Decreased Inappropriate Shocks with New Generation ICDs in Children and Patients with Congenital Heart Disease

Stephanie A. Goldstein[a], MD, Martin J. LaPage[a], MD, MPH, Brynn E. Dechert-Crooks[a], RN, CPNP, Gerald A. Serwer[a], MD, Sunkyung Yu[a], MS, Ray E. Lowery[a], BS, David J. Bradley[a], MD

Affiliations:

[a]University of Michigan Congenital Heart Center, Ann Arbor, MI

Conflicts of interest: The research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosures: Medtronic provides partial support for a pediatric electrophysiology trainee position at the University of Michigan Congenital Heart Center

Address for correspondence:

Stephanie Goldstein, MD

University of Michigan Congenital Heart Center

1540 East Hospital Dr.

Ann Arbor, MI 48109

734-936-8765 phone

734-936-9470 fax

steph.a.goldstein@gmail.com

Abstract

Objective: Inappropriate implantable cardioverter defibrillator (ICD) shocks in children and patients with congenital heart disease remain a major complication of device therapy, occurring in as many as 50% of children with ICDs. New generation devices include algorithms designed to minimize inappropriate shocks. This study aimed to evaluate the effect of new generation-ICDs on the incidence of inappropriate shocks in the pediatric and congenital heart disease population.

Design: Retrospective study of patients with congenital heart disease or under age 25 receiving ICDs between 2000-2015. New generation-ICDs were defined as those with Medtronic "SmartShock" algorithms.

Results: 208 devices were implanted in 146 patients. Rates of inappropriate shocks were similar between diagnoses (p=0.71). The rate of inappropriate shock was 15% over median 5.8 years follow-up. In the 36 patients (25%) with new generation-ICDs, the rate of inappropriate shock was 6.3% over 4 years. Comparing old to new-generation-ICDs, freedom from first inappropriate shock was 90.6% vs 97.1% at 1 year and 80.4% vs 97.1% at 3 years (p=0.01). Lead fracture was associated with having inappropriate shock (Hazard ratio 8.5, p<0.0001), and there was no significant difference between the device groups when lead fractures were excluded. Clinical actions were taken in 69% of patients after initial inappropriate shock (such as medication or program change, system revision or explant). When an action was taken, subsequent inappropriate shock was reduced (5.3% vs 49.2% at 1 year; p=0.002).

Conclusions: Pediatric and congenital heart disease patients are experiencing reduced inappropriate shocks with new generation-ICD systems, though reduced lead fracture may

account for this improvement. Clinical interventions after inappropriate shock favorably impact the subsequent rate of shocks once an inappropriate shock occurs.

Keywords: ICD, pediatric, congenital heart disease, inappropriate shock, lead fracture, complication

Abbreviations:

CHD: congenital heart disease

HR: hazard ratio

ICD: implantable cardioverter-defibrillator

IS: inappropriate shock

LF: lead fracture

NG-ICD: new-generation ICD

TWOS: T-wave oversensing

Introduction

Inappropriate implanted cardioverter-defibrillator (ICD) shocks in children and patients with congenital heart disease (CHD) remain a major complication of this potentially life-saving device therapy. Their incidence is as high as 18-50% in children, often a rate greater than that for appropriate shocks[1–4]. Children and patients with congenital heart disease constitute as little as 1% of the total population with ICDs, and thus the majority of data available on factors contributing to inappropriate shocks and approaches to decreasing them are from older populations with different clinical characteristics[5–12]. Children have been shown to have significant morbidity from inappropriate shock therapies, including post-traumatic stress disorder, anxiety, depression, and refusal of therapy,[13,14] and there has been at least one reported death due to inappropriate therapy leading to ventricular fibrillation[15]. There has not been any clear association of inappropriate shocks with patient characteristics, medications, device types, or particular programming, with the notable exception of now recalled small-caliber lead models in this population[16–20].

Recently manufacturers have incorporated inappropriate shock-reduction algorithms in the newer generation of devices, and a recent study suggests that they decrease inappropriate shock rates in adult patients[21], though their clinical benefit in the pediatric and congenital population remains to be demonstrated. This single-center retrospective study aimed to evaluate the impact of new generation ICDs on the incidence of inappropriate shocks in this population. A secondary aim was to determine if clinical decisions after an initial inappropriate shock decreased the rate of subsequent inappropriate therapies.

