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Clinical paper

Leakage current from transvenous and subcutaneous implantable cardioverter defibrillators (ICDs): A risk to the rescuer?

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Abstract

Background: Implantable cardioverter-defibrillators (ICDs) are a well-established therapy for patients at risk of life-threatening ventricular arrhythmias. With rising implant rates, the risk of a rescuer performing chest compressions during discharge is increasing, leading to concerns over rescuer safety from the resultant leakage current. More recently, subcutaneous ICDs (S-ICD) have been developed, which utilise a higher energy and more superficial electrodes compared with transvenous ICDs (T-ICD), raising safety concerns further.

Objective: We measured the current a rescuer would potentially receive from T-ICDs and S-ICDs if they were in contact with the patient at the time of ICD discharge to assess its magnitude in relation to international safety standards.

Methods: Surface voltages adjacent to ICD electrodes were measured on patients undergoing defibrillation threshold checks. Rescuer current was then calculated assuming a total rescuer circuit impedance of 1696 Ω.

Results: Twenty-five patients were recruited. Rescuer current from S-ICDs was significantly higher than those from T-ICDs (S-ICD: Median RMS 135 mA range 91 mA–164 mA, T-ICD: Median RMS 31 mA, range 9 mA–75 mA, $P < 0.0001$). Surface voltages (median RMS) to which the rescuer is likely to be exposed are higher when performing chest compressions from the patient's left side compared with the right (127 V vs 67 V respectively, 95% CI of difference −34 V to −67 V, $P < 0.0001$).

Conclusions: Rescuers performing chest compressions on ICD patients are at risk from leakage current, particularly from S-ICDs. Chest compressions should be performed from the opposite side to the ICD to reduce rescuer risk.

Keywords: Implantable cardioverter-defibrillator, Resuscitation, CPR, Safety

Abbreviations: ICD, implantable cardioverter-defibrillator; T-ICD, transvenous ICD; S-ICD, subcutaneous ICD; IEC, International Electrotechnical Commission; UHS, University Hospital Southampton; DFT, defibrillation threshold test; REC, Research Ethics Committee; ECG, electrocardiogram; VF, ventricular fibrillation; SF, scaling factor; RMS, root mean square; CPR, cardiopulmonary resuscitation; ICNRP, International Commission on Non-Radiological Protection.

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https://doi.org/10.1016/j.resuscitation.2019.02.011
Received 27 July 2018; Received in revised form 23 January 2019; Accepted 12 February 2019

Introduction

Implantable cardioverter-defibrillators (ICD) are now well established as an effective therapy for malignant life-threatening ventricular arrhythmias. In the United States, it is estimated that about 800,000 ICDs have been implanted in total, with approximately 10,000 more being implanted every month in addition to 7000 implanted monthly in Europe.[1] Transvenous ICDs (T-ICD) form the bulk of implanted devices and comprise endocardial leads and a generator that is typically placed in subclavicular tissue. Since 2009, increasing numbers of patients have received a subcutaneous ICD (S-ICD), which aims to reduce the significant morbidity associated with T-ICDs. These devices typically involve a subcutaneous parasternal lead and a generator placed subcutaneously in the left mid-axillary line. Although, S-ICDs account for less than 10% of all implanted ICDs, numbers are set to rise in future.[2]

During discharge, ICDs pass a large current between an electrode mounted in the lead and the metal casing of the ICD that is referred to as the 'active can'. A rescuer in contact with the patient during resuscitation risks partial exposure to this electrical discharge; an occurrence that becomes increasingly more likely as increasing numbers of ICDs are implanted. The consequence depends upon the magnitude of the resulting 'rescuer current', which is determined by the patient surface voltage and the impedance of the rescuer, along with the path the current follows through the rescuer.[3,4] Peters et al. directly measured the current through a simulated rescuer from patients with a T-ICD device and found current between ICD can and heart apex ranged from 8 to 47 mA.[5] Niwano et al. also investigated the current and noted that the magnitude varied in relation to the T-ICD discharge vector.[6] In a measured orientation parallel with the defibrillator discharge current (the orientation where rescuer current is maximal), a mean current of 48 mA was observed with an instantaneous peak of 105 mA.

