



A Questionable Indication For ICD Extraction After Successful VT Ablation

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Abstract

Sustained ventricular tachyarrhythmias represent a kind of complication shared by a number of clinical presentations of heart disease, sometimes leading to sudden cardiac death. Many efforts have been made in the fight against such a complication, mainly being represented by the implantable cardioverter defibrillator (ICD). In recent years, catheter ablation has grown as a means to effectively treat patients with sustained ventricular arrhythmias, in the contest of different cardiac substrates. Since carrying an ICD is associated with a potential risk deriving from its possible infective or malfunctioning complications, and given the current effectiveness of lead extraction procedures, it has been thought not to be unreasonable to ask ourselves about how to deal with ICD patients who have been successfully treated by means of ablation of their ventricular arrhythmias. To date, no control data have been published on transvenous lead extraction in the setting of VT ablation. In this paper we will review the current evidence about ICD therapy, catheter ablation of ventricular arrhythmias and lead extraction, trying to outline some considerations about how to face this new clinical issue.

Introduction

Sudden cardiac death (SCD) accounts for half of all cardiovascular deaths in western countries.¹ Antiarrhythmic drug approaches to prevention of SCD have been resoundingly ineffective. The implantable cardioverter defibrillator (ICD) is the most effective therapy currently available to prevent SCD, especially in patients with heart failure and low ejection fraction.² Consequently, ICD use has increased exponentially, although its implementation has been quite variable geographically and with respect to other measures. Although effective in reducing mortality, ICDs are associated with significant limitations and complications, like infections, malfunctions and shocks. ICDs effectively terminate ventricular tachycardia (VT), but do not prevent VT episodes.³⁻⁷

Radiofrequency (RF) ablation has recently been proposed like an effective treatment for VT. VT ablation seems to be effective in reducing ventricular arrhythmias recurrences and ICD shocks, even if without a significant impact on mortality.⁸ This new therapy has further complicated the risk-benefits ratio estimation of ICD therapy in ICD patients, suggesting, in some cases, to avoid ICD implant after successful ablation or considering in particular cases the

attractive hypothesis of transvenous device removal after a successful VT ablation.

The aim of the following review is to focus on the potential indication to transvenous lead extraction (TLE) in ICD patients after a successful VT ablation.

ICD, VT And Lead Extraction

Initially, the ICD was developed to prevent SCD from recurrent arrhythmias in high-risk patients who had survived one or more resuscitations because of VT or ventricular fibrillation (VF). This group of indications in patients having already experienced a life-threatening event of documented or presumed ventricular tachyarrhythmia was later classified as “secondary prevention”. The results of three large prospective ICD trials comparing ICD to antiarrhythmic drug therapy (mainly amiodarone) in patients with life-threatening ventricular tachyarrhythmia have consistently shown that ICD improves overall survival (Table 1). In the AVID trial, enrolling more than 1000 patients, ICDs resulted in a 31% reduction in total mortality rate (25 vs 36%) at 3 years compared to the antiarrhythmic drug therapy group.⁵ The CIDS trial randomized over 600 patients to treatment with either the ICD or amiodarone; after 3 years of follow-up, patient randomized to receive the ICD had a 20 % reduction in total mortality rate (25 vs 30%) compared to amiodarone treated patients.⁹ The CASH trial randomized 346 cardiac arrest survivors; during the follow-up, patients randomized to receive an ICD had a 37% reduction in total mortality rate (12 vs 20%) compared to antiarrhythmic-treated patients.¹⁰ A meta-analysis of these three trials found that the ICD reduced the total mortality

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Table 1: Studies on secondary-prevention ICD implantation

Author	Year	Eligibility	Patient, n	EF %	Aim	FU	Results
AVID ⁵	1997	VF 45%, VT 55%	1016	32±13	AA vs ICD	2.6 y	31% reduction of mortality with ICD
CASH ¹⁰	2000	VF 100%	288	45±18	AA vs ICD	3 y	23% reduction of all cause mortality with ICD
CIDS ⁹	2000	VF 48%, VT 38% SY 14%	655	34±14	AA vs ICD	3 y	20% reduction of all cause mortality with ICD

