

Management of malfunctioning and recalled pacemaker and defibrillator leads: results of the European Heart Rhythm Association survey

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The aim of this survey was to describe the different strategies regarding the management of malfunctioning and recalled pacemaker and defibrillator leads across Europe. A questionnaire has been designed to assess the current practice and physician's approach to the management of leads which are faulty, unnecessary, and/or recalled. Responses to the questionnaire were received from 34 hospitals—members of the European Heart Rhythm Association (EHRA) electrophysiology (EP) research network. The survey involved both very high and low volume implanting centres, with 85% of the responding centres performing lead extraction. The survey provides a panoramic view of operator's decision making in the field of malfunctioning, recalled, and redundant leads and outlines a common point of view on lead abandonment and factors influencing the decision about lead extraction. The main factors strongly influencing the decision making were patient's age (59%), the presence of the damaged leads (44%), and the lead dwelling time (44%). Regarding the lead abandonment, the main concern (61%) was the potential greater difficulty associated with lead extraction in the future. High volume extracting centres showed a greater propensity to removing the malfunctioning or recalled leads compared with low volume or non-extracting centres. This EP Wire survey gives a snapshot of the operators' approaches and options regarding redundant, malfunctioning, and recalled lead management and may form the basis for future prospective research on this topic.

Keywords

Cardiac implantable electronic devices • Pacemaker • Implantable Cardioverter-defibrillator • Leads • Malfunction • Recall • Extraction • Abandonment • EHRA survey • EP wire

Introduction

Cardiovascular implantable electronic device (CIED) use has increased exponentially over the last decade. With expanding evidence-based indications for the implantation of these devices and despite advance in technology, the number of lead malfunctions has increased.¹ Leads are very often the weak point of CIED systems,^{2,3} especially for implantable cardioverter-defibrillators (ICD)^{4,5} and several recalls were made by the industry during past decades.

Clinicians are facing the choice of extraction or abandonment of functioning, not functioning, and recalled leads;^{6–8} and this could be an issue especially in young patients who have a high risk of lead failure during the entire course of their life. We aimed to investigate the procedural practice in lead management and the decision-making

process of malfunctioning, redundant, or recalled pacemaker (PM) and ICD leads in Europe.

Methods

A questionnaire was sent to the centres—members of the European Heart Rhythm Association (EHRA) electrophysiology (EP) research network. In this survey, we asked questions regarding the physician's approaches to the management of CIED leads which are faulty, unnecessary, and/or recalled. We also investigated the importance of various factors that usually influence the choice between extraction and abandonment of the lead. We then tried to understand which factors influence the clinical management of recalled leads and to explore the most important factors of concern when abandoning the lead. In addition,

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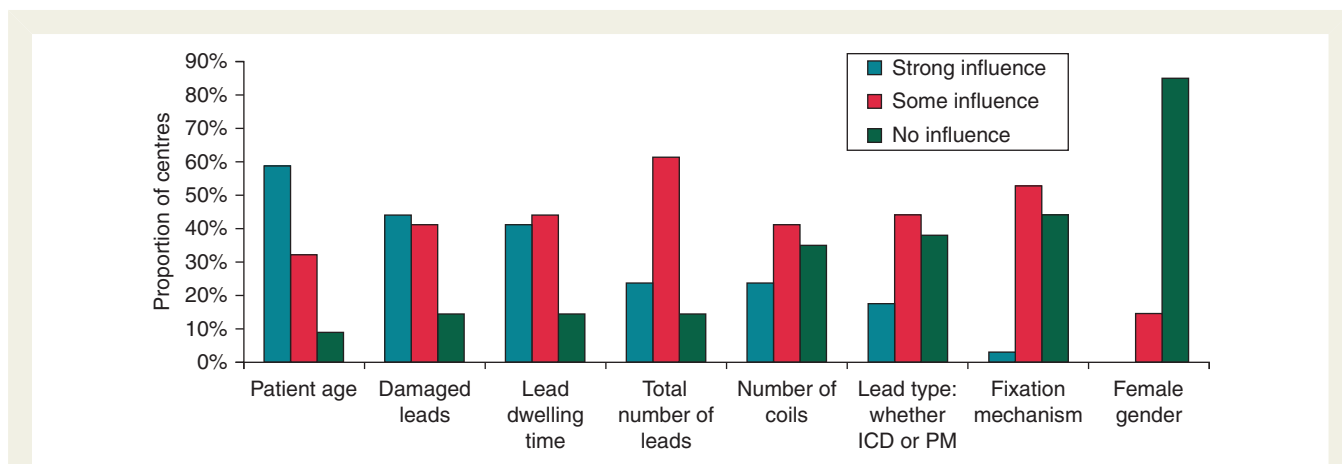


