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Clinical experience of entirely subcutaneous implantable cardioverter–defibrillators in children and adults: cause for caution

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Aims This paper describes our clinical experience of using an entirely subcutaneous implantable cardioverter–defibrillator (S-ICD) in children and adults. Maintaining lead integrity and long-term vascular access are critical challenges of ICD therapy, especially in younger patients. The S-ICD has considerable theoretical advantages in selected patients without pacing indications, particularly children and young adults. Although sensing in an S-ICD may be influenced by age, pathology, and posture, there are currently few published data on clinical sensing performance outside the setting of intra-operative testing or in younger patients.

Methods and results Patients were selected by a multi-disciplinary team on clinical grounds for S-ICD implantation from a broad population at risk of sudden arrhythmic death. Sixteen patients underwent implantation [median age 20 years (range 10–48 years)]. Twelve had primary electrical disease and four had congenital structural heart disease. There were no operative complications, and ventricular fibrillation (VF) induction testing was successful in all cases. During median follow-up of 9 months (range 3–15 months), three children required re-operation. Eighteen clinical shocks were delivered in six patients. Ten shocks in four patients were inappropriate due to T-wave over-sensing. Within the eight shocks for ventricular arrhythmia, three were delivered for VF, among which two had delays in detection with time to therapy of 24 and 27 s.

Conclusion The S-ICD is an important new option for some patients. However, these data give cause for caution in light of the limited published data regarding clinical sensing capabilities, particularly among younger patients.

Keywords Implantable cardioverter defibrillator • Sudden cardiac death • Paediatric • Congenital heart disease

Introduction

Implantable cardioverter–defibrillators (ICDs) are established as life-saving therapy for children and adults at risk of sudden arrhythmic death.[1] However, transvenous and epicardial systems are associated with significant complications related to the difficulty of maintaining long-term lead integrity and vascular access.[2,3] This is a particular problem in younger patients due to their longer life expectancy, continuing growth, and greater activity levels, as well as in some other patient groups, including patients with congenital heart disease and obstructed venous access.[4,5]

An entirely subcutaneous ICD (S-ICD, Cameron Health, San Clemente, CA, USA), comprising the SQ-RX^{TM} 1010 pulse generator and Q-TRAK^{TM} 3010 subcutaneous electrode, has recently become commercially available.[6] The entirely subcutaneous design with mid-axillary line generator and left parasternal subcutaneous lead obviates the need for venous access (*Figure 1*). This is potentially a very important new option for some patients, particularly those in whom it is challenging to maintain long-term venous access. However, only post-shock bradycardia pacing is possible and anti-tachycardia pacing (ATP) is not available. It is a less appropriate choice if pace-terminable monomorphic ventricular tachycardia (VT) is likely to be the dominant arrhythmia, and usually

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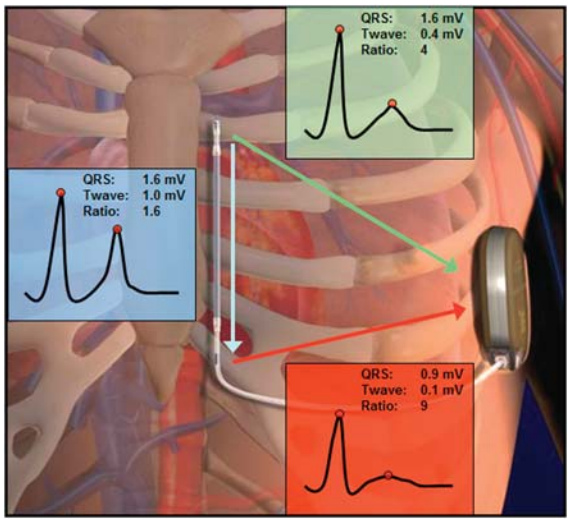

Figure 1 Subcutaneous implantable cardioverter–defibrillator position and sensing vectors. The three available sensing vectors are shown: these utilize two sensing electrodes at either end of the coil electrode and the generator. Diagrams of typical sensed electrograms are shown for each vector.

inappropriate for patients with a bradycardic pacing indication. On the basis of these considerations, it seems to offer particular benefits to younger patients with primary electrical disease in whom the clinical arrhythmias are likely to be ventricular fibrillation (VF) or polymorphic VT, as well as to patients with structural congenital heart disease in whom transvenous access to the right ventricle is either limited or absent.

