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DEVICES

# Value of defibrillation threshold testing in children with nontransvenous implantable cardioverter defibrillators: Are routine DFT tests indicated?

David Backhoff MD[1,*] | Matthias J. Müller MD[1,*] | Mohammed Dakna PhD[2] | Andreas Leha PhD[2] | Heike Schneider MD[1] | Ulrich Krause MD[1] | Thomas Paul MD[1]

[1] Department of Pediatric Cardiology and Intensive Care Medicine, Georg August University Medical Center, Göttingen, Germany

[2] Department of Medical Statistics, University Medical Center Göttingen, Göttingen, Germany

**Correspondence**
David Backhoff, MD, Department of Pediatric Cardiology and Intensive Care Medicine, Georg August University Medical Center, Robert-Koch-Str. 40, D-37075 Göttingen, Germany.
Email: david.backhoff@med.uni-goettingen.de

*David Backhoff and Matthias J. Müller contributed equally to this work.

## Abstract

**Background:** Nontransvenous implanted cardioverter defibrillators (NT-ICD) are used in infants and small children with life-threatening ventricular tachyarrhythmias. With growth, shock vector shift may result in increase of defibrillation threshold (DFT) and fatal ICD failure.

**Objectives:** To date, the only way to verify ICD function in children with NT-ICD is repetitive DFT testing, which is potentially harmful and may even be life threatening. The aim of the study was to analyze data from NT-ICD DFT testing to prospectively predict individual DFT.

**Patients and methods:** Data from all pediatric patients with NT-ICD implanted in our center from July 2004 to August 2019 were collected. Postoperative DFT testing was scheduled according to individual DFT but at least annually. Surgical revision of NT-ICD was performed if DFT was > 25 J. Selected noninvasive parameters from DFT testing were analyzed as predictors for DFT using a logistic regression model.

**Results:** A total of 46 children with NT-ICD underwent a total of 402 DFT tests. Mean age at implantation had been 5.4 ± 3.3 years, mean follow-up was 5.6 ± 3.7 years in 5 (1%) DFT testing, maximum device output failed, and external defibrillation was necessary. A retrospective multiple mixed logistic regression model was able to predict a DFT ≥25 J (area under the curve [AUC] = 0.836). However, when prospectively validated the model showed moderate performance only (AUC = 0.70).

**Conclusion:** A significant number of NT-ICD failures were detected by serial DFT testing. Serial DFT testing was safe in pediatric patients with an NT-ICD as all induced arrhythmia could be terminated. Prediction of DFT with noninvasive markers remains difficult and might help to schedule intervals for routine DFT tests to avoid unnecessary tests.

KEYWORDS
defibrillation-ICD, noninvasive risk assessment tests, pediatrics

**Abbreviations:** AUC, area under the curve; BSA, body surface area; CHD, congenital heart defects; CI, confidence interval; DFT, defibrillation threshold; ICD, implantable cardioverter defibrillator; IQR, interquartile range; NT-ICD, nontransvenous ICD; VF, ventricular fibrillation.

  

## 1 | INTRODUCTION

The implantable cardioverter defibrillator (ICD) is seldom needed in the pediatric population.[1] However, while ICD systems in adult individuals with normal cardiac anatomy are implanted transvenously or as a subcutaneous device as standard of care, a variety of extracardiac implantation techniques are used in infants and children often placing the shock coil subcutaneously or into the pericardial or pleural space.[2,3] These techniques, however, require careful follow-up as infants and children grow, and significant changes in the geometry of the shock field, that is, between the ICD device and the shock coil, have to be considered.[4] The only way to directly assess the ability of the device to properly sense a lethal ventricular arrhythmia and effectively terminate the rhythm is through and repetitive defibrillation threshold (DFT) testing. Ventricular tachycardia (VT) or ventricular fibrillation (VF) is induced, and the lowest amount of energy needed to terminate the arrhythmia is measured by approximation, that is, the DFT. Data on impact of serial DFT testing in children, however, are sparse.[4]

The aim of the present study was to analyze data from nontransvenous ICD (NT-ICD) DFT tests to prospectively predict individual DFT and the possibility of ineffective ICD therapy avoiding further DFT testing.

## 2 | PATIENTS AND METHODS

For the present study, data of all children with an NT-ICD system who had had repetitive DFT tests between July 2004 and August 2019 in our tertiary pediatric electrophysiology (EP) referral center were collected. Patients with a mixed transvenous/NT-ICD system were not included in this study. Informed consent was given by the legal guardian of all individuals as part of the medical treatment contract of our hospital. The study had been approved by the local scientific committee of the Children's Hospital of Georg August University Medical Center, Göttingen, Germany.

