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Prospective Evaluation of Defibrillation Threshold and Postshock Rhythm in Young ICD Recipients

ANDREW E. RADBILL, M.D.[*], **JOHN K. TRIEDMAN, M.D.**[‡], **CHARLES I. BERUL, M.D.**[§], **EDWARD P. WALSH, M.D.**[‡], **MARK E. ALEXANDER, M.D.**[‡], **GREGORY WEBSTER, M.D.**[¶], **FRANK CECCHIN, M.D.**[‡]

[*]Department of Pediatrics, Vanderbilt University School of Medicine, and the Monroe Carell Jr. Children's Hospital at Vanderbilt, Nashville, Tennessee

[‡]Department of Cardiology, Children's Hospital Boston, Harvard Medical School, Boston, Massachusetts

[§]Department of Cardiology, Children's National Medical Center, Washington, DC

[¶]Division of Cardiology, Lurie Children's Hospital, Northwestern University Feinberg School of Medicine, Chicago, Illinois

Abstract

Background: Adaptation of implantable cardioverter defibrillator (ICD) systems to the needs of pediatric and congenital heart patients is problematic due to constraints of vascular and thoracic anatomy. An improved understanding of the defibrillation energy and postshock pacing requirements in such patients may help direct more tailored ICD therapy. We describe the first prospective evaluation of defibrillation threshold (DFT) and postshock rhythm in this population.

Methods: We prospectively studied patients ≤60 kg at time of ICD intervention. DFTs were obtained using a binary search protocol with three VF inductions. Postshock pacing was programmed using a stepwise protocol, lowering the rate prior to each VF induction.

Results: Twenty patients were enrolled: 11 had channelopathy, five congenital heart disease, and four cardiomyopathy. The median age was 16 years, median weight 48 kg. Twelve patients had a transvenous high-voltage coil; eight had pericardial +/− subcutaneous coil(s). Median DFT was 7 J (range 3–31 J); 19/20 patients had DFT ≤15 J and all patients <25 kg had DFT ≤9 J (n = 6). There was no difference in DFT between patients with transvenous versus pericardial +/− subcutaneous coils (median 7 J vs 6 J, P = 0.59). No patient with normal atrioventricular conduction prior to defibrillation required postshock pacing (n = 16). There were no adverse events.

Conclusions: These data suggest that many pediatric ICD patients have low DFTs and adequate postshock escape rhythm. This may help determine appropriate parameters for future design of pediatric-specific ICDs.

Address for reprints: Andrew E. Radbill, M.D., 2200 Children's Way, Suite 5230/Nashville, TN 37232-9119. Fax 615-322-2210; andrew.radbill@vanderbilt.edu.

Institution of all authors at the time of study was Department of Cardiology, Children's Hospital Boston, Harvard Medical School, Boston, MA

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Keywords

pediatrics—electrophysiology; pediatrics—implantable devices; implantable device—defibrillation; implantable devices—pacemaker-bradyarrhythmias

Introduction

Some children with cardiac channelopathy, congenital heart disease, and cardiomyopathy have an increased risk of sudden cardiac death.[1–3] The use of implantable cardioverter-defibrillator (ICD) therapy in these children has benefited from recent advances in patient selection, downsized devices, improved implant techniques, and programming strategies.[4–9] Nonetheless, the vast majority of pediatric ICD practice and literature has been limited to extrapolation of data gained from experience with ICD therapy in adults. There are unique challenges to ICD implantation in younger children: limited venous capacitance increases the risk of vessel occlusion, and rapid somatic growth and physical activity likely predispose to premature lead failure. In addition, patients with congenital heart disease not infrequently have abnormal systemic venous pathways, intracardiac shunts, right-sided atrioventricular valve disease, and lack of venous access to the ventricle, all of which present additional challenges for standard ICD implantation.[10] Because the conventional ICD paradigm generally assumes uncomplicated transvenous access and adult body habitus, there is a growing need to differentiate between that which is necessary, superfluous, and detrimental in an ideal pediatric-specific ICD. This study focused on two questions toward that end: (1) what are the actual defibrillation energy requirements in pediatric patients, and (2) is postshock pacing necessary?

