Journal of Interventional Cardiac Electrophysiology (2019) 54:65–72
https://doi.org/10.1007/s10840-018-0443-y

Single and dual coil shock efficacy and predictors of shock failure in patients with modern implantable cardioverter defibrillators—a single-center paired randomized study

Jacob Moesgaard Larsen [1] · Finn P. Heath [1] · Sam Riahi [1,2] · Katja Holm [1] · Martin B. Johansen [1] · Søren P. Hjortshøj [1,2] · Anna M. Thøgersen [1]

Received: 24 June 2018 / Accepted: 6 September 2018 / Published online: 18 September 2018

Abstract

Purpose Implantable cardioverter defibrillators (ICDs) can treat life-threatening tachyarrhythmia with high-voltage shocks. The aims were to compare the efficacy of single and dual coil shock vectors in modern ICDs and to identify predictors of shock failure.

Methods This is a single-center paired randomized study including 216 patients with mixed indications and ICDs from four manufacturers. All patients underwent two implant defibrillation tests using single and dual coil vectors with the test order randomized. Tested shock energy differed slightly between manufacturers because of differences in device programmability: first shock approximately 15 J below maximal output—if failed, second shock approximately 10 J below maximal output—if failed, third shock at maximal output.

Results First shock success rate was 399/432 (92.4%). Comparing single and dual coil vectors, no differences were seen in first shock efficacy (91.7% vs. 93.1%, $P = 0.629$) or lowest tested succesfully stored energy (27.2 J vs. 27.1 J, $P = 0.620$). All successive internal shocks failed in 4/432 (0.9%) of inductions requiring external rescue shocks to restore circulation. Multivariate predictors of first shock failure were QRS duration (relative risk 0.81 per 10 ms, $P = 0.001$), amiodarone treatment (relative risk 3.30, $P = 0.003$), and body height (relative risk 1.70 per 10 cm, $P = 0.019$).

Conclusions Implant defibrillation testing of modern intravenous ICD systems demonstrates high shock efficacy with no difference between single and dual coil vectors.

Keywords Implantable cardioverter defibrillator · Defibrillation · Shock efficacy · Leads · Coil

1 Introduction

The prevention of sudden cardiac death with implantable cardioverter defibrillators (ICDs) is standard of care in high-risk patients [1, 2]. ICDs deliver high-voltage shocks between a distal right ventricular coil and the generator shell (single coil vector) and, if a dual coil lead is implanted, an optional proximal coil in the superior vena cava (dual coil vector). Shock efficacy can be evaluated by inducing ventricular fibrillation and delivery of submaximal shocks to estimate the defibrillation threshold (DFT) [3].

In the last two decades, several randomized studies with small sample sizes have demonstrated no differences [4–6] or marginally lower [7–11] implant DFTs using dual coil vectors with right ventricular apical lead position and, in most studies, with reversed polarity. This does not represent current clinical practice with more common non-apical lead placements [12] and for most manufacturers standard shock polarity with the distal coil as anode [13]. In the majority of non-randomized studies, the shock vector has not been associated with shock efficacy in spontaneous arrhythmias [14, 15], but a substudy of the Nordic ICD trial has suggested a possible higher clinical shock success with dual coil leads [16]. A recent metaanalysis combining data from randomized and non-randomized studies has demonstrated a marginally lower implant DFT with dual coil vector but no difference in clinical shock efficacy [17]. This is in line with the rise in clinical preference of single coil

✉ Jacob Moesgaard Larsen
jaml@rn.dk

[1] Department of Cardiology, Aalborg University Hospital, Hobrovej 18-22, PO Box 365, 9000 Aalborg, Denmark

[2] Department of Clinical Medicine, Aalborg University, Aalborg, Denmark

ICD leads [12, 14], which are considered easier and safer to extract in case of lead failure or device infection [18].

The SIMPLE and Nordic ICD trials have demonstrated no impact of defibrillation testing on clinical shock efficacy and mortality [19, 20]. However, small subsets of patients with increased risk of higher DFTs were excluded or sparsely represented e.g., right-sided implants and hypertrophic cardiomyopathy. The value of defibrillation testing in these patients is uncertain.

The aims of the present study were to compare shock efficacy of single and dual coil vectors in unselected patients with high-output ICDs and to identify predictors of shock failure.

2 Methods

2.1 Study design

This is a single-center paired, randomized clinical study with patients being their own controls.

2.2 Study population

All consecutive patients ≥ 18 years of age with an ICD indication from 2011 to 2015 at the Department of Cardiology at Aalborg University Hospital in Denmark were eligible to enter the study. They had to be able to understand the oral and written study information and sign a study consent form. Patients with unstable hemodynamics and patients in which sustained ventricular fibrillation was not obtained during DFT testing were excluded.