IEC technical committee 64 summarized the physiological effects resulting from a current for the general case (Table 1) and case reports in the literature suggest that rescuer current resulting from T-ICDs is sufficient to result in some of these effects.[4] More specifically, reports have documented musculoskeletal pain[7,8] and nerve damage[9] but the most concerning physiological effect is the potential to induce a malignant tachyarrhythmia in the rescuer. S-ICDs discharge a significantly higher energy to terminate ventricular fibrillation (VF) compared to their T-ICD counterparts (37 J vs 11 J respectively)[10] and hence, combined with their superficial electrode location, are likely to lead to a larger surface current and morbidity to the rescuer.

This study was therefore undertaken to investigate the increased risk from S-ICDs through measuring rescuer currents from these devices and comparing them to those from T-ICDs.

Table 1 – The increasing physiological effects of the passage of an electric current with magnitude and duration.[25]

Zone	Physiological effect
AC-1	Perception possible but usually no 'startled' reaction
AC-2	Perception and involuntary muscular contractions likely but usually no harmful electrical physiological effects
AC-3	Strong involuntary muscular contractions. Difficulty in breathing. Reversible disturbances in heart function. Immobilization may occur. Usually no organic damage expected
AC-4	Pathophysiological effects may occur such as cardiac arrest, and burns or other cellular damage. Probability of Ventricular Fibrillation (VF) increases with current magnitude and duration

Methods

Study population and enrolment

Patients invited to participate in this study were drawn from a convenience sample of those undergoing elective conventional T-ICD or S-ICD implantation at University Hospital Southampton (UHS). Participants were enrolled between February 2014 and August 2017 following informed written consent. Inclusion criteria were age >18 years and those receiving a defibrillation threshold (DFT) check as part of the individuals' specific clinical management.

The research protocol was approved by the UK multicentre National Research Ethics Committee (REC reference 13/SC/0427) and UHS prior to the commencement of the project. The study was registered at clinicaltrials.gov (NCT03271619).

Measurement methods

In a previous study using T-ICDs, Niwano et al. drew peak currents of 105 mA from the patient, which exceeds recommendations for maximum auxiliary currents for patient measuring devices.[6,11] Due to the higher energies and superficial electrode position, S-ICD's may be expected to produce higher currents still and hence measuring current directly risks harm to the patient.

To ensure patient safety, we therefore used an indirect technique, measuring the voltage across a high impedance circuit to minimise the current drawn. From this, an expected rescuer current was calculated based upon a rescuer impedance circuit likely to be encountered in a clinical scenario. Accordingly, a measurement of voltage on the surface of the patients' chest was made at the time of ICD discharge.

Measurement electrode positions

ECG electrodes were placed on the patients' chest and connected to an attenuator in order to reduce the magnitude of the signal to a level compatible with a Biopac® MP-150 acquisition unit (Biopac Systems, Inc., CA 93117, USA) which was used to digitise the voltage. A low pass filter ensured aliasing effects during sampling were avoided (Fig. 1).

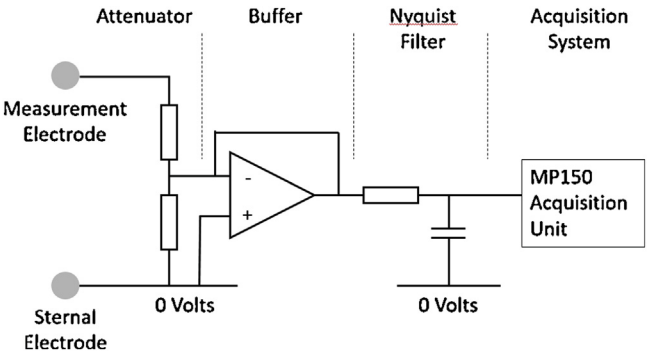

Fig. 1 – Electrical circuit of the measurement system.

Electrodes were positioned at sites aligned with the discharge vector, corresponding to the maximum surface voltage a rescuer is likely to be exposed to if the ICD discharges whilst they are performing chest compressions. Accordingly, they were positioned along an imaginary line linking the lower half of the sternum to the centre of the active can. Consequently, orientation varied according to the type of ICD (subcutaneous vs transvenous) being investigated (Fig. 2). A reference electrode was placed 2 cm laterally to the right of the centre of the sternum (to avoid the sterile field during surgery) representing the sternal point of contact during chest compressions. To represent inadvertent contact between rescuer and active can (with chest compressions being performed from patient's left), a second electrode was placed 2 cm anteriorly of the can. To represent inadvertent contact between rescuer fingertips and the patient (chest compressions from patient's right), a third electrode was placed 10 cm to the right of the sternum (Fig. 2). By placing outermost electrodes distal to the ICD electrodes, minimum impact on measured voltage may be expected.

