Society Guidelines

Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines

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ABSTRACT

Sudden cardiac death is a major public health issue in Canada. However, despite the overwhelming evidence to support the use of implantable cardioverter defibrillators (ICDs) in the prevention of cardiac death there remains significant variability in implantation rates across Canada. Since the most recent Canadian Cardiovascular Society position statement on ICD use in Canada in 2005, there has been a plethora of new scientific information to assist physicians in their discussions with patients considered for ICD implantation to prevent sudden cardiac death due to ventricular arrhythmias. We have reviewed, critically appraised, and synthesized the pertinent evidence to develop recommendations regarding: (1) ICD implantation in the primary and secondary prevention of sudden cardiac death in patients with and without ischemic heart disease; (2) when it is reasonable to

RÉSUMÉ

La mort subite d'origine cardiaque constitue un important problème de santé publique au Canada. Cependant, en dépit des importantes preuves appuyant le recours aux défibrillateurs cardioverteurs implantables (DCI) pour prévenir ce type de décès, le taux d'implantation de ces dispositifs demeure très variable à l'échelle nationale. Depuis le dernier énoncé de position de la Société canadienne de cardiologie en 2005 concernant l'usage des DCI au pays, une pléthore de nouvelles données scientifiques se sont ajoutées pour aider les médecins à aborder avec leurs patients la question du DCI pour prévenir la mort subite d'origine cardiaque causée par l'arythmie ventriculaire. Nous avons procédé à la revue, à l'évaluation critique et à la synthèse des données pertinentes afin de formuler des recommandations concernant : 1) l'implantation d'un DCI dans la prévention primaire et

Sudden cardiac death (SCD) is a major public health issue. Of the > 200,000 deaths in Canada annually, approximately one-quarter are cardiac in nature, and half are sudden and unexpected.[1] Since the most recent Canadian Cardiovascular

Society (CCS) position statement on implantable cardioverter defibrillator (ICD) use in Canada in 2005,[2] new scientific information and technologies are available to assist physicians in their discussions with patients considered for

topic with a mandate to formulate disease-specific recommendations. These recommendations are aimed to provide a reasonable and practical approach to care for specialists and allied health professionals obliged with the duty of bestowing optimal care to patients and families, and can be subject to change as scientific knowledge and technology advance and as practice patterns evolve. The statement is not intended to be a substitute for physicians using their individual judgement in managing clinical care in consultation with the patient, with appropriate regard to all the individual circumstances of the patient, diagnostic and treatment options available and available resources. Adherence to these recommendations will not necessarily produce successful outcomes in every case.

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withhold ICD implantation on the basis of comorbidities; (3) ICD implantation in patients listed for heart transplantation; (4) implantation of a single- vs dual-chamber ICD; (5) implantation of single- vs dual-coil ICD leads; (6) the role of subcutaneous ICDs; and (7) ICD implantation infection prevention strategies. We expect that this document, in combination with the companion article that addresses the implementation of these guidelines, will assist all medical professionals with the care of patients who have had or at risk of sudden cardiac death.

secondaire de la mort subite d'origine cardiaque chez les patients atteints ou non d'une cardiopathie ischémique; 2) les circonstances où il est préférable d'éviter l'implantation d'un DCI en raison de la présence de comorbidités; 3) l'implantation d'un DCI chez les patients devant subir une transplantation cardiaque; 4) l'implantation d'un DCI monochambre vs un DCI double chambre; 5) l'implantation d'une sonde à simple ou double serpentin; 6) le rôle du DCI sous-cutané; et 7) les stratégies de prévention des infections lors de l'implantation d'un DCI. Nous croyons que ce document, combiné à l'article traitant de la mise en œuvre des lignes directrices, aidera les professionnels de la santé dans la prise en charge des patients à risque de mort subite d'origine cardiaque.

ICD implantation to prevent SCD due to ventricular arrhythmias.

The intended audience for these guidelines includes specialist and generalist physicians and surgeons, medical trainees, allied professionals, and administrators involved in the care of patients who present with or are at risk of malignant ventricular arrhythmias.

These guidelines were developed through a critical evaluation of the existing literature, expert consensus, and use of the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system. The strength of the evidence was weighed, with full consideration for any risks of bias, including publication bias and any imprecision, inconsistency, and indirectness of the available data. The strength of each recommendation was categorized as "strong" or "weak (conditional)," and the quality of evidence as "high," "moderate," "low," or "very low." Valid systematic methods were used when possible, on the basis of published evidence similar to previous guidelines. These guidelines were externally reviewed by experts and modified, on the basis of those reviews.

We have intentionally not addressed specific populations that are not well represented in clinical trials and have been discussed by the Canadian Heart Rhythm Society (CHRS) and/or CCS or Heart Rhythm Society, in particular for ICD use in congenital, genetic diseases and refer the reader to these position statements or guidelines.[3-6]

These revised guidelines address the primary and secondary indications for ICD insertion in the prevention of SCD from a Canadian perspective, but will likely also be relevant to decision-making in many other jurisdictions throughout the world. These guidelines focus on the update of the previous 2005 guidelines. An accompanying article will address the implementation of these guidelines, device programming, and management of common clinical conditions in patients with ICDs.

Patient Selection

Risk assessment of SCD

Standard criteria for assessing the risk of ventricular tachycardia (VT)/ventricular fibrillation (VF) include left ventricular ejection fraction (LVEF) and the presence of reversible/treatable causes of VF or certain specific diseases (eg, hypertrophic cardiomyopathy, cardiac sarcoidosis); these are the cornerstones of indications for an ICD. Additional

factors that have been associated with a higher risk of VT/VF include an elevated heart rate, frequent premature ventricular complexes or nonsustained VT, a myocardial aneurysm or extensive scarring, and prolonged QRS duration on the electrocardiogram.[5,7] Additionally, newer noninvasive predictors for SCD, such as estimates of autonomic function and cardiac repolarization that include heart rate variability, baroreflex sensitivity, heart rate turbulence, and microvolt T-wave alternans, along with neurohormonal markers such as B-type natriuretic peptide.[7] Although ongoing research is investigating the utility of these tools to guide ICD therapy, they are not presently used for this purpose in clinical practice because of their lack of predictive value in individuals and a lack of evidence that their use alters clinical outcome.

Primary prevention of SCD due to ventricular arrhythmias

An aid in decision-making for primary prevention ICD use is shown in Figure 1.

Ischemic cardiomyopathy. The ability of an ICD to reduce the risk of death in patients with chronic ischemic cardiomyopathy, mostly a previous myocardial infarction (MI), is well established. Several large randomized trials, the first **M**ulticenter **A**utomatic **D**efibrillator **I**mplantation **T**rial (MADIT),[8] **M**ulticenter **UnS**ustained **T**achycardia **T**rial (MUSTT),[9] the second **M**ulticenter **A**utomatic **D**efibrillator **I**mplantation **T**rial (MADIT-II),[10] and the **S**udden **C**ardiac **D**eath in **He**art **F**ailure **T**rial (SCD-HeFT),[11] have shown a reduction in total mortality with ICD implantation in addition to optimal medical therapy (OMT) in patients with a remote MI and a reduced LVEF. The MADIT-II study, which included patients with an LVEF $\leq$ 30%, at least 1 month after MI, reported a 5.6% (14.2% vs 19.8%; $P = 0.016$) reduction in mortality over 20 months of average follow-up, with an ICD vs OMT alone. The MADIT study included patients with LVEF up to 35%, and the MUSTT trial included patients with LVEF up to 40% and only included patients with spontaneous, nonsustained VT before enrollment and VT or VF induction at electrophysiology study (EPS). ICD use was not randomized in the MUSTT study. Both trials showed a decrease in mortality in patients treated with an ICD (MADIT: 15.8% vs 38.6%; $P = 0.009$; MUSTT: 21.7% vs 44.8%; $P < 0.001$). SCD-HeFT included ischemic and nonischemic patients with an LVEF $\leq$ 35%. The ischemic
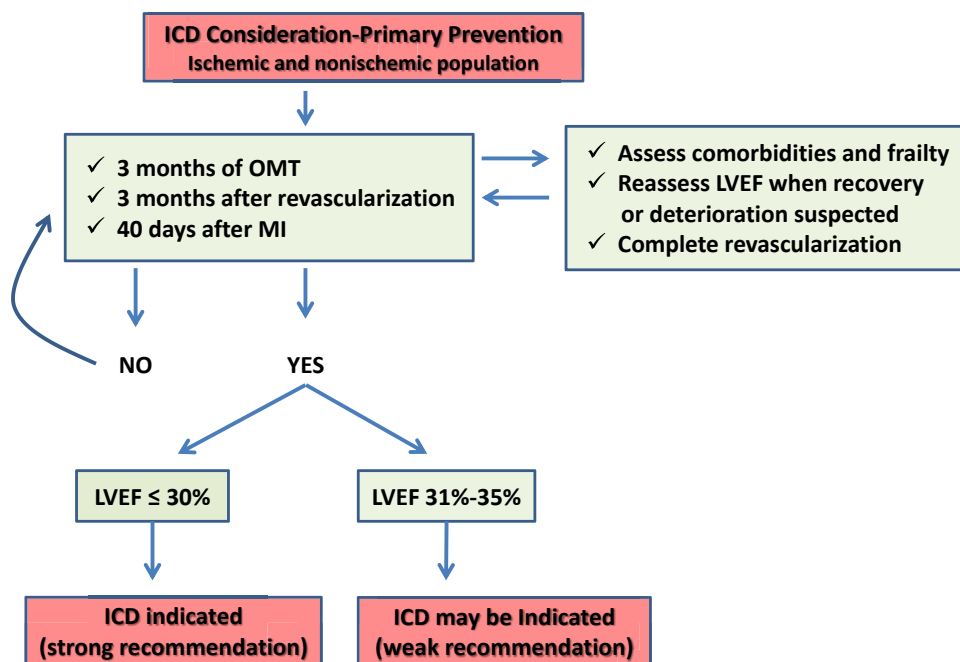
Figure 1. Aid in decision-making for primary prevention ICD. ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MI, myocardial infarction; OMT, optimal medical therapy.

cohort showed a mortality reduction of 21% in ICD patients compared with placebo, but there was no mortality reduction in the prespecified subgroup with LVEF of 31%-35%. Although these studies support ICD use in patients with an LVEF of 31%-35%, the data in this range are not as robust as for those with an LVEF of ≤ 30%.