AA = antiarrhythmic agents, mainly amiodarone; EF = left ventricular ejection fraction; FU = follow-up; ICD = implantable cardioverter defibrillator; VF = ventricular fibrillation; VT = ventricular tachycardia, SY = syncope; y = years

rate by 27 % and the arrhythmic death rate by 50% compared to amiodarone ($p < 0.05$).¹¹ As a result of evidence from these clinical trials, the ICD is now accepted as the first choice therapy in survivors from symptomatic sustained ventricular tachyarrhythmias. Originally developed for patients resuscitated from cardiac arrest, the vast majority of today's ICDs are implanted in patients with heart failure at increased risk for ventricular arrhythmias ("primary prevention indication"). Based on a convincing body of evidence confirming a significant mortality benefit, post-infarction patients with severely depressed left ventricular function (left ventricular ejection fraction (LVEF) $\leq 30\%$) have a class I indication for ICD implantation. The same is true for patients with symptomatic heart failure (NYHA II-III) of ischemic or non-ischemic origin and LVEF $\leq 35\%$. Analysis of subgroups showed the benefits of the ICD in patients at risk for life-threatening ventricular tachyarrhythmias.¹² The role of ICD therapy for patients with asymptomatic sustained monomorphic VT and structural heart disease but with a LVEF greater than 40% is less clear.¹³

Endocardial lead, implanted transvenously, represent the weak link of ICD technology. Since their introduction into clinical practice, ICD leads were supposed to be significantly more troublesome than conventional pacing leads.^{14,15} Even in the most skilled hands, lead implantation can still have periprocedural serious complications (cardiac perforation, cardiac valve injury, hemothorax, pneumothorax, arterial-venous fistula) in up to 3.5% of cases.² Despite advances in ICD system design and manufacturing, devices remain imperfect. Structural failure of an implanted device has tremendous adverse effects on patient morbidity, both medically and psychologically. Inappropriate sensing due to conductor or insulation fracture, sensing lead adapter failure, loose set screws, or frank dislodgement can lead to oversensing of electrical noise with resultant inappropriate shocks.

Malfunction due to insulation defect or conductor failure can affect up to 40% of ICD leads 8 years after implantation,¹⁶ especially in young and active patients, probably due to the hard physical stress imposed to the lead implanted in the subclavian vein by the vascular system. It is, however, important to underline that the benefits of the ICD in the reduction of mortality have been reached in clinical trials employing such imperfect devices with all their known malfunction and infection issues.

In the last years many technical failures involving endocardial transvenous leads have caused recalls or advisory, as in the cases of Medtronic Sprint Fidelis or Saint Jude Medical Riata, requiring lead management strategies that involves extraction procedures. ICD infections are increasing, because older and sicker patients are receiving devices and more patients are surviving and undergo generator changes with higher infection risk.¹⁷ In case of device infection, local or systemic, lead extraction (most often by the transvenous approach) is mandatory¹⁸ and even if the procedure is safe in experienced hands, major complications are described in 1.8% of patients.¹⁹ Based on these data, lead extraction procedures should not be considered as a routine procedure: a risk benefit ratio should ever be made before each extraction procedure. Cardiac implanted electronic devices (CIED)-associated infections are the strongest indication for complete CIED system removal: when an infection is identified, all components of the CIED system, including the device and leads, should be removed in order to definitely resolve the infection. In addition to extraction, 2 to 6 weeks of intravenous or sometimes oral antibiotics are usually required, depending on the microbiologic isolate, antibiotic sensitivities and clinical scenario.¹⁸ Currently, infection accounts for approximately two-thirds of all extractions.

