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Validation of the PRAETORIAN score in a large subcutaneous implantable cardioverter-defibrillator collective: Usefulness in clinical routine

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ABSTRACT

BACKGROUND To assess the risk of unsuccessful conversion of ventricular fibrillation during defibrillation testing (DFT) with the subcutaneous implantable cardioverter-defibrillator (S-ICD), the PRAETORIAN score has been proposed.

OBJECTIVE The purpose of this study was to validate the PRAETORIAN score in a large S-ICD collective.

METHODS A retrospective single-center analysis of S-ICD patients receiving intraoperative DFT was performed. DFT was performed using a stepwise protocol with 65-J standard polarity, change of polarity, increase to 80 J, and repositioning if necessary. If all DFTs failed, we switched to a transvenous ICD.

RESULTS Overall, 398 patients were analyzed (268 male [67.3%]; mean age 42.4 ± 15.9 years; mean body mass index [BMI] 25.9 ± 4.8 kg/m^2). Successful DFT with the first ICD shock was observed in 264 patients (66.3%). One hundred fourteen patients were defibrillated with the second (n = 104) or third (n = 10) DFT after changing shock polarity and/or shock energy. Overall, 20 patients needed at least 3 DFT (ie, 80 J and/or re-positioning). The majority (n = 88 [65.7%]) of DFT failures occurred before 2015 with the first-generation S-ICD. PRAETORIAN score was an independent predictor of DFT failure (odds ratio [OR] 1.007; 95% confidence interval [CI] 1.003–1.011 $P \leq .001$), while whereas BMI alone was not ($P = .31$). Presence of hypertrophic cardiomyopathy (HCM) (OR 2.6; 95% CI 1.3–4.4; $P = .004$) was predictive for at least 1 unsuccessful DFT in our multivariate regression analysis.

CONCLUSION PRAETORIAN score proved to be a useful and valid predictive tool for successful DFT, whereas BMI only had a limited role. Patients with HCM were at increased risk for DFT failure or needed higher DFT energy.

KEYWORDS PRAETORIAN score; Subcutaneous implantable cardioverter-defibrillator; Validation; Defibrillation testing; S-ICD

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Introduction

Implantable cardioverter-defibrillators (ICDs) are established for the treatment of life-threatening tachyarrhythmias (ventricular arrhythmia [VA]) in either primary or secondary prevention.[1] If no pacing need is anticipated, a subcutaneous implantable cardioverter-defibrillator (S-ICD) can be used as an alternative to a conventional transvenous ICD system with fewer lead complications during follow-up.[2–4]

Efficacy in terminating VA with the S-ICD is greatly dependent on the amount of subcutaneous fat and the implantation technique.[5–8] To assess the risk of unsuccessful conversion of ventricular fibrillation (VF) during defibrillation testing (DFT) with the S-ICD, the PRAETORIAN score has been proposed.[9] It is based on device and electrode positioning. Lower scores (30–90 points) go along with a lower risk of conversion failure, and higher scores (>150 points) predict a higher risk of ineffective shocks by the device.[9] In randomized

