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Prevalence and Short-Term Clinical Outcome of Mobile Thrombi Detected on Transvenous Leads in Patients Undergoing Lead Extraction

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Disclosures
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Structured Abstract

Objectives: The objective of this study was to prospectively evaluate the prevalence, risk factors and short term major clinical outcomes of mobile thrombus detected on transvenous leads in patients undergoing lead extraction.

Background: The prevalence and clinical significance of thrombus on transvenous leads in patients undergoing lead extraction is not well characterized.

Methods: Consecutive patients undergoing transvenous lead extraction for non-infectious indications were enrolled. Pre-operative trans-esophageal echocardiograms were performed prospectively for all patients to examine for mobile thrombus. Anticoagulation was not started for thrombus unless other indications were present. Clinical endpoints of mortality and cardiovascular morbidity (symptomatic pulmonary embolism, myocardial infarction or cerebrovascular accident) were assessed at minimum of two month follow-up.

Results: 108 patients underwent lead extraction for non-infectious indications. Lead thrombi were detected in 20 patients (18.5%) and all were less than 2cm. Clinical and lead characteristics were not associated with formation of lead thrombi, except for younger patient age. In patients with detected thrombi, there were no short-term deaths, symptomatic pulmonary embolism, nor myocardial infarction, except one patient with a stroke 3 months after lead extraction (7% vs 5%, p=1.00). Median follow-up was 9 months.

Conclusions: Mobile thrombi on transvenous leads are commonly found in patients referred for transvenous lead extraction and are rarely associated with acute major adverse outcomes. Careful extraction of leads with small incidentally detected thrombi can likely be performed without major acute clinical sequelae. Larger studies with longer follow-up are needed to further assess the long term clinical significance of lead thrombi.

Keywords

Transvenous lead extraction

Cardiac implantable devices

Trans-esophageal echocardiography

Thrombogenesis

Condensed Abstract

The prevalence and clinical outcome of mobile thrombi on transvenous leads are unknown in patients undergoing transvenous lead extraction. In this prospective study of 108 consecutive patients undergoing lead extraction for non-infectious indications, there was a high prevalence of patients with lead thrombi. These patients were rarely associated with short-term major adverse outcomes despite use of extraction sheaths and a strategy of no routine anticoagulation for incidentally detected lead thrombi. Thus, careful extraction of leads with small incidentally detected thrombi can likely be performed without major acute clinical sequelae.

Abbreviations

AF: atrial fibrillation

BMI: body mass index

CIED: cardiac implantable electronic device

CTEPH: chronic thromboembolic pulmonary hypertension

CVA: cerebrovascular accident

FDA: Food and Drug Administration

ICE: intracardiac echocardiography

INR: international normalized ratio

LVEF: left ventricular ejection fraction

MI: myocardial infarction

PE: pulmonary embolism

TEE: trans-esophageal echocardiogram

VT: ventricular tachycardia

Introduction:

The prevalence of mobile intracardiac thrombi detected on transvenous leads from cardiac implantable electronic devices (CIED) varies widely in the literature, from 1.4% to 30% using a variety of imaging modalities[1-4] in different patient populations. The clinical significance of these incidentally detected thrombi is unclear, with some studies reporting a low incidence of pulmonary embolism, but there are cases of patients with recurrent pulmonary embolism requiring surgical lead and thrombus extraction. Furthermore, it is unclear whether anticoagulation is indicated in these patients in whom incidental thrombi without embolic sequelae are found.

In patients undergoing transvenous lead extraction, the prevalence and clinical outcome of incidental mobile lead thrombi has not been reported, and it is unknown whether these patients have a higher incidence of embolic events. We performed a prospective cohort study of consecutive patients referred for transvenous lead extraction to evaluate the prevalence and short term major clinical outcomes of thrombus detected on transvenous leads at time of lead extraction.