Three studies have shown that primary prevention ICD implantation early after MI does not improve survival. The **D**efibrillator **in A**cute **M**yocardial **I**nfarction **T**rial (DINAMIT) and **I**mmediate **R**isk **S**tratification **I**mproves **S**urvival (IRIS) trial (within 31 days and 40 days, respectively) showed that early ICD implantation decreased SCD, but was offset by a similar increase in nonsudden death.[12,13] Another small post-MI trial showed similar results, but was halted early because of poor enrollment. The **C**oronary **A**rtery **B**ypass **G**raft **P**atch (CABG-Patch) trial showed no survival benefit with early ICD implantation in high-risk patients who underwent bypass surgery with a low LVEF, presumably because of an altered risk of SCD with revascularization.[14] Because of these negative studies, assessment for primary prevention ICD therapy should be made at least 40 days after MI or 3 months after revascularization.

Nonischemic cardiomyopathy. The data for ICD benefit in nonischemic cardiomyopathy (NICM) is less clear-cut. Before the widespread use of OMT for heart failure, the 5-year mortality for NICM was estimated to be 50%. Observational studies suggest that up to 30% of these deaths are sudden.[10,15] Five randomized studies have evaluated the use of ICDs in patients with NICM. The **Amio**darone **V**ersus **I**mplantable **C**ardiover**t**er-Defibrillator (AMIOVIRT) trial and **Ca**rdiomyopathy **T**rial (CAT) did not show benefit from

ICD therapy but were small and likely underpowered to do so.[16,17] Two large, older trials, the SCD-HeFT and the **Defi**brillators **in No**nischemic **C**ardiomyopathy **T**reatment **E**valuation (DEFINITE) trials, showed a decrease in arrhythmia-related death associated with ICD use.[10,11,15,18] The DEFINITE trial randomized patients with NICM, New York Heart Association (NYHA) class I-III limitation, an LVEF ≤ 35%, and more than 10 premature ventricular complexes per hour or nonsustained VT to OMT alone or OMT with an ICD. Although the primary end point of all-cause mortality was not significantly different in the 2 groups (OMT with ICD 7.9% vs OMT alone 14.1%; P = 0.08), the risk of SCD was significantly lower in the ICD group (OMT with ICD 1.3% vs OMT alone 6.1%; P = 0.006). The large, more recent **D**efibrillator Implantation in Patients With **N**onischemic **S**ystolic **H**eart Failure (DANISH) trial enrolled 1116 patients to either ICD or usual therapy with OMT and cardiac resynchronization therapy (CRT) if indicated.[19] Again, there was no difference in overall mortality (relative risk [RR], 0.87 for ICD vs control; P = 0.28), however, SCD was significantly decreased by 50% (P = 0.005). Subgroup analysis suggested an overall mortality benefit to patients younger than age 68 years (RR, 0.64; P = 0.01). This study differed from the earlier studies with extensive CRT use in both arms (58% in DANISH vs 0% in SCD-HeFT and DEFINITE) and the use of mineralocorticoid antagonists in 58%. It is possible that these more advanced therapies could have tempered the benefit of ICDs in these patients. With the exception of the DEFINITE trial, ICD therapy in primary prophylaxis in NICM has not generally included patients with NYHA functional class I limitation; therefore, the efficacy of ICDs in this population is less certain.

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One important aspect of ICD therapy in the NICM population is the appropriate timing for ICD implantation and trying to predict which patient's LVEF might recover. Although the CAT study showed no benefit to ICD implantation in patients with NICM within 9 months of diagnosis, it included only 10% of the originally planned patients and was underpowered to show a difference.[17] In the DEFINITE study the average duration of NICM before randomization was almost 3 years. In a subanalysis in which outcomes from duration of NICM diagnosis vs ICD implantation were compared similar risk reduction with ICD therapy was reported when patients were stratified by ≤ 3 vs > 3 months or ≤ 9 vs > 9 months.[18] Similarly, a single-centre study of patients with NICM implanted with an ICD reported similar rates of appropriate ICD therapies in patients diagnosed at < 9 (27%) vs ≥ 9 months (27%).[20]

A significant proportion of patients with newly diagnosed NICM will have improvement in their LVEF with OMT and are unlikely to derive benefit from an ICD implantation.[21] Thus, an ICD is not recommended within the first 3 months after the initial NICM diagnosis unless other potential reasons for ICD implantation are present (indication for pacing, sustained or hemodynamically significant ventricular arrhythmia, and syncope likely due to a ventricular tachyarrhythmia).[11,16]

Optimal medical management of these patients is crucial; for details, we refer readers to recent CCS guidelines.[22]

RECOMMENDATION

1. We recommend that patients with persistent left ventricular dysfunction due to either ischemic or NICM and ejection fraction ≤ 30% receive an ICD, when persistent refers to at least 3 months of OMT in all patients and, in patients with ischemic heart disease, at least 3 months after revascularization and at least 40 days after an MI (Strong Recommendation; High-Quality Evidence).

2. We suggest an ICD be considered for patients with persistent left ventricular dysfunction due to either ischemic or NICM and ejection fraction 31%-35% when persistent refers to at least 3 months of OMT in all patients and, in patients with ischemic heart disease, at least 3 months after revascularization and at least 40 days after an MI (Weak Recommendation; Moderate-Quality Evidence).

3. We recommend that patients likely to have left ventricular dysfunction 3 months after revascularization for MI or 40 days after MI without revascularization or 3 months following OMT in NICM undergo an assessment of ejection fraction at those time points (Strong Recommendation; Low-Quality Evidence).

Practical tip. Because the LVEF might worsen in the first 3 months after an MI, we recommend repeat assessment of LVEF (40 days or 3 months after MI depending on the clinical circumstances) for patients with an ejection fraction ≤ 45% at the time of or immediately after an MI. The method of ejection fraction assessment depends on local expertise and the reliability and accuracy of available assessment methods.

RECOMMENDATION

4. We suggest that an ICD be considered in patients with an acute indication for cardiac pacing within 3 months after revascularization or 40 days of MI and before achieving OMT when there is a high probability that the ejection fraction will remain < 35% (Weak Recommendation; Low-Quality Evidence). (OMT refers to evidenced-based heart failure therapies at their maximally tolerated doses.)

Practical tip. There is a high probability that the ejection fraction will remain < 35% if there is a high burden of scar on magnetic resonance imaging, minimal myocardial viability, the ejection fraction is significantly low despite a minor biomarker level increase at the time of an MI, or when revascularization addressed only a small amount of myocardium.

Prediction of the degree of benefit from ICD implantation

The benefit of an ICD is highly dependent on a patient's individual risk of death due to ventricular arrhythmias, death due to other causes, and the acute and chronic complications of an ICD. It is important to consider that there is risk to ICD implantation, including periprocedural risks, inappropriate shocks, and device infection. The level of risk is known to be higher in patients who are frail or have significant comorbidities (eg, chronic kidney disease).[23]

Age. As people age, they are increasingly more likely to develop diseases that put them at risk for SCD and, as such, be considered for an ICD. So too, they are more likely to become frail[24] and develop comorbidities that reduce their life expectancy from nonsudden death and limit the benefit from an ICD.[25] At present, health care providers face the dilemma of whether the outcomes achieved by ICDs in younger and fit people enrolled in clinical trials can be generalized to older or frail patients. A meta-analysis on the survival benefit of primary prevention ICDs in older patients, using pooled data from 5 randomized clinical trials reported an attenuated benefit in patients older than 75 years of age because of competing causes of death. There are limited clinical trial data, because there were fewer than 400 patients eligible for analysis in this age group.[26]

Age alone should not be a deterrent to ICD implantation because, although older patients (older than 75 years) exhibit higher mortality and complications after ICD implantation, they still receive similar rates of appropriate therapies and derive a significant mortality benefit.[26-28]

Sex differences in ICD therapy and complication rates. The results of studies that examined the effect of sex on the rate of appropriate ICD therapies and the effect of ICDs on mortality have been conflicting. Subgroup analyses performed on data from the MUSTT and MADIT-II trials[8-10] suggested that there was no sex difference in mortality, whereas analysis from SCD-HeFT[11] reported a statistically significant improvement in mortality for men only. Further subgroup analyses,[29,30] meta-analyses,[31,32] and a number of

population-based studies[33,34] have also shown discrepant effects of sex on ICD benefit in primary and/or secondary prevention populations. Whereas some studies reported an increased incidence of appropriate therapy in men,[29] others suggest that sex has no effect on the likelihood of appropriate therapy.[30,33-35] With relatively low numbers of women in these trials (8%-32%)[8,36] and registries, many studies were not powered to detect a mortality benefit in women. The National Cardiovascular Data Registry (NCDR) ICD Registry reported that women had a higher rate of periprocedural complications than men (7.2% vs 4.8%; 95% confidence interval [CI], 1.25-1.53; $P < 0.001$). Using the available data, we conclude that women and men have similar benefit from ICDs, particularly at an older age. However, women appear to have an increased rate of device-related complications.

