United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: important lessons to learn

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Aims

The aim of this study was to describe the early phase United Kingdom (UK) clinical experience with a novel entirely subcutaneous implantable cardioverter-defibrillator (S-ICD).

Methods and results

A questionnaire was sent to all UK hospitals implanting S-ICDs. Nineteen of 25 (76%) hospitals responded with the details of 111 implanted patients [median 5/hospital (range 1-18)]. Mean duration of follow-up was 12.7 ± 7.1 months. Median patient age was 33 years (range 10-87 years). Underlying pathology was primary electrical disease in 43%, congenital heart disease 12%, hypertrophic cardiomyopathy 20%, ischaemic cardiomyopathy 14%, idiopathic dilated cardiomyopathy 5%, and other cardiomyopathies 7% patients. Nineteen (17%) patients required 20 re-operations, including permanent device explantation in 10 (9%). Twenty-four appropriate shocks were delivered in 13 (12%) patients, including 10 for ventricular fibrillation. One patient suffered arrhythmic death, but there were no failures to detect or terminate ventricular arrhythmias above the programmed detection rate. Fifty-one inappropriate shocks were delivered in 17 (15%) patients. Forty-one (80%) were for T-wave over-sensing and 1 (2%) for atrial flutter-wave over-sensing. The 11 patients who received inappropriate shocks due to T-wave over-sensing were significantly younger than patients who did not $(24 \pm 10 \text{ vs. } 37 \pm 19 \text{ years; } \textit{P} = 0.02)$.

Conclusion

The S-ICD is an important innovation in ICD technology. However, these data indicate that adverse event rates are significant during early clinical adoption. Important lessons in patient selection, implant technique, and device programming can be learnt from this experience.

Keywords

Implantable cardioverter-defibrillator • Sudden cardiac death • Ventricular fibrillation

Introduction

Multiple randomized trials have established the efficacy of implantable cardioverter-defibrillators (ICDs) as a life-saving therapy for individuals at risk of sudden arrhythmic death. The great majority of implanted systems utilize a conventional design, in which a transvenous lead within the right ventricle is employed for detection and defibrillation of arrhythmia. However, many of the complications of ICD therapy are related to the transvenous lead, and are cumulative over time, presenting a particular challenge in

the treatment of younger patients who might be expected to survive for decades following implantation. In addition, avoiding implantation of a transvenous lead, including the associated requirement for fluoroscopy, has the potential to simplify the ICD implantation procedure.

With these issues in mind, an entirely subcutaneous ICD (S-ICD, Cameron Health) has been developed and now approved for use in the United Kingdom (UK), Denmark, Czech Republic, Germany, Italy, Netherlands, Portugal, Sweden, New Zealand, and USA. In this novel design a robust bipolar lead implanted subcutaneously

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at the left sternal edge is utilized in association with a left midaxillary line subcutaneous generator for far-field detection and defibrillation of ventricular arrhythmias (Figure 1). Following a decade of development and the first publication describing clinical use in 2010, $^3\sim 1300$ implants have now taken place worldwide. The system is only able to deliver very limited post-defibrillation pacing, and therefore is contraindicated in patients with pacing indications, and generally inappropriate for those anticipated to suffer from pace-terminable monomorphic ventricular tachycardia (VT). For these reasons, its greatest benefits might be anticipated in younger patients who both have a lesser likelihood of requiring bradycardia or anti-tachycardia pacing, and also a greater cumulative risk of complications from a transvenous lead.

To date, reports of clinical use of the S-ICD have been published in six cohorts, including a maximum of 329 patients, the majority with ischaemic or idiopathic dilated cardiomyopathy (*Table 1*).^{3–8} The results of intra-operative testing have been impressive overall, with good ability to detect and terminate ventricular fibrillation (VF). However, the far-field sensing characteristics of the system, critically dependent on adequate discrimination between R-waves and T-waves, might be affected by factors such as posture, body habitus, age, cardiac pathology, and device programming.^{5,9} Therefore more data on clinical performance are needed, particularly among younger patients.