Methods

This is a single-center retrospective study of all patients under the age of 25 years or with congenital heart disease, and having Medtronic ICDs followed by our center between January 1, 2000 and June 30, 2015. The study received institutional review board approval. Patients were identified through the University of Michigan Congenital Heart Center device database and manufacturer remote monitoring database, with additional data obtained from the electronic medical record. Patients were excluded if an ICD was implanted at an outside institution without full availability of data related to the device. Date of last follow up was determined as date of death, date of last contact or clinic visit, or June 30, 2015 for current patients. Information gathered included demographics, disease type, device and lead information, shock events and characteristics of each shock. "New generation devices" (NG-ICDs) were defined as recent Medtronic devices with 4 algorithms explicitly devised to reduce inappropriate shocks ("SmartShock" algorithms, found in Protecta, VivaXT, and Evera models). Medical charts were reviewed for documentation of each event, and available tracings were evaluated, in blinded fashion, for appropriateness of therapy. Therapy was considered appropriate only when ventricular tachyarrhythmias with cycle length shorter than the programmed cutoff were identified and received at least one shock.

Statistical analysis

Analyses were performed at the *patient* level and at the *device* level separately to account for potentially different functionality of different devices in the same patient. Cumulative incidence of inappropriate shocks at both patient and device level was calculated as the number of first inappropriate shocks during the study period divided by the total number of patients or devices included in the analysis. Additionally, the rate of inappropriate shocks was also calculated in the

device level as the number of first inappropriate shocks during the study period divided by the sum of the device-time of each device included in the analysis, and was reported as per 100 device-years. Freedom from first inappropriate shock after device implanted was calculated by Kaplan-Meier method and compared between old vs. NG-ICDs using log-rank test. Univariate Cox regression model was used to identify factor(s) associated with increased risk of having an inappropriate shock. Hazard ratio (HR) and its 95% confidence interval (CI) from the model were reported. Freedom from subsequent inappropriate shock after first inappropriate shock was also computed by Kaplan-Meier method and compared with freedom from first inappropriate shock after device implanted by log-rank test. In addition, freedom from subsequent inappropriate shock was also compared between patients who had clinical actions taken after an inappropriate shock vs. those who were not using log-rank test. All analyses were performed using SAS Version 9.4 (SAS Institute Inc., Cary, North Carolina), with statistical significant set at a p-value < 0.05 using a two-sided test.

Results

Patient Analysis

There were 146 patients, including 55 (38%) with CHD, 37 (25%) with cardiomyopathy, and 54 (37%) with primary electrical disease. Males comprised 58%, and 15% were of non-Caucasian race. Proportions of inappropriate shocks were similar between diagnostic groups (31%, 28%, 41% respectively for CHD, cardiomyopathy, and primary electrical disease; p=0.71). Median age at device implant was 16.8 years (Table 1). There were 36 patients (25%) with NG-ICDs. Median follow-up duration was 5.8 years (range 0.7-14.8 years). Eleven patients (8%) died during the study period.

Twenty-nine patients (20%) had an inappropriate shock and 23 (16%) had an appropriate shock. Reasons for first inappropriate shock included supraventricular tachycardias (41%), sinus tachycardia (3%), lead fracture or noise (31%), T-wave oversensing (TWOS, 24%). Median time to first inappropriate shock was 0.9 years (interquartile range [IQR] 0.2-2.0 years), and median time to first appropriate therapy was 1.4 years (IQR 0.3-3.3 years).

Of the 29 patients who received an inappropriate shock, 9 patients (31%) had a second inappropriate shock. In these patients, the median time from first to second inappropriate shock was 0.5 years (IQR 17 days- 1.4 years). Non-caucasian race trended toward significance ($p=0.06$) but no other patient factors including sex, diagnosis category, or age at device implant, were significantly associated with having an inappropriate shock (Table 1).

Device level analysis

Of the 208 ICDs, 32 (15%) delivered an inappropriate shock during the study period (Table 2). Comparing old and NG-ICD devices as defined above, freedom from first inappropriate shock significantly decreased in old devices over time ($p=0.01$, Fig 1). Old generation devices showed an increased risk of delivering inappropriate shocks when compared to NG-ICDs (HR 5.8, 95% CI 1.7-36.0). The overall rate of inappropriate shocks was 4.1%, i.e. 4.1 inappropriate shocks per 100 device-years. By device type, the rate of old versus NG-ICDs was 4.7 vs.1.3 per 100 device-years, respectively.

