coverage.

It was demonstrated that frozen tissues are easily visible as signal voids in conventional and real-time MR images. References^{14–16} In our study, the freeze zone was measured as the signal void region in the MR images. It should be noted that the signal void region includes the region occupied by the catheter tip or cryo-balloon and the region of frozen tissue or ice formation on the catheter/balloon. Dimensions of acute cryo-lesions were estimated using 3D LGE images.

Results

We implemented a MRI based cryo-ablation system and tested it in 4 animals. Table 1 summarizes the main procedure steps of MRI guided cryo-ablation performed during these studies. We successfully tracked the cryo-catheters in the MRI in real time and tested for SVC occlusion in all four animals. Focal ablation lesions of septal RV wall were created in three out of four animals. Circumferential ablation with no gaps at the SVC-RA junction was achieved in two animals. During one of the studies the custom extension coaxial umbilicals failed. This unforeseen event prevented any ablation to be performed during this study.

Figure 1a shows good occlusion of the SVC validated by contrast injection. RT-MRI was also used to validate balloon occlusion without any contrast injection (Fig. 1b). Video 1 shows clips in two different imaging planes acquired near simultaneously (about 250 ms separation) as the balloon is inflated which show good apposition of the balloon to the vessel wall. Figure 2 illustrates formation of cryo-balloon freeze zone during a 3 minute freeze (video 2). Significant increase in freeze zone was observed during the ablation. Dimensions of the freeze zone were measured in two orthogonal planes both along the shaft of the balloon/SVC and perpendicular to it. The increase in freeze zone diameter is greater in the plane touching the SVC walls (from 23 mm to 32 mm) as opposed to the axis of the shaft that is open to blood pool (from 23 mm to 27 mm). Such an observation is in agreement with the cryo-balloon design where only the frontal hemisphere is actively cooled. Also, slightly longer time to effective ablation and increase of freeze zone during initial 50 seconds of cryo-ablation may be explained by specifics of research cryo-system using a very long umbilical. The system did not have a separate inflation mode and the balloon was completely inflated as refrigerant reached it.

Figures 3a–d show the T1w and LGE MRI images confirming the circumferential lesion creation with tissue pathology validation. T1w images acquired 8 minutes after the ablation demonstrated circumferential ablation with no gaps at SVC-RA junction (Fig. 3b, 3e). It should be noted that good contrast between injured and normal tissues in these T1w images was achieved using a very small dose of contrast (0.03 mmol/kg) injected for validation of SVC occlusion. LGE images acquired after additional contrast injection (0.1 mmol/kg) demonstrate high contrast between ablated and normal tissues (Fig. 3c, 3f). Figures 3e–g

show collateral damage to the lungs just around the SVC detected by the T1w and LGE MRI images and confirmed by tissue examination (Fig. 3g).

Figure 4 illustrates the change in freeze zone dimensions with freeze time for the focal cryo-ablation in the right ventricle (video 3). The freeze zone quickly expands during the first minute of the freeze and continues increasing slowly during the next 3 minutes of freezing. Creation of focal RV lesions was confirmed by LGE-MRI and tissue examination (Fig. 5).

Discussion

We have successfully implemented novel MRI based cryo-ablation system. This system allows us to visualize the exact location of the cryo-ablation device in the heart in relation to other structures. This is important for both the delivery of lesions at the optimal location as well as avoidance of collateral damage. Atrio-esophageal fistula continues to be a dreaded complication of atrial fibrillation ablation for both radiofrequency and cryo ablation.¹⁷ Using the current fluoroscopy based system one is quite limited in determining the exact location of the balloon in relation to other anatomical structures. With MRI one can visualize multiple planes in real time to determine the exact location of the balloon in relation to other cardiac and non-cardiac structures and use this information to position the balloon to avoid collateral damage.

The MRI based cryo-ablation system also allows visualization of vessel occlusion without contrast and validation of catheter tip-tissue contact. Complete occlusion of the pulmonary vein being ablated is very important when using cryo-ablation to get a circumferential lesion set and electrical isolation of the pulmonary vein.¹⁸ If incomplete occlusion is seen and cryo-therapy is still delivered, it creates the possibility of gaps in the lesion set, allowing for AF recurrence. With real time MRI we can image different planes and observe the apposition of the balloon to the vessel wall in addition to the traditional observation of injecting contrast and confirming occlusion.

The ability to monitor the increasing freeze zone during the freeze cycle is a direct measure of effective cooling and ice formation. Here in real-time we assessed an increase in the freeze zone for both the balloon and the focal cryo ablation. For the balloon the increase in diameter was greater in the plane perpendicular to the vessel or the catheter shaft. This is likely because of the balloon design and close apposition of the balloon to the vessel wall in this plane leading to more area being cooled more effectively. In the other plane, parallel to the catheter shaft the proximal end of the balloon is exposed to blood flow leading to less effective cooling and hence a smaller increase in the freeze zone. Monitoring increase in freeze zone in real time can also be used as a surrogate for effective occlusion because if there is a leak with blood flow along the edges, the freeze zone is unlikely to expand to the same extent. Our study tended to have a longer freezing time than seen in a normal clinical settings because of the increased refrigerant pathway stemming from the use of long coaxial umbilical connecting the console to the catheters. The long umbilical led to increased evaporation of the liquid refrigerant as it travelled the length of the coaxial umbilical undergoing a pressure decrease and warm up. As a result the quality of liquid/vapor mix

arriving in the balloon was not optimal even when delivering a refrigerant flow equivalent to that used clinically leading a marginally longer effective ablation time.