In the UK, conventional ICD implantation rates are ~ 100 / million¹⁰ with implantation performed by cardiologists mainly in specialized cardiac centres, and usually with local anaesthesia and



Figure I S-ICD system *in situ*. Postero-anterior chest X-ray from a patient following implantation of an S-ICD. The sub-axillary generator and tunnelled shock lead with shock electrode running parallel to the left sternal edge are clearly visible. The entire system lies within the subcutaneous tissues.

sedation. Reporting of ICD-related complications is not mandated nationally. The S-ICD has been implanted commercially in the UK since the world's first commercial implant in July 2009, following participation by some centres in early development of the system.³ In this paper, we present the results of a national survey describing the outcomes of unrestricted clinical use of the S-ICD nationwide.

Methods

Study design

Data describing the use of the S-ICD in a series of patients at one of our UK centres were presented in early 2011 to Heart Rhythm UK, the national professional body. In light of questions about clinical performance raised by these data, a decision was made to gather data from all S-ICD implanting centres in the UK. The manufacturer supplied a list of all UK implants up until July 2011. Implanting physicians were contacted by Heart Rhythm UK and asked to complete an electronic data spreadsheet for all patients they had implanted with S-ICDs. Multiple email and telephone contacts were made to maximize data returns from all centres. Where required, further details were sought for specific issues.

The data spreadsheet was formatted in Excel 2010 (Microsoft Corporation) and contained 22 questions to determine patient age and pathology, indication for implantation, initial programming, operative outcome, duration of follow-up, details of appropriate or inappropriate shock therapy including programming at the time, re-interventions, and any other concerns. Appropriate shocks were defined as those delivered in response to sustained ventricular arrhythmia. Data were collated and analysed at a single centre.

Statistical analysis

Normally distributed data are presented as mean \pm standard deviation. Otherwise, they are presented as median and range, with interquartile range also presented where particularly informative. Comparison between groups was performed with the unpaired Student's *t*-test. Two-sided *P* values < 0.05 were considered significant.

Results

On 15 July 2011 the manufacturer could identify 144 UK device implants among 25 hospitals. Nineteen hospitals (76%) responded to the survey with details of 111 implanted patients [median 5 patients/hospital (range 1–18)], including those described with a shorter follow-up duration in a previously published UK series. The mean duration of follow-up data available was 12.7 ± 7.1 months. The main reason given for non-return of data was participation within the manufacturer's own 'EFFORTLESS' registry. 11

Study population

Median patient age was 33 years (range 10–87 years; interquartile range 19–48 years) (*Table 2*). Among patients with specific pathologies, median ages were as follows: primary electrical disease, 28 years (range 10–63 years); congenital heart disease, 20 years (range 14–47 years); hypertrophic cardiomyopathy, 29 years (range 10–56 years); ischaemic cardiomyopathy, 65 years (range 34–87 years); idiopathic dilated cardiomyopathy, 38 years (range

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Table I Published S-ICD case series									
	Jarman et al. ⁵	Current study	Aydin et al. ⁶	Köbe et al. ⁷	Olde Nordkamp et al. ⁸	Dabiri Abkenari et al. ⁴	Bardy et al. ³		
Number of patients	16	111	40	69	118	31	55		
Patients age [median (range)/ mean \pm SD]	23 (10–48)	36 (10–87)	42 ± 15	46 ± 16	50 ± 14	53 <u>+</u> 16	56 ± 13		
Ischaemic or idiopathic dilated cardiomyopathy	0%	18%	45%	52%	57%	71%	85%		
Mean/median follow-up duration (months)	9	12	8	7	18	9	10		
Patients with re-interventions	19%	16%	13%	4%	14%	10%	11%		
Patients with inappropriate shocks	25%	15%	5%	4%	13%	16%	9%		