### 2.1 | Patients and ICD systems

A total of 46 children with NT-ICD were into the study. Eighteen of 46 (39.1%) subjects were female. Median age at implantation was 5.8 (interquartile range [IQR] 2.4-8.0, range 44 days-11.5 years) years, median body weight was 20.6 kg (IQR 11.7-25.1), and mean body height was 116 cm (IQR 90-129). A total of four of 46 children were ≤12 months of age at NT-ICD implantation. Indication for ICD implantation was secondary prevention in 30 children (66.2%) and primary prevention of sudden cardiac death in 16 subjects (34.8%). A total of 28 (61%) children had cardiac channelopathies, 14 (31 %) had dilated or hypertrophic cardiomyopathy, and four (8%) suffered from complex congenital heart defects. At implantation, the ICD generator (Medtronic Inc., Minneapolis, MN) was placed in the abdominal cavity behind the musculus rectus abdominis in 13 (28%) or between heart and diaphragm (i.e., "subcardiac device") in 33 (72%) subjects.[5] The position of the shock coil (Transvene® SVC 6937; 35-58 cm Medtronic Inc.) was left lateral subcutaneously in six (13%) subjects or within the left pleural space along the fourth to sixth rib in 36 (78%) children. Another four (9%) children had a vertical arrangement of the shock coil around the left pleural apex. All ICD systems had bipolar steroid-eluting epicardial ventricular pace/sense electrodes (CapSure Epi® 4968; 25–35 cm, Medtronic Inc.). Figure 1 depicts the ICD generator and lead configuration in our patients. In general, the abdominal generator/subcutaneous lead configuration performed worse compared with a subcardiac/subpleural technique[5] and was abandoned during the follow-up of this study. Whenever a surgical ICD revision was needed, the later technique was used. At the time of last DFT testing, the study cohort had a median follow-up of 5.6 years (IQR 1.6-8.1, range 0.1-14.9). Children had reached a median age of 10.5 years (IQR 7.6-14.5; range 0.5-17.4), a median body weight of 33.9 kg (IQR 22.7-54), and a median body height of 137 cm (IQR 126–163).

### 2.2 | DFT test protocol

A uniform modified DFT test protocol was performed in all subjects to measure DFT by 5 J approximation. At the end of the implantation procedure, the first DFT test was performed in the operating room. VF was induced either by T-wave shock or high-frequency stimulation (50 Hz). A 5 J shock was delivered and if not successful, energy was increased in 5 J steps till termination of arrhythmia was achieved. A DFT ≤ 15 J at the end of surgery was considered to be sufficient.[5] If DFT was > 15 J, device or shock coil was rearranged in order to improve the shock field until DFT was <15 J. Prior to discharge from the hospital, a repeat DFT test was performed under sedation with propofol 1-2 mg/kg. First energy output was identical with prior DFT, and a step-up protocol with 5 J steps was used if needed until arrhythmia termination. A safety margin ≥15 J to maximum device output (35 J) was considered sufficient to assure a safe device function. Three months after ICD implantation, patients had repeat follow-up DFT test using the protocol as before. For each DFT test, first shock was identical or 5 J below the last DFT at the discretion of the responsible physician. In general, subsequent DFT test was performed annually if a safety margin ≥10-15 J to maximum device output was given. In individuals with DFT rise ≥5 J due to significant growth or dislodgment of the NT-ICD on chest X-ray, DFT test intervals were shortened at the discretion of the attending physician. Indication for surgical revision was given if DFT was > 25 J, while an individual decision was made in subjects with a DFT of 25 J.

### 2.3 | Descriptive statistics

This study includes repeat measurements (biometrical data, electrical data of the ICD, etc.) of 46 patients, and data sequences were summarized to a "streak" for each individual and ICD system. Following surgical revision, the ICD systems were considered as de novo, and a new