Intra-operative testing has demonstrated reliable sensing and defibrillation during VF induction[6,7] as well as an impressive ability to discriminate supraventricular from ventricular arrhythmias.[8] However, its sensing characteristics are relatively dependent on posture,[9] and current published data on sensing performance during sustained clinical ventricular arrhythmias are derived from only five patients, most having experienced VT.[6,7] Existing data are also derived from a relatively old population, the majority having ischaemic or dilated cardiomyopathy. There are currently few published data derived from the populations described above as particularly likely to benefit from these devices: the worldwide published data from clinical episodes of VF, and from clinical episodes of any arrhythmia in children, are all derived from a single individual.[7]

During the past year, we have been implanting S-ICDs at a large volume tertiary referral centre in patients selected on clinical grounds as being most likely to benefit from this technology: this paper describes our experience.

Methods

Patient selection

Clinical use of the S-ICD was approved by the Clinical Practice Committee of the Royal Brompton & Harefield NHS Foundation Trust which reviews the introduction of all new technologies into our hospital.

The hospital serves a mixed adult and paediatric patient population. Consideration was given to implantation of an S-ICD in all patients judged at risk of sudden arrhythmic death. Decisions on whether to implant an S-ICD or a transvenous ICD were taken entirely according to the clinical need based on individual patients' characteristics. Factors considered to favour S-ICD implantation included younger age, difficulty of transvenous access to the right ventricle, the absence of bradycardic or resynchronization pacing indications, and primary VF. Factors considered to favour transvenous ICD implantation included bradycardic or resynchronization pacing indications, and anticipation of monomorphic VT as a dominant clinical arrhythmia. Final decisions to implant an S-ICD were taken following case review by a multidisciplinary team of experienced clinicians, including at least three senior electrophysiologists. All patients selected for S-ICD implantation underwent pre-implantation screening of the electrocardiographic R-wave/T-wave (R/T) ratio while lying flat and sitting up in accordance with the manufacturer's recommendation and were found to be suitable for implantation.

Surgical procedure

All patients, and parents where appropriate, signed a procedure-specific consent form which had previously been agreed with the Clinical Practice Committee. Procedures were performed in a catheter laboratory or operating theatre under general anaesthesia following administration of prophylactic intravenous antibiotics and employing conventional aseptic techniques. Operators were highly experienced in the implantation of ICDs and were supported in all procedures by representatives of the manufacturer. The surgical technique has been described in detail elsewhere,[6] but in short the generator is placed subcutaneously via an anterior axillary line incision at the level of the sixth rib, and the lead is tunnelled to an incision 1–2 cm left of midline at the level of the xiphoid process where it is secured with sutures and then tunnelled to a second incision 1–2 cm left of midline at the level of the second rib where it is also secured (*Figure 1*). The manufacturer advises the generator be placed posterior and inferior to the incision (*Figure 2*); however, during the course of our experience among smaller individuals, we modified our surgical technique to place the generator slightly more superior to the incision towards the axilla for greater tissue thickness, protection, and comfort.

Ventricular fibrillation induction

The device was tested intra-operatively in all patients by induction of VF via the device with a single zone programmed from 170 bpm according to the manufacturer's recommendations. Defibrillation was performed with a single 65J shock (15J below the maximum shock output of 80J).

Programming and follow-up

Post-operative chest X-rays were performed in 14 patients and all confirmed correct generator and lead positions. All programming was individually tailored to a patient's clinical characteristics with the aid of the manufacturer's representatives. Two therapy zones can be programmed, a Shock Zone (equivalent to the VF zone in a transvenous ICD) and an optional Conditional Shock Zone (equivalent to the VT zone in a transvenous ICD), in which discrimination of non-ventricular from ventricular rhythms is attempted on the basis of electrogram morphology. The optimal sensing vector is automatically selected by the device, primarily on the basis of the R/T ratio, and manually confirmed. Clinical shock energy is non-programmable,