Table 2 Study population

Underlying pathology	Number (% of total)	Median age (range), years	
•••••			
Ischaemic cardiomyopathy	15 (14%)	65 (34–87)	
Idiopathic dilated cardiomyopathy	5 (5%)	38 (18–73)	
Hypertrophic cardiomyopathy	22 (20%)	29 (10-56)	
Other cardiomyopathies	8 (7%)	38 (11–63)	
Congenital heart disease	13 (12%)	20 (14-47)	
Primary electrical disease	48 (43%)	28 (10-63)	
Idiopathic VF	16 (14%)	32 (15-54)	
Brugada syndrome	14 (13%)	37 (11–63)	
Long QT syndrome	10 (9%)	24 (10-48)	
CPVT	7 (6%)	20 (14-39)	
ldiopathic right ventricular outflow tract tachycardia	1 (1%)	17	
Primary prevention	55 (50%)	37 (18-75)	
Secondary prevention	56 (50%)	30 (10-87)	
All patients	111 (100%)	33 (10-87)	

CPVT, catecholaminergic polymorphic ventricular tachycardia; VF, ventricular fibrillation.

18-73 years); and other cardiomyopathies, 38 years (range 11-63 years).

The most frequent pathology group was primary electrical disease, present in 48 (43%) patients—idiopathic VF 16 (14%), Brugada syndrome 14 (13%), long QT syndrome 10 (9%), catecholaminergic polymorphic VT (CPVT) 7 (6%), and idiopathic right ventricular outflow tract tachycardia 1 (1%). Other pathology groups were congenital heart disease, present in 13 (12%); hypertrophic cardiomyopathy, 22 (20%); ischaemic cardiomyopathy 15 (14%); idiopathic dilated cardiomyopathy 5 (5%); and other cardiomyopathies 8 (7%).

The indication for implantation was primary prevention of sudden cardiac death in 55 (50%) patients, and secondary prevention following clinically significant ventricular arrhythmia in the

remaining 56 (50%) patients. The patient with right ventricular outflow tract tachycardia had suffered aborted cardiac arrest and had expressed a personal preference for an S-ICD system.

Ventricular fibrillation induction and initial programming

No failures of detection or of conversion to sinus rhythm were reported during intra-operative VF induction. Data on device programming at time of discharge was available for 106 (95%) patients. Shock Zones (equivalent to the VF zone in a conventional ICD) were programmed at rates of 220 \pm 14 b.p.m. A Conditional Shock Zone (equivalent to a VT zone, with supraventricular tachycardia discrimination functionality) was programmed in 34 (31%) patients, with rates of 205 \pm 15 b.p.m.

Re-operations

Nineteen patients (17%) underwent 20 re-operations, among whom the device was permanently explanted in 10 (9%). Infection led to explant in four (4%) patients, and in seven (6%) other patients apparently superficial infection was noted and managed conservatively with antibiotics. T-wave over-sensing in multiple vectors, with inappropriate shock therapy, led to explant in five (5%) patients (one also suffering infection). Device erosion with chronic pain led to permanent explant in two (2%) patients and repositioning in seven (6%) patients. One lead was also repositioned for T-wave over-sensing. In a further two (2%) patients, unexpected early battery depletion required generator replacement, and this problem is now the subject of a Medical Device Alert from the UK Medicines and Healthcare products Regulatory Agency (MDA/2011/067 issued 14 June 2011).

Appropriate shocks and single arrhythmic death

Post-operatively, 24 appropriate shocks (median 1, range 1–5) were delivered in 13 (12%) patients. Ten were for VF and 14 were for VT. None failed to terminate ventricular arrhythmia. One episode with relatively long time to therapy (27 s) due to under-sensing has been described in detail elsewhere.⁵