The risk of a first inappropriate shock was significantly increased by the presence of a lead fracture (HR 8.5, 95% CI 4.2-17.3, $p<0.0001$). Devices in non-Caucasian patients had an increased risk of inappropriate shock (HR 2.7, 95% CI 1.2-5.6, $p=0.01$). As in the patient level analysis, all other factors were found non-significant, including sex, diagnosis, and age at implant (Table 2), and there was no significant difference in the demographics between the two

device groups (Table 3). During the study period, only two NG-ICDs delivered a shock inappropriately.

Lead Fracture Analysis

There were 29 total lead fractures, 17 of which (59%) were associated with an inappropriate shock ($p<0.0001$). Eighteen of the 29 (62%) total lead fractures occurred in small-caliber Fidelis leads, and 12 of the 17 inappropriate shocks (71%) associated with a lead fracture were from Fidelis leads. There were two lead fractures that occurred in NG-ICDs, neither of which were associated with an inappropriate shock, nor invoked the noise suppression algorithm; one was a Fidelis lead. Notably both of these were signaled by home monitors and acted upon clinically. When inappropriate shocks associated with fractured leads were excluded, freedom from first inappropriate shock between old and NG-ICD devices were not significantly different: 92.8% vs. 97.0% at 1 year and 89.9% vs. 97.0% at 3 years, respectively ($p=0.13$). Non-Caucasian race, however, was significantly associated with increased risk of inappropriate shock (HR 5.9, 95% CI 2.1-16.6, $p=<0.0001$) even after excluding lead fractures from the analysis.

Subsequent Inappropriate Shocks

Freedom from a second inappropriate shock after a first inappropriate shock declined more steeply than freedom from a first inappropriate shock after device implant ($p=0.04$, Fig 2). Clinical actions taken in patients after an inappropriate shock with the intent to prevent further shocks were assigned to four categories: a change in medication, ICD system revision, a change in ICD programming or discontinuation of ICD therapy. For the 69% of patients (20/29) who had an initial inappropriate shock in whom such an action was taken, freedom from subsequent inappropriate shock was significantly higher than for those in whom there was no clinical action

taken (p=0.002, Fig 3). None of the four categories had enough power to determine if they were independently associated with a significant reduction.

Discussion

Inappropriate shocks have tempered enthusiasm for ICDs despite their demonstrated life-saving potential. Their psychological harm[13,14,22,23] and relation even to mortality[15], have made the decision to initiate ICD therapy in this population clinically perilous.

Four new algorithms for inappropriate shock reduction were incorporated in the ICD models designated "new-generation" in this study: One identifies TWOS and suppresses shock therapy when R wave signals vary in an alternating fashion. Another withholds therapy when noise on the near-field electrogram is not corroborated by the far-field electrogram. A third is an improved verification of anti-tachycardia pacing success. Finally, there is a refined morphology and timing algorithm devised to distinguish ventricular tachycardia from others. This combination of algorithms reduced inappropriate shocks in an adult cohort[21].

While the data in this series did not demonstrate the beneficial implementation of these new algorithms, the important finding of our study was that pediatric and CHD patients are experiencing significantly reduced inappropriate shocks with newer generation ICD systems compared to older ICD models.

The rate of inappropriate shocks from all devices in our study was 4.1 per 100 device-years, within the range previously reported for children and patients with CHD: 3.5 to 9.8 per 100 device years[1–4,24]. When isolating the new generation devices, however, the incidence of inappropriate shocks was much lower: 6.3% over 4 years follow-up, or 1.3 per 100 device-years.

