

Insertion of a subcutaneous implantable cardioverter defibrillator for prevention of sudden cardiac death

Interventional procedures guidance

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nice.org.uk/guidance/ipg454

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not 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.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

1 Guidance

- 1.1 Current evidence on the efficacy of the insertion of a subcutaneous implantable cardioverter defibrillator (ICD) for the prevention of sudden cardiac death in the short and medium term is adequate. Evidence on its safety in the short term is adequate but there are uncertainties about long-term durability. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

- 1.2 Clinicians wishing to insert a subcutaneous ICD for the prevention of sudden cardiac death should take the following actions:
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
- 1.3 Patient selection and treatment should only be done by teams with extensive experience in the insertion of ICDs.
- 1.4 Clinicians should enter details about all patients undergoing insertion of a subcutaneous ICD for the prevention of sudden cardiac death onto the [Central Cardiac Audit Database](#). Audit should be carried out locally and should include clinical outcomes and their relationship to patient characteristics.
- 1.5 NICE encourages further data collection, particularly on the efficacy of the procedure for converting spontaneous arrhythmias, on the durability of the devices used and on the need for procedures to revise or replace defibrillators.

2 The procedure

2.1 *Indications and current treatments*

- 2.1.1 Sudden cardiac death is often caused by ventricular arrhythmias (ventricular tachycardia or ventricular fibrillation). The most common cause of ventricular arrhythmia is underlying heart disease.
- 2.1.2 Prevention of sudden cardiac death is either primary, defined as preventing a person's first life-threatening arrhythmic event, or secondary, which refers to preventing further life-threatening events (either ventricular tachycardia or ventricular fibrillation) in survivors of previous serious ventricular arrhythmias. Treatment with an ICD is recommended in [Implantable cardioverter defibrillators for arrhythmias](#) (NICE technology appraisal guidance 95) for patients with arrhythmias and those at risk of sudden cardiac death (that is, for both secondary and primary prevention).

2.1.3 The ICD consists of a generator, which contains a battery, capacitor and sophisticated electronic circuitry, and one or more leads. The ICD senses and detects arrhythmias, and delivers pacing impulses or defibrillating shocks to the heart as necessary, to restore normal cardiac rhythm. A conventional transvenous ICD consists of a generator under the skin below the clavicle and 1 or more leads passed through a vein into the heart. A transvenous ICD can also provide long-term permanent pacing if the heart rate falls below a pre-set rate, or if cardiac resynchronisation therapy, as recommended in [Cardiac resynchronisation therapy for the treatment of heart failure](#) (NICE technology appraisal guidance 120), is needed.

2.2 *Outline of the procedure*

2.2.1 An entirely subcutaneous ICD differs from a conventional ICD in that the lead is placed subcutaneously, rather than transvenously. The lead comprises 2 sensing electrodes and a shocking coil. The ICD senses cardiac signals, but the lead is not directly attached to the heart. Unlike a conventional ICD, the subcutaneous device is not designed to provide long-term pacing.

2.2.2 The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks without the use of fluoroscopy or other medical imaging. A subcutaneous pocket is created on the left side of the chest for the generator. The lead is tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum, and then to a second small incision at the upper end and secured, so that the sensing electrodes and shocking coil lie alongside the sternum. The proximal end of the lead is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing, pacing and recording functions of the ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the ICD can appropriately detect and correct it.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

