Complete Summary

GUIDELINE TITLE

Implantable cardioverter defibrillators for arrhythmias.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan 1. 33 p. (Technology Appraisal; no. 95).

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously published version: National Institute for Clinical Excellence (NICE). Guidance on the use of implantable cardioverter defibrillators for arrhythmias. London (UK): National Institute for Clinical Excellence (NICE); 2000 Sep.

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SCOPE

DISEASE/CONDITION(S)

- Arrhythmias
- Life-threatening arrhythmic events
- Sudden cardiac death (SCD)

GUIDELINE CATEGORY

Prevention
Technology Assessment

CLINICAL SPECIALTY

Cardiology

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To review the clinical effectiveness and cost-effectiveness of implantable cardioverter defibrillators (ICDs) for arrhythmias
- To update a previous technology assessment review

TARGET POPULATION

- Patients at risk of sudden cardiac death (SCD), including those who have:
    - Left ventricular ejection fraction (LVEF) of less than 30% and a QRS duration of equal to or more than 120 milliseconds
    - Undergone surgical repair for congenital heart conditions
- Patients who have survived sudden cardiac events
- Patients with recurrent unstable heart rhythms

INTERVENTIONS AND PRACTICES CONSIDERED

Implantable cardioverter defibrillators (ICDs)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Mortality rates (all cause mortality, arrhythmic death, and nonarrhythmic death)
    - Quality of life
    - Adverse effects of treatment
- 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Searches of Unpublished Data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 Southampton Health Technology Assessments Centre, Wessex Institute for Health Research and Development, University of Southampton (See the "Availability of Companion Documents" field.)

Clinical and Cost Effectiveness

Search Strategy

The following databases were searched for published studies and ongoing research:

- Cochrane Library (Database of Systematic Reviews and Controlled Trials Register
- Medline (OVID)
- Premedline (OVID)
- Excerpta Medica Database (EMBASE)
- NHS Economic Evaluations Database (NHS Centre for Reviews and Dissemination, University of York)
- National Research Register
- Current controlled trials
- National Health Service Health Technology Assessment (NHS HTA) database
- EconLit (ARC2)

Searches were restricted to English language. Bibliographies of related papers were assessed for relevant studies.

Industry submissions to NICE were searched for studies that met the inclusion criteria (Submissions were requested from Biotronik UK Ltd, ELA Medical UK, Guidant, Medtronic UK Ltd and St Jude Medical UK Ltd.)

Search terms used for implantable cardioverter defibrillators (ICDs) and economic searches are listed in Appendix 3 of the Assessment Report (See "Availability of Companion Documents" field).

Inclusion and Exclusion Criteria

- The intervention should be implantable cardioverter defibrillator compared with antiarrhythmic drug therapy, or if no direct comparison, placebo/control.
- Participants were adults at high risk of sudden cardiac death due to arrhythmia, usually due to ventricular tachyarrhythmia. Specifically, patients in two categories:
    1. "Secondary Prevention"
        - Cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation (VF)

        - Spontaneous sustained VT causing syncope or significant haemodynamic compromise
        - Sustained VT without syncope/cardiac arrest, and who have an associated reduction in ejection fraction (less than 35%) but are no worse than III of New York Heart Association functional classification of heart failure.
    2. "Primary Prevention"
        - A history of previous myocardial infarction (MI) and
            - i) Non sustained VT on Holter (24 hour electrocardiograph [ECG]) monitoring:
            - ii) Inducible VT on electrophysiological testing:
            - iii) Left ventricular dysfunction with an ejection fraction less than 35% and no worse than III of the New York Heart Association functional classification of heart failure.
        - A history of previous myocardial infarction (MI) and depressed heart function (ejection fraction 0.30 or less).
        - Non-ischaemic (dilated) cardiomyopathy with arrhythmia at high risk of sudden cardiac death and depressed heart function (ejection fraction 0.30 or less).
- *Study Design*: Systematic reviews and meta-analyses of randomized controlled trials (RCTs), as well as individual RCTs, were included in the review of effectiveness. Reports published only as abstracts and non-English language studies were excluded from the review.
- The primary outcome for the review was mortality. Secondary outcome of quality of life was data extracted from the studies included in the systematic review on the primary outcome measure.

Studies identified by the search strategy were assessed for inclusion through three stages (see figure 2 of the Assessment Report [See "Availability of Companion Documents" field). Titles and abstracts were screened independently for inclusion by two reviewers. The full text of those studies included at this stage was examined for inclusion by two reviewers, with any disagreements resolved through discussion.