Though it might be presumed that this difference was due to new algorithms which prevent inappropriate shock therapy, we could not confirm this. We found the predominant correlate of the reduced inappropriate shocks was reduced lead fractures. The older generation devices in this study coincided with use of the Medtronic Sprint Fidelis lead (2004-2007). The literature regarding inappropriate shocks in this population largely reflects the Fidelis era as well[25,26]. Widely adopted by our and other pediatric/congenital centers due to its smaller caliber, the lead failed at a particularly high rate in young patients, usually due to pace-sense conductor failures, which commonly resulted in oversensing[20]. Neither of the lead fractures in the NG-ICD group led to an inappropriate shock. One might suspect that the algorithms in the NG-ICDs accounted for improved performance in the setting of a lead fracture, however the noise suppression algorithm was apparently not invoked on specific review. The small number of lead fractures in NG-ICDs resulted in an underpowered analysis of the relationship between shocks to lead fractures.

Even relatively recent studies have reported higher rates of inappropriate shocks in this patient group. In one recent report, a rate of inappropriate shocks nearly as low was described (9.7% over median 42 month follow up; on our calculations 3.5 per 100 device years), but multivariate analysis failed to identify factors associated with inappropriate shocks[24]. Though the data did not point conclusively to a cause, the authors attributed their relatively favorable rate of inappropriate shocks to their institutional practices of extended arrhythmia detection time and use of beta blockers. Newer generation devices were not specifically assessed.

In our secondary aim to evaluate clinical interventions after inappropriate shock, freedom from first inappropriate shock declined more gradually than that from a second inappropriate shock. Clinical interventions taken after inappropriate shocks—which included medication change,

explant, lead revision and programming change—when grouped together, significantly decreased the risk of subsequent inappropriate shock. Identifying and acting on a cause of an inappropriate shock was clearly better than not doing so, as has been appreciated in an adult study[10].

Non-Caucasian race was identified as the only correlate of inappropriate shock when lead fractures were excluded from analysis, a finding not seen in other studies on this subject. This entirely unexpected observation may reflect availability or quality of care based on socioeconomic status. Particularly given the disparities seen in initiation of ICD therapy[27,28], among many gaps in healthcare distribution in the United States, this finding warrants further evaluation.

This study was limited by its retrospective design and local practice patterns. Further limitations include the following: follow-up was not uniform due to care sometimes at affiliate centers, and certain programming data were not available on all patients. Though there was an evolution in tachycardia detection programming observed nationally in response to data published during the study period,[29] the documentation of detection programming in our study was inadequate for analysis of changes in tachycardia detection programming over time. Improvements in home monitoring over this time also represent a secular trend whose impact on the results could not be quantified. Notably, the two lead fractures in the NG-ICDs were all detected by remote monitor transmissions, and none resulted in inappropriate shock. Better remote ICD surveillance in the NG-ICD era may have contributed to more prompt identification of, and response to other impending device problems.

In conclusion, the current era of ICD care for children and patients with congenital heart disease is characterized by a marked reduction in inappropriate shocks compared to prior years likely due to improved lead performance. Racial disparity in inappropriate shocks warrants further

attention. This study suggests an improved balance between reward and risk for ICDs in the pediatric and congenital population.

Author contributions:

Stephanie Goldstein: contributed to design, analysis and interpretation of data and was the lead author on the manuscript

Martin LaPage: contributed to the interpretation of the data and critical review of the manuscript

Brynn Dechert: contributed to interpretation of the data and critical review of the manuscript.

Gerald Serwer: contributed to interpretation of data, critical review of the manuscript

Sunkyung Yu: contributed to the design, performed statistical analysis, and reviewed the manuscript

Ray Lowery: contributed to analysis of the data, and reviewed the manuscript

David Bradley: contributed to conception, design of the study, analysis and interpretation of the data and senior manuscript revision.

References

1. Kalra Y, Radbill AE, Johns JA, Fish FA, Kannankeril PJ. Antitachycardia pacing reduces appropriate and inappropriate shocks in children and congenital heart disease patients. *Hear Rhythm*. 2012;9(11):1829-1834. doi:10.1016/j.hrthm.2012.06.042.

2. Lawrence D, Von Bergen N, Law IH, et al. Inappropriate ICD discharges in single-chamber versus dual-chamber devices in the pediatric and young adult population. *J Cardiovasc Electrophysiol*. 2009;20(3):287-290. doi:10.1111/j.1540-8167.2008.01322.x.

3. DeWitt ES, Triedman JK, Cecchin F, et al. Time dependence of risks and benefits in pediatric primary prevention implantable cardioverter-defibrillator therapy. *Circ Arrhythmia Electrophysiol*. 2014;7(6):1057-1063. doi:10.1161/CIRCEP.114.001569.

