



***National Institute for
Clinical Excellence***

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Guidance on

the use of

implantable

cardioverter

defibrillators for

arrhythmias

This document has been circulated to the following:

- Health Authority Chief Executives in England and Wales
- NHS Trust Chief Executives in England and Wales
- PCG Chief Executives
- Local Health Group General Managers
- Medical and Nursing Directors in England and Wales
- Consultant cardiologists in England and Wales
- Consultant cardiothoracic surgeons in England and Wales
- NHS Director Wales
- Chief Executive of the NHS in England
- NHS Executive Regional Directors
- Special Health Authority Chief Executives
- Community Health Councils in England and Wales
- Patient advocacy groups
- Commission for Health Improvement
- NHS Clinical Governance Support Team
- Chief Medical and Nursing Officers in England and Wales
- Medical Director & Head of NHS Quality – National Assembly for Wales
- Clinical Effectiveness Support Unit - Wales
- Representative bodies for health services, professional organisations and statutory bodies, Royal Colleges

This Guidance is written in the following context:

This guidance represents the view of the Institute's Appraisal Committee, the membership of which is set out in Appendix A, 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 about the use of implantable cardioverter defibrillators for arrhythmias. 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.

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Guidance on the use of implantable cardioverter defibrillators for arrhythmias

1. Guidance

1.1. The use of implantable cardioverter defibrillators (ICDs) should be routinely considered for patients in the following categories:

1.1.1 'Secondary prevention' i.e. for patients who present, in the absence of a treatable cause, with:-

- 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 class 3 of the New York Heart Association functional classification of heart failure.

1.1.2 'Primary prevention' for patients (see paragraph 2.5 for definition) with:

- a history of previous myocardial infarction (MI) and all of the following:
 - i) non sustained VT on Holter (24 hour ECG) monitoring;
 - ii) inducible VT on electrophysiological testing;
 - iii) left ventricular dysfunction with an ejection fraction (EF) less than 35% and no worse than class III of the New York Heart Association functional classification of heart failure.
- a familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia (ARVD) and following repair of Tetralogy of Fallot.

1.2 The use of implantable cardioverter defibrillators should not be routinely considered for patients in the following categories:-

This section, Section 1, constitutes the Institute's Guidance on the use of implantable cardioverter defibrillators for arrhythmias. The remainder of the document is structured in the following way:

2 Clinical Need and Practice	8 Implementation
3 The Technology	9 Clinical Audit Advice
4 Evidence	10 Review of Guidance
5 Implications for the NHS	Appendix A: Appraisal Committee
6 Related Guidance	Appendix B: Sources of Evidence
7 Further Research	Appendix C: Information for Patients.

The full document and a Summary of Evidence are available from our website at www.nice.org.uk or by telephoning 0541 555 455 and quoting the reference number 22392.

Mae'r adran hon (adran 1) hefyd ar gael yn Gymraeg ar ein gwefan neu drwy gysylltu â 0541 555 455, rhif cyfeirnod 22393.

2

Clinical Need and Practice

- 1.2.1 Those with spontaneous sustained VT associated with minimal symptoms and good cardiac function (EF > 35%).
 - 1.2.2 Those who present with syncope of unknown cause (with no previous history of myocardial infarction) and who have inducible VT on electrophysiological testing (EPS) in the presence of normal cardiac function (EF > 35%)
 - 1.3 At this stage, the Institute considers that the evidence for patients with syncope of unknown origin, with haemodynamically significant sustained VT or VF induced at EPS and in the presence of impaired cardiac function (i.e. ejection fraction (EF) < 35%) is insufficient to recommend the use of ICDs.
- 2.1 Cardiovascular disease is the leading cause of death in the UK, with over 300,000 victims each year. Sudden cardiac death (SCD) represents some 25% to 30% of all cardiovascular deaths, claiming an estimated 70,000 to 90,000 lives each year.
 - 2.2 SCD is defined as an abrupt loss of consciousness and unexpected death due to cardiac causes, which occur within one hour of onset of symptoms. About 80% of SCD events are caused by ventricular tachyarrhythmias, that is, ventricular tachycardia (VT) and ventricular fibrillation (VF). The remaining 20% consists of a number of conditions, including bradycardia (slow heartbeats). The survival rates for SCD are less than 5% in most industrialised countries. Survival rates for out-of-hospital sudden cardiac episodes in Britain are about 2%.
 - 2.3 About 15% of sudden cardiac episode survivors will experience another SCD event within one year. Untreated, the recurrence is usually fatal. However, some survivors live for many years without treatment.
 - 2.4 SCD is different, and often occurs separately, from a myocardial infarction (MI – heart attack), in which one or more coronary arteries become blocked, leading to damage to heart tissue or tissue death.
 - 2.5 Risk factors for SCD include:
 - a previous SCD episode
 - previous VT
 - a prior MI
 - coronary artery disease
 - family history of SCD and familial cardiac conditions e.g. long QT syndrome
 - poor cardiac function (low left ventricular ejection fraction)
 - heart failure

