TECHNOLOGY AND GUIDELINES

Cardiac resynchronisation therapy for the treatment of heart failure: NICE technology appraisal guidance

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Heart 2007;**93**:1134–1135. doi: 10.1136/hrt.2007.127563

This NICE technology appraisal guidance on cardiac resynchronisation therapy provides additional treatment options for some of the groups of people covered in the earlier guidance on implantable cardioverter defibrillators.

GUIDANCE

This was published in the NICE technology appraisal guidence in May 2007.[1]

1. Cardiac resynchronisation therapy with a pacing device (CRT-P) is recommended as a treatment option for people with heart failure who fulfil all the following criteria:

- They are currently experiencing or have recently experienced New York Heart Association (NYHA) class III–IV symptoms.
- They are in sinus rhythm:
  - *either* with a QRS duration of 150 ms or longer estimated by standard ECG
  - *or* with a QRS duration of 120–149 ms estimated by ECG and mechanical dyssynchrony that is confirmed by echocardiography.
- They have a left ventricular ejection fraction of 35% or less.
- They are receiving optimal pharmacological treatment.

2. Cardiac resynchronisation therapy with a defibrillator device (CRT-D) may be considered for people who fulfil the criteria for implantation of a CRT-P device in section 1.1 and who also separately fulfil the criteria for the use of an implantable cardioverter-defibrillator (ICD) device as recommended in NICE technology appraisal guidance 95.[2]

DEVELOPMENT OF THE GUIDANCE

The Appraisal Committee understood that the benefits of implantation of a CRT device are related to improvements in the symptoms of heart failure and the extension of life of patients with heart failure, as well as a reduction in the incidence of sudden cardiac death in this patient group. It also appreciated that the risk of sudden cardiac death in patients with heart failure is related to the presence of both ventricular dyssynchrony and other underlying cardiac conditions that might add to the risk of sudden cardiac death.

The Appraisals Committee considered the evidence base for the clinical effectiveness of CRT-P and CRT-D in patients with heart failure. Four randomised controlled trials (RCTs) were assessed but particular attention was paid to the larger studies—COMPANION[3] and CARE-HF.[4] These two RCTs reported different results for the rate of death from heart failure. The CARE-HF study reported a statistically significant reduction in the incidence of death from heart failure for CRT-P compared with optimal pharmacological treatment alone, whereas the COMPANION study reported no difference in treatment effect. Pooled analysis, however, demonstrated a statistically significant reduction in death from heart failure for CRT-P compared with optimal pharmacological treatment alone. In addition, the studies indicated a statistically significant reduction in the risk of worsening heart failure, improvements in NYHA class and quality of life and overall a reduction in admissions to hospital for heart failure. Similar results were reported for CRT-D compared with optimal pharmacological treatment.

The COMPANION[3] study was the only RCT that provided a basis for direct comparison between the effectiveness of CRT-P and CRT-D, but it was not powered to detect differences for this comparison. However, in this trial the use of CRT-D was associated with a statistically significant reduction in incidence of both death from all cardiac causes and, specifically, sudden cardiac death.

The cost-effectiveness analysis compared:

- CRT-P with optimal pharmacological treatment
- CRT-D with optimal pharmacological treatment
- CRT-P with CRT-D.

CRT-P and CRT-D were both considered to be a cost-effective use of NHS resources when compared with optimal pharmacological treatment alone on the basis of cost per quality-adjusted life year (QALY—NICE's preferred measure) at about £16 000 and £23 000, respectively.

The Appraisals Committee took into consideration all the available evidence, including the testimony of both specialist clinicians and patients with experience of these technologies, and concluded that the case for the cost-effective use of CRT-P had been made. This was specifically for the group of patients with low left ventricular ejection fraction (<35%) who have (or have recently experienced) symptoms of heart failure rated as NYHA class III–IV despite optimal pharmacological treatment, and who additionally have evidence of cardiac dyssynchrony on the basis of the criteria defined in the principal RCTs.

Although CRT-D was cost effective when compared with optimal pharmacological treatment alone, the Appraisals Committee was not persuaded that this was an appropriate comparison. The comparison of CRT-D with CRT-P was more complex. In the absence of head-to-head trial evidence for these two technologies, the cost-effectiveness analysis indicated that implanting a CRT-D rather than a CRT-P device would have a cost per QALY of about £40 000, making it not a cost effective use of NHS resources.

However, the Committee accepted that the cost effectiveness of CRT-D is likely to be considerably improved in people with additional risk factors for sudden cardiac death over and above those associated with cardiac dyssynchrony. Thus the Committee concluded that adding a defibrillator in the form of a CRT-D device should be considered for people with heart

Abbreviations: CRT-D, cardiac resynchronisation therapy with a defibrillator device; CRT-P, cardiac resynchronisation therapy with a pacing device; ICD, implantable cardioverter-defibrillator; NYHA, New York Heart Association; QALY, quality-adjusted life year; RCT, randomised controlled trial

failure due to left ventricular systolic dysfunction who fulfil the criteria in section 1 of the guidance for the implantation of a CRT-P device, and also have additional risk factors for sudden cardiac death that separately fulfil the criteria for the use of an ICD device (as detailed in NICE technology appraisal guidance 95).[2]

The decision as to whether a CRT-P, CRT-D or ICD device is most appropriate should be made for each patient individually. It will depend on the relative importance of the risks associated with the underlying left ventricular dysfunction, ventricular dyssynchrony and symptomatic heart failure, as well as other factors that might contribute to the risk of sudden cardiac death.