Methods

Study Population

A prospective single-center pilot study was performed from June 2009 through May 2010. Appropriate review and approval of the Institutional Review Board was obtained. Inclusion criteria for study participants included: (1) weight ≤60 kg, (2) new or existing ICD system, and (3) clinically necessary assessment of the defibrillation efficacy of the ICD system. Transvenous systems utilized a high-voltage ICD coil with active-fixation lead attached to the right ventricular endocardial surface, whereas nontransvenous systems depended upon a high-voltage shocking coil placed (“off-label”) within the pericardial, subcutaneous, or pleural space. To be included in the postshock pacing portion of the study, adequate sinus and atrioventricular (AV) node function had to be present at baseline. Exclusion criteria included (1) tenuous hemodynamic status felt to warrant abbreviation of the defibrillation efficacy testing or (2) inability to induce fibrillation during defibrillation threshold testing (DFT). Informed consent was obtained from all subjects/legal guardians, and when appropriate, assent was also obtained from minors.

Binary Search Protocol for Defibrillation Threshold Testing

Precise measurement of the DFT was performed using a modified binary search protocol (Fig. 1). This protocol specified three distinct inductions of ventricular fibrillation (VF) for

all subjects, with a 3–5-minute observation/waiting period between inductions. The initial shock energy was programmed at 9 J for all patients, with internal rescue shocks at 31 J followed by device-specific maximum deliverable energy. The outcome of the initial induction determined the programmed energies for both the initial and internal rescue shocks for the second induction, and likewise for the third induction. All shocks were biphasic and delivered at manufacturers' default tilt, polarity, and duration, and all final programmed shock vectors included an active can. External defibrillation pads were in place for delivery of external rescue shock should the internal shocks fail. Monte Carlo analysis demonstrated that the study algorithm would predict the E70% (shock energy associated with 70% defibrillation success), with high concordance in conditions of low, average, or high true DFT.

Postshock Pacing Protocol

To address the second study question, postshock intrinsic rhythm was assessed in all subjects who met the additional inclusion criteria of adequate sinus node function and intact AV node conduction. Prior to each of the three VF inductions performed as part of the binary search protocol, postshock pacing was reprogrammed using a predetermined, stepwise protocol that progressively decreased the lower rate limit (Fig. 2). For the purpose of this protocol, postshock pacing was considered necessary if (1) ≥7 ventricular-paced beats or (2) asystole >4 seconds was observed in the first 20 seconds after defibrillation, or if the systolic blood pressure demonstrated a >10% decrease from preinduction baseline at follow-up measurement 1 minute postdefibrillation. Rescue ventricular pacing via the programmer was available for all subjects.

Statistical Analysis

Continuous variables were described using medians and interquartile ranges, with comparisons between groups performed using the nonparametric Mann-Whitney test. If ICD system configuration was revised during the study procedure, the final measured DFT was used in the analysis.

Results

Patient Characteristics

There were 26 ICD procedures in patients weighing ≤60 kg during the study period. Subject recruitment is detailed in Figure 3, with 20 subjects undergoing DFT testing using the binary search protocol and 16 participating in the postshock pacing portion. Baseline demographic data are outlined in Table I. Of the 11 patients with underlying channelopathy, seven had long QT syndrome, two catecholaminergic polymorphic ventricular tachycardia, and two idiopathic ventricular tachycardia/fibrillation. Three patients had hypertrophic cardiomyopathy, and one patient had left ventricular noncompaction cardiomyopathy. System configuration was relatively evenly divided amongst transvenous single coil (n = 7), transvenous dual coil (n = 5), and nontransvenous (n = 8) systems. All but one transvenous system included a left pectoral active can, and nontransvenous systems utilized both right (n = 5) and left (n = 3) subrectus muscle active cans located in the upper abdomen.