Comorbidity. Comorbidities can increase the risk of SCD and, as such, the derived benefit of an ICD, and also increase the risk of nonarrhythmic death resulting in lesser benefit. Those shown to increase nonarrhythmic death in ICD recipients are diuretic use, older age, increased NYHA class, hypertension, atrial fibrillation, increased QRS duration, LVEF < 30%, nonprescription use of a β-blocker, reduced heart rate variability, low serum sodium, chronic lung disease, peripheral vascular disease, diabetes, and chronic kidney disease.[37-42] These must be balanced with the factors that increase the risk of SCD such as reduced LVEF, increased NYHA class, and inducible VT.

Use of risk scores to assist with decision-making. Many risk scores have been developed that combine individual markers in an attempt to provide greater ability to discriminate those who would from those who would not benefit from an ICD. The ideal risk score that would assist with decision-making in a potential ICD recipient would identify patients with high risk of nonarrhythmic death and those with a very low risk of arrhythmic death. In both of these groups the benefit from ICD would be limited.

There have been risk scores derived to predict mortality in the chronic heart failure population and in populations eligible for primary prevention ICD therapy. The scores with some validation and most frequently cited include the Seattle Heart Failure Model,[43] and the SHOCKED,[44] and MADIT risk scores.[45] All have modest predictive abilities. In one study of patients in a heart function clinic, the **C**harlson **C**omorbidity **I**ndex (CCI) (Table 1) was potently associated with SCD as the CCI decreased, and had an even stronger association with nonsudden death, as the index increased.[46] The CCI, as well as other measures of comorbidity and frailty, have the advantage of being easily derived at the bedside.[47]

Frailty. There are many methods of estimating frailty. Table 2 shows a global assessment tool in which the clinician makes a gestalt judgement about the patient's frailty on the basis of a 7-point ordinal scale.[48] This method shows predictive validity for estimating outcomes such as death and institutionalization that is comparable with other methods, and is feasible in a clinical setting.

There are many limitations to the use of risk scores in patients being evaluated for an ICD. These include limited prediction of ICD mortality benefit over the short- and

Table 1. List of comorbidities to consider in assessment of ICD benefit

Components of Charlson Comorbidity Index: myocardial infarction, congestive heart failure, peripheral vascular disease, dementia, chronic pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes, hemiplegia, renal disease, leukemia/lymphoma, metastatic tumour
Age
Atrial fibrillation
New York Heart Association class
Serum sodium
Heart Rate Variability

ICD, implantable cardioverter defibrillator.

long-term, limited generalizability, assessment of only quantity and not quality of life, and that the studies from which these scores were derived assessed risk as a static, not dynamic variable. However, estimating the ICD benefit using risk scores promotes honest communication and evidence-based decision-making between patients and physicians to achieve the most appropriate therapy that is consistent with the patient's values and preferences regarding their quantity and quality of life.[49]

How should we use risk scores?. Inclusion of appropriate risk scoring should be encouraged as part of the assessment not only before implantation but also at the time of replacement. This could improve recognition of patients likely to benefit and those at very high risk of mortality despite ICD therapy who likely will not benefit or might forgo ICD therapy on the basis of personal values.

Physicians should use a combination of a statistical predictive model and clinical impression including a multidisciplinary approach (heart failure clinics, primary care physician, geriatric evaluation) to guide the appropriate discussion with the patient and family about the absolute risk reduction in the overall context of life expectancy and quality of life of each ICD candidate.

Because of the very dynamic status of some patients, one should not hesitate to delay decisions regarding device implantation or replacement to reassess their appropriateness. Risk scores are tools to improve assessment and inform discussion and should complement, not supplant, clinical expertise.

RECOMMENDATION

5. We recommend that an ICD not be offered to patients in whom comorbidities make it unlikely that an ICD will substantially increase a patient's life expectancy (Strong Recommendation; Moderate-Quality Evidence).
6. We recommend that an ICD be replaced by a pacing system, removed, or abandoned at the time of ICD generator end of life/service in patients with life-threatening comorbidities, at the request of the patient, or when an ICD is unlikely to increase life expectancy (Strong Recommendation; Low-Quality Evidence).

Practical tip. Validated risk calculators/risk assessment tools such as the CCI, the Seattle Heart Failure Model, or the SHOCKED or MADIT risk scores can be of aid in the

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Table 2. Frailty scale

Value	Description	Details
1	Very fit	Robust, active energetic, well-motivated, and fit. Commonly exercise regularly
2	Well	Without active disease but less fit than category 1
3	Well with treated comorbid disease	Disease symptoms are well controlled compared with those in category 4
4	Apparently vulnerable	Although not frankly dependent, commonly complain of being slowed or have disease symptoms
5	Mildly frail	Limited dependence on others for instrumental activities of daily living
6	Moderately frail	Help is needed with activities and instrumental activities of daily living
7	Severely frail	Completely dependent, or terminally ill

estimation of each patient's benefit/risk of an ICD implantation.

Secondary prevention

The basis for ICD use in secondary prevention assumes the exclusion of all reversible causes (Fig. 2). Three randomized trials have studied ICD use vs antiarrhythmic drug therapy (mainly amiodarone) in patients after cardiac arrest in the absence of a reversible cause (**A**ntiarrhythmics **V**ersus **I**mplantable **D**efibrillators [AVID], **C**anadian **I**mplantable **D**efibrillator **S**tudy [CIDS], **C**ardiac **A**rrest **S**tudy **H**amburg [CASH]). A meta-analysis that included these 3 trials showed a 28% reduction in the relative risk of death with an ICD that is almost entirely due to a 50% reduction in arrhythmic death. Most of the benefit was seen in the population with an LVEF ≤ 35%.[50]

RECOMMENDATION

7. We recommend use of an ICD for patients after cardiac arrest due to ventricular arrhythmias in the absence of a reversible cause (Strong Recommendation; High-Quality Evidence).
8. We suggest an ICD be considered after MI in the presence of sustained VT or VF > 48 hours after MI or > 48 hours after revascularization for MI in the absence of reversible causes (Weak Recommendation; Low-Quality Evidence). (Sustained VT refers to hemodynamically significant VT or VT > 30 seconds in duration.)
9. We recommend an ICD for patients with sustained VT in the presence of significant structural heart disease in the absence of reversible causes (Strong Recommendation; Moderate-Quality Evidence).

Significant structural heart disease pertains to conditions in which the risk of cardiac arrest in the presence of VT is high. These are conditions such as infiltrative cardiomyopathies or those associated with a reduced LVEF. This does not pertain to conditions in which the risk of cardiac arrest is low such as atrial septal defect, most valvulopathies, and atriopathies. Syncope of unknown origin that prompts consideration for an ICD should be symptomatically
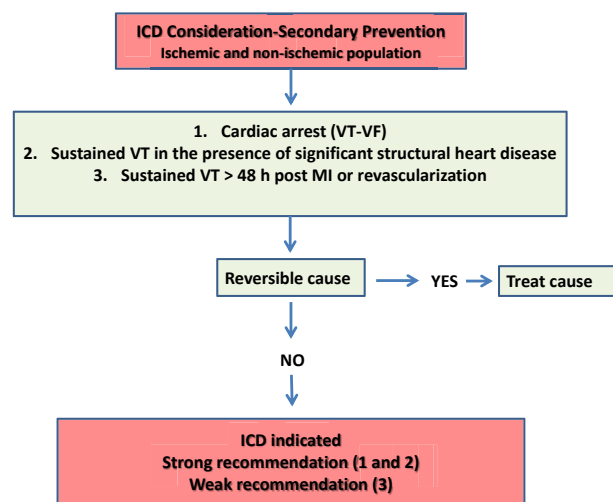

Figure 2. Aid in decision-making for secondary prevention ICD. ICD, implantable cardioverter defibrillator; MI, myocardial infarction; VF, ventricular fibrillation; VT, ventricular tachycardia.

consistent with that due to a ventricular arrhythmia, associated with significant structural heart disease, and not due to a specific nontachyarrhythmic cause like vasovagal syncope. EPS should only be considered in conditions in which its result is known to be predictive (this pertains primarily to patients with ischemic heart disease). Furthermore, the VT induced during an EPS that prompts consideration of an ICD is not idiopathic VT in which ablation or medical therapy has a high efficacy of eliminating or suppressing the VT such as outflow tract VT, fascicular VT, or bundle branch reentry VT.

Table 3 shows a summary to help in decision-making for ICD implantation.

RECOMMENDATION

10. We suggest an ICD be considered in patients with significant structural heart disease and syncope of unknown origin for whom the cause of syncope is most likely VT/VF and in whom the risk of recurrent VT/VF is high (Weak Recommendation; Moderate-Quality Evidence).
11. We recommend an ICD for patients with syncope of unknown origin with inducible VT at the time of EPS and structural heart disease (Strong Recommendation; Moderate-Quality Evidence).

Practical tip. All patients with a history of VT or VF should undergo evaluation for reversible causes of ventricular arrhythmias. Depending on the clinical circumstances this will likely include, but not be limited to, evaluation for coronary artery anomalies, ischemia, or acute MI immediately preceding the arrhythmic arrest (angiogram or computed tomography coronary angiogram), structural heart disease (echocardiography, magnetic resonance imaging, or positron emission tomography), or risk of recurrent arrhythmias (electrophysiology testing).

