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Incidence, Risk Factors, and Outcome of Traumatic Tricuspid Regurgitation After Percutaneous Ventricular Lead Removal

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Objectives This study sought to evaluate the incidence, risk factors, and outcome of traumatic tricuspid regurgitation (TTR) induced by percutaneous removal of chronically implanted transvenous leads.

Background Although lead removal using modern tools has been shown to be highly effective and safe, TTR has not been systematically evaluated.

Methods All patients undergoing ventricular lead removal at our center were studied. Lead removal was performed by simple traction, laser sheath, and/or lasso technique. Presence of a new TTR after removal was assessed by transthoracic echocardiography. Pre-defined clinical and technical parameters were studied for their association with TTR. Patients were followed up by outpatient visits.

Results We removed 237 ventricular leads in 208 patients. Median time from lead implantation was 46.4 months (range 0.7 to 260.5 months). A TTR occurred in 19 patients (9.1%), severe in 14. Three independent risk factors of TTR were found: use of laser sheath ($p = 0.004$), use of both laser sheath and lasso ($p = 0.02$), and female sex ($p = 0.02$). After a follow-up of 4,130 person-months (median 17.9 months), 5 TTR patients were medically treated for new right-sided heart failure symptoms, 2 had undergone surgical repair of the tricuspid valve, and 6 had died (2 from heart failure and 4 from noncardiac causes). Right-sided heart failure occurred only in patients with severe TTR.

Conclusions This study found that TTR is not uncommon after percutaneous lead removal. It is strongly associated with the use of additional tools beyond simple traction and also with female sex. In the long term, right-sided heart failure is frequent in patients with severe TTR. (J Am Coll Cardiol 2009;53:2168–74) © 2009 by the American College of Cardiology Foundation

The number of patients with permanent pacemakers or implantable cardioverter-defibrillators (ICDs) has increased markedly over the last 20 years (1,2). Therefore, an increasing number of lead removal procedures are required. Because manual traction is often ineffective for removal of leads implanted for a long time, percutaneous lead removal tools have been developed (3,4). They have been shown to be highly effective, although large-scale studies have emphasized a small risk of major complications possibly associated with their use, mainly cardiac tamponade or vessel laceration (5,6). Other complications that do not carry an immediate risk for the patients have not been thoroughly evaluated. Because the fibrous attachments to surrounding structures involve the tricuspid valve, valvular damage may be provoked by lead removal. Indeed, traumatic tricuspid regurgitation (TTR) was occasionally described once percutaneous lead removal had been performed using various techniques (6–9). It was mainly recognized because of severe clinical consequences and has not been systematically evaluated in large series to date. Little is known about this complication in the era of modern percutaneous lead removal.

Our hypothesis was that TTR might occur in a significant number of patients after percutaneous removal of ventricular leads and that it may be influenced by patient-related or technical factors. We designed a prospective single-center study to evaluate the incidence, risk factors, and outcome of TTR induced by percutaneous lead removal procedures performed with modern tools.

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Methods

Patient population. We included in the study all of the consecutive patients from whom at least 1 ventricular lead was

removed percutaneously at our center between May 2003 and April 2008. Patients who had experienced a previous lead removal procedure, either successful or not, were not included in the study. Patients were informed about the study and gave written consent. The study was approved by the ethics committee of our academic hospital.

Lead extraction technique. All removal procedures were performed in the operating room or the electrophysiology laboratory, under general anesthesia or heavy sedation. The procedures were performed by 3 experienced operators (J-C.D., F.F., X.A.). Our stepwise approach for lead removal was as follows: 1) When the lead was long enough to be reached from the device pocket, gentle traction was applied on the lead from the pocket. For leads implanted more than 6 months prior, the traction was performed after introduction of a locking stylet into the lead lumen (LLD, Spectranectics, Colorado Springs, Colorado). 2) When removal by simple traction was not successful, we used at least 1 of the following tools: laser sheath (SLS II, Spectranectics) or lasso (either Amplatz Goose Neck Snare kit, ev3 Inc., Plymouth, Minnesota, or Needle's Eye Snare Retrieval Set, Cook, Leechburg, Pennsylvania). The choice between these tools was left to the operator, lasso techniques being mainly used when the lead had been detached from the endocardium by traction, or was too short for being extracted from the pocket. Lasso was also used rather than laser sheath when the lead was detached but not easily removable through the laser sheath, or when it was broken during laser removal attempt.

