

Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death

Interventional procedures guidance

Published: 20 December 2017

www.nice.org.uk/guidance/ipg603

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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG454.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians should enter details about all patients having subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death onto a register by submitting data to the National Audit of Cardiac Rhythm Management database at the UK National Institute for Cardiovascular Outcomes Research (NICOR), and should review local clinical outcomes.
- 1.3 The procedure should only be done by clinicians with specific training on inserting the device.

2 Indications and current treatments

- 2.1 Sudden cardiac death is often caused by ventricular arrhythmias

(ventricular tachycardia or ventricular fibrillation). The most common cause of ventricular arrhythmias is underlying heart disease.

- 2.2 Prevention of sudden cardiac death can be primary, which is defined as preventing a first life-threatening arrhythmic event in someone who is at high risk of such an event. Or, it can be secondary, which refers to preventing further life-threatening events in survivors of previous serious ventricular arrhythmias. Treatment with an implantable cardioverter defibrillator (ICD) is recommended in [NICE's technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure](#) for patients with arrhythmias and those at risk of sudden cardiac death.
- 2.3 An ICD consists of a generator, which contains a battery, capacitor and sophisticated electronic circuitry, and 1 or more leads. The device 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.

3 The procedure

- 3.1 An entirely subcutaneous implantable cardioverter defibrillator (ICD) differs from a transvenous ICD in that a single lead is placed subcutaneously. This single lead comprises 2 sensing ring electrodes and a shocking coil. The subcutaneous ICD senses cardiac signals, but the lead is not directly attached to the heart. Also, unlike a conventional transvenous ICD, the subcutaneous device is not designed to provide long-term pacing.
- 3.2 The implantation procedure is carried out with the patient under general anaesthesia, or with local anaesthesia and sedation. Implantation is guided by anatomical landmarks with or without the use of fluoroscopy or other medical imaging. A subcutaneous pocket for the generator is created on the left side of the chest. The lead is tunneled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunneled to the upper end of the sternum so that

the sensing ring electrodes and shocking coil lie alongside the sternum. The lead can be secured using either a 2- or 3-incision technique, and is then connected to the generator in the pocket. Finally, the incisions are closed and the sensing and recording functions of the subcutaneous ICD are adjusted using an external programmer. Ventricular fibrillation is induced to test that the subcutaneous ICD can appropriately detect and correct it.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 In a matched-controlled study of 138 patients comparing 69 patients with subcutaneous implantable cardioverter defibrillators (ICD) and 69 patients with transvenous ICDs, the conversion rates of induced ventricular fibrillation at implantation were similar ($p=0.81$): 90% (60/67) for 65 J of energy (15-J safety margin) in the subcutaneous ICD group and 91% (59/65) for a device-dependent 10-J safety margin in the transvenous ICD group. In a systematic review of 5,380 patients from 16 studies, the defibrillator threshold test was successful on the first attempt in 89% of patients (range 70 to 100%) and in 96% after reprogramming.
- 4.2 In a retrospective propensity-matched cohort study of 280 patients (140 with subcutaneous ICDs and 140 with transvenous ICDs), appropriate ICD intervention rates (shocks and anti-tachycardia pacing) were lower in the subcutaneous ICD group, at 17% (95% confidence intervals [CI] 6 to 26%) compared with 31% (95% CI 23 to 40%) in the transvenous ICD group (hazard ratio [HR] 2.42; $p=0.01$). However, the incidence of appropriate shocks was similar in both groups (HR 1.46; $p=0.36$). In a case series of 889 patients, which combined patients from the IDE study and from an international registry (Effortless), 111 episodes of spontaneous ventricular arrhythmias were treated in 59 patients within a mean 22-month follow-up; 90% (100/111) of these events were stopped with 1 shock and 98% (109/111) were stopped within the 5 available shocks. In the systematic review of 5,380 patients, the range of the first

shock efficacy rate was 58 to 90% and the overall shock efficacy rate was 96% or more.

