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CARDIAC RESYNCHRONIZATION THERAPY

Canadian Cardiovascular Society Guidelines on the Use of Cardiac Resynchronization Therapy: Evidence, Patient Selection and Implementation

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Pocket Guide Version: April 2014

CARDIAC RESYNCHRONIZATION THERAPY GUIDELINES

About This Pocket Guide

This pocket guide is a quick-reference tool that features essential diagnostic and treatment recommendations based on the 2013 CCS Cardiac Resynchronization Therapy (CRT) Guidelines.

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

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Canadian Cardiovascular Society Guidelines on the Use of Cardiac Resynchronization Therapy: Evidence and Patient Selection

Co-chairs and Authors

Derek V. Exner and Ratika Parkash

Authors

David H. Birnie, Gordon Moe, Bernard Thibault, François Philippon, Jeffrey S. Healey, Anthony S.L. Tang and Eric Larose

Canadian Cardiovascular Society Guidelines on the Use of Cardiac Resynchronization Therapy: Implementation

Co-chairs and Authors

Derek V. Exner and Ratika Parkash

Authors

François Philippon, Miriam Shanks, Bernard Thibault, Jafna Cox, Aaron Low, Vidal Essebag, Jamil Bashir, Gordon Moe, David H. Birnie, Eric Larose, Raymond Yee, Elizabeth Swiggum, Padma Kaul, Damian Redfearn and Anthony S. Tang

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Table of Contents

Guiding Principles 5-10

When to Consider CRT 11-12

Role of Imaging 13

Atrial Fibrillation 14

CRT-P vs. CRT-D 15

Lead Placement 16

Preimplant Assessment 17-18

Procedural Preparation 19

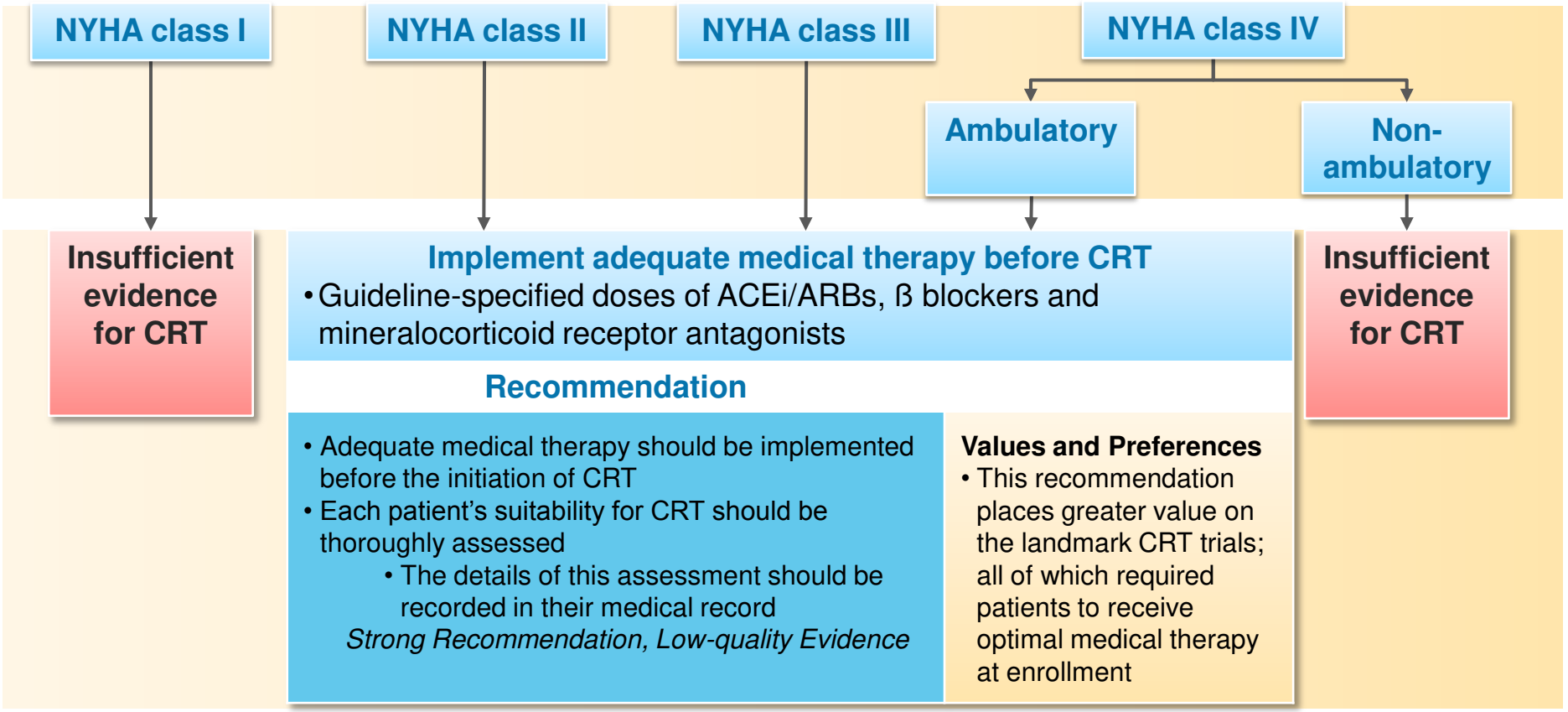
Operative Issues 20

Device Follow-up 21

Health Economics and Accessibility of CRT 22

CRT: cardiac resynchronization therapy; CRT-D: CRT plus implantable cardioverter-defibrillator; CRT-P: CRT pacemaker.