Removal procedures were terminated after complete removal of the leads or when lead fragments could not be removed. The procedural success was defined according to the criteria of the North American Society of Pacing and Electrophysiology (10).

Pacemaker-dependent patients were equipped with an epicardial right ventricular pacemaker in the days preceding the removal procedure. The others were reimplanted when needed, after several days or weeks, depending on the indication of removal.

Study design. Before lead removal, all patients underwent transthoracic echocardiography (TTE) and/or transesophageal echocardiography (TEE), as previously described (11). The presence and quantification of a pre-existent tricuspid regurgitation (TR) was evaluated at that time, along with right ventricular function and dimensions. Lead-related infective endocarditis was also diagnosed at that time as definite or possible according to the Duke criteria (12,13), or in the presence of lead or valve vegetation. Vegetation was defined as an oscillating intracardiac mass on the electrode leads, cardiac valve leaflets, or endocardial surface in the setting of valve or lead infection confirmed by imaging in more than 1 echocardiographic plane, and positive blood and/or lead tip cultures (14). A complete TTE study was performed before patient discharge, as part of the study protocol, to detect new tricuspid valve damage. Follow-up data were collected for all patients.

Abbreviations and Acronyms

CI = confidence interval
HR = hazard ratio
ICD = implantable cardioverter-defibrillator
OR = odds ratio
TEE = transesophageal echocardiography
TR = tricuspid regurgitation
TTE = transthoracic echocardiography
TTR = traumatic tricuspid regurgitation

ECHOCARDIOGRAPHIC EVALUATION OF THE TRICUSPID VALVE AND THE RIGHT VENTRICLE. For evaluation of TR, comprehensive TTE was consistently performed throughout the study period with a Vivid 7 apparatus (GE Medical Systems, Milwaukee, Wisconsin). The TEE was performed with the same apparatus, only in cases of poor acoustic windows by TTE. Echocardiographic evaluation was performed before and after lead removal in each patient by the same operator (F.T. or G.H.). A TR was considered to be related to lead removal, and called TTR, when the early post-removal TEE showed the apparition of a new flail leaflet as the mechanism of TR. Although flail leaflet is usually associated with severe TR, the severity was confirmed with an integrative approach as recommended by the international guidelines (15). The TR severity was ranked according to the international guidelines criteria and classified as mild, moderate, or severe (15). These qualitative, semiquantitative, and quantitative parameters were used: the visualization of chordae or papillary muscle rupture, a vena contracta with >0.7 cm, or a flow convergence radius 0.9 cm (with a baseline shift with Nyquist limit of 28 cm/s).

Right ventricular dilation was assessed at follow-up TEE and defined as either a right ventricle end-diastolic diameter >43 mm in the short axis view, or a ratio of right ventricle to left ventricle end-diastolic area >0.6 in the 4-chamber view.

RISK FACTORS OF TTR. Risk factors were a priori defined on the basis of current knowledge. They included demographic data of the patients, characteristics of implanted device, presence of a previous TR, number and characteristics of the implanted ventricular leads, removal technique and outcome, and presence of a lead-related infective endocarditis.

FOLLOW-UP. When a TTR was observed, the patients were submitted to clinical follow-up every 6 months and an annual TTE to detect clinical signs of right-sided heart failure and to evaluate right ventricular dimensions and function. For the other patients, clinical and mortality data were collected, during an outpatient visit or by telephone, at the end of the study.