Figure 1 Proportion of respondents and factors influencing the decision on lead abandonment or lead extraction. ICD, implantable cardioverter-defibrillator; PM, pacemaker.

clinical cases from the real world were simulated and the physician’s approach in those circumstances was analysed. The cases were based on the specific situations involving the Sprint Fidelis and Riata leads, indications for system upgrade, failure of the pace/sense portion of the defibrillation lead, perforation of the heart wall by the lead, and other circumstances.

Participating centres

Responses were received from 34 of the EHRA EP research network hospitals. The country-specific distribution of the centres was as follows: Italy, 7; Belgium, 3; Germany, 3; France, 3; Spain, 3; UK, 3; Sweden 2; Denmark, 2; Austria 2, then there was participation of a single centre in the remaining six countries (Argentina, Georgia, Greece, Lithuania, Luxembourg, and Norway). The response rate was 98.5%.

Characteristics of the centres

The majority (82%) of the centres were university hospitals, 9% were private hospitals, and 9% were other types of hospital. Nine per cent of the centres performed more than 400 ICD implantations, 21% between 200 and 399, 32% between 100 and 199, and 38% performed < 100 procedures. Regarding PMs, 35% of the centres reported implanting more than 400 devices, 35% implanted 200–399 PMs, 21% between 100 and 199 PMs, and 9% implanted < 100 devices.

In the last calendar year, 85% of the responding centres reported performing lead extractions: 47% performed >30 extractions (high volume, HV) and 38% <30 extractions (low volume, LV). Sixty-four per cent of the responding centres performed >200 catheter ablations for all types of arrhythmias, 6% from 100 to 199, 26% <100, and 4% did not perform this procedure.

Results

Factors influencing decision making on lead abandonment or lead extraction

The main factors strongly influencing the decision making were patient’s age (59%), the presence of the damaged leads (44%), and the lead dwelling time (44%). Several other factors had at least some influence: the total number of leads (62%), fixation mechanism (53%), followed by the lead type, type of CIED (ICD or PM) (44%),

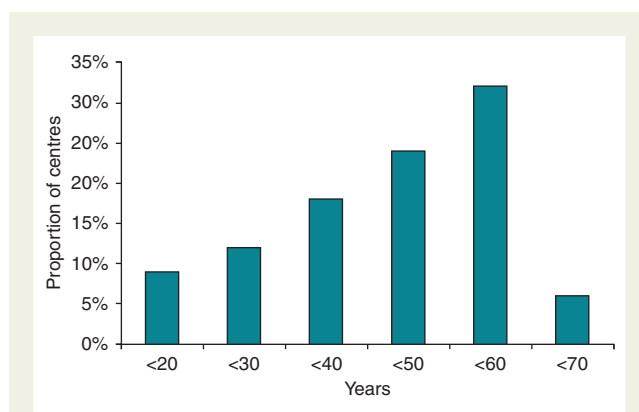


Figure 2 Proportion of respondents and age (years) under which a patient is considered ‘young’ in lead management.

and the number of coils (41%). In contrast, gender did not affect the decision: 85% of the operators would not modify their choice in female patients (Figure 1).

The majority of the participants defined a patient as “young” if they were <60 years (32%) or <50 years (24%), but there were also some centres considering young only patients <40 years (18%), <30 years (12%), or <20 years of age (9%) (Figure 2).

The survey also asked to define the maximum number of leads that would be implanted through the same vein. For the superior vena cava the cut-off for older patients was 7 (5%), 6 (15%), 5 (24%), 4 (41%), 3 (12%), 2 (3%); for younger patients, the cut-off for the same vein was 6 (6%), 5 (15%), 4 (34%), 3 (30%), 2 (15%). For the subclavian vein, the cut-off for older patients was 6 (3%), 5 (12%), 4 (48%), 3 (33%), 2 (3%); for younger patients, the cut-off for the same vein was 6 (3%), 5 (3%), 4 (27%), 3 (52%), 2 (15%).