Methods:

Patient Population

Consecutive patients with prior cardiac implantable devices with transvenous leads who were referred for transvenous lead extraction at the

University of California, San Diego between March 2015 to December 2016 for non-infectious indications such as lead malfunction were enrolled into this prospective study. Inclusion criteria included any patient greater than 18 years of age who was referred for transvenous lead extraction for any indication except infection, bacteremia, or pocket infection. Exclusion criteria included any patient who could not tolerate a trans-esophageal echocardiogram.

Study Design

A routine pre-operative trans-esophageal echocardiogram (TEE) was performed prospectively for all patients on the day of the lead extraction procedure, focusing on all transvenous leads from the superior vena cava to endocardial insertion points to examine for mobile thrombus located in the intracardiac portion of the leads. A mobile thrombi was defined as any echodensity seen on the intracardiac portion of a lead that appeared distinct (sharp, irregular edges) from the lead material, could move freely (not be affixed to a vessel wall and either move along with or be independent of the direction of lead movement. Care was taken to exclude artifact or venous occlusion in the SVC. Figure 1 shows two representative examples of differing mobile thrombi; Both move freely in the right atrium with the lead. Figure 1A and Video 1 show a large thrombus with significant paradoxical movement with the RV lead. Figure 1B and Video 2 show a thrombus affixed to the RA lead that moves with the lead with a small component moving paradoxically to the lead.

Then, lead extraction was performed according to standard clinical protocol using traction and laser or mechanical sheaths. Relevant baseline clinical and lead characteristics were recorded such as: patient age, gender, body mass index (BMI), left ventricular ejection fraction (LVEF), comorbid conditions, basic labs, anticoagulant use at time of extraction, number of leads, lead age, lead recall status, presence of defibrillation coil, abandoned leads, type of malfunction, lead chamber, insulation material, and manufacturer.

Clinical endpoints of mortality and cardiovascular morbidity (symptomatic pulmonary embolism, myocardial infarction, or cerebrovascular accident) were assessed at a minimum two month follow-up clinic visit or phone call. Clinically indicated pulmonary imaging was only performed if patients expressed symptoms of new dyspnea or chest pain after the lead extraction. Of note, given unclear optimal anticoagulation approach in context of limited retrospective studies,[4, 5] anticoagulation was not routinely started for an incidental finding of a small thrombus less than 2 cm, unless other clinical indications such as atrial fibrillation with high CHA_2DS_2VASc score were present.

Statistical Analysis

Baseline characteristics and outcomes were analyzed using R Commander. ANOVA, Welch two sample t-test, Pearson's chi squared and Fisher's exact test were used for statistical analysis depending on the frequency and variance of the sample. Results are expressed as mean ± standard deviation, median (Q1 –Q3), or frequency count (percent of sample), when applicable. A statistically significant difference had a p-value of <0.05.

Results:

Incidence of Incidental Mobile Lead Thrombi

Of the 166 patients referred for transvenous lead extraction, 108 patients with 237 transvenous leads had a non-infectious indication and were included in the analysis. A thrombus was found on 29 (12.2%) of the leads amongst 20 (18.5%) patients. The mean thrombus size was 1.4 ± 0.4 cm, with smallest 0.6 cm and the largest 1.9 cm. They were predominantly located in the right atrium compared to the right ventricle (86% vs 14%, p<0.001). Clinical characteristics associated with thrombus formation are outlined in Table 1. Each patient had between one to five transvenous leads implanted at the time of evaluation, with a mean of 2.2 ± 0.7 leads per patient. To support the absence of infection, patients with thrombi did not have higher white blood cell counts nor higher maximum temperature (Tmax) compared to the group without thrombi.

