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Electrocardiographic changes during haemodialysis and the potential impact on subcutaneous implantable cardioverter defibrillator eligibility

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ABSTRACT

Introduction: Haemodialysis patients who require defibrillator therapy are expected to benefit from the entirely avascular subcutaneous defibrillator (S-ICD), but haemodialysis is associated with dynamic changes in R and T wave amplitude which can impact S-ICD eligibility. A continuous assessment of S-ICD eligibility during haemodialysis has not previously been performed.

Material and methods: Continuous surface ECG recordings were obtained from a cohort of patients undergoing maintenance haemodialysis, but without an indication for an ICD. Automated vector screening was retrospectively performed at one-minute intervals throughout the dialysis session. Variations in S-ICD eligibility were calculated and in vectors with high degrees of variation, the underlying mechanism was identified.

Results: 72 vector recordings (mean duration 254.1 ± 6.0 min) were obtained from 24 patients (mean age 64.3 ± 5.5 years, 68% male). At the start of haemodialysis 47 vectors were S-ICD eligible (65.2%). At the end of session, all of these vectors had remained eligible, and an additional 6 vectors had also become eligible (73.6%). High vector score variability was observed in 7 patients and the commonest cause was a progressive change in R:T ratio (71.5%).

Conclusion: In a haemodialysis population, a single haemodialysis session can be associated with a potential change in S-ICD eligibility in 8.4% of vectors, with up to 12.5% of vectors showing high degrees of variability, most commonly due to variations in R:T ratio. In an S-ICD population with similar characteristics S-ICD screening prior to haemodialysis would be expected to more accurately identify vectors that retain eligibility.

Introduction

Patients undergoing maintenance haemodialysis have an increased risk of sudden cardiac death and a high prevalence of ventricular arrhythmia [1]. Implantable cardioverter defibrillators (ICD) have shown a survival benefit in haemodialysis registries but the causal relationship between haemodialysis and arrhythmic death remains poorly understood [2,3].

Presently, only around 6% of haemodialysis patients are treated with a primary prevention ICD. Device implantation in end stage renal disease is also associated with a four-fold increase in infection rates and a 60 fold increase in peri-procedural bleeding [4–8]. The subcutaneous ICD (S-ICD) is an attractive possible solution, as its avascular location is expected to benefit patients with challenging vascular access and a high risk of bacteraemia.

Prior to S-ICD implantation automated ECG screening is routinely performed to ensure that recipients have at least one vector of suitable morphology [9]. A 'vector score' is calculated by the system, but not reported to the implanter. Instead, outcomes are reported in a binary fashion, with vectors either passing (vector score > 100) or failing screening. A key determinant of vector score is the ratio of R wave amplitude to T wave amplitude, with low R:T ratios presenting an unacceptable risk of cardiac over-sensing, the commonest cause of inappropriate shock therapies in the S-ICD population [10].

Haemodialysis challenges the sensing mechanism of the S-ICD as it is associated with rapid changes in fluid volume, dynamic shifts

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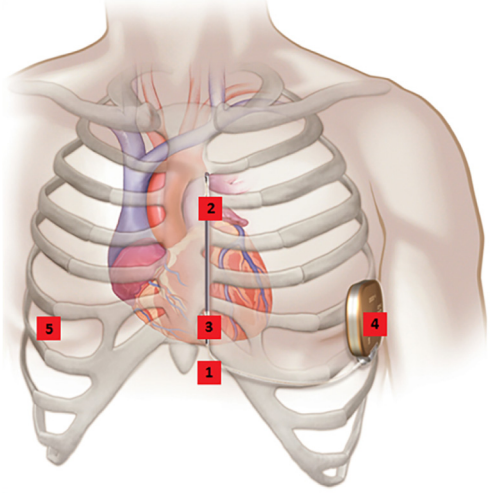
in electrolyte concentration, and acute myocardial stunning. Haemodialysis and changes in fluid status have been shown to cause fluctuations in QTc, T wave amplitude, T wave duration, QRS amplitude and QRS/T axis, whilst dynamic changes in left ventricular function have also been observed with echocardiography [11–19]. Haemodialysis patients have a higher incidence of S-ICD screening failure overall, particularly prior to dialysis, although the underlying mechanism is not well understood [20].