Defibrillation Thresholds

Measured DFTs in the study cohort are shown in Figure 4. The median DFT was 7 J (interquartile range 4–9 J). The DFT was ≤15 J in 19/20 subjects, and all six subjects with a weight <25 kg had a DFT ≤9 J. There was no significant difference observed in DFT between transvenous and nontransvenous ICD systems (median 7 J vs 6 J) or single and dual coil ICD leads (median 7 J in both groups). Of note, clinical care required that three subjects received more than the specified three VF inductions with a single configuration: two because of recurrent secondary terminations, and one at the discretion of the implanting EP. Conversely, one subject who had secondary termination received only two sustained inductions at the discretion of the implanting EP, and one subject who required intraoperative system revision received only two inductions in testing of the revised configuration. Eleven subjects required 1-J deviations from protocol for programmed shock energy secondary to manufacturer-specific constraints on available shock energies.

Two subjects required revision of the original ICD system configuration secondary to elevated initial DFT measurement. Both subjects had nontransvenous ICD systems. The first was a 7-year-old, 19-kg boy with long QT syndrome whose initial shock vector between a left lateral subcutaneous high-voltage coil and an active right upper quadrant subrectus generator yielded a DFT of 21 J. With addition of a right anterior subcutaneous coil to the vector, the repeat DFT assessment was 5 J. The other subject was a 20-year-old, 52-kg young woman with an unbalanced complete atrioventricular canal defect status postpalliation to a Fontan circulation. The initial system was tested with the shock vector between an inferior/leftward pericardial coil and a second rightward pericardial coil, with DFT of 35 J. Reprogramming the shock vector to include the left upper abdominal generator decreased the repeat DFT measurement to 4 J.

In those subjects with previous clinical DFT assessment and no interval revision of the shocking vector configuration, the DFT measurements obtained using the binary search protocol in this study were compared to that individual patient's prior measured DFT (median time interval between DFTs = 56 months, range 14–73 months). Five subjects had a previous true DFT recorded, and although two subjects displayed a potentially clinically significant increase in DFT, this did not qualitatively track with somatic growth (Fig. 5). Another seven subjects had undergone previous DFT assessment using a less rigorous "lowest energy tested" strategy; the current DFT utilizing this study's binary search protocol was, not surprisingly, lower in six of seven of these patients.

Postshock Rhythm

Sixteen subjects of the 20 subjects underwent evaluation of postshock intrinsic rhythm. Of the four subjects excluded from this assessment, two had complete AV block, one had second-degree AV block, and one was excluded at the discretion of the implanting electrophysiologist. Fifty-six VF inductions were performed in the 16 subjects, with postshock rhythm evaluable following 49 events. No patient required >7 paced beats, developed asystole >4 seconds, or experienced >10% decrease in systolic blood pressure. Of note, 2/49 events had data collection truncated to ~10 seconds postevent secondary to interference of wireless telemetry. The postshock rhythm was nonevaluable following 7/56

events secondary to inadvertent failure to reprogram prior to two inductions, interference of wireless telemetry following three conversions, and other unavailable data on two occasions.

There were no adverse events related to the study protocol.

Discussion

ICD therapy has been used in children and young adults for primary and secondary prevention of sudden cardiac death.[4–9] There is a growing body of pediatric ICD literature addressing technical implant considerations, programming strategies, and clinical outcomes. Unfortunately, ICD therapy remains suboptimal in pediatric and congenital heart disease patients as compared to the adult cohorts for whom ICD therapy was primarily intended.[5,6,11,12] This study was designed with the goal of starting to identify which elements of the conventional ICD system are truly necessary in pediatric-specific ICD therapy, while conversely recognizing those features which may be superfluous or even detrimental. In other words, this represents an attempt to step away from describing “how” adult ICD therapy can be applied to the pediatric population and instead asks “what” high-risk pediatric patients need from ICDs.

