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Mobile Thrombus on Cardiac Implantable Electronic Device Leads of Patients Undergoing Cardiac Ablation: Incidence, Management and Outcomes

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Abstract

Purpose—The rates of cardiovascular implantable electronic device (CIED) implantations and cardiac ablation procedures are increasing worldwide. To date, the management of CIED lead thrombi in the periablation period remains undefined and key clinical management questions remained unanswered. We sought to describe the clinical course and management strategies of patients with a CIED lead thrombus detected in the periablative setting.

Methods—We performed a retrospective analysis of all patients who underwent a cardiac ablation procedure at Mayo Clinic Rochester from 2000-2014. Patients were included in our study cohort if they had documented CIED lead thrombus noted on periablation imaging studies. Electronic medical records were reviewed to determine the overall management strategy, outcomes, and embolic complications in these patients.

Results—Our overall cohort included 1833 patients, with 27(1.4%) having both cardiac ablation procedures as well as CIED lead thrombus detected on imaging. Of these 27 patients, 21 were male (77%), and the mean age was 59.2 years. The mean duration of follow-up was 16.5 months (range; 3 days – 48.3 months). Anticoagulation was an effective therapeutic strategy, with 11/14 (78.6%) patients experiencing either resolution of the thrombus or reduction in size on re-imaging. For atrial fibrillation ablation, the most common management strategy was a deferment in ablation with initiation/intensification of anticoagulation medication. For ventricular tachycardia ablations, most procedures involved a modified approach with the use of a retrograde aortic approach to access the left ventricle. No patient had any documented embolic complications.

Conclusions—The incidence of lead thrombi in patients undergoing an ablation was small in our study cohort (1.4%). Anticoagulation and deferral of ablation represented successful

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management strategies for atrial fibrillation ablation. For patients undergoing ventricular tachycardia ablation, a modified approach using retrograde aortic access to the ventricle was successful. In patients who are not on warfarin anticoagulation at the time of thrombus detection, we recommend initiation of this medication, with a goal INR of 2-3. For patients on warfarin at the time of thrombus detection, we recommend an intensification of anticoagulation with a goal INR of 3.0.

Keywords

Lead thrombus; cardiovascular implantable electronic devices; cardiac ablation

Introduction

Over the last decade, rates of cardiovascular implantable electronic devices (CIED) implantations are increasing worldwide.[1-7] With an aging population, increasing life expectancy, advancement in technology, and broadening of clinical indications for insertion of cardiac devices,[8, 9] this number is predicted to continue to rise. Paralleling the rise of device implantation is the number of patients undergoing cardiac ablation procedures. [10-13] As a consequence of expanded CIED indications and increasing use of catheter ablation to treat arrhythmias cardiologist will face more patients undergoing cardiac ablations with CIEDs.

There is minimal data examining the impact of CIED on ablation procedures, with some highlighted concerns relating to an increased risk for developing venous complications, especially thrombosis[14-16] and subsequent embolization.[17] It has been recently reported that mobile lead thrombosis is a frequent discovery, occurring in 30% of individuals undergoing ablations.[18] During an ablation access to either the left ventricle or left atrium is attempted by transseptal puncture. The identification of lead thrombi raises practical concerns due to the subsequent risk for stroke from embolization of lead thrombi through the iatrogenic patent foramen ovale (PFO).[19, 20] Therefore when a lead thrombosis is present there is much hesitancy in proceeding with transseptal puncture and ablation is often aborted.

Despite our ability to detect intracardiac device lead thrombus; the management of these in an ablative environment to date remains elusive. Many key questions remain unanswered: What happens to those that are noticed to have a lead thrombus? How are these individuals managed? Do they experience any embolic phenomena? What is their natural history? With a lack of clear guidance in the management of lead thrombus in an ablative environment, the aim of our study was to systematically review our experience with patients who had a mobile thrombus detected on a CIED lead by periblation imaging to define their clinical course and management.