Recent studies in which continuous vector assessment has been performed have also shown that S-ICD eligibility is a more dynamic phenomenon than previously considered [21]. However, device recipients continue to be routinely screened on a single occasion prior to implant and no specific guidance exists for the screening of haemodialysis patients.

Material and methods

Adult patients undergoing maintenance haemodialysis were invited to wear a two-channel digital research Holter (Model AFT-1000, Holter Supplies, Paris) for the duration of a single haemodialysis session. All study participants gave informed written consent prior to enrolment. The study was purely observational, and all dialysis sessions were conducted as clinically indicated. Study participants were not required to have a primary or secondary indication for ICD therapy and no patients received an ICD during the period of the study.

Holter recordings were obtained in 1000 Hz ASCII format using surface ECG electrodes placed to record all three S-ICD vectors. [Fig. 1] An S-ICD simulator (Boston Scientific, Ma, USA) was then used to perform automated screening of each vector, at one-minute intervals, throughout the duration of the recordings. The simulator program, which is the intellectual property of Boston Scientific, recreates the exact process by which surface ECG is filtered and analysed by the Automated Screening Tool of the Boston Scientific ICD programmer. For every one-minute period R wave amplitude, T wave amplitude and vector score were determined, by the simulator, using an average of six consecutive complexes, exactly replicating the clinical pre-implant screening process using with the automated screening tool.



1 = 1cm infero-lateral to the xiphisternum, 2 = 14 cm superior to position 1, 3 = immediately superior to position 1, 4 = 6th intercostal space left mid axillary line, 5 (neutral electrode) = 5th intercostal space right mid clavicular line. The primary vector is recorded between points 3 and 4 and the alternate vector is recorded between points 2 and 1. The secondary vector (between points 2 and 4) is then determined by simple mathematics rather than recorded directly. Image prior to annotation © Boston Scientific Corporation or its affiliates (reproduced with permission).

Fig. 1. Surface ECG lead positions displayed on an S-ICD schematic.

R wave amplitude, T wave amplitude and vector score at the start and end of haemodialysis were calculated for each vector using the mean values of the first five screenings (start of haemodialysis) and the final five screenings (end of haemodialysis). Variations in both T wave amplitude and R wave amplitude across all the tested vectors was also assessed.

The percentage of total screenings that were passed by an individual vector was calculated and denoted as the 'eligible vector time' (EVT). Vectors with high variability, those with >10% of their screenings both passing and failing, (i.e. an EVT between 10% and 90%) were subjected to further analysis to determine the likely underlying cause.

For every patient total dialysis volume was recorded and correlated to eligible vector time, percentage change in R wave amplitude and percentage change in T wave amplitude.

Results

A total of 72 vector recordings were obtained from 24 individuals. The studied population had a low prevalence of structural heart disease, ischaemic heart disease and baseline conduction disease. [Full patient demographics are detailed in Table 1]. The mean duration of recordings was 254.1 ± 6.0 min.

At the start of a haemodialysis session 47 vectors were S-ICD eligible (65.2%). At the end of session, eligibility status had changed in 6 vectors (8.4%), with 53 vectors now eligible (73.6%). Importantly, all the passing vectors at the start of dialysis were also eligible at the end of the session.

Eligible vector times were calculated for all 72 vectors [Fig. 2]. 45 vectors (62.5%) had an EVT >90%, whilst 18 vectors (25%) had an EVT of <10%. 9 vectors (12.5%), recorded from 7 different individuals, were found to have highly variable vector status (EVT 10–90%).

Variations in both R and T wave amplitude were noted across the cohort, but no correlation could be identified. Overall increases and decreases in both parameter amplitudes were observed in individual vectors. [Fig. 3] Patients in the high variability group were not distinguished by either the degree of change in amplitude, or the direction of change, in either parameter. No correlation was identified between total dialysis volume and EVT, percentage change in R wave amplitude or percentage change in T wave amplitude.

In the highly variable group, changes in eligibility were found to be caused by four distinct mechanisms. In patients with more than one

Table 1
Patient demographics.