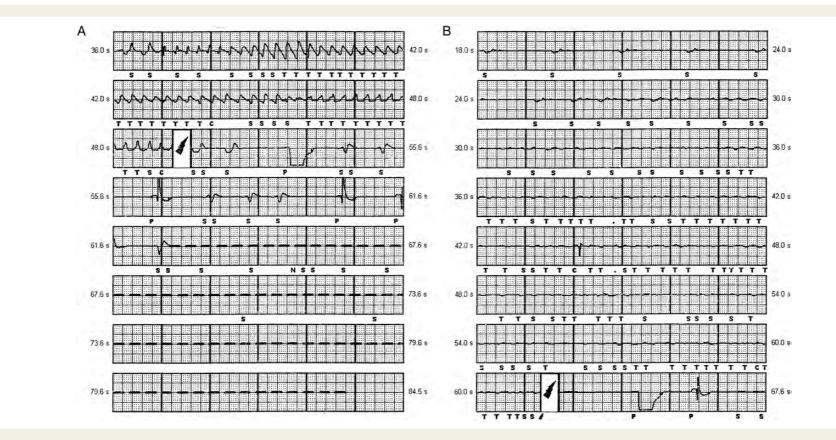


Figure 2 (A) Ventricular fibrillation followed by post-shock asystole. Subcutaneous implantable cardioverter-defibrillator electrogram showing two final beats of a sustained monomorphic VT degenerating into VF which is terminated by a shock (indicated with lightning symbol). Subsequently there is a slow ventricular rhythm interspersed with pacing. At 62 s, electrograms are no longer stored, but events continue to be marked. During the last 17 s of the episode there are only two sensed events and no paced events. C, onset of charging and then commitment to shock delivery when seen a second time; N, a sensed event classified as noise; P, a paced event; S, a sensed event not classified as tachycardia; T, a sensed event classified as tachycardia. (B) Fine VF. Subcutaneous implantable cardioverter-defibrillator electrogram showing a slow ventricular rhythm degenerating into fine VF which is terminated by a shock (indicated with lightning symbol) after 30 s. During post-shock asystole, there are two paced beats followed by over-sensing of noise as ventricular events. C, onset of charging and then commitment to shock delivery when seen a second time; N, a sensed event classified as noise; P, a paced event; S, a sensed event not classified as tachycardia; T, a sensed event classified as tachycardia.

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One patient died following appropriate therapy. With a programmed lowest detection rate of 180 b.p.m., a monomorphic VT was appropriately sensed but its rate fell below 180 b.p.m. and therapy was aborted while VT continued at rates between 160 and 175 b.p.m. Six minutes later VT degenerated into VF and 12 s after onset this was shocked into a ventricular escape rhythm interspersed with post-shock pacing (Figure 2A). During the final 17 s of this episode there are only two sensed events and no paced events due to suspension of post-shock pacing in response to the earlier sensed events. Sixteen minutes later a further episode was recorded in which a ventricular escape rhythm at 46 b.p.m. degenerated into fine VF which was shocked after a 30 s delay (Figure 2B). During the next 11 s there is underlying asystole with four over-sensed noise events and six paced events. Over the subsequent 19 s of the episode the device delivered no pacing and recorded 20 sensed events: the electrograms were not stored, so it is not possible to determine whether these were over-sensed. There are no further recordings from the device but the patient died. No other arrhythmic or devicerelated deaths were reported.

Inappropriate shocks

Inappropriate shocks were delivered in 17 (15%) patients (Figure 3). Among 51 inappropriate shocks delivered [median 2/patient (range 1-8)], 41 (80%) were for T-wave over-sensing and 1 for atrial flutter-wave over-sensing.

Three were for supraventricular arrhythmias causing ventricular rates greater than the programmed Shock Zone detection rates.

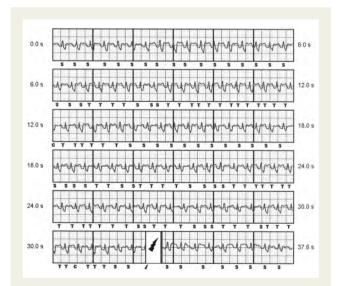


Figure 3 Inappropriate shock due to T-wave over-sensing. An inappropriate shock is delivered due to T-wave over-sensing in a 20-year-old patient with Ebstein's anomaly and mechanical tricuspid valve replacement. Sensing is initially appropriate during a sinus tachycardia, however T-wave over-sensing suddenly develops leading to a shock (indicated with lightning symbol). C, onset of charging and then commitment to shock delivery when seen a second time; S, a sensed event not classified as tachycardia; T, a sensed event classified as tachycardia.

