Assessment of cardiac structure and function by cardiac MRI in patients undergoing atrial fibrillation catheter ablation

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1) Introduction
   a) Overview

Atrial fibrillation catheter ablation (AFCA) is a treatment option for patients with symptomatic atrial fibrillation (AF) despite medical therapy. In addition to reduction in AF burden, AFCA has been associated with improvements in cardiac structure and function, including reductions in atrial volumes and increased left ventricular ejection fraction, as measured by echocardiography (1-3). Cardiac MRI can provide more accurate assessment of cardiac anatomy and better assessment of right ventricular function than echocardiography. Small studies have demonstrated similar improvements in cardiac structure and function by cardiac MRI performed before and after AFCA (4-6). However, these changes have not been rigorously assessed and data on right-sided cardiac function before and after AFCA is limited.

   b) Hypothesis and Specific Aim
      i) Aims

i) To define changes in cardiac structure and function associated with AFCA
ii) To identify predictors of AFCA outcomes based on pre-procedure cardiac MRI

      ii) Hypothesis

i) Patients with good clinical response to AFCA (defined as maintenance of sinus rhythm ≥ 3 months following AFCA without the need for anti-arrhythmic drugs or repeat ablation procedures) will demonstrate significant improvements in cardiac structure (atrial and ventricular volumes) and function (ventricular ejection fraction, valvular regurgitation) as detected by cardiac MRI.
ii) Increased left atrial volume, increased severity of mitral regurgitation and reduced left and right ventricular systolic function on pre-operative cardiac MRI will be associated with lower likelihood of good clinical response to AFCA.

2) Research Design and Methods
   a) Overview

This is a retrospective study in which the electronic charts of patients admitted to Emory University Hospital Midtown for AFCA will be accessed and data relating to the procedure will be examined and saved. All data necessary was previously collected as part of usual clinical care.

   b) Patient Population

Patients will be identified by searching the cardiac electrophysiology (EP) lab database at EUHM to identify all patients who have undergone AFCA from January 1st 2002 until December 31st 2013. Certain operators have routinely performed cardiac MRIs before AFCA for procedural

planning and then at 3 months post-procedure to monitor for pulmonary vein stenosis, which is a known complication of AFCA. Electronic medical records will be reviewed to identify all patients who have undergone paired pre- and post-procedure MRI. For all such patients, data from the electronic medical record will be collected. All stored data will be de-identified by the study coordinator and organized with the use of a coding system in an excel spreadsheet. The PI will be responsible for support and oversight of the coordinators, including supervision of data maintenance, maintaining confidentiality and quality control.

c) Data Acquisition

Data collection will take place using the Emory electronic medical record (Powerchart), as well as the cardiac EP lab database (Filemaker Pro). All cases indicated as AFCA procedures performed at EUHM during the aforementioned date range in Filemaker Pro will be included in the chart review, and only the patient records corresponding to those procedures will be accessed in Powerchart. Based on review of Powerchart, full data extraction will be performed on patients who are found to have paired pre- and post-procedure MRI. Data collected on these patients will include basic demographic and clinical information, measurements from pre- and post-procedure MRI reports that are entered in Powerchart and details regarding the AFCA procedure, which will be obtained from Filemaker Pro. No additional data collection will be performed on patients who do not have paired pre- and post-procedure MRIs based on review of Powerchart. We anticipate reviewing about 1500 charts in Powerchart and collecting complete data on about 500 patients for the final database.

d) Study Endpoints

We plan to compare MRI measurements of left and right atrial and ventricular size, left and right ventricular ejection fraction and pulmonary vein dimensions before and after AFCA and correlate those changes with likelihood of good clinical response to AFCA. All data used for this study has been previously collected as part of the usual plan of care. Given that all patients included in this study will have pre- and post-procedure MRIs, we intend to use statistical methods where paired comparisons can be performed for each patient comparing MRI measurements before and after AFCA.

e) Future Directions

If characteristics on pre-AFCA MRI can be identified which are significantly associated with the likelihood of good clinical response to AFCA, this data could be used in the future for counseling patients before AFCA on the likelihood of a good outcome.

3) Protection of Human Subjects

a) Enrollment of Women and Minorities

Women and minorities will be retrospectively included in the data analysis at rates proportionate to the patients who have undergone AFCA in the EUHM cardiac electrophysiology lab. Demographic data collected will include race and gender, but this will not be used in anyway during screening for inclusion.

b) Enrollment of Children and Special Populations

Children (under the age of 18 years old) will not contribute to the data pool. They are unlikely to have been referred for AFCA because AF is very rare in patients under the age of 18. No special populations will be enrolled.

c) Risks to Subjects

This is a minimal risk study, as the only risks to those who participate will be the potential for a breach in confidentiality of their patient records. Every effort will be made to ensure patient confidentiality including following appropriate HIPAA guidelines and de-identifying stored patient data. All members of the study team who access and store PHI have been fully trained to Emory's confidentiality standards.

d) Potential Benefits of Participation in the Proposed Research to the Subjects and Others

There are no direct benefits to the subjects participating in the study. There is a possible benefit to others as the study could illustrate potentially useful information in predicting response to AFCA.

4) Vertebrate Animals

N/A

5) Select Agent Research

N/A

References

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