Methods

Study Population

We retrospectively reviewed the electronic medical record at Mayo Clinic Rochester from 1st January 2000- 31st December 2014 to identify those patients that had a detected lead thrombus noticed on periablation echocardiogram (either intracardiac (ICE), transesophageal(TEE) or transthoracic echocardiogram(TTE)). The chart was electronically searched for the key words “lead thrombus,” “lead mass,” “lead clot,” and “mobile echodensity.” Patients were included if they fulfilled the following criteria, 1) undergoing or planned cardiac ablation, 2) detection of lead thrombus on periablation imaging. To determine the incidence of the lead thrombus, we reviewed all ablations and determined CIED status at time of ablation through the use of a combination of diagnosis (CIED in situ) and billing codes (which address periprocedural CIED device adjustment and interrogation). Patient characteristic data was collected through examination of the patient electronic medical record. Device data was collected from the nearest device check before the ablation procedure. If the patient happened to undergo placement of either an atrial or ventricular lead at a different time, the age of the lead with the thrombus was calculated. Baseline echocardiographic data was collected from the closest echocardiogram to the ablation date.

Results

Baseline demographics

Twenty-seven patients with a CIED were discovered to have a lead thrombosis on periablative imaging (12 periablation TEE/TTE, 15 ICE) with a mean follow up of 16.5 months (range, 3 days – 48.3 months). Baseline demographic data is shown in Table 1. Patients were predominately male (21/27, 78%) with a mean age of 59.2 ± 14.1 years. Indication for the ablation was predominately atrial fibrillation and ventricular tachycardia (both 48.1%). A majority of patients had atrial fibrillation at baseline (19/27, 70.3%). Cardiomyopathy was common (66.7%) with an average ejection fraction 45.8 ± 17.0 (ischemic cardiomyopathy the most common type). Table 2 summarizes the device characteristics. ICD was the most common CIED (16/27, 59.3%), with average age of device 38 months and average age of leads 106.1 months. The mean right ventricular systolic pressure (RVSP) was 32.5 ± 11.4 mmHg. Four patients had a documented patent foramen ovale determined by both bubble and Doppler evaluation.

Incidence of lead thrombus

Based upon the review of our charts and review of periablation imaging performed, we identified that 1833 (18% of total ablations during the time period) ablations occurred on individuals with a CIED during the defined time period. The incidence of lead thrombus in patients with a CIED who underwent an ablation was determined to be 27/1833 (1.4%).

Detection and characteristics of thrombus

ICE was the superior imaging modality for detection of thrombus. Thrombus was not reported on routine TTE in 9 patients (but noticed on TEE and ICE), while both TTE and TEE did not visualize thrombus in 5 patients despite visualization with ICE. The lead

thrombus was detected on the atrial lead in 10/27 cases and on the ventricular lead in 17/27 cases, with an average size of 16.1 mm × 8.4 mm.

Management of thrombus

Figure 1 highlights the different management approaches and outcomes across our cohort. In those undergoing AF ablations the most common approach was to defer the ablation procedure, with very few proceeding. In those patients undergoing a VT ablation, thrombi inhibited the use of transseptal access and many required retrograde aortic access to access the left ventricle. Preceding the ablation 15 patients (55%) were receiving anticoagulation, 13 were on warfarin and 2 were on rivaroxaban. All patients received coagulation in our cohort post identification of the thrombus. Table 3 shows the impact of anticoagulation upon thrombus resolution. 11/14 (78.6%) patients experienced either resolution of the thrombus or reduction in size with the use of warfarin, either from initiation or intensification (defined as goal INR>3.0) of anticoagulation. In the 8 patients who experienced complete resolution of the thrombus, 6 were initiated on warfarin, and 2 underwent intensification. In those already on warfarin (n = 5), intensification to achieve a higher INR >3.0 was a successful strategy with 4/5 having either a reduction or resolution of the thrombus.

Outcomes

Five patients who had resolved thrombus underwent repeat procedures with no complications at an average length to repeat procedure of 3.4 ± 1.9 months. No patient had documented embolic complications related to lead thrombosis over the follow up period.

Discussion

CIED mobile thrombus is reported to occur in 30% of patients[18] undergoing an ablation procedure, however the management of these thrombi remains undefined. We are the first to report on long-term outcomes and management of CIED lead thrombus in patients undergoing a cardiac ablation. In this retrospective series, the incidence of lead thrombus is low (1.4%) and we highlight that the most common management approach in AF ablations was to defer the ablation with initiation or intensification of anticoagulation. In those undergoing VT ablation, modification of the procedure was performed with retrograde aortic access. These were largely successful strategies. Over our follow up period, clinical sequelae, in particular embolization from these thrombi were minimal.