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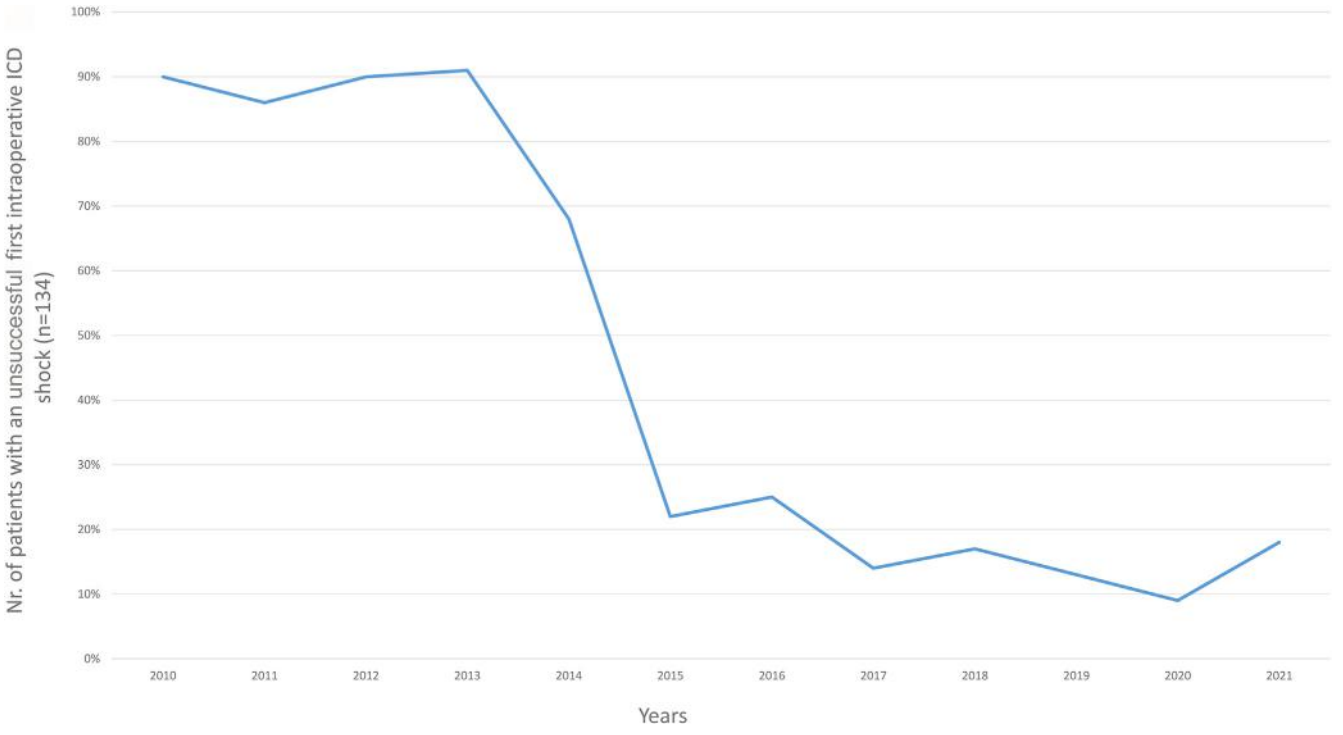

Figure 1
Incidences of unsuccessful defibrillation testing according to the year the subcutaneous implantable cardioverter-defibrillator was implanted.

trials, shock efficacy and prevention of arrhythmic death were not improved by DFT in transvenous ICD systems.[10,11] However, DFT still is recommended for patients undergoing S-ICD implantation, although the conversion rate of DFT in S-ICD is high and first shock efficacy seems similar to transvenous ICD efficacy rates.[1]

Data on clinical applicability of the PRAETORIAN score in real-life patient cohorts are scarce, as the score initially was developed to potentially omit intraoperative DFT.[12] Thus, we aimed to retrospectively test the score in our large patient cohort as well as assess possible other parameters predicting defibrillation success. The ongoing randomized PRAETORIAN-DFT (Prospective Randomized Comparative Trial of Subcutaneous Implantable Cardioverter-Defibrillator Implantation With and Without Defibrillation Testing) trial aims to gain additional scientific evidence to potentially omit a routine DFT after S-ICD implantation in patients with an appropriate PRAETORIAN score.[13]

Abbreviations

BMI: body mass index

CI: confidence interval

DFT: defibrillation testing

HCM: hypertrophic cardiomyopathy

ICD: implantable cardioverter-defibrillator

OR: odds ratio

S-ICD: subcutaneous implantable cardioverter-defibrillator

VA: ventricular arrhythmia

VF: ventricular fibrillation

Methods

Data acquisition

Data for this single-center analysis were derived from our large center S-ICD patient cohort,[14,15] which contains all consecutive patients who received a S-ICD until 2022 (n = 398). All consecutive patients older than 18 years who underwent S-ICD implantation in our clinic until September 2022 were included. Patients who did not receive intraoperative DFT at the time of implantation (n = 7) because of intracardiac thrombi or noninducibility of sustained VF/VA were excluded. A case-based analysis was performed to extract clinical and operational data to calculate the PRAETORIAN score.[9] Calculation of the score consisted of 3 steps—step 1: determination of the number of coil widths of fat tissue between the nearest half of the S-ICD coil and the sternum or ribs; step 2: determination of the position of the S-ICD generator in relation to the midline is performed; and step 3: determination of the amount of fat tissue between the nearest point of the generator and the thoracic wall.