Table 3. Checklist to help the clinician prescribe ICDs in various clinical contexts

ICD implantation checklist (all indications)
☐ ICD therapies and implantation wished by the patient and consistent with the patient's goals of care
☐ After an assessment of comorbidities, an ICD is expected to substantially increase the patient's life expectancy

ICD implantation checklist (primary prevention)
☐ The left ventricular ejection fraction remains ≤ 30% (strong recommendation) or ≤ 35% (weak recommendation)
☐ The patient has been receiving optimal medical therapy for at least 3 months
☐ In patients with ischemic heart disease, revascularization has been considered
☐ In patients with ischemic heart disease, it has been at least 3 months after revascularization or at least 40 days after a myocardial infarction

ICD implantation checklist (secondary prevention)
☐ The patient has had a cardiac arrest due to ventricular tachycardia or ventricular fibrillation
☐ All reversible causes of ventricular arrhythmias have been excluded (common reversible conditions include myocardial infarction within the preceding 48 hours, reversible hypokalemia, reversible hypomagnesemia, and QT-prolonging medications)
☐ Sustained ventricular tachycardia in the presence of significant structural heart disease in the absence of reversible causes

ICD, implantable cardioverter defibrillator.

Other Issues

Left ventricular assist devices and ICDs

The prevalence of advanced heart failure has continued to increase worldwide, and left ventricular assist devices (LVADs) are being implanted more frequently for the treatment of end-stage congestive heart failure. Ventricular arrhythmias are common in patients with LVADs, occurring in 20%-50% of patients with the most episodes arising in the first 30 days after implantation.[51] Whereas some patients might experience hemodynamic compromise attributable to the deleterious effects of the arrhythmia on the right ventricular (RV) function, others tolerate extended episodes of ventricular arrhythmias without symptoms or significant change in LVAD output.[51,52]

There are no prospective randomized controlled trials of primary prevention ICD after LVAD implantation. In an observational study of 478 patients from the Cleveland Clinic, of whom 90 patients had an ICD, one-third of patients had their first arrhythmic event beyond 30 days after LVAD implantation. Furthermore, survival was improved in ICD patients ($P = 0.024$), and they were more likely to survive to transplantation ($P = 0.015$). Survival curves in these studies separate early between ICD and non-ICD recipients, usually within the first 3 months.[53] These benefits of an ICD in LVAD patients were confirmed in another study in which the addition of an ICD increased the likelihood of survival to transplantation (2.72 times more likely to survive to transplantation in a multivariable model). Although shock frequency tended to decrease after LVAD implantation, appropriate shocks for ventricular tachyarrhythmias still occurred in 21% of patients.[54]

LVADs might interact with the ICD (lead parameters, ventricular tachyarrhythmias, and electromagnetic interference). ICD programming should take this into consideration and be tailored in this special population.[55,56]

Patients listed for heart transplantation

Before the era of ICD implantation in patients awaiting heart transplantation, the expected 1-year mortality was 30%.[57] Advances in heart transplantation candidate selection and in the medical and device treatment of listed patients explain, in part, the decline in ICD-related improvements in the waiting list mortality.[58] Patients listed for heart transplantation are highly selected patients and have an expected 10-year survival of > 50% after transplantation.[59] In an analysis of 310 patients awaiting transplantation at the University of Minnesota, the survival to transplantation was more likely with than without an ICD and the survival benefit remained significant up to 4 years after ICD implantation ($P = 0.0001$).[60] In an analysis of 854 patients awaiting transplantation in Europe with a median follow-up of 4.7 months, total mortality in ICD patients was 11.8% compared with 21.5% in non-ICD patients ($P = 0.03$).[61] Therefore, heart failure patients listed for heart transplantation, who are expected to be discharged to wait as outpatients, should receive primary prevention ICD implantation.

RECOMMENDATION

12. We suggest that ICDs be considered in patients with an LVAD (Weak Recommendation; Low-Quality Evidence).
13. We recommend that an ICD be implanted in outpatients who have been listed for cardiac transplantation (Strong Recommendation; Moderate-Quality Evidence).

Device Selection

All patients referred for ICD implantation should undergo evaluation by a specialist in hearth rhythm disorders to determine ICD eligibility and CRT criteria. Please refer to the CCS guidelines for CRT indications.[62,63]

Single vs dual-chamber devices

In ICD candidates, the decision to proceed with a single chamber ICD (with only a RV lead) vs dual-chamber ICD (with a right atrial and RV lead) device (Fig. 3A) is primarily dependent on whether there is an indication for permanent pacing. The implantation of a dual-chamber ICD is reasonable in patients who require pacing because of sinus node dysfunction. However, there are limited data to support the use of dual-chamber devices to improve arrhythmia discrimination. The **D**ual Chamber and **A**trial **T**achyarrhythmias **A**dverse **E**vents **S**tudy (DATAS) randomized 335 patients eligible for a primary prevention ICD to receive a single or dual-chamber device.[64] During the mean 16-month follow-up period, the primary outcome was a composite, which included: (1) all-cause mortality; (2) invasive intervention because of a cardiovascular cause; (3) hospitalization or prolongation of hospitalization because of cardiovascular cause; (4) inappropriate shocks (2 or more episodes with inappropriate shocks); and (5) sustained symptomatic atrial tachyarrhythmias. The
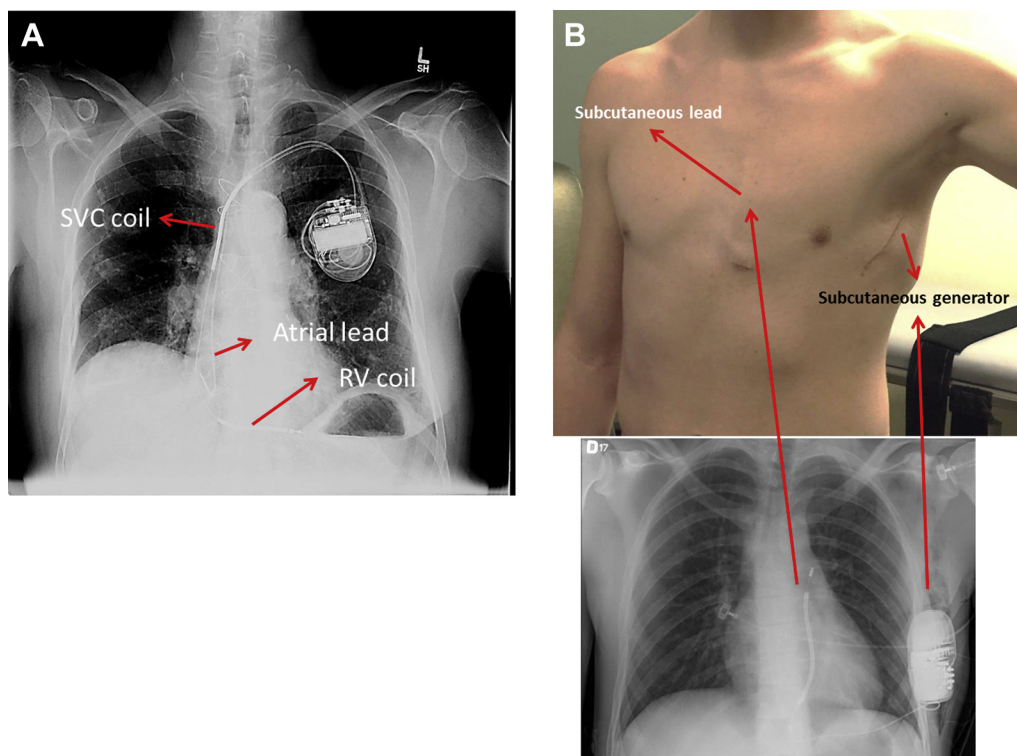
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Figure 3. (A) Conventional dual chamber, dual coil transvenous implantable cardioverter defibrillator (ICD). **Arrows** point to the atrial lead, the right ventricular (RV) high-voltage lead with dual coils (RV and superior vena cava [SVC]). **(B)** Subcutaneous ICD. **Arrows** point to the entirely subcutaneous components; the generator in the mid/posterior-axillary line and the subcutaneous defibrillation lead tunneled in the left parasternal subcutaneous tissue. Both pictures from the same 19-year-old patient. **(B)** Courtesy of Dr Philippon.

incidence of the composite outcome was 33% lower in the dual-chamber ICD group (odds ratio, 0.31; 95% CI, 0.14-0.67; $P = 0.0028$). However, there were no statistically significant reductions in any individual component. This study has important limitations including a small sample size, high crossover rate (10%), and the use of previous-era ICD programming. ICD programming trials have shown that reductions in appropriate and inappropriate ICD therapies can be achieved with no worsening in the syncope or mortality rates. The ICD programming in the Use of Dual-chamber ICD with Special Programmed Features to Lower the Risk of Inappropriate Shock (RAPTURE) study randomized 100 subjects to either single or dual-chamber ICDs with contemporary arrhythmia discrimination programming.[65] The incidence of inappropriate therapies was the same (2%) in both groups. One hypothesis for the findings was that the magnitude of shock reduction through programming was so substantial that the ability to differentiate between the dual-chamber and single-chamber discrimination was not possible. However, there might be specific subgroups in which the implantation of dual-chamber ICDs is reasonable (eg, previously documented slow VT or subjects with supraventricular tachycardia and VT with similar heart rates.