4. Korte T, Köditz H, Niehaus M, Paul T, Tebbenjohanns J. High incidence of appropriate and inappropriate ICD therapies in children and adolescents with implantable cardioverter defibrillator. *Pacing Clin Electrophysiol PACE*. 2004;27:924-932.

5. Kolb C, Sturmer M, Sick P, et al. Reduced risk for inappropriate implantable cardioverter-defibrillator shocks with dual-chamber therapy compared with single-chamber therapy: Results of the randomized OPTION study. *JACC Hear Fail*. 2014;2(6):611-619. doi:10.1016/j.jchf.2014.05.015.

6. Hendrik S, Thomas B, Johannes K, et al. Reduction of inappropriate ICD therapies in patients with primary prevention of sudden cardiac death : DECREASE study. *Clin Res Cardiol*. 2015;104:1021-1032. doi:10.1007/s00392-015-0870-z.

7. Wathen MS, DeGroot PJ, Sweeney MO, et al. Prospective randomized multicenter trial of empirical antitachycardia pacing versus shocks for spontaneous rapid ventricular

tachycardia in patients with implantable cardioverter-defibrillators: Pacing fast ventricular tachycardia reduces shock therapies . *Circulation*. 2004;110(17):2591-2596. doi:10.1161/01.CIR.0000145610.64014.E4.

. Wilkoff BL, Williamson BD, Stern RS, et al. Strategic Programming of Detection and Therapy Parameters in Implantable Cardioverter-Defibrillators Reduces Shocks in Primary Prevention Patients. Results From the PREPARE (Primary Prevention Parameters Evaluation) Study. *J Am Coll Cardiol*. 2008;52(7):541-550. doi:10.1016/j.jacc.2008.05.011.

. Moss AJ, Schuger C, Beck C a, et al. Reduction in inappropriate therapy and mortality through ICD programming. *N Engl J Med*. 2012;367(24):2275-2283. doi:10.1056/NEJMoa1211107.

0. Daubert JP, Zareba W, Cannom DS, et al. Inappropriate Implantable Cardioverter-Defibrillator Shocks in MADIT II. Frequency, Mechanisms, Predictors, and Survival Impact. *J Am Coll Cardiol*. 2008;51(14):1357-1365. doi:10.1016/j.jacc.2007.09.073.

1. Mastenbroek MH, Pedersen SS, Van Der Tweel I, Doevendans PA, Meine M. Results of ENHANCED Implantable Cardioverter Defibrillator Programming to Reduce Therapies and Improve Quality of Life (from the ENHANCED-ICD Study). *Am J Cardiol*. 2016;117(4):596-604. doi:10.1016/j.amjcard.2015.11.052.

2. Biton Y, Huang DT, Goldenberg I, et al. Relationship between age and inappropriate implantable cardioverter-defibrillator therapy in MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy). *Hear Rhythm*. 2016;13(4):888-893. doi:10.1016/j.hrthm.2015.12.032.

3. Webster G, Panek KA, Labella M, et al. Psychiatric functioning and quality of life in young patients with cardiac rhythm devices. *Pediatrics*. 2014;133(4):e964-e972. doi:10.1542/peds.2013-1394.

4. Costa R, Silva KR da, Mendonça RC, et al. Incidence of shock and quality of life in young patients with implantable cardioverter-defibrillator. *Arq Bras Cardiol*. 2007;88(3):258-264. doi:10.1590/S0066-782X2007000300002.

5. Messali A, Thomas O, Chauvin M, Coumel P, Leenhardt A. Death due to an implantable cardioverter defibrillator. *J Cardiovasc Electrophysiol*. 2004;15(8):953-956. doi:10.1046/j.1540-8167.2004.03611.x.

6. Atallah J, Erickson CC, Cecchin F, et al. Multi-institutional study of implantable defibrillator lead performance in children and young adults results of the Pediatric Lead Extractability and Survival Evaluation (PLEASE) Study. *Circulation*. 2013;127(24):2393-2402. doi:10.1161/CIRCULATIONAHA.112.001120.