2.3 ICD implant and defibrillation testing

The devices were implanted by five experienced electrophysiologists with local anesthetic and, if needed, intravenous sedation. The choices of generator and lead manufacturer (Biotronik, Boston Scientific, Medtronic, or Abbot), implant site (left or right pectoral), venous access (cephalic or subclavian vein), lead tip position (low apical, mid septal, high septal), and proximal coil position (low = > ½ coil in right atrium, mid, high = > ½ coil in innominate vein) were at the discretion of the implanting physician. Lead positions were validated by chest X-ray evaluation by two investigators. Dual coil transvenous active fixation leads were implanted in all patients. The implant procedure was completed in general anesthesia with two inductions of sustained ventricular fibrillation and shock delivery with single and dual coil shock vectors with distal coil as anode with 5 min separation to ensure hemodynamic stability. The testing order between single coil first and dual coil first was randomized by alternating assignment to ensure an unbiased comparison of the shock efficacy. The applied shock energy differed slightly between manufacturers because of differences in device programmability. The testing series for devices from Biotronik (stored energy programmable), Boston Scientific (stored energy programmable), and Medtronic (delivered energy programmable) were as follows: first shock 15 J below maximal output—if failed, second shock 10 J below maximal output—if failed, third shock at maximal output. The testing series for Abbot ICDs (stored voltage programmable and "tuned wave form" with high-voltage impedance adjusted pulse wave duration) were as follows: first shock stored voltage 700 V—if failed, second shock stored voltage 800 V—if failed, third shock at maximal stored voltage 875–890 V. If all internal shocks were unsuccesful, external 200 J biphasic rescue shocks were immediately delivered. The applied level of the first submaximal shock energy was to ensure an appropriate single shock test to confirm a clinically acceptable safety margin between the DFT and maximal output [3].

2.4 Endpoints

The primary endpoint was *first shock failure* i.e., no successful conversion of ventricular fibrillation. The secondary endpoint was *lowest tested succesfully stored energy* as a rough estimate of DFT. Lowest tested delivered shock energy was not considered a valid study endpoint as the large difference in shock impedance between single coil (high) and dual coil (low) configuration at a given stored capacitor energy would result in lower delivered energy with single coil in Abbot devices with high-voltage lead adjusted pulse duration i.e., "tuned waveforms" [11].

2.5 Statistical analysis

The statistical analysis was performed using Stata Statistical Software 13.1 (StataCorp, College Station, TX). P values < 0.05 were considered statistically significant. The randomization was evaluated by testing the differences in the baseline characteristics with non-paired t test (normally distributed variables), Mann-Whitney test (non-normally distributed variables), and Fisher's exact test (dichotomous variables). First shock efficacy was analyzed using McNemar's test for paired data. Continuous variables were analyzed using paired t test. Subanalyses included type of waveform and positions of generator, lead tip, and proximal coil. Univariable predictors of first shock failure were analyzed using modified Poisson regression with robust variance to estimate relative risk (RR) [21]. Explorative multivariable Poisson regression with automatic forward selection was made with an inclusion significance level of 0.05.

2.6 Power calculation

To obtain a probability of type 1 error of 0.05, a power of 0.80 and assuming first shock failure proportions in the two groups of 0.02 and 0.08 required a sample size of 216 patients. To obtain a probability of type 1 error of 0.05, a power of 0.80 and assuming a 2.5 J difference in lowest tested successfully stored energy and a standard deviation of 5 J required a sample size of 63 patients.

2.7 Ethical considerations

The use of implant defibrillation testing has for many years been the recommended clinical practice with a low risk of severe major complications [22]. Only patients with stable hemodynamics were included to reduce patient risk. All patients signed an informed consent form after thorough oral and written information. The study protocol was approved by the local science ethics committee of the North Denmark Region (N-20110038) and the Danish Data Protection Agency (2008-58-0028).

3 Results

3.1 Patient and device characteristics

Two hundred eighteen patients accepted to participate, but two patients were excluded as induction of sustained ventricular fibrillation was not successful. The characteristics of the included 216 patients and their devices are seen in Table 1. The patients were mostly men (83.3%), with ischemic heart disease (61.6%), secondary prophylactic indication (54.2%), and left pectoral implants (95.8%) with the defibrillator lead tip in a non-apical right ventricular position (83.4%) and the proximal coil in mid position (73.0%) between the right atrium and the innominate vein. No differences were seen but a slightly lower body height (175 cm vs. 178 cm, $P = 0.014$) and a higher use of beta blockers (86.8% vs. 75.5%. $P = 0.034$) in patients randomized to first shock with single coil vector.