Considering that lead damage or malfunction may have dramatic consequences and that in most cases these complications require lead removal in order to implant a new one, it is easy to understand that ICD lead extraction represents an important issue for implanting centers. All experiences reported a high rate of binding sites related to the coils, into the right ventricle as well as in the superior vena cava, where dilatation can be challenging and risky.^{20,21} As shown in a multicenter study,²¹ the presence of a superior vena cava coil is associated with significantly higher complication rates; TLE of dual-coil ICD leads is 2.6 times more difficult than that of single-coil leads and is more frequently associated with the use of powered sheaths and with higher complication rates. The backfilled/covered coils seems to make the extraction procedure easier.²² A complication

Table 2: Published experiences of ICD lead extraction

Author	Year	Report Type	Leads, n	Pacing Period, months	Technique	Manual traction, %	Complete Removal%	Major Complications
Byrd et al ²⁴	2000	Multi-center	443	25	Mechanical	NA	96	2.1
Kantharia et al ²⁵	2000	Single-center	47	25	Mechanical	23	100	0
Saad et al ²⁶	2003	Single-center	161	31.8	Laser	24	96.9	1.2
Jones et al ³³	2008	Single-center	233	90*	Laser	16	98.3	0
Kennergren et al ³⁴	2009	Single-center	58	58	Laser	29	98.3	1.7
Wazni et al ^{27 M}	2009	Multi-center	61	NA	Laser	NA	100	0
Malecka et al ²⁸	2010	Single-center	83	38.5	Mechanical	NA	98.7	2.5
Maytin et al ^{29 M}	2010	Multi-center	349	27.5	Mechanical and Laser	49	100	0
Bongiorni et al ³²	2014	Single-center	582	45	Mechanical	6	99.1	0
Maytin et al ^{30 R}	2014	Multi-center	577	44.7	Mechanical and Laser	17.7	99.1	0.87

M = Sprint Fidelis leads, R = Riata leads, * = pacing and ICD leads together

in these vascular districts can lead to serious consequences that may not be mitigated by emergency surgery.²³ The concern about ICD extraction using conventional equipment was averted by clinical results:²⁴⁻³⁰ in some large experiences³¹⁻³⁴ success rate approximated 98% (Table 2).

ICDs effectively terminate VT, but do not prevent VT episodes. Approximately 20% of patients in primary prevention and 45% of patients in secondary prevention receive an appropriate ICD intervention within the 2 years following ICD implantation.³⁻⁵ Moreover, VT storm (3 or more appropriate ICD therapies within a 24-hour period) may affect 4% and 20% of the patients in the primary and secondary prevention, respectively.^{6,7} ICD shocks reduce the risk of SCD by approximately 60% but the occurrence of shocks is associated with progressive heart failure symptoms, a significant decline in quality of life, and a two- to fivefold increase in mortality. ICDs are not a cure for VT: concomitant drug therapy is necessary in the majority of patients, patients may lose consciousness prior to shock, defibrillator shocks are painful and psychiatric disturbances are common.

Defibrillator shocks may increase mortality and worsen quality of life.³⁵⁻³⁷ Altitude study reported outcomes on 185,778 ICD patients undergoing remote follow-up. Inappropriate shock occurred in 6% at 1-year and 16% at 5 years, constituted 30% of device therapy and carried a significant increase in mortality.³⁸ Possible ways to reduce inappropriate shocks as well as mortality through a judicious device programming include the use of anti-tachycardia pacing, prolonged detection times, higher detection rate cut-offs and various algorithms to classify rhythms.³⁹

As ICDs are not effective in VT cure and prevention, RF ablation strategies have been recently implemented.

VT Ablation

Radiofrequency ablation of the VT substrate and circuits was mainly indicated in patients with several recurrences of VT in order to reduce the negative effect of ICD interventions.^{3,8,40} This strategy was based on the results of two randomized prospective multicenter trials. The SMASH-VT study,⁴¹ published in 2007, enrolled patients with coronary artery disease (CAD), unstable and inducible VT, showing a significant decrease in appropriate ICD therapy (12 vs 33%, $p = 0.007$) and electrical storms in the ablation group during an average follow-up period of 22.5 ± 5.5 months. The VTACH study,⁴² published in 2010, assessed the role of VT ablation in patients with prior myocardial infarction, LVEF $\leq 50\%$ and haemodynamically stable VT. VT recurrences were less frequent in the ablation group (47