- 4.3 In the prospective case series of 321 patients, the mean time to therapy (defined as the interval starting 2,000 milliseconds after the last induction artefact and ending at the onset of the shock deflection on a standard ECG) was 14.6 seconds (range 9.6 to 29.7 seconds). A time to therapy of greater than 18.0 seconds was noted in 13% of episodes. In an international registry of 985 patients, there was a statistically significant difference between the mean (\pm standard deviation) time to therapy for induced episodes and for spontaneous episodes (15.1 ± 3.5 seconds compared with 18.4 ± 4.3 seconds, $p < 0.001$).
- 4.4 In the retrospective propensity-matched cohort study of 280 patients comparing 140 patients with subcutaneous ICDs and 140 patients with transvenous ICDs, 5-year patient survival was similar in both groups (96% and 95% respectively, $p = 0.42$).
- 4.5 In a propensity-matched case-control study of 334 patients comparing 167 patients from the Effortless registry with 167 patients with transvenous ICDs from the Midas prospective observational study cohort, there were no statistically significant differences between groups on physical ($p = 0.8157$) and mental quality-of-life scores measured using the SF-12 questionnaire ($p = 0.9080$) at baseline, and 3 months and 6 months after implantation in adjusted analyses. The evolution in physical ($p = 0.0503$) and mental scores ($p = 0.3772$) during 6-month follow-up was similar for both cohorts. Both patients with subcutaneous ICDs and patients with transvenous ICDs experienced statistically significant improvements in physical and mental quality of life between implantation and 3-month follow-up ($p < 0.0001$) and 6-month follow-up ($p < 0.0001$). However, the difference between 3- and 6-month follow-up was not statistically significant.
- 4.6 In the systematic review of 5,380 patients, the median device longevity was 5.0 years (range 4.4 to 5.6 years).
- 4.7 The specialist advisers listed the following key efficacy outcomes: successful detection of ventricular arrhythmias, successful delivery of

shock to restore normal rhythm, prevention of sudden death and low rate of inappropriate shocks.

- 4.8 Seven commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Death was reported in 1% (2/140) of patients in the subcutaneous implantable cardioverter defibrillators (ICD) group (1 from a non-cardiac cause and 1 from a cardiac cause) and in 4% (6/140) of patients in the transvenous ICD group (3 from non-cardiac causes, 2 from cardiac causes and 1 for an unknown reason) in a retrospective propensity-matched cohort study of 280 patients with a 5-year follow-up. Death from congestive heart failure was reported in 1 patient in the subcutaneous ICD group in a matched-controlled study of 138 patients comparing 69 patients with subcutaneous ICDs and 69 matched patients with transvenous ICDs (average follow-up 217 days). All-cause mortality rate was 3% (26/882) in a case series of 889 patients with a mean 22-month follow-up that combined patients from a prospective case series and from an international registry (Effortless). There was only 1 known arrhythmic death due to Loeffler's syndrome. The 3-year Kaplan–Meier estimate was 5% (95% confidence interval [CI] 1 to 9%), with 26 deaths (3%). Death was reported in 5% (48/985) of patients in an international registry of 985 patients, within a 3.1-year follow-up. The primary cause was cardiac-related in 44% (21/48) of these patients: 1 was arrhythmic and the other deaths related to pump failure (14 deaths), ischaemic events (2 deaths) or other cardiac causes (4 deaths), and 98% (47/48) of deaths occurred outside the perioperative window of 30 days. No deaths were associated with the subcutaneous ICD system procedure.
- 5.2 Inappropriate shock rate was 21% in the subcutaneous ICD group (17% because of oversensing and 4% because of supraventricular tachycardia)

compared with 19% in the transvenous ICD group (1% because of oversensing and 18% because of supraventricular tachycardia) in the retrospective propensity-matched cohort study of 280 patients. In the same study, inappropriate sensing rate was 3% in the subcutaneous ICD group and zero in the transvenous ICD group. The estimated 3-year inappropriate shock rate was 13% in the case series of 889 patients. The causes were T-wave oversensing in 39%, supraventricular arrhythmia above the discrimination zone in 24%, low amplitude signal in 21%, non-cardiac oversensing in 8%, oversensing of ventricular tachycardia and fibrillation below the rate zone in 4%, other or combined types of cardiac oversensing in 2%, supraventricular arrhythmia discrimination errors in 1%, and committed shock for ventricular tachycardia and fibrillation in 1%. Inappropriate shocks were reported in 8% (15/985) of patients during the first year and in 12% (115/985) of patients within a mean 3.1-year follow-up in the international registry of 985 patients (some of these patients were also included in the case series of 889 patients). The causes were oversensing in 11 of the patients and supraventricular tachycardia above the discrimination zone (normal device function) in 2 of the patients (no cause reported for the other 2 patients). Inappropriate shocks were reported in 4% of patients (range 0 to 15%) in the systematic review of 5,380 patients. The most common cause was T-wave oversensing. Inappropriate therapy due to supraventricular tachycardia, and artefact from noise or myopotentials were rare.

