

IRB Proposal
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“Atrial thrombus and the role of TEE prior to atrial flutter ablation”

A. Study Purpose and Rationale

The risk for systemic embolization in patients with atrial fibrillation (AF) is both well known and widely believed to originate from clots formed in the left atrium. Lack of organized mechanical activity in the atria is believed to lead to clot-promoting stasis of blood and ultimately to atrial thrombus (AT). Furthermore, the risk for embolization is substantially increased at the time of cardioversion. Knowledge of the thromboembolic potential of AF has led to recommendations in the guidelines of the American College of Cardiology and the American Heart Association that include chronic anticoagulation for most patients with sustained AF. Moreover, for most patients in whom restoration of sinus rhythm is planned and who have not been adequately anticoagulated, transesophageal echocardiography (TEE) aimed at the detection of AT is recommended before attempted cardioversion. The guidelines further recommend that cardioversion be aborted in patients in whom AT is detected and undertaken only after a period of appropriate anticoagulation.

Our understanding of thrombogenicity in patients with Atrial flutter (AFL) lacks robust evidence, especially in the setting of AFL ablation. Nevertheless many physicians apply the AF guidelines to patients with AFL. Previous studies report the prevalence of AT in patients with AFL as 1.8% and thromboembolic events have been reported in as high as 7.8% of cases. Prior to catheter ablation of AFL and restoration of sinus rhythm, transesophageal echocardiography (TEE) is commonly used in the setting of subtherapeutic anticoagulation or new onset AFL of duration greater than 48 hours to rule out AT. This practice is an extrapolation of guidelines regarding Afib as expert opinion suggests that similar comorbidities may predispose AFL patients to thromboembolism.

Echocardiographically, AT is not the only feature reported as a risk factor for thromboembolism. Spontaneous echo contrast (SEC) correlates with blood stasis and subsequent erythrocyte rouleaux formation. In addition to AT, the presence of moderate or severe SEC (scored as 3+/4+) is classified as thrombogenic milieu (TM). TM describes dense spontaneous echo contrast (SEC) in addition to AT as a risk factor for thromboembolism.

It would be useful to understand the clinical and echocardiographic parameters associated with AT and thrombogenic milieu (TM) in patients presenting for AFL ablation such that TEE can be used more judiciously. The purpose of this study would be to report the prevalence of AT and TM in patients presenting for ablation of AFL as a validation of current practice standards. Additionally, a scoring system I developed known as the DECAMS score will be used in an attempt to risk stratify patients. The score stands for a collection of strong univariate clinical associations with TM. D= diabetes E = EF below 35% K = CKD (Cr > 1.4) A = Afib M = MI S = Stroke. We hypothesize that if a patient has a score of 0 (none of these clinical associations) they will not form AT.

B. Study Design and Statistical Analysis

We will analyze consecutive patients presenting to this academic medical center for TEE followed by catheter ablation of AFL in a cross-sectional, retrospective fashion. Indications for AFL ablation will be defined as symptomatic or recurrent AFL. These patients will be referred by primary internists, and subspecialty physicians, and undergo history and physical exams in the inpatient or outpatient setting prior to the procedure. Inclusion criteria for this study includes one of the above indications for catheter ablation of AFL and an indication for TEE prior to AFL ablation.

Indications for a TEE prior to catheter ablation will be defined as patients on chronic anticoagulation with coumadin with a subtherapeutic INR (goal range 2.0 to 3.0) in the previous month, or new onset atrial flutter of longer duration than 48 hours. TEEs will be performed and interpreted by experienced echocardiographers. If thrombus is not identified in any of the cardiac chambers during TEE, the patients are allowed to proceed with catheter ablation. All TEE's will be performed within four days of catheter ablation of AFL. All patients will be recorded consecutively in an electrophysiology laboratory electronic notebook.

The degree of SEC was categorized as being either absent (0), mild (1+), mild-to-moderate (2+), moderate (3+) or severe (4+), as reported in a system originally described by Fatkin et al. Patients with grade 3+ spontaneous echo contrast or higher were grouped with patients with thrombus and classified as having "thrombogenic milieu" (TM) as previously reported.

A database of consecutive patients will be constructed using the EP Log, clinical data, and echocardiographic reports obtained from the electronic medical record at our hospital. We will look at the following variables: Age, CHADS2 score, AF, Hypertension, Diabetes, tobacco use, CKD, CVA, HLD, thyroid disorder, obesity, anticoagulation, new AFL dx, MI, CAD, bypass, CHF, EP device, INR, BNP, Hct. We will record these different comorbidities as well as echocardiographic data (LEF, LA diameter, LAA emptying velocity, LA SEC, mitral stenosis, MR, AR, AS) for statistical analysis. Of note CKD will be defined as a documented baseline creatinine of above 1.4.

Continuous variables between groups will be compared by a t test for unpaired observations. Nominal data to be compared by the chi-square test. Categorical data (degree of spontaneous echo contrast) to be compared by the Wilcoxon signed rank test for matched pairs. In all cases, a p-value 0.05 will be considered statistically significant.

C. Study Procedure

This study will be retrospective chart review. We will obtain the MRNs of all patients who presented to NYP-Columbia/Cornell for AFL ablation. Using the electronic medical record system, we will analyze the data from all those patients who presented for ablation from 2008 through 2013. We will report the incidence of AT as well as TM in this group. Subsequently we will analyze for any statistically significant co-morbidities or echocardiographic findings that are associated with AT formation. We will then apply the DECAMS score: D= diabetes E = EF below 35% K = CKD (Cr > 1.4) A = Afib M = MI S = Stroke to calculate a 0 to 6 score per patient. We can then hypothesize the accuracy

of this score given the number of patients who have a score of zero and also have no thrombus.

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaires

N/A

G. Study Subjects

All patients above the age of 18 presenting for atrial flutter ablation with indications for TEE prior to procedure. Indications for a TEE prior to catheter ablation are defined as patients on chronic anticoagulation with coumadin with a subtherapeutic INR (goal range 2.0 to 3.0) in the previous month, or new onset AFL of longer duration than 48 hours.

H. Recruitment of Subjects

Retrospective chart analysis

I. Confidentiality of Study Data

All patient data obtained for the study will be de-identified and given a unique patient code corresponding to safeguarded identifying information. Patient information will be entered into a computer database which will be stored in encrypted and password-protected computers only available to qualified study investigators and study coordinator.

J. Potential Conflict of Interest

None

K. Location of the Study

Inpatient cardiology wards of both campuses of NY Presbyterian Hospital: CUMC and Weill-Cornell.

L. Potential Risks

None, we are analyzing data and procedures that have already occurred and thus there is no added risks inherent in our analysis of the data.

M. Potential Benefits

Although there will be no immediate benefits from this study, results may decrease invasive procedures such as the TEE in a certain patient population.

N. Alternative Therapies

N/A

O. Compensation to Subjects

None

P. Costs to Subjects

None.

Q. Minors as Research Subjects

N/A

R. Radiation or Radioactive Substances

N/A

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