3.2 Shock efficacy and lowest tested successful shock energy

The 216 patients underwent 432 inductions of sustained ventricular fibrillation with an overall first shock success rate of 399/432 (92.4%). Comparing single and dual coil shock vectors, there were no differences in first shock efficacy (91.7% vs. 93.1%, $P = 0.629$) and lowest tested succesfully stored energy (27.2 J vs. 27.1 J, $P = 0.620$) (Table 2). No differences were observed in first shock efficacy and lowest successfully stored energy between single and dual coil vectors in all ten tested subgroups i.e., type of waveform and positions of generator, lead tip, and proximal coil. However, the lowest tested succesfully delivered shock energy was significantly lower using single coil vector (mean difference 0.9 J, $P < 0.001$), and subgroup analysis showed that this finding was driven by the Abbot devices with "tuned wave form" (mean difference 1.7 J, $P < 0.001$) and not devices from other manufacturers (mean difference − 0.3 J, $P = 0.394$). The shock impedance was significantly higher using single coil vector (68.6 Ω vs. 42.7 Ω, $P < 0.001$).

In four inductions, the three internal shocks failed to defibrillate the patients requiring an external rescue shock (Fig. 1):

- A 67-year-old male with a right-sided pectoral implant, low apical lead position, proximal coil in mid position between right atrium and innominate vein, ischemic heart disease, left ventricular ejection fraction 20%, and amiodarone treatment. All single coil shocks failed. Only the final 40 J dual coil shock was successful.
- A 54-year-old male with left-sided pectoral implant, low apical lead position, proximal coil in mid position between right atrium and innominate vein, non-ischemic dilated cardiomyopathy, left ventricular ejection fraction 50%, and left ventricular end-diastolic diameter 7 cm. All dual coil shocks failed. The first 20 J single coil shock was successful.
- A 23-year-old male with left-sided pectoral implant, mid septal lead position, proximal coil in high position in the innominate vein, Danon's disease with hypertrophic cardiomyopathy with left ventricular wall thickness 20 mm and ejection fraction 60%. All internal single coil and dual coil shock failed. A subcutaneous shock coil was implanted with one final successful 30 J shock.

3.3 Predictors of first shock failure at submaximal implant defibrillation test

There were several univariable predictors of first shock failure as seen in Table 3 i.e., lower age, increasing body height, arrhythmogenic right ventricular cardiomyopathy, shorter QRS duration, low apical lead position, and treatment with amiodarone. There was only a weak trend for lower shock impedance being a predictor of shock failure ($P = 0.086$). Multivariable predictors of first shock failure were shorter QRS duration with adjusted RR 0.81 (0.71–0.92) per 10 ms, $P = 0.001$, amiodarone treatment with adjusted RR 3.28 (1.49–7.22), $P = 0.003$, and increasing body height with adjusted RR 1.70 (1.09–2.65) per 10 cm, $P = 0.019$.

Table 1 Patient and device characteristics

	All ($n = 216$)	Single coil first ($n = 106$)	Dual coil first ($n = 110$)	P value
Age, years	65 (54–70)	66 (57–70)	63 (52–71)	0.281
Male, *n* (%)	180 (83.3)	87 (82.1)	93 (84.5)	0.626
Height, cm	176 (170–182)	175 (169–181)	178 (172–184)	0.014
Weight, kg	84 (75–94)	83 (75–95)	84 (76–92)	0.936
Body mass index, kg/m^2	27.1 (24.1–30.0)	27.8 (24.2–30.8)	26.6 (24.0–29.2)	0.106
Primary prophylaxis, *n* (%)	99 (45.8)	49 (46.2)	50 (45.5)	0.909
Implant diagnosis, *n* (%)				0.126
Ischemic heart disease	133 (61.6)	74 (69.8)	59 (53.6)	
DCM	26 (12.0)	9 (8.5)	17 (15.5)	
HCM	10 (4.6)	5 (4.7)	5 (4.5)	
ARVC	8 (3.7)	3 (2.8)	5 (4.5)	
Other	39 (18.1)	15 (14.2)	24 (21.8)	
QRS duration, ms	116 (96–140)	114 (97–135)	118 (95–146)	0.594
NYHA-class, *n* (%)				0.638
I	80 (37.0)	36 (34.0)	44 (40.0)	
II	92 (42.6)	48 (45.3)	44 (40.0)	
III	44 (20.4)	22 (20.8)	22 (20.0)	
LVEF, %	35 (25–50)	35 (30–50)	31 (25–50)	0.628
eGFR, mL/min/1.73m^2	70 (56–85)	70 (55–83)	71 (58–88)	0.275
Beta blockers, *n* (%)	175 (81.0)	92 (86.8)	83 (75.5)	0.034
Amiodarone, *n* (%)	31 (14.4)	19 (17.9)	12 (10.9)	0.142
Left pectoral implant, *n* (%)	207 (95.8)	102 (96.2)	105 (95.5)	0.777
Generator manufacturer, *n* (%)				0.874
Biotronik	21 (9.7)	11 (10.4)	10 (9.1)	
Boston Scientific	13 (6.0)	5 (4.7)	8 (7.3)	
Medtronic	45 (20.8)	22 (20.8)	23 (20.9)	
Abbot	137 (63.4)	68 (64.2)	69 (62.7)	
Lead tip position, *n* (%)*				0.312
Low apical	35 (16.6)	16 (15.7)	19 (17.4)	
Mid septal	96 (45.5)	42 (41.2)	54 (49.5)	
High septal	80 (37.9)	44 (43.1)	36 (33.0)	
Proximal coil position, *n* (%)*				0.988
Low right atrium	12 (5.7)	6 (5.9)	6 (5.5)	
Mid SVC	154 (73.0)	74 (72.5)	80 (73.4)	
High innominate vein	45 (21.3)	22 (21.6)	23 (21.1)	