Data acquisition

Data were acquired at a sample rate of 10 kHz. Acquisition commenced in advance of the induction of VF, which formed part of the routine DFT. Acquisition was manually terminated once the ICD had successfully discharged.

Data analysis

To calculate the Root Mean Square Current (I_{RMS}) of each ICD discharge waveform the method described by the International Electrotechnical Commission (IEC) was adapted to this application.[12] Accordingly, voltage samples were initially multiplied by a scaling factor (SF) to correct for the attenuation applied to the signal prior to acquisition. V_{RMS} was then calculated for the N samples collected over the duration of the discharge waveform (Eq. (1)).

$$V_{RMS} = \sqrt{\frac{\sum_{n=0}^{N} (SF.V(n))^2}{N+1}} \quad (1)$$

From this the Root Mean Square current, I_{RMS} was calculated by assuming the impedance of the rescuer circuit (Eq. (2)). The actual value is dependent on a particular scenario; however, to aid comparison with similar studies, a value of 1696 Ω was chosen as being a likely low impedance value.[5]

$$I_{RMS} = \frac{V_{RMS}}{1696\,\Omega} \quad (2)$$

Statistical analysis

Data are expressed as medians throughout. The significance of differences between groups was tested using a Mann Whitney Test, or, where paired data are present, a Wilcoxon Signed rank test.

Results

Patients' demographic and clinical characteristics

A total of 25 patients were recruited to the study (13 T-ICD, 12 S-ICD). The demographics of the two groups are summarised in Table 2.

The delivered energy (median) during ICD discharge (as reported by the ICD software) was significantly higher for S-ICDs compared with T-ICDs (65 J (Range 60.0–80.0 J) vs 32.5 J (Range 15.0–41.0 J), $P < 0.0001$) and the pulse duration (median) was slightly longer in the S-ICD group (13.9 ms vs 11.1 ms, $P = 0.042$).

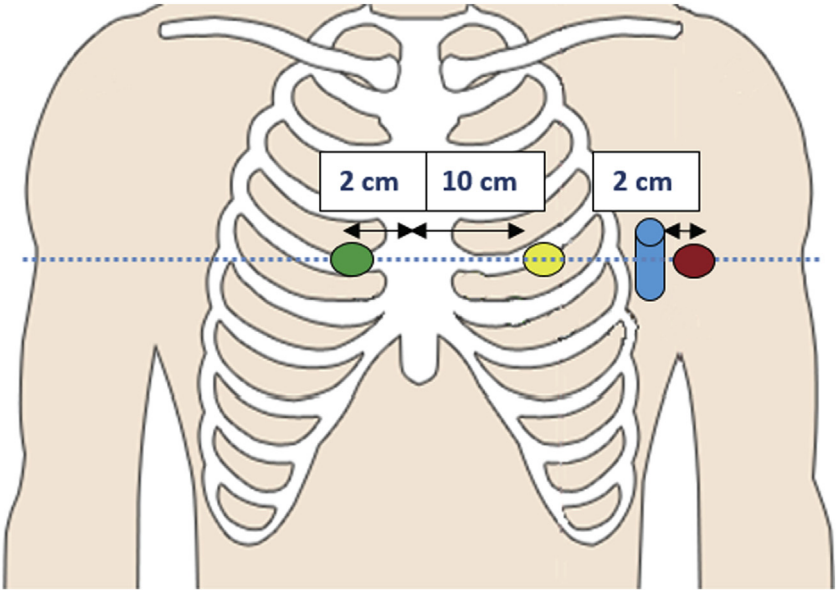

Fig. 2 – Schematic showing electrode placement for ICD electrodes. Green– reference, yellow– rescuer fingertip, red– active can.

Table 2 – Demographic data (T-ICD = transvenous ICD; S-ICD = subcutaneous ICD).

	S-ICD	T-ICD
Number	12	13
Body mass index median (range)	31.5 (22.9–44.3)	29.0 (21.0–39.9)
Age (years) median (range)	57 (22–100)	69.5 (22–86)
Gender (male/female)	8/4	8/5

Rescuer current

Voltages were successfully measured at the time of ICD discharge for all 25 subjects. However, in four cases, the electrode representing the position of rescuer's fingertips had become displaced. Consequently there were 25 surface voltage measurements between sternum and can, but 21 measurements between sternum and the electrode placed in the position of the rescuer's fingertips.