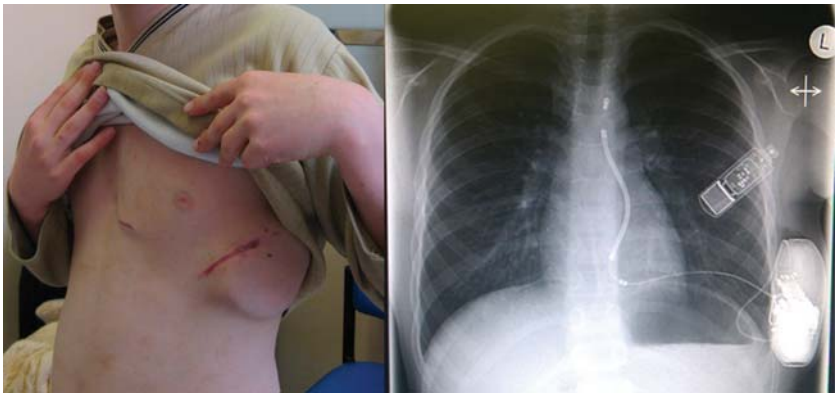

Figure 2 Post-operative images from patient 2. Ten years old and 32 kg weight. The manufacturer's recommended generator position, posterior and inferior to the anterior axillary line incision, is seen.

with all clinical shocks delivered at 80J. Programming was reviewed prior to discharge and follow-up was routinely performed 6 weeks following the procedure and then at 6 monthly intervals. Patients were also asked to attend immediately if they experienced shocks or any other adverse event.

Control group

We identified a control group of patients who had undergone transvenous ICD implantation between 2006 and 2010 in our hospital. Patients were matched 1:1 for age and pathology. Follow-up duration for controls was the same as for index cases.

Statistical analysis

Where normally distributed, data are presented as mean $\pm$ standard deviation. Otherwise, they are presented as median and range. Comparison between groups was performed with the unpaired Student's *t*-test where normally distributed, or with the Mann–Whitney test otherwise. Dichotomous variables were compared using the Fisher's exact test. Two-sided *P*-values < 0.05 were considered significant.

Results

Study population

Between February 2010 and February 2011, 274 patients were referred for implantation of an ICD (ages 60 ± 19 years). Sixteen were felt suitable for S-ICD implantation: they represented 6% of the total referred ICD population, 67% of patients $\leq$21 years, and 88% of patients $\leq$16 years.

Among 16 patients who underwent S-ICD implantation, 9 were male, median age was 20 years (range 10–48 years), and median weight 65 kg (range 32–90 kg) (*Table 1*). Twelve patients had primary electrical disease: 4 long QT syndrome (LQTS), 3 catecholaminergic polymorphic VT (CPVT), 3 Brugada syndrome, and 2 idiopathic VF. Four had structural congenital heart disease: two had tetralogy of Fallot with previous definitive surgical correction, one of whom had tricuspid stenosis, one had transposition of the great arteries and previous arterial switch operation, and one had Ebstein's anomaly and tricuspid valve replacement. Patient 4, a 20-year-old male with CPVT, was the only patient with a bradycardic pacing indication: a previous transvenous ICD had been extracted via median sternotomy following development of infective endocarditis, and in light of superior vena cava stenosis and tricuspid valve damage, bipolar pacing leads were placed epicardially and later connected to an abdominal pacemaker generator.

Surgical procedure and ventricular fibrillation induction

All procedures were completed without acute complications. All generators were initially placed posterior and inferior to the incision apart from patient 12 in whom it was placed superior to the incision following modification of our surgical technique in smaller individuals during the course of our experience. Ventricular fibrillation induction was successful in all patients with a single episode of VF appropriately sensed and then terminated with a single 65J shock in all cases.

Initial programming and follow-up duration

The Shock Zone was programmed at a median rate of 220 bpm (range 190–250 bpm). Patients 1, 4, and 16 had an additional Conditional Shock Zone programmed at 180, 190, and 210 bpm, respectively. Sensing vectors were automatically chosen by the device and did not require manual modification. Median follow-up duration was 9 months (range 3–15 months).