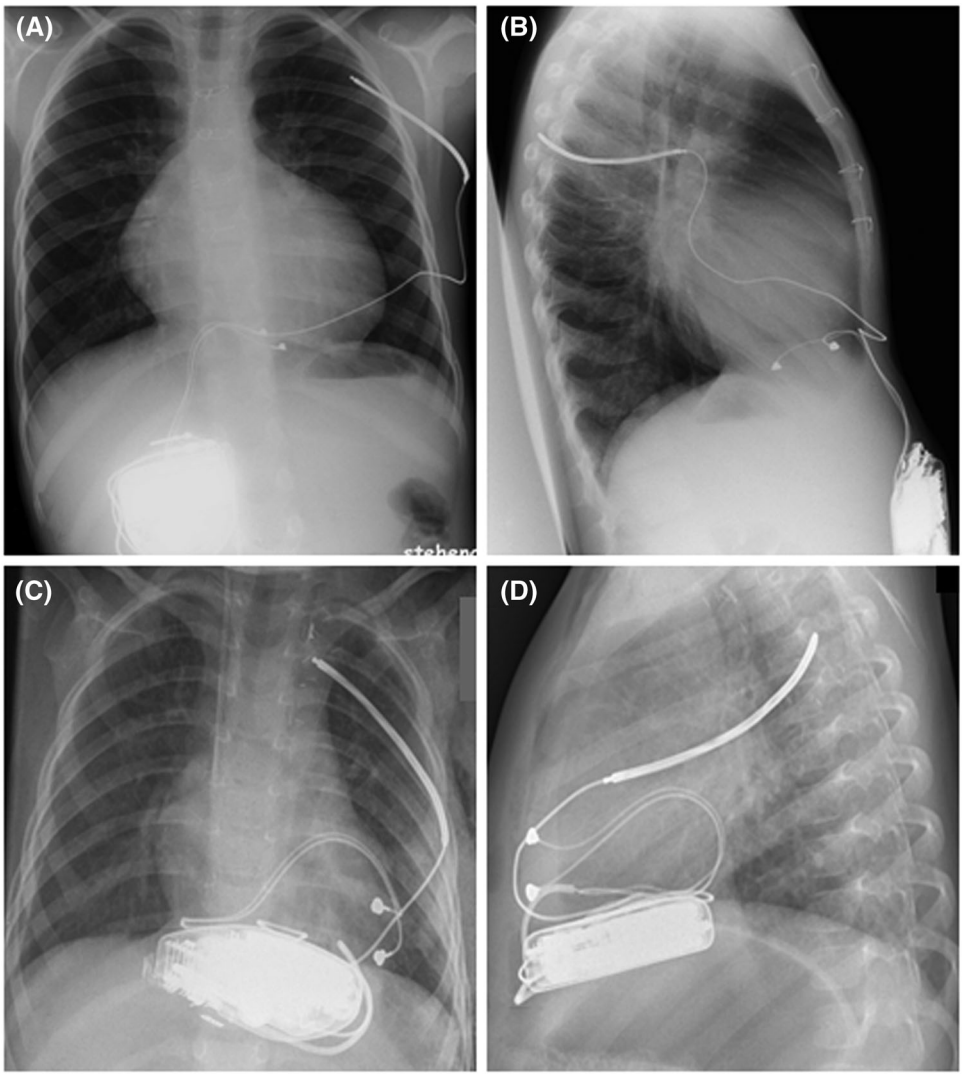


**FIGURE 1** Posterior-anterior and lateral chest X-rays after NT-ICD implantation. Panels (A) and (B) show abdominal/subcutaneous ICD configuration in an 8-year-old boy with Taussig-Bing complex (body weight 18.5 kg, height 119 cm). The ICD device is placed in the abdominal cavity behind the musculus rectus abdominis with the shock coil being fixed subcutaneously along the posterior course of the fifth left rib. Epicardial pace/sense electrodes are sutured to the anterior right ventricular wall. Panels (B) and (C) show subcardiac/pleural ICD configuration in a 9-month-old girl with long QT syndrome (body weight 9.7 kg, height 83 cm). The ICD device has been positioned in a horizontal extra-pericardial position below the right ventricle while the shock coil is fixed in the posterior pleural space along the course of the ribs

"streak" was created. Device exchange due to battery depletion without change of the ICD configuration did not result in a new "streak." Within these "streaks," absolute and relative differences to previous time points as well as the time of last intervention (ICD implantation or surgical revision, if appropriate) or last DFT test of a variety of variables were calculated (see below). Data were summarized by absolute and relative frequencies or median and IQR as appropriate.

## 2.4 | Modeling

To predict a DFT ≥ 25 J, a two-stage mixed multiple regression model was used. For this purpose, all DFT measurements between July 2004 and July 2018 were used to fit this model ("training model"). A total of 360 DFT measurements were identified while only measurements until the occurrence of a DFT ≥ 25 J were considered. As modeling was possible only if data sets were complete, a total of 79 DFT data points could not be included into analysis. The main reason (in 63 of 79 DFT tests) to exclude measurements from further analysis was a first data point of an individual "streak" lacking previous measurements (like "previous DFT") by definition. Accordingly, a total of 281 data points of 38 patients with 54 "streaks" were included in the "training model" covering a total of 14 DFTs ≥ 25 J. This model was subsequently used for prospective predicting DFT as validated by all subsequent DFT measurements (n = 35) until August 2019. Due to two incomplete data sets (see above), this prospective model finally included 33 DFT tests.