The remaining six shocks were caused by electrical noise or device interaction: 50 Hz mains electricity supply in one case while fixing home electrical wiring, two shocks caused by 40 Hz noise from an implanted ventricular assist device, unidentified source of noise in two other cases, and sensing of a pacemaker check performed in unipolar mode caused a shock in one final case. No shocks occurred due to failure to discriminate supraventricular arrhythmia with ventricular rates falling within the Conditional Shock Zone.

The 11 patients who received inappropriate shocks due to T-wave over-sensing were significantly younger than patients who did not $(24 \pm 10 \text{ vs. } 37 \pm 19 \text{ years}; P = 0.02)$ (*Table 3*). Underlying pathologies were tetralogy of Fallot in three, Ebstein's anomaly in one, hypertrophic cardiomyopathy in three, CPVT in three, and long QT syndrome in one. Data on programmed detection rates at the time of inappropriate therapy was available for 9 of 11 (82%) patients: lowest programmed detection rate at time of first inappropriate therapy was lower than that programmed in patients who did not receive inappropriate therapy for T-wave over-sensing $(201 \pm 14 \text{ vs. } 214 \pm 15 \text{ b.p.m.; } P = 0.01)$. All inappropriate shocks occurred subsequent to the introduction of a new software upgrade in October 2009 designed to reduce inappropriate shocks due to T-wave over-sensing.

Discussion

The advent of a new class of ICD technology has offered exciting new capabilities to physicians treating patients at risk of sudden cardiac death, but also presented challenges in appropriate patient selection, implantation technique, and programming.

This study is the second largest experience of the use of S-ICD technology published to date. As such it makes an important contribution towards understanding this very promising new technology, about which there are currently few clinical trials published. Additionally, the initial UK experience has proved different from previously reported series, both in the population selected and in the outcomes.^{3–8} It is important to understand why the outcomes were different in this cohort, and whether this was related to patient characteristics, number of implanting centres, or other factors, so that similar problems can be minimized during clinical adoption elsewhere.

The S-ICD has several key differences from conventional ICD technology that attracted UK physicians to implant the system in some of their most challenging patients. Avoidance of a transvenous lead motivated widespread use in younger patients, resulting in a population considerably different to that selected for regulatory studies. The low patient age [33 years (interquartile range 19–48 years)] and low proportion of patients with ischaemic or dilated cardiomyopathy (19%) make these data particularly valuable for coming from a population for which the technology might promise the greatest benefits, but about which limited data are available (*Table 1*). In addition, previous concerns over S-ICD performance have been raised in this population.⁵ The data also provide insight into the type of patients clinicians may select as appropriate for S-ICD therapy during early commercial use of the system, at least in the UK. The two commonest

Table 3 Patients with inappropriate shocks caused by T-wave over-sensing

	Pathology	Age	Lowest detection rate programmed (b.p.m.)	Number of shocks for TWOS
Patient 1	Tetralogy of Fallot	30	180	6
Patient 2	Tetralogy of Fallot	20	220	5
Patient 3	Tetralogy of Fallot	31	Unknown	3
Patient 4	Ebstein's anomaly and TVR	20	200	8
Patient 5	Hypertrophic cardiomyopathy	19	200	1
Patient 6	Hypertrophic cardiomyopathy	49	210	1
Patient 7	Hypertrophic cardiomyopathy	23	190	8
Patient 8	CPVT	16	Unknown	1
Patient 9	CPVT	20	190	6
Patient 10	CPVT	20	200	1
Patient 11	Long QT syndrome	14	220	1
All patients with TWOS [Mean ± SD/median (range)]		24 ± 10	201 ± 14	3 (1–8)
All patients without TWOS (Mean \pm SD)		37 ± 19	214 ± 15	N/A
P value for difference between groups		0.02	0.01	N/A

CPVT, catecholaminergic polymorphic ventricular tachycardia; TVR, tricuspid valve replacement; TWOS, T-wave over-sensing.

adverse events encountered in the UK were re-operations and inappropriate therapy.

