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Lead-related infective endocarditis with vegetations: Prevalence and impact of pulmonary embolism in patients undergoing transvenous lead extraction

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Abstract

Introduction: The prevalence and impact of pulmonary embolism (PE) in patients with lead-related infective endocarditis undergoing transvenous lead extraction (TLE) are unknown.

Methods: Twenty-five consecutive patients with vegetations ≥10 mm at transoesophageal echocardiography were prospectively studied. Contrast-enhanced chest computed tomography (CT) was performed before (pre-TLE) and after (post-TLE) the lead extraction procedure.

Results: Pre-TLE CT identified 18 patients (72%) with subclinical PE. The size of vegetations in patients with PE did not differ significantly from those without (median 20.0 mm [interquartile range: 13.0–30.0] vs. 14.0 mm [6.0–18.0], $p = 0.116$). Complete TLE success was achieved in all patients with 3 (2–3) leads extracted per procedure. There were no postprocedure complications related to the presence of PE and no differences in terms of fluoroscopy time and need for advanced tools. In the group of positive pre-TLE CT, post-TLE scan confirmed the presence of silent PE in 14 patients (78%). There were no patients with new PE formation. Large vegetations (≥20 mm) tended to increase the risk of post-TLE subclinical PE (odds ratio 5.99 [95% confidence interval (CI): 0.93–38.6], $p = 0.059$). During a median 19.4 months follow-up, no re-infection of the implanted system was reported. Survival rates in patients with and without post-TLE PE were similar (hazard ratio: 1.11 [95% CI: 0.18–6.67], $p = 0.909$).

Conclusion: Subclinical PE detected by CT was common in patients undergoing TLE with lead-related infective endocarditis and vegetations but was not associated with

Luca Bontempi and Gianmarco Arabia contributed equally to this study.

the complexity of the procedure or adverse outcomes. TLE procedure seems safe and feasible even in patients with large vegetations.

KEYWORDS
ICD, infection, pacemaker, pulmonary embolism, transvenous lead extraction, vegetations

1 | INTRODUCTION

Cardiovascular implantable electronic devices (CIEDs) infective endocarditis is a serious medical complication and is unfortunately on the rise.[1] An endocardial lead represents a foreign body in contact with the circulation and has a tendency to form a thrombus with potential embolization to the pulmonary circulation. A specific sign of infection is the presence of vegetations, which are infected masses observed on the leads by echocardiography. Even if they represent a risk factor for the procedure, transvenous lead extraction (TLE) is an essential intervention, usually achieved by a percutaneous approach using multiple techniques. It is standard practice that patients are treated with antibiotics for a period of time before the procedure, to reduce the size of the vegetations and thus perform TLE under safer conditions.[2] The inherent risk of embolization during extraction could depend on the size of the mass attached to the leads; however, the impact of vegetation size on pulmonary embolism (PE) is not fully elucidated.[3] It is known that lead-related thrombi can embolize to the pulmonary circulation and in most cases result in asymptomatic PE.[4]

We conducted a prospective cohort study of consecutive patients with CIED referred for TLE due to an infective indication with vegetations to evaluate the prevalence of PE assessed by computed tomography (CT) angiography performed before and after lead extraction.

2 | METHODS

In this study, consecutive CIED patients who were referred for TLE at Spedali Civili of Brescia with an infective indication and evidence of vegetations larger than 10 mm at transoesophageal echocardiography were enrolled. Patients gave informed consent and the study was approved by the competent ethics committee. In this cohort of patients, a first contrast-enhanced chest (CT) was performed one day before the TLE (pre-TLE) and another was performed after the procedure (post-TLE) with the objective of confirm persistency or new formation of PE.

TLE was performed with a standard stepwise approach: once the device pocket was opened, the leads were disconnected, and the active fixations, if present, were retracted. Then, manual traction was carried out, sometimes with the use of a locking stylet. If adhesions or fibrosis were present, a powered tool was used, such as a telescopic dilator sheath or a laser sheath. Extractions were defined as simple if removal was obtained applying only manual traction, while they were defined as advanced if it was necessary to proceed with powered tools.[5] After extraction, patients underwent a period of antibiotic prophylaxis and after negative blood culture were re-implanted. In case of pacing-dependent patient, temporary pacing was used before delayed reimplantation or immediate surgical epicardial approach. Patients with documented PE in the pre- or post-TLE CT scan received unfractionated heparin during hospitalization and were discharged on new oral anticoagulants for 3–6 months.

Complete procedural success was defined as the removal of all targeted leads and material. Long-term follow-up data were obtained from routine clinical management of patients to assess mortality and re-infection rates, including visits 7 days after discharge, at 3 months, and then every 6 months.