A generalized estimating equation model with autoregressive correlation structure of the repeats was used for each potential predictor

as first step of our approach. The predictive information of each single predictor was assessed using likelihood ratio tests against the reduced model without this predictor. Predictors reaching a *P*-value <5% were considered for the "second step" multiple model. Body weight and height were dropped in favor of body surface area (BSA) while one representative variable was taken in case of clusters of correlating variables with a correlation coefficient > 0.8. As an example, time variables were highly correlated (i.e., interval since implantation, interval since last surgically revision, and interval since last DFT test). To build a subject level predictive model, as a "second step," a multiple mixed effect logistic regression model using the identified predictors was fit to the data. The model performance on the "training model" was evaluated by predicting without the random part and evaluated with receiver operating characteristic curves. Accuracy of the model was calculated by the area under the curve (AUC). The best cutoff was calculated with the Youden index. The significance level was defined as 0.05 for all statistical tests. All analyses were performed with R software (version 3.6.0, R core team 2018) using the R-packages lme4 (version 1.1.21)[6] for the mixed effect logistic regression and geepack (version 1.2.1)[7] for the generalized estimating equation modeling.

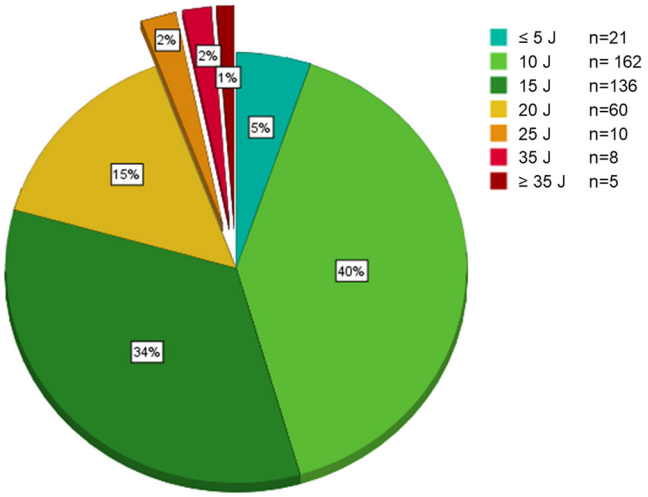


**FIGURE 2** Pie chart depicts the result of DFT tests (n = 402) in 46 subjects. A low DFT (≤20 J) was noticed in 379 tests. Of those tests with a high DFT (separated sections), DFT was 25 J in 10 (2.4%) tests. NT-ICD failure (DFT > 25 J) was observed in 13 tests: maximum device output of 35 J was needed in 8 (2%) tests to terminate arrhythmia, and maximum device output failed to terminate the arrhythmia in another 5 (1.2%) tests [Color figure can be viewed at wileyonlinelibrary.com]

## 3 | RESULTS

For the purpose of this study, data of a total of 402 DFT tests in 46 children could be analyzed. Patients had a median of 9 (IQR 4-11) DFT tests. DFT was ≤20 J in 379 (94%) tests. A DFT ≥25 J was found in 23 tests in 15 children (Table 1). Regarding tests with a high DFT, DFT was 25 J in 10 tests while maximum device output of 35 J was needed in eight (2%) tests to terminate arrhythmia. In five (1%) tests in five patients (11%), maximum device output failed to terminate the arrhythmia, and external defibrillation was needed (i.e., total ICD failure). Figure 2 shows the DFT results. In summary, NT-ICD failure (DFT < 25 J) had an incidence of 0.05 per patient and year. A total of 17 surgical ICD revisions in 13 patients were the result of serial DFT tests, which accounted for 4% of all tests and 17 of 58 (29%) of the NT-ICD systems. There was no relevant complication attributable to surgical revisions of the NT-ICD system. Ventricular arrhythmias, that is, VT and VF, could be terminated in all tests. No serious complications were noted.

### 3.1 | Predicting DFT with noninvasive parameters

For development of the model ("training model, July 2004 to July 2018), only measurements until the first occurrence of a high DFT (i.e., ≥25 J) in each patient were considered (see above). Additionally, a "streak" was created for each patient and NT-ICD system. Finally, a total of 281 data points of 38 patients (and 54 "streaks") were included in the training with a total of 14 measurements ≥25 J. On univariate modeling, biometric data (recent BSA, body weight and height, and absolute and relative increase of the parameters compared to previous DFT tests), previous DFT, and impedance of the shock electrode (recent value as well as absolute and relative change compared to previous DFT test) contributed significantly to the model of DFT ≥25J (Table 2). In a mixed multiple logistic regression model, only the previous DFT ($P$ = .008) correlated independently with a DFT ≥25 (Table 3). The logistic regression model defined a score S that predicted DFT ≥25 J:

$$S = -13.1 - 0.170 \times T + 0.227 \times \mathrm{DFT}_{\mathrm{impl}} - 0.958 \times \mathrm{BSA}_{\mathrm{recent}} + 0.018 \times Sh - \mathrm{Impedance}_{\mathrm{recent}} + 0.03 \times Sh - \mathrm{Impedance}_{\mathrm{last}} + 0.224 \times \mathrm{DFT}_{\mathrm{last}}$$

where $T$ = time after NT-ICD implantation or last surgically revision (years); $\mathrm{DFT}_{\mathrm{impl}}$ = DFT at NT-ICD implantation or last surgically revision (J), $\mathrm{BSA}_{\mathrm{recent}}$ = actual body surface area (kg/m$^2$), Sh-$\mathrm{Impedance}_{\mathrm{recent}}$ = actual impedance of the shock-coil (Ω), Sh-$\mathrm{Impedance}_{\mathrm{last}}$ = impedance of the shock-coil (Ω) at last DFT measurement, $\mathrm{DFT}_{\mathrm{last}}$ = last measured DFT (J).