2.3 *Efficacy*

- 2.3.1 A case series of 118 patients reported that all induced tachyarrhythmias during defibrillation testing (at 65 J of energy) were successfully detected and converted to sinus rhythm. A case series of 55 patients reported that 2 consecutive episodes of induced ventricular fibrillation (each at 65 J of energy) in 53 patients were successfully detected in 100% and successfully converted in 98% (52/53) of patients.
- 2.3.2 The case series of 118 patients reported that the device successfully detected 45 episodes of spontaneous, ventricular arrhythmias (in 8 patients) and first shock therapy was successful in 98% of the episodes during 18 months of follow-up.
- 2.3.3 A case series of 40 patients reported that 25 spontaneous episodes of ventricular tachyarrhythmias occurred in 4 patients during a median follow-up of 229 days. Of these, 21 episodes were accurately detected and 20 were successfully treated with 28 appropriate subsequent shocks. The overall subcutaneous ICD shock efficacy was 96% (95% CI 12.8 to 100%). The efficacy of first shocks was 58% (95% CI 35.6 to 77.4%).
- 2.3.4 The case series of 55 patients reported that the mean time delay between induction and defibrillation was 14 seconds.
- 2.3.5 The case series of 55 patients reported that 98% (54/55) of patients were alive after a mean follow-up of 10 months.
- 2.3.6 The Specialist Advisers listed additional key efficacy outcomes as treatment of malignant ventricular arrhythmias, successful discrimination of other detected fast signals (such as benign arrhythmias and noise) and thereby non-treatment, and health-related quality of life.

2.4 *Safety*

- 2.4.1 Confirmed or suspected infections were reported in 6% (18/321) of patients in a case series of 330 patients at a mean follow-up of 321 days. Of these, 1% (4/321) were infections in the subcutaneous ICD system that occurred early in the

study and were treated by explantation of the device, and 5% (14/321) were superficial wound infections, managed by antibiotics (13) or wound revision (1).

- 2.4.2 Ten inappropriate shocks due to T-wave oversensing were reported in 25% (4/16) of patients in the non-randomised comparative study of 16 patients at a median follow-up of 9.5 months. Further inappropriate shocks were reported in 2 of 3 patients after new vectors were selected. Thirty three inappropriate shocks were reported in 13% (15/118) of patients in the case series of 118 patients. This was due to myopotentials (caused by lead migration in 2 patients) in 3 patients, T wave oversensing in 9 patients, double counting in 1 patient during a complete right bundle branch block 421 days after implantation, atrial flutter in 1 patient, and noise sensing by transcutaneous electric nerve stimulation therapy in 1 patient. These were resolved by updating the software, lead repositioning (2 patients), a new template for the electrogram (2 patients) and selection of better vectors (7 patients).
- 2.4.3 Re-interventions (including explants, replacing or repositioning) were performed in 19% (3/16) of patients in the non-randomised comparative study of 16 patients during median follow-up of 9.5 months, in 14% (16/118) of patients in the case series of 118 patients during a mean follow-up of 18 months, and in 12% (38/321) of patients in the case series of 330 patients with a median follow-up of 321 days. The reported reasons for reintervention in these studies included infection (12 cases), suboptimal placement of generator or electrode (5 cases), device or battery failure (6 cases), discomfort (4 cases), lead migration (3 cases), healing problems (3 cases), premature battery depletion (4 cases), failure of communication between the pulse generator and the programmer (2 cases), threatened erosion (4 cases), generator migration (2 cases), incomplete insertion of the electrode connection to the device (1 case), haematoma (1 case), need for antitachycardia pacing (1 case) and wound dehiscence following an accident (1 case).
- 2.4.4 Atrial fibrillation or flutter was reported in 4% (14/321) of patients immediately after cardioversion testing in the case series of 330 patients. This was managed by electrical cardioversion in 10 patients, spontaneous conversion in 3 patients and pharmacological cardioversion in 1 patient. All patients returned to normal sinus rhythm and there were no recurrences.

2.4.5 The Specialist Advisers listed an additional theoretical adverse event as trauma during implant surgery (for example rib fracture or collapsed lung).

2.5 *Other comments*

2.5.1 The Committee was advised that the procedure may have advantages for younger patients, in whom longer-term follow-up is important, and for patients in whom venous access is difficult.

2.5.2 The Committee noted that the design of the technology continues to evolve.

2.5.3 The Committee noted that further long-term follow-up data of 3–5 years are needed. Uncertainties over the durability of the technology underpinned the recommendation in 1.1.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk.

Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#).

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