Total number of participants		$n = 25$	
Demographics	Mean age [years ±95% CI]	64.3 [± 5.5]	
	Male	17	68.0%
Cardiac co-morbidities:	Hypertension	11	44.0%
	Diabetes	5	20.0%
	Cerebrovascular disease	4	16.0%
	Ischaemic heart disease	4	16.0%
	LV systolic dysfunction	2	8.0%
	Previous atrial fibrillation or atrial flutter	2	8.0%
	Previous cardiac surgery	1	4.0%
	Bundle branch block	1	4.0%
Dialysis Indication:	Adult polycystic kidney disease	4	16.0%
	Glomerulonephritis	3	12.0%
	Bilateral small kidneys	3	12.0%
	Hypertensive nephropathy	2	8.0%
	Diabetic nephropathy	2	8.0%
	Alport's syndrome	2	8.0%

vector in the highly variable group, the mechanism was consistent across that individual's vectors.

In 5 out of 7 patients (71.5%), a gradual change in R:T ratio was observed during the recording. In two patients, this was the result of a progressive increase in R wave amplitude with relatively consistent T wave values. [Fig. 4] Whilst in three patients, a gradual decrease in T wave amplitude was observed with consistent R wave amplitudes recorded. [Fig. 5] In both scenarios a favourable R:T ratio resulted, and a change in eligibility was observed.

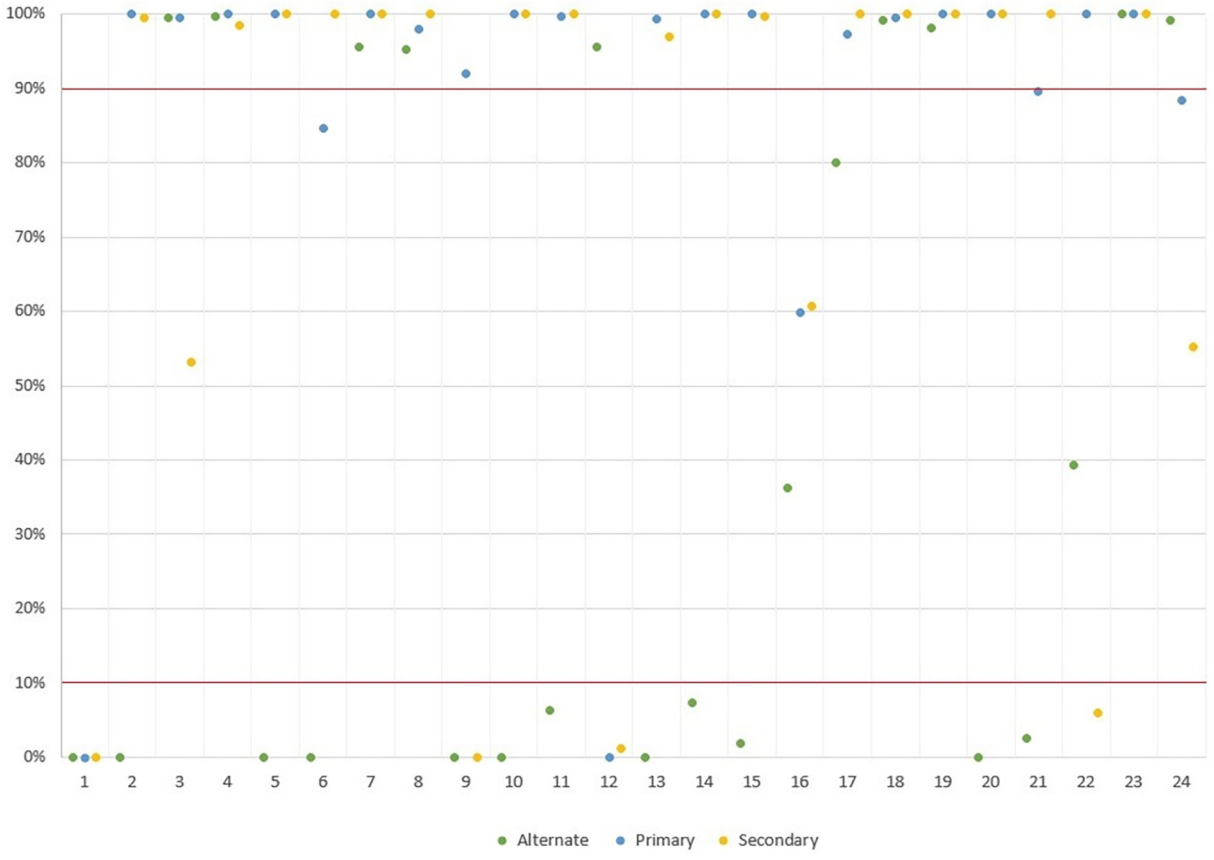
In one patient a vector score of around 100 was produced throughout the recording period. This borderline eligibility meant that minor variations in both R and T wave amplitudes caused the vector to alternate between eligible (>100) and ineligible (⟨100) numerous times during the period of analysis. [Fig. 6].