vs 29%, $p = 0.045$ in a mean follow-up period of 22.5 ± 9.0 months: catheter ablation extended the time to recurrent VT from a median of 5.9 months to 18.6 months). The significantly higher number of centers participating in VTACH (16) compared with SMASH-VT (3) and the non-standardized approach to ablation used in VTACH (ablation was guided by a combination of substrate mapping, activation mapping and pace mapping) compared with SMASH-VT (ablation was performed using a substrate-guided approach) may explain the different rate of VT recurrence (SMASH-VT: 12%, VTACH: 53%). Of interest, in VTACH, patients with a LVEF $> 30\%$ benefited most from catheter ablation. A retrospective European multicenter study⁴³ published in 2014 analysed the outcome of 166 patients with structural heart disease (55% ischemic cardiomyopathy, 19% non ischemic cardiomyopathy, 12% arrhythmogenic right ventricular cardiomyopathy [ARVC]) and a LVEF $> 30\%$ (mean $50 \pm 10\%$) undergoing catheter ablation for stable, well tolerated VT, without subsequent implantation of an ICD as recommended by current guidelines.⁴⁴ A group of 378 patients with similar diagnoses undergoing catheter ablation of VT followed by ICD implant served as a non matched control group. After a mean follow-up of 32 ± 27 months, all cause mortality was 12%, while only 2.4% of the patients died suddenly; in the control group, all cause mortality was the same (12%). Authors conclude that patients with well-tolerated sustained monomorphic VT, structural heart disease, and LVEF $> 30\%$ undergoing primary VT ablation without a back-up ICD had a very low rate of arrhythmic death and recurrences were generally non-fatal.⁴⁵ Limits of the study were: the retrospective nature and the low rate of VT recurrence in the absence of standardized protocol for catheter ablation.

In these studies RF ablation of VT substrate had no significant impact on mortality; moreover a meta-analysis of trials including patients with structural heart disease undergoing catheter ablation for VT, demonstrated that VT ablation reduced recurrence of ventricular arrhythmias without significant impact on mortality.⁸ In this regard, a future prospective study in patients not receiving an ICD seems imperative in order to assess the rate of mortality throughout the follow-up period.⁴⁵ An overview of studies on ventricular tachycardia ablation is reported in Table 3:⁴⁶⁻⁵¹ of note, only one retrospective study compared VT ablation versus VT ablation plus ICD and so clinical evidence in this regard is still quite weak.

Catheter ablation reduces VT/VF recurrences and thereby ICD interventions by more than 75% in patients after multiple ICD shocks. In this patient population, the incidence of procedure-related death ranges from 0% to 3% and the incidence of major complications

Table 3: Studies on catheter ablation of ventricular tachycardia

Author	Year	Report Type	Patient, n	EF %	Substrate	Treatment VT	Follow-up, months	Long term success %	Mortality %
Reddy et al ⁴⁴	2007	Prospective Randomized	64 vs 64	31 vs 33	ICM	VT Ablation+ICD vs ICD	22.5	88 vs 67	9 vs 17
Kuck et al ⁴²	2010	Prospective Randomized	52 vs 55	34 vs 34	ICM	VT Ablation+ICD vs ICD	22.5	47 vs 29	10 vs 7
Maury et al ⁴³	2014	Retrospective	160 vs 378	50	ICM/NICM/ARVC	VT Ablation vs ICD	32	83	12 vs 12
Calkins et al ⁴⁹	2000	Prospective Non-randomized	146	31	ICM/NICM	VT Ablation	8	46	25
Stevenson et al ⁴⁸	2008	Prospective Non-randomized	231	25	ICM	VT Ablation	6	53	18
Tanner et al ⁴⁷	2010	Prospective Non-randomized	63	30	ICM	VT Ablation	12	51	9
Niwano et al ⁵⁰	2008	Prospective Non-randomized	58	37	ICM/NICM	VT Ablation	31	75	16
Carbucicchio et al ⁵¹	2008	Prospective Non-randomized	95	36	ICM/NICM/ARVC	VT Ablation	22	66	16