Continuous variables were expressed with median and interquartile range (IQR), binary or categorical variables as counts and percentages. Baseline characteristics were reported by presence/absence of PE at pre-TLE CT. Comparisons between groups were performed with the Wilcoxon rank-sum test for continuous variables, Pearson's or Fisher's exact test, as appropriate, for binary variables. A 2×2 contingency table was created for the presence of PE at pre- and post-TLE CT, and the McNemar's test was used to test marginal homogeneity. Logistic models were applied to estimate the association of clinical and procedural characteristics with PE. Follow-up data was analyzed with the Kaplan–Meier method and compared between groups with the log-rank test. Statistical significance was defined as $p < 0.05$. All statistical analyses were performed using STATA version 11 software (StataCorp LP).

3 | RESULTS

3.1 | Study population and prevalence of PE before TLE

A total of 25 patients implanted with a pacemaker ($n = 5$), an implantable cardioverter defibrillator (n = 10) or a cardiac resynchronization therapy device ($n = 10$) were included in the study. Pre-TLE CT identified 18 patients (72%) with subclinical PE, while 7 patients (28%) did not have evidence of PE. Table 1 reports the clinical characteristics of all patients of the study cohort. No significant differences were observed between patients with PE and those without (Table 1). The median age was 64 years (IQR: 57–74) and 17 (68%) of them were male. The most prevalent comorbidities were kidney disease (40%) and diabetes (40%). Vegetations were located on the right atrial lead in 15 patients (60%) and on the ventricular lead in 10 patients (40%); 16% had compromised the tricuspid valve. In the largest longitudinal diameter, the median size of vegetations on the endocardial leads was 17.5 mm (IQR: 11.5–29). The maximum size of the thrombotic formation observed in six patients was 30 mm.

TABLE 1 Patients characteristics

	Overall (n = 25)	Presence of PE at pre-TLE CT (n = 18)	Absence of PE at the pre-TLE CT (n = 7)	p Value
Sex, male	17 (68%)	11 (61%)	6 (86%)	0.362
Age (years)	64 (57–74)	63.5 (58–73)	74 (54–78)	0.467
Body mass index (kg/m^2)	26.0 (22.6–28.1)	25.5 (22.3–28.3)	26.0 (23.7–28.0)	0.976
Left ventricular ejection fraction (%)	36 (30–50)	35 (30–50)	39 (30–55)	0.460
Creatinine (mg/dl)	0.9 (0.8–1.6)	0.9 (0.8–1.6)	1.39 (0.9–1.8)	0.132
Medical history				
Atrial fibrillation	8 (32%)	6 (33%)	2 (29%)	1.000
Kidney disease	10 (40%)	6 (33%)	4 (57%)	0.378
Diabetes	10 (40%)	8 (44%)	2 (20%)	0.659
Valvular prosthesis	1 (4%)	1 (6%)	0	1.000
CABG	2 (8%)	2 (11%)	0	1.000
Cardiomyopathy				
None	5 (20%)	3 (17%)	2 (29%)	0.762
Ischemic	9 (36%)	6 (33%)	3 (43%)	0.673
Dilated	8 (32%)	7 (39%)	1 (14%)	0.362
Congenital	3 (12%)	2 (11%)	1 (14%)	1.000
Device types				1.000
PM	5 (20%)	4 (22%)	1 (14%)	-
ICD	10 (40%)	7 (39%)	3 (43%)	-
CRT-P	1 (4%)	1 (6%)	0	-
CRT-D	9 (36%)	6 (33%)	3 (33%)	-
Vegetations				
Size (mm)	17.5 (11.5–29.0)	20.0 (13.0–30.0)	14.0 (6.0–18.0)	0.116
Positive lead culture	8 (32%)	6 (33%)	2 (29%)	1.000
Positive pocket culture	6 (24%)	5 (28%)	1 (14%)	0.637
Previous pocket revision	9 (36%)	6 (33%)	3 (43%)	0.673
Previous TLE	5 (20%)	3 (18%)	2 (33%)	0.576
Number of leads to extract	3 (2–3)	3 (2–3)	3 (1–3)	0.872

Note: Data are reported as median (interquartile range) or number (percentage).

Abbreviations: CABG, coronary artery bypass graft; CRT-P/D, cardiac resynchronization therapy pacemaker/defibrillator; CT, computed tomography; ICD, implantable cardioverter defibrillator; PE, pulmonary embolism; PM, pacemaker; TLE, transvenous lead extraction.