Defibrillation Energy Requirements in Young ICD Recipients

Although there has been much progress over the past two decades in reducing ICD generator size, the requirement for relatively large-volume cans limits pocket site selection and increases the risk for pocket breakdown in younger pediatric patients. Many factors have driven the default to manufacture only ICDs capable of delivering ≥31 J, but the defibrillation energy requirements in the pediatric ICD population remain incompletely defined. The two largest reports of pediatric ICD therapy provide a global report of implant experience and clinical outcomes without specific report of systematic DFTs.[4,5] The adult DFT experience has well demonstrated that the testing strategy matters,[13] but the pediatric ICD series that have specifically reported DFTs have not typically specified the method used to assess defibrillation efficacy.[11,14–19] The notable exception is the retrospective report by Stefanelli et al.,[20] which found a median DFT of 10 J in 27 subjects by use of the step-down method. The current prospective trial used a binary search algorithm for measurement of defibrillation efficacy in a pediatric and congenital heart disease cohort. The median DFT was 7 J in 20 subjects, suggesting that it may be possible to identify a group for whom lower-energy devices may be a sufficient “bridge” therapy until somatic growth accommodates standard therapy.

Postshock Intrinsic Rhythm in Young ICD Recipients

For those pediatric patients who are not candidates for transvenous ICD systems, an epicardial pacing lead has been the sole option for pace-sense function. In regard to sensing, there has been recent development of an alternative approach to recognition of tachyarrhythmias using only minimally invasive subcutaneous leads.[21] From a pacing perspective, many pediatric patients at high risk for sudden death do not have a concomitant indication for antibradycardia or biventricular pacing.[5] The role of antitachycardia pacing in the pediatric population continues to evolve, but clinical practice has demonstrated that this

therapy offers minimal benefit for some pediatric subcohorts such as children with a primary channelopathy. In subjects who at baseline had no primary indication for antibradycardia pacing, this study specifically examined the postshock intrinsic rhythm by temporarily reprogramming postshock pacing. None of the 16 evaluated subjects demonstrated clinically significant bradycardia or pauses following defibrillation. If such pilot findings are confirmed in broader pediatric cohorts and there is increased availability of technology allowing identification of tachyarrhythmias without dependence on near-field endo- or epicardial sensing, there may be increased confidence in deferring placement of an epicardial pacing lead for selected patients without transvenous ventricular access.

Special Considerations in Young ICD Recipients

Although anecdotal, the observed influence of shocking vector on defibrillation efficacy for two subjects in this cohort reinforces the need for improved processes to allow preprocedural assessment of multiple potential shock vectors in subjects requiring nonconventional (e.g., wholly nontransvenous) ICD configurations. Such predictive modeling is currently in development,[22] but has not yet progressed to be readily available for implanting physicians to apply to specific clinical patients. Also worth noting are the changes in defibrillation energy requirements over time for those subjects in this cohort who had previous rigorously measured DFTs. We observed that two of five such subjects had a 10-J increase in serial DFTs. Although there remains an active debate in the electrophysiology community regarding the utility of DFTs, these very small numbers are in concordance with data from both pediatric and adult series finding a clinically significant increase in 15% of patients undergoing routine surveillance DFTs.[23,24] *A priori* identification of these patients remains an elusive goal that is prerequisite for the advancement of defibrillation therapy.