Re-operations

Three children required re-operation during the follow-up period: patients 1 and 13 suffered threatened erosion, in the latter case having continued semi-professional Irish dancing during the post-operative period against medical advice. Patient 6 experienced wound dehiscence following a cycling accident impacting the incision site. Retaining the original leads, all three generators were repositioned superior to the incision without further complication.

Table 1 Patient characteristics and outcomes

Patient	Sex	Age (years)	Weight (kg)	Pathology	Follow-up (months)	Redo procedure	Appropriate shocks	Inappropriate shocks
1	M	16	70	Congenital	15	Yes	0	0
2	M	10	32	LQTS	14	No	0	0
3	F	14	60	CPVT	13	No	0	0
4	M	20	53	CPVT	13	No	3	2
5	F	16	77	Congenital	12	No	0	0
6	F	11	37	LQTS	12	Yes	0	0
7	F	20	49	CPVT	11	No	0	1
8	M	27	79	Brugada	10	No	0	0
9	M	48	79	Brugada	9	No	0	0
10	M	26	55	Idiopathic VF	8	No	2	0
11	F	48	90	LQTS	7	No	0	0
12	F	11	41	Brugada	7	No	0	0
13	M	14	49	LQTS	5	Yes	0	1
14	F	43	85	Congenital	5	No	3	0
15	M	20	79	Congenital	5	No	0	6
16	M	24	70	Idiopathic VF	3	No	0	0
All	M: 9 (56%)	Median: 20; range: 10–48	Median: 60; range: 32–90	N/A	Median: 9.5; range: 3–15	Redo: 3 (19%)	Shocked: 3 (19%)	Shocked: 4 (25%)

Table 2 Characteristics of patients with and without inappropriate shocks

	Inappropriate shocks	No inappropriate shocks	*P*-value for difference
Number of patients	4	12	N/A
Male sex	3 (75%)	6 (50%)	0.58
Age: median (range), years	20 (14–20)	20 (10–48)	0.76
Weight: median (range), kg	51 (49–79)	70 (32–90)	0.52
Pathology	2 CPVT, 1 LQTS, 1 congenital	1 CPVT, 3 LQTS, 3 brugada, 2 idiopathic VF, 3 congenital	N/A

Only patient 1 underwent repeat VF induction, which was successful. Among the four patients with a superior generator position, none experienced arrhythmia during subsequent follow up and thus clinical arrhythmia sensing capabilities in this position were not tested.

Inappropriate shocks

Four patients experienced a total of 10 inappropriate shocks. All were related to T-wave over-sensing. There were no significant differences between characteristics of patients with and without inappropriate shocks (*Table 2*). In patients 4 and 7 with CPVT, these occurred during frequent polymorphic ventricular ectopy. The seven shocks in patients 13 (LQTS) and 15 (Ebstein's anomaly) occurred during sinus tachycardia (*Figure 3*). The median detection rate programmed at the time of the events was 220 bpm (range 190–220 bpm). All patients underwent exercise testing following initial shocks. In three patients, an alternative sensing vector was chosen in which T-wave over-sensing was absent during the test. In patient 7, it was not possible to find an alternative vector with acceptable sensing characteristics, and therefore the sensing vector was not changed and the detection rate increased from 210 to 240 bpm. In patients 4 and 15, further inappropriate shocks occurred despite selection of a new vector in this way.

Appropriate shocks

Three patients experienced a total of eight appropriate shocks for ventricular arrhythmia. Three were delivered for monomorphic VT (patient 14, tetralogy of Fallot) with median time to therapy of 19 s (range 18–20 s), two for polymorphic VT, and three for VF. Two of the VF episodes (patients 4 and 10, CPVT and idiopathic VF) were associated with delays in therapy. Onset of charging took 11 and 14 s, respectively, and subsequent apparent under-sensing further delayed therapy with time to therapy of 24 and 27 s, respectively (*Figure 4*). Both patients experienced syncope.