Finally, in one patient, large minute to minute fluctuations were seen in T wave amplitude, resulting in numerous variations in eligibility during the session. [Fig. 7] The magnitude of these changes did not appear to be consistent with a physiological change in T wave, and this was confirmed with a visual assessment of the raw ECG data. These findings were consistent with over-sensing due to movement artefact during the recording.

Discussion

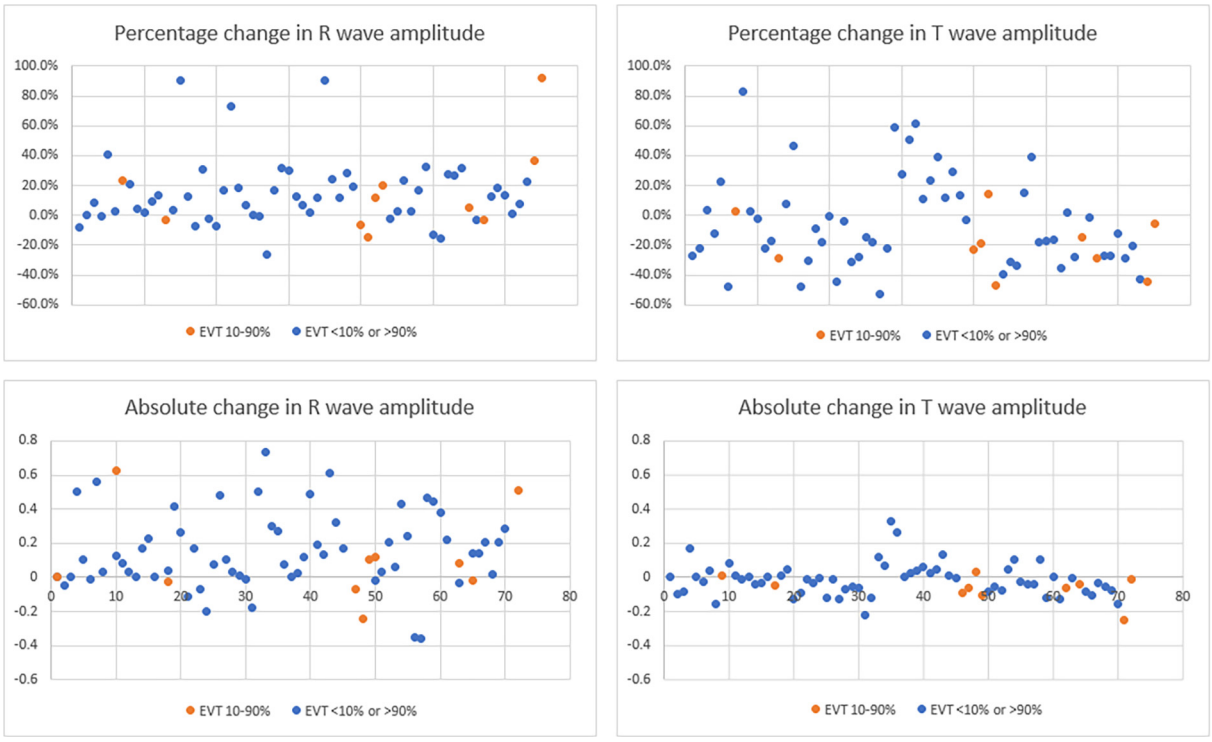
Variations in both R and T wave amplitude are expected during haemodialysis and several possible mechanisms have been previously described in the literature. The aim of this study was not to determine why these changes occur, but to calculate the potential impact that they have on S-ICD eligibility. This was achieved using a novel technique in which continuous S-ICD screening was performed using an S-ICD simulator, which also allowed for a detailed assessment of the individual ECG parameters that determine eligibility. This is unique as prior studies on S-ICD vectors have been limited to a handful of separate screening assessments and have only been able to report binary screening outcomes.