Rescuer current for S-ICD devices was found to be significantly higher than current from T-ICDs (Median RMS 135 mA (range 90.7–164.0 mA) vs 31 mA (range 8.9–75.0 mA), $P < 0.0001$), as shown in Fig. 3. The corresponding voltages (median RMS) were 229 V vs 52 V.

Surface voltage measurements between sternum and can (representing the circuit shown in Fig. 4a) and measurements between sternum and rescuer's fingertips (representing the circuit shown in Fig. 4b) for all ICDs (T-ICD & S-ICD) are shown in Fig. 5.

Discussion

This is the first published study to document rescuer current during S-ICD discharge. The higher energy used by these devices together with the more superficial electrode placement results in greater rescuer current than that documented by this and other studies for T-ICDs.[5,6] A (median RMS) rescuer current of 135 mA is well in excess of the 1 mA maximum current recommended by international safety standards,[3] suggesting a cautious approach is required when performing chest compressions on patients with an S-ICD if physiological effects in the rescuer are to be avoided. Further, rescuer current in clinical settings may be higher still, as the measurements reported in this study were taken during ICD testing when the device was discharged at an energy level lower than that subsequently set for clinical use.

As expected, results showed considerable variation between patients. To accurately mimic hand positioning during chest compressions, measurement locations were determined based upon externally identifiable anatomical locations. In common with the clinical scenario the exact location of the ICD leads in relation to these sites may vary. Additional variability may be attributed to patient characteristics and energy used. Despite these variables, T-ICD current values calculated from measured surface voltages in this study were consistently of similar magnitudes and compare well with those found in previous studies using the alternative, direct measurement of current methodology. RMS rescuer current values using T-ICDs from this study (9 mA–75 mA, median 31 mA) were comparable with those recorded by Peters et al. (8 mA–47 mA) and Niwano (3 mA–43 mA, mean 19 mA).[5,6] Having confirmed the validity of the method for T-ICD, this supports our finding that rescuer currents from S-ICDs are much larger.

To aid comparison with previous studies, rescuer current was calculated based upon a total impedance in the rescuer circuit of 1696 Ω. This value was proposed by Peters et al., based upon a 1000 Ω rescuer impedance and two rescuer/patient skin interfaces each of 348 Ω.[5]

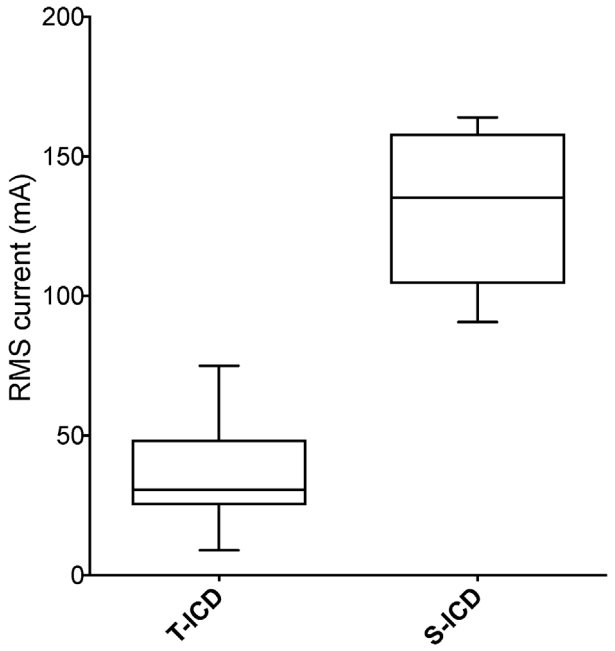

Fig. 3 – A Box and Whisker plot showing the difference in RMS rescuer escape current (between sternum and can) for T-ICDs and S-ICDs. The Box extends from the 25th to 75th percentiles, the whiskers reach from minimum to maximum values.

Peters et al measured the skin interface impedance and assumed a typical 1000 Ω between the arm and leg based upon other studies.[13,14] In practice, skin impedance for a given scenario could vary significantly. For a 'dry' skin interface the impedance could be as high as 100,000 Ω[14] meaning almost no rescuer current would flow, whereas for a large, damp area of contact, the interface impedance would be much lower. In this latter scenario, current would be limited only by the impedance of the rescuer themselves, leading to a maximum current value. A value of 1696 Ω was therefore chosen to avoid either extreme and represent realistic rescuer circuit impedance likely to be encountered.