Clinical and Procedural Outcomes

The median length of follow up was 9 months (2-14 months). There were four deaths in the patients without thrombus compared to no deaths in the patients with detected lead thrombus (4.5% vs 0%, p=1.00). Two of the deaths in patients without thrombus occurred due to post-operative superior vena cava tear, one death was due to pneumonia, and the cause of the fourth is unknown as the patient died at home 7 months post-operatively. Major short-term adverse cardiovascular events (pulmonary embolus, myocardial infarction, cerebrovascular accident or transient ischemic attack) occurred in one patient with a lead thrombus (ischemic stroke) compared to two patients without lead thrombi (transient ischemic attack and myocardial infarction, 5% vs 2%, p=0.50). The patient with lead thrombi who had an ischemic stroke was on warfarin before and after lead extraction with a subtherapeutic pre-operative INR of 1.4 at the time of stroke. Similarly, the composite endpoint (mortality, pulmonary embolus, myocardial infarction, cerebrovascular accident and transient ischemic attack) was not significantly different between patients with and without lead thrombi (7% vs 5%, p = 1.00). Short-term adverse major clinical outcomes are summarized in Table 3.

Out of the 20 patients with a detected lead thrombus, 18 patients (90%) underwent extraction of a lead with a thrombus on it. In the leads with thrombi that were extracted, 85% were extracted with a laser sheath and 15% were extracted with a mechanical sheath; none were extracted using traction only. For all patients, regardless of thrombus status, extraction sheaths were used in the majority of patients, 81% using laser sheaths, 6% using mechanical sheaths, and 13% using traction only. Operative outcomes, such as fluoroscopy time per transvenous lead extracted were not significantly different among patients with and without lead thrombus (11 ± 8 minutes vs 14 ± 9 minutes, p=0.26). There was also no significant difference in post-operative hospital length of stay.

Clinical Characteristics Associated with Lead Thrombi Formation

Out of all the baseline clinical characteristics, only patient age was significant, with younger age as more likely to be associated with a lead thrombus (56 ± 19 vs 64 ± 14 years, p=0.04). Table 2 displays all the clinical risk factors analyzed. There was no difference in baseline anticoagulant use in patients with thrombi compared to patients without lead thrombi (30% vs 38%, respectively, p = 0.47). There was no difference in the incidence of thrombus formation between the patients treated with warfarin versus direct oral anticoagulants (14% vs 17%, p = 1.00).

Lead Characteristics Associated with Lead Thrombi

No specific lead characteristics were associated with the formation of incidental mobile thrombi (Table 2). The functioning status of the leads and the reasons for extraction for each lead are illustrated in Figure 2. There were 66 (28%) leads that were not extracted. The other 171 (72%) leads were extracted for various indications, which are all displayed in Figure 2. The most common indications were device upgrade (19%), followed by lead fracture (16%) and malposition (9%). There was no statistically significant association of thrombus with functioning vs malfunctioning lead (9% with thrombus vs 15%, $p = 0.19$) or by extraction indication ($p = 0.06$). No specific insulating material was associated with presence of thrombus. Lead body insulation materials were comprised of three main groups—silicone, polyurethane, and combination. The combination materials included silicone and polyurethane copolymers ($n = 44$), proximal polyurethane and distal silicone ($n = 3$), and silicone with polyurethane sleeve ($n = 6$). Leads recalled for various reasons were issued on 20 (9%) of the leads at the time of this study, and overall, these recalled leads were not associated with a higher prevalence of lead thrombus (10% vs 8%, $p=0.61$). However, Riata leads appeared to be more thrombogenic, with 3 of 6 total Riata leads (50%) having thrombus. Lead thrombus was also not associated with abandoned status of a lead (7% vs 3%, $p = 0.35$) nor passive fixation (17% vs 15%, $p=0.56$).

Discussion:

There are three key findings in this study. First, there was a high prevalence (18.5%) of incidental mobile lead thrombi detected prospectively in a consecutive cohort of patients undergoing transvenous lead extraction. Secondly, we found that patients who undergo lead extraction of leads with small mobile lead thrombi experienced minimal short-term major adverse outcomes despite not routinely anticoagulating patients with lead thrombi. Finally, we found that lead characteristics were not associated with the formation of incidental lead thrombus.