Concerns about lead abandonment

The potential concerns and the respective answers from the participating centres are listed in Table 1. The main concern was the expected greater difficulty of future extraction. Operators had also

Table 1 List of concerns related to lead abandonment

	Strong concerns (%)	Some concerns (%)	No concerns (%)
Difficulty for future extraction	61	30	9
Future infections	32	50	18
CIED interferences	24	68	8
Venous thrombosis	15	56	29
MRI preclusion	12	50	38
Bulk in the pocket	9	62	29
Tricuspid regurgitation	15	59	26

CIED, cardiac implantable electronic devices; MRI, magnetic resonance imaging.

some concerns about the potential interference with other leads (68%), the formation of a bulk in the pocket (62%), worsening of tricuspid regurgitation (59%), risk of venous thrombosis (56%), and infections (50%). In the era of magnetic resonance imaging (MRI) conditional devices, the MRI preclusion was another important issue reported 50% of the operators.

Factors influencing lead recall management

The strongest influence came from the literature data (76%) and current guidelines (71%). Other factors with some influence were patient request (79%), legal concerns (74%), personal experience (47%), and industry issues (59%).

Lead management

Management of recalled and malfunctioning leads

The survey asked how the operator would manage both the functional Sprint Fidelis lead and externalized 1570 Riata lead at the time of generator replacement in a 26 year-old man with normal life expectancy.

In case of the functional Sprint Fidelis lead, the majority of the operators would continue using the lead (62%), some of them would extract it (35%), and only a minor proportion (3%) would cap and leave it. There were differences related to the centre volume: 60% of HV centres would extract the lead, while 77% of LV centres would continue using it. All centres that do not perform lead extraction stated that they would continue using the lead.

In case of the functional externalized 1570 Riata lead, 50% of the operators would extract it, 21% of them would cap and leave it, and 29% would continue using it. In this case, 69% of HV extracting centres preferred to extract the lead, while the preferences among LV centres were equally distributed between abandonment, extraction, and utilization.

The survey then asked how the operator would manage both the malfunctioning Sprint Fidelis and 1570 Riata lead without externalization implanted 8 years ago in a 50 year-old man with normal life expectancy.

In case of the malfunctioning Sprint Fidelis lead, 71% of the centres would extract it and 29% would abandon it. The majority of

respondents from the extracting centres would select extraction, while 100% of respondents from the non-extracting centres would abandon the lead. In case of the malfunctioning 1570 Riata lead, 68% of the centres would extract it and 32% would abandon it. The HV extracting centres have a higher percentage of respondents who would opt for lead extraction, whereas 38% of LV centres would abandon the Riata lead as would 100% of the centres that do not perform lead extraction (Figure 3).

Ventricular wall perforation

In a special case when a lead is malfunctioning because it perforated through the ventricular wall, 60% of the operators would extract it transvenously (60%), and others would refer the patient for surgical extraction.

Indications for system upgrade

If PM needs to be upgraded to ICD and the right ventricular pacing lead is functional but not being used, 33% of the operators would extract the lead to avoid the potential difficulties associated with future lead extraction. Others would abandon the lead because it could be useful in the future (26%) in order to avoid risks associated with extraction (29%), and 12% of responders would provide other solutions.

In a special case of the indication for system upgrade and ipsilateral venous occlusion, a strategy of extraction and ipsilateral reimplantation would be chosen in 38% of cases; a contralateral implant and tunnelling in 29%; a complete contralateral reimplant with lead abandonment in 18%; an epicardial approach in 9%; a venoplasty and ipsilateral reimplantation in 6%. Among HV centres, 60% preferred lead extraction and ipsilateral reimplantation, while contralateral implantation with tunnelling was chosen by 40% of the respondents; 60% of non-extracting centres preferred contralateral implant with tunnelling.