7. Van Rees JB, Van Welsenes GH, Borleffs CJW, et al. Update on small-diameter implantable cardioverter-defibrillator leads performance. *PACE - Pacing Clin Electrophysiol*. 2012;35(6):652-658. doi:10.1111/j.1540-8159.2011.03338.x.

8. Beukema RJ, Misier AR, Delnoy PP, Smit JJ, Elvan A. Characteristics of Sprint Fidelis lead failure. *Neth Hear J*. 2010;18(1):12-17.

9. Farwell D, Green MS, Lemery R, Gollob MH, Birnie DH. Accelerating risk of Fidelis lead fracture. *Hear Rhythm*. 2008;5(10):1375-1379. doi:10.1016/j.hrthm.2008.06.024.

0. Hauser RG, Maisel WH, Friedman PA, et al. Longevity of sprint fidelis implantable cardioverter-defibrillator leads and risk factors for failure: Implications for patient

management. *Circulation*. 2011;123(4):358-363. doi:10.1161/CIRCULATIONAHA.110.975219.

1. Auricchio A, Schloss EJ, Kurita T, et al. Low inappropriate shock rates in patients with single- and dual/triple-chamber implantable cardioverter-defibrillators using a novel suite of detection algorithms: PainFree SST trial primary results. *Hear Rhythm*. 2015;12(5):926-936. doi:10.1016/j.hrthm.2015.01.017.
2. Keren A, Sears SF, Nery P, et al. Psychological adjustment in ICD patients living with advisory fidelis leads. *J Cardiovasc Electrophysiol*. 2011;22(1):57-63. doi:10.1111/j.1540-8167.2010.01867.x.
3. Eicken A, Kolb C, Lange S, et al. Implantable cardioverter defibrillator (ICD) in children. *Int J Cardiol*. 2006;107(1):30-35. doi:10.1016/j.ijcard.2005.02.048.
4. Garnreiter JM, Pilcher TA, Etheridge SP, Saarel E V. Inappropriate ICD shocks in pediatrics and congenital heart disease patients: Risk factors and programming strategies. *Hear Rhythm*. 2015;12(5):937-942. doi:10.1016/j.hrthm.2015.01.028.
5. Von Bergen NH, Atkins DL, Dick M, et al. Multicenter study of the effectiveness of implantable cardioverter defibrillators in children and young adults with heart disease. *Pediatr Cardiol*. 2011;32(4):399-405. doi:10.1007/s00246-010-9866-7.
6. Ten Harkel ADJ, Blom NA, Reimer AG, Tukkie R, Sreeram N, Bink-Boelkens MTE. Implantable cardioverter defibrillator implantation in children in The Netherlands. *Eur J Pediatr*. 2005;164(7):436-441. doi:10.1007/s00431-005-1668-1.
7. Mezu U, Ch I, Halder I, London B, Saba S. Women and minorities are less likely to receive an implantable cardioverter defibrillator for primary prevention of sudden cardiac

death. *Europace*. 2012;14(3):341-344. doi:10.1093/europace/eur360.

8. Russo AM, Hafley GE, Lee KL, et al. Racial differences in outcome in the Multicenter UnSustained Tachycardia Trial (MUSTT): A comparison of whites versus blacks. *Circulation*. 2003;108(1):67-72. doi:10.1161/01.CIR.0000078640.59296.6F.

9. Gasparini M, Proclemer A, Klersy C, et al. Effect of Long-Detection Interval vs Standard-Detection Interval for Implantable Cardioverter-Defibrillators on Antitachycardia Pacing and Shock Delivery. *JAMA*. 2013;309(18):1903. doi:10.1001/jama.2013.4598.

Figure Titles and legends:

Figure 1: Freedom from 1st inappropriate shocks by type of device

By device type, freedom from 1st inappropriate shocks were 90.6% vs. 97.1% at 1 years and 80.4% vs. 97.1% at 3 years (Old vs. New; p=0.01 from log-rank test; Hazard ratio 5.80 and 95% confidence interval 1.73-36.0).

Figure 2. Freedom from 2nd inappropriate shocks vs. Freedom from 1st inappropriate shocks

Freedom from 1st inappropriate shock after implant was significantly higher than freedom from 2nd inappropriate shock after 1st inappropriate shock (92.7% vs. 82.1% at 1 year, 85.1% vs. 77.2% at 3 years, and 83.0% vs. 67.6% at 5 years; p=0.04 from log-rank test).

