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Replacement of implantable cardioverter defibrillators and cardiac resynchronization therapy devices: results of the European Heart Rhythm Association survey

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The aim of this EP Wire was to assess the management, indications, and techniques for implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy (CRT) device replacement in Europe. A total of 24 centres in 14 European countries completed the questionnaire. All centres were members of the European Heart Rhythm Association Electrophysiology Research Network. Replacement procedures were performed by electrophysiologists in 52% of the centres, by cardiologists in 33%, and both in the remaining centres. In the majority of centres, the procedures were performed during a short hospitalization (<2 days; 61.2%), or on an outpatient basis (28%). The overwhelming majority of centres reported that they replaced ICDs at the end of battery life. Only in a small subset (<10%) of patients with ICD for primary prevention and without ventricular tachycardia (VT) since implantation, ICD was not replaced. In inherited primary arrhythmia syndromes, 80% of the centres always replaced the ICD at the end of battery life. After VT ablation, only few centres (9%) explanted or downgraded the device that was previously implanted for secondary prevention, but only in those patients without new VT episodes. Patient's life expectancy <1 year was the most commonly reported reason (61%) to downgrade from a CRT-D to a CRT-P device. While warfarin therapy was continued in 47% of the centres, non-vitamin K oral anticoagulants were discontinued without bridging 24 h prior to replacement procedures in 60%. Finally, in 65% of the centres, VT induction and shock testing during ICD and CRT-D replacement were performed only in the case of leads with a warning or with borderline measurements. This survey provides a snapshot of the perioperative management, indications, and techniques of ICD and CRT device replacement in Europe. It demonstrates some variations between participating centres, probably related to local policies and to the heterogeneity of the ICD population.

Keywords Cardiac implantable electronic device • Implantable cardioverter defibrillator • Pacemaker • Cardiac resynchronization therapy • Replacement • EHRA survey • EP Wire

Introduction

Implantation of cardiac devices is the most common interventional procedure performed by cardiac electrophysiologists in Europe and worldwide.[1] There is the sufficient knowledge on the clinical benefit of *de novo* implanted cardiac devices and international guidelines that deal with the indications for sudden cardiac death prevention, cardiac pacing, and cardiac resynchronization therapy (CRT).[2–6] However, scientific and real-world data as well as practice guidelines on device replacement are sparse.

The purpose of this European Heart Rhythm Association (EHRA) EP Wire survey was to assess the management, indications, and techniques for implantable cardioverter defibrillator (ICD) and CRT device replacement in Europe.

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Methods and results

A questionnaire was sent via the Internet to the participating centres of the EHRA Electrophysiology (EP) Research Network, which included questions on standards and policies applied by the centres and physicians regarding the management, indications, and techniques of ICD and CRT device replacement.

Participating centres

Overall, 24 centres from 14 countries responded to the questionnaire, with a wide geographic distribution of responders. Of these, 21 (87%) were university hospitals and 3 (12%) were private hospitals. Among responding centres, 29% implanted 1–99 devices during the previous year, 8% implanted 100–199 devices, 29% performed 200–399 implantations, and 33% >400 implantations. Device replacement procedures were performed during a short hospitalization (<2 days) in 61% of the centres, on an outpatient basis in 28%, and during 3- to 4-day hospitalization in 9%. In 66% of the centres, ICD and CRT replacement procedures were performed in an EP or coronary angiography laboratory; in 9%, replacements were performed only in a surgical theatre, and in 23% of the centres, replacement procedures were performed in an EP laboratory or a surgical theatre. Just over in half the centres (52%), ICD and CRT replacement procedures were performed by electrophysiologists, in 33% by cardiologists, and by a combination of both in the remaining 15% of the centres.

Primary prevention ICD in the absence of VT episodes since implantation

At the end of battery life, in patients with ICD implanted for primary prevention for ischaemic or non-ischaemic cardiomyopathy, about one-third of the responding centres (38%) reported that, in the last 2 years, they had always replaced ICD and had never downgraded the device, even if there were no episodes of ventricular arrhythmias. The remaining 61% of the centres reported that they did not replace ICD or that they downgraded the device from ICD to a pacemaker (PM) in selected cases (<10%) if no episodes of ventricular tachycardia (VT) were retrieved from ICD (*Figure 1*).

In inherited primary arrhythmia syndrome patients with primary prevention ICD, 80% of the responding centres always replaced ICD at the end of battery life, even if there were no recorded VT episodes. On the contrary, in the absence of VT, ICD was not replaced in 9% of the centres for long QT syndrome and in further 9% for Brugada syndrome, in 4% for short QT syndrome, and in 4% for catecholaminergic polymorphic VT (*Figure 2*).