Guiding Principles – Patient Classification

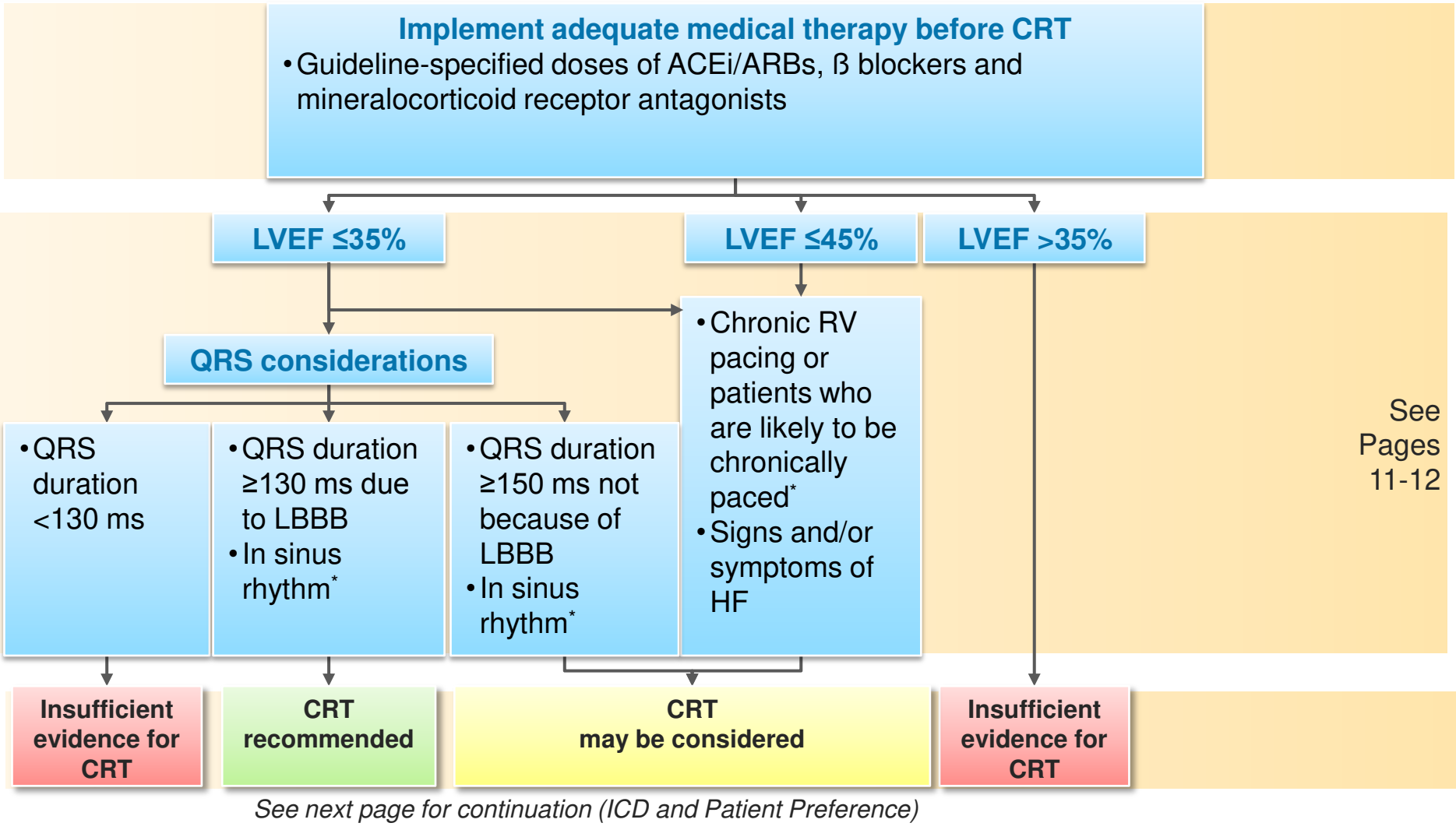


See next page for continuation (CRT Considerations)

Practical tip:
- Reasons for nonuse or prescription of lower doses of heart failure medication should be recorded
- The following should be recorded in the patient's medical record:
  - At a minimum, assessment NYHA functional class; 6-minute hall walk distance, disease-specific HRQoL and cardiopulmonary testing should also be considered
  - QRS duration should be measured from a standard 12-lead ECG and LVEF quantified using a validated assessment method

ACEi: angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blocker; CRT: cardiac resynchronization therapy; ECG: electrocardiograph; LVEF: left ventricular ejection fraction; HRQoL: health-related quality of life; NYHA: New York Heart Association.

