Complete Summary

GUIDELINE TITLE

Cardiac resynchronisation therapy for the treatment of heart failure.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Cardiac resynchronisation therapy for the treatment of heart failure. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 28 p. (Technology appraisal guidance; no. 120).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Heart failure

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Cardiology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assess the clinical and cost-effectiveness of cardiac resynchronisation therapy for people with heart failure and evidence of dyssynchrony by comparing cardiac resynchronisation therapy with a pacing device (CRT-P) and cardiac resynchronisation therapy with a defibrillator device (CRT-D) each with optimal pharmacological therapy (OPT) and each other

TARGET POPULATION

Patients with heart failure

INTERVENTIONS AND PRACTICES CONSIDERED

1. Cardiac resynchronisation therapy with a pacing device (CRT-P)
2. Cardiac resynchronisation therapy with a defibrillator device (CRT-D)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Mortality (all cause, cardiac-related, sudden death, and non-cardiac death)
    - Morbidity (heart failure hospitalization, worsening heart failure, and arrhythmias)
    - New York Heart Association (NYHA) class
    - Exercise capacity
    - Adverse events
    - Health-related quality of life
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology

considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by Peninsula Technology Assessment Group (PenTAG), University of Southampton (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Identification of Studies

Search Strategy

Electronic databases were searched for published systematic reviews and/or meta-analyses, randomised controlled trials (RCTs) and ongoing research in January 2006 and updated in June 2006. The updated search revealed no new systematic reviews or RCTs. Appendix 1 in the Assessment Report (see the "Availability of Companion Documents" field) shows the databases searched and the strategies in full. Bibliographies of articles were also searched for further relevant studies and the U.S. Food and Drug Administration (FDA) and European Regulatory Agency Medical Device Safety Service websites were searched for relevant material. No language restriction was applied to the search strategy.

Study Identification

Relevant studies were identified in two stages. Abstracts returned by the search strategy were examined independently by two researchers and screened for inclusion or exclusion. Disagreements were resolved by discussion. Full texts of the identified studies were obtained. Two researchers examined these independently for inclusion or exclusion and disagreements were resolved by discussion. The process is illustrated by the QUOROM flow chart in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field).

Inclusion and Exclusion Criteria

The inclusion criteria for studies of clinical effectiveness were as follows:

Study Design

Included studies for clinical effectiveness had to be systematic reviews of randomised controlled trials or randomised controlled trials. These criteria were relaxed for examining the adverse effects of cardiac resynchronization therapy (CRT) where observational studies were also included.

Intervention

The intervention was either cardiac resynchronisation therapy with a pacing device (CRT-P) or cardiac resynchronisation therapy with a defibrillator device (CRT-D).

Comparators

- Optimal pharmaceutical therapy alone

- Or the alternative CRT device i.e., CRT-P or CRT-D

Population

The population of interest is people with a diagnosis of heart failure due to left ventricular systolic dysfunction (LVSD) with evidence of cardiac dyssynchrony.

Data Abstraction Strategy

Data were independently extracted by two researchers. Disagreements were resolved by discussion. Actual numbers were extracted where possible. Such data is identified in the data extraction sheets. Data extraction forms for each included study are shown in Appendix 3 of the Assessment Report (see the "Availability of Companion Documents" field).

Cost-Effectiveness

Search Strategy

Appendix 1 of the Assessment Report (see the "Availability of Companion Documents" field) describes the sources searched and the search strategy for MEDLINE. No language restriction was applied to the search strategy.

Study Selection Criteria

The inclusion and exclusion criteria for the systematic review of economic evaluations were identical to those for the systematic review of clinical effectiveness, except that:

- Non-randomised studies were included (including, for example, decision model based analyses or analyses of patient-level cost and effectiveness data alongside observational studies.)
- Only full cost-effectiveness analyses, cost utility analyses, cost benefit analyses, and cost consequence analyses were included. (Economic evaluations which only report average cost-effectiveness ratios were only included if the incremental ratios could easily be calculated from the published data).
- Stand alone cost analyses based in the United Kingdom National Health Service (UK NHS) were also sought.

Based on the above inclusion/exclusion criteria, study selection was made by one reviewer (RA).

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Literature searches identified a total of 10 studies of cardiac resynchronisation therapy (CRT) compared with optimal pharmacological therapy: five systematic reviews and five randomised controlled trials (RCTs)

Cost Effectiveness

Literature searches identified six relevant studies that evaluated the cost effectiveness of CRT in the treatment of heart failure: three modelling studies, two based on the COMPANION trial, and one based on the CARE-HF trial.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by Peninsula Technology Assessment Group (PenTAG), University of Southampton (see the "Availability of Companion Documents" field).