Study Limitations

There are inherent limitations that influence the interpretation and applicability of the findings from this study. The small sample size is of particular importance given the pronounced heterogeneity of the patient population and the configuration of the ICD systems. Of note, patients with primary channelopathy were relatively overrepresented in our cohort as compared to larger registry data[5] (55% vs 31%). Both patients with congenital heart defects and very young patients were under-represented in this single-center pilot study. The physiology of defibrillation in adolescents with long QT syndrome may be as different from infants with palliated single ventricle congenital heart disease as adults with ischemic cardiomyopathy, and it may be no more appropriate to indiscriminately combine the first two “pediatric” cohorts as it would be to merge the latter two groups. Furthermore, defibrillation is by nature probabilistic and not deterministic, and any generalizations (particularly those arising from anecdotal observations) need be tempered by acknowledgement of this reality. Any proposed modification of clinical ICD therapy in children must be constrained by the potentially extraordinarily high cost of failed therapy in an outlying patient. In addition, it should be recognized that measurement of the DFT is simply one approach to measuring defibrillation efficacy; this study was not designed as an analysis of the DFT measurement in a pediatric cohort.

Conclusion

These data suggest that many pediatric ICD patients have low DFTs and hemodynamically adequate postshock intrinsic rhythm. These findings may help determine appropriate parameters for future design of pediatric-specific ICDs.

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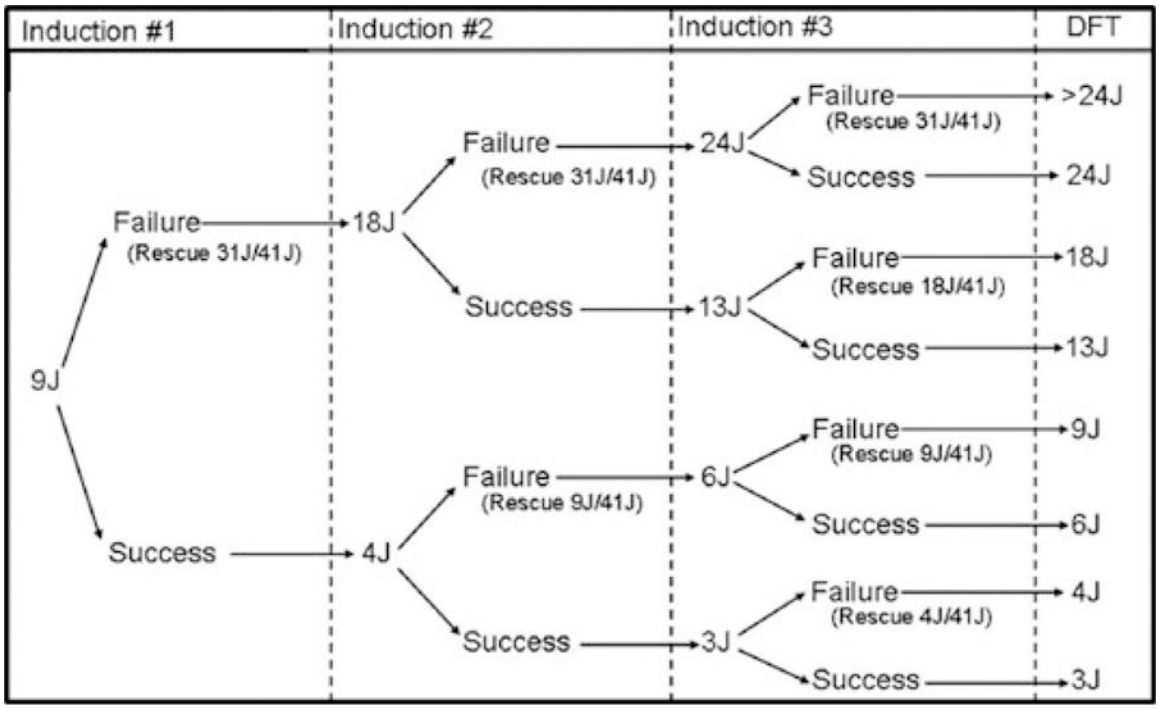

Figure 1.

Modified binary search study protocol. All shock energies are displayed in joules (J); internal rescue shock energies are displayed in parentheses.