The Resuscitation Council (UK) and British Cardiovascular Society have recently published guidelines for the management of ICDs during cardiac arrest, which recommend chest compressions should be delivered using the standard technique.[15] To determine if mitigation of the associated risk to the rescuer is required, it is necessary to understand the physiological effects resulting from the rescuer current should inadvertent contact be made. ICD manufacturers' advise that "If the implanted device delivers a shock during CPR, the responder may feel a tingling sensation on the patient's body surface. However, the shocks delivered by the implanted defibrillator will not pose a danger to the person administering CPR".[16] Applying the pulse duration and current magnitude observed in this study to IEC standards suggests that rescuer currents from T-ICD are consistent with "*Perception (of current) and involuntary muscular contractions likely but usually no harmful electrical physiological effects*" (zone AC-2, Table 1) while the higher currents from S-ICDs border on "*reversible disturbances of heart function" and "effects increase with current magnitude*" (zone AC-3, Table 1) and, under maximum energy, clinical, conditions rescuer current from S-ICDs may well fall into this latter category.[4]

Although patients receive much higher currents than rescuers and seem to escape the pathophysiological effects observed at the

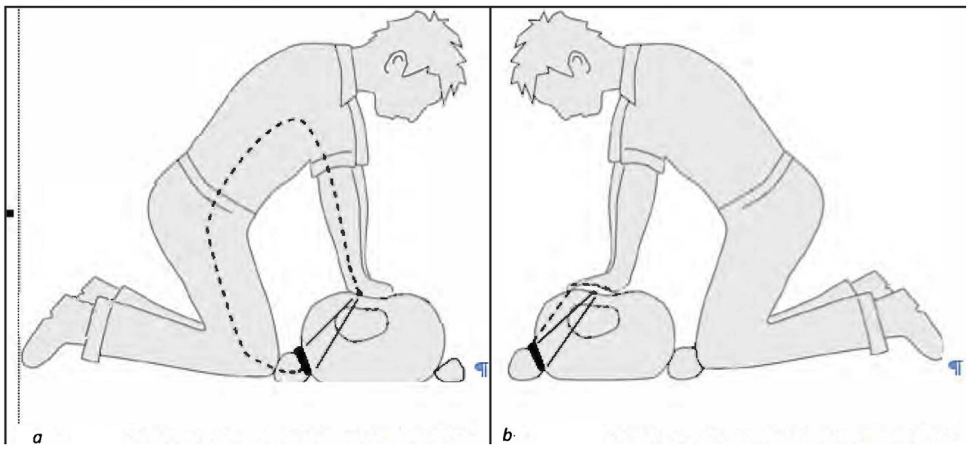

Fig. 4 – Dominant current pathway through the patient (solid line) and the rescuer (dotted line) during S-ICD discharge, demonstrating how the maximum surface voltage likely to be experienced by the rescuer reduces when chest compressions are performed from the patients' left (4b) compared with right side (4a). (Modified from Hoke RS et al. Is external defibrillation an electric threat for bystanders? Resuscitation 2009;80(4);395-401. Copyright (2009), and reproduced with permission from Elsevier).