Implantation for patients with one or both of the first two of these risk factors is called, in this context, secondary prevention. Implantation for patients with neither of the first two risk factors, but one or more of the other risk factors, is called, in this context, primary prevention.

- 3.1 Treatments are aimed at either suppressing or terminating the arrhythmia. The main treatments are:
 - 3.1.1 Antiarrhythmic (AA) drug therapy (which may be guided by Holter monitoring (24 hour ECG tape recording) or electrophysiological (EP) testing. AA drugs are divided into classes I to IV. Class III drugs, which include amiodarone, are the most commonly used for long-term management of ventricular arrhythmias. Chronic prophylactic AA drug therapy is aimed at suppressing the development of arrhythmias, but not terminating an arrhythmia once it is initiated.
 - 3.1.2 The implantable cardioverter defibrillators actively sense and can terminate life-threatening ventricular tachyarrhythmias.
- 3.2 Amiodarone is the most commonly used AA as an alternative treatment to ICD for the treatment of ventricular tachyarrhythmias. However, empiric AA drug therapy or EP guided AA drug therapy is not effective in improving mortality for high-risk patients.
- 3.3 ICD therapy consists of implanting a device about two inches square and half an inch deep (40 cc) into the upper chest below the left shoulder, with leads into the heart to pace, sense and defibrillate. An ICD senses continuously until an arrhythmia is recognised, after which therapy is delivered to the heart.
- 3.4 Current devices require only local anaesthesia and a length of stay in hospital of 2 to 4 days for fitting. They are battery operated with a battery life of up to 9 years, depending on the number of therapeutic shocks delivered, and may be programmed to optimise the detection of abnormalities in heartbeat and provide diagnostics and specific therapy for any patient.
- 3.5 In 1995, the first dual function ICDs were produced, combining pacemaker and ICD capabilities in one device. This is particularly important for those patients who are required to take AA medication along with an ICD, as the medication sometimes fails to allow heartbeat rates to adjust with exercise or may induce bradycardia. The device acts as a pacemaker in these circumstances. Technology that recognises and discriminates between a number of arrhythmias may allow more appropriate therapy, and in particular, lessen the incidence of painful shocks for tachycardias that can now be terminated painlessly by a pacing device.

- 3.6 Current ICD costs range up to £22,000, including leads and accessories. Quantity discounts may be available from manufacturers.
- 3.7 In 1999, the number of implants of ICDs was 185 per million of population in the USA, 67 in Germany, 25 in Italy, 17 in the UK and 12 in France. The average for Western Europe was about 30.
- 3.8 Regional implantation rates in 1998 in the UK varied from 23 per million in South Thames to 7 per million in Wales for all implants, and from 17 per million (South Thames) to 5 per million (Wales) for new (i.e. first) implants.