Continuous variables are displayed as medians with interquartile range. *ARVC* arrhythmogenic right ventricular cardiomyopathy; *DCM* dilated cardiomyopathy; *eGFR* glomerular filtration rate estimated from creatinine, age, and sex; *HCM* hypertrophic cardiomyopathy; *LVEF* left ventricular ejection fraction; *SVC* superior vena cava. *Missing X-ray data on five patients for validation of lead tip and coil position

4 Discussion

The best shock vector for use in modern high-output ICDs and hence type of defibrillator lead is not settled, and knowledge about the impact of different shock vectors is imperative as systematic defibrillation testing has been widely abandoned. The present study is the largest randomized study to investigate differences in shock efficacy between single and dual coil vectors. The unselected study population reflects current clinical practice with a mix of modern devices from four major manufacturers with a high rate of non-apical lead position. The main findings were a high overall submaximal shock success of 92.4% with no significant differences between single and dual coil vectors and no differences in lowest tested succesfully stored shock energy. Multivariable predictors of first shock failure were shorter QRS duration, amiodarone treatment, and increasing body height. A minor subset of patients had repetitive internal shock failures requiring external rescue shocks.

Table 2 Implant defibrillation testing with single coil and dual coil shock vectors

	Single coil test	Dual coil test	*P* value
All ($n = 216$)			
First shock success, *n* (%)	198 (91.7)	201 (93.1)	0.629
Lowest stored energy, mean J (SD)	27.2 (3.8)	27.1 (3.8)	0.620
Lowest delivered, mean J (SD)	22.5 (3.0)	23.5 (3.1)	< 0.001
Shock impedance, mean Ω (SD)	68.6 (13.3)	42.7 (6.4)	< 0.001
Subgroup analysis—first shock efficacy, *n* (%)			
Tuned waveform: Abbot ($n = 137$)	128 (93.4)	129 (94.2)	1.0
Fixed tilt waveform: BIO, BSC, and MDT ($n = 79$)	70 (88.6)	72 (91.1)	0.727
Left-sided implant ($n = 207$)	190 (91.8)	193 (93.2)	0.629
Right-sided implant ($n = 9$)	8 (88.9)	8 (88.9)	1.0
Lead tip position*			
Low apical ($n = 35$)	31 (88.6)	29 (82.3)	0.500
Mid septal ($n = 96$)	91 (94.8)	92 (95.8)	1.0
High septal ($n = 80$)	71 (88.8)	75 (93.8)	0.344
Proximal coil position*			
Low right atrium ($n = 12$)	10 (83.3)	11 (91.7)	1.0
Mid SVC ($n = 154$)	143 (92.9)	144 (93.5)	1.0
High innominate vein ($n = 45$)	40 (88.9)	41 (91.1)	1.0
Subgroup analysis—lowest stored energy, mean J (SD)			
Tuned waveform: Abbot ($n = 137$)	28.4 (2.7)	28.4 (3.1)	0.820
Fixed tilt waveform: BIO, BSC, and MDT ($n = 79$)	25.1 (4.5)	24.7 (3.7)	0.312
Left-sided implant ($n = 207$)	27.1 (3.7)	27.0 (3.8)	0.620
Right-sided implant ($n = 9$)	28.4 (4.8)	28.4 (4.8)	1.0
Lead tip position*			
Low apical ($n = 35$)	27.6 (5.2)	28.3 (5.6)	0.33
Mid septal ($n = 96$)	26.9 (3.7)	26.7 (3.4)	0.468
High septal ($n = 80$)	27.4 (3.3)	27.0 (3.3)	0.380
Proximal coil position*			
Low right atrium ($n = 12$)	28.9 (3.8)	28.2 (3.0)	0.339
Mid SVC ($n = 154$)	27.0 (3.7)	27.0 (4.0)	0.982
High innominate vein ($n = 45$)	27.4 (4.3)	27.0 (3.4)	0.225

