Echo for Infected Electrical Devices

Usefulness of Intracardiac Echocardiography for the Diagnosis of Cardiovascular Implantable Electronic Device—Related Endocarditis

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Objectives

The goal of this study was to compare transesophageal echocardiography (TEE) and intracardiac echocardiography (ICE) for the diagnosis of cardiac device-related endocarditis (CDI).

Background

The diagnosis of infective endocarditis (IE) was established by using the modified Duke criteria based mainly on echocardiography and blood culture results. No previous studies have compared ICE with TEE for the diagnosis of IE.

Methods

We prospectively enrolled 162 patients (age 72 ± 11 years; 125 male) who underwent transvenous lead extraction: 152 with CDI and 10 with lead malfunction (control group). Using the modified Duke criteria, we divided the patients with infection into 3 groups: 44 with a "definite" diagnosis of IE (group 1), 52 with a "possible" diagnosis of IE (group 2), and 56 with a "rejected" diagnosis of IE (group 3). TEE and ICE were performed before the procedure.

Results

In group 1, ICE identified intracardiac masses (ICM) in all 44 patients; TEE identified ICM in 32 patients (73%). In group 2, 6 patients (11%) had ICE and TEE both positive for ICM, 8 patients (15%) had a negative TEE but a positive ICE, and 38 patients (73%) had ICE and TEE both negative. In group 3, 2 patients (3%) had ICM both at ICE and TEE, 1 patient (2%) had an ICM at ICE and a negative TEE, and 53 patients (95%) had no ICM at ICE and TEE. ICE and TEE were both negative in the control group.

Conclusions

ICE represents a useful technique for the diagnosis of ICM, thus providing improved imaging of right-sided leads and increasing the diagnostic yield compared with TEE. (J Am Coll Cardiol 2013;61:1398–405) © 2013 by the American College of Cardiology Foundation

The incidence of infection of cardiac rhythm devices has been reported in 0.8% to 19.9% of patients with a previous cardiac device implantation (1–4). The complete removal of all hardware is the recommended treatment for patients with established cardiovascular implantable electronic device infection (5). The main indications for lead removal

are cardiovascular implantable electronic device-related endocarditis, local device infection (LDI), and lead malfunction. In particular, the incidence of cardiovascular

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implantable electronic device-related endocarditis ranges from 20% to 25% of all device-related infections, as described in recent studies (6-8).

In clinical practice, the diagnosis of infective endocarditis (IE) is established by using the modified Duke criteria based on clinical and imaging diagnosis; transesophageal echocardiography (TEE) may be a useful tool in this clinical setting (9,10). However, the diagnosis of IE can be particularly challenging in cases with prosthetic valves or pacemaker leads, even with the use of TEE (11-13). These structures can cause acoustic shadowing and reverberation artifacts, limiting the detection of infective vegetations. The main limitation is the inability to obtain high-resolution images due to the large distance between the transesophageal probe and the right ventricle (far-field limitation) (14). Because of the increased morbidity and mortality due to a delayed diagnosis of IE, the current European Society of Cardiology (ESC) (9) and American Heart Association (AHA) (10) guidelines recommend repeat TEE examinations in cases of high clinical suspicion of IE if any initial echocardiographic findings are negative. Moreover, the original or modified Duke criteria do not specifically address the diagnosis of cardiac device-related IE (9,10). As proposed by Sohail et al. (2,7), the presence of lead vegetation and clinical evidence of LDI could be considered major criteria for the diagnosis of cardiac device-related IE.

Recently, intracardiac echocardiography (ICE) was reported to be useful for the diagnosis of intracardiac vegetation when there is a high clinical suspicion of IE and a negative TEE (15,16), but these 2 diagnostic tools have not yet been directly compared. We designed this prospective observational study in patients subjected to transvenous lead extraction to test initial findings regarding the accuracy of ICE compared with standard TEE in the diagnosis of intracardiac masses (ICM).