The surgical procedure was performed by 2 experienced senior consulting cardiologists/cardiac surgeons. Between 2010 and 2013, we used the 3-incision technique; from 2013 onward, the 2-incision technique has been applied.[7] Since its implementation in 2016, an intramuscular device placement was also applied in all procedures in accordance with current recommendations and the existing evidence.[6]

Our standard defibrillation protocol was applied as described previously.[16] A successful shock was defined by the conversion of induced VF into sinus rhythm. Routinely, in every patient VF was induced via a 4-second, direct-current burst with the detection rate programmed at a minimum of 170 bpm. The first shock energy was programmed to 65 J assuming a safety margin of 15 J. If the first shock in standard polarity was not successful, an additional shock was delivered in reverse polarity (65 J). If this shock also was not successful, the shock energy was raised to 80 J.

Table 1 Baseline and procedural characteristics of the patient cohort

	Overall	Successful	Unsuccessful	*P* value
No.	398	264	134	
Age (y)	42.4 ± 15.9	41.8 ± 16.3	43.7 ± 15.2	.11
BMI (kg/m^2)	25.9 ± 4.8	25.5 ± 4.7	27.0 ± 4.9	.24
Male sex	268 (67.3)	173 (65.5)	95 (70.9)	.44
Left ventricular ejection fraction (%)	50.2 ± 14.4	50.3 ± 14.3	50.4 ± 14.4	.94
PRAETORIAN score (points)	60.0 [30.0–60.0]	60.0 [30.0–60.0]	60.0 [30.0–150.0]	.01
Low risk (<90)	293 (73.6)	210 (79.6)	83 (61.9)	**<.01**
Intermediate risk (90≤150)	53 (13.3)	30 (11.4)	23 (17.2)	.11
High risk (>150)	52 (13.1)	24 (9.1)	28 (20.9)	**<.01**
Structural heart disease				
Ischemic cardiomyopathy	63 (15.8)	39 (14.8)	24 (17.9)	.47
Dilatative cardiomyopathy	58 (14.6)	36 (13.6)	22 (16.4)	.51
Hypertrophic cardiomyopathy	56 (14.1)	28 (10.6)	28 (20.9)	**<.01**
Congenital cardiomyopathy	32 (8.0)	27 (10.2)	5 (3.7)	**.02**
Valvular cardiomyopathy	19 (4.8)	12 (4.6)	7 (5.2)	.8
Idiopathic ventricular fibrillation	47 (11.8)	35 (13.3)	12 (9.0)	.18
Channelopathy	64 (16.1)	42 (15.9)	22 (16.4)	.97
Other	44 (11.1)	30 (11.4)	14 (10.5)	.73
Left bundle branch block	26 (6.7)	16 (6.1)	10 (7.5)	.97
Right bundle branch block	39 (10.0)	25 (9.5)	14 (10.5)	.86
AV block	24 (6.2)	16 (6.1)	8 (6.0)	.75
QRS width (ms)	106.1 ± 26.0	105.6 ± 25.8	106.9 ± 26.5	.71
Impedance (Ω)	77.0 [65.0–94.0]	72.0 [62.0–87.0]	80.0 [72.0–101.0]	**<.001**
Shock energy (J)				**<.01**
65	373 (93.7)	257 (97.4)	110 (82.1)	
75	17 (4.3)	3 (1.1)	8 (6.0)	
80	8 (2.0)	—	8 (6.0)	
Sensing vector				**<.01**
Primary	198 (49.8)	116 (43.9)	80 (59.7)	
Secondary	152 (38.2)	106 (40.2)	44 (32.4)	
Alternative	48 (12.1)	38 (14.4)	10 (7.5)	
Defibrillation polarity				**<.01**
Standard	342 (85.9)	258 (97.7)	78 (58.2)	
Reversed	56 (14.1)	3 (1.1)	47 (35.1)	

Qualitative data are given as n (%). Quantitative data are given as mean ± SD and median [interquartile range].
Bold *P*-values are <.05.
AV = atrioventricular; BMI = body mass index.

Furthermore, the S-ICD was repositioned to achieve successful shocks in case of unsuccessful DFT with 80 J. If this also was not successful, we switched to a transvenous ICD.

The primary endpoint was defined as successful DFT with the first 65 J. If that was not reached, we defined DFT as unsuccessful. In line with the PRAETORIAN score and other studies,[9,17] we also defined a secondary endpoint for first or second shock in standard/reverse polarity with 65 Joule as a successful DFT.

All patients underwent supine chest radiography on the day of the operation and anterior/posterior and lateral chest radiography on the first postoperative day in the standing position. All chest radiographs were evaluated by 2 senior cardiologists. In addition to PRAETORIAN score baseline characteristics, the type of structural heart disease as well as electrocardiographic data were collected (Table 1).