The score $S$ could be transformed to a probability $p = 1/(1 + e^{(-S)})$.

On the training data, this model achieved a high classification performance (AUC = 0.836, confidence interval [CI] = [0.75; 0.92], $P$ < .001, Figure 3). At the Youden index (cutoff 0.02), a sensitivity of 100% was attained, implying that all 14 DFT tests ≥25 J could have been predicted using this approach. Specificity at this cutoff was 54% meaning that of 267 DFT < 25; J, a total of 142 could correctly be identified (Table 4).

The prospective validation data model, however, achieved only moderate classification performance (AUC = 0.70, CI = [0.37; 1.00], $P$ = .288, Figure 4). Using the cutoff as established from the

**TABLE 1** Patients with a high DFT

| Patient # | DFT tested (J) | DFT predicted (J) | Years after NT-ICD-implantation | Body weight (kg) | Body height (cm) | Δ Impedance shock coil to last measurement (Ω) | Part of the prospective model validation cohort | Consequence |
|---|---|---|---|---|---|---|---|---|
| 9 | 25 | ≥25 | 0.3 | 22.4 | 127 | 23 | | Next DFT test in 6 months |
| 13 | 25 | ≥25 | 0.3 | 13.4 | 98 | −1 | | Next DFT test in 3 months |
| 13 | 25 | ≥25 | 0.5 | 13.6 | 99 | 20 | | Next DFT test in 6 months |
| 37 | 25 | ≥25 | 0.5 | 22 | 116 | 16 | | Change of subcutaneous shock coil |
| 27 | 25 | ≥25 | 0.9 | 25 | 125 | 0 | | Implantation of additional coil |
| 22 | 25 | ≥25 | 6.2 | 83 | 185 | 0 | | Next DFT test in 3 months |
| 34 | 25 | ≥25 | 6.5 | 50 | 169 | 0 | | Explantation and change to transvenous ICD |
| 2 | 25 | <25 | 8.3 | 31.4 | 147 | −1 | Yes | Next DFT test in 6 months |
| 31 | 25 | ≥25 | 9.3 | 41 | 157 | −6 | | Additional shock coil in pericardial space |
| 31 | 25 | ≥25 | 11.8 | 59 | 176 | −2 | | Explantation and change to transvenous ICD |
| 44 | 35 | ≥25 | 0.0 | 21.3 | 123 | n/a | | Next DFT test after 3 days: DFT was 20 J |
| 40 | 35 | ≥25 | 1.5 | 34 | 133 | 21 | Yes | Device reposition (subcardiac = > subcardiac) |
| 33 | 35 | ≥25 | 1.7 | 17 | 111 | 2 | | Device reposition/change |
| 31 | 35 | ≥25 | 2.3 | 18 | 109 | −2 | | New pleural shock coil (subcutaneous = > pleural) |
| 31 | 35 | ≥25 | 2.5 | 19 | 112 | 19 | | Device reposition (abdominal = > subcardiac) |
| 27 | 35 | ≥25 | 5.8 | 45 | 148 | −2 | | Device reposition |
| 9 | 35 | ≥25 | 6.2 | 53 | 165 | 1 | | Explantation and change to transvenous ICD |
| 22 | 35 | ≥25 | 6.9 | 87 | 187 | 8 | Yes | Explantation and change to transvenous ICD |
| 32 | > 35 | ≥25 | 0.1 | 32 | 139 | n/a | | Implantation of an additional coil |
| 11 | > 35 | ≥25 | 1.1 | 33 | 149 | −9 | | Device reposition |
| 37 | > 35 | ≥25 | 1.7 | 26 | 126 | −5 | | New shock coil in pleural space |
| 29 | > 35 | ≥25 | 2.0 | 40 | 153 | −10 | | Device reposition |
| 17 | > 35 | ≥25 | 4.7 | 46 | 154 | 2 | | Explantation and change to transvenous ICD |

Please note that Δ shock coil impedance exceeded ±5 Ω in 10 of 23 tests.