Statistical analysis. No sample size determination has been performed because no large-scale data were available about TTR induced by percutaneous removal of chronically implanted transvenous leads. Therefore, all of the consecutive patients who fulfilled the selection criteria were included in the study. The relation between categorical variables and TTR was studied by chi-square test or Fisher exact test, when appropriate. Mann-Whitney *U* test was

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used for continuous variables. Logistic regression with a forward stepwise approach ($p = 0.10$ as the threshold for entering or removing variables) was used to identify the independent risk factors of TTR and to calculate adjusted odds ratios (ORs) and their 95% confidence intervals (CIs). The crude effect of TTR on overall mortality was estimated by the Kaplan-Meier method, and survival curves were compared with the log-rank test. Then, a Cox proportional hazards model was used to calculate the hazard ratio (HR), and its 95% CI associated with the TTR adjusted for pre-defined prognostic factors: patient age, type of implanted device (i.e., pacemaker or ICD), presence of resynchronization therapy, and lead-related endocarditis as an indication for lead removal. The proportional hazards assumption was assessed using Schoenfeld residuals. All statistical tests were 2-sided, and the threshold for statistical significance was $p = 0.05$. Analyses were performed with SPSS software (version 15.0, SPSS Inc., Chicago, Illinois).

Results

At our center, during the study period, 208 patients had a first procedure of removal of at least 1 ventricular lead. Four hundred and fifty leads were removed in these patients. Two hundred and thirty-seven were ventricular leads and are the subject of the present study. A single ventricular lead was removed in 180 patients, 2 in 27, and 3 in 1. Three patients had removal of both ventricular defibrillating and pacing leads. All of the pacemaker or ICD generators were implanted in the pre-pectoral region. The number of pacemaker or ICD generators that had been implanted per patient was: 1 generator in 113 patients, 2 in 60, more than 2 in 22, and unknown in 13.

Table 1 Patient Characteristics (n = 208)

Male sex	151 (72.6)
Age, yrs, mean ± SD	69.8 ± 15.0
Resynchronization therapy	30 (14.4)
Device implanted in the left pre-pectoral region	135 (64.9)
Primary indication for implantation	
Atrioventricular block	94 (45.2)
Sinus node disease	42 (20.2)
Primary prevention of sudden cardiac death	35 (16.8)
Documented VT/VF	30 (14.4)
Unknown	7 (3.4)
Implanted device: pacemaker/ICD	151 (72.6)/57 (27.4)
Presence of TR before lead extraction	25 (12.0)
Structural heart disease	
Ischemic heart disease	62 (29.8)
Systemic hypertension	44 (21.2)
Idiopathic dilated cardiomyopathy	36 (17.3)
Valvular heart disease	16 (7.7)
Congenital heart disease	5 (2.4)
None	45 (21.6)

Values are n (%) unless otherwise indicated.
ICD = implantable cardioverter-defibrillator; TR = tricuspid regurgitation; VT/VF = ventricular tachycardia/ventricular fibrillation.

Table 2 Ventricular Lead Characteristics (n = 237)

Defibrillating leads	
Single coil	15 (6.3)
Double coil	45 (19.0)
Pacing leads	
Unipolar	32 (13.5)
Bipolar	144 (60.8)
Tripolar	1 (0.4)
Lead fixation	
Active	63 (26.6)
Passive	174 (73.4)
Time from implantation (months)	46.4 (0.7–260.5)

Values are leads, n (%) or median (range).

No patient had a moderate or severe TR or a flail leaflet before lead removal. Other patient characteristics are presented in Table 1. Lead characteristics are presented in Table 2.

Table 3 is a patient-based presentation of the indications for lead removal, the tools used, and the outcome of the procedure. When multiple ventricular leads were removed in the same patient, the mentioned tools are the ones used during the procedure, for any of the ventricular leads.

TTR incidence and risk factors. The post-removal TEE was performed 1 to 8 days after the procedure. Among the 208 patients, 19 (9.1%) had a TTR. The TTR was moderate in 5 patients and severe in 14; no patient had a mild TTR.