Statistical analysis

For descriptive statistics, continuous data are given as mean ± SD) or median [interquartile range]. For all analyses, missing values were imputed in advance. Categorical data are given as proportions. Normality of data distribution was assessed graphically and using the Shapiro-Wilk test. Comparisons between groups were performed using the Pearson χ^2 test for categorical variables, Student *t* test, or Mann-Whitney *U* test for unpaired continuous variables and Wilcoxon rank sum test for paired variables according to data distribution. Predictors of the endpoint of an unsuccessful shock were assessed with binomial logistic regression with backward elimination. Candidate predictors with level of significance <.05 were considered in the multivariable regression analysis. Results are expressed as odds ratio (OR) with 95% confidence interval (CI). *P* <.05 was considered significant.

IBM SPSS Statistics 28.0.1.1 software (IBM Corp., Armonk, NY) used for data analysis and visualization. There was no commercial support for conduction of the research or the preparation of this report. The study was approved by the local ethics committee (Ärzte-Kammer Westfalen-Lippe: 2020-241-f-S).

Results

Baseline data

A total of 398 patients were analyzed, with successful intraoperative DFT with the first shock (ie, primary endpoint) in

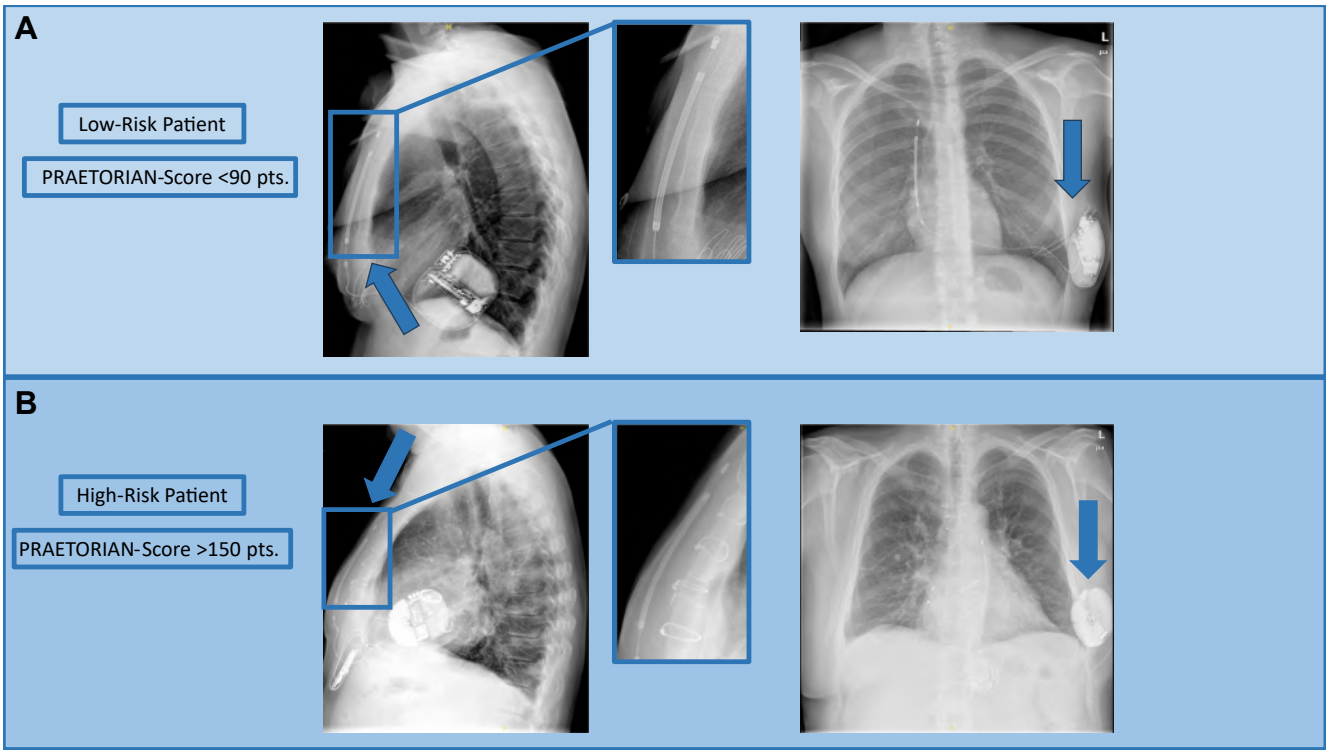

Figure 2
Chest radiographs of a patient with a low PRAETORIAN score (<90 points) with low risk of defibrillation testing (DFT) failure (**A**) and a patient with a high PRAETORIAN score (>150 points) with high risk of DFT failure (**B**).

