NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death

A subcutaneous implantable cardioverter defibrillator (ICD) is a device that is placed under the skin of the chest. It detects and treats fast irregular heartbeats called arrhythmias. The device uses electrical shocks to help control life-threatening arrhythmias that can cause sudden cardiac death.

The National Institute for Health and Care Excellence (NICE) is examining subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.

- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 25 September 2017

Target date for publication of guidance: December 2017

1 Draft 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.

1.2 Clinicians should enter details about all patients having subcutaneous implantable cardioverter defibrillator insertion for

preventing sudden cardiac death onto a registry such as the UK Central Cardiac Audit Database and review local clinical outcomes.

1.3 The procedure should only be done by interventional cardiologists 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. 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. 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 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 tunnelled subcutaneously from the pocket to a small incision at the lower end of the sternum. Then, it is tunnelled to a second small incision at the upper end of the sternum and secured so that the sensing electrodes and shocking coil lie alongside the sternum. 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.

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 prospective case series of 321 patients (the IDE study), the acute induced ventricular arrhythmia conversion success rates were 100% for the 304 evaluable results and 95% (304/321) when 17 excluded tests were imputed as failures.

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.

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 seconds to 29.7 seconds). A time to therapy of greater than 18.0 seconds was noted in 13% of episodes.

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 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.

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%).

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%. There were 73 episodes of inappropriate shocks reported in 7% (32/456) of patients in the international registry of 472 patients. The causes were inappropriate sensing (cardiac) in 24 patients, supraventricular tachycardia above the discrimination zone in 6, inappropriate sensing (non-cardiac) in 4 patients, and ventricular tachycardia and fibrillation discrimination error in 1 patient (patients also included in the case series of 889 patients).

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.

5.4 Inability to communicate with the device was reported in 3 patients in the case series of 889 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 a 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 years– 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.

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.

5.10 Haematoma was reported in 4 patients in the case series of 889 patients.

5.11 Inadequate or prolonged healing of the incision site was reported in 3 patients in the case series of 889 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 7 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 (5% versus 12%; p=0.03). The only lead complication reported in the subcutaneous ICD group was lead displacement, which occurred in 1 patient out of 140.

5.14 Near syncope, dizziness, shortness of breath or confusion were reported in 1 patient in the international registry of 472 patients.

5.15 Pleural effusion was reported in 1 patient in the international registry of 472 patients.

5.16 Pneumothorax was reported in 1 patient in the international registry of 472 patients.

5.17 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.

6 Committee comments

6.1 The committee noted that, despite the existence of an international registry, not all insertions of a subcutaneous implantable cardioverter defibrillator were being recorded.

6.2 The committee recognised that patients with a subcutaneous implantable cardioverter defibrillator may develop psychological disturbance, including anxiety and fear of shocks.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 This guidance is a review of NICE's interventional procedure guidance on insertion of a subcutaneous implantable cardioverter defibrillator for prevention of sudden cardiac death.

Andrew Cook

Vice Chairman, interventional procedures advisory committee

August 2017