We determined the incidence of lead thrombus to be 1.4% at our institution. Our data is similar to Rabher et al[21] who reported lead thrombus in 1.4% of their population who underwent a TTE. Our incidence is smaller when compared to Supple et al,[18] who reported thrombus at 30%. We hypothesize that our incidence is smaller because most of these imaging studies were not looking specifically for lead thrombus. Some thrombus is small and therefore may be difficult to detect unless one is specifically looking for it and there are added human factors such as operator experience, which could also limit thrombus detection. Supple et al, exclusively used ICE imaging, where we examined all imaging modalities.

In our cohort, the most common management strategy of CIED lead thrombus was to defer the ablation procedure with anticoagulation. This represents a successful approach with most patients (n=9, 64.3%) eventually having a repeat ablation or planning a repeat ablation in the near future. The concern with proceeding to ablation in those with CIED lead thrombus is transseptal access, which is frequently performed to access the left side of the heart during cardiac procedures. By performing transseptal access, an iatrogenic ASD is created and there is a risk that thrombi for the lead may dislodge and subsequently enter the left heart causing paradoxical embolization. Nevertheless, it has to be recognized that 2 patients proceeded with transseptal access despite the inherent risk. The actual risk of proceeding with transseptal puncture is not clearly defined and may also be a safe approach as these patients did not experience any adverse outcome. In both of these patients the decision to procedure was based upon clinical symptoms, with one patient having highly symptomatic atrial fibrillation and the other with incessant VT and concern for further deterioration in ventricular function and hemodynamic compromise. Although proceeded was not associated with any adverse outcome, given the potential devastating impact of an embolism should clinical circumstances allow, we would still recommend deferring the procedure with anticoagulation.

The impact of anticoagulation (warfarin) on thrombus in general is well acknowledged amongst the medical community. However, its role in the management of lead thrombus has not been reported in those undergoing a cardiac ablation. Our study confirms that anticoagulation is an effective management strategy to enable clot dissolution (table 3). Initiation of warfarin was successful in resolving and reducing thrombus in 8/10 patients (80%) while intensification of warfarin (n=5) to an INR of 3.0 was associated with resolution in two patients and reduction in one. In those patients on warfarin who did not undergo intensification, one experienced reduction and another no change in thrombus size. Based upon this data, we propose a two-pronged approach to anticoagulation (Figure 2). In those who are not on anticoagulation, initiation of warfarin with an INR of 2-3 will result in dissolution of the thrombus in a large majority of cases. In those already on warfarin, we recommend an intensification of warfarin to an INR 3.0, to enable thrombus resolution. The impact of warfarin on lead thrombi tells us mechanistically that these are likely to be truly thrombotic in nature and are not fibrotic. We hypothesize that those already on warfarin get benefit from intensification as they likely have a lack of time with a therapeutic INR[22, 23] (a significant issue, well recognized in patients taking warfarin). Therefore, initiation of a higher goal enables more time in the therapeutic window.

Our data supports the study by Rahbar et al.[21] where they showed that the initiation of intensified anticoagulation therapy resulted in reduction or shrinkage of thrombus in 9 of their patients whom they had follow up data on. The one major limitation of their study is that they only used TTE as the imaging modality. The concern regarding the sensitivity of TTE to identify thrombus is emphasized in our results, wherein a significant number of patients (n=5) did not have thrombus identified on regular TTE or TEE imaging but later diagnosed with ICE. Therefore, in their study it is unclear if those that were recorded as dissolved truly dissolved or simply shrunk in size and were not visible to repeat TTE. Supple et al[18] report similar data, it was noted that thrombus was not reported on any routine TTE in 26 patients who had detected mobile thrombus. This underlies the importance of ICE in

the detection of lead thrombus. ICE is a relatively new addition to the electrophysiologists' armamentarium, and there is growing data showing it to have increased diagnostic accuracy in the diagnosis of CIED thrombus.[24]

In our cohort we did observe thrombus across a variety of devices and leads (Table 2). The most common device type in whom we detected thrombus was an ICD. The average age of the device was 38 months, with a mean lead age of 106 months. The average number of leads in our patients was 2, with most having both atria and ventricular leads. Ventricular leads were the most common site of thrombus. Given the small number of patients in our study, it is difficult to deduce any association between device/lead characteristics and risk of thrombus, future study of this could potentially help identify those patients at greatest risk.

Embolitic phenomena from these thrombi are a major concern. However, no recorded embolic events occurred in our cohort. There is data to suggest that lead thrombus is associated with a significant increase in pulmonary artery pressure. Persistent thromboembolism from endocardial leads has been proposed as a potential mechanistic cause for this increase.[18] We did not find an increased RVSP among our patients with lead thrombus. Further evidence from a large study of 5646 CIED patients highlighted that the PE rate was low and suggests that it is possible that embolism of lead thrombus is uncommon or emboli are too small to cause consequential pulmonary infarction.[25] We would agree with these findings based upon our data.