Methods

Study population and procedural management. We prospectively enrolled 162 consecutive patients (mean age 72 ± 11 years; 125 male) referred to our center from January 2006 to January 2012 for transvenous lead extraction: 152 patients with cardiac device–related infection and 10 patients with lead malfunction (control group). At admission, 68 patients (42%) had an LDI, 63 patients (39%) had LDI and sepsis, and 21 patients (13%) had a diagnosis of sepsis with no evidence of LDI. All clinical data were accurately collected for all patients. Collected data included previous hospital admissions and device implantation, cardiovascular risk factors, pharmacological therapy, clinical presentation related to device infection, echocardiographic parameters, and all procedural data. Blood, swab, and lead-tip cultures were obtained in a sterile manner (5).

All patients underwent transvenous lead extraction, as described previously (17), following the latest Heart Rhythm Society consensus document recommendations (5),

and no surgical lead extractions were performed in these patients.

TEE was performed before transvenous lead extraction on the same day, while ICE was performed right before starting the procedure and ICE monitoring was continued throughout the procedure. Offline TEE and ICE images were presented independently and in randomized order to 2 expert interpreters.

The study was approved by the institutional review board, and all patients gave their written informed consent.

Abbreviations and Acronyms

AHA = American Heart

ESC = European Society of Cardiology

ICE = intracardiac echocardiography

ICM = intracardiac masses

 $\mathbf{IE} = \mathbf{infective}$ endocarditis

LDI = local device infection

TEE = transesophageal echocardiography

Definitions of IE. IE was defined according to the modified Duke criteria, following the current guidelines (9,10). A diagnosis of "definite" IE was defined as the presence of either 2 major criteria or 1 major and 3 minor criteria (group 1 patients); a diagnosis of "possible" IE was defined as the presence of either 1 major and 1 minor criteria or 3 minor criteria (group 2 patients); a diagnosis of IE was "rejected" in patients who did not meet the aforementioned criteria for IE (group 3 patients). Moreover, as proposed by Sohail et al. (2,7), the diagnosis of definite cardiac device—related IE was obtained in patients with echocardiographic evidence of lead vegetations (without using ICE for the diagnosis of IE) and clinical evidence of LDI.

Finally, due to the lack of a gold standard for the diagnosis of IE, we used both the different criteria (Duke and Sohail) for the diagnosis of IE, to extract from our population with infection a larger number of patients with a definite diagnosis of IE.

Transesophageal echocardiography. TEE was performed in all patients in a fasting state for more than 4 h (18). We assessed TEE by using a 5-MHz phased multiplane probe transducer (Philips, iE 33, Andover, Massachusetts) mounted on a flexible monoplane probe connected to a Toshiba Medical System (Artida 2D, Toshiba Medical System, Tokyo, Japan). The pacemaker/defibrillator leads and tricuspid valve leaflets were imaged from the 4-chamber projection, frontal long-axis view of the coronary sinus, and gastric short-axis view. ICM were defined as discrete, echogenic, floating masses found on a valve, lead, or endocardial surface.

Intracardiac echocardiography. ICE (19,20) was performed by using a 10-F probe AcuNav (Siemens Medical Solutions distributed by Biosense Webster, Diamond Bar, California) or 10-F probe SoundStar (Biosense Webster), advanced through a femoral vein percutaneous access in the setting of the extraction procedure, which was performed on the same day as the TEE. These catheters were equipped with a linear phased array multifrequency (5.5 to 10 MHz) transducer, and this was connected to a Sequoia system (Acuson Corporation, Mountain View, California). The

catheter was initially positioned in the inferior vena cava to overview the leads along the right chambers; it was successively advanced in the right atrium and rotated to visualize all the atrial lead segments including the appendage. It was then advanced in the superior vena cava and brachiocephalic vein, and finally it was curved and advanced into the right ventricle for a better visualization of the lead segments localized under the tricuspid valve plane and in the ventricle. ICM suggestive for vegetation were defined as discrete, echogenic, floating masses found on a valve, lead, or endocardial surface. Moreover, ICE was used during the extraction procedure for the identification of procedure-related complications.