Importantly, most of the patients enrolled in the multicentre trials that established the survival benefit of ICDs received single-chamber devices.[10,65,66] Furthermore, it is established that there is a higher rate of early complications with the use of dual- vs single-chamber ICDs. Prospective data from the Ontario ICD database on 3340 patients showed an increased risk of major complications in subjects who received a dual-chamber defibrillator compared with subjects who received single-chamber devices (adjusted hazard ratio, 1.82; 95% CI, 1.19-2.79; $P = 0.006$).[67] Using data from the NCDR, Peterson et al. reported that among 32,034 patients who received an ICD for primary prevention without indications for pacing, the use of a dual-chamber device compared with a single-chamber device was associated with a higher risk (4.7% vs 3.5%; $P < 0.001$) of device-related complications.[68] In a larger study Dewland et al. also reported NCDR data from 104,049 subjects who underwent first-time ICD implantation. Adverse events were more frequent with dual- than with single-chamber ICDs (3.17% vs 2.11%; $P < 0.001$), as was the rate of in-hospital mortality (0.40% vs 0.23%; $P < 0.001$). These differences were maintained after adjusting for demographic characteristics, medical comorbidities, and ICD indication. In these studies, only 40% of the patients with a dual-chamber ICD had a fulfilled indication for a dual-chamber device.[69]

On the basis of current data, we recommend the implantation of a single-chamber ICD in all patients who undergo ICD insertion for primary prevention. Dual-chamber devices should only be implanted in patients who fulfil

guideline recommendation for pacing (eg, sinus node dysfunction or atrioventricular block) and who are not candidates for CRT.

RECOMMENDATION

14. We suggest a single-chamber ICD instead of a dual chamber ICD in patients with no indication for atrial pacing and in whom the indication for ICD implantation is for the primary prevention of SCD due to ventricular arrhythmias (Weak Recommendation; Moderate-Quality Evidence).

ICD lead selection

Up until recently, most implanted ICD leads were dual-coil leads with a coil in the RV and superior vena cava (SVC) ([Fig. 3]A). ICDs with dual-coil leads coordinate ICD shocks between these coils and the ICD generator. It was previously thought that the use of an SVC coil was necessary to achieve a satisfactory defibrillation threshold (DFT). The improvement in DFTs with newer ICDs and concern regarding an increased risk of complications at the time of lead extraction associated with the SVC coil has decreased the use of dual-coil leads in favour of single-coil (RV only) leads.

There have been no randomized trials to address the superiority of a dual-coil compared with a single-coil system. Although early, small studies reported superior defibrillation efficacy with dual-coil leads, several recent reports have shown that the use of dual-coil leads is unlikely to have any clinical effect on the likelihood of a successful shock. A substudy of SCD-HeFT in which 811 subjects were evaluated showed no difference in mean DFT (12.1 ± 4.7 J vs 12.8 ± 4.8 J; $P =$ 0.087), and similar first shock efficacy of (82.2% vs 91.9%, dual vs single coil; odds ratio, 0.41; $P =$ 0.085).[70] The addition of an SVC coil was not associated with improved outcomes in this study.

Epstein et al. performed a retrospective analysis of patient and lead characteristics, procedural outcomes, and complications of 2201 consecutive patients who underwent transvenous ICD lead extraction at 9 high-volume centres. Data were available on 2176 extracted leads (385 single-coil and 1791 dual-coil). Eighteen major complications were observed, all in patients with dual-coil leads.[71]

Because of the abundance of data showing no benefit of dual-coil over single-coil leads and a higher associated complication rate during lead extraction, single-coil leads should be regarded as the standard of care for ICDs. Therefore, we recommend the implantation of single-coil ICD leads in most patients who undergo ICD implantation. Dual-coil leads might be considered in populations in which the DFT threshold might be higher and/or when DFT safety margin fails with a single-coil lead. Because active fixation leads can be implanted in different RV positions (apical, septal, outflow tract) and because most lead extractors agree that the extraction procedure is less

complicated compared with passive fixation leads, we suggest the use of active fixation high-voltage (HV) RV leads.

RECOMMENDATION

15. We suggest a single-coil HV ICD lead is preferred over a dual-coil HV ICD lead at the time of implantation (Weak Recommendation; Moderate-Quality Evidence).

Site of ICD implantation

Decisions regarding the location of device implantation are heavily influenced by the fact that the likelihood of a successful defibrillation is influenced by the location of the ICD generator in an active can configuration. There are no randomized studies that compared the clinical efficacy of left- vs right-sided ICD systems. However, observational data support improved ICD shock efficacy of a left pectoral implantation, consistent with the hypothesis that more of the ventricular myocardium is within the shock vector created between an RV coil and ICD generator when the ICD generator is on the left compared with the right pectoral region. Contraindications to ICD implantation on a specific side include chronic intravenous indwelling catheters, mastectomy with lymph node resection, previous infection, and subclavian vein thrombosis of the ipsilateral side.

The DFT is affected by the shock vector and impedance. Left-sided ICD systems are associated with lower DFTs because of the vector formed by the active device can and the lead system compared with the vector formed by only the lead (between the 2 coils). This difference was not reproducible on the right side. Although some right-sided ICD systems have a satisfactory DFT because of a low shock impedance, this impedance is not predictable or consistently low resulting in an unpredictable DFT with right-sided ICD systems.[72] Gold et al. reported that among 627 patients, 5.9% received a right-sided implant.[73] This group had higher DFTs at the time of implantation (10.6 ± 3.8 J) than those who received a left pectoral implant (8.9 ± 4.2 J; $P =$ 0.014) despite similar shock impedances. Of note, the conversion efficacy for induced VF was similar at 99% on the right vs 98% on the left ($P =$ 0.18). In addition, there was no difference in the efficacy for converting spontaneous arrhythmias among patients who received right and left pectoral implants (100% vs 97%, respectively; $P =$ 0.31). However, the all-cause mortality rate was higher for patients who received right-sided implants (hazard ratio, 1.93; $P <$ 0.004). This might have been because of the association of comorbidities (eg, dialysis for chronic kidney disease, previous infection) and implantation site.

In summary, we recommend routine left-sided ICD systems. Right-sided ICD implantation should only be considered in subjects with contraindications to a left-sided ICD implantation.

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RECOMMENDATION

16. We recommend that transvenous ICDs be implanted on the left side as the first option for endovascular systems (Strong Recommendation; Moderate-Quality Evidence).

Subcutaneous ICDs

A number of subjects at risk for SCD are not suitable candidates for transvenous ICD leads or are at high risk of developing complications associated with transvenous leads. The development of new technology such as the subcutaneous ICD (S-ICD; Fig. 3B) allows for the implantation of a defibrillator system without transvenous ICD leads.[74] This provides life-saving therapy to patients who would otherwise require more extensive procedures such as epicardial lead placement via thoracotomy with or without subcutaneous array. Recently published data showed that S-ICDs are effective in preventing SCD.[74] To date, however, the number of patients studied is relatively small (approximately 10,000 patients worldwide) and data on the system's long-term performance are limited. The inability to provide pacing (including antitachycardia pacing) is an important limitation of S-ICD systems. Noteworthy, although no lead failures were reported in a nonrandomized multicentre trial,[75] the annual incidence of inappropriate shocks due to T-wave oversensing or supraventricular arrhythmias was 13%,[75] significantly higher than the reported 2%-5% rate of inappropriate shocks with a transvenous system using modern programming strategies.[76] Pooled data from patients enrolled in the initial S-ICD approval study[75] and the EFFORTLESS registry[77] were similar. The rate of device-related complications was 11.1% at 3 years, predominantly driven by infection (1.7%) and erosion (1.2%).[78]

The ongoing **Pr**ospective, **R**andomized Comparison of Subc**u**tane**o**us And **T**ransvenous **Impla**ntable Cardioverter Defibrillator Therapy Trial (PRAETORIAN; NCT01296022) might help to identify the best candidates for this technology.

RECOMMENDATION

17. We recommend an S-ICD be considered in patients with limited vascular access or pocket sites in whom an ICD is recommended (Strong Recommendation; Low-Quality Evidence).

Practical tip. The implantation of an S-ICD might be considered in patients in whom an ICD is recommended who have 1 of the following conditions: (1) congenital heart disease with no access to the ventricles; (2) congenital heart disease with right to left shunt resulting in increased risk of thromboembolic complications with transvenous ICD system; and (3) absence of a pocket site due to either previous device-related infection and/or chronic indwelling catheters.

Practical tip. Although S-ICD systems have been shown to be effective at terminating life-threatening arrhythmias and might have some advantages compared with transvenous ICD systems, we believe that the use of S-ICDs should be limited because of concerns regarding the risk of inappropriate shocks with present devices and the lack of long-term studies and randomized trials that compared transvenous vs S-ICDs.

Other Considerations at the Time of Implant

Venous access

Many different venous access routes can be used for ICD implants. Most commonly, the cephalic, axillary, or subclavian veins are used.[79] Lateral access strategies using the cephalic or axillary vein are preferred to prevent such complications as a pneumothorax or lead impingement by the costoclavicular ligament. Many techniques to visualize the axillary vein can be used including fluoroscopic landmarks, venography, or surface sonography.[80-82] There is still controversy surrounding the benefit from the axillary vein or cephalic vein approach over the subclavian route to prevent lead failure, because no randomized trials exist, although registry data suggest a lower complication rate using the cephalic approach.[83,84]

Venous access during device revisions or upgrade to an ICD might be challenging because venous obstruction or stenosis might often be encountered. A simple venogram performed with contrast injection from a peripheral vein on the ipsilateral side of the device upgrade can identify these issues before skin incision. It is estimated that at the time of upgrade, 26% of patients will present with some degree of vein stenosis and 9% will have complete occlusion.[85-87] Venoplasty or lead extraction can be performed in experienced centres to obtain vascular access instead of implanting on the contralateral side.[88-91] Alternative nontraditional venous access (supraclavicular or innominate vein) can also be considered in selected cases.[92,93] It should be remembered that lead extraction in patients with multiple leads is associated with an increase in the absolute major event rate. In such complex cases, discussion with or referral to a specialized centre should be considered before proceeding.