Secondary prevention ICD in the absence of VT episodes since implantation

In 76% of the responding centres, ICD replacement was performed at the end of battery life in all patients with ICD implanted for secondary prevention after a haemodynamically stable VT with no aborted sudden cardiac death, preserved left ventricular ejection fraction (LVEF), and no recorded episodes of ventricular arrhythmia since implantation. However, 14% of the centres reported that they already explanted device or downgraded it from ICD to PM in such patients, whereas 9% of the centres explanted the ICD or downgraded to PM in such patients after a VT ablation procedure (*Figure 3*).

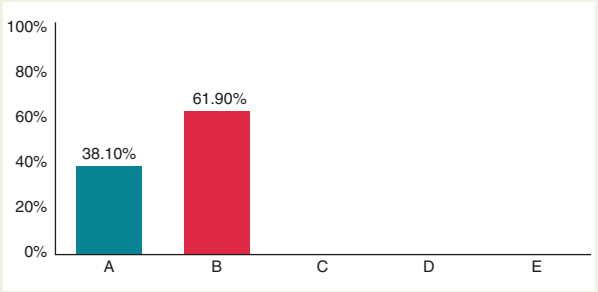

Figure 1 In patients with ICD implanted for primary prevention for ischaemic or non-ischaemic cardiomyopathy, battery end-of-life service, and no episodes of ventricular arrhythmia since implantation, what is the percentage of patients in whom you have not replaced the ICD or have downgraded the device from ICD to PM in the last 2 years? Each bar represents one possible answer (proportion of replies to each question). A: never; B: <10%; C: 10–29%; D: 30–49%; E: >50%.

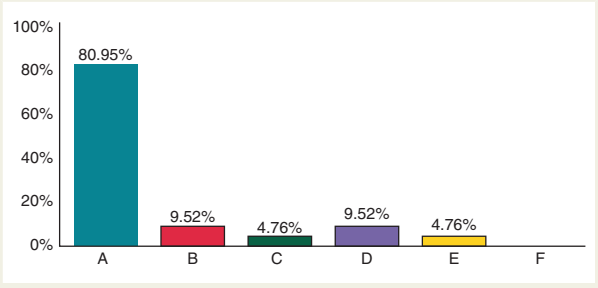

Figure 2 In patients with ICD implanted for primary prevention in inherited primary arrhythmia syndromes, battery end-of-service, and no episodes of ventricular arrhythmia since implantation, in which syndrome(s) have you not replaced the ICD in the last 2 years (multiple answers)? Each bar represents one possible answer (proportion of replies to each question). A: never, so far I always replaced ICDs in these patients; B: in long QT syndrome; C: in short QT syndrome; D: in Brugada syndrome; E: in catecholaminergic polymorphic VT; F: in early repolarization syndrome.

Downgrading from a CRT-D to a CRT-P device

Patient's life expectancy <1 year was the most common reason to downgrade from a CRT-D to a CRT-P device reported by 61% of the centres. Less frequent reasons were irreversible severe heart failure (42%), advanced (>80 years) age (38%), LVEF >40% with non-ischaemic cardiomyopathy and without appropriate device therapies (38%), LVEF >40% with ischaemic cardiomyopathy and without appropriate device therapies (23%), frailty (28%), prior inappropriate ICD therapies and no appropriate therapies since implantation regardless of cardiomyopathy type (4%), and no

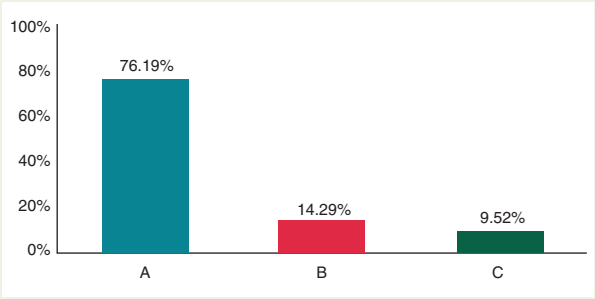

Figure 3 In patients with ICD implanted for secondary prevention after haemodynamically stable VT, no aborted sudden cardiac death, preserved LVEF, no episodes of ventricular arrhythmia since implantation, and battery end-of-service, in which proportion did you explant or downgrade the device? Each bar represents one possible answer (proportion of replies to each question). A: I never explant or downgrade the device from ICD to PM; B: I already explanted or downgraded the device from ICD to PM; C: I already explanted or downgraded the device from ICD to PM, but after VT ablation only.