Re-operations

Re-operations were required in 17% of patients, more than reported in previous studies of S-ICDs (*Table 1*). Rapid dissemination of a new technology to multiple centres may have contributed, and increased familiarity with the implant technique is likely to reduce such incidences. The procedure may appear alluringly simple, however, these data serve as a warning to those adopting this technology to treat this new implantation techniques with care, particularly in this patient population. Infection led to explant in 4% of patients and erosion in 2%: these relatively high rates may be a clue that the unfamiliarity of cardiologists with lateral chest wall surgery and relevant draping techniques could have been a contributory factor. Additionally, 5% of patients had explant due to T-wave over-sensing in multiple vectors, indicating that patient selection is important.

Inappropriate shocks

Over approximately a year of follow-up, 15% of patients received inappropriate shocks, the great majority for T-wave over-sensing. All patients were required to meet strict criteria on R-wave and T-wave ratio and morphology [as judged by the manufacturer's electrocardiogram (ECG) template] prior to implantation. All implants were performed following joint assessment by the implanting physician and the technical support team from the manufacturer. Although another group found that a software upgrade introduced in October 2009 reduced the inappropriate shock rate, ⁸ it is notable that all shocks in our study occurred following this upgrade.

The inappropriate shocks rate due to T-wave over-sensing is higher than recent published rates from transvenous ICDs: from typical conventional ICD populations (2.5-9%), 1,12,13 younger patients (3-12%), $^{14-18}$ and patients with pathologies similar to those in our study (2-10%). ¹⁹⁻²⁵ Of note, in studies of patients with primary electrical diseases and transvenous ICDs, yearly rates of inappropriate shocks vary from 2 to 6% and those caused by T-wave over-sensing from 0 to 1.6%, suggesting that the far-field detection algorithm employed by the S-ICD is more prone to T-wave over-sensing as one might expect. 22-25 However, while the percentage of patients experiencing shocks from transvenous ICDs was cumulative over years (largely related to lead failure and non-ventricular arrhythmia), one might theoretically expect the percentage of patients experiencing shocks for T-wave over-sensing to increase more slowly after the first year following re-programming to a more appropriate

Among published studies of S-ICDs there is a trend towards a higher inappropriate shock rate in younger populations, as seen in our study (*Table 1* and *Figure 4*).^{3–8} However, it is not possible to determine whether this is due to a difference in the populations' ages, or pathologies, both of which vary roughly in parallel. Although the numbers are too small to draw any definitive conclusions, in our study the highest rate of shocks due to T-wave oversensing was seen among patients with congenital heart disease (4 of 13 patients), with 3 of those shocked having repaired tetralogy of Fallot and the other patient with Ebstein's anomaly also having right bundle branch block. The other patients experiencing shocks due to T-wave over-sensing would also be expected to have abnormal baseline ECGs, with the exception of those with CPVT.

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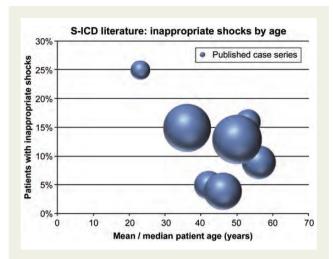


Figure 4 Inappropriate shock rate and age of patients in S-ICD literature. The published case series on S-ICDs described in *Table 1* are presented in this graph. The size of each bubble reflects the number of patients in the series. On the X-axis are the mean or median ages of the patients in the studies, and on the Y-axis the inappropriate shock rate for each study. A trend towards a greater inappropriate shock rate with decreasing age is apparent.