In this study we have demonstrated that R and T wave amplitude changes do occur, but that when expressed as either absolute values, or as a percentage change from baseline, the changes are not consistent. Across the studied cohort neither parameter increased nor decreased, by a statistically significant amount. Yet, despite this, we have been able to demonstrate that such changes may still impact significantly on S-ICD eligibility, with changes observed in 8.4% of analysed vectors.



X-axis: individual recruited patients (1-24), each of whom has three analysed vectors differentiated by colour. Y-axis: eligible vector time (%). Vectors between the two red horizontal lines represent those with high degrees of eligibility variation (EVT 10-90%).

Fig. 2. Eligible vector time.



In all four panels the x-axis represents the 72 individual vectors that were analysed, with highly variable vectors shown in orange. Left panels: changes in R wave amplitude. Right panels: changes in T wave amplitude. Top panels: amplitude changes expressed as a percentage change from the start of haemodialysis. Bottom panels: amplitude change from the start of haemodialysis in mV.

Fig. 3. Changes in R and T wave amplitude during haemodialysis.

S-ICD vector eligibility appears to be dynamic with some vectors having an inherent vulnerability to small changes in R or T wave amplitude. The eligibility of these vectors can be changed by a single haemodialysis session, even in patients with structurally normal hearts and a low prevalence of pre-existing ECG abnormalities. This is hypothesis generating but would of course need to be further demonstrated in a cohort meeting either primary or secondary prevention indications for an S-ICD.

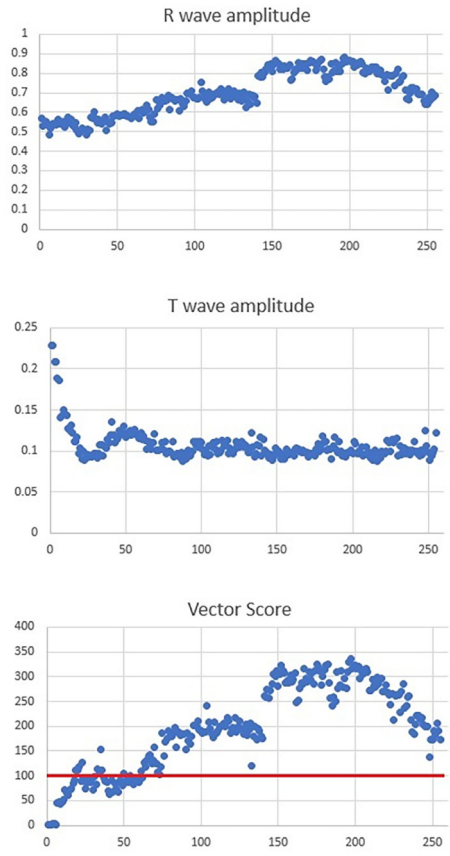
Importantly, the current S-ICD screening process, performed at a single moment in time, would be unable to identify vectors prone to this vulnerability. For patients on maintenance haemodialysis, our results suggest that vulnerable vectors are more accurately identified by screening prior to a haemodialysis session. In our cohort this would have successfully labelled all of the vulnerable vectors as inappropriate for clinical use. It would therefore be reasonable to adopt this approach in clinical practice, where manufacturer guidelines recommend a single vector screening assessment, with no indication as to when this should be performed within the dialysis cycle.

In the absence of a control group, it is unclear if the variability that we have observed in this cohort is due to the direct effect of haemodialysis. It may be that all S-ICD vectors display some variation in ECG parameter amplitudes and that vulnerable vectors might be identifiable in any patient cohort. Although, if this is the case, then the notion of vulnerable vectors has even greater clinical relevance, as they might impact on the entire population of S-ICD recipients.

Dynamic vector eligibility and the idea of vector vulnerability would certainly explain why cardiac over-sensing, the commonest cause of inappropriate shock therapies in the S-ICD population, can occur in vectors that have not only passed earlier screening, but continue to demonstrate appropriate sensing after the event. Although, we cannot be certain that variations in vector score necessarily convey a greater risk of inappropriate shock therapy, this relationship would need to be demonstrated clinically.