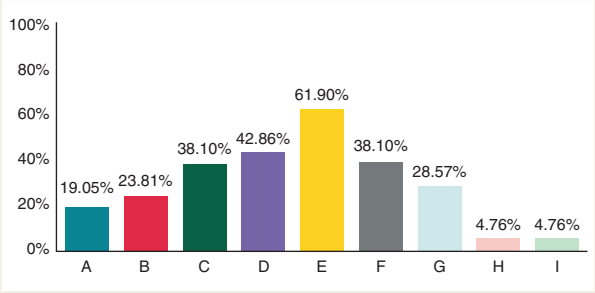

Figure 4 When replacing a CRT-D device in which of the following cases would you downgrade to a CRT-P device (multiple answers)? Each bar represents one possible answer (proportion of replies to each question). A: never; B: LVEF >40%, ischaemic cardiomyopathy without appropriate device therapies; C: LVEF >40%, non-ischaemic cardiomyopathy without appropriate device therapies; D: irreversible severe heart failure (NYHA IV); E: severe medical conditions (e.g. neoplasia) with <1 year life expectancy; F: advanced age (e.g. >80 years); G: frailty; H: prior inappropriate ICD therapies and no appropriate therapies since implantation, regardless of cardiomyopathy type; I: no appropriate therapies, high risk of inappropriate therapy (e.g. AF developed).

appropriate therapies and high risk of inappropriate therapy (e.g. development of atrial fibrillation; 4%). However, 19% of the centres had never downgraded a CRT-D to a CRT-P device (*Figure 4*).

Peri-procedural use of antibiotic therapy

Most centres (95%) used a systematic prophylactic antibiotic therapy at the beginning of the operation as a 'single-shot application', whereas 19% also used systematically prophylactic antibiotic therapy after the operation. Local antibacterial envelopes were also used in 14% of the centres, and local application of antibiotics (e.g. with a sponge placed in the wound) were used in 14% of the centres.

Peri-procedural anticoagulation

Warfarin therapy was continued in all patients before procedures in 48% of the centres, and 19% of the centres continued the warfarin therapy only in patients with mechanical valves or high stroke risk, whereas in 14% of the centres, warfarin was continued in patients with mechanical valves only. In 14% of the centres, discontinuation of warfarin with bridging was permitted in patients with mechanical valves or high stroke risk only, but only 5% of the centres discontinued warfarin with bridging in patients with mechanical valves.

In patients on non-vitamin K oral anticoagulant (NOAC) therapy, the protocol followed before ICD and CRT replacement was heterogeneous. In 60% of the centres, NOAC therapy was discontinued without bridging 24 h prior to replacement procedures, with 20% of the centres discontinuing NOAC with bridging in patients with high stroke risk and 10% more continued NOAC in patients with high stroke risk only. Finally, NOACs were continued in all patients in 10% of the centres.

Incision location for ICD and CRT replacement

The choice of the incision location varied between centres. In 40%, the incision was targeting the last scar, while 30% performed the incision always above the generator. In other 30% of the centres, the incision location depended on the procedure type (with or without device upgrade).

Induction of VF and shock testing during ICD and CRT-D replacement

Only 5% of the centres performed VT or ventricular fibrillation induction and shock testing during device replacement in all patients, whereas 20% of the centres did not perform VT induction in any patient. In the majority of the responding centres (65%), VT induction and shock testing during ICD and CRT-D replacement were performed in case of leads being subjected to a warning or showing borderline results of measurements during routine follow-up. Less frequent reasons for VT induction were right-sided device location (40%), system upgrade (25%), or ICD implantation for secondary prevention (25%) (*Figure 5*).

Discussion

This EP Wire provides an insight into contemporary European practice for replacement of ICD and CRT devices, mostly in university hospitals. The main findings of this survey are the following: (i) the overwhelming majority routinely replaced ICD except for very selected patients with ICD for primary prevention without VT episodes since implantation; (ii) in inherited primary arrhythmia syndromes, the centres almost always replaced ICD at the end of battery life; (iii) patient's life expectancy <1 year was the most commonly reported reason to downgrade from a CRT-D to a CRT-P device; (iv) the peri-procedural anticoagulation protocol varied greatly between centres especially with regard to NOACs; (v) VT induction and shock testing during ICD and CRT-D replacement

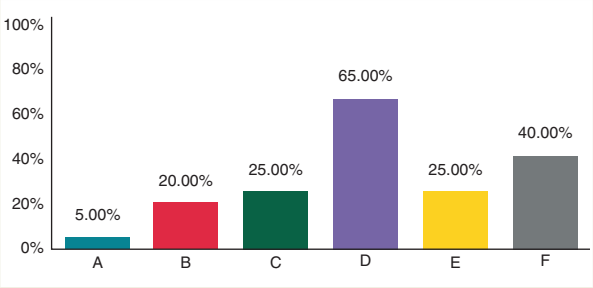

Figure 5 VF induction and shock testing during ICD and CRT-D replacement (multiple answers). Each bar represents one possible answer (proportion of replies to each question). A: is always performed; B: is never performed; C: is performed in case of upgrading; D: is performed in case of leads subject to a warning or borderline measurements during routine follow-up; E: is performed in secondary prevention patients; F: is performed in right-sided devices.

were performed only in case of leads subject to a warning or with borderline measurements.