Critical Appraisal Strategy

Assessments of randomised controlled trial (RCT) quality were performed using the indicators shown below. Results were tabulated and these aspects described.

Internal Validity

- Sample size
    - Power calculation at design
- Selection bias
    - Explicit eligibility criteria
    - Proper randomisation and allocation concealment
    - Similarity of groups at baseline
- Performance bias
    - Similarity of treatment other than the intervention across groups
- Attrition bias and intention to treat analysis
    - All patients are accounted for
    - Number of withdrawals specified and reasons described
    - Analysis undertaken on an intention to treat (ITT) bases
- Detection bias
    - Blinding

    - Objective outcome measures
- Appropriate data analysis
    - Any potential conflict of interest was noted (for example, financial support provided to studies and/or authors by manufacturers of the devices).

External Validity

External validity was judged according to the ability of a reader to consider the applicability of findings to a patient group in practice. Study findings can only be effectively generalisable if they (a) describe a cohort that is representative of the affected population at large or (b) present sufficient detail in their outcome data to allow the reader to extrapolate findings to a patient group with different characteristics.

Generalisability of included studies was assessed by examining the age, the percentage of participants with AF and the gender profile of the included patients, as well as their baseline QRS and left ventricular ejection fraction (LVEF) levels. Studies that appeared representative of the United Kingdom (UK) population with regard to these factors were judged to have high external validity.

Methods of Analysis and Synthesis

Given the time-related nature of mortality and morbidity, where possible these outcomes were reported as hazard ratios (HRs) (with their 95% confidence intervals). Where not reported, hazard ratios were derived from Kaplan-Meier curves or log rank test using the method of Parmar and colleagues. The trials in this review reported outcomes at differing follow-up points. Pooling results at different time points depends on the assumption of a constant treatment effect over time. Using the outcome of time to all cause death, the Assessment Group tested and confirmed the appropriateness of this assumption (see Appendix 5 of the Assessment Report [see the "Availability of Companion Documents" field]). Binary and continuous outcomes were summarised as relative risks and weighted mean differences respectively. Given the potential for repeated events, hospitalisation related to heart failure was also expressed as a rate ratio. Risks of adverse events were combined using simple pooling, i.e., without weights and by study.

Where appropriate, data were pooled using a fixed-effects model, except where statistical heterogeneity existed ($p<0.1$) according to the chi-squared statistic, when a random-effects model was used instead. Reasons for heterogeneity were explored using meta-regression. Data are expressed as means and 95% confidence intervals. All analyses were performed using Stata Software. Forest plots were produced using Stats Direct.

Five subgroups were identified at the outset. These were age, atrial fibrillation, New York Heart Association (NYHA) class, degree of left ventricular systolic dysfunction (LVSD) (i.e., % LVEF) and degree of dyssynchrony (i.e., QRS duration). The study reports of included trials were examined for data on these particular subgroups.

Potential publication bias was assessed by visual inspection of funnel plots and inferential testing using the Egger test.

Cost-Effectiveness

Study Quality Assessment

The methodological quality of the economic evaluations was assessed according to the international consensus-developed criteria list of questions developed by Evers and colleagues. Any studies based on decision models were also assessed against the ISPOR guidelines for good practice in decision analytic modelling.

Data Extraction Strategy

Data were extracted by one researcher into two summary tables: one to describe the study design of each economic evaluation and the other to describe the main results. See Appendix 6 of the Assessment Report (see the "Availability of Companion Documents" field).

In study design table: author and year; model type or trial based; study design (e.g., cost-effectiveness analysis (CEA), cost utility analysis (CUA) or cost-analysis); service setting/country; study population; comparators; research question; perspective, time horizon, and discounting; main costs included; main outcomes included; sensitivity analyses conducted; and other notable design features were recorded. See Table 80 in the Assessment Report (see the "Availability of Companion Documents" field).

For modelling-based economic evaluations a supplementary study design table recorded further descriptions of: model structure (noting its consistency with the study perspective, and knowledge of disease/treatment processes; sources of transition and chance node probabilities; sources of utility values; sources of resource use and unit costs; handling of heterogeneity in populations; evidence of validation (e.g., debugging), calibration against external data and comparison with other models).