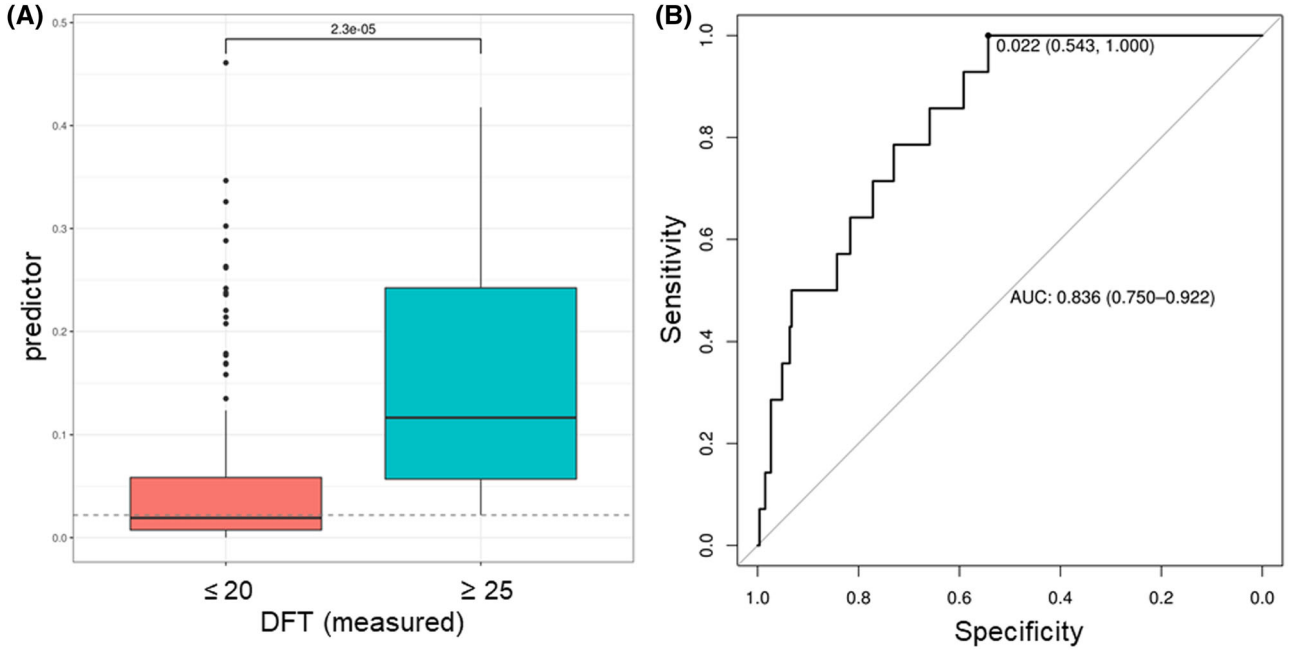


**FIGURE 3** Model performance on the training data. Panel (A) shows the predicted probabilities of an event (DFT ≥ 25) on the *y*-axis grouped by measured DFT on the *x*-axis. Panel (B) shows the corresponding ROC curve [Color figure can be viewed at wileyonlinelibrary.com]