While we are reporting on our experience with lead thrombus and show that anticoagulation represents a successful management approach, it is important to note a few limitations of this study. Its retrospective nature largely inhibits the ability to detect embolic phenomena from these thrombi as some may have had embolic events outside the Mayo Health System network. Further as we were only reporting on our experiences we have no comparison group in which thrombus was detected and anticoagulation was not given. In addition, the operators of the pericardial imaging may not have been looking exclusively for lead thrombus and therefore lead thrombus may not have been specifically recorded, coded, or put in the ablation procedure report/note potentially leading to underreporting, which could have influence on the low incidence that we observed. Lastly, different imaging modalities on the follow up of the lead thrombus limited our ability to have larger numbers to determine the impact of anticoagulation. Further prospective studies are needed to truly determine the incidence of lead thrombus.

Conclusion

We have demonstrated in this retrospective study that the incidence of lead thrombi in patients undergoing an ablation is small at 1.4%. Initiation of anticoagulation and deferral of ablation represents a successful management strategy in those receiving an AF ablation. In those requiring left ventricular access for VT ablation retrograde aortic modification is a successful approach.

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Figure 1. Impact of thrombus on cardiac ablation procedure

Figure 2. Flowchart highlighting the management of anticoagulation in periablative lead thrombus detection

Table 1**Patient Characteristics (n=27)**

Male, n (%)	21 (78.0)
Age, years (SD)	59.2 ($\pm$ 14.1)
Reason for ablation, n (%)	
Atrial Tachycardia	1 (0.03)
Atrial fibrillation	13 (48.1)
Ventricular Tachycardia	13 (48.1)
Atrial fibrillation, n (%)	19 (70.3)
Paroxysmal	6 (31.6)
Persistent	13 (68.4)
Permanent	0 (0)
Comorbidities, n(%)	
History of MI	10 (37.0)
Diabetes	13 (48.1)
HTN	19 (70.4)
Hyperlipidemia	17 (46.0)
History of thrombus in past	3 (11.1)
DVT/PE	2 (7.4)
Atrial	1 (3.7)
Cardiomyopathy, n (%)	18 (66.7)
Ischemic	8 (44.4)
Non-ischemic	5 (18.5)
HCM	4 (14.8)
ARVC	1 (3.7)
Anticoagulation at time of procedure	15
Warfarin	13
Other	2
INR at time of procedure, average (SD)	1.7 ($\pm$ 0.5)
Echocardiographic data	
LVEF, %	45.8 $\pm$ 17.0
RVSP, mmHg (SD)	32.5 (11.4)
Patent Foramen Ovale, n (%)	4 (15)

Table 2**Device characteristics**

Device Type, n (%)	
ICD	16 (59.3)
PPM	9 (11.1)
CRT	2 (7.4)
Age of device ^{*†} , months (min,max)	38.0 (3.4, 94.0)
Number of devices implanted, average (SD)	1 (±0.5)
Age of leads ^{*†}	106.1 (3.4, 1345.0)
Number of leads per patient, n (SD)	2 (±0.7)
Atrial lead only	0
Ventricular leads only	5 (19%)
Atria and Ventricular leads	20 (74%)
Atria, Ventricular and coronary sinus (CRT)	2 (7%)

^{*} Age taken from new implant date

[†] n =26, one patient exclude as unaware of ICD device implant dates

Table 3
Impact of Anticoagulation on thrombus (n= 14^{*})

Resolved	8 (57.1)
On warfarin, n (%)	
Higher INR [†]	2 (25%)
INR 2-3	0
Initiated on warfarin, n (%)	
INR 2-3	6 (75%)
Reduction	3 (21.4)
On warfarin, n (%)	
Higher INR [†]	1 (33%)
INR 2-3	1 (33%)
Initiated on warfarin, n (%)	
INR 2-3	1 (33%)
No Change	3 (21.4)
On warfarin, n (%)	
Higher INR [†]	0
INR 2-3	1 (33%)
Initiated on warfarin, n (%)	
INR 2-3	2 (66%)

^{*} Excluding 13 patients (6 no repeat imaging, 7 TEE/ICE initially identified thrombus, repeat imaging was only TTE)

[†] INR >3.0