Implantation rates of devices, especially ICDs, grew significantly in the last decade, as a consequence of favourable results of numerous clinical studies. In the USA, over 100 000 ICD implantation procedures are being performed each year, 25% of which are generator replacements due to battery depletion.[7] Similar figures are reported in Europe.[8,9] The indications for *de novo* implantation are relatively well specified, but device replacement lacks specification. Consequently, many patients who undergo replacement procedure will receive devices based on their initial indications, regardless of their clinical evolution during the device lifetime. This is an important aspect since many ICD recipients have device-related complications, including inappropriate shocks. Furthermore, ICD replacement procedure by itself confers a 5% risk of severe complications.[10] Age, atrial fibrillation, and congestive heart failure as well as non-cardiac co-morbidities are associated with higher mortality following ICD replacement. These factors should be considered when planning device replacement.[11]

Primary prevention ICD in the absence of VT episodes since implantation

The results of this survey suggest that there is a general trend towards replacing ICD regardless of the patient's clinical evolution since the initial implant. However, over half of the responding sites reported that they did not replace ICD for primary prevention in ischaemic or non-ischaemic cardiomyopathy in selected patients (albeit this percentage was only $<10\%$) if the device did not record any VT. It seems highly probable that this decision is guided by patients' co-morbidities, as stated previously. Indeed, even if the majority of primary prevention ICD patients did not experience ventricular arrhythmias during first battery service-life, a non-negligible part of these patients experienced appropriate ICD therapy after replacement.[12]

In inherited primary arrhythmias, 80% of the responding sites systematically performed replacement in all cases. This difference is probably due to the sparse knowledge regarding the stratification of arrhythmic risk, younger age, and less co-morbidity in these patients.

Secondary prevention ICD in the absence of VT episodes since implantation

For secondary prevention, the general trend was also to replace ICDs, regardless of the lack of arrhythmia during the life of the former device. There were few centres, which did not perform a device re-implantation after VT ablation if there was no arrhythmic episode recurrence. In the absence of clinical trials comparing outcomes in specific populations, approach to ICD replacement will remain empirical. Under these circumstances, the decision to not replace ICD at the end of battery life is similar to deactivate a still functional device, and it raises important moral, ethical, and legal issues.[13–16]

A patient-centred approach could improve decisions on ICD replacement. A comprehensive medical evaluation should take place allowing the direct communication between an electrophysiologist, a primary care physician, and other specialists involved in patient's care. Patient's preferences, past experiences, and advanced care planning should be explicitly included in the decision-making process.[16,17]

Downgrading from a CRT-D to a CRT-P device

Currently, there is no clinical study designed to directly compare the effectiveness and the safety of CRT-D with those of CRT-P. The COMPANION is the only trial indirectly addressing this issue. However, this study lacks the statistical power to derive any conclusion on this topic.[18] Subsequently, two meta-analyses failed to demonstrate the superiority of CRT-D over CRT-P.[19,20] In addition, a recent analysis of registry data did not show a benefit of CRT-D over CRT-P therapy with respect to survival, despite a less favourable clinical profile of CRT-P recipients (older, with more co-morbidities, including atrial fibrillation, more severe heart failure).[21]

Despite this evidence, in the real world, the CRT-D is preferred to CRT-P in most circumstances. Therefore, the decision to downgrade from CRT-D to CRT-P in the present survey was determined by the same factors used to decide the initial implant of a CRT-P: patient's life expectancy <1 year, irreversible forms of heart failure, age >80, and non-ischaemic cardiomyopathy without appropriate device therapies.

Peri-procedural anticoagulation

There is a large variety of strategies regarding the peri-procedural use of anticoagulants when replacing a device. Although there is a lot of evidence proving that warfarin bridging does not offer a significant advantage,[22] this approach is still widely used. In patients on NOAC therapy, the anticoagulation protocol by ICD and CRT replacement was very heterogeneous between different centres. This may reflect the limited data about the optimal peri-procedural anticoagulation protocol.[23]

Induction of VF and shock testing during ICD and CRT-D replacement

Induction of VF and shock testing during ICD and CRT-D replacement is extremely rare in routine clinical practice. This approach is similar to that followed for the initial implantation in the majority of the implanting centres. It is based on evidence that routine testing of the defibrillation threshold would not offer a significant benefit.[24–26] In addition, the SIMPLE trial has shown that routine defibrillation testing at the time of ICD implantation, although being generally well tolerated, neither improves shock efficacy nor reduces arrhythmic death.[27]

Conclusion

This survey provides a snapshot of the perioperative management, indications, and techniques of ICD and CRT device replacement in a cohort of the European centres. It demonstrates some different approaches, depending on local policies and the heterogeneity of the implanted patients.

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