3.2 | Characteristics and outcomes of TLE

Although high TLE-related risk scores (median LED index[6] and MB score[5] of 11 and 5, respectively), all patients underwent successful complete TLE with a median of 3 (2–3) extracted leads.

Overall procedural characteristics and outcomes of TLE are detailed in Table 2. Most patients (76%) needed advanced tools (laser only or combined laser and mechanical approach) to achieve complete success, and two patients required femoral extraction using loop snares. Endovascular occlusion balloon[7] was not used in any procedure, neither for prophylactic purposes nor for urgent need. The median fluoroscopy time was 15.1 [7.2–21.4] min and only one (4%) minor complication consisting of transitorily hypotension was reported. During the procedures, transthoracic echocardiography did not detect embolization. There were no complications after the procedure or symptoms potentially related to the presence of PE. No differences were identified between patients with and without PE at pre-TLE CT (Table 2).

TABLE 2 Overall procedural characteristics and outcomes of TLE

	Overall (*n* = 25)	Presence of PE at pre-TLE CT (*n* = 18)	Absence of PE at the pre-TLE CT (*n* = 7)	*p* Value
Fluoroscopy time (min)	15.1 (7.2–21.4)	15.1 (4.7–23.4)	16.0 (7.2–21.4)	0.666
TLE obtained with				
Simple extraction	6 (24%)	6 (33%)	0 (0%)	0.137
Manual traction without locking stylet	4 (16%)	4 (22%)	0 (0%)	0.294
Manual traction with locking stylet	2 (8%)	2 (11%)	0 (0%)	0.358
Advanced extraction	19 (76%)	12 (67%)	7 (100%)	0.080
Laser sheath only	11 (44%)	6 (33%)	5 (71%)	0.085
Combined (laser and mechanical)	8 (32%)	6 (33%)	2 (29%)	0.819
Femoral approach	2 (8%)	2 (11%)	0 (0%)	0.358
Complete procedural success	25 (100%)	18 (100%)	7 (100%)	-
Partial procedural success	0 (0%)	0 (0%)	0 (0%)	-
Unsuccessful procedure	0 (0%)	0 (0%)	0 (0%)	-
Patients with major complications	0 (0%)	0 (0%)	0 (0%)	-
Patients with minor complications	1 (4%)	1 (6%)	0 (0%)	0.524
Hypotension	1 (4%)	1 (6%)	0 (0%)	0.524

Note: Data are reported as median (interquartile range) or number (percentage).

Abbreviations: CT, computed tomography; PE, pulmonary embolism; TLE, transvenous lead extraction.

3.3 | Post-TLE CT evaluation

Each patient underwent the thoracic CT scan after the procedure. In the group of negative pre-TLE CT (seven patients), no patients developed PE at post-TLE CT. In the group of positive CT pre-TLE (18 patients), post-TLE CT scan confirmed the presence of silent PE in 14 patients in the same lobes of the lungs, while in 4 of them, PE was not detected. Seven (28%) patients were free from PE both at pre- and post-TLE CT scan. Interestingly, there were no patients with new formation or worsening of PE after the extraction procedure. TLE had no significant effect on the presence of PE (McNemar's $p = 0.125$) (Table 3).

At logistic regression analysis, the size of vegetation was the only baseline and procedural variable that showed a tendency to association with the presence of PE after the procedure. Although large vegetations (≥20 mm) were not associated with PE pre-TLE ($p = 0.128$), they tended to increase the risk of silent PE post-TLE by sixfold (odds ratio 5.99 [95% confidence interval (CI): 0.93–38.6], $p = 0.059$).

TABLE 3 Contingency table for assessing pulmonary embolism prevalence before and after transvenous lead extraction (McNemar $p = 0.125$)

	Post-TLE: PE present	Post-TLE: PE absent	Total
Pre-TLE: PE present	14 (56%)	4 (16%)	18
Pre-TLE: PE absent	0 (0%)	7 (28%)	7
Total	14	11	

Abbreviations: PE, pulmonary embolism; TLE, transvenous lead extraction.

3.4 | Long-term follow-up

All patients underwent a period of antibiotic therapy and hospitalized until reimplantation (mean hospital stay, 21.0 ± 10.8 days). After discharge, during a median follow-up of 19.4 months (IQR: 5.8–32.8), there were five deaths (20%): two patients with chronic kidney disease (baseline serum creatinine of 1.6 and 4.07 mg/dl) died of acute kidney injury 78 and 67 days after TLE, two patients of heart failure, and one suffered sudden cardiac death. No reinfection of the implanted system was reported. Survival rates did not differ between patients with post-TLE silent PE as compared to those without (hazard ratio: 1.11 [95% CI: 0.18–6.67], $p = 0.909$). Figure 1 shows the Kaplan–Meier survival curves after TLE.