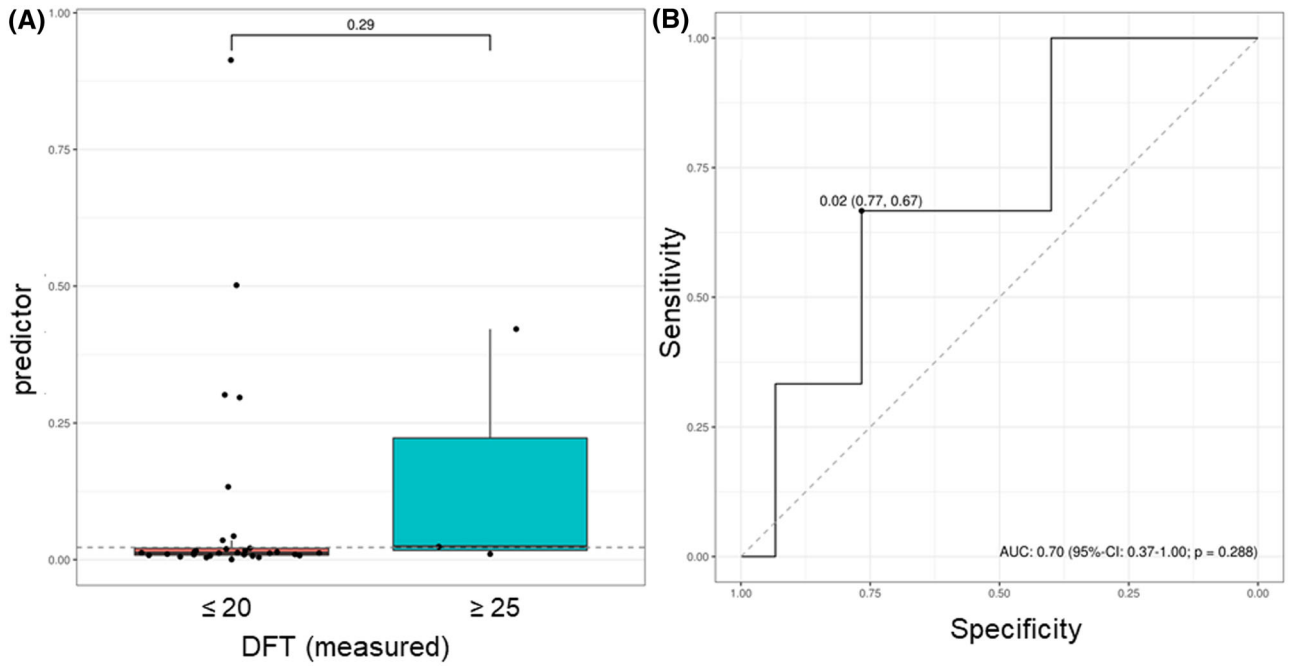


**FIGURE 4** Model performance on the validation data. Panel (A) shows the predicted probabilities of an event (DFT ≥ 25) on the *y*-axis grouped by measured DFT on the *x*-axis. Panel (B) shows the corresponding ROC curve [Color figure can be viewed at wileyonlinelibrary.com]

training data (0.02), two out of three cases with DFT ≥ 25 could be predicted while one was missed (Table 5; see also patient #2 in Table 1). In this particular case, a low probability for a high DFT ($P = .01$) was calculated due to the longevity of the "streak" (i.e., time since implantation of the NT-ICD) and stable impedance of the shock coil as both variables had a protective effect in the training data. Of the 30 cases with DFT < 25, a total of 22 were correctly identified (specificity 73%).

**TABLE 2** Selected results from the univariate correlation as the "first step"

| Parameter | *P*-value |
|---|---|
| Gender | .1163 |
| Shock coil position (subcutaneous/pleural) | .23829 |
| ICD can position (abdominal/subcardiac) | .47377 |
| Age at NT-ICD implantation | .1519 |
| Time since NT-ICD implantation | .8399 |
| Time since last DFT test | .42 |
| DFT recent | $2.034 \times 10^{-06}$ |
| DFT last DFT test | .0004336 |
| DFT delta to last DFT (absolute) | .7094 |
| DFT delta to last DFT (relative) | .6287 |
| Body weight recent | .04171 |
| Body weight last DFT test | .0104 |
| Body weight delta to last DFT test (absolute) | .5976 |
| Body weight delta to last DFT test (relative) | .4708 |
| Body height recent | .03441 |
| Body height last DFT | .00642 |
| Body height delta to last DFT test (absolute) | .8888 |
| Body height delta to last DFT test (relative) | .3725 |
| BSA recent | .03945 |
| BSA last DFT test | .007121 |
| BSA delta to last DFT test(absolute) | .7833 |
| BSA delta to last DFT test (relative) | .4187 |
| Impedance shock coil recent | .03766 |
| Impedance shock coil last DFT test | .002221 |
| Impedance shock coil delta to last DFT test (absolute) | .743 |
| Impedance Shock coil delta to last DFT test (relative) | .5969 |

*P* values are the result of a likelihood ratio tests comparing a null model (including "time since NT-ICD implantation or last surgical revision" only) with the parameter plus the null model.

## 4 | DISCUSSION

Routine DFT tests following ICD implantation are widely abandoned in adult patients with standard transvenous ICD systems.[8–10] Transvenous and subcutaneous ICD implantation is not recommended in children <20 kg body weight due to limited vessel diameter and the risk for tricuspid valve damage. In addition in children with congenital malformations and limited venous access to the heart, transvenous implantation is not feasible at all.[1] In these patients, NT-ICD is the preferred technique, although a shorter longevity of the systems is given when compared with standard ICDs.[1,5,11] A variety of different NT-ICD implantation techniques have been described. During growth of the children, spatial shift of the heart within the shock field has an impact on defibrillation function and may even result in device failure.

General recommendations for follow-up of children with an NT-ICD are lacking. We decided for routine DFT tests to assure proper ICD function being aware that this approach repeatedly puts children in life-threatening arrhythmias. In addition, repeat DFT tests consumes time, resources, and battery lifetime. It is therefore of upmost importance and a main finding of our series that all induced ventricular arrhythmias could be terminated.