Statistical analysis. The homogeneity of variances was assessed by using the Levene test. All variables had a normal distribution, as assessed according to the Kolmogorov-Smirnov test, and were compared by using the unpaired Student *t* test. The Fisher exact test was used to compare categorical variables. Correlations between data were calculated by using the Pearson and Spearman correlation coefficient.

Data are reported as mean \pm SD or proportions. A 2-tailed p value <0.05 was considered statistically significant. These data were analyzed by using SPSS version 17.0 (SPSS Italia, Inc., Florence, Italy). A Bland-Altman plot was used to analyze the agreement between TEE and ICE methods in evaluation of the maximum length of ICM. The Bland-Altman plot was calculated by using MedCalc 12.1.4 (MedCalc Software, Ostend, Belgium).

Results

Study population and procedural data. Patients' characteristics are reported in Table 1. In 96 patients (60%), the implanted device was a pacemaker (15 of 96 [16%] single lead atrial-triggered ventricular pacemaker; 58 of 96 [60%] dual-chamber; 14 of 96 [15%] biventricular; 9 of 96 [9%] VDD); in the remaining 66 patients (40%), the device was an implantable cardioverter-defibrillator (22 of 66 [33%] single-chamber; 14 of 66 [21%] dual-chamber; 30 of 66 [46%] biventricular). In the group of patients with infection, 78 patients (51%) had fever present at admission, and 133 patients (88%) were already receiving antimicrobial prophylaxis before admission because of fever or clinical evidence of LDI.

In terms of the patients with cardiac device—related infection, 44 patients (29%) with a definite diagnosis of IE were included in group 1; 52 patients (34%) with a possible diagnosis of IE were included in group 2; and 56 patients (37%) without a diagnosis of IE were included in group 3. **Microbiological data.** Bacteriological data regarding the 152 patients with infection are summarized in Table 2. Blood culture results were positive in 52 patients (34%), swab culture results were positive in 115 patients (75%), and lead-tip culture results were positive in 80 patients (53%). Coagulase-negative staphylococci and *Staphylococcus aureus* were the most common bacteria in positive blood culture

Table 1	Clinical Characteristics of the 162 Stu	udy Patients			
Male		125 (77)			
Mean age (72 ± 11				
Transvenou	s lead placement indication				
Sinus noo	39 (24)				
Atriovent	43 (26)				
Primary p	16 (10)				
Secondar	Secondary prevention of sudden death				
CRT-D/P	CRT-D/P				
Type of dev	ice				
Pacemak	er	82 (51)			
Implanta	ble cardioverter-defibrillator	36 (22)			
CRT-P		14 (9)			
CRT-D		30 (18)			
Transvenou	s lead extraction indication				
Local dev	ice infection	68 (42)			
Local dev	ice infection and sepsis	63 (39)			
Sepsis		21 (13)			
No. of device	No. of device-related procedures before extraction				
First impl	First implantation				
<3 proce	dures	44 (27)			
≥3 proce	dures	38 (24)			
Comorbidity	1				
Heart fail	Heart failure				
Heart fail	Heart failure with EF <30%				
Diabetes	Diabetes				
Hypertens	Hypertension				
Creatinin	Creatinine clearance < 60 ml/min/1.73 m ²				
Hemodia	lysis	7 (4)			
Coronary	Coronary artery disease				
Coronary	Coronary artery disease with EF $<$ 30%				
	Valvular prosthesis				
	Chronic obstructive pulmonary disease				
	Left ventricular ejection fraction				
Medical therapy					
Angiotens	76 (47)				
Angiotens	22 (14)				
Beta-bloc	100 (62)				
Antiaggre	92 (57)				
Diuretics	64 (39)				
Statins	90 (56)				
Antiarrhy	25 (15)				
Oral antic	47 (29)				

Values are n (%) or mean \pm SD.