4 | DISCUSSION

This study has shown that patients with lead-related infective endocarditis and vegetations had a high prevalence of subclinical PE identified by CT that was not associated with acute or long-term adverse outcomes. The second major finding was that the presence of large vegetations tend to increase the risk of post-TLE PE, but the TLE procedure itself does not contribute to their formation or worsening. An overview of the study is reported in Figure 2.

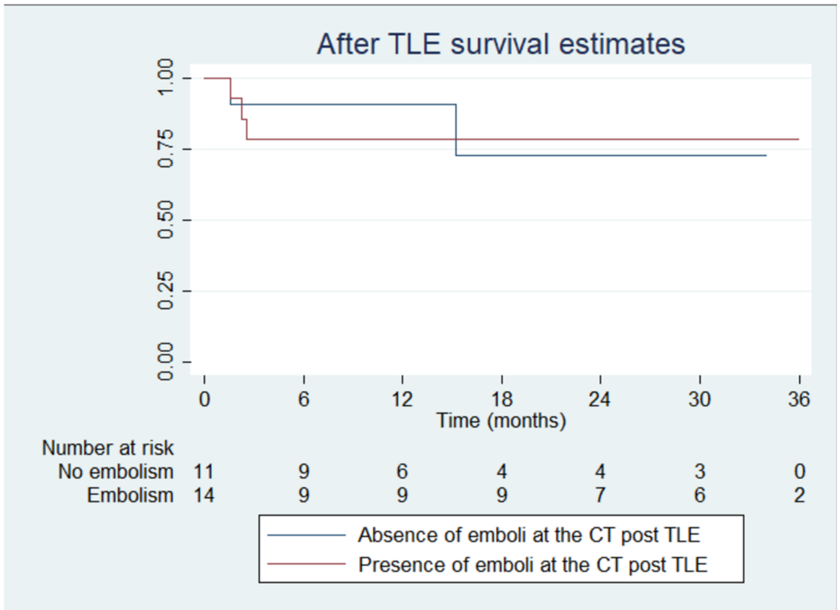

FIGURE 1 Kaplan–Meier survival curves for all-cause death after transvenous lead extraction by the presence of pulmonary emboli at postprocedural computed tomography.