Results are based on 432 implant defibrillation tests in 216 patients. *BIO* Biotronik, *BSC* Boston Scientific, *MDT* Medtronic, *SD* standard deviation. *Missing X-ray data on five patients for validation of lead tip and coil position

4.1 Shock efficacy using single and dual coil vectors

In the early ICD era from 1994 to 2004, seven small randomized studies have demonstrated numerically lower (0.1–2.7 J) DFTs using dual coil vectors and apical lead positions [4–10]. The findings were only statistically significant in four of the studies [7–10]. In 2008, a larger randomized study by Gold and coworkers with 113 patients using Abbot devices, with shock impedance adjusted pulse wave duration and apical lead position, demonstrated only a 0.4 J lower DFT using dual coil vectors [11]. The mean DFTs of all studies were close to 10 J stored energy giving abundant mean safety margins in perspective of the high maximal stored energy of modern ICDs of 40–45 J. This is in line with the finding of no differences in shock efficacy in spontaneous arrhythmias in most non-randomized studies comparing single and dual coil leads [14, 15]. However, a substudy of the ICD-arm of the Nordic ICD trial did find an association between single coil lead and a higher risk of clinical shock failure, but this finding may be explained by residual confounding, and the authors have suggested new larger randomized trials including longterm outcomes [16]. A recent metaanalysis combining data from 18 randomized and non-randomized studies from the last two decades demonstrated a marginally lower implant DFT with dual coil vector but no difference in clinical shock efficacy [17]. Conversely, this study also demonstrated a higher all-cause mortality in patients with dual coil leads based on subanalysis of the non-randomized observational data most likely because of confounding by indication. In the present randomized study, no differences were observed in shock

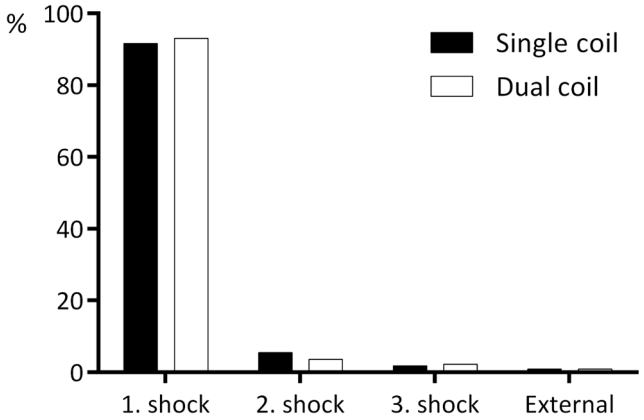

Fig. 1 Shock success at implant defibrillation test. The figure displays the proportion of successful shock at implant defibrillation testing with single and dual coil shock vectors. Testing protocol for each shock vector: first shock approximately 15 J below maximal output—if unsuccessful, second shock approximately 10 J below maximal output—if unsuccessful, third shock at maximal output—if unsuccessful, external defibrillation. $N = 216$ patients with a total of 432 inductions of ventricular fibrillation

efficacy at submaximal shock test and lowest tested succesfully stored shock energy regardless of device manufacturer and position of generator and lead (Fig. 1 and Table 2). On the other hand, the lowest tested successfully delivered shock energy was as expected 0.9 J higher in dual coil leads ($P < 0.001$). This finding was driven by the Abbot devices with shock impedance adjusted pulse wave duration, which, at a given stored energy, will deliver a slightly lower shock energy at higher shock impedance, as seen with single coil systems, due to truncation of the fixed tilt wave form [11].

The present randomized study emphasizes that shock efficacy in modern ICDs is high for both single and dual coil systems irrespective of manufacturer and generator and lead positions. However, dual coil leads are known to be more difficult and hazardous to extract due to fibrotic adherence of the proximal coil to the vessel wall of the superior vena cava [18, 23], but in newer lead generations, these adhesions are reduced by treating the coils with silicone backfilling or a Gore-Tex cover [24]. We suggest that single coil leads should be considered first choice in routine implants, especially in younger patients with a higher cumulative risk of future lead extraction. This is in line with the rise in single coil lead use in recent years [12, 14], where device communities still struggle with the repercussions of the major defibrillator lead recalls i.e., Sprint Fidelis (Medtronic) and Riata (St. Jude Medical).