 $\label{eq:crt-def} \text{CRT-D/P} = \text{cardiac resynchronization therapy with/without defibrillator backup; EF} = \text{ejection fraction}.$

results (26 patients [50%] and 16 patients [31%], respectively) and in positive swab culture results (70 patients [60%] and 66 patients [57%]), followed by Gram-negative bacilli (9 patients [17%] in blood culture and 22 patients [19%] in swab culture) and fungi (2 patients [4%] and 2 patients [2%] in blood culture and swab culture). The most common microorganism isolated from lead-tip cultures was coagulase-negative staphylococci (38 patients [47%]), followed by other Gram-positive bacilli (24 patients [30%]), Gram-negative bacilli (20 patients [25%]), and *S aureus* (11 patients [14%]).

Table 2	Microbiological Data of the 152 Patients With Infection		
Positive blo	52 (34)		
Polymicro	1(2)		
Staphylod	16 (31)		
Coagulas	26 (50)		
Other Gra	2 (4)		
Gram-neg	9 (17)		
Fungal	2 (4)		
Positive swa	115 (75)		
Polymicro	56 (49)		
Staphylod	66 (57)		
Coagulas	70 (60)		
Other Gra	6 (5)		
Gram-neg	22 (19)		
Fungal	Fungal		
Positive lea	Positive lead-tip culture result		
Polymicro	7 (9)		
Staphylod	11 (14)		
Coagulas	38 (47)		
Other Gra	24 (30)		
Gram-neg	Gram-negative		
Fungal	7 (9)		

Values are n (%).

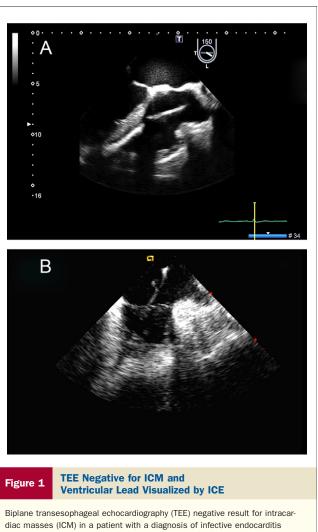
Echocardiographic data. The Levene test confirmed the homogeneity of our study population (p = 0.21). In group 1 (definite IE), ICE identified ICM in all 44 patients (100%), whereas TEE identified ICM in 32 patients (73%). In group 2 (possible IE), 6 patients (11%) had ICE and TEE both positive for ICM, 8 patients (15%) had a negative TEE but an ICE finding of ICM, and 38 patients (73%) had ICE and TEE both negative for ICM (p < 0.001). In group 3 (rejected IE), 2 patients (3%) had ICM both at ICE and TEE, 1 patient (2%) had ICM at ICE but not at TEE, and 53 patients (95%) had no ICM at both ICE and TEE (p = 0.02) (Table 3). ICE and TEE were both negative for ICM in the group of patients with lead malfunction (control group).

Furthermore, by using both the modified Duke and Sohail criteria, we extracted from the population with infection a larger number of patients with a definite diagnosis of IE (58 patients [38%]). In this group, ICE still identified the presence of ICM in all 58 patients (100%),

Table 3	Echocardiographic Data Related to the Duke and Sohail Criteria					
		TEE		ICE		
Criteria		Negative	Positive	Negative	Positive	
Duke definite		12 (27)	32 (73)	0	44 (100)	
Duke possible		46 (88)	6 (12)	38 (73)	14 (27)	
Duke rejected		54 (96)	2 (4)	53 (95)	3 (5)	
Duke definite and Sohail		20 (35)	38 (65)	0	58 (100)	

Values are n (%)