Additional inclusion criteria for economic evaluations were that studies must

- Include a comparator
- Include both costs and consequences
- Demonstrate high external and internal validity

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

In total, eight randomized controlled trials (RCTs), two systematic reviews and a meta-analysis met the inclusion criteria of the review.

Cost Effectiveness

Eleven economic evaluations of implantable cardioverter defibrillators (ICDs) for arrhythmias were identified. None were shown to have high internal and external

validity. One unpublished study relevant to the United Kingdom (UK) was identified.

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

Review of Published Meta-Analyses
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 Southampton Health Technology Assessments Centre, Wessex Institute for Health Research and Development, and the University of Southampton (See the "Availability of Companion Documents" field).

Clinical and Cost Effectiveness

Data Extraction Strategy

Data extraction and quality assessment of the studies included in the review were undertaken by one reviewer and checked by a second reviewer, with any disagreements resolved through discussion.

Quality Assessment Strategy

- Quality assessment of randomized controlled trials (RCTs) was judged using Jadad criteria (Appendix 4 of the Assessment Report [see "Availability of Companion Documents" field]).
- The quality of included systematic reviews was assessed using criteria recommended by NHS CRD (University of York) (Appendix 5 of the Assessment Report [see "Availability of Companion Documents" field]).
- Quality of economic evaluations were assessed for their internal validity (i.e. the methods used) using modified Drummond and Jefferson criteria, and external validity (i.e. the generalisability of the economic study to the population of interest) using a series of relevant questions.

Methods of Analysis/Synthesis

- Clinical effectiveness of implantable cardioverter defibrillators (ICDs) for arrhythmia was synthesised through a narrative review with full tabulation of results of all included studies.
- Data was not combined statistically by meta-analysis, using Cochrane Review Manager software, as it was deemed inappropriate in terms of heterogeneity and number of studies.

Methods for Estimating Qualify of Life, Costs and Cost-Effectiveness and/or Cost/Quality Adjusted Life Years (QALY)

- Published cost-effectiveness studies were reviewed in detail, comprising a narrative review with a tabulation of results where appropriate. Cost-effectiveness studies were identified as part of the search strategy (see "Description of Methods Used to Collect/Select the Evidence" field).
- An economic model was devised by adapting an existing cost-effectiveness model using the best available evidence to determine cost-effectiveness in a United Kingdom (UK) setting.
- In order to determine applicability and resource implications to the National Health Service (NHS), resources and costs were sought from the published literature, NHS sources and industry submissions where appropriate and available. The perspective of the economic analysis was that of the NHS and Personal Social Services.
- Effectiveness data, in terms of the outcomes described in the above section, were extracted from published trials and used in association with cost data to populate the model to obtain measures of cost-effectiveness. Quality of life information obtained from the literature and other sources were used to calculate cost effectiveness/utility estimates in terms of cost per quality adjusted life year (QALY).
- The robustness of the results to the assumptions made in the model were examined through sensitivity analysis and/or probabilistic sensitivity analysis.

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

Several economic evaluations relating to primary and secondary use of cardioverter defibrillators (ICDs) were available to the Committee. The Assessment Group reviewed 11 published economic evaluations and one unpublished analysis (the Buxton and Sharples model), and performed their own evaluation. The ICD manufacturers also jointly submitted an evaluation of primary and secondary sudden cardiac death (SCD) prevention.

Summary of Costs and Cost-Effectiveness

Previous studies show that ICDs improve survival compared to drug treatment, but with considerably increased cost. This evaluation points at incremental cost-effectiveness results of over £100,000 per quality adjusted life year (QALY) under the main base case relative risk strategy. Incremental cost per QALY ranged from £57,000 to £117,000 depending on mortality risk for secondary prevention. For primary prevention the incremental cost per QALY was estimated at £93,000, and £29,000 for patients at high risk. The incremental cost per QALY was estimated at £80,000 for patients with a previous myocardial infarction and depressed heart function.

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness 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 appraisal does not cover the use of implantable defibrillators for non-ischaemic dilated cardiomyopathy.