ARVC = arrhythmogenic right ventricular cardiomyopathy; EF = left ventricular ejection fraction; ICD = implanted cardioverter defibrillator, (N)ICM = (non)ischemic cardiomyopathy, VT = ventricular tachycardia. Modified from reference [52]

from 3.6% to 10%.⁵² Nonetheless, most patients with post-infarction VT have multiple types of monomorphic VTs, and elimination of all VTs is often not feasible. As the recurrence of an ablated VT or the occurrence of a new VT can be fatal, RF ablation is rarely used as the only therapy for VT. Additionally, catheter ablation is necessary and can be life-saving in patients with electrical storm and incessant VT: acute suppression of clinical VT in electrical storm can be achieved in approximately 90% of patients, however, arrhythmic recurrences are frequent during follow-up. Ablation targeting critical isthmuses for stable VTs is successful, abolishing the inducible targeted or clinical VT in 71% to 86% of selected patients. During average follow-up ranging from 9 to 42 months, non-inducibility of the clinical VT immediately post-procedure is associated with a lower risk of VT recurrence and nonfatal VT (13 to 46%) compared with persistent inducibility of the clinical VT (up to 80%): the risk of SCD is low (0% to 6%) reflecting common use of ICDs for patients felt to be at risk.⁵³ Lack of inducible ventricular arrhythmias following VT ablation is associated with improved survival.⁵⁴ In patients with ablation failure or other inducible VTs, the 3- to 4-year risk of VT recurrence is much higher (60% to 64%) as compared with patients with no inducible monomorphic VT of any morphology (recurrence 14% to 20%). Additionally, induction of multiple VT morphologies during the procedure may predict higher risk of arrhythmia recurrence post ablation.⁵⁵

Outcomes for VT due to non-ischemic cardiomyopathies are less well evidenced because the VT substrate is more variable and may require epicardial ablation with additional risk: such an approach was mainly considered at least in Europe after failure of initial endocardial approach.⁵⁶ In a series of patients with ARVC and hemodynamically stable recurrent VT, extensive endocardial-epicardial catheter ablation without insertion of an ICD resulted in freedom from recurrent VT and symptoms off antiarrhythmic drugs at > 2 years of average follow-up.⁵⁷

ICD Lead Extraction After VT Ablation

The encouraging results of VT ablation raised the question about a potential indication to ICD removal after ablation. After ablation, a risk-benefits assessment should balance the probability of VT recurrences (and the related SCD risk), with the risk of overall ICD complications. In other words, is it better for an ablated patient to have

an ICD or not? And if the patient benefits from the ICD removal, is the procedural risk of extraction appropriate and acceptable?

According to Guidelines, hemodynamically tolerated sustained monomorphic VT is considered separately from hemodynamically unstable VT or VF, given the potential differences in arrhythmia substrate as well as in the response of VT to catheter ablation [44]. When occurring in the setting of LVEF \leq 35%, regardless of the underlying disease process or history of VT ablation, ICD implantation is considered appropriate.⁵⁸ Otherwise, with a normal LVEF (\geq 50%) and hemodynamically tolerated monomorphic VT, ICD implantation is rated appropriate in the setting of prior myocardial infarction or non-ischemic dilated cardiomyopathy in the absence of VT ablation, but it is rated as “may be appropriate” if successful VT ablation is performed.⁴⁴

The identification of patients who do not need no more ICD after ablation is not easy. RF catheter ablation of VT, if successful in the short term and follow-up, confers both qualitative and quantitative protection against VT recurrence and SCD,⁵⁹ without significantly affecting total mortality. In ICD patients, even in the low-LVEF population, an U-shaped pattern for ICD efficacy in primary prevention was described, with pronounced benefit in intermediate-risk patients and attenuated efficacy in lower- and higher-risk subsets.⁶⁰ Both low LVEF and inducible tachyarrhythmias identify patients with CAD at increased mortality risk. LVEF does not discriminate between modes of death, whereas inducible tachyarrhythmia identifies patients for whom death, if it occurs, is significantly more likely to be arrhythmic, especially if LVEF is \geq 30%.⁶¹

According to evidences and guidelines, it seems reasonable to consider patients with ICD, who had a successful ablation for tolerated VT in the setting of normal heart or structural heart disease (mainly ischemic and nonischemic dilated cardiomyopathies) with relatively preserved LVEF (>45%).^{44,62}

According to guidelines, the ICD can be avoided in:

- CAD and prior MI, sustained hemodynamically stable monomorphic VT, all inducible VTs successfully ablated and LVEF \geq 50%;
- CAD and prior MI, sustained hemodynamically stable monomorphic VT without troponin elevation (not secondary to

Table 4: Risks of lead abandonment

Author	Year	Report Type	Leads, n	Patients, n	Groups	Follow-up	Results: Abandon vs Remove
Rettig et al ⁶⁵	1979	Retrospective	NA	25	pts with \geq 1 aband. lead	1.8 y	nc (fatal embolization of cut lead)
Furman et al ⁶⁶	1987	Retrospective	N/A	152	pts with \geq 1 aband. lead	4 y	nc (1 fatal case of DRE)
Parry et al ⁶⁷	1991	Retrospective	N/A	119	pts with \geq 1 aband. lead	N/A	nc (42% inf vs 3% not inf MC)
deCock et al ⁷⁶	2000	Prospective	3.2 vs 2.0	48	pts \geq 3 leads vs control	7.4 y	nc
Suga et al ⁶⁸	2000	Retrospective	2.8	433	pts with \geq 1 aband. lead	3.1 y	nc (higher complication in aband.)
Bohm et al ⁶⁹	2001	Retrospective	1.0 ab.	60	pts with \geq 1 aband. lead	N/A	nc (20% migration of cut leads)
Sweeney et al ⁷⁰	2002	Prospective	N/A	58	upgrade: add vs replace	1.1 y	\approx no difference
Wollman et al ⁷¹	2005	Retrospective	2.3	151	Add P/S	3.6 y	Remove best (28.5% failure P/S)
Wollman et al ⁷²	2007	Retrospective	2.6 vs 1.4	33a vs 53r	add HV vs replace HV	9.3 vs 6.7 y	\approx (70% add HV after failed TLE)
Silvetti et al ⁷⁴	2008	Retrospective	1.1 ab.	18	young pts&aband leads	4 y	nc(11% DRE and 28% reimplant)
Glikson et al ⁷⁵	2009	Retrospective	1.5 ab.	78	aband. HV or P/S	3.1 y	nc(no malfunction or thrombosis)
Amelot et al ⁶⁴	2011	Retrospective	3.4 vs 1.7	26a vs 32r	ab. vs replace HV or P/S	3.2 y	\approx no difference

HV = high-voltage defibrillation lead; P/S = pace-sense lead; \approx = no significant difference between extraction and abandonment; ab., aband. = abandonment; inf. = infective; DRE = device-related endocarditis; MC= major complications; N/A = not available; nc = not conclusive, refers to studies in which comparative analysis is not possible; TLE = transvenous lead extraction. Modified from reference [19]

VT), all inducible VTs successfully ablated and LVEF between 36 and 49%;

- Non-ischemic dilated cardiomyopathy, sustained hemodynamically stable monomorphic VT, all inducible VTs successfully ablated and LVEF \geq 50%;

- Non-ischemic dilated cardiomyopathy, sustained hemodynamically stable bundle branch reentry VT successfully ablated and LVEF \geq 50%.

Sustained VT occurring in the setting different heart diseases, including genetic diseases, ARVC and infiltrative cardiomyopathy require special attention. Many of these scenarios are not specifically addressed in the guidelines or clinical trials, and represent a relatively small percentage of the population undergoing ICD implantation. Therefore, a careful clinical judgment based on review of limited evidence is required when making these decisions. In particular, despite promising experiences in literature,⁵⁷ ARVC after successful ablation of all inducible monomorphic VTs still represents an indication to ICD implantation.⁴⁴

After successful VT ablation, patients still requiring ICD will be identified based on:

- history and clinical status;
- patient's preference: the decision should be shared with a completely informed patient about risk-benefits ratio;
- appropriate informed consent;
- legal issues: the decision should be made according to guidelines and shared with the patient;
- electrophysiological data (electrophysiological study with electroanatomical mapping); persistent VT inducibility after catheter ablation requires an ICD implant and/or repeat ablation;
- imaging data (magnetic resonance imaging (MRI) evaluation, eventually after TLE).