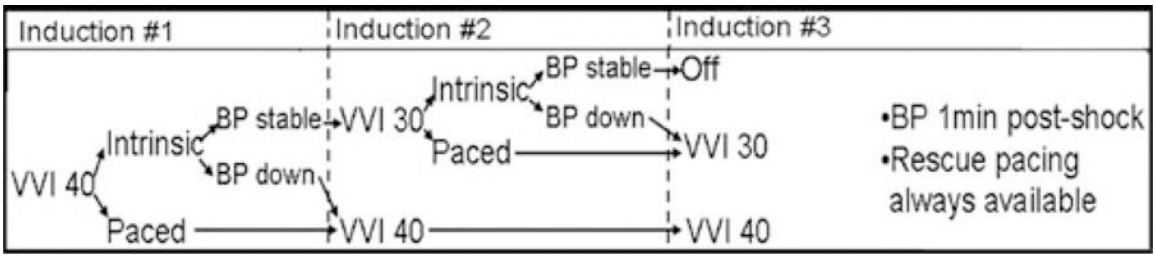

Figure 2.
Postshock pacing protocol.

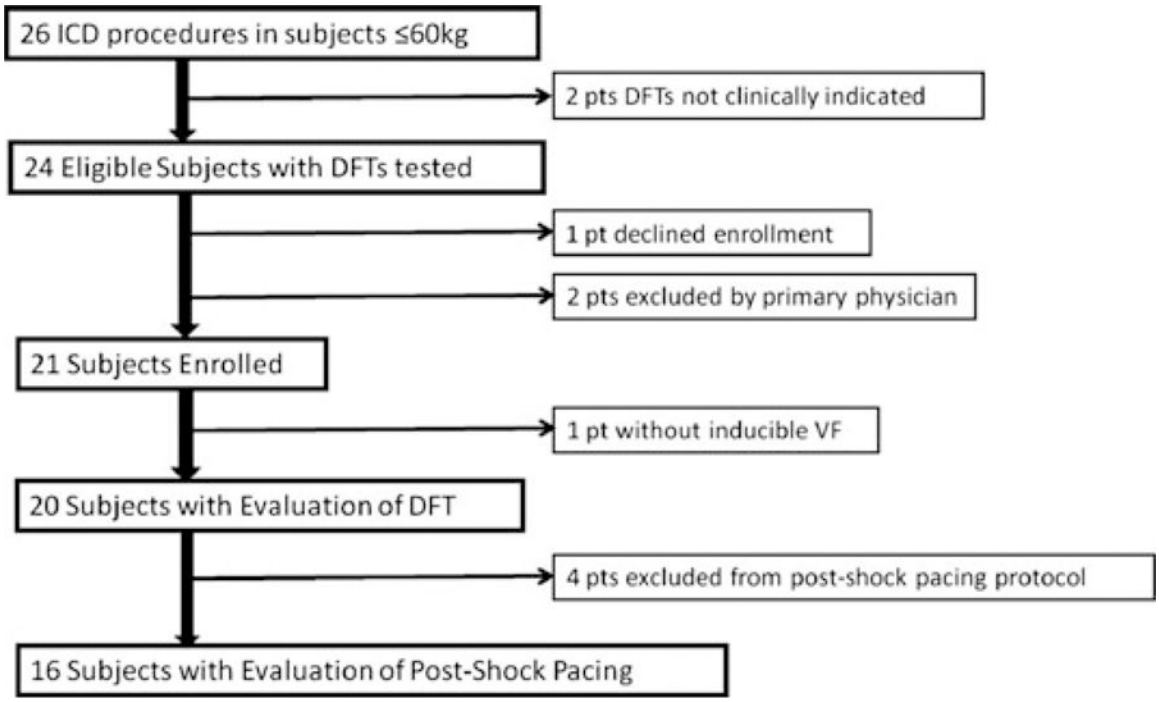

Figure 3.