The guidance on CRT should therefore be seen as complementing the earlier NICE guidance on ''Implantable cardioverter-defibrillators for arrhythmias''(NICE technology appraisal guidance 95),[2] because it provides additional treatment options for some of the groups of people covered in that guidance.

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Accepted 26 June 2007

Competing interests: None declared.

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IMAGES IN CARDIOLOGY

doi: 10.1136/hrt.2006.101600

''Dynamic imaging'' (systolic compression) of myocardial bridge visualised by electronic beam computed tomography

A 59-year-old man with history of hypertension and heavy smoking presented with recurrent dizziness, palpitation and chest pain during exertion. At admittance, an ECG recording showed rapidly conducting atrial fibrillation (mean heart rate 140 bpm) and otherwise normal findings. Blood pressure and a laboratory examination were normal. Within a few minutes after admission, atrial fibrillation spontaneously converted to sinus rhythm. To exclude coronary artery disease, the patient underwent 64-slice electronic beam computed tomography (EBCT). No calcification or coronary plaque was detected. However, a myocardial bridge of the mid-segment of the left anterior descending coronary artery (LAD) was found (panels). Selection of different phases of the scanning cycle showed systo-diastolic diameter change of the vessel.

A myocardial bridge occurs when the myocardium covers a discrete portion of an epicardial coronary artery. A myocardial bridge is most commonly localised in the middle segment of the LAD. Systolic vessel compression and delayed diastolic relaxation may impair coronary blood flow, resulting in angina-like chest pain. Usually, myocardial bridging is a benign, congenital condition with a favourable long-term outcome; infrequently, it may be associated with myocardial infarction, conduction disturbances and even sudden death.

When a diastolic ''cuff-like'' picture is noticed at EBCT, analysis of both diastolic and systolic images helps to confirm the systolic compression of the artery. This ''dynamic'' imaging such as provided by EBCT may be particularly helpful in linking clinical history to the anatomical finding.

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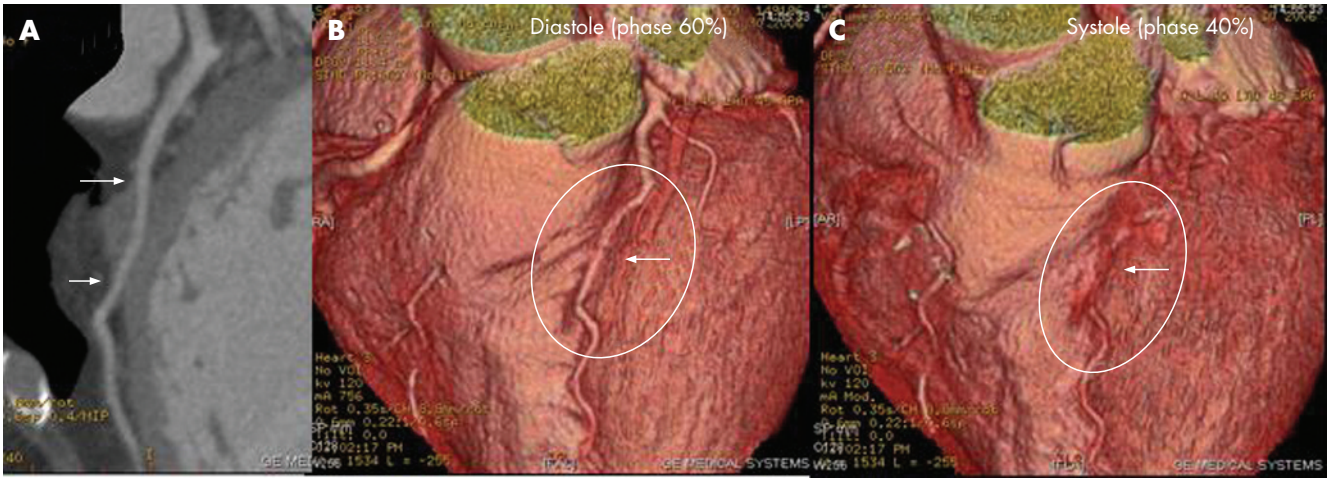

(A) Curved multiplanar reconstruction showing the mid-portion of the left anterior descending coronary artery (LAD). Note the course of the vessel within the myocardium. Arrows indicate entry and exit point of the vessel. (B) Volume rendering modality taken in diastole (60% of the R–R cycle), showing the uncompressed portion of the LAD. (C) Same as in B but taken in systole (40% of the R–R cycle), showing full compression of the LAD.