Univariate and multivariate analysis of the pre-defined predictors of TTR are presented in Table 4. In case of removal of multiple ventricular leads, the effects of lead fixation, lead polarity, and number of coils were studied only

Table 3 Lead Removal Indications, Techniques, and Outcomes

Indication for extraction	
Lead-related endocarditis	87 (41.8)
Pocket infection	40 (19.2)
Pocket erosion	25 (12.0)
Lead dysfunction	26 (12.1)
Upgrading from pacemaker to ICD	16 (7.7)
Nonfunctional lead	9 (4.3)
Treatment of ipsilateral breast malignancy	2 (1)
Symptomatic venous occlusion	2 (1)
Heart perforation	1 (0.5)
Extraction technique	
Traction only (with or without locking stylet)	99 (47.6)
Additional tools	109 (52.4)
Laser only	75 (36.0)
Lasso only	22 (10.6)
Laser and lasso	12 (5.8)
Laser sheath size	
14-F	36 (17.3)
16-F	51 (24.5)
Complete removal	186 (89.4)

Values are patients, n (%).
ICD = implantable cardioverter-defibrillator.

Table 4 Studied Risk Factors for TTR in Univariate and Multivariate Analysis

	No TTR	TTR	p Univariate	p Multivariate	OR (95% CI) Multivariate
Patient-related factors					
Sex (female/male)	47/142	10/9	0.01	0.02	3.38 (1.21–9.41)
Age, yrs, mean ± SD	69.94 ± 14.51	68.02 ± 19.53	0.82		
Implanted device (pacemaker/ICD)	136/53	15/4	0.52		
Side of implantation (left/right)	122/67	13/6	0.74		
Resynchronization therapy (yes/no)	29/160	1/18	0.32		
Presence of a previous TR (yes/no)	21/168	4/15	0.26		
Lead-related endocarditis (yes/no)	78/111	9/10	0.63		
Lead-related factors					
Implant duration, months, mean ± SD	62.36 ± 58.51	90.96 ± 63.33	0.03		
Polarity (unipolar/bipolar)	16/103	1/9	1		
Single/double coil defibrillating lead	12/36	0/2	1		
Lead fixation (passive/active)	123/45	11/1	0.3		
Removal-related factors					
Number of extracted ventricular leads (1/≥2)	168/21	12/7	0.006		
Removal tools					
Traction only/traction and any additional tool	97/92	2/17	0.001		
Traction only/traction and laser only	97/62	2/13	<0.001	0.004	9.43 (2.03–43.77)
Traction only/traction and lasso only	97/20	2/2	0.15	0.15	4.45 (0.58–34.19)
Traction only/traction and laser and lasso	97/10	2/2	0.06	0.02	13.10 (1.58–108.92)
Laser sheath size (14-/16-F)	31/43	5/8	0.8		
Removal (complete/incomplete)	170/19	16/3	0.43		

CI = confidence interval; ICD = implantable cardioverter-defibrillator; OR = odds ratio; TR = tricuspid regurgitation; TTR = traumatic tricuspid regurgitation.

when the same factor was present for all removed leads (i.e., in 180 leads for fixation, 129 leads for polarity, and 50 leads for number of coils).

UNIVARIATE ANALYSIS. Five factors were significantly associated with the occurrence of TTR: use of laser sheath beyond simple traction was the most significant predictor (OR: 10.17, 95% CI: 2.16 to 94.74, $p < 0.001$); use of any additional tool (either laser sheath, lasso, or both) beyond simple traction (OR: 8.96, 95% CI: 2.02 to 81.45, $p = 0.001$); ≥2 leads extracted per patient (OR: 4.67, 95% CI: 1.38 to 14.48, $p = 0.003$); female sex (OR: 3.36, 95% CI: 1.14 to 9.90, $p = 0.01$); and a longer time from lead implantation (OR: 1.01, 95% CI: 1.00 to 1.01, $p = 0.03$) (Table 4). There was a trend toward a significant association with the use of both laser sheath and lasso (OR: 9.70, 95% CI: 0.61 to 141.62, $p = 0.06$).