4

Evidence

- 4.1 ICDs have been shown to be clinically effective in secondary prevention of SCD. In trials, ICDs have been compared with both the best medical therapy (but excluding AA drug therapy) and with AA drug therapy, commonly amiodarone. A meta-analysis of three trials shows a relative risk reduction of 27% for total mortality, and of 52% for arrhythmic death. Overall, ICDs clearly and significantly reduced deaths, adding an estimated 0.36 years of life (on average) at six years. One death in the first three years was averted per 10 patients treated.
- 4.2 In primary prevention, there have been three trials, two of which (MADIT and MUSTT) have demonstrated gains while the other (CABG patch) has shown no gain.
- 4.3 The estimates of cost effectiveness submitted to the Institute covered a considerable range. The costs of ICD treatment are sensitive to the cost of the device, but the incremental costs of the treatment (the costs over and above treatment with amiodarone) are also sensitive to the number and length of hospital admissions under both sets of treatment. The number of years of life gained from ICD therapy has to be extrapolated from trials lasting mainly three to four years (and with relatively short average follow-up periods) and these extrapolations are subject to considerable uncertainty.
- 4.4 The Institute believes that the economic model contained in the joint industry (Eucomed) submission (prepared for Eucomed by Medtronic), based closely on the US evidence from the AVID trial, provides a reasonable and realistic indicative estimate of the cost effectiveness of ICDs in secondary prevention. It suggests a cost per life year gained, using a 5-year model with ICD replacement where necessary, of some £26,000 to £31,000. Estimates of cost-effectiveness of ICDs over a longer period, of say eight years, are more uncertain but more favourable. As the technology has improved (in particular, as the length of device life has increased) costs per life year and cost per QALY gained will have fallen, and should continue to do so.

- 4.5 Because these average incremental cost-effectiveness ratios themselves hide a wider range of cost-effectiveness ratios for ICDs in different patient sub-groups, the Institute has carefully examined the patient groupings that most benefit from this intervention. Its recommendation in deciding a boundary between those who should be considered for ICD implantation, and those who should not, (section 1) reflects its best judgement of how to ensure that the devices are provided to those who will most clearly benefit from them.
- 4.6 Data of good quality on the impact of ICDs on the quality of life of patients are equivocal. According to results of the largest trial (AVID, n = 1016), patients whose devices are rarely or never activated have improved mental well-being and fewer quality of life concerns than those whose devices are often activated. On the other hand, the majority of ICD patients report the same or higher quality of life following implantation. It is not clear how much extra benefit is to be gained from the more expensive ICDs. While the additional features are effective, their benefits, which improve the patient's quality of life more than life expectancy, are difficult to quantify.

5

Implications for the NHS

- 5.1 The Spanish and Danish guidelines are similar to the ones proposed here. If the implantation rate rises to the levels recommended in these guidelines, the number of implants in the UK is likely to rise from 17 per million population to the order of 50 per million. Assuming an all-up cost of £25,000 (based upon an average device cost, with discount, plus overhead costs) per implant for 1800 implants, the budget impact for the NHS in England and Wales would be £45 million per year. Some savings may accrue from fewer hospital visits for those patients no longer on amiodarone, offset by additional visits to check the functioning of the implant. This is likely to reduce the cost to the NHS, over time, to some £25 to £30 million (excluding capital expenditure mentioned in the next paragraph).
- 5.2 In order to accommodate an increase in implantation, the capacity of the existing centres will need to be reviewed to establish whether they could manage the additional patients or whether more centres should be established. Centres accredited for implantation should follow the guidelines produced by the European Society of Cardiology. It will be necessary to recognise where the most significant bottlenecks to an orderly expansion of services are likely to occur. In particular, early attention should be given to the training and availability of electrophysiologists, currently in short supply and to the recruitment and training of cardiac technicians, who will be needed to support this proposed expansion in service. Additional anaesthetists and access to cardiac catheterisation or pacemaker laboratories and follow-up clinics will also be required.

6

Related Guidance

- 6.1 The Institute issued guidance on the use of coronary artery stents in April 2000.

7

Further Research

- 7.1 A detailed cost-effectiveness study should be undertaken in at least two of the larger implantation centres, building on data from the National Pacemaker Database Registry of ICDs.

8

Implementation

- 8.1 NHS trusts managing cardiothoracic services should review their current clinical practice against this guidance.
- 8.2 Since implantation and activation of an ICD can cause adverse psychological impact, adequately funded and staffed support services, including support for self-management, should be provided for patients at all implantation centres.
- 8.3 Protocols for the implantation of ICDs should be developed, to include:
 - 8.3.1 early referral of appropriate patients
 - 8.3.2 rapid decision making and implantation
 - 8.3.3 conscious sedation rather than general anaesthesia
 - 8.3.4 A rehabilitative approach to after-care which includes psychological preparation for living with an ICD
 - 8.3.5 early discharge
 - 8.3.6 efficient and comprehensive follow-up
- 8.4 Protocols for screening high risk patients, post MI, should be developed, which may include:
 - 8.4.1 measurement of ejection fraction
 - 8.4.2 Holter monitoring
 - 8.4.3 Baroreflex sensitivity
 - 8.4.4 Heart rate variability
 - 8.4.5 T wave alternans
- 8.5 The NHS Purchasing and Supply Agency should be asked to undertake a review of current purchasing arrangements for ICDs by NHS trusts, with a view to establishing the most effective supply mechanism for these devices.