Subject recruitment flow diagram. A total of six patients were not enrolled in the binary search protocol. Two did not have clinical indication for DFT assessment secondary to previously acceptable DFT, no lead revision, and (1) hypertrophic cardiomyopathy with tenuous hemodynamic status or (2) unpalliated complete atrioventricular canal with a risk-benefit ratio that weighed against repeating DFT assessment. Two patients were excluded by the primary physician for the following reasons: One with catecholaminergic polymorphic ventricular tachycardia felt to be at high-risk for protocolized DFT assessment due to perceived risk of electrical storm, and one with extenuating social circumstances. One patient with long QT syndrome had no inducible ventricular fibrillation.

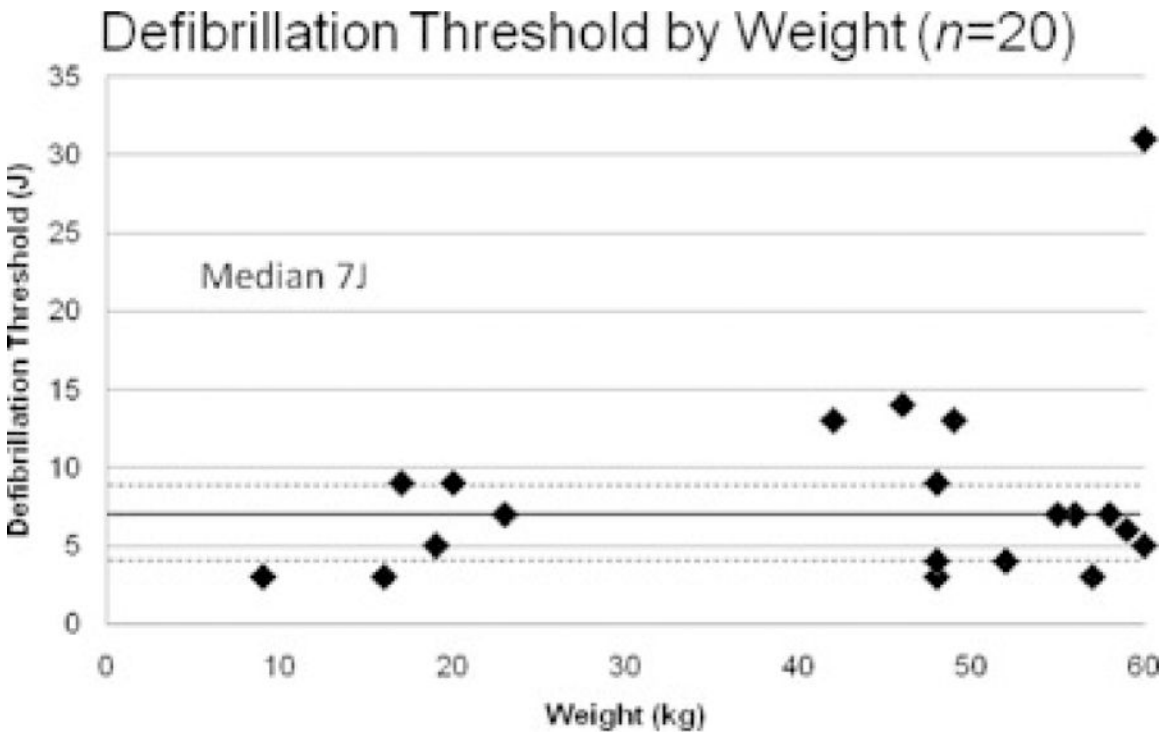

Figure 4.

Defibrillation thresholds as measured by the binary search protocol. The solid horizontal line at 7 J marks the median DFT, with the dashed horizontal lines at 4 J and 9 J representing the 25th and 75th quartiles, respectively.