In the results table, for each comparator, we show incremental cost; incremental effectiveness/utility and incremental cost-effectiveness ratio(s) (ICER). Excluded comparators on the basis of dominance or extended dominance were also noted. The original authors' conclusions were noted, and also any issues they raised concerning the generalisability of results. Finally the reviewers' comments on study quality or generalisability (in relation to the TAR scope) of their results were recorded.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Literature searches identified six relevant studies that evaluated the cost effectiveness of CRT in the treatment of heart failure: three modelling studies, two based on the COMPANION trial, and one based on the CARE-HF trial. However, these studies were of limited relevance because none were conducted from a United Kingdom (UK) perspective.

Two models were submitted by consultees: a joint submission on behalf of Biotronik UK, Guidant, Medtronic, Sorin Biomedical CRM UK, and St Jude Medical UK, and a separate submission by Guidant. All models calculated the incremental cost-effectiveness ratios (ICERs) of cardiac resynchronisation therapy (CRT) compared with optimal pharmacological therapy alone for a 5-year time horizon. Neither of the manufacturers' analyses directly analysed the cost effectiveness of CRT-defibrillator device (CRT-D) compared with CRT-pacing device (CRT-P). The results from the manufacturers' models gave ICERs of 2800 pounds sterling for CRT-P and 22,400 pounds sterling for CRT-D (each compared with optimal pharmacological therapy alone) based on effectiveness data from the COMPANION randomised controlled trial (RCT), and an ICER of 15,600 pounds sterling for CRT-P compared with optimal pharmacological therapy based on effectiveness data from the CARE-HF randomised controlled trial (RCT).

The Assessment Group developed separate models that compared the costs and outcomes of CRT-P versus optimal pharmacological therapy, CRT-D versus optimal pharmacological therapy, and CRT-D versus CRT-P. The Assessment Group constructed a lifetime model, which was populated by a mixed-age cohort of patients with clinical characteristics that are representative of the general population of people with heart failure. The model included device-related adverse events (device replacement, perioperative complications, infection, device upgrade, lead dislodgement), hospitalisation due to heart failure or arrhythmia, heart transplant, surgical failure, death and failure to respond. These events could be experienced in each arm of the model (CRT-P, CRT-D and optimal pharmacological therapy).

See section 4.2 in the original guideline document for a detailed discussion of the cost analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors

- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This guidance should be read in conjunction with "Implantable cardioverter defibrillators for arrhythmias" (National Institute for Health and Clinical Excellence [NICE] technology appraisal guidance 95 – see appendix C in the original guideline document). This guidance on cardiac resynchronisation therapy provides additional treatment options for some of the groups of people covered in the guidance on implantable cardioverter defibrillators (ICDs).

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 electrocardiogram (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 therapy.

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 given above and who also separately fulfil the criteria for the use of an ICD device as recommended in NICE technology appraisal guidance 95 (see appendix C in the original guideline document).

CLINICAL ALGORITHM(S)

A clinical algorithm is provided for cardiac resynchronisation therapy and implantable cardioverter defibrillators (see Implementation Advice in the "Availability of Companion Documents" field).

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of cardiac resynchronisation therapy with a pacing device (CRT-P) and cardiac resynchronisation therapy with a defibrillator device (CRT-D) for the treatment of heart failure

POTENTIAL HARMS

Device-related adverse events (device replacement, perioperative complications, infection, device upgrade, lead dislodgement)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA120).
    - Local costing template incorporating a costing report to estimate the savings and costs associated with implementation.

- Audit criteria to monitor local practice.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Cardiac resynchronisation therapy for the treatment of heart failure. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 28 p. (Technology appraisal guidance; no. 120).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 May

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Cardiac resynchronisation therapy for the treatment of heart failure. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 2 p. (Technology appraisal 120). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Cardiac resynchronisation therapy for the treatment of heart failure. Costing template and report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. Various p. (Technology appraisal 120). Available in Portable Document Format (PDF) from the NICE Web site.
- Cardiac resynchronisation therapy for the treatment of heart failure. Audit criteria. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 11 p. (Technology appraisal 120). Available in Portable Document Format (PDF) from the NICE Web site.
- NICE guidance on cardiac resynchronisation therapy and implantable cardioverter defibrillators. Implementation advice. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 1 p. (Technology appraisal 120). Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1265. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Cardiac resynchronisation therapy for heart failure. Understanding NICE guidance. Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007 May. 4 p. (Technology appraisal 120).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1266. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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