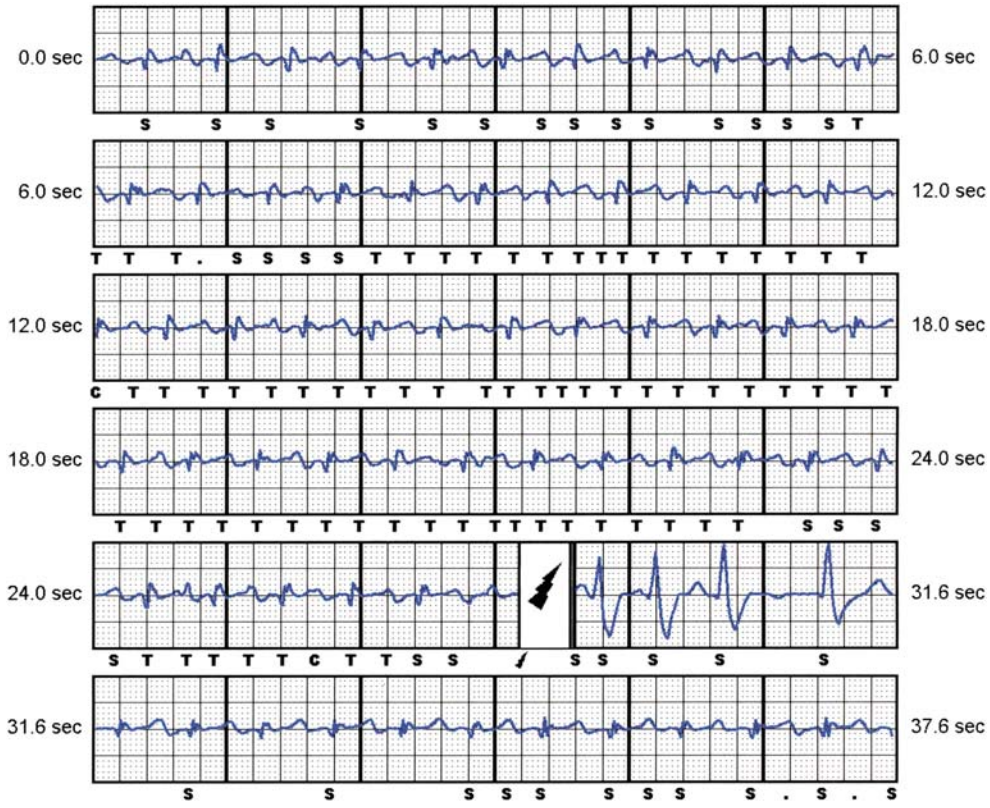

Figure 3 Subcutaneous implantable cardioverter–defibrillator electrogram of T-wave over-sensing during sinus tachycardia from patient 13. T-wave over-sensing leads to a shock illustrated by the lightning symbol. C indicates onset of charging when first seen and commitment to shock delivery when seen a second time. S indicates sensing of a ventricular event not classified as tachycardia. T indicates sensing of a ventricular event classified as tachycardia. A dot indicates sensing of an event which is unclassifiable.

Analysis of ventricular fibrillation episodes with delayed therapy

Analysis by the manufacturer of the two VF episodes with delayed therapy suggested that the device had not malfunctioned. Classification of some events as noise occurred due to fine noise on the electrogram.

Both patients were programmed with a single Shock Zone from 220 bpm. Sensitivity is automatically set at a threshold which is the mean voltage of the previous two sensed events, and then decays with time to become more sensitive. When tachycardia is detected, the sensitivity threshold decay rate is increased. In the 27 s VF episode, analysis revealed that the presence of a Conditional Shock Zone from 200 bpm would have reduced the time to onset of charging from 14 to 9 s. This is because the earlier events in the episode, prior to detection of tachycardia, were sensed with a frequency between 200 and 220 bpm. The presence of a zone from 200 bpm would have therefore caused these earlier events to be classified as tachycardia, and this in turn would have further increased sensitivity to subsequent events as described above.

It was recommended by the manufacturer that a Conditional Shock Zone be programmed from 200 bpm; however, it was noted that this action would decrease specificity and increase the likelihood of inappropriate shocks due to T-wave over-sensing. A review of programming in all patients was undertaken in association with the manufacturer. Despite a detection rate of 200 bpm being advised, it was only felt appropriate to programme this in 3 of 16 patients due to concerns about the risk of inappropriate shocks: currently, the median lowest zone detection rate programmed among all patients is 225 bpm (range 180–250 bpm).