9

Clinical Audit Advice

- 9.1 To enable clinicians to audit their own compliance with this guidance, it is recommended that the criteria used to determine suitability for ICD implantation should be recorded in the treatment plan for each patient.
- 9.2 This information should be incorporated into local clinical audit data recording systems, and consideration given (if not already in place) to the establishment of appropriate categories in routine electronic record keeping systems used in primary care groups and hospitals.
- 9.3 Prospective clinical audit programmes should record the proportion of treatments adhering to the guidance. Such programmes are likely to be more effective in improving patient care when they form part of the organisation's formal clinical governance arrangements and where they are linked to specific post-graduate activities.

10

Review of Guidance

- 10.1 This guidance will be reviewed in September 2003.

Andrew Dillon
Chief Executive

September 2000

APPENDIX A

Appraisal Committee Members

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APPENDIX B

Sources of Evidence

1. The following documentation and opinion was made available to the Committee:
 - a) Assessment Report Prepared by the Wessex Institute for Health Research and Development, University of Southampton (Implantable Cardioverter Defibrillators for Arrhythmias, May 2000)
 - b) Manufacturer/Industry submissions:
 1. Joint Submission from EUCOMED UK ICD Working Group (includes all Manufacturers, ABHI and EUCOMED)
 2. Biotronik UK Ltd.
 3. ELA UK Ltd.
 4. Guidant Ltd.
 5. Medtronic Ltd.
 6. St. Jude Medical UK Ltd.
 - c. Professional/Specialist Group, Patient/carer Group and Trade Association submissions:
 1. British Pacing and Electrophysiology Group
 2. The Association of British Health-Care Industries
 3. EUCOMED.
 - d. The following experts were invited to make submissions to the Committee:
 1. Professor John Camm, Professor of Clinical Cardiology, St. George's Hospital Medical School

APPENDIX C

Guidance on the use of implantable cardioverter defibrillators for arrhythmias – patient information

The patient information in this appendix has been designed to support the production of your own information leaflets; you can download it from our web site (www.nice.org.uk) where it is available in English and Welsh. A printed version of this text is available in English/Welsh or English alone. If you would like copies of the printed leaflet please contact 0541 555 455, and quote the reference number 22395 for the English/Welsh version and 22394 for the English only version.

What is NICE Guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment and clinical procedures and where they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal takes around 12 months to complete and involves the manufacturers of the drug or device, professional organisations and the groups who represent patients.

NICE was asked to look at the available evidence on the use of Implantable Cardioverter Defibrillators and provide guidance that would help the NHS decide when they should be used in the management of arrhythmias.

Background information

The heart is a muscle that circulates blood through 2 separate systems. The two chambers on top (atria) receive the blood and pump it into the ventricles. The ventricles are the two lower chambers of the heart and they act as pumping stations. The heart muscle contracts regularly and develops a normal rhythm (heart beat). An arrhythmia occurs when there is a variation from the normal rhythm of the heartbeat.

The left ventricle squeezes oxygen-rich blood into the arteries, which carry it throughout the body. The blood returns to the right atrium, which passes it down to the right ventricle. The right ventricle then pumps this blood to the lungs, where it picks up oxygen. Oxygen-rich blood then returns to the left atrium of the heart, which pumps it into the left ventricle, and the cycle repeats. There are valves between the chambers that prevent the blood going backwards.

When the left ventricle squeezes and forces blood out around the body, it is called “ejection”. This is because it is ejecting the blood out into the arteries. The ventricle does not pump out all the blood inside it. The amount that is pumped out per heartbeat is called the “ejection fraction”. The ejection fraction is used as a measure of how well the heart is working.

Cardiovascular disease is the leading cause of death in the UK, with over 300,000 victims each year. Around 3 out of 10 of these deaths are sudden cardiac deaths, claiming an estimated 70,000 to 90,000 lives each year.