Insights into the Prevalence of Incidental Lead Thrombi

This study is the largest prospective series to date of 108 patients and is the only study to evaluate the prevalence of mobile thrombi and outcomes in patients undergoing lead extraction. Incidental thrombi were discovered in 20 (18.5%) patients. To our knowledge, only two prior studies have prospectively evaluated the prevalence of mobile lead thrombi, the first study in 66 patients 6 months after CIED implantation using TEE and venography[1] and the second study in 86 patients undergoing AF or VT ablation using intracardiac echocardiography (ICE).[4] These studies identified a high incidence of thrombi in 20% and 30% of patients, respectively, similar to our findings. Conversely, three prior retrospective studies reported a prevalence of lead thrombi ranging from 1.4% to 12%,[2, 3, 6] which is lower than that reported in the prospective studies likely due to undersampling from retrospective study methodologies.

Short-term Clinical Outcomes in Patients with Incidental Mobile Lead Thrombi

During the follow up period (median 9 months), the presence of a lead thrombus was not associated with increased short-term combined adverse clinical outcomes (all-cause mortality, clinical PE, CVA or MI). No deaths or symptomatic PE occurred in patients with a lead thrombus. Only one patient with a lead thrombus experienced an ischemic stroke three months after transvenous lead extraction of the lead with a thrombus. This patient also had atrial fibrillation and subtherapeutic INRs which were a more likely etiology of his cerebrovascular accident than embolization of the lead thrombus. No patients with detected lead thrombus had a history of pulmonary embolism. Similar to our findings, the largest retrospective study to date of 1833 patients undergoing ablation found no difference in clinical outcomes in patients with and without lead thrombi.[3]

Short-term Clinical Outcomes in Patients Undergoing Extraction of Leads with a Thrombus

The majority of patients (90%) with any detected lead thrombi underwent extraction of at least one lead to which a thrombus was attached. In all leads with thrombi that were extracted, extraction was performed using either a laser or mechanical sheath. Theoretically, it is possible that mobile thrombi are sheared off by the extraction sheath during extraction, and may be embolized, although this aspect was not specifically studied. However, no patients with detected lead thrombi acutely developed symptomatic PE after extraction. Our findings may suggest that despite this embolization risk, use of extraction sheaths is associated with minimal acute adverse outcomes. However, our study is underpowered to address this specific question due to low event rates, and our findings must be interpreted in a patient-specific approach.

It is important to note that although there were minimal acute major adverse events in patients with lead thrombi, the long-term effects of thrombi are unknown, particularly with subacute pulmonary thromboembolic disease. In a prospective study by Supple and colleagues of 86 patients undergoing AF or VT ablation,[4] they found a high prevalence of patients (30%) with mobile lead thrombi, and these patients were found to have a higher pulmonary artery systolic pressure by echocardiogram. Similar to our findings, none of their patients had a history of symptomatic clinical pulmonary embolism, and supports the hypothesis that small embolized thrombi may not be acutely hemodynamically significant. However, the long-term effects of thrombi are unknown, and the signal of elevated pulmonary artery pressures may suggest the development of subacute pulmonary thromboembolic disease. Larger studies with longer follow-up in patients with lead thrombi are needed to assess the risk of developing chronic pulmonary thromboembolic disease.

Insights into the Use of Anticoagulation in Patients with Incidentally Discovered Lead Thrombus

The effect of anticoagulation on lead-associated thrombus formation and clinical outcomes remains unclear. Numerous studies indicate that mobile and fixed thrombi can occur on transvenous leads despite patients being anticoagulated.[2-4] The risk of pulmonary and systematic thromboemboli associated with implanted cardiac devices has not shown to be different among patients on anticoagulants.[7-9] Although the majority of lead-associated thrombi can resolve with intensification or initiation of anticoagulation,[2, 6] it is unclear whether anticoagulation improves clinical outcomes in patients with incidentally discovered mobile lead thrombi.

In our study, no patient with an incidentally discovered lead thrombus was started on anticoagulation if they did not have any other indications for anticoagulation such as atrial fibrillation with high CHA_2DS_2VASc score. Although larger, randomized studies are needed to confirm this, these findings suggest that patients with lead thrombi may not need to be anticoagulated. Furthermore, all thrombi detected in our study were 2cm or less, and thus these findings can only apply to patients with small lead thrombi.