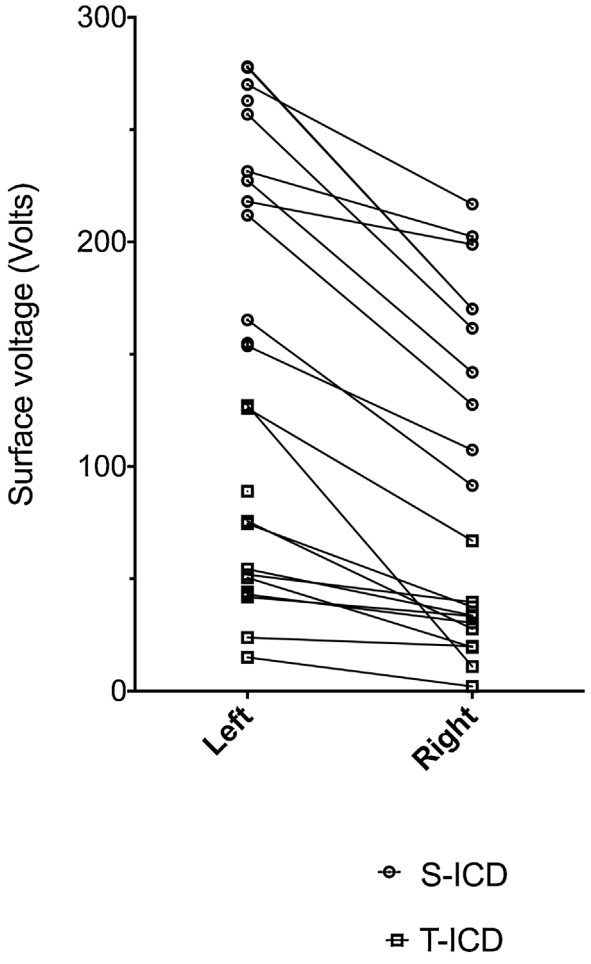

Fig. 5 – Difference in the surface (RMS) voltage a rescuer is exposed to when performing chest compressions from the patients' left side (sternum-can), compared with right side (sternum to rescuer fingertip). (Left: 127 V vs: right: 67 V, 95% CI of difference −34 V to – 67 V, $P < 0.0001$). □ = T-ICD, O = S-ICD.

lower currents experienced by rescuers, we surmise that this is may be due to very different current pathways in a patient receiving an intended ICD shock, compared with someone inadvertently in contact with the patient receiving an unintended shock. In a previous study focusing on the effects of T-ICDs on the rescuer, Peters et al. concluded that there is minimal risk of inducing a tachyarrhythmia at the current levels resulting from T-ICDs.[5] Niwano et al. comment that the peak currents they observed were consistent with causing macroshock and tetany in the rescuer, but currents may not be harmful due to the small time over which peak current is sustained and hence the small energies involved.[6] Consistent with rescuer current causing a physiological response, several cases are reported relating to inadvertent shocks during T-ICD discharge. Although these case reports generally only document musculoskeletal effects, at least one has reported significant palmar and digital nerve damage.[9] Despite rescuer currents presenting a minimal risk of tachyarrhythmia, there is clear evidence that inadvertent contact with a patient during ICD discharge risks generating an undesirable physiological responses in the rescuer. Since some of these effects may be irreversible, it is suggested that they are incompatible with an acceptable level of occupational exposure. Petley et al. considered the maximum acceptable rescuer current and drew attention to the recommendation of the International Commission on Non-Radiological Protection (ICNRP) which suggests keeping occupational exposures to contact currents below 1 mA; a level consistent with a small chance of perception.[3,17].

Whilst this study demonstrates current levels consistent with physiological effects, health professionals are encouraged to continue to perform chest compressions on all ICD patients, but consider adopting one of a number of approaches to minimise risk from ICD discharge. We have shown in this study that rescuer current is lower if the rescuer performs chest compressions from the patients' right side at the time of ICD discharge. Further, in this scenario the main current pathway traverses the rescuers' hand (Fig. 4b) rather than heart (Fig. 4a), thereby minimising risk. For patients receiving CPR who are known to have an ICD fitted, it is recommended that a strong magnet is placed over the ICD can to

suspend tachyarrhythmia detection and deactivate shock delivery.[15] Although this is viable for hospital-based cardiac arrests, it is generally not an option for out-of-hospital cardiac arrests where, even if the patient is known to have an ICD implanted, a magnet is not usually available. The safest option of all is for the rescuer to stand clear at the time of shock delivery. ICDs are generally fitted with an audible buzzer that sounds a warning for example when the internal battery is running low.[18] It may be worth manufacturers consistently using the same circuitry to provide an audible alarm when the ICD is about to discharge.

Peters et al advise rescuers to wear gloves.[5] Wearing of clinical examination gloves has been recommended during CPR in the hope that it may confer some electrical protection to the rescuer performing chest compressions during ICD discharge.[19] However, as we[20] and others[21] have discussed, clinical examination gloves are only designed as a protective barrier to bodily fluids, and are an unreliable electrical barrier to defibrillation currents,[22] even when not torn or perforated during CPR.[23] Whilst wearing of suitably designed electrical safety gloves is a potential barrier to current flow, we would not agree with the statement of Boston Scientific that "*The unpleasant tingling sensation can be prevented by wearing gloves during CPR.*"[24] The only gloves that would be suitable are class 1 electrical safety gloves as we have previously demonstrated.[26]

Conclusions

S-ICD devices present a greater risk to the rescuer than T-ICDs. Consideration should be given to enabling all ICDs to give an audible warning prior to discharge and ensuring that during CPR, chest compressions are performed from the opposite side to that which the ICD is implanted.

Funding

We thank the Resuscitation Council (UK) for the award of a research grant to fund this study.

Conflict of interest

PRR has received speaker's fees and consultancy fees from Medtronic and speaker's fees, consultancy fees and research funding from Boston Scientific. CDD, GWP, BA and PB declare no conflicts.

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