The ability to detect ablation related tissue changes in real time is one of the main advantages of a MRI based system.⁹ Validation of tissue changes during the procedure is essential to allow targeted re-ablation in acute settings if required. Here we show that both T1w and LGE MRI can be used to validate the tissue changes as a result of cryo-ablation immediately after ablation. MRI confirmed the delivery of circumferential and focal lesions, which agreed with gross pathology. LGE MRI has long been used to detect scar and ablation lesions.^{19–21} It has also been used before in radiofrequency based real time MRI systems but for the first time in a cryo-based MRI system in this study.

Another important consideration when ablating is to achieve a transmural lesion without extending the lesion beyond the vessel wall. Here we show the usefulness of MRI in detecting tissue damage beyond the vessel wall into the lungs. The reason for collateral damage here could be the long freeze times of 3 minutes for SVC-RA junction. It was our intent in this study to show the capability of a real time MRI based system in acutely visualizing the lesions and not necessarily to limit freezing to avoid any damage to adjacent tissue. With this in mind, it is important to note that our study does illustrate that such systems can be effectively used to determine the correct freezing dose to prevent collateral damage during the ablation procedure.

A fully functional real time MRI cryo-ablation system will need further development of other tools like the lasso catheter. An active tracking system will be more useful for such a system as then one can identify the location of individual electrodes beyond the use of signal void to track catheters.⁹ Real time MRI ablation system with active tracking has been developed for radiofrequency ablation.⁹ Similarly, MRI compatible deflection system will need to be added to the catheters used here. Such systems have been developed for radio-frequency ablation.²²

Conclusion

In conclusion, we demonstrate feasibility of a real time MRI based cryo-ablation system which has the number of potential advantages over a traditional fluoroscopy based system.

Limitations

The cryo devices used here did not have any active tracking features so the position of the catheter was estimated based on the signal void regions. This is similar to how the radiofrequency ablation catheters were tracked initially before active coils were added for better tracking. The other major limitation in the balloon catheter used here was that it lacked any deflection mechanism and as a result we ablated at the right atrial – superior vena cava junction which does not require too much catheter manipulation. Problems with investigational equipment did not allow performing any cryo-ablations in one animal and only focal ablation in another one.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1a

Figure 1b

Figure 1.

Validation of SVC vessel occlusion. The inflated cryo-balloon is positioned at the right atrial-superior vena cava junction. (A): Contrast based approach. The left panel is before contrast injection and the right panel is after contrast injection in the superior vena cava showing good vessel occlusion. (B): Occlusion validation without contrast injection. Left panel – before occlusion, middle panel - partial occlusion (blue arrow indicates residual blood flow), right panel – complete occlusion. Red arrows show the SVC region to be occluded.

Figure 2.

Real-time visualization of freeze zone formation during cryo-balloon ablation. The balloon was positioned at the right atrial-superior vena cava junction. The images illustrate increase in freeze zone during 3 minutes of cryo-ablation. The plot shows diameter of freeze zone (balloon + frozen tissue) versus freeze time. Diameter was measured parallel and orthogonal to SVC/catheter shaft axis.

Figure 3.

Assessment of SVC-RA junction ablation. (a) Freeze zone at the end of 3 minutes ablation; (b, e) 3D T1w MRI: (b) sagittal and (e) axial views; (c, f) 3D LGE-MRI: (c) sagittal and (f) axial views; (d, g) Tissue pathology: (d) SVC-RA lesion, (g) injury to lung tissue. Red arrows indicate circumferential ablation at SVC-RA junction. Blue arrows show injury to lung tissue.

Figure 4.

Real-time visualization of freeze zone formation during focal cryo-ablation. The catheter was positioned at the septal wall of the right ventricle. The images illustrate increase in freeze zone during 4 minutes cryo-ablation. Plot shows area of freeze zone/signal void region (catheter tip + frozen tissue) versus freeze time.

Figure 5. Assessment of focal cryo-ablation of RV septal wall. (a) Freeze zone at the end of 4 minutes ablation; (b) 3D LGE-MRI; (c) Tissue pathology.

Table 1

The main procedure steps of MRI guided cryo-ablation

Cryo Device	Procedure Step	Animal 1	Animal 2	Animal 3	Animal 4
<i>Focal Catheter</i>	Navigation	+	+	+	+
	Validation of Tip-Tissue Contact	+	+	+	+
	Visualization of Freeze Zone	1 RV location, 2 freezes, each 4 mins	1 RV location, 4 mins freeze	2 RV locations, 4 mins freeze	Coaxial Umbilical Failure
	Lesion MRI	LGE: 676 mm ³	LGE: 420 mm ³	LGE: 336, 222 mm ³	-
<i>Cryo-Balloon</i>	Navigation	+	+	+	+
	Validation of Occlusion	+	+	+	+
	Visualization of Freeze Zone	Coaxial Umbilical Failure	RA-SVC junction, 3 mins freeze	RA-SVC junction, 2 freezes, each 3 mins	Coaxial Umbilical Failure
	Lesion MRI	-	LGE: Circumferential lesion, diameter=21 mm, length=24 mm	LGE: Circumferential lesion, diameter = 18 mm, length = 20 mm	-

RV – right ventricle, RA - right atrium, SVC - superior vena cava