4.2 Is implant defibrillation testing obsolete in all patients?

Implant defibrillation testing is performed to check the integrity of the ICD-system, sensing of ventricular fibrillation, and shock efficacy. Defibrillation is a probabilistic phenomenon, and a successful shock approximately 15 J below maximal output indicates a low risk of clinical shock failure at maximal output [3]. Defibrillation testing has a low rate of life-

Table 3 Predictors of first shock failure at submaximal implant defibrillation test

	Relative risk (95% CI)	*P* value
Univariable analysis		
Age, years/10	0.72 (0.57–0.90)	0.004
Male	1.45 (0.35–5.94)	0.606
Height, cm/10	1.87 (1.17–3.01)	0.009
Weight, kg/10	1.06 (0.81–1.38)	0.679
Body mass index, kg/m^2	0.95 (0.86–1.05)	0.293
Secondary prophylaxis	1.48 (0.63–3.45)	0.364
Implant diagnosis		0.018
IHD (ref.)	1 (ref.)	
DCM	1.20 (0.34–4.32)	
HCM	1.56 (0.22–11.00)	
ARVC	4.89 (1.86–12.82)	
Other	1.00 (0.37–2.73)	
QRS duration, ms/10	0.81 (0.71–0.92)	0.002
NYHA-class, I-III	0.68 (0.39–1.20)	0.183
LVEF, %/10	1.12 (0.85–1.47)	0.432
eGFR, mL/min/1.73m^2/100	1.09 (0.98–1.21)	0.101
Beta blockers	0.62 (0.26–1.48)	0.285
Amiodarone	2.98 (1.33–6.69)	0.008
Left pectoral implant	0.67 (0.10–4.49)	0.683
Tuned waveform (Abbot)	0.61 (0.28–1.35)	0.222
Dual coil vector	0.83 (0.51–1.36)	0.469
Second shock test	0.94 (0.58–1.54)	0.809
Shock impedance, Ohm/10	0.84 (0.69–1.02)	0.086
Lead tip position		0.127
Low apical	3.05 (1.04–8.96)	
Mid septal (ref.)	1 (ref.)	
High septal	1.87 (0.73–4.78)	
Proximal coil position		0.564
Low right atrium	1.83 (0.44–7.68)	
Mid SVC (ref.)	1 (ref.)	
High innominate vein	1.47 (0.58–3.70)	
Multivariable analysis		
Height, cm/10	1.70 (1.09–2.65)	0.019
QRS duration, ms/10	0.81 (0.71–0.92)	0.001
Amiodarone	3.30 (1.50–7.27)	0.003

Results are based on 432 implant defibrillation tests in 216 patients. The table displays the relative risk of first shock failure at defibrillation test with a submaximal shock of approximately 15 J below maximal output with 95% confidence intervals and *P* values for the univariable (top) and multivariable (bottom) Poisson regressions. *ARVC* arrhythmogenic right ventricular cardiomyopathy, *CI* confidence interval, *DCM* dilated cardiomyopathy, *HCM* hypertrophic cardiomyopathy, *eGFR* calculated glomerular filtration rate, *IHD* ischemic heart disease, *LVEF* left ventricular ejection fraction, *NYHA* New York Heart Association functional class, *Ref.* reference group, *SVC* superior vena cava

threatening complications [22], and it has been a compulsory step in all major trials that demonstrate survival benefit of ICD treatment. In 2015, the SIMPLE trial and Nordic ICD trial have demonstrated no impact of implant defibrillation testing on shock efficacy and mortality [19, 20]. However, both studies excluded patients ≤ 18 years, expected right-sided implants, severe heart failure on waiting list for a heart transplant, and replacements/upgrades. Furthermore, patients with hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, and severe renal failure were excluded from the Nordic ICD trial. Hence, safety data on implantation without defibrillation testing are sparse in these subsets of patients. The reason for excluding the patients has most likely been possible association to higher DFTs, but studies on predictors of high DFTs have shown conflicting results undoubtedly due to differences in included explanatory variables in the statistical models and differences in the definitions of high DFT and testing protocols. However, some of the more consistent findings have been higher risk with amiodarone treatment [25–28] and right-sided implants [27]. Other suggested predictors are left ventricular dilatation [28], non-ischemic etiology, replacement/upgrade, and younger age [26]. The multivariable predictors of submaximal first shock failure in the present study (Table 3) are shorter QRS duration, amiodarone treatment, and increasing body height. The shorter QRS duration and increasing body height may be proxies for young age and subtypes of the non-ischemic etiologies. The three patients in the present study with failure of all internal shocks with single and/or dual coil vectors were all characterized by known suggested predictors of high DFT. This emphasizes the need for careful consideration before extrapolating the results of the SIMPLE and Nordic ICD trials to smaller subsets of patients with known risk of high DFT. This caution is also highlighted in the 2015 worldwide consensus statement on ICD programming and testing [29] in which implant defibrillation testing is considered reasonable in patients with cardiomyopathies, channelopathies, at generator replacement, at right-sided implants, and in case of question of the adequacy of the lead position or function.