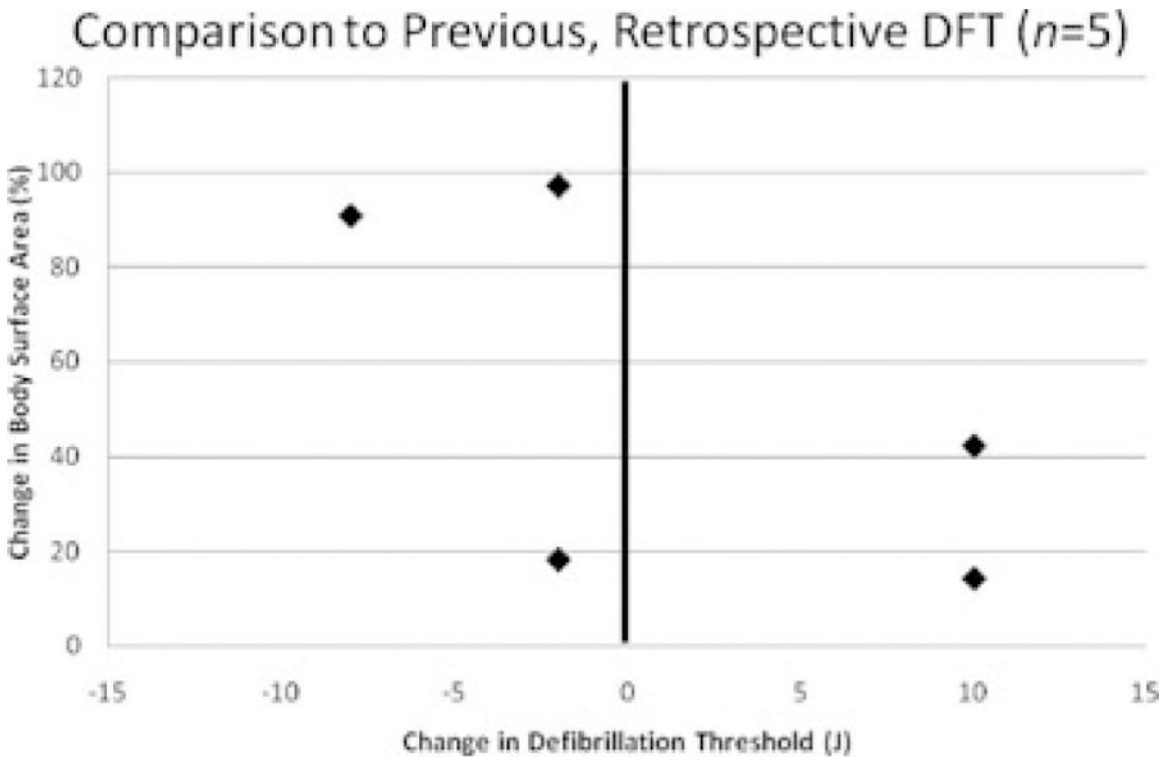

Figure 5.
Change in defibrillation threshold (study DFT minus previous DFT) plotted against somatic growth (change in body surface area).

Table I.

Baseline Demographics of Study Cohort

		n = 20
Cardiac diagnosis	Channelopathy	11
	Congenital heart disease	5
	Cardiomyopathy	4
Age (years) *		16 (8–23)
Weight (kg) *		48 (22–57)
ICD system configuration	Transvenous	12
	Nontransvenous	8
Location of high-voltage coil	Transvenous single coil	7
	Transvenous dual coil	5
	Pericardial	6
	Subcutaneous	1
	Pleural	1
Indication for defibrillation threshold testing	New implant	7
	Lead revision	5
	Generator change	5
	Surveillance	3
Antiarrhythmic medications at testing †	Beta-blocker	13
	Calcium-channel blocker	3
	Amiodarone	2
	Other	3

* Age and weight are medians (interquartile range).

† Five patients were on >1 antiarrhythmic agent; other agents included sotalol (1), mexiletine (1), and labetolol (1).