Control group

Sixteen patients with prior transvenous ICD implantation were matched for age and pathology to the index cases (*Table 3*). Age did not differ significantly from index cases (median 18.5 vs. 20 years; $P = 0.49$). Pathology type was matched in 11 cases (69%). Rates of re-operations (6 vs. 19%; $P = 0.25$) and inappropriate shocks (6 vs. 25%; $P = 0.14$) were lower in the control group, but the difference did not reach significance among this small sample.

Discussion

Implantable cardioverter–defibrillator implantation rates in children are increasing.[10] A critical challenge is maintaining venous viability in the face of lifelong therapy, and a greater incidence of

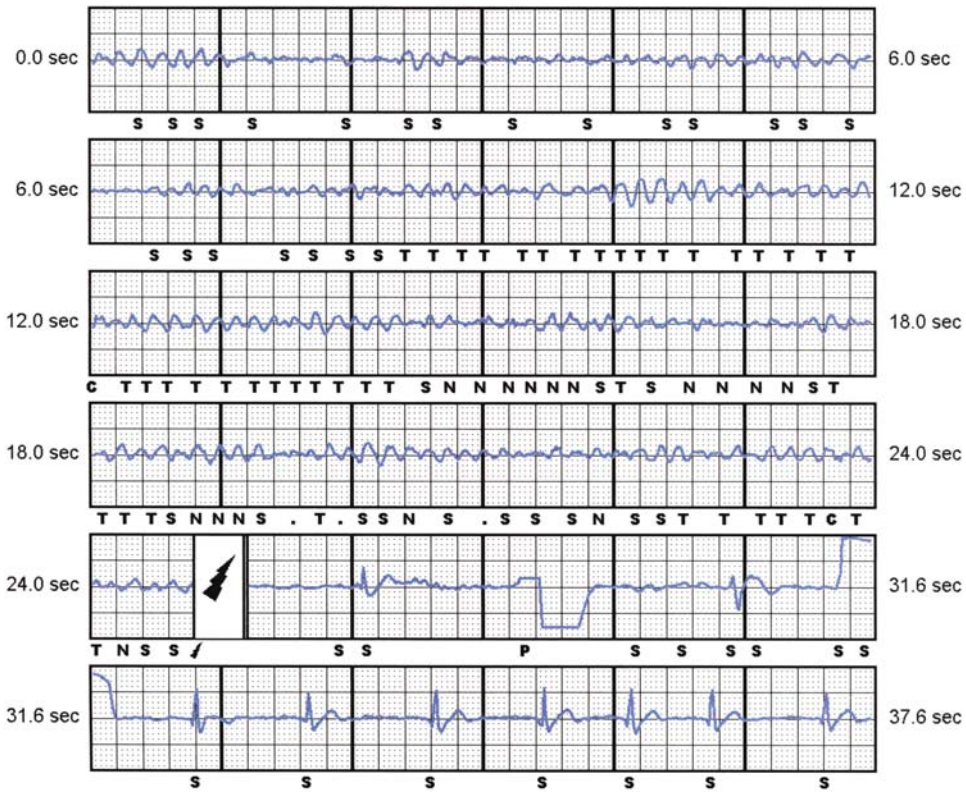

Figure 4 Subcutaneous implantable cardioverter–defibrillator electrogram of ventricular fibrillation from patient 10. Ventricular fibrillation (VF) onset occurred 2 s prior to this recording. Charging begins 14 s after VF onset. Subsequent inaccurate classification begins to occur 2 s later, partly due to fine noise not apparent on visual inspection. The majority of sensed events during the next 11 s are not classified as tachycardia, further delaying therapy until 26.8 s after VF onset (shock indicated with lightning symbol). C indicates onset of charging when first seen and commitment to shock delivery when seen a second time. N indicates sensing of an event which is classified as noise. S indicates sensing of a ventricular event not classified as tachycardia. T indicates sensing of a ventricular event classified as tachycardia. A dot indicates sensing of an event which is unclassifiable.

lead failure than is seen with conventional pacing leads.[2,5,11] The S-ICD design is therefore an attractive option for young patients.