Prevention of infections

The cardiac implantable electronic devices (CIED) infection rate varies from 0.5%-1.8% for *de novo* implants to 2.1%-5.6% for complex procedures. Prevention of infection starts with proper surgical technique and skin preparation. It is recommended to shave the skin as close to the procedure area as possible with an electric shaver. Skin wash with soap or chlorhexidine before surgery is also recommended. Skin preparation with chlorhexidine 2% in 70% isopropyl alcohol is preferable over povidone-iodine solutions. Intravenous administration of antimicrobial agents 1 hour before skin incision has been shown to reduce the infection rate.[94] The choice of antibiotics might vary according to local prevalence of methicillin-resistant staphylococcus (MRSA). In MRSA carriers, preoperative (3-5 days) nasal application of mupirocin might be considered. Cefazolin, clindamycin, or vancomycin might be used in most patients before skin incision. There is

Table 4. Checklist for the prevention of CIED infection

Recommended infection reduction strategies
☐ Electrical shaving of hair at device insertion site close to procedure time
☐ Skin preparation with chlorhexidine 2% in 70% isopropyl alcohol
☐ Intravenous antibiotic administration that covers pertinent organisms (including MRSA if appropriate) and has been completed before skin incision (30 minutes to 1 hour)
☐ Rigourous hemostasis to prevent device pocket hematoma

CIED, cardiac implantable electronic devices; MRSA, methicillin-resistant staphylococcus.

no scientific evidence that additional antibiotic doses after skin closure, combining 2 antibiotics preoperatively (cefazolin and vancomycin), or washing the pocket with antibiotics before closure reduces the infection rate. The ongoing **P**revention of **A**rrhythmia **D**evice **I**nfection **T**rial (PADIT; NCT01628666) is comparing one intravenous cefazolin dose preoperatively with an incremental antibiotic strategy (vancomycin with cefazolin preoperatively, pocket wash, and 48 hours of oral antibiotics).[95] There is also no definitive value to perform a capsulectomy at the time of replacement to decrease the infection rate. The use of a resorbable antibiotic envelope is being evaluated in the **W**orld-**W**ide **R**andomized **A**ntibiotic **E**nvelope **I**nfection **P**reven**t**ion **T**rial (WRAP-IT; NCT02277990).[96-100]

It has been shown that the presence of hematomas significantly increases the infection rate. A substudy of the **Br**idge or Contin**u**e Coumad**i**n for Device **S**urgery Randomized **Control**led Trial (BRUISE CONTROL) showed that the overall 1-year device-related infection rate was 2.4% (16 of 659). Infection occurred in 11% of patients (7 of 66) with previous hematomas and in 1.5% (9 of 593) without. Hematoma was the only independent predictor and was associated with a > sevenfold increased risk of infection (hazard ratio, 7.7; 95% CI, 2.9-20.5; $P < 0.0001$).[101,102]

A summary is presented in Table 4.

RECOMMENDATION

18. We recommend the use of comprehensive CIED infection prevention measures in all patients who undergo ICD insertion (Strong Recommendation; Moderate-Quality Evidence).

Practical tip. CIED infection prevention measures include use of an electric shaver and chlorhexidine skin preparation, administration and completion of antibiotic infusion before the initial skin incision with an antibiotic that covers the organisms with which the patient might be colonized (including MRSA if appropriate), and rigourous hemostasis.

Defibrillation testing at the time of implantation

Defibrillation testing (DT) at the time of implantation has been routinely performed for the past 20 years but in a minority of patients was associated with complications such as prolonged hypotension or hemodynamic instability, myocardial injury, thromboembolic events, and even death (0.18%).[103] The **S**hockless **Impl**ant **E**valuation (SIMPLE)[104] and **No R**egular **D**efibrillation Testing **in C**ardioverter

Defibrillator Implantation (NORDIC)[105] trials are 2 randomized trials that compared DT or no DT at the time of implantation. Both showed noninferiority of the no DT strategy.

There are no data to suggest that a no DT strategy is safe in the S-ICD population. Thus, at time of a S-ICD implantation, DT is required. Further, it should be recognized that certain populations are not well represented or studied in these trials (hypertrophic cardiomyopathy and channelopathies) and DT can be considered in these groups.[106]

There are data to support that a small R wave detection in sinus rhythm (< 3 mV) can be associated with undersensing of VF.[107]

RECOMMENDATION

19. We recommend that defibrillation safety margin testing not be performed for endovascular left-sided devices that are implanted for prevention of SCD due to ventricular arrhythmias in the absence of conditions known to increase the DFT (right-sided implants, hypertrophic cardiomyopathy, channelopathies, at the time of generator replacement when a lead is on advisory) or if detection of VF could be impaired (such as an unusual lead position or small R wave detection) (Strong Recommendation; High-Quality Evidence).

20. We suggest that defibrillator safety margin testing be considered at the time of implantation for right-sided implants and for patients with hypertrophic cardiomyopathy or channelopathies (Weak Recommendation; Low-Quality Evidence).

21. We recommend defibrillation safety margin testing for all subcutaneous defibrillation systems (Strong Recommendation; Moderate-Quality Evidence).

Practical tip. Because the R waves in sinus rhythm correlate with the device's ability to sense VF we recommend defibrillator safety margin testing in all patients whose R waves are ≤ 3 mV. In this group, the ICD shock can be at the device's highest output but it is recommended that ICD R wave sensitivity be programmed to the least sensitive value during testing.

Anticoagulation

In patients at risk of thromboembolism who are receiving a vitamin K antagonist (eg, warfarin), it has been reported that implantation with a therapeutic international normalized ratio (INR; INR of 2-3) was associated with a significant reduction in the risk of hematomas.[102,108,109] We also refer the reader to the previous CCS/CHRS CRT guidelines where this topic was addressed.[62,63]

There is less evidence for continuation of the direct-acting anticoagulants at the time of device implantation. The ongoing second BRUISE CONTROL (BRUISE CONTROL 2) trial (NCT01675076) will address this issue prospectively.[110]

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RECOMMENDATION

22. We recommend that ICD implantation should be performed with a therapeutic INR in patients who receive vitamin K antagonists with an estimated annual risk of embolic events ≥ 5%. For patients who receive vitamin K antagonists with an estimated annual risk of embolic events < 5%, we recommend ICD implantation be performed with a therapeutic INR or temporary discontinuation of a vitamin K antagonist (no bridging) (Strong Recommendation; High-Quality Evidence).

Practical tip. The risks of bleeding and stroke must be evaluated on a patient by patient basis. In the absence of higher than expected bleeding with CIED insertion, we recommend the continuation of vitamin K antagonists with a therapeutic INR in all patients with a mechanical valve (or valves), previous transient ischemic attack/stroke, recent thromboembolism, or atrial fibrillation with a higher risk of stroke (ie, **C**ongestive Heart Failure, **H**ypertension, **A**ge, **D**iabetes, **S**troke/Transient Ischemic Attack [CHADS$_2$] score ≥ 3).

References

1. Heart & Stroke Foundation. Statistics. Available at: http://www.heartandstroke.com/site/c.ikIQLcMWJtE/b.3483991/k.34A8/Statistics.htm. Accessed September 1, 2015.

2. Tang AS, Ross H, Simpson CS, et al. Canadian Cardiovascular Society/Canadian Heart Rhythm Society position paper on implantable cardioverter defibrillator use in Canada. Can J Cardiol 2005;21(suppl A):11A-8A.

3. Ackerman MJ, Priori SG, Willems S, et al. HRS/EHRA expert consensus statement on the state of genetic testing for the channelopathies and cardiomyopathies this document was developed as a partnership between the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA). Heart Rhythm 2011;8:1308-39.

4. Pedersen CT, Kay GN, Kalman J, et al. EHRA/HRS/APHRS expert consensus on ventricular arrhythmias. Heart Rhythm 2014;11:e166-96.

5. Priori SG, Blomstrom-Lundqvist C, Mazzanti A, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: the Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC) Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC). Eur Heart J 2015;36:2793-867.

6. Gollob MH, Blier L, Brugada R, et al. Recommendations for the use of genetic testing in the clinical evaluation of inherited cardiac arrhythmias associated with sudden cardiac death: Canadian Cardiovascular Society/Canadian Heart Rhythm Society joint position paper. Can J Cardiol 2011;27:232-45.

7. Wellens HJ, Schwartz PJ, Lindemans FW, et al. Risk stratification for sudden cardiac death: current status and challenges for the future. Eur Heart J 2014;35:1642-51.

8. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. N Engl J Med 1996;335:1933-40.

9. Buxton AE, Lee KL, Fisher JD, et al. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. N Engl J Med 1999;341:1882-90.

10. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877-83.

11. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225-37.

12. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med 2004;351:2481-8.

13. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med 2009;361:1427-36.

14. Bigger JT Jr. Prophylactic use of implanted cardiac defibrillators in patients at high risk for ventricular arrhythmias after coronary-artery bypass graft surgery. Coronary Artery Bypass Graft (CABG) Patch Trial Investigators. N Engl J Med 1997;337:1569-75.

15. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death). J Am Coll Cardiol 2006;48:e247-346.

16. Strickberger SA, Hummel JD, Bartlett TG, et al. Amiodarone versus implantable cardioverter-defibrillator:randomized trial in patients with nonischemic dilated cardiomyopathy and asymptomatic nonsustained ventricular tachycardia—AMIOVIRT. J Am Coll Cardiol 2003;41:1707-12.