Figure 3: Freedom from subsequent inappropriate shocks following clinical actions

Freedom from subsequent inappropriate shocks in patients with any actions taken after the 1st inappropriate shock was significantly higher than those without (94.7% vs. 50.8% at 1 year, p=0.002 from log-rank test)

Figure 1

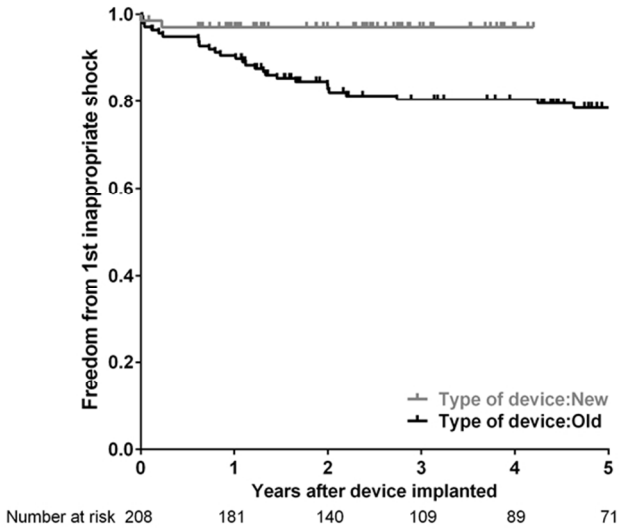

Figure 1: Freedom from 1st inappropriate shocks by type of device† . By device type, freedom from 1st inappropriate shocks were 90.6% vs. 97.1% at 1 years and 80.4% vs. 97.1% at 3 years (Old vs. New; p=0.01 from log-rank test; Hazard ratio 5.80 and 95% confidence interval 1.73-36.0).┬

254x167mm (96 x 96 DPI)

Figure 2

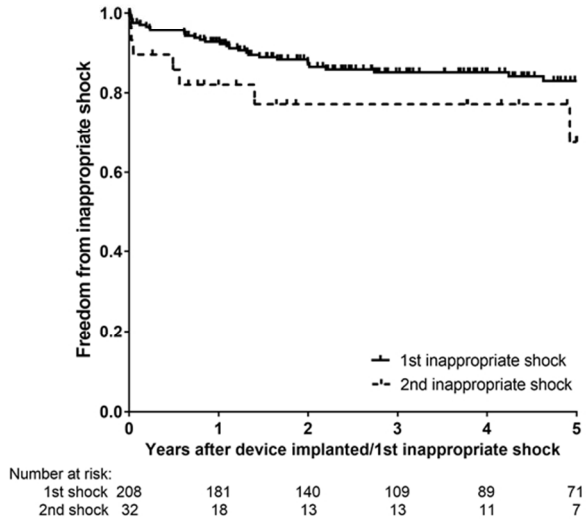

Figure 2. Freedom from 2nd inappropriate shocks vs. Freedom from 1st inappropriate shocks. Freedom from 1st inappropriate shock after implant was significantly higher than freedom from 2nd inappropriate shock after 1st inappropriate shock (92.7% vs. 82.1% at 1 year, 85.1% vs. 77.2% at 3 years, and 83.0% vs. 67.6% at 5 years; p=0.04 from log-rank test).

Figure 3

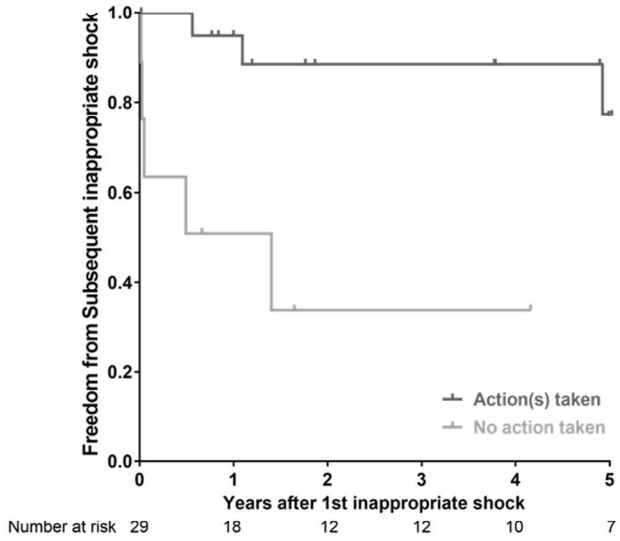

Figure 3: Freedom from subsequent inappropriate shocks following clinical actions. Freedom from subsequent inappropriate shocks in patients with any actions taken after the 1st inappropriate shock was significantly higher than those without (94.7% vs. 50.8% at 1 year, p=0.002 from log-rank test)†