Subcutaneous implantable cardioverter–defibrillators cannot deliver ATP and only deliver limited post-shock bradycardia pacing and so are not suited to many older patients with pacing indications or with structural heart disease where monomorphic pace-terminable VT predominates.[12,13] However, published clinical data are largely confined to older patients, usually with structural heart disease[6,7] and published sensing data during clinical VF are derived from one patient. This is the first study describing the clinical arrhythmia sensing capabilities of these devices among children and young adults, mostly suffering from primary electrical disease, in whom this therapy would appear to be particularly attractive.

Surgical technique

Young patients with transvenous ICDs have increased risk of re-intervention at the generator site.[14] We found the recommended generator position to be relatively prominent in children, resulting in erosion in two cases and injury from a cycling accident in another. We converted to a slightly higher position in smaller individuals, providing greater tissue coverage. Only one patient underwent repeat VF induction, and no patient suffered clinical arrhythmia or shocks with the generator in the modified position. As the arrhythmia sensing capabilities in this position were not tested extensively, these data do not allow us to recommend routine modification of the usual generator position.

Inappropriate shocks

Seven per cent of a typical adult transvenous ICD population receives inappropriate shocks within a year of implantation.[15] Data on inappropriate shock rates in younger patients are mixed, with rates higher than adults only in some studies—up to 25% over 2-year follow-up. Most shocks are caused by lead failure and non-ventricular arrhythmias, with only a minority due to T-wave over-sensing.[5,16–18]

Recent studies among mixed adult and paediatric populations with primary electrical diseases and transvenous ICDs describe yearly inappropriate shock rates of 2% in LQTS,[19] 5% in CPVT,[20] and 6% in Brugada syndrome.[21] Inappropriate shock rates were no higher among younger patients when this question was examined.[19] Nonetheless, children with CPVT are a challenging group to manage with any defibrillator, suffering repetitive non-sustained

Table 3 Control group patient characteristics and outcomes

Patient	Age (years)	Pathology	ICD type: single or dual chamber	Follow-up (months)	Redo procedure	Appropriate shocks	Inappropriate shocks
C1	16	Congenital	Single	15	No	0	0
C2	10	LQTS	Single	14	Yes	0	0
C3	15	CPVT	Single	13	No	0	0
C4	20	CPVT	Dual	13	No	0	15
C5	16	ARVC	Single	12	No	0	0
C6	11	LQTS	Dual	12	No	0	0
C7	17	CPVT	Single	11	No	3	0
C8	27	DCM	Dual	10	No	0	0
C9	49	Brugada	Single	9	No	0	0
C10	26	LQTS	Dual	8	No	0	0
C11	48	LQTS	Dual	7	No	0	0
C12	7	Congenital	Dual	7	No	0	0
C13	14	LQTS	Single	5	No	0	0
C14	43	Congenital	Dual	5	No	0	0
C15	20	ARVC	Dual	5	No	0	0
C16	25	Idiopathic VF	Dual	3	No	0	0
All	Median: 18.5; range: 7–49	N/A	Single: 7 (44%)	Median: 9.5; range: 3–15	Redo: 1 (6%)	Shocked: 1 (6%)	Shocked: 1 (6%)

ARVC, arrhythmogenic right ventricular cardiomyopathy; DCM, dilated cardiomyopathy.

polymorphic runs of VT, and sometimes experiencing failed defibrillations.

The S-ICD has superior discrimination of non-ventricular arrhythmias than most transvenous systems[8] and its rate of inappropriate shocks in an adult population was low.[6] Therefore, despite involving a challenging group of patients, it was still disappointing that during our study 25% of patients received inappropriate shocks after 9-month median follow-up.

It is possible that some groups have an increased risk of inappropriate shocks due to T-wave over-sensing by S-ICDs. These might theoretically include any group in which cardiac repolarization characteristics differ from the adult population from which the great majority of published data are derived: young patients, those with low body mass index, or those with particular primary electrical diseases or hypertrophic cardiomyopathy. However, we also observed inappropriate shocks during sinus tachycardia in an adult patient with Ebstein's anomaly.

Shocks due to T-wave over-sensing were not predictable, sometimes occurring following previously normal sensing (*Figure 3*). Exercise testing was only partially successful in determining appropriate re-programming: two of four patients experiencing further inappropriate shocks. It is possible that pre-implantation screening of the R/T ratio, currently recommended while resting, should also be performed during exercise.