MULTIVARIATE ANALYSIS. Independent predictors of TTR were: use of laser sheath as a single technique beyond traction ($p = 0.004$); use of both laser sheath and lasso ($p = 0.02$); and female sex ($p = 0.02$) (Table 4).

Follow-up and survival. The 208 patients were followed up for 4,130 person-months (median 17.9 months, range 0.03 to 81.4 months), during which 32 (15.4%) died. In the non-TTR population, 26 patients (13.7%) died: 10 from severe sepsis, 8 from pre-existing heart failure, 3 from sudden cardiac death, 1 from stroke, 1 from neoplasia, 1 from renal failure, and 3 from an unexplained cause. Among the 19 patients with TTR, 6 (31.6%) died, 2 of them from heart failure, 1 from pulmonary embolism after bone fracture, 1 from severe sepsis not related to the device, and 2 from neoplasia. In patients with TTR, 9 patients have been treated for new (i.e., not present before lead removal) right-sided heart failure symptoms; surgical repair of the tricuspid valve had to be performed in 2 of them. At last TEE evaluation, new right ventricular enlargement was present in 6 of 13 surviving patients (46%). We did not observe any significant progression of TTR magnitude over time. Right-sided heart failure symptoms occurred exclusively in patients who had a severe TTR after lead removal.

Survival curves of patients with and without TTR are shown in Figure 1. A nonsignificant increase in mortality was observed in the TTR population ($p = 0.26$). A similar nonsignificant trend was still observed after adjustment for the pre-specified prognostic factors (HR: 2.07, 95% CI: 0.78 to 5.48, $p = 0.14$). Figure 2 summarizes the outcome of the 19 patients with TTR.

Discussion

Our systematic study of patients undergoing percutaneous removal of ventricular leads with modern tools shows that TTR is not uncommon. It also shows, for the first time, that the use of a laser sheath for lead removal, after failure of simple traction, is the most powerful risk factor of subsequent TTR. In long-term follow-up, patients with severe TTR have a high incidence of right-sided heart failure symptoms.

Incidence of TTR after lead removal. It is well known that chronically implanted leads are embedded into adher-

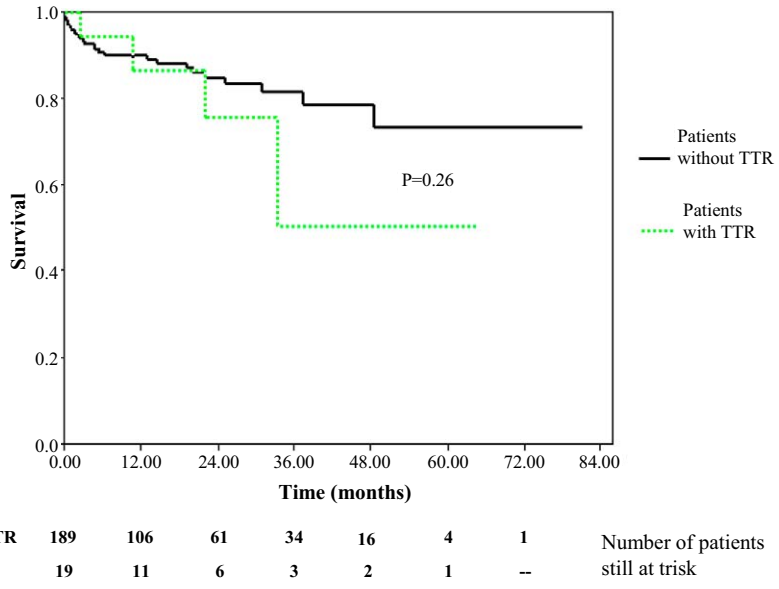

Figure 1 **Survival Curves of Patients With and Without TTR**

Survival curves obtained before adjustment for pre-specified prognostic factors (see the Statistical Analysis section). TTR = traumatic tricuspid regurgitation.