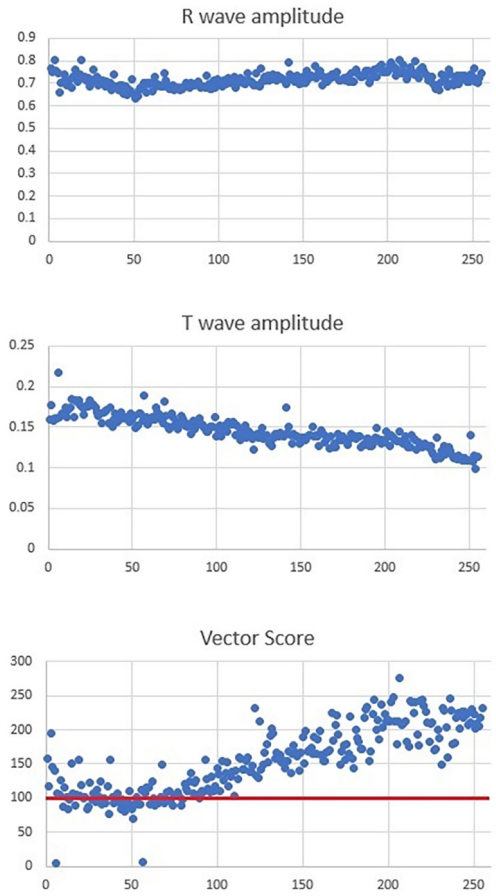
Further comparisons against a more typical ICD cohort, which would comprise a high percentage of patients with both structural heart disease and intrinsic conduction disease, is certainly warranted. Although, one might reasonably expect even greater degrees of variation in this group, with a higher prevalence of vector vulnerability.

Electrolyte levels taken pre and post dialysis may have added value to this study. Although, we do not believe that the overall findings would have been altered. It was never our intention to provide a comprehensive explanation for why R and T wave changes occur. Instead, we sought to quantity the degree of change and more importantly, the effect this has on S-ICD eligibility. Furthermore, electrolyte changes that are associated with haemodialysis are not necessarily immediate and electrolyte values immediately after dialysis values may have been misleading.



Findings from a single patient in the highly variable group. Top: R wave amplitude (mV) against time (minutes). Middle: T wave amplitude (mV) against time (minutes). Bottom: vector score against time (minutes), with the passing vector score (100) marked in red. In this example there is a progressive rise in R wave amplitude during dialysis whilst the T wave amplitude remains relatively consistent. This small increase (0.2 - 0.3mV) is associated with a favourable change in vector score.

Fig. 4. Gradual increase in R wave amplitude during haemodialysis.



Findings from a single patient in the highly variable group. Top: R wave amplitude (mV) against time (minutes). Middle: T wave amplitude (mV) against time (minutes). Bottom: vector score against time (minutes), with the passing vector score (100) marked in red. In this example there is a progressive fall in T wave amplitude whilst the R wave amplitude remains relatively consistent. This small decrease (0.05 mV) is associated with a favourable change in vector score.

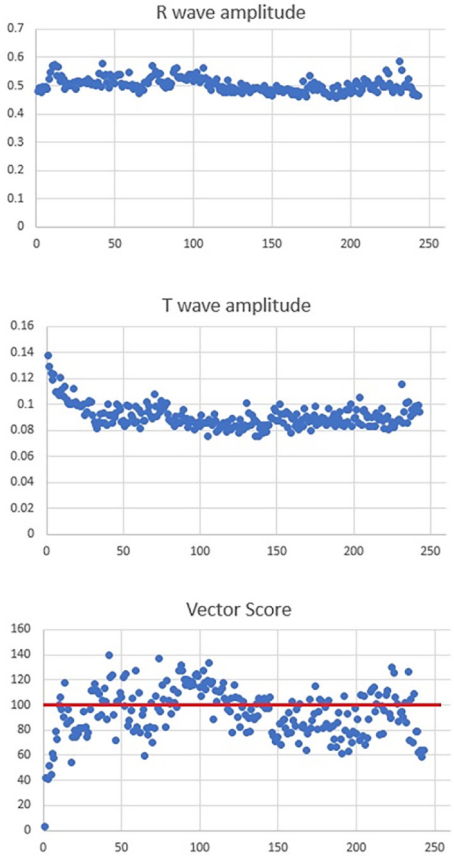
Fig. 5. Gradual decrease in T wave amplitude during haemodialysis.