The second main finding of our study is the fact that we identified five tests (1%) with failure of the NT-ICD to terminate the arrhythmia even by maximal output due to an otherwise unexpected DFT increase. Additionally, the NT-ICD system was not safe (safety margin to maximum device output <10 J) in another eight (2%) DFT tests reflecting an NT-ICD failure rate of 0.05 per patient and year. A total of 17 surgical ICD revisions were the result of serial DFT tests that account for 4% of all tests and are notably higher than in the "routine" DFT group of the only published pediatric series so far (1/58 [2%]),[12] which included "standard" transvenous ICD systems. However, routine DFT testing has not been performed in previous reports on NT-ICD systems,[11,13] and we confess that the majority of our routine DFT tests just approved a low DFT and proper function of the system. It is therefore challenging to identify subjects at risk for a high DFT while the notable number of ICD failure underscores the need for close surveillance of children with an NT-ICD.

To overcome the problems adherent to repetitive DFT tests, we tried to predict individual DFT by noninvasive parameters in order to abandon routine DFT testing. A safe prediction by using a univariate analysis (increase of body length or shock coil impedance as described before[4]) or a scoring system was not possible in our larger series, and a complex multivariate model was needed. Applying the retrospective "training model," we were able to identify all patients with a high DFT resulting in a sensitivity of 100%. This model was based merely on time variables (time since implantation), biometric data, the previous DFT, and changes in shock coil impedance. Applying this model prospectively to the last 33 DFT tests, however, failed to identify one of three subjects with a high DFT. In this missed case with a DFT of 25 J, the model predicted a low DFT. However, there are a variety of different reasons for NT-ICD failure such as lead fracture of the shock coil or spatial shift of the shock field due to growth, which all needs to be incorporated in the model. Adding more data of DFT tests may increase accuracy to prospectively identify subjects at risk for a high DFT. As a consequence, our recent model could therefore be used to reduce the number of scheduled DFT tests (scheduled routine test with a very low pretest probability for a high DFT could be suspended) but will not replace DFT testing at all. If the probability for a high DFT is low, we will now significantly stretch intervals of routine DFT tests.

Our data strongly support the need for close surveillance of ICD therapy in the young implying assessment of proper device function. Following children with NT-ICD without routine DFT tests will put patients on a significant risk for undiscovered DFT increase permitting situations where the ICD may fail to rescue. We think that the proposed model might add some information to decision-making when to perform and when to pass on routine DFT testing.

**TABLE 3** Model coefficients with 95% CI and *P* values of the model for DFT ≥25

| | Estimate | CI | *P*-value |
|---|---|---|---|
| (Intercept) | 0.000 | (0.000; 0.001) | <.001 |
| BSA recent | 2.605 | (0.484; 14.035) | .265 |
| DFT at NT-ICD implantation or last surgically revision | 1.255 | (0.977; 1.611) | .075 |
| Time since NT-ICD implantation or last surgical revision | 0.843 | (0.625; 1.137) | .264 |
| Shock impedance last DT | 1.031 | (0.967; 1.099) | .353 |
| DFT at last DT | 1.251 | (1.061; 1.476) | .008 |
| Shock impedance recent | 1.018 | (0.958; 1.081) | .570 |

**TABLE 4** Confusion matrix of measured DFT and predictions obtained from the logistic regression model of the "training data" at the Youden index cutoff (0.02), and a high sensitivity was achieved while the DFTs of 142 of 281 DT were correctly predicted to be low ≤20

| | Predicted DFT ≤ 20 | Predicted DFT ≥ 25 | ∑ |
|---|---|---|---|
| Measured DFT ≤ 20 | 142 | 125 | 267 |
| Measured DFT ≥ 25 | 0 | 14 | 14 |
| ∑ | 142 | 139 | 281 |

**TABLE 5** Confusion matrix of measured DFT and predictions obtained from the logistic regression model of the "validation data" at the Youden index cutoff derived from the "training data" (0.02), and one of three patients with a high DFT was not detected by the model

| | Predicted DFT ≤ 20 | Predicted DFT ≥ 25 | ∑ |
|---|---|---|---|
| Measured DFT ≤ 20 | 22 | 8 | 30 |
| Measured DFT ≥ 25 | 1 | 2 | 3 |
| ∑ | 23 | 10 | 33 |

## 5 | LIMITATIONS

This report on NT-ICD is limited by its retrospective single-center design and the limited number of children affected with a variety of cardiac conditions. Additionally, even in our series from a single center, implantation technique of NT-ICDs was not uniform over time but had been modified with growing experience. It must be stated that our DFT test protocol was not a real DFT measurement but rather a 5 J approximation. The statistical model to predict individual DFT may therefore probably only be valid for our patients with the lead configuration/geometry used in our cohort.

It is not clear if this model fits for other system configurations (such as epicardial shock coil) as conditions affecting the defibrillation efficacy over time, such as growth, might primarily depend on configuration and fixation of the system. Impact could be improved if data are derived from patients with a single cardiac condition and a uniform implantation technique. To overcome these limitations at least in part, a multicenter study is needed to close this gap of knowledge.

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## ORCID

*David Backhoff MD* https://orcid.org/0000-0001-7478-5005

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