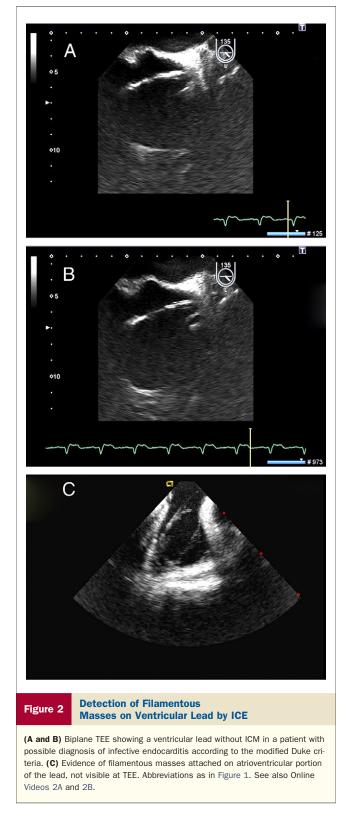


diac masses (ICM) in a patient with a diagnosis of infective endocarditis according to both modified Duke and Sohail criteria. (B) Evidence of an echodense mass attached to the atrial portion of the lead, not visible at TEE. ICE = intracardiac echocardiography. See also Online Videos 1A and 1B.

whereas TEE identified the presence of ICM in 38 patients (65%) (Figs. 1A and 1B, Online Videos 1A and 1B).

Moreover, among the 20 patients with negative TEE but an ICE finding of ICM, 16 (80%) had ICM on the ventricular lead in the tricuspid valve plane in 3 patients (Figs. 2A, 2B, and 2C, Online Videos 2A and 2B); 2 patients (10%) had ICM on the atrial portion of the ventricular lead, also involving the tricuspid valve; 1 patient (5%) had ICM on the ventricular lead within the right ventricle; and 1 patient (5%) had ICM on the atrial lead (Table 4).

In all 3 groups of patients with infection, ICE identified larger ICM compared with TEE (mean maximum length 16 ± 9 mm vs. 11.5 ± 7 mm, respectively; p=0.02) (Fig. 3A), with precise assessment of filamentous masses (Online Videos 3A, 3B, 3C, and 3D). The mean maximum length of ICM identified at ICE was lower in the group with negative TEE compared with the group with positive TEE (8 ± 3 mm vs. 20 ± 9 mm, respectively; p<0.001) (Fig. 3B). Furthermore, no significant differences were found among the 3



groups of patients with regard to the mean maximum length of ICM identified at ICE (17.6 \pm 10 mm in group 1; 11 \pm 7 mm in group 2; 15.7 \pm 7.5 mm in group 3; p = 0.09).

A statistically significant correlation was found between the maximum length of ICM values assessed by TEE and ICE (r = 0.95; p < 0.001). The Bland-Altman plot showed agreement between TEE and ICE methods in the evaluation of the maximum length of ICM, as reported in Figure 4. Considering TEE as a gold standard for the diagnosis of ICM, ICE had a sensitivity of 100%, a specificity of 82.8%, a positive predictive value of 65.6%, and a negative predictive value of 100%.

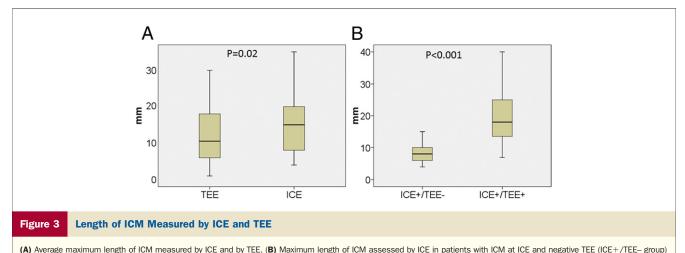
In our study population, no lead-related masses were found in the superior vena cava or brachiocephalic vein. Regarding the procedure-related complications, ICE was also able to identify mild pericardial effusions in 2 (1.2%) of 152 patients after lead extraction, without the need for drainage.