An assessment of newer S-ICD sensing algorithms, i.e. SmartPass, would also have strengthened this work and provided a greater understanding of the clinical impact of the observed ECG changes in S-ICD recipients. This should be considered in further studies.

In clinical practice an individual's most favourable vector is selected for clinical use. As such, once could argue that there would be no relevant clinical risk should a given patient also have a second vector which might intermittently fail an eligible assessment, and that our findings should therefore have been analysed at a patient level, and not at a vector level. However, in clinical practice the most favourable vector is not always clear. Additionally, patients who have experienced inappropriate shocks whilst sensing from a certain vector, are often routinely switched to another passing vector on the balance of probabilities. As such, we felt that analysis by vector, and not by patient, was justifiable.

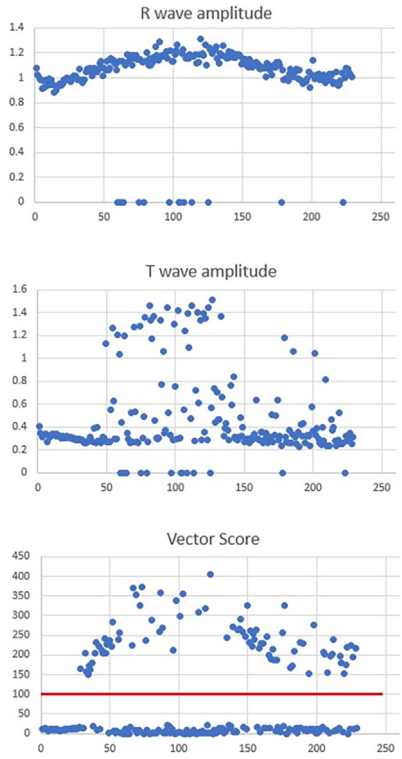
Conclusion

In a population of patients on maintenance haemodialysis, and with no requirement for S-ICD therapy, a single haemodialysis session was associated with a potential change in S-ICD vector eligibility in 8.4% of vectors. In this population, 12.5% of S-ICD vectors also showed high degrees of variation in eligibility during a haemodialysis session and this was most commonly associated with variations in R:T ratio. In an S-ICD population with similar characteristics, S-ICD screening prior to haemodialysis would be expected to more accurately identify vectors that retain eligibility during haemodialysis. Further work is needed to understand the true nature of vulnerable vectors, the impact they may have on inappropriate shock therapies, and how they could be identified prior to device implantation.



Findings from a single patient in the highly variable group. Top: R wave amplitude (mV) against time (minutes). Middle: T wave amplitude (mV) against time (minutes). Bottom: vector score against time (minutes), with the passing vector score (100) marked in red. In this example there is very subtle variation in both parameters, but this results in significant variation in vector score. This is an example of a borderline vector.

Fig. 6. Minimal changes in amplitude during haemodialysis.



Findings from a single patient in the highly variable group. Top: R wave amplitude (mV) against time (minutes). Middle: T wave amplitude (mV) against time (minutes). Bottom: vector score against time (minutes), with the passing vector score (100) marked in red. In this example there are non-physiological variations in T wave amplitude that are likely the result of over-sensing due to artefact.

Fig. 7. Significant minute by minute T wave changes.

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Ethical approval

Ethical approval was obtained from the Health Regulatory Authority, United Kingdom.

Author contributions

BW, JM, AK, and PR were responsible for the study concept and design. BW, VA and ME were responsible for data collection and analysis. BW and ME were responsible for drafting the article. All of the authors were responsible for critical revisions of the article and all of the authors have approved the final content.

Declaration of Competing Interest

The authors would like to declare the following potential conflicts of interest: Benedict M Wiles has received an unrestricted research grant and consultancy payments from Boston Scientific. Venugopal Allavatam and John M Morgan are current employees of Boston Scientific. Paul R Roberts receives consultancy and advisory board payments from both Medtronic and Boston Scientific. No other conflicts of interest are declared.

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