Insights into Clinical and Lead Characteristics Associated with Lead Thrombi

There were no significant clinical characteristics associated with thrombus formation, except patient age; more lead thrombi were found in younger patients for an unknown reason. Otherwise, clinical comorbidities such as atrial fibrillation were not associated with lead thrombi, which is consistent with prior prospective studies[1, 4, 10, 11], but inconsistent with one larger retrospective older study that found an association of atrial fibrillation with thrombus.[2] This finding may be due to the fact that contemporary patients with atrial fibrillation are usually appropriately anticoagulated; in our study, 78% of patients with atrial fibrillation were on anticoagulation. Surprisingly, lead thrombi formation was not associated with anticoagulation status, which is consistent with prior studies.[4]

Interestingly, lead characteristics such as number of leads, lead insulation material, cardiac chamber of lead fixation, abandoned lead status and lead age were not associated with mobile thrombus formation on intracardiac transvenous leads. Although there have been small conflicting studies associating certain risk factors associated with venous occlusion in the subclavian veins such as number of leads,[10-12] our findings support the assertion that differences in lead design and configuration may not influence formation of mobile thrombi in the intracardiac portion of transvenous leads. Finally, we found that abandoned leads were not associated with intracardiac lead thrombi formation. These aspects have not been evaluated comprehensively in prior work.

In our unique study population of patients referred for lead extraction, a high percentage of patients (51%) had functional problems with their leads. Despite this, the prevalence of lead thrombi was still generally lower than prior prospective studies, and this supports our finding that lead malfunction is not associated with formation of thrombi. Although overall FDA recall status was not associated with thrombus formation, there was a low number of Riata leads or externalized cables in our study population, in which one would expect higher risk of thrombus formation.[8] Only 6 of the 20 recalled leads were Riata leads or externalized cables, and as expected, a thrombus was detected on high proportion of these leads (N=3, 50%).

Study Limitations:

Several limitations of our study are noted, including the lack of statistical power to detect differences in clinical outcomes, lack of definitive pulmonary imaging and lack of lead thrombi histology. First, although this was the largest prospective study to date, it still lacked statistical power to confidently report no difference in clinical outcomes between patients with and without lead thrombus. Given the small event rate, it would take a study population that is around 15 times our study population to achieve statistical power, which is not feasible for a prospective study. To improve the statistical power of our study, we reported a combined clinical adverse event rate. Out of all retrospective and prospective studies reported in the literature, our study was the 3rd largest, after two retrospective studies[2, 3] with the largest study including 1833 patients, which also found no difference in clinical outcomes between patients with and without lead thrombi, consistent with our findings.

Secondly, our study follow-up did not include routine performance of imaging studies to detect pulmonary embolism for all patients; these studies were only performed in patients who were symptomatic with clinical suspicion for PE. Given the uncertain clinical significance of asymptomatic PE suggested in prior studies,[3, 4] it was felt that these imaging studies were not necessarily indicated and did carry risk, in particular the adverse effects of potentially unnecessary radiation and risks of unnecessary anticoagulation in patients who are asymptomatic. Consistent with our methodology, routine pulmonary imaging was not performed in the other five studies of mobile thrombi in live patients.[1-4, 6]

Thirdly, our study protocol was not designed to retrieve thrombi seen on TEE to verify the presence of thrombus detected on TEE. Despite performing extraction of the leads with thrombus, it was difficult to identify and collect thrombi from the leads during extraction, as they usually were not present on the lead after removal from the extraction sheath. Thus, histologic examination was not possible to elucidate the structure of the thrombus. Although the phenomenon of “ghosts” is well known after a lead extraction procedure, we did not include findings of mobile echogenic material noted after lead extraction. However, this study did not exclude patients that may have undergone prior lead extraction procedures, so visualization of ghosts remains a possibility.

Conclusion

This prospective study identified a high incidence of mobile intracardiac thrombi on transvenous leads in patients. No particular lead characteristic increased risk of thrombi formation. Extraction of these leads with small thrombi was rarely associated with short-term major adverse clinical outcomes despite not starting or intensifying anticoagulation. Larger studies with longer follow-up are needed to assess the long-term clinical effects of incidental lead thrombi.