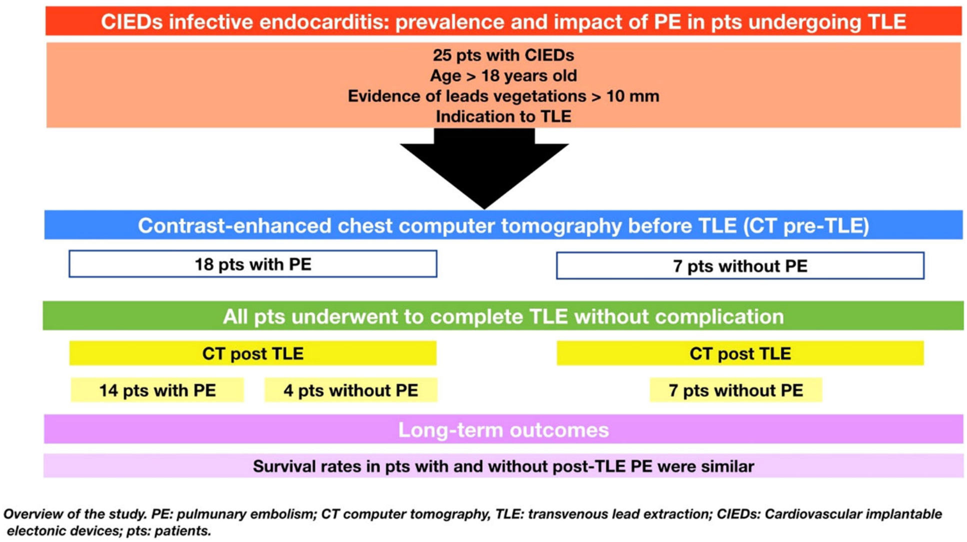

FIGURE 2 Overview of the study

The occurrence of symptomatic or clinically relevant PE is a known complication of TLE.[4,8,9] Symptoms associated with PE are dyspnea, tachycardia, and tachypnea, but devastating outcomes, including abscess formation, refractory sepsis, or death, have also been reported in the case of massive thrombi. Published data suggest a relatively low incidence of such events ranging between 0.24% and 0.59%.[10] However, the real incidence of silent PE in these patients is unknown. Lead-related thrombi have been known to dislodge into the pulmonary circulation and potentially lead to subclinical PE in a high percentage of patients, especially those without heparin prophylaxis.[11] This mechanism has also been suggested by increased pulmonary artery systolic pressure.[12] Data from autopsies reported asymptomatic PE in 8%–10% of CIED patients,[13,14] but the incidence in the case of lead-related infective endocarditis is expected to be much higher. In this study, we recruited patients with lead-related infective endocarditis with vegetations greater than 10 mm and, therefore, considered at high risk of embolization of the thrombi and development of subclinical PE. For the first time, a systematic evaluation was performed by contrast-enhanced thoracic CT that showed evidence of PE in 72% of patients. From these data, we can speculate that embolism of lead-related thrombi in patients with vegetations is common, but emboli are often too small to cause consequential pulmonary infarction and clinically relevant symptoms. Furthermore, we observed that the presence of subclinical PE did not increase procedural risks or survival rates in long-term follow-up. The potential impact of different diagnostic tools on the therapeutic care pathway of patients with lead endocarditis has recently been suggested by a pilot study that investigated the role of 18-fluorodeoxyglucose positron emission tomography scanning and identified septic emboli, mainly clinically silent, in 29% of patients.[15] Our study does not recommend the systematic use of an advanced diagnostic tool before TLE, as a careful assessment of preoperative echocardiogram and fluoroscopy with venography can provide many information to plan a safe and effective procedure.[10,16] However, the specific design of our study that includes a post-TLE CT scan can add some interesting information on this topic. We observed a tendency toward an increased risk of post-TLE PE in patients with vegetations larger than 20 mm. Consistent with the literature on clinical PE,[4] we did not observe any association with baseline clinical or device-related characteristics, even if the low power of our study limits our ability to draw conclusions on PE predictors. Interestingly, there were no patients with new formation or worsening of PE after the extraction procedure.

The management of large vegetations remains a controversial issue, and the expert consensus statement of the 2017 Heart Rhythm Society expert consensus statement included large lead messes (>2.5 cm) among the reasons to justify the morbidities associated with open heart surgery.[10] However, there are no specific rules for the size of a vegetation before a decision is made to remove the leads and vegetation with open surgical techniques, and there are several factors to be considered when making this decision (e.g., presence or absence of a patent foramen ovale, prior extraction procedure, other surgical indications and goals, health or hemodynamic instability of the patient, pacemaker dependency, plans for reimplantation). Percutaneous vacuum-assisted aspiration is an alternative option that has recently been proposed to debulk and remove vegetations and thrombi before and/or during TLE. Some case reports and preliminary observational studies showed a high success rate with a low complication rate.[17] Thrombolytics have also been used to reduce vegetation size in patients with CIED-associated infective endocarditis.[18] A growing body of literature indicates that patients with large vegetations who have historically been referred for surgical lead extraction can be treated less invasively with the hybrid surgical approach,[19,20] but also using TLE techniques.[21,22] In this study, the percutaneous lead extraction in 25 patients with significant vegetations (median diameter 17.5 mm; IQR: 11.5–29.0) was safe and feasible. After extraction, patients underwent a period of antibiotic therapy and new CIEDs were implanted after consultation with a specialist in infectious diseases and negative blood cultures. No reinfection of the implanted system was reported. In the literature, 1-year mortality has been reported to be higher among patients with endovascular infection compared with patients with pocket infection, but this increase in mortality seems not related to the presence of vegetations.[23] Although, in this study, TLE of infected leads with large vegetations appears feasible in a high-volume center, our data are not statistically solid enough to provide evidence-based lead extraction recommendations in this special patient population. The choice of the optimal extraction approach should always be personalized to patient characteristics and should also include a detailed patient informed consent to review all potential risks of the different procedures.

This prospective cohort study has limited power to study associations of predictors with PE outcomes due to a limited number of patients. We characterized the vegetations based on the largest dimension observed on transoesophageal echocardiogram, while the shape of the masses, which has recently been proposed as a risk stratification factor,[8] was not evaluated. We did not also quantify the size of the detected PE. Since the formation and dissolution of lead-related thrombi in vivo is a dynamic process, it is difficult to definitively establish a causal link between these thrombi and the occurrence of PE events in patients with CIED leads.

5 | CONCLUSIONS

In this study, subclinical PE detected by CT was common in patients undergoing TLE with lead-related infective endocarditis and vegetations, but it was not associated with procedure complexity, and acute or long-term adverse outcomes. TLE procedure did not contribute to the formation or worsening of PE and seems safe and feasible even in patients with large vegetations.

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DATA AVAILABILITY STATEMENT

The data underlying this article will be shared on reasonable request to the corresponding author.

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