Guiding Principles – CRT Considerations



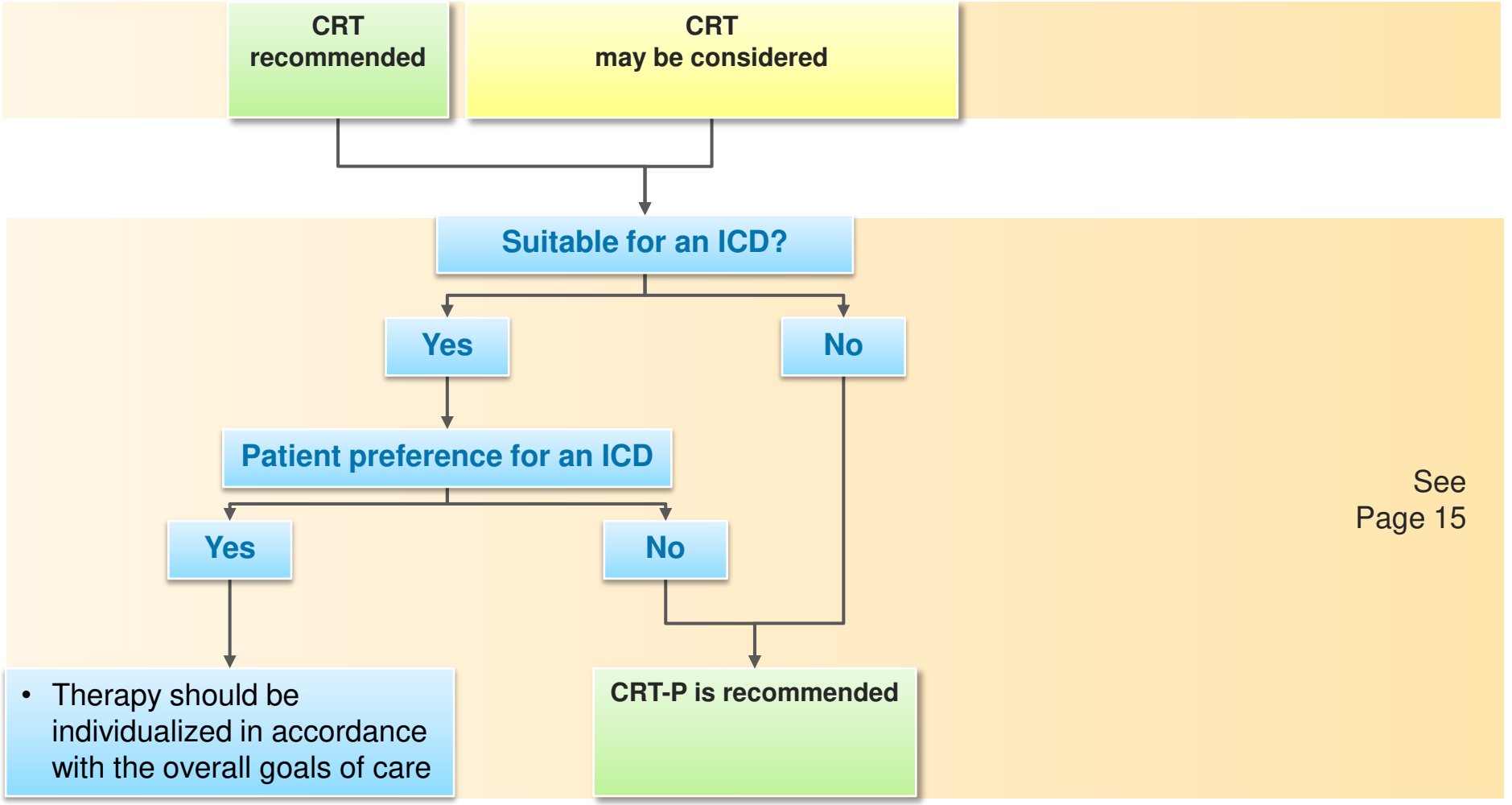
See next page for continuation (ICD and Patient Preference)

- Routine assessment of dyssynchrony with present echo techniques is not recommended to guide prescription of CRT (see Page 13)

*CRT may be considered for patients in permanent AF who are otherwise suitable for therapy (see Page 14)

ACEi: angiotensin-converting enzyme inhibitor; AF: atrial fibrillation; ARB: angiotensin receptor blocker; CRT: cardiac resynchronization therapy; HF: heart failure; ICD: implantable cardioverter-defibrillator; LBBB: left bundle branch block; LVEF: left ventricular ejection fraction; RV: right ventricular.