ent fibrotic tissue, which can take place all along the course of the lead, including the tricuspid valve (16,17). In a report of 2 cases of lead extraction performed by traction, TEE showed traumatic rupture of papillary muscle head or of multiple chordae tendineae (7). However, traumatic lesions of the tricuspid apparatus complicating extraction of pacemaker ventricular leads have been reported rarely in the modern era of lead extractions (4–9,14). This complication might be underestimated in the absence of systematic ultrasound evaluation of the tricuspid valve (7). In the study by Sohail et al. (14), 163 patients had percutaneous lead removal for cardiac device infection. Of these, 3 had tricuspid valve damage, requiring surgery in 2 cases. In the study by Roux et al. (6), a severe tricuspid valvular damage requiring surgery occurred in 1 of 177 procedures of lead extraction. However, the presence of a TTR was not systematically assessed in these studies. In a study of 43 patients by Roeffel et al. (8), systematic TEE evaluation performed during lead extraction showed a 12% incidence of new severe TR in the global population and a 17% incidence in case of lasing across and beyond the valve. Our systematic evaluation confirms and extends these results in a larger series of patients, in

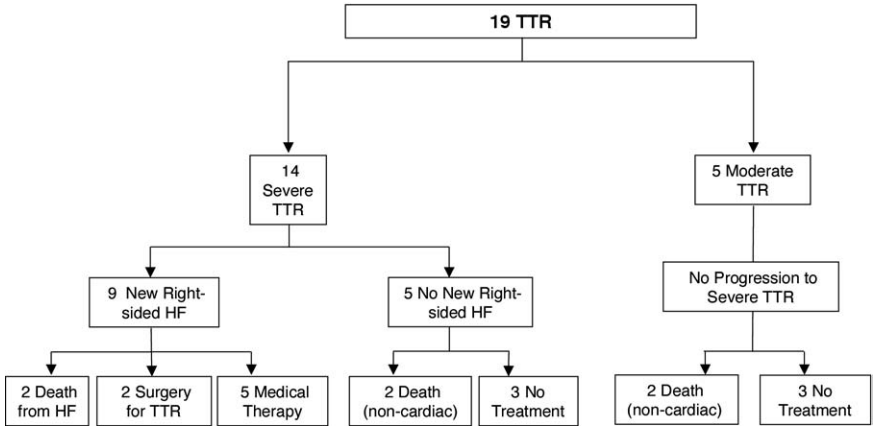

Figure 2 **Outcomes of the 19 Patients With Post-Removal Traumatic Tricuspid Regurgitation**

HF = heart failure; TTR = traumatic tricuspid regurgitation.

whom extraction was performed with a common set of extraction tools, including the lasso technique.

Risk factors of TTR. The use of laser sheath alone or in association with the lasso technique seems to play an important role in the occurrence of a further TTR. The study by Roeffel et al. (8) emphasized an increased number of TTRs in the laser group (4 of 23) than in the nonlaser group (1 of 20). However, this difference did not reach statistical significance, and the investigators suggested studying a larger number of patients. In our study, a causal role of the use of laser sheath in the occurrence of TTR is difficult to state because the use of such a tool was reserved for difficult lead extractions, after failure of simple traction. Failure of simple traction indicates important fibrosis along the lead, which may involve the tricuspid valve. Our study shows that in this situation, the dissection of tissues that is performed by the thermal energy does not rule out severe valvular damage. Furthermore, as shown by multivariate analysis, the addition of the lasso technique, which sometimes allows one to exert further traction on the lead, may also create valvular damage. On the other hand, because a lasso was mostly used, beyond simple traction, for removal of leads already detached from the endocardium and pulled into the right atrium, it is not surprising that it is not an independent predictor of TTR.