The lead through a patent foramen ovale

Another real-world scenario was that of an anomalous placement of the lead in the left ventricle through patent foramen ovale (PFO) detected 2 months after implantation. The majority of the centres would perform a transvenous removal of the lead (74%). Twenty-four per cent would start anticoagulation therapy (24%) and a minority would prefer to start only an antiplatelet therapy (2%); none choose a surgical approach.

Device at end-of-life in a patient with a Class III indication

The decision making could also be challenging in a 35 year-old patient with an end-of-life (EOL) single-chamber ICD implanted for primary prevention in the absence of appropriate therapy and a current Class III indication because of the evolution of the guidelines. In this case, the preferred management by the majority of the centres was to abandon the lead and remove the device (44%), followed by the removal of the entire system (21%), and no ICD replacement (21%). However, a significant minority of the operators (15%) would perform ICD replacement.

Patient request to change to a subcutaneous implantable cardioverter-defibrillators

Another specific question was whether it was reasonable to accept the patient's request to extract a functioning transvenous single-

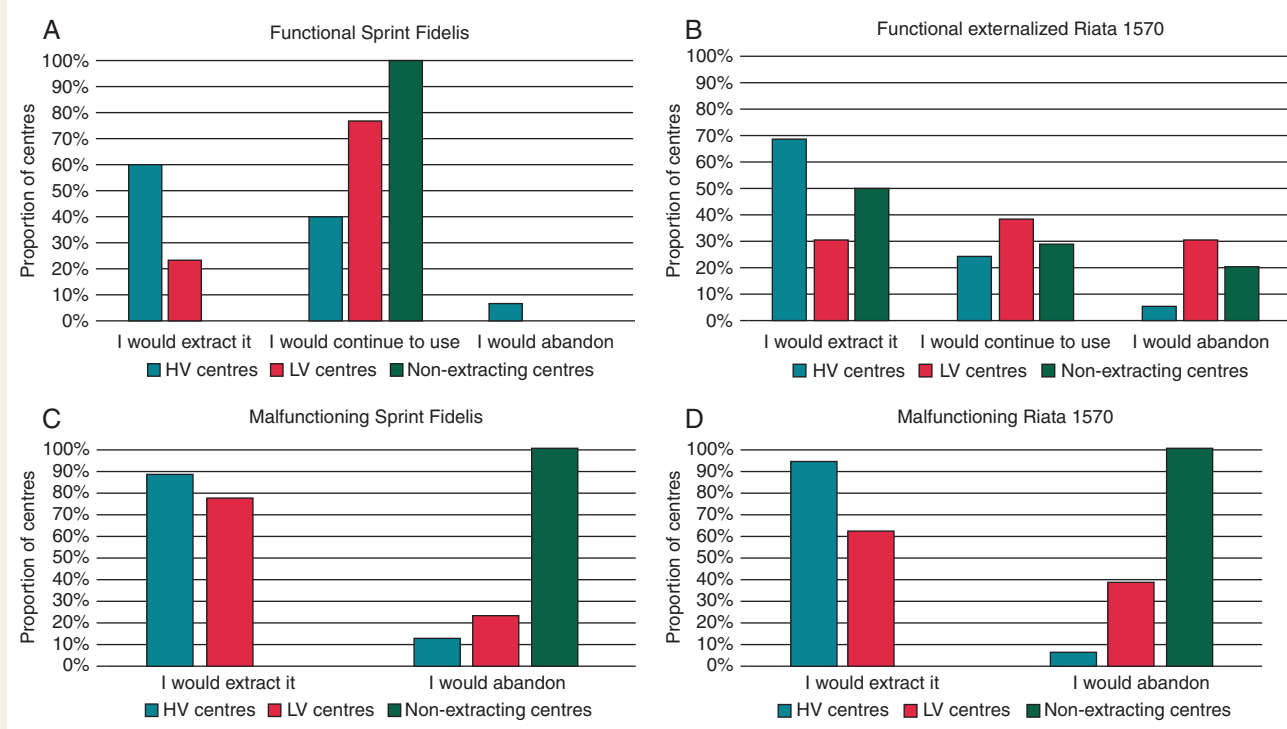


Figure 3 Different strategies among high volume (HV), low volume (LV) and non-extracting centres, in case of a patient with: (A) a functional Sprint Fidelis lead; (B) a functional externalized Riata 1570 lead; (C) a malfunctioning Sprint Fidelis lead; (D) a malfunctioning Riata 1570 lead.

chamber ICD and implant a subcutaneous ICD for primary prevention of sudden death in the absence of the need for antibradycardia or antitachycardia pacing. Of interest, 21% of the operators would follow such a request.