Perspectives

Clinical Competencies

The findings from this original research report supports lifelong learning skills and enhances several clinical competencies for professional caregivers.

Medical knowledge: This study informs physicians that the incidental finding of thrombus on a transvenous lead can be expected in about 19% of patients presenting for lead extraction, and the careful extraction of leads with small thrombi under 2cm diameter may be performed without acute major sequelae. Furthermore, clinical characteristics or lead characteristics rarely predict formation of lead thrombi.

Patient Care and Procedural Skills: These findings add to the body of medical knowledge a series of patients in whom successful extraction of leads with thrombi has been performed with extraction sheaths without major adverse events. When a clinician encounters clinical scenarios in which thrombi is detected prior to a lead extraction procedure, one can expect a low incidence of acute adverse events. Also depending on the patient, a strategy of not starting anticoagulation for a finding of incidental lead thrombus is not associated with acute adverse events.

Translational Outlook

This study produced several important clinical findings focusing on a specific patient population of lead extraction patients, but the results raise new interesting questions regarding thrombogenicity of transvenous leads. First, although extraction of small thrombi did not seem to be associated with major acute adverse events, the long term effects of incidental lead thrombi are still unknown, such as the development of long-term subacute disease such as chronic thromboembolic pulmonary hypertension (CTEPH). Clinical studies are currently underway to address this particular question. Secondly, this study found that lead thrombi is rather common, consistent with prior studies. There is a paucity of bioengineering and materials science literature assessing factors in lead design that lead to thrombogenicity. Thus, future basic science studies are needed to evaluate improved structural and material lead design to reduce thrombogenicity of transvenous leads, such as lead structure to reduce turbulent flow particularly on uneven lead surfaces and improved biocompatibility of lead insulation material. Thirdly, advancements in technology may provide tools to predict the personalized risk of lead thrombus. Computational modeling of blood flow in the heart and advanced dynamic cardiac imaging could potentially be used to predict where lead thrombi may form; in a similar fashion, these same tools could potentially predict where binding sites may potentially form and cause difficulties for lead extraction.

Author Contributions

Gordon Ho, MD: Drafting article, Concept/design, Data Collection, Data analysis/interpretation, Statistics, Approval of article

Prerana Bhatia, MD: Drafting article, Data Collection, Data analysis/interpretation, Statistics, Approval of article

Ishan Mehta, BS: Data analysis/interpretation, Statistics, Approval of article

Timothy Maus, MD: Concept/design, TEE protocol design/image acquisition and analysis, Critical revision/Approval of article

Swapnil Khoche, MD: TEE protocol design/image acquisition and analysis, Critical revision/Approval of article

Travis Pollema, DO: Data Collection, Critical revision/Approval of article

Victor Gert Pretorius, MBChB: Concept/design, Data Collection, Critical revision/Approval of article

Ulrika Birgersdotter-Green, MD: Concept/design, Data Collection, Data analysis/interpretation, Critical revision/Approval of article

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Figure 1: Examples of Intracardiac Mobile Thrombus Detected by Trans-Esophageal Echocardiography:

Figure 1A shows a modified midesophageal bicaval view demonstrating a large 1.9cm thrombus in the right atrium (RA) affixed to the right ventricular (RV) lead with significant paradoxical movement with the lead. Figure 1B shows a modified midesophageal bicaval view demonstrating a 1.2cm thrombus affixed to the RA lead that moves freely in the right atrium along with the lead, but has a small component with paradoxical motion (yellow arrow). No acute symptomatic pulmonary embolism occurred in these patients.

Figure 2: Lead Functional Status and Extraction Indication:

The proportion of transvenous leads organized by the indication for lead extraction stratified by functioning or malfunctioning status of the lead.