Sudden Cardiac Death (SCD) is a very serious condition. It is defined as an abrupt loss of consciousness and unexpected death due to problems with the heart. It occurs within one hour of symptoms starting. About 8 out of 10 SCDs are caused by problems with the ventricles, (ventricular tachycardia or ventricular fibrillation). In most industrialised countries less than 5 out of 100 patients survive SCD.

About 15 out of 100 sudden cardiac episode survivors will experience another SCD within one year. Untreated, the recurrence is usually fatal. However, some survivors live for many years without further treatment.

SCD is different, and often occurs separately, from a myocardial infarction (heart attack), in which one or more blood vessels in the heart become blocked, leading to damage to heart tissue (muscle).

What are Implantable Cardioverter Defibrillators?

Implantable Cardioverter Defibrillators are small devices that are put into the upper chest below the left shoulder. Leads from the device go into the heart where they:

- Monitor the heart,
- Control the rate of the heart beat (pace),
- Sense an irregular heart beat and deliver a small electric shock to return the heart beat to its normal rhythm (defibrillate)

An Implantable Cardioverter Defibrillator checks the heart continuously until an arrhythmia (a variation from the normal rhythm of the heart beat) is recognised. Then the device delivers the appropriate treatment to the heart.

Fitting of the device requires the patient to have a local anaesthetic and stay in hospital for around 2 to 4 days. The devices are battery operated and the battery lasts for up to 9 years, depending on the number of treatments the device delivers. The devices may be programmed to meet the specific needs of the individual patient.

In 1995, the first dual function Implantable Cardioverter Defibrillators were produced. These combine the functions of a pacemaker and an Implantable Cardioverter Defibrillator in one device. This is particularly important for those patients who need to take drugs to prevent arrhythmias, as well as having an Implantable Cardioverter Defibrillator fitted. This is because these drugs sometimes don't allow the heart rate to change in response to exercise. In these circumstances the dual function device acts as a pacemaker and controls the rate of the heartbeat.

What has NICE recommended about the use of Implantable Cardioverter Defibrillators for arrhythmias?

1. NICE has recommended that implantable cardioverter defibrillators should be routinely considered for the following:

- **'Secondary prevention'**. This means patients who have one of the following conditions, the cause of which cannot be treated:
 - a heart attack that has been caused by problems with the rhythm of the ventricle (ventricular tachycardia or ventricular fibrillation)

- A sudden, unexpected and prolonged increase in the rhythm of the ventricle (ventricular tachycardia) that results in the patient fainting because of a lack of blood getting to the brain and/or the blood being unable to circulate around the body properly.
 - A lasting increase in the rhythm of the ventricle (ventricular tachycardia), where the patient does not faint and the heart does not stop beating, but where the patient's ejection fraction (see background section) decreases to less than 35% and the patients' heart failure is no worse than class 3 of the New York Heart Association Classification. This is a system that is used by doctors to describe a patient's heart condition, level 1 being the least serious and level 5 the most serious.
- **'Primary prevention'**, that is use in patients with a history of previous heart attacks and all of the following:
 - sustained increase in the rhythm of the ventricle when undergoing (Holter) monitoring;
 - an increase in the rhythm of the ventricle that results from electrophysiological testing;
 - problem with the functioning of the left ventricle, an ejection fraction of less than 35% and no worse than class 3 of the New York Heart Association functional classification.
 - a inherited heart problem that your doctor has informed you has a high risk of sudden death. These include: long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia and following repair of Tetralogy of Fallot.
2. Implantable cardioverter defibrillators should not be routinely considered for patients who go to the doctor with:
- a sudden, unexpected and prolonged increase in the rhythm of the ventricle (ventricular tachycardia) that have minimal symptoms and good cardiac function (an ejection fraction of more than 35%).
 - fainting of unknown cause (with no previous history of heart attacks).

What should I do next?

SCD is different, and often occurs separately, from a myocardial infarction (heart attack). This is a specialist area of medicine. If you are unsure as to whether this guidance applies to you, then you should discuss it with your doctor/specialist at your next appointment.

Will NICE review its guidance?

Yes. The guidance will be reviewed in September 2003

Further Information

Further information on NICE, and the full guidance issued to the NHS is available on the NICE web site (www.nice.org.uk). It can also be requested from 0541 555 455, quoting reference 22392.