When encountering high DFTs, various actions can be taken to improve shock efficacy e.g., reversing polarity, changing pulse waveform, and changing lead position. Most efficient is to implant a subcutaneous shock coil in the lateral left pectoral area, which can dramatically reduce the DFT [28, 30]. This was also seen in the present study in the patient with failure of all internal shocks with both single and dual coil configuration.

4.3 Limitations

This was a single-center paired randomized study with the patients being their own controls reducing the risk of confounding. The statistical power of the predefined subgroup analysis was underpowered and should be interpreted with caution due to risk of type 2 error. The use of automatic forward selection increased the risk of type 1 error, and the low event count only allowed inclusion of a limited number of variables in the model. Hence, the multivariable predictor analysis was considered explorative.

5 Conclusions

Implant defibrillation testing of modern intravenous ICD systems demonstrates high shock efficacy with no difference between single and dual coil vectors. Our data suggest that single coil leads should be considered first choice in routine implants, especially in younger patients with a higher cumulative risk of future lead extraction.

Acknowledgements We thank senior biostatistician Søren Lundbye-Christensen for help planning the statistical analysis and research nurses Charlotte Schmidt Skov, Kasper Villefrance and Pauline Gøgsig Johansen for making completion of the study feasible. The study is dedicated to our deceased colleague, consultant cardiologist Ole Eschen PhD, who was a key investigator.

Funding The study was funded by the Department of Cardiology at Aalborg University Hospital, Aalborg, Denmark.

Compliance with ethical standards

The study protocol was approved by the local science ethics committee of the North Denmark Region (N-20110038) and the Danish Data Protection Agency (2008-58-0028).

References

1. Nanthakumar K, Epstein AE, Kay GN, Plumb VJ, Lee DS. Prophylactic implantable cardioverter-defibrillator therapy in patients with left ventricular systolic dysfunction: a pooled analysis of 10 primary prevention trials. J Am Coll Cardiol. 2004;44:2166–72.
2. Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, et al. Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. AVID, CASH and CIDS studies. Eur Heart J. 2000;21:2071–8.
3. Gold MR, et al. Safety of a single successful conversion of ventricular fibrillation before the implantation of cardioverter defibrillators. Pacing Clin Electrophysiol. 2003;26:483–6.
4. Bardy GH, Dolack GL, Kudenchuk PJ, Poole JE, Mehra R, Johnson G. Prospective, randomized comparison in humans of a unipolar defibrillation system with that using an additional superior vena cava electrode. Circulation. 1994;89:1090–3.
5. Schulte B, Sperzel J, Carlsson J, Schwarz T, Ehrlich W, Pitschner HF, et al. Dual-coil vs single-coil active pectoral implantable defibrillator lead systems: defibrillation energy requirements and probability of defibrillation success at multiples of the defibrillation energy requirements. Europace. 2001;3:177–80.
6. Rinaldi CA, et al. A randomized prospective study of single coil versus dual coil defibrillation in patients with ventricular