Table 1: Patient Characteristics Analyzed for Association with Thrombus Formation

Patient Characteristics	**Thrombus Present**		**p-value**
	No (n = 88)	**Yes (n = 20)**	
Patient age[a], years	64 ± 14	56 ± 19	0.04
Female	33 (38%)	10 (50%)	0.30
Body mass index[a], Kg/m^2	30 ± 7	27 ± 5	0.08
Co-morbidities			
Atrial fibrillation	30 (34%)	8 (40%)	0.62
Congestive heart failure	50 (57%)	11 (55%)	0.88
Diabetes mellitus	27 (31%)	6 (30%)	0.95
Hypertension	51 (58%)	12 (60%)	0.87
Left ventricular assist device	2 (2%)	0 (0%)	1.00
Prior cerebrovascular accident	6 (7%)	3 (15%)	0.36
Prior myocardial infarction	16 (18%)	3 (15%)	1.00
Left ventricular ejection fraction[a], %	44 ± 15	51 ± 20	0.09
More than one lead	79 (90%)	18 (90%)	1.00
Anticoagulation use			
None	54 (61%)	14 (70%)	0.47
Coumadin or NOAC	34 (38%)	6 (30%)	
Antiplatelet agent use			
None	38 (43%)	12 (60%)	0.29
Aspirin only	39 (44%)	5 (25%)	

Ticagrelor or Clopidogrel	11 (13%)	3 (15%)	
Creatinine[a], mg/dL	1.2 ± 1.2	1.2 ± 1.1	0.82
INR[b]	1.5 ± 0.7	1.2 ± 0.3	0.13
Platelet count[a], x10^3	210 ± 76	233 ± 63	0.19
White blood cell count[a], x10^3	7.1 ± 2.1	7.3 ± 2.4	0.80
Maximum temperature (Tmax)[c], deg	98.0 ± 0.6	98.3 ± 0.5	0.06

[a] Values are expressed as mean ± standard deviation

[b] INR: international normalized ratio

[c] Maximal temperature of the patient in the week preceding the extraction procedure

Table 2: Lead Characteristics Analyzed for Association with Thrombus Formation

	Thrombus Present		
Lead Characteristics	No (n = 208)	Yes (n = 29)	p-value
Lead age[a], years	7.1 ± 5.2	7.9 ± 4.7	0.44
Recalled	17 (8%)	3 (10%)	0.61
Defibrillation coil	55 (26%)	9 (31%)	0.61
Malfunctioning	102 (49%)	18 (62%)	0.19
Completely extracted	149 (72%)	22 (76%)	0.63
Passive fixation (excluding CS leads)[b]	28 (15%)	4 (17%)	0.56
Abandoned lead[c]	6 (3%)	2 (7%)	0.35
Lead chamber			0.39
Right atrium	90 (43%)	9 (31%)	
Right ventricle	100 (48%)	16 (55%)	
Coronary sinus	18 (19%)	4 (14%)	
Insulation material[c]			0.54
Silicone	125 (60%)	13 (48%)	
Polyurethane	37 (18%)	7 (26%)	
Combination	46 (22%)	7 (26%)	
Manufacturer[c]			0.13
Biotronik	31 (15%)	2 (7%)	
Boston Scientific	23 (11%)	2 (7%)	
Guidant	10 (5%)	2 (7%)	
Medtronic	69 (33%)	10 (34%)	
Oscor Medical	3 (1%)	0 (0%)	
Other/Unknown	0 (0%)	2 (7%)	
St Jude Medical	68 (33%)	11 (38%)	

Sorin	4 (2%)	0 (0%)

[a] Values are expressed as mean ± standard deviation

[b] Coronary sinus leads excluded from method of fixation analysis

[c] Two abandoned leads excluded due to lack of identifying information

Table 3: Short-term Clinical Outcomes in Patients with Incidental Lead Thrombi

Clinical Endpoints	Presence of Lead Thrombi No (n = 88)	Yes (n = 20)	p-value
All-cause death	4	0	1
Combined (cardiovascular events)	2	1	0.50
Symptomatic pulmonary embolism	0	0	1
Myocardial infarction	1	0	1
Cerebrovascular event / Transient ischemic attack	1	1	1