In addition, the overall prognosis of a VT patient successfully ablated should be integrated by a risk benefits ratio estimation of ICD removal with or without a transvenous extraction procedure.

TLE carries risks and surgical back-up is mandatory. To minimize risk to the patient, an individualized plan is required, taking into account the patient's heart disease, the indications to extraction, the comorbidities, and the procedure's technical challenges, as well as a plan following extraction. When considering the indication for lead extraction, it is important to relate the strength of the clinical indication to TLE to the early and long term outcome and the risk of the intervention, evaluated on an individualized patient basis. The risk of TLE is highly dependent on the training and experience of the extraction team.⁶³

Table 5:

Proposed management after successful ablation. These recommendations are applicable in patients with ICD who had successful ablation for tolerated VT in the setting of structural heart disease with relatively preserved ejection fraction (>45%)

	Wait and see	Lead abandonment	Lead extraction
Normally functioning ICD	+++		
Device end of life			
• Low-Volume, Low-Experience Centers, Patient Preference		++	+
• High-Volume, High-Experience Centers, Patient Preference		+	++
Lead malfunction		+	++
Infection			+++

TLE for patients without infection is a controversial topic. Since it is less common for a patient to exhibit symptoms or to be at risk of death from the abandonment of not infected leads, it is more difficult to calculate the risk-benefits ratio of TLE in those patients.^{19, 64-72} In these situations, there must be a clinical goal that balances the risk of removal with reasonable alternatives, such as switching off/removing the ICD and abandoning the lead. However, a long term perspective is required to allow the decision to be made, since in the first few years the risk of leaving the lead implanted would be outweighed by the potential risks of lead extraction. Table 4.

Factors favouring lead extraction, instead of abandonment:

- risk of future lead extraction: leads, when left behind, are more difficult to remove and when removed are associated with an increased risk of major complications, which is much higher as the implantation duration prolongs. When planning an extraction procedure it is important to consider how long the lead has been implanted, the fragility or tensile robustness of each particular lead, and the extraction feasibility of that particular lead model.²⁰ In a prospective registry of more than 3500 leads, extracted at 266 centers, Byrd et al. reported a 2-fold increase in the risk of extraction failure with every 3 years of implant duration.²⁴

- MRI scanning is always contraindicated in presence of superfluous or abandoned leads. Not all patients with indications for MRI scanning have reasonable alternatives. Apart from extra-cardiac MRI indications, cardiac MRI could be very useful in patients at risk from sudden cardiac death. A recent study shows the prognostic value of scar detected by MRI, irrespective of LVEF value: myocardial scarring detected by cardiac MRI is an independent predictor of adverse outcome in patients being considered for ICD placement. In patients with LVEF > 30%, significant scarring (>5% LV) identifies a high-risk cohort, similar in risk to those with LVEF \leq 30%. Conversely, in patients with LVEF \leq 30%, minimal or no scarring identifies a low-risk cohort similar to those with LVEF > 30%.⁷³

- preserving venous access: several clinical studies have demonstrated the common occurrence of venous stenosis and occlusion correlated with pacing and defibrillating leads: as a matter of fact, venous thrombosis is commonly observed in patients with abandoned leads.⁷⁴⁻⁷⁶ Moreover, Suga et al.⁶⁸ noted a significant increase in infection and asymptomatic venous occlusion in patients with multiple leads. In contrast, little is known about the effects of lead extraction on venous patency, and attempts to study this have been confounded by coexistent infection or ipsilateral reimplantation.⁷⁷ However, acute occlusion with thrombus (reported sometimes after extraction) usually responds to anticoagulation, while chronic occlusion (related to lead-venous interaction), that comes from progressive fibrosis, does not.