Appropriate therapies and arrhythmic death

It is reassuring that there was no failure to detect or terminate ventricular arrhythmia, including 10 episodes of clinical VF. Post-shock asystole or severe bradycardia following VF shocks are concerns^{26,27} partially ameliorated by the availability of up to 30 s of post-shock pacing with the S-ICD. In the arrhythmic death, we observed there was a long period of VT below the programmed detection rate which undoubtedly contributed to the patient's death, and reinforces the concept that the presence of monomorphic VT may be seen as a contraindication to the use of this device. It is uncertain whether pacing inhibition due to over-sensing, unavailability of sustained pacing, and a 30 s delay to treatment of fine VF, also contributed to the death. No similar events have been reported in other S-ICD studies to date, which have included 23 patients who have suffered sustained ventricular arrhythmia during follow-up.^{3–8} However, in one study, among the four patients suffering sustained ventricular arrhythmia during follow-up, two had multiple ineffective shocks with one patient requiring resuscitation.⁶

Lessons for the future

Some key lessons have been learned. Although S-ICD technology appears relatively simple to adopt, patient selection and implantation technique may both be harder than they first appear, particularly in these patients.

The re-operation rate observed highlights the fact that implanting these devices is quite different from implanting a conventional ICD. There is undoubtedly an element of a 'learning curve' during adoption of a new technology which mentoring from an

experienced centre may improve. A trend towards an improved complication rate with later implants was indeed observed in another study of S-ICD implantation.⁸ In our study some centres had less re-operation and felt that working jointly with a cardiac surgeon was advantageous. It may be that the rates of infection and erosion could be reduced with more experience of appropriate draping techniques and anatomical considerations for the lateral chest wall.

Physicians seem more inclined to consider this device in younger patients, those with primary electrical disease, and patients with repaired congenital heart disease where transvenous access is more complicated. Among this natural target population, the lack of anti-tachycardia and bradycardia pacing may remain limitations, for instance, in patients with congenital heart disease who develop monomorphic VT, or those patients with long QT syndrome in whom atrial pacing may help to prevent Torsades de Pointes. Additionally, T-wave over-sensing may be a greater problem than in older populations and several devices were permanently explanted for T-wave over-sensing in multiple vectors. Currently the manufacturer recommends that the screening ECG template must be satisfied in at least one of the three available sensing configurations. From the UK experience it seems very likely that it is an advantage if the template is satisfied in >1 configuration to allow some flexibility in programming should sensing change with posture or exercise. Some physicians have reported that screening during exercise is advantageous to identify change in the R-wave/T-wave ratio occurring on exertion. More data are required to determine performance in sub-groups and while this is the case, the decision to implant an ICD should remain a careful individualized one, with consideration given to a conventional transvenous ICD when in doubt.

Limitations

There are several important limitations to this study. It is a retrospective collection of data from a number of centres, mostly with limited experience of the device. It is not possible to know whether the data contain under or over-reporting of outcome events. In addition, a minority of centres did not return data. The lack of a randomized control group means that complication rates can only be compared with data from other studies, which will inevitably have different patient characteristics. Furthermore, relative safety of the device cannot be definitely established with this number of patients, in light of very low therapy failure rates with conventional ICDs. Nonetheless, during early adoption of a new technology these data are valuable in providing a snapshot of the outcomes resulting from relatively uncontrolled dissemination of this technology to multiple centres nationally.

Conclusions

The S-ICD is an important innovation which significantly expands the options available to cardiologists treating patients at risk of sudden arrhythmic death. It has particular potential to reduce the long-term lead-related morbidity of younger patients. However, this UK experience across multiple centres treating a relatively young population is instructive. While reassuring

regarding the efficacy of detection and termination of ventricular arrhythmias, the rate of adverse events was relatively high. Important lessons about patient selection, implantation techniques, and programming have been learned from this experience. Although further data are awaited from registries¹¹ and randomized controlled trials,²⁸ we hope that reporting of these data can prevent the same lessons from having to be learned by other implanting physicians.

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