Discussion

In this study, we directly compared for the first time the diagnostic yield of ICE versus TEE in the detection of ICM suggestive for vegetation in patients undergoing lead extraction for cardiovascular implanted electronic device-related infection. The main findings of our feasibility study are: 1) ICE shows high diagnostic accuracy in the detection of ICM among patients with a definite diagnosis of cardiac device-related IE; 2) in patients with a clinical suspicion of device-related IE undergoing transvenous lead extraction, ICE provides a significantly higher diagnostic power for the detection of ICM compared with TEE; 3) in the group of patients with a high risk of device-related IE according to the modified Duke criteria and the new, not standardized, Sohail criteria, ICE was still able to successfully identify more patients with ICM compared with TEE; and 4) the

Table 4	Localization and Dimension of Intracardiac Masses in Patients With Positive ICE and Negative TEE				
Case #	Maximum Length (mm)	Vegetation Localization on Lead	Valvular Endocarditis		
1	15	VL-TV plane	_		
2	15	VL-TV plane	_		
3	10	AL-A tract	_		
4	12	VL-TV plane	_		
5	11	VL-A tract	Tricuspid		
6	10	VL- V tract	_		
7	4	VL-TV plane	Tricuspid		
8	8	VL-TV plane	Tricuspid		
9	7	VL-TV plane	_		
10	9	VL-A tract	Tricuspid		
11	7	VL-TV plane	Tricuspid		
12	6	VL- TV plane + V tract	_		
13	8	VL-TV plane	_		
14	6	VL-TV plane	_		
15	8	VL-TV plane	_		
16	6	VL-TV plane	_		
17	6	VL-TV plane	_		
18	4	VL-TV plane	_		
19	5	VL-TV plane	_		
20	8	VL-TV plane	_		

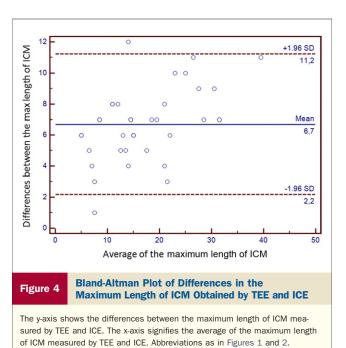
A=atrial; AL=atrial lead; TV=tricuspid valve; V=ventricular; VL=ventricular lead; other abbreviations as in Table 3.



and in patients with ICM both at ICE and TEE (ICE+/TEE+ group). Abbreviations as in Figures 1 and 2. See also Online Videos 3A, 3B, 3C, and 3D.

size of ICM measured at ICE was directly correlated to the size at TEE, although ICE was able to identify significantly larger ICM compared with TEE.

TEE plays a major role in the diagnosis of IE, as reported by the current ESC and AHA guidelines (9,10), and most studies regarding lead extraction for cardiac rhythm management device infection use this method for the diagnosis of intracardiac vegetations (4,6,8,17). However, atypical or doubtful results have been obtained by using this method, particularly in the early stage of the disease and in patients with intracardiac devices (11,14). In particular, TEE sensitivity for the diagnosis of intracardiac vegetations is suboptimal because a falsenegative result on echocardiogram may be observed in about 15% of patients (9). The most frequent explanations for a negative TEE are small intracardiac vegetations, vegetations



localized on cardiac valves with severe lesions (e.g., mitral valve prolapse and degenerative lesions), nonfloating and/or atypically located ICM, an early stage of the disease when vegetations are not yet present, and the presence of prosthetic valves or cardiac device leads (9–14). In particular, with regard to prosthetic valves and cardiac device leads, these structures may cause acoustic shadowing and reverberation artifact, which can limit the detection of vegetations (11–13). Moreover, due to the large distance between the echocardiographic probe and the tricuspid valve plane (far-field limitation), TEE may provide limited information and not visualize all tricuspid valve leaflets simultaneously (12–14).

In our population, TEE failed to detect ICM when they were located on the right ventricle lead crossing the tricuspid valve. Several studies have reported suboptimal assessment of pacemaker leads and tricuspid valve with TEE due to their anterior location within the heart, far from the TEE transducer (11–15). In these cases, ICE may provide better imaging of right-sided structures prosthetic devices (16).