arrhythmias undergoing implantable cardioverter defibrillator therapy. Pacing Clin Electrophysiol. 2003;26:1684–90.
7. Gold MR, Foster AH, Shorofsky SR. Lead system optimization for transvenous defibrillation. Am J Cardiol. 1997;80:1163–7.
8. Gold MR, Olsovsky MR, Pelini MA, Peters RW, Shorofsky SR. Comparison of single- and dual-coil active pectoral defibrillation lead systems. J Am Coll Cardiol. 1998;31:1391–4.
9. Gold MR, et al. Optimization of transvenous coil position for active can defibrillation thresholds. J Cardiovasc Electrophysiol. 2000;11:25–9.
10. Libero L, Lozano IF, Bocchiardo M, Marcolongo M, Sallusti L, Madrid A, et al. Comparison of defibrillation thresholds using monodirectional electrical vector versus bidirectional electrical vector. Ital Heart J. 2001;2:449–55.
11. Gold M, Val-Mejias J, Leman RB, Tummala R, Goyal S, Kluger J, et al. Optimization of superior vena cava coil position and usage for transvenous defibrillation. Heart Rhythm. 2008;5:394–9.
12. Bongiorni MG, Proclemer A, Dobreanu D, Marinskis G, Pison L, Blomstrom-Lundqvist C, et al. Preferred tools and techniques for implantation of cardiac electronic devices in Europe: results of the European Heart Rhythm Association survey. Europace. 2013;15:1664–8.
13. Baccillieri MS, Gasparini G, Benacchio L, Zorzi A, Marras E, Zerbo F, et al. Multicentre comparison of shock efficacy using single-vs. dual-coil lead systems and anodal vs. cathodaL polarITY defibrillation in patients undergoing transvenous cardioverter-defibrillator implantation. The MODALITY study. J Interv Card Electrophysiol. 2015;43:45–54.
14. Hsu JC, Saxon LA, Jones PW, Wehrenberg S, Marcus GM. Utilization trends and clinical outcomes in patients implanted with a single- vs a dual-coil implantable cardioverter-defibrillator lead: insights from the ALTITUDE study. Heart Rhythm. 2015;12:1770–5.
15. Larsen JM, Hjortshøj SP, Nielsen JC, Johansen JB, Petersen HH, Haarbo J, et al. Single-coil and dual-coil defibrillator leads and association with clinical outcomes in a complete Danish nationwide ICD cohort. Heart Rhythm. 2016;13:706–12.
16. Bansch D, et al. Shock efficacy of single and dual coil electrodes-new insights from the NORDIC ICD trial. Europace. 2017;20:971–8.
17. Sunderland N, et al. Outcomes with single-coil versus dual coil implantable cardioverter defibrillators: a meta-analysis. Europace. 2018;20:e21–9. https://doi.org/10.1093/europace/euw438.
18. Epstein LM, Love CJ, Wilkoff BL, Chung MK, Hackler JW, Bongiorni MG, et al. Superior vena cava defibrillator coils make transvenous lead extraction more challenging and riskier. J Am Coll Cardiol. 2013;61:987–9.
19. Healey JS, Hohnloser SH, Glikson M, Neuzner J, Mabo P, Vinolas X, et al. Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). Lancet. 2015;385:785–91.
20. Bansch D, et al. Intra-operative defibrillation testing and clinical shock efficacy in patients with implantable cardioverter-defibrillators: the NORDIC ICD randomized clinical trial. Eur Heart J. 2015;36:2500–7.
21. Zou G. A modified poisson regression approach to prospective studies with binary data. Am J Epidemiol. 2004;159:702–6.
22. Birnie D, Tung S, Simpson C, Crystal E, Exner D, Ayala Paredes FA, et al. Complications associated with defibrillation threshold testing: the Canadian experience. Heart Rhythm. 2008;5:387–90.
23. Segreti L, di Cori A, Soldati E, Zucchelli G, Viani S, Paperini L, et al. Major predictors of fibrous adherences in transvenous implantable cardioverter-defibrillator lead extraction. Heart Rhythm. 2014;11:2196–201.
24. Di Cori A, et al. Transvenous extraction performance of expanded polytetrafluoroethylene covered ICD leads in comparison to traditional ICD leads in humans. Pacing Clin Electrophysiol. 2010;33:1376–81.
25. Shukla HH, et al. High defibrillation thresholds in transvenous biphasic implantable defibrillators: clinical predictors and prognostic implications. Pacing Clin Electrophysiol. 2003;26:44–8.
26. Russo AM, Sauer W, Gerstenfeld EP, Hsia HH, Lin D, Cooper JM, et al. Defibrillation threshold testing: is it really necessary at the time of implantable cardioverter-defibrillator insertion? Heart Rhythm. 2005;2:456–61.
27. Varma N, Efimov I. Right pectoral implantable cardioverter defibrillators: role of the proximal (SVC) coil. Pacing Clin Electrophysiol. 2008;31:1025–35.
28. Verma A, Kaplan AJ, Sarak B, Oosthuizen R, Beardsall M, Higgenbottam J, et al. Incidence of very high defibrillation thresholds (DFT) and efficacy of subcutaneous (SQ) array insertion during implantable cardioverter defibrillator (ICD) implantation. J Interv Card Electrophysiol. 2010;29:127–33.
29. Wilkoff BL, et al. HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. Europace 2016. 2015;18:159–83.
30. Osswald BR, de Simone R, Most S, Tochtermann U, Tanzeem A, Karck M. High defibrillation threshold in patients with implantable defibrillator: how effective is the subcutaneous finger lead? Eur J Cardiothorac Surg. 2009;35:489–92.