In our study, female sex is strongly associated with the occurrence of TTR. Byrd et al. (18,19) have shown that the risk of major complications after extraction is higher for women. There is no clear explanation for this. A more extensive fibrotic reaction and/or more fragile tissues than in men might be implicated.

Univariate analysis showed that more than 1 ventricular lead removal and a longer lead implantation time were associated with the occurrence of a subsequent TTR. Byrd et al. (18) have already shown that the risk of major and minor complications is proportional to the number of removed leads. A longer time from implantation has been described as a predictor of extraction failure (4,18–20). We can assume that TTR is probably the result of more problematic removal in these situations.

The most common class I indication for pacemaker lead extraction is a device-related infection (4,5,20). In our study, the presence of a lead-related endocarditis did not seem to be a predictor of subsequent TTR. It has been shown (18,20) that the success rate of lead extraction was increased in case of infected lead. A simpler removal of infected leads may be the explanation for less traumatic lead removal.

Fibrous tissue that grows into the grooves of the defibrillation coils of ICD leads (21) might result in more problematic lead extraction procedures (4). However, in accordance with Roeffel et al. (8), we did not observe an increased risk of TTR after ICD lead removal.

The majority of patients in this study had passive fixation leads. There was a trend toward less frequent TTR after active fixation lead removal ($p = 0.3$). We cannot exclude that if a higher proportion of active fixation leads were included in the study, the risk of TTR might have been lower. However, consistent with our results, other investigators did not show any difference in the outcomes of extraction procedures of active or passive leads (6,18).

Outcome. Few data exist on the outcome of TR caused by flail leaflet (22,23). In the series of 60 patients reported by Messika-Zeitoun et al. (23), it appears as a serious disease with a high event rate over time. Increased mortality, congestive heart failure, and right-sided chamber dilation are emphasized by these investigators. This series differs from ours because the TR was not related to lead removal. However, the mechanism of TR did not influence the outcome (23). The incidence and rate of occurrence of heart failure symptoms seem higher in our study than in the one of Messika-Zeitoun et al. (23). This poorer outcome might have been influenced by a much older age in our population and by associated comorbidities, including right ventricular pacing. It is not explained by the presence of a previous underlying heart disease because the great majority of TTR patients had no severe heart disease. In the study by Sohail et al. (14), TTR required surgery in 2 of 3 cases. However, the severity of this complication might have been overestimated if only severely symptomatic patients were diagnosed.

Study limitations. The limited number of TTR events and deaths might have been critical for statistical analysis. However, to overcome this potential problem, the multivariate analysis included only a limited number of risk factors. Similarly, the adjusted effect of TTR on overall mortality was assessed in a Cox proportional hazards model including only 4 pre-defined prognostic factors. Nevertheless, larger series are needed for further analysis of possible risk factors and natural history.

Some tools, such as nonpowered and electrosurgical dissection sheaths, are not used in our center and may merit evaluation.

Our data did not include information on the eventual site of lasing along the lead course. Therefore, we could not evaluate the role of this factor. However, from a practical point of view, this factor seems difficult to control because lasing is commonly performed as far as possible along the lead until the lead can be detached from the endocardium, or laser sheath progression is no longer possible.

Our study protocol was designed to detect TTR occurring early after lead removal to allow a close relationship between the procedure and the new TTR. Therefore, although unlikely, TTR that might have occurred later could not have been diagnosed.

Conclusions and Clinical Implications

TTR is a possible complication after percutaneous ventricular lead removal. The risk of this complication should influence the decision regarding ventricular lead removal when the indication is not mandatory. Some pre-removal parameters help to anticipate the complication: female

sex, number of ventricular leads, and mean time from implantation. However, the strongest risk factor is related to the use of specific extraction tools, because of failure of simple traction, and therefore cannot be anticipated. The natural history of this complication is not benign, meaning that a clear recognition and a careful follow-up are mandatory.

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