The current ESC and AHA guidelines suggest performing TEE for the diagnosis of IE due to its lower costs and feasibility (9,10), but our data showed that ICE, although an invasive tool, may reach a higher diagnostic yield, thus representing a valid option for overcoming some limitations linked to TEE. In fact, we found that ICE could detect vegetations in a larger number of high-risk patients compared with TEE, as well as when IE was suspected on the basis of extended criteria (including clinical and echocardiographic data). In particular, ICE had greater sensitivity for detecting small ICM localized in cardiac areas that are not easily scanned from TEE, such as the atrio-ventricular part of the right ventricular lead and the tricuspid valve. These results could be explained by the major resolution power of the intracardiac probe (9 MHz vs. 5 MHz) and its shorter distance from the leads and the tricuspid valve, as well as by the chance to freely orient the probe in any direction within the heart. Moreover, in patients with a diagnosis of ICM

established by TEE, ICE confirmed the presence of ICM but revealed larger sizes of the ICM themselves.

An important issue is the lack of a gold standard to confirm the diagnosis of IE (e.g., a tissue specimen). Considering TEE as a gold standard, ICE has a high sensitivity (100%) but a lower specificity (82.8%). A false-positive diagnosis of IE might occur in several situations; for example, it may be difficult to differentiate between IE and thrombi, prolapsed cusp, cardiac tumors, myxomatous changes, Lambl's excrescences, strands, or noninfective vegetations (marantic endocarditis) (9–14). Moreover, a recent study reported that ICE also identified ICM in patients undergoing ablation without an infective process (21). However, even though it cannot be completely proven that all apparent ICM are really of infectious origin, the combination of ICE data, modified Duke and Sohail criteria, and microbiological data allow us to feel confident in considering most ICM as infective.

Furthermore, Bongiorni et al. (22) first described the potential applications of ICE during lead extraction procedures, reporting that ICE was helpful both in evaluating the procedural risk stratification (localization of cardiac leads and fibrous adherences, relationship of leads with venous wall and cardiac structures, and presence of thrombosis or lead endocarditis) and in the identification of procedurerelated complications (vessel or cardiac wall tear). Compared with this study in which a mechanical rotational probe was used, our study used a phased array technology echo probe, which has more advantages in terms of resolution and deeper penetration and thus allows better assessment of all cardiac structures. Furthermore, our study demonstrated that ICE was helpful not only for the procedural risk stratification and the identification of procedure-related complications, but it was also a valuable tool for the diagnosis of device-related IE.

In the scientific literature, only a few case reports have assessed the role of ICE in detecting intracardiac vegetations (16,19–21). Our data suggest that, because small ICM (especially involving cardiac devices) may be difficult to diagnose with TEE, when the clinical suspicion of IE is high, ICE may be a valuable tool in confirming or rejecting the diagnosis of ICM. Furthermore, its greater cost and invasiveness compared with TEE could be justified, especially if we consider that reported mortality rates of cardiac device—related endocarditis range from 31% to 66% if the infected device is not removed, and 18% or less with a combined approach consisting of complete device removal and antimicrobial therapy (5,9,10).

Study limitations. The main limitation of this study is the lack of a gold standard (e.g., a tissue specimen) to confirm diagnosis of IE. Moreover, we did not perform an outcome or a cost-effective analysis of ICE; however, the use of ICE during lead extraction procedures can also be justified by safety reasons while performing such an invasive and potentially dangerous procedure, as stated by other authors (22).

Conclusions

In patients with a clinical suspicion of cardiovascular implantable electronic device—related IE undergoing transvenous lead extraction, ICE showed a higher diagnostic power in detecting ICM suggestive of vegetations compared with TEE. ICE may be a valuable tool in confirming or rejecting the diagnosis of device—related IE in patients with high clinical suspicion of IE and a negative result on TEE.

Further investigations are needed to assess the role of ICE in the clinical outcome of these patients and the cost-effectiveness of this new tool.

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Key Words: infective endocarditis ■ intracardiac echocardiography ■ transesophageal echocardiography ■ transvenous lead extraction.