17. Bansch D, Antz M, Boczor S, et al. Primary prevention of sudden cardiac death in idiopathic dilated cardiomyopathy: the Cardiomyopathy Trial (CAT). Circulation 2002;105:1453-8.

18. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med 2004;350:2151-8.

19. Kober L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med 2016;375:1221-30.

20. Makati KJ, Fish AE, England HH, et al. Equivalent arrhythmic risk in patients recently diagnosed with dilated cardiomyopathy compared with patients diagnosed for 9 months or more. Heart Rhythm 2006;3:397-403.

21. McNamara DM, Starling RC, Cooper LT, et al. Clinical and demographic predictors of outcomes in recent onset dilated cardiomyopathy: results of the IMAC (Intervention in Myocarditis and Acute Cardiomyopathy)-2 study. J Am Coll Cardiol 2011;58:1112-8.

22. Howlett JG, Chan M, Ezekowitz JA, et al. The Canadian Cardiovascular Society Heart Failure Companion: bridging guidelines to your practice. Can J Cardiol 2016;32:296-310.

23. Krahn AD, Lee DS, Birnie D, et al. Predictors of short-term complications after implantable cardioverter-defibrillator replacement: results from the Ontario ICD Database. Circ Arrhythm Electrophysiol 2011;4:136-42.

24. Rockwood K, Mitnitski A. Frailty in relation to the accumulation of deficits. J Gerontol A Biol Sci Med Sci 2007;62:722-7.

25. Manian U, Gula LJ. Arrhythmia management in the elderly-implanted cardioverter defibrillators and prevention of sudden death. Can J Cardiol 2016;32:1117-23.

26. Hess PL, Al-Khatib SM, Han JY, et al. Survival benefit of the primary prevention implantable cardioverter-defibrillator among older patients: does age matter? An analysis of pooled data from 5 clinical trials. Circ Cardiovasc Qual Outcomes 2015;8:179-86.

27. Yung D, Birnie D, Dorian P, et al. Survival after implantable cardioverter-defibrillator implantation in the elderly. Circulation 2013;127:2383-92.

28. Ascoeta MS, Marijon E, Defaye P, et al. Impact of early complications on outcomes in patients with implantable cardioverter-defibrillator for primary prevention. Heart Rhythm 2016;13:1045-51.

29. Santini M, Russo M, Botto G, et al. Clinical and arrhythmic outcomes after implantation of a defibrillator for primary prevention of sudden death in patients with post-myocardial infarction cardiomyopathy: the Survey to Evaluate Arrhythmia Rate in High-risk MI patients (SEARCH-MI). Europace 2009;11:476-82.

30. Russo AM, Day JD, Stolen K, et al. Implantable cardioverter de-fibrillators: do women fare worse than men? Gender comparison in the INTRINSIC RV trial. J Cardiovasc Electrophysiol 2009;20:973-8.

31. Henyan NN, White CM, Gillespie EL, et al. The impact of gender on survival amongst patients with implantable cardioverter defibrillators for primary prevention against sudden cardiac death. J Intern Med 2006;260:467-73.

32. Ghanbari H, Dalloul G, Hasan R, et al. Effectiveness of implantable cardioverter-defibrillators for the primary prevention of sudden cardiac death in women with advanced heart failure: a meta-analysis of ran-domized controlled trials. Arch Intern Med 2009;169:1500-6.

33. Pires LA, Sethuraman B, Guduguntla VD, et al. Outcome of women versus men with ventricular tachyarrhythmias treated with the implantable cardioverter defibrillator. J Cardiovasc Electrophysiol 2002;13:563-8.

34. Chen HA, Hsia HH, Vagelos R, et al. The effect of gender on mortality or appropriate shock in patients with nonischemic cardiomyopathy who have implantable cardioverter-defibrillators. Pacing Clin Electrophysiol 2007;30:390-4.

35. Russo AM, Poole JE, Mark DB, et al. Primary prevention with defi-brillator therapy in women: results from the Sudden Cardiac Death in Heart Failure Trial. J Cardiovasc Electrophysiol 2008;19:720-4.

36. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004;350:2140-50.

37. Hofmann M, Bauer R, Handrock R, Weidinger G, Goedel-Meinen L. Prognostic value of the QRS duration in patients with heart failure: a subgroup analysis from 24 centers of Val-HeFT. J Card Fail 2005;11:523-8.

38. Parkash R, Stevenson WG, Epstein LM, Maisel WH. Predicting early mortality after implantable defibrillator implantation: a clinical risk score for optimal patient selection. Am Heart J 2006;151:397-403.

39. Koller MT, Schaer B, Wolbers M, et al. Death without prior appro-priate implantable cardioverter-defibrillator therapy: a competing risk study. Circulation 2008;117:1918-26.

40. Marijon E, Trinquart L, Otmani A, et al. Competing risk analysis of cause-specific mortality in patients with an implantable cardioverter-defibrillator: the EVADEF cohort study. Am Heart J 2009;157:391-7.

41. Lee DS, Tu JV, Austin PC, et al. Effect of cardiac and noncardiac conditions on survival after defibrillator implantation. J Am Coll Car-diol 2007;49:2408-15.

42. Buxton AE, Ellison KE, Lorvidhaya P, Ziv O. Left ventricular ejection fraction for sudden death risk stratification and guiding implantable cardioverter-defibrillators implantation. J Cardiovasc Pharmacol 2010;55:450-5.

43. Levy WC, Lee KL, Hellkamp AS, et al. Maximizing survival benefit with primary prevention implantable cardioverter-defibrillator therapy in a heart failure population. Circulation 2009;120:835-42.

44. Bilchick KC, Stukenborg GJ, Kamath S, Cheng A. Prediction of mortality in clinical practice for medicare patients undergoing defibril-lator implantation for primary prevention of sudden cardiac death. J Am Coll Cardiol 2012;60:1647-55.

45. Cygankiewicz I, Gillespie J, Zareba W, et al. Predictors of long-term mortality in Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) patients with implantable cardioverter-defibrillators. Heart Rhythm 2009;6:468-73.

46. Clarke B, Howlett JG, Parkash R. A risk score predicting non sudden cardiac death in congestive heart failure [abstract]. Can J Cardiol 2006;22(suppl D):185D.

47. Charlson ME, Pompei P, Ales KL, Mackenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987;40:373-83.

48. Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-95.

49. Heckman GA, Braceland B. Integrating frailty assessment into cardio-vascular decision-making. Can J Cardiol 2016;32:139-41.

50. Connolly SJ, Hallstrom AP, Cappato R, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Antiarrhythmics vs Implantable Defibrillator study. Cardiac Arrest Study Hamburg. Canadian Implantable Defi-brillator Study. Eur Heart J 2000;21:2071-8.

51. Andersen M, Videbaek R, Boesgaard S, et al. Incidence of ventricular arrhythmias in patients on long-term support with a continuous-flow assist device (HeartMate II). J Heart Lung Transplant 2009;28:733-5.

52. Enriquez AD, Calenda B, Miller MA, Anyanwu AC, Pinney SP. The role of implantable cardioverter-defibrillators in patients with contin-uous flow left ventricular assist devices. Circ Arrhythm Electrophysiol 2013;6:668-74.

53. Cleland JG, Daubert JC, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med 2005;352:1539-49.

54. Refaat MM, Tanaka T, Kormos RL, et al. Survival benefit of implantable cardioverter-defibrillators in left ventricular assist device-supported heart failure patients. J Card Fail 2012;18:140-5.

55. Boudghene-Stambouli F, Boule S, Goeminne C, et al. Clinical impli-cations of left ventricular assist device implantation in patients with an implantable cardioverter-defibrillator. J Interv Card Electrophysiol 2014;39:177-84.

56. Yokota J, Fujiu K, Tanimito H, et al. Electromagnetic interference between continuous-flow left ventricular assist device and cardiac resynchronization therapy defibrillator due to an unrecognized mecha-nism. Int J Cardiol 2015;179:510-3.

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57. Mancini DM, Eisen H, Kussmaul W, et al. Value of peak exercise oxygen consumption for optimal timing of cardiac transplantation in ambulatory patients with heart failure. Circulation 1991;83:778-86.

58. Singh TP, Almond CS, Taylor DO, Graham DA. Decline in heart transplant wait list mortality in the United States following broader regional sharing of donor hearts. Circ Heart Fail 2012;5:249-58.

59. Singh TP, Milliren CE, Almond CS, Graham D. Survival benefit from transplantation in patients listed for heart transplantation in the United States. J Am Coll Cardiol 2014;63:1169-78.

60. Ermis C, Zadeii G, Zhu AX, et al. Improved survival of cardiac transplantation candidates with implantable cardioverter defibrillator therapy: role of beta-blocker or amiodarone treatment. J Cardiovasc Electrophysiol 2003;14:578-83.

61. Sweeney MO, Ruskin JN, Garan H, et al. Influence of the implantable cardioverter/defibrillator on sudden death and total mortality in patients evaluated for cardiac transplantation. Circulation 1995;92:3273-81.

62. Exner DV, Birnie DH, Moe G, et al. Canadian Cardiovascular Society guidelines on the use of cardiac resynchronization therapy: evidence and patient selection. Can J Cardiol 2013;29:182-95.

63. Parkash R, Philippon F, Shanks M, et al. Canadian Cardiovascular Society guidelines on the use of cardiac resynchronization therapy: implementation. Can J Cardiol 2013;29:1346-60.

64. Almendral J, Arribas F, Wolpert C, et al. Dual-chamber defibrillators reduce clinically significant adverse events compared with single-chamber devices: results from the DATAS (Dual chamber and Atrial Tachyarrhythmias Adverse events Study) trial. Europace 2008;10:528-35.