- Implantable cardioverter defibrillators (ICDs) are recommended for patients in the following categories.
    - "Secondary prevention," that is, for patients who present, in the absence of a treatable cause, with one of the following:
        - Having survived a cardiac arrest due to either ventricular tachycardia (VT) or ventricular fibrillation (VF)
        - Spontaneous sustained VT causing syncope or significant haemodynamic compromise
        - Sustained VT without syncope or cardiac arrest, and who have an associated reduction in ejection fraction (left ventricular ejection fraction [LVEF] of less than 35%) (no worse than class

III of the New York Heart Association functional classification of heart failure)

- "Primary prevention," that is, for patients who have:
  - A history of previous (more than 4 weeks) myocardial infarction (MI) and:

    either

    - Left ventricular dysfunction with an LVEF of less than 35% (no worse than class III of the New York Heart Association functional classification of heart failure), **and**
    - Non-sustained VT on Holter (24-hour electrocardiogram [ECG]) monitoring, **and**
    - Inducible VT on electrophysiological (EP) testing

    or

    - left ventricular dysfunction with an LVEF of less than 30% (no worse than class III of the New York Heart Association functional classification of heart failure) **and**
    - QRS duration of equal to or more than 120 milliseconds
  - A familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia (ARVD), or have undergone surgical repair of congenital heart disease.

CLINICAL ALGORITHM(S)

None provided

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 implantable cardioverter defibrillators (ICDs) for arrhythmias

POTENTIAL HARMS

Adverse Effects

Serious adverse events due to implantable cardioverter defibrillators (ICDs) were reported infrequently. However, recorded complications included infection, haematomas and bleeding, lead dislodgement and migration, cardiac perforation,

pleural effusion and pneumothorax, and device dysfunction/malfunction of the generator. Additionally, some people for whom defibrillation is initiated while they remain conscious report that they become fearful of the severe jolt to the thorax occasioned by device activation.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- Clinicians caring for people who are at risk of sudden cardiac death (SCD) should review their current practice and policies to take account of the guidance (see the "Major Recommendations" field).
- Local guidelines, protocols or care pathways that refer to the care of people who have experienced ventricular tachycardia (VT), ventricular fibrillation (VF), myocardial infarction (MI), left ventricular dysfunction, long QRS duration, a familial cardiac condition with a high risk of sudden death or surgical repair for congenital heart disease should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
    - An implantable cardioverter defibrillator (ICD) is provided for a person who is in one of the following categories.
    - A person presents, in the absence of a treatable cause, with one of the following:
        - Having survived a cardiac arrest due to either VT or VF, **or**
        - Spontaneous sustained VT causing syncope or significant haemodynamic compromise, **or**
        - Sustained VT without syncope or cardiac arrest, and who has an associated reduction in ejection fraction (EF) and is no worse than class III of the New York Heart Association (NYHA) functional classification of heart failure.
    - A person has a history of an MI more than 4 weeks previously and

      either:

        - **all of the following**:
            - left ventricular dysfunction with an left ventricular ejection fraction (LVEF) of less than 35%

              and

        - No worse than class III NYHA functional classification of heart failure **and**
        - Non-sustained VT on Holter monitoring **and**
        - Inducible VT on electrophysiological testing
    - **or all of the following**:
        - left ventricular dysfunction with an LVEF of less than 30%

          and

        - No worse than class III NYHA functional classification of heart failure **and**
        - QRS duration of equal to or more than 120 milliseconds.
- A person has a familial cardiac condition with a high risk of sudden death.
- A person has undergone surgical repair of congenital heart disease.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

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
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Implantable cardioverter defibrillators for arrhythmias. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan 1. 33 p. (Technology Appraisal; no. 95).

ADAPTATION

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

DATE RELEASED

2000 Sep (revised 2006 Jan)

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.

It updates a previously published version: National Institute for Clinical Excellence (NICE). Guidance on the use of implantable cardioverter defibrillators for arrhythmias. London (UK): National Institute for Clinical Excellence (NICE); 2000 Sep.

GUIDELINE AVAILABILITY

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

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Implantable cardioverter defibrillators for arrhythmias. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. 2 p. (Technology appraisal 95). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Costing template and costing report. Arrhythmia - implantable cardioverter defibrillators (ICDs). London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. Various p. (Technology appraisal 95). Available in Portable Document Format (PDF) from the NICE Web site.
- The clinical effectiveness and cost effectiveness of implantable cardioverter defibrillators: arrhythmias. Assessment report. Southampton Health Technology Assessment Centre (SHTAC), University of Southampton. 2005 May 23. Electronic copies: Available from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0973. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Implantable cardioverter defibrillators (ICDs) for arrhythmias. Understanding NICE guidance –information for people with arrhythmias, their families and carers, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Jan. 10 p. (Technology appraisal 95).

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: N0974. 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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