Table 1. Patient characteristics (N=146 patients)

Characteristics	Overall* (N=146)	Inappropriate shock: Yes* (N=29)	Inappropriate shock: No* (N=117)	HR	95% CI	P-value§
Male sex	84 (57.5)	20 (69.0)	64 (54.7)	1.83	0.86-4.23	0.13
Non-Caucasian race	22 (15.1)	7 (24.1)	15 (12.8)	2.21	0.87-4.93	0.06
Diagnosis						0.71
CHD	55 (37.7)	9 (31.0)	46 (39.3)	Ref		
Cardiomyopathy	37 (25.3)	8 (27.6)	29 (24.8)	1.39	0.52-3.65	0.50
Electrical disease	54 (37.0)	12 (41.4)	42 (35.9)	1.40	0.59-3.43	0.45
Age at device implanted, years	16.8 (13.6-24.8)	15.8 (11.7-23.1)	16.8 (14.5-25.6)	0.97	0.94-1.01	0.14

Abbreviations: HR, hazard ratio; CI, confidence interval; Ref, reference.

* Data are presented as N (%) for categorical variables and Median (interquartile range) for continuous variables.

§ P-value from univariate Cox regression.

Table 2. Device characteristics (N=208 devices)

Characteristics	Overall* (N=208)	Inappropriate shock: Yes* (N=32)	Inappropriate shock: No* (N=176)	HR	95% CI	P-value§
Male sex	125 (60.1)	23 (68.8)	118 (58.5)	1.58	0.77-3.48	0.23
Non-Caucasian race	31 (14.9)	9 (28.1)	22 (12.5)	2.68	1.17-5.61	**0.01**
Diagnosis						0.71
CHD	79 (38.0)	11 (34.4)	68 (38.6)	Ref		
Cardiomyopathy	48 (23.1)	9 (28.1)	39 (22.2)	1.44	0.59-3.47	0.42
Electrical disease	81 (38.9)	12 (37.5)	69 (39.2)	1.09	0.48-2.46	0.85
Age at device implanted, years	18.8 (14.7-24.8)	16.3 (12.3-23.1)	19.4 (15.1-25.8)	0.97	0.93-1.00	0.07
Type of device†						**0.01**
NG-ICD	69 (33.2)	2 (6.3)	67 (38.1)	Ref		
Old	139 (66.8)	30 (93.8)	109 (61.9)	5.80	1.73-36.0	

Abbreviations: HR, hazard ratio; CI, confidence interval; Ref, reference.

† NG-ICDs are Evera, Protecta and VivaXT. Old Devices are Consulta, Enrust, Gem, Intrinsic, Marquis, Maximo, Secura, Virtuoso

* Data are presented as N (%) for categorical variables and Median (interquartile range) for continuous variables.

§ P-value from univariate Cox regression.

Table 3. Patient characteristics by device type (N= 208 devices)

Characteristics	Type of Device†		P-value¥
	NG-ICD (N=69)	Old (N=139)	
Male sex	42 (60.9)	83 (59.7)	0.87
Non-Caucasian race	12 (17.4)	19 (13.7)	0.48
Diagnosis			0.10
CHD	24 (34.8)	55 (39.6)	
Cardiomyopathy	22 (31.9)	26 (18.7)	
Electrical disease	23 (33.3)	58 (41.7)	
Age at device implanted , years	20.4 (15.7-26.0)	17.4 (14.0-24.4)	0.11

* Data are presented as N (%) for categorical variables and Median (interquartile range) for continuous variable.

† NG-ICDs are Evera, Protecta and VivaXT. Old Devices are Consulta, Enrust, Gem, Intrinsic, Marquis, Maximo, Secura, Virtuoso.

¥ P-value from Chi-square test for categorical variables and Wilcoxon rank sum test for continuous variable.