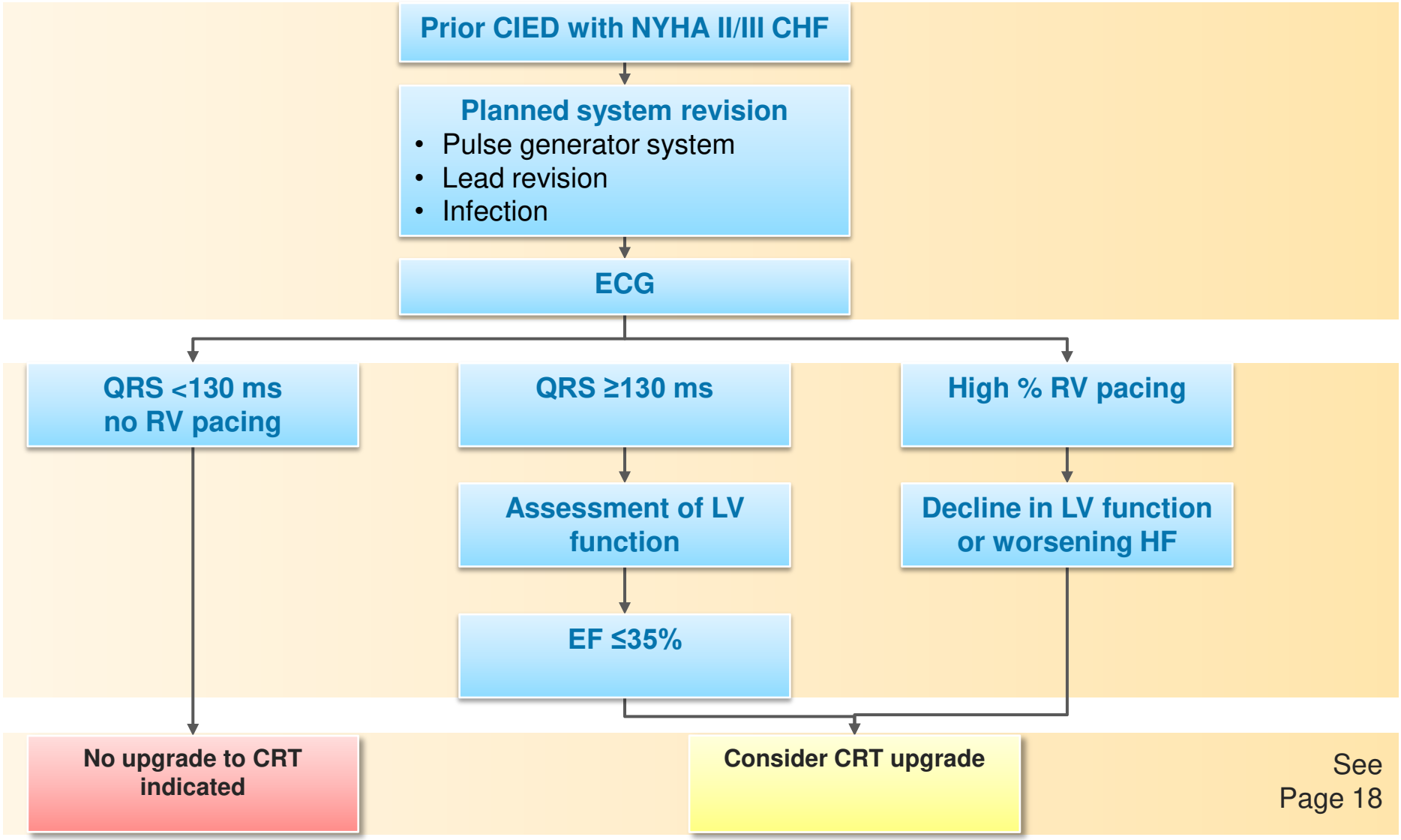
Guiding Principles – ICD and Patient Preference



See Page 15

CRT: cardiac resynchronization therapy; CRT-P: CRT pacemaker; ICD: implantable cardioverter-defibrillator.