- 5.3 Pulse generator replacement due to battery depletion did not differ between the groups at 5-year follow-up in the retrospective propensity-matched cohort study of 280 patients ($p=0.18$). Premature battery depletion was reported in 5 patients in the case series of 889 patients. Rapid battery depletion causing premature elective replacement of the device was reported in 9% (5/55) of devices, with a mean service time of 1.5 years, in a case series of 55 patients; 71% of devices were still in service at 5-year follow-up. Premature battery depletion was reported in 1% of patients (range 0 to 9%, 16 events, 1,384 patients from 10 studies) in the systematic review of 5,380 patients.
- 5.4 Failure to communicate with the device was reported in less than 1% of patients (range 0 to 1%, 4 events, 1,249 patients from 8 studies) in the systematic review of 5,380 patients.

- 5.5 Twiddler syndrome rate was 1% in both groups in the retrospective propensity-matched cohort study of 280 patients.
- 5.6 Device failure rate was 1% in the subcutaneous ICD group and none in the transvenous ICD group in the retrospective propensity-matched cohort study of 280 patients. Failure of the device to convert during the procedure was reported in 7 patients in the US registry of 1,637 patients. Failure of the device to cardiovert ventricular arrhythmia was reported in 1 patient out of 69 patients in a propensity-matched case-control study of 138 patients within a mean 31-month follow-up.
- 5.7 Explantation of the subcutaneous ICD for pacing was reported in 4 patients because of the need for ventricular pacing in the case series of 889 patients: 1 patient developed a new bradycardia indication; in 1 patient, the device was explanted because of the need for anti-tachycardia pacing; and 1 patient with 3 ventricular tachycardia storm events had replacement with a transvenous ICD in an attempt to suppress ventricular arrhythmias using overdrive pacing. In addition, 1 device was extracted for a cardiac resynchronisation therapy upgrade. Device replacement was reported in 47% (26/55) of patients and device explantation (permanent removal) was reported in 9% (5/55) of patients during a median 5.8-year follow-up in the case series of 55 patients. The indications for device replacement or explantation were battery depletion in 81% (25/31) of patients, replacement with a transvenous ICD system in 13% (4/31), infection in 1 patient and 'other' in 1 patient. The median time for device replacement was 5 years (first quartile–third quartile, 4.4 to 5.6 years) and the event-free rates for device replacement were 94% (95% CI 83 to 98%) after 2 years, 89% (95% CI 76 to 96%) after 4 years and 30% (95% CI 15 to 46%) after 6 years. Device explantation was reported in 4% of patients (range 0 to 12%, 57 events, 1,514 patients from 11 studies) in the systematic review of 5,380 patients. The explant indications were pocket infection (2%, 29 events, 1,585 patients, number of studies not reported), need for pacing, inappropriate shocks and unsuccessful defibrillation threshold testing. Generator repositioning or explant for erosion were needed in 2% of patients (total number of patients not reported).
- 5.8 Erosion rate was 3% in the subcutaneous ICD group and 2% in the

transvenous ICD group in the retrospective propensity-matched cohort study of 280 patients. Erosion was reported in 1% (11) of patients in the case series of 889 patients.

- 5.9 Infection needing device removal or revision was reported in 2% (14) of patients in the case series of 889 patients. In the same study, incision or superficial infection were reported in 3 patients. Pocket infection was reported in 3% of patients (range 0 to 19%, 44 events, 1,654 patients from 14 studies) in the systematic review of 5,380 patients.
- 5.10 Haematoma was reported in less than 1% of patients (range 0 to 3%, 22 events, 5,044 patients from 10 studies) in the systematic review of 5,380 patients.
- 5.11 Delayed wound healing was reported in less than 1% of patients (range 0 to 19%, 7 events, 1,145 patients from 7 studies) in the systematic review of 5,380 patients.
- 5.12 Suboptimal electrode position was reported in 7 patients in the case series of 889 patients. In the same study, suboptimal pulse generator position was reported in 2 patients and, suboptimal pulse generator and electrode position were reported in 4 patients.
- 5.13 Electrode movement was reported in 5 patients in the case series of 889 patients. The lead complication rate was statistically significantly lower in the subcutaneous ICD group than in the transvenous ICD group in the retrospective propensity-matched cohort study of 280 patients (1% versus 12%; $p=0.03$). The only lead complication reported in the subcutaneous ICD group was lead movement, which occurred in 1 patient out of 140.
- 5.14 Pleural effusion was reported in 1 patient in the US registry of 1,637 patients.
- 5.15 Pneumothorax was reported in 1 patient in the US registry of 1,637 patients.
- 5.16 In addition to safety outcomes reported in the literature, specialist

advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse event: discomfort around the device. They did not identify any theoretical adverse events.

- 5.17 Seven commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

6 Committee comments

- 6.1 The committee recognised that patients with implantable cardioverter defibrillators of any kind may develop psychological disturbance, including anxiety and fear of shocks.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

Information for patients

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

ISBN: 978-1-4731-2753-1

Endorsing organisation

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