- reducing the risk of infection: over the last years, the increasing use of CIEDs for the management of cardiac conditions has been associated with higher infection rates.⁷⁸ Expanded CIED use alone cannot account for this rise, that involves both patient, leads and device-related factors. Indeed, nowadays patients tend to be older, with many comorbidities, while devices are more sophisticated, requiring more leads and surgical revision in the follow-up.⁷⁹ Several risk factors for CIED infection have been identified, including the presence of more than 2 pacing leads⁸⁰ and cardiac resynchronization therapy.⁸¹ Data regarding the risk of CIED infection in patients with abandoned leads have failed to demonstrate an increased risk of device-related infection, but are limited by small sample

sizes and reduced follow-up periods (Table 4). In young patients with abandoned leads, even if the trial was underpowered to reach statistical significance, Silveti and Drago reported an incidence of 11% of CIED infection compared with a 2 % in all pacemaker patients.⁷⁴ The occurrence of abandoned lead infection increases both the difficulty and risk of the extraction procedure, due to the longer implant duration and lead-lead binding.

- lead-lead interaction: lead-lead interaction between superfluous and active leads can result in noise oversensing, inappropriate pacing and ICD therapies with potential serious sequelae.^{82,83} These risks affect patients with active ICD device and not those with only abandoned leads.

- lead burden: removal of leads when there are multiple (4 or more) leads implanted through a single vein or 5 or more through the superior vena cava is not only more difficult but also more dangerous.¹⁸ Moreover, multiple leads, in addition to infection, polyurethane leads and thrombophilia, are risk factors for the development of superior vena cava syndrome.⁸⁴ Finally, cases of tricuspid regurgitation and/or stenosis from excessive lead burden have been reported in patients with 4 and 5 endovascular pacing leads.^{84,85}

Considering patients with ICD who had successful ablation for tolerated VT in absence of structural heart disease or in the setting of structural heart disease with relatively preserved LVEF (>45%),⁴⁴ the following situations are reported (table 5):

- 1) Normally functioning device.
- 2) Device at the end of its life.
- 3) Lead malfunction.
- 4) Infection.

Normally Functioning Device

In patients with normally functioning devices, waiting device end of life in order to increase follow-up after VT ablation and postpone the decision represent a reasonable approach.

Device At The End Of Its Life

Device replacement carries a risk of infection. The choice is between device replacement, lead abandonment (\pm ICD in situ) and lead extraction. Patient clinical status and preference plays a remarkable role. If there is an inconsistent follow-up after VT ablation, the first choice is device replacement. If there is a consistent follow-up without VT recurrences, lead extraction or abandonment can be considered.

Due to the increased risk of future lead extraction, a risk benefit ratio between lead abandonment and removal should be made, and decisions should be taken case by case, according to patient clinical status and preferences. In high volume centers, highly experienced in lead extraction, lead removal could be the first choice. This approach, still carrying a higher short term risk, avoids long term ICD complications and abandoned lead risk.

In low-volume centers with low experience in lead extraction, lead abandonment could be preferred. This approach avoids ICD complications risks (i.e. inappropriate shocks) and lead extraction risks, still exposing the patient to abandoned lead risks; moreover the same lead can be used if required in the future.

Lead Malfunction

In case of malfunctioning leads, the choice is between lead replacement, lead abandonment and lead extraction; the decision should be made before the planned procedure. Since lead malfunctions are usually related to implant technique, lead characteristics and

patients characteristics, patients presenting with malfunctioning leads could be at increased risk of recurrences. Lead replacements present a high risk of infection. Lead extraction can be performed if there is a consistent follow-up without VT recurrences. In this clinical situation, since the patient has a malfunctioning lead, lead extraction is preferred over lead abandonment.

Infection

Lead extraction, as class I indication, is first performed in order to treat infective complication.

Conclusion

The risk-benefits ratio assessment of ICD extraction after VT ablation continues to be challenging. The high probability of VT recurrences with the related SD risk has to be balanced with the risk of overall cumulative ICD related complications. The benefits of the ICD in the reduction of mortality have been reached in clinical trials employing such imperfect devices. On the other hand, radiofrequency VT ablation, even if often successful in the short term, continues to not significantly affect total mortality. The progressive substrate disease plays a significant role in VT recurrences and risk of SD. To date, no control data have been published on transvenous lead extraction in the setting of VT ablation. Until then, ICD lead extraction may be considered only in patients with no structural (or minimal) heart disease, with preserved (or mild impaired) LV systolic function, with sustained, hemodynamically stable monomorphic VTs successfully ablated, after a suitable follow up.

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