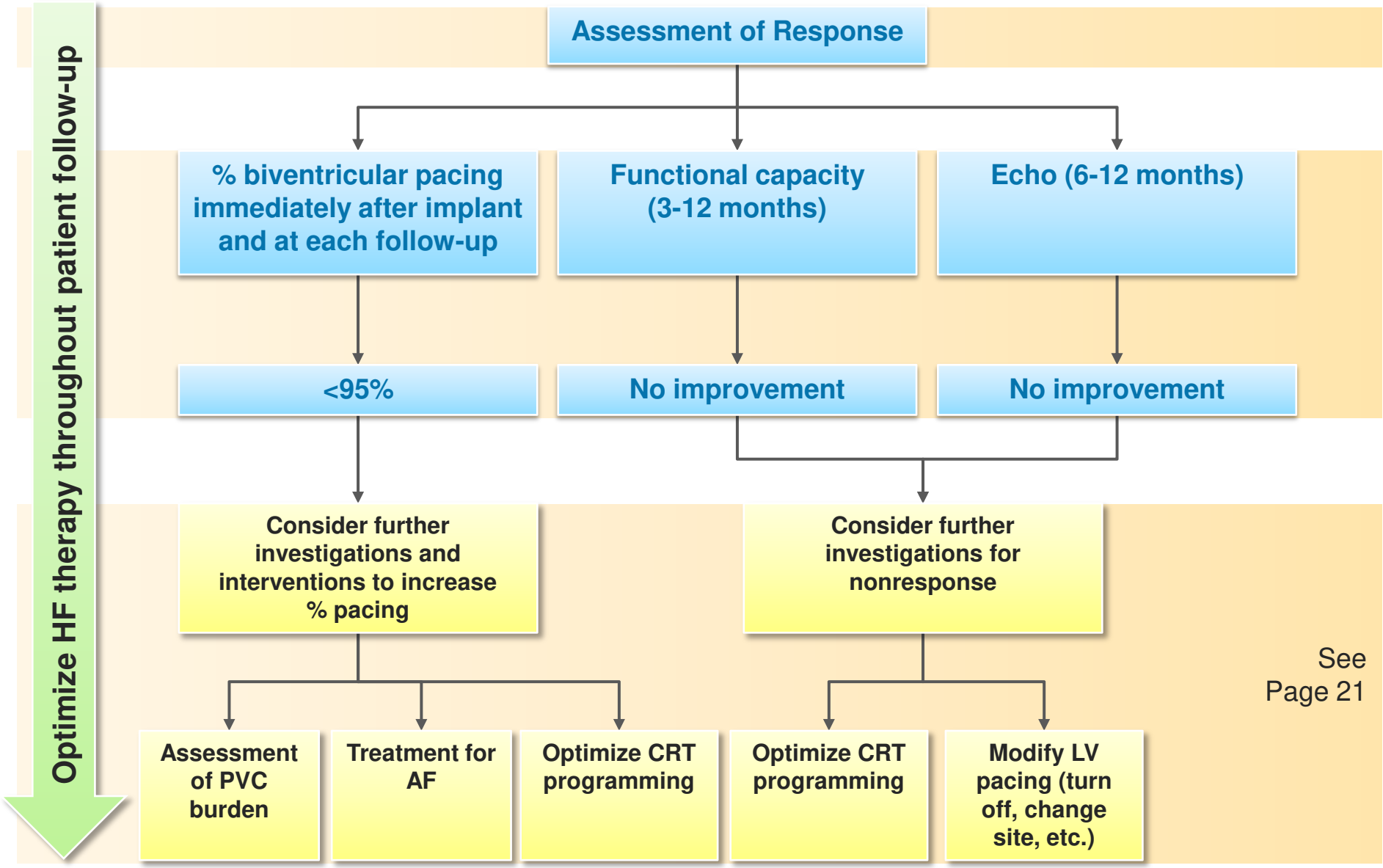
Guiding Principles – CIED and HF



See Page 18

CHF: congestive heart failure; CIED: cardiovascular implantable electronic device; CRT: cardiac resynchronization therapy; ECG: electrocardiogram; EF: ejection fraction; HF: heart failure; LV: left ventricular; NYHA: New York Heart Association; RV: right ventricular.