Discussion

Despite the increased number of malfunctioning and recalled PM and ICD leads in Europe, there are still limited and unsystematic data on how the physicians act in clinical practice. It still remains unknown how the operators choose among the wide variety of approaches. The aim of this EP Wire survey was, therefore, to investigate the implanters' approaches in case of malfunctioning and recalled PM or ICD leads, especially considering that transvenous lead extraction in HV centres has evolved into a specialized procedure with well-defined indications and excellent results.^{9,10}

A recently published expert consensus on lead extraction¹¹ provides recommendations on indications, procedures, and facilities lead extraction. While in the presence of Class I indications for lead extraction, there are no doubts about the strategy, the decision making is more challenging for Class II indications regarding non-functional, dysfunctional, recalled, potentially dangerous or redundant leads.

In this survey, extraction of a recalled lead is still preferred over implantation of an additional lead, especially if the patient is young and the lead dwelling time is relatively short. The total number of leads, fixation mechanism, and the number of coils¹² are taken into account for the final decision. On the other hand, female gender

has no impact on lead management, despite published data suggesting that female gender may be associated with extraction-related complications.⁸ Moreover, the potential risks for the future management influence lead abandonment. The MRI preclusion in the case of lead abandonment should be taken into account.

It is interesting to note the lack of a clear age cut-off. While the majority of the participants would define a patient as young if the age is <50–60 years, some centres consider a patient young if they are <40 years or <30 years and even <20 years. It should be noted that a significant number of operators from HV centres report a higher age cut-off. In other words, the more experienced the operator is in lead management, the higher the age threshold is raised.

Surprisingly, in case of the functional recalled leads, the approach appears to depend on the specific lead model: while the majority of the operators would continue to use a functional Sprint Fidelis lead, in case of the functional 1570 Riata lead, the majority of the operators would prefer to extract it. A more aggressive approach to extraction of the functional 1570 Riata leads could be due to the recent concerns that have come to light about the entire Riata lead family (insulation defect, with or without externalized conductors), while the Sprint Fidelis recall, even if not less dangerous, has been known and dealt with for longer.^{13,14}

Notably, a different approach related to the expertise of HV centres compared with LV centres was observed.¹⁵ While the non-extracting and LV centres would continue to use a functional recalled lead (both Sprint Fidelis^{16,17} and Riata¹⁸ leads), HV centres would prefer to extract it. Some differences between centres also exist in

the management of a malfunctioning lead. For example, in case of a failing Sprint Fidelis lead, the majority of extracting centres opted for an extraction while the non-extracting centres would abandon the lead. This approach is confirmed by the malfunctioning 1570 Riata lead example. The difference between HV and LV centres is also apparent in case of upgrade indications and ipsilateral venous occlusion. The majority of HV centres preferred lead extraction and ipsilateral reimplantation, while contralateral implantation with tunnelling was chosen by the majority of non-extracting centres preferred contralateral implant with tunnelling.

A more aggressive approach from HV centres is due in part to the better knowledge of the recalled lead issue, but also to the proper perception of their skills. Riata and Sprint Fidelis leads were recalled because of an increased rate of failure due to conductor fracture or insulation abrasion. According to the lead design and type of failure, the extraction procedure could be challenging but showed good success rates in expert centres. Regarding the indications for upgrade and ipsilateral venous occlusion, the survey showed how HV centres would preserve patient venous access.

Another finding of this survey is the perception that subcutaneous ICD may be an alternative to transvenous ICD in the prevention of sudden death.¹⁹ Of note, the participants appear very keen that their decisions would not add problems to the future of their patients.

Conclusion

This survey provides a snapshot of the operators' approach to management of redundant, malfunctioning, and recalled CIED leads and may form the basis for future prospective research in this field. We hope that this survey will help all physicians to critically consider their choices to motivate some changes in their clinical practice in lead management to improve patient care.

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