Delayed therapy of ventricular fibrillation

Patients 4 and 10 experienced times to therapy for VF of 24 and 27 s, respectively. These seem prolonged when compared with typical detection times below 3 s and charging times below 10 s for new transvenous ICDs.[22]

Manufacturer analysis of intra-operative VF inductions from the first 400 commercial implants revealed a mean time to therapy of 14.9 $\pm$ 3.2 s (unpublished data from Cameron Health by email 4 May 2011). Therefore, these clinical episodes were near or outside the third standard deviation of the intra-operative data.

The sensing characteristics of the S-ICD are affected by posture[9] and also by the detection rate programmed for its therapy zones. Increasing the programmed detection rate effectively reduces the sensitivity of the device to VF. While VF inductions are typically performed with detection programmed from 170 bpm (per manufacturer's recommendations), subsequently increasing this rate will reduce sensitivity to VF. This contrasts with conventional transvenous ICD practice of performing VF induction at least sensitivity and then programming greater sensitivity at discharge.

Conversely, reducing the detection rate will reduce specificity and increase the likelihood of inappropriate shocks due to T-wave over-sensing. Balancing concerns about both sensitivity and specificity to ventricular arrhythmia resulted in a narrow window for detection rate programming. The detection rates associated with inappropriate shocks [median 220 bpm (range 190–220 bpm)] were similar to those associated with delayed therapy for VF (220 bpm). In practice, we could not programme detection rates below a median value of 225 bpm, and in four patients they remain programmed at 240 bpm or higher.

It is therefore somewhat concerning that there are currently few published data on the sensing characteristics of the S-ICD during sustained clinical ventricular arrhythmias, with results confined to

two studies. In one study, three patients received appropriate shocks for sustained VT.[6] In the other, one patient experienced shocks for multiple episodes of sustained VF and another for sustained VT.[7]

Reassuringly, during 62 clinical episodes of VF among 14 patients worldwide, there were no failures of detection and time to therapy of 20.1 $\pm$ 3.9 s (unpublished data from Cameron Health by email 4 May 2011). While these unpublished data are reassuring, until more data are published, the sensing capabilities of S-ICDs in the setting of clinical VF cannot be considered fully proven.

Further investigation of sensing characteristics

The S-ICD is an important innovation with potential to reduce the device-related morbidity of many patients at risk of arrhythmic death. Clinical data should be systematically registered to allow better characterization of this promising new technology. This would further confirm sensing characteristics during clinical VF, and allow determination of performance among specific subgroups. Additionally, it may be possible to modify the sensing algorithm to improve its specificity for ventricular arrhythmia.

Until these data are available, physicians should bear in mind the facts above when assessing the suitability of the S-ICD for individual patients. Additionally, they should consider two manoeuvres; first, assessment of the R/T ratio on exercise during pre-implantation screening; secondly, programming higher detection rates during VF induction testing on at least one occasion. Rates chosen should anticipate those which may be required in future programming, which can be as high as 250 bpm.

Limitations

Our study has several important limitations. The small number of patients does not have the statistical power to answer many important questions about S-ICD performance. Additionally, it is retrospective and non-randomized. Finally, its subjects are not representative of all patients that may be suitable for S-ICD implantation and its findings can only be directly applied to similar patients. Despite these limitations, the data presented are unique in several ways and make an important contribution to the limited published data regarding the clinical performance of these devices.

Conclusions

The S-ICD is an important new option for many patients at risk of sudden arrhythmic death, and particularly for younger patients. Following implantation in several hundred patients, these devices have never failed to detect or successfully defibrillate an episode of clinical ventricular tachyarrhythmia. However, there are currently few published data regarding sensing capabilities during clinical VF, or from many of the most important populations which might especially benefit from this technology. In our experience, among a small group of patients selected from a broad population entirely on clinical grounds for S-ICD therapy, we found a high rate of inappropriate shocks as well as prolonged times to VF therapy in some patients. More data are required to clarify the clinical sensing characteristics, determine appropriate patient selection criteria, and optimize programming recommendations for these devices.

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