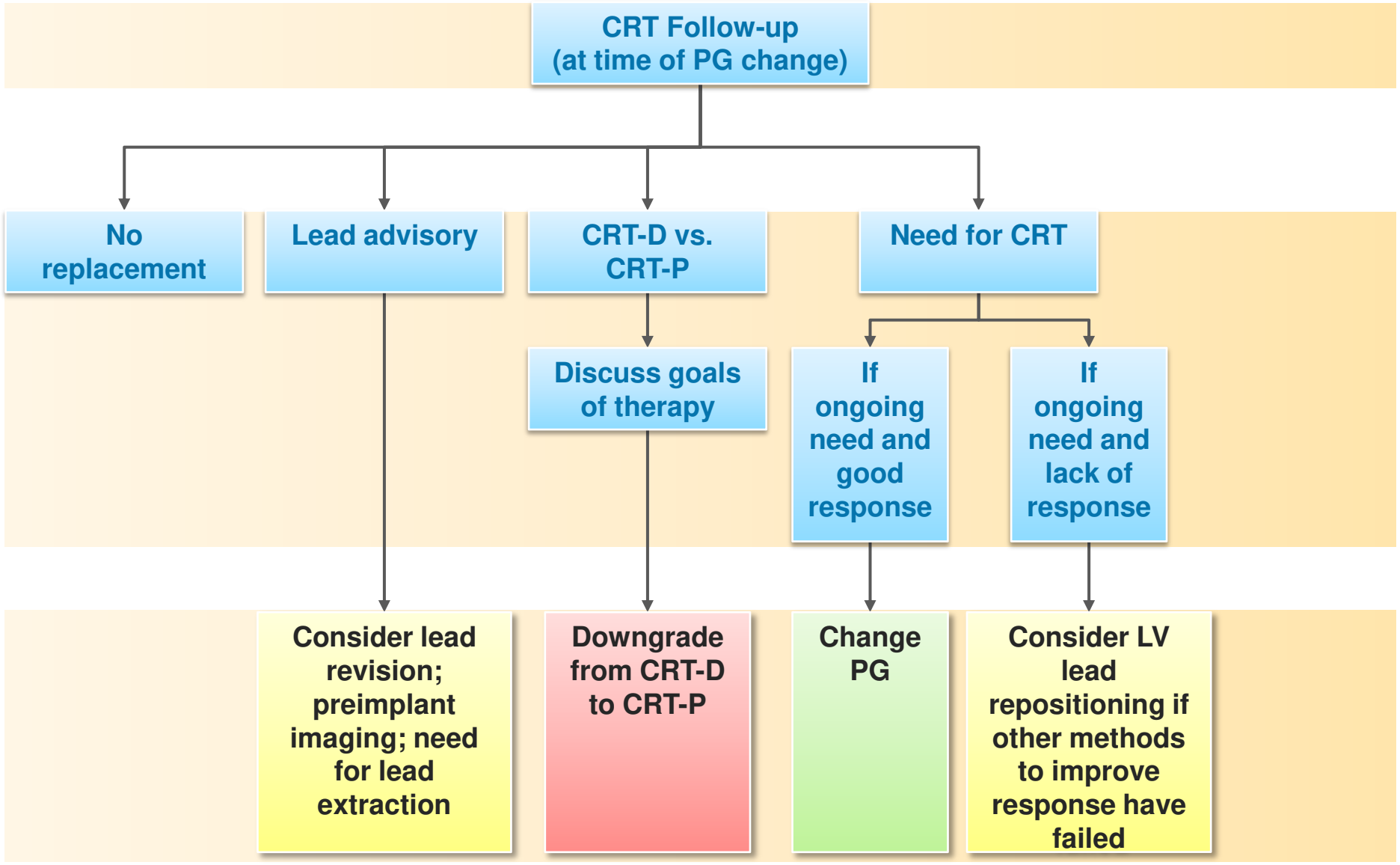
Guiding Principles – Follow-up and Optimization



See Page 21

AF: atrial fibrillation; CRT: cardiac resynchronization therapy; HF: heart failure; LV: left ventricular; PVC: premature ventricular contraction.

Guiding Principles – Generator Change



CRT: cardiac resynchronization therapy; CRT-D: CRT defibrillator; CRT-P: CRT pacemaker; LV: left ventricular; PG: pulse generator.

When to Consider CRT

Recommendation

- CRT is recommended for patients in sinus rhythm with NYHA class II, NYHA class III or ambulatory NYHA class IV heart failure symptoms, a LVEF ≤35%, and QRS duration ≥130 ms because of LBBB
  Strong Recommendation, High-quality Evidence

Values and preferences

- This recommendation places great value on the inclusion criteria of the landmark CRT trials, the characteristics of the patients enrolled in these trials, and the derived benefit of CRT in patient groups identified in subsequent analyses of these landmark trials

Practical tip:

- Because these patients were largely excluded in major CRT studies, there is insufficient evidence to recommend CRT in:
  - NYHA class I limitation
  - Nonambulatory class IV NYHA
  - QRS duration <130 ms
- Patients with LBBB and QRS duration ≥150 ms appear more likely to benefit from CRT than patients with non-LBBB conduction and/or QRS prolongation

CRT: cardiac resynchronization therapy; LBBB: left bundle branch block; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association.

When to Consider CRT, Continued

Recommendations

- CRT may be considered for patients in sinus rhythm with NYHA class II, NYHA class III or ambulatory NYHA class IV heart failure, a LVEF ≤35%, and QRS duration ≥150 ms not because of LBBB conduction
  Weak Recommendation, Low-quality Evidence

Practical tip:
- There is no clear evidence of benefit with CRT among patients with QRS duration <150 ms because of non-LBBB conduction

Values and preferences
- This recommendation places great value on the inclusion criteria of the landmark trials, the characteristics of the patients enrolled, and the quality of this evidence
- This recommendation also places greater weight on QRS duration as a determinant of CRT response

- CRT may be considered for patients with chronic RV pacing or who are likely to be chronically paced, have signs and/or symptoms of heart failure, and a LVEF ≤35%
  Weak Recommendation, Low-quality Evidence

Values and preferences
- This recommendation places great value on the inclusion criteria of the landmark trials and the characteristics of the patients enrolled

Practical tip:
- Attempts to minimize RV pacing should be undertaken before consideration of CRT upgrade
- There is less evidence for the utility of CRT in patients who do not have pre-existing LBBB and are chronically RV-paced
- Risks of CRT upgrade must be considered and balanced with the potential benefits of CRT upgrade
- Patients undergoing AV junctional ablation with moderate LV dysfunction might benefit from CRT, as may those who have an indication for chronic pacing and characteristics similar to patients randomized in BLOCK HF
- It is often difficult to predict reliably which patients will be chronically RV paced at the time of pacemaker therapy

AV: atrioventricular; CRT: cardiac resynchronization therapy; LBBB: left bundle branch block; LV: left ventricular; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; RV: right ventricular.