65. Friedman PA, Bradley D, Koestler C, et al. A prospective randomized trial of single- or dual-chamber implantable cardioverter-defibrillators to minimize inappropriate shock risk in primary sudden cardiac death prevention. Europace 2014;16:1460-8.

66. Berenbom LD, Weiford BC, Vacek JL, et al. Differences in outcomes between patients treated with single- versus dual-chamber implantable cardioverter defibrillators: a substudy of the Multicenter Automatic Defibrillator Implantation Trial II. Ann Noninvasive Electrocardiol 2005;10:429-35.

67. Lee DS, Krahn AD, Healey JS, et al. Evaluation of early complications related to De Novo cardioverter defibrillator implantation insights from the Ontario ICD database. J Am Coll Cardiol 2010;55:774-82.

68. Peterson PN, Varosy PD, Heidenreich PA, et al. Association of single- vs dual-chamber ICDs with mortality, readmissions, and complications among patients receiving an ICD for primary prevention. JAMA 2013;309:2025-34.

69. Dewland TA, Pellegrini CN, Wang Y, et al. Dual-chamber implantable cardioverter-defibrillator selection is associated with increased complication rates and mortality among patients enrolled in the NCDR implantable cardioverter-defibrillator registry. J Am Coll Cardiol 2011;58:1007-13.

70. Aoukar PS, Poole JE, Johnson GW, et al. No benefit of a dual coil over a single coil ICD lead: evidence from the Sudden Cardiac Death in Heart Failure Trial. Heart Rhythm 2013;10:970-6.

71. Epstein LM, Love CJ, Wilkoff BL, et al. Superior vena cava defibrillator coils make transvenous lead extraction more challenging and riskier. J Am Coll Cardiol 2013;61:987-9.

72. Kirk MM, Shorofsky SR, Gold MR. Comparison of the effects of active left and right pectoral pulse generators on defibrillation efficacy. Am J Cardiol 2001;88:1308-11.

73. Gold MR, Shih HT, Herre J, et al. Comparison of defibrillation efficacy and survival associated with right versus left pectoral placement for implantable defibrillators. Am J Cardiol 2007;100:243-6.

74. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010;363:36-44.

75. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 2013;128:944-53.

76. Ruwald AC, Schuger C, Moss AJ, et al. Mortality reduction in relation to implantable cardioverter defibrillator programming in the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy (MADIT-RIT). Circ Arrhythm Electrophysiol 2014;7:785-92.

77. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J 2014;35:1657-65.

78. Burke MC, Gold MR, Knight BP, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry. J Am Coll Cardiol 2015;65:1605-15.

79. Lau EW. Upper body venous access for transvenous lead placement—review of existent techniques. Pacing Clin Electrophysiol 2007;30:901-9.

80. Hsu JC, Friday J, Lee BK, et al. Predictors of axillary vein location for vascular access during pacemaker and defibrillator lead implantation. Pacing Clin Electrophysiol 2011;34:1585-92.

81. Seto AH, Jolly A, Salcedo J. Ultrasound-guided venous access for pacemakers and defibrillators. J Cardiovasc Electrophysiol 2013;24:370-4.

82. Antonelli D, Feldman A, Freedberg NA, Turgeman Y. Axillary vein puncture without contrast venography for pacemaker and defibrillator leads implantation. Pacing Clin Electrophysiol 2013;36:1107-10.

83. Birnie DH, Parkash R, Exner DV, et al. Clinical predictors of Fidelis lead failure: report from the Canadian Heart Rhythm Society Device Committee. Circulation 2012;125:1217-25.

84. Kron J, Herre J, Renfroe EG, et al. Lead- and device-related complications in the antiarrhythmics versus implantable defibrillators trial. Am Heart J 2001;141:92-8.

85. Lickfett L, Bitzen A, Arepally A, et al. Incidence of venous obstruction following insertion of an implantable cardioverter defibrillator. A study of systematic contrast venography on patients presenting for their first elective ICD generator replacement. Europace 2004;6:25-31.

86. Korkeila P, Nyman K, Ylitalo A, et al. Venous obstruction after pacemaker implantation. Pacing Clin Electrophysiol 2007;30:199-206.

87. Haghjoo M, Nikoo MH, Fazelifar AF, et al. Predictors of venous obstruction following pacemaker or implantable cardioverter-defibrillator implantation: a contrast venographic study on 100 patients admitted for generator change, lead revision, or device upgrade. Europace 2007;9:328-32.

88. Ji SY, Gundewar S, Palma EC. Subclavian venoplasty may reduce implant times and implant failures in the era of increasing device upgrades. Pacing Clin Electrophysiol 2012;35:444-8.

89. Spittell PC, Vlietstra RE, Hayes DL, Higano ST. Venous obstruction due to permanent transvenous pacemaker electrodes: treatment with percutaneous transluminal balloon venoplasty. Pacing Clin Electrophysiol 1990;13:271-4.

90. Worley SJ. Implant venoplasty: dilation of subclavian and coronary veins to facilitate device implantation: indications, frequency, methods, and complications. J Cardiovasc Electrophysiol 2008;19:1004-7.

91. Wilkoff BL, Love CJ, Byrd CL, et al. Transvenous lead extraction: Heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA). Heart Rhythm 2009;6:1085-104.

92. Aleksic I, Kottenberg-Assenmacher E, Kienbaum P, et al. The innominate vein as alternative venous access for complicated implantable cardioverter defibrillator revisions. Pacing Clin Electrophysiol 2007;30: 957-60.

93. Antonelli D, Freedberg NA, Turgeman Y. Supraclavicular vein approach to overcoming ipsilateral chronic subclavian vein obstruction during pacemaker-ICD lead revision or upgrading. Europace 2010;12:1596-9.

94. de Oliveira JC, Martinelli M, Nishioka SA, et al. Efficacy of antibiotic prophylaxis before the implantation of pacemakers and cardioverter-defibrillators: results of a large, prospective, randomized, double-blinded, placebo-controlled trial. Circ Arrhythm Electrophysiol 2009;2:29-34.

95. Connolly SJ, Philippon F, Longtin Y, et al. Randomized cluster cross-over trials for reliable, efficient, comparative effectiveness testing: design of the Prevention of Arrhythmia Device Infection Trial (PADIT). Can J Cardiol 2013;29:652-8.

96. Uslan DZ, Gleva MJ, Warren DK, et al. Cardiovascular implantable electronic device replacement infections and prevention: results from the REPLACE Registry. Pacing Clin Electrophysiol 2012;35:81-7.

97. Kolek MJ, Dresen WF, Wells QS, Ellis CR. Use of an antibacterial envelope is associated with reduced cardiac implantable electronic device infections in high-risk patients. Pacing Clin Electrophysiol 2013;36: 354-61.

98. Sandoe JA, Barlow G, Chambers JB, et al. Guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection. Report of a joint Working Party project on behalf of the British Society for Antimicrobial Chemotherapy (BSAC, host organization), British Heart Rhythm Society (BHRS), British Cardiovascular Society (BCS), British Heart Valve Society (BHVS) and British Society for Echocardiography (BSE). J Antimicrob Chemother 2015;70: 325-59.

99. Padfield GJ, Steinberg C, Bennett MT, et al. Preventing cardiac implantable electronic device infections. Heart Rhythm 2015;12: 2344-56.

100. Sastry S, Rahman R, Yassin MH. Cardiac implantable electronic device infection: from an infection prevention perspective. Adv Prev Med 2015;2015:357087.

101. Essebag V, Verma A, Healey JS, et al. Clinically significant pocket hematoma increases long-term risk of device infection: BRUISE CONTROL INFECTION study. J Am Coll Cardiol 2016;67:1300-8.

102. Birnie DH, Healey JS, Wells GA, et al. Pacemaker or defibrillator surgery without interruption of anticoagulation. N Engl J Med 2013;368:2084-93.

103. Birnie D, Tung S, Simpson C, et al. Complications associated with defibrillation threshold testing: the Canadian experience. Heart Rhythm 2008;5:387-90.

104. Healey JS, Hohnloser SH, Glikson M, et al. Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). Lancet 2015;385:785-91.

105. Bansch D, Bonnemeier H, Brandt J, et al. Intra-operative defibrillation testing and clinical shock efficacy in patients with implantable cardioverter-defibrillators: the NORDIC ICD randomized clinical trial. Eur Heart J 2015;36:2500-7.

106. Phan K, Ha H, Kabunga P, et al. Systematic review of defibrillation threshold testing at de novo implantation. Circ Arrhythm Electrophysiol 2016;9:e003357.

107. Ruetz LL, Koehler JL, Brown ML, et al. Sinus rhythm R-wave amplitude as a predictor of ventricular fibrillation undersensing in patients with implantable cardioverter-defibrillator. Heart Rhythm 2015;12: 2411-8.

108. Cano O, Andres A, Jimenez R, et al. Systematic implantation of pacemaker/ICDs under active oral anticoagulation irrespective of patient's individual preoperative thromboembolic risk. Pacing Clin Electrophysiol 2015;38:723-30.

109. Yang X, Wang Z, Zhang Y, Yin X, Hou Y. The safety and efficacy of antithrombotic therapy in patients undergoing cardiac rhythm device implantation: a meta-analysis. Europace 2015;17:1076-84.

110. Essebag V, Healey JS, Ayala-Paredes F, et al. Strategy of continued vs interrupted novel oral anticoagulant at time of device surgery in patients with moderate to high risk of arterial thromboembolic events: the BRUISE CONTROL-2 trial. Am Heart J 2016;173:102-7.