Role of Imaging

Recommendation

- Routine assessment of dyssynchrony with present echo techniques is not recommended to guide the prescription of CRT

  Strong Recommendation, Low-quality Evidence

Values and preferences

- This recommendation takes into account the quality of the evidence and the results of larger, multicentre studies

Practical tip:

- Issues of reproducibility and inter/intra-rater assessment identified in the larger studies limit the routine role of echo to guide the prescription of CRT
- Ongoing imaging research (e.g. scar, viability) is presently under investigation

CRT: cardiac resynchronization therapy.

Atrial Fibrillation

Recommendation

- CRT may be considered for patients in permanent AF who are otherwise suitable for this therapy
  Weak Recommendation, Low-quality Evidence

Values and preferences

- This recommendation places great value on the inclusion criteria of the landmark trials, the characteristics of the patients enrolled, the derived benefit of CRT in patients with permanent AF, and the quality of the evidence

Practical tip:

- The amount of biventricular pacing needs to be evaluated
- Arrhythmia device counters alone might not accurately reflect the true percent of biventricular pacing
- It is important to ensure a very high percentage of biventricular pacing
- AV junctional ablation might be necessary to achieve sufficient biventricular pacing

AF: atrial fibrillation; AV: atrioventricular; CRT: cardiac resynchronization therapy.

CRT-P vs. CRT-D

Recommendation

- A CRT-P is recommended for patients who are suitable for resynchronization therapy, but not for an ICD
  Strong Recommendation, Moderate-quality Evidence

Values and preferences

- This recommendation places a greater value on quality of life and improvement of heart failure symptoms, rather than prevention of sudden death

Practical tip:

- CRT-P has been shown to reduce morbidity and mortality in patients with NYHA class III and ambulatory class IV symptoms
- Therapy should be individualized in accordance with the overall goals of care

CRT: cardiac resynchronization therapy; CRT-D: CRT plus ICD; CRT-P: CRT pacemaker; ICD: implantable cardioverter-defibrillator; NYHA: New York Heart Association.

Lead Placement

Recommendation

- In patients treated with CRT, pacing from a nonapical LV epicardial region might be considered
  Weak Recommendation, Low-quality Evidence

Values and preferences

- This recommendation places great value on the quality of the evidence

CRT: cardiac resynchronization therapy; LV: left ventricular.

Preimplant Assessment

Practical tip:

- Objective evaluation of the pre-CRT implantation functional capacity and symptoms is important, particularly in patients in whom there is disparity between the reported symptoms and the clinical assessment, or to distinguish the non-HF related causes of functional limitation

Recommendation

- We recommend that the prescription of CRT and the choice of platform (CRT-P vs. CRT-D) should take into account clinical factors that would affect the overall goals of care

  Strong Recommendation, Moderate-quality Evidence

Values and preferences

- This recommendation places great value on the benefit of CRT in appropriately selected patients with HF, and minimization of risk

Practical tip:

- Comorbid conditions and clinical factors (e.g. age, renal function, frailty) should be considered together, and one alone should not preclude a patient from CRT implantation
- Therapy should be individualized in accordance with the overall goals of care and patient preference

CRT: cardiac resynchronization therapy; CRT-D: CRT plus implantable cardioverter-defibrillator; CRT-P: CRT pacemaker; HF: heart failure.

Preimplant Assessment, Continued

Recommendations

- We suggest that CRT might be considered for patients with new-onset high-degree AV block requiring chronic RV pacing, signs and/or symptoms of HF, and LVEF ≤45%
  Conditional Recommendation, Moderate-quality Evidence

Values and preferences
- This recommendation places value on the knowledge that CRT might provide more benefit than RV apical pacing, even though the strength of evidence is moderate and the available data result in a conditional rating

Practical tip:
- Most patients in BLOCK HF had LVEF ≤45% and were NYHA class II/III
- BLOCK HF enrolled patients with de novo implants and the same considerations might not apply in patients who are chronically RV-paced
- There is limited RCT data with respect to CRT upgrade and potential benefits must be balanced with the significantly higher risk with CRT vs. generator replacement alone

- We recommend that all patients with HF who are planned to receive a CIED system revision should be considered for their eligibility for upgrade to CRT
  Strong Recommendation, Low-Quality Evidence

Practical tip:
- Risk/benefit of adding an LV lead when a procedure is being performed may be favourable

Values and preferences
- Careful evaluation of risks/benefits of upgrades in CRT-eligible patients with existing CIED systems should be considered

- We suggest that placement of an LV lead at the time of open heart surgery, for the purpose of facilitating future CRT, might be considered in patients for whom CRT is recommended and the need for device therapy is unlikely to be changed by the surgical procedure
  Conditional Recommendation, Low-quality Evidence

Values and preferences
- This recommendation places value on practical considerations and multidisciplinary discussion in absence of substantial data

Practical tip:
- Patients with severe structural abnormalities that can be easily corrected with cardiac surgery are the least likely to benefit from LV lead placement
- Balance risk/cost of placing an unnecessary lead with feasibility of placing/testing an LV lead during surgery in an eligible patient
- Avoid apical LV lead position

AV: atrioventricular; CIED: cardiac implantable electronic device; CRT: cardiac resynchronization therapy; HF: heart failure; LV: left ventricular; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; RCT: randomized controlled trial; RV: right ventricular.

Procedural Preparation

Recommendation

- We recommend that in patients taking warfarin for whom perioperative anticoagulation is deemed necessary, continued warfarin is recommended over the use of heparin-based bridging

  Strong Recommendation, Moderate-quality Evidence

Values and preferences

- This recommendation places great value on safely preventing perioperative bleeding and the quality of the evidence

Practical tip:

- Perioperative OAC is usually deemed necessary in $CHADS_2$ ≥3 or >5% annual risk
- No data are presently available on the use of novel OAC in this population
  - Interruption of these agents should be of short duration in patients at high risk of thromboembolism, but renal function, procedural risk, and complexity of the procedure might need to be considered in these situations
  - Rapidity of onset and offset make these more facile to control periprocedurally
- Discontinuation of OAC in patients at lower risk of thromboembolism should be considered to minimize the risk of bleeding

OAC: oral anticoagulation.

Operative Issues

Recommendations

- We recommend that CRT implantation be performed only in facilities that have strict infection prevention control standards
  Strong Recommendation, Low-quality Evidence

Values and preferences

- This recommendation takes into account that infection prevention is a key aspect to CRT implantation and system revision

- We recommend that appropriate fluoroscopic equipment, radiation shielding, and radiation reduction imaging methods be used to minimize radiation exposure to the operator, patient and other staff
  Strong Recommendation, Low-quality Evidence

Values and preferences

- This recommendation takes into account that fluoroscopic exposure poses risk to patients, staff and operators, and must be minimized using all available means

Practical tip:

- In patients with an ischemic etiology or non-LBBB patterns of QRS morphology, correlation of venous anatomy using CMR with mechanical dyssynchrony might be helpful in guiding LV lead placement and optimizing response to CRT
- At the time of implantation the anatomy of the venous system remains the most important limitation (even though concordance between position of LV lead and the area of latest activation seem to predict better response to CRT)
- A secondary analysis of the SMART-AV study revealed Q-LV >95 ms was associated with improved reverse modelling
- Basic determinants of successful LV lead placement remain the same:
  - Pacing with an adequate threshold
  - Avoiding capture of the nearby phrenic nerve
  - Long-term stability of the LV lead
- Emerging technologies to assist in 3-D reconstruction of venous anatomy and its electrical activation patterns are being investigated

CMR: cardiac magnetic resonance; CRT: cardiac resynchronization therapy; LBBB: left bundle branch block; LV: left ventricular.

Device Follow-up

Practical tip:

- Define response to CRT using “treatment effect” based on: individual patient goals of improved QoL, symptom reduction, fewer hospitalization and improved survival
  - Include validated composite endpoints (death, hospitalization, QoL)
  - Preferred over more ambiguous “response rate” comprised of a myriad of variables that might not correspond with clinical outcomes or be relevant to CRT recipients

Recommendation

- We recommend that alterations in clinical parameters after vs. before CRT be assessed within 6-12 months after CRT implantation to guide ongoing HF management

  Strong Recommendation, Low-quality Evidence

Values and preferences

- This recommendation is based on the importance of ensuring optimal medical therapy and deriving important benefit in improvement in reverse remodelling and QoL with CRT delivery

Practical tip:

- Process of LV remodelling is a dynamic process that begins at time of CRT implantation but requires ongoing reassessment throughout follow-up

Practical tip:

- Suggested starting point: alternating RM visits with direct device clinic follow-up visits in a 1:1 ratio
- Proportion of RM-based follow-up assessments might increase or decrease as dictated by individual patient characteristics

CRT: cardiac resynchronization therapy; HF: heart failure; LV: left ventricular; RM: remote monitoring; QoL: quality of life.

Health Economics and Accessibility of CRT

Recommendation

- We suggest that CRT implantation should occur within 6-8 weeks from the decision to implant to avoid preventable adverse events, such as HF hospitalizations and death

  Conditional Recommendation, Low-quality Evidence

CRT: cardiac resynchronization therapy; HF: heart failure.

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