264 patients (66.3 %) and unsuccessful in 134 patients (33.7 %). Of these 134 patients, most (n = 114 [85.1 %]) were successfully defibrillated with the second (n = 104) or third (n = 10) DFT after changing shock polarity or shock energy, respectively. Overall, 20 patients (5%) needed at least 3 DFT before successful DFT was observed (ie, did not reach the secondary endpoint). Only 7 patients left the operating room without testing due to either an intracardiac thrombus (n = 2) or noninducibility of sustained VF/VA (n = 5) and therefore were not included in the statistical analysis.

Overall, patients where mostly male (n = 268 [67.3 %]), with mean age of 42.4 ± 15.9 years and mean body mass index (BMI) of 25.9 ± 4.8 kg/m^2. Most of the patients with unsuccessful DFT with the first 65 J were operated before 2015 (n = 88 [65.7%]) and therefore before introduction of the second-generation S-ICD. There was no significant difference in BMI between successful and unsuccessful DFT (P = .24). Patients before 2015 had a significantly higher median PRAETORIAN score than patients after 2015 (59.0 [29.0–89.0] vs 59 [29.0–59.0]; $P \leq .01$). Patients with at least 1 unsuccessful DFT had a significantly higher PRAETORIAN score (60.0 [30.0–60.0] vs 60.0 [30.0–150.0]; P = .01) than those with a primarily effective first ICD shock (Figures 1 and 2).

More patients wit hypertrophic cardiomyopathy (HCM) (10.7 % vs 20.6 %; $P \leq .01$) had unsuccessful DFT. In addition, in the 56 included HCM patients, VF was not successfully defibrillated in 28 patients (20.9 %), of whom 16 (11.9 %) had unsuccessful DFT with the first shock and 6 (4.5%) were not successfully defibrillated by the second shock. In the remaining 6 patients, induced VF was terminated by the third or fourth shock with 80 J. No HCM patient had to be switched to an intravenous ICD.

Validation of the PRAETORIAN score

Univariate as well as multivariate logistic regression confirmed the PRAETORIAN score to be an independent predictor for the occurrence of an unsuccessful DFT (OR 1.007; 95% CI 1.003–1.011; $P \leq .001$). Even after adapting the definition of defibrillation success to at least 2 consecutively induced VF episodes that failed to convert at 65 J or with or without reversed polarity, the observed predictive value of the score persisted (P = .006). Presence of HCM (OR 2.6; 95% CI 1.3–4.4; P= .004) also was predictive for DFT failure in our multivariate analysis (Table 2).

Discussion

Patients with an S-ICD often are young and at risk for sustained life-threatening tachyarrhythmias.[1] Because multiple factors influence the efficacy of defibrillation (eg, BMI, cardiomyopathy, device and electrode location),[5,9,18,19] adequate risk stratification regarding efficacy of these devices is important.[1] The PRAETORIAN score was introduced as a noninvasive tool to predict DFT success by evaluating implant position.[9]

Against this background, our analysis revealed the following: in a large consecutive, heterogeneous S-ICD population, most patients had successful DFT after primary device implantation; the PRAETORIAN score was found to be a valid and useful tool to predict the risk of DFT failure; and the

Table 2 Univariate and multivariate logistic regression analyses

	Univariable			Multivariable		
Characteristic	OR	95% CI	*P* value	OR	95% CI	*P* value
Age (y)	0.99	0.98, 1.01	.75			
Male sex	1.05	0.64, 1.69	.85			
BMI (kg/m^2)	0.85	0.53, 1.22	.31			
Praetorian score	1.004	1.001, 1.008	**<.001**	**1.007**	**1.003, 1.011**	**<.001**
Structural heart disease						
Ischemic cardiomyopathy	3.3	0.82, 13.37	.09			
Dilatative cardiomyopathy	10.4	0.8, 13.2	.09			
Hypertrophic cardiomyopathy	2.1	1.22, 3.85	**.008**	**2.6**	**1.3, 4.4**	**.004**
Congenital cardiomyopathy	0.332	0.11, 0.81	**.027**			
Valvular cardiomyopathy	3.1	0.6, 15.0	.16			
Idiopathic ventricular fibrillation	1.8	0.4, 7.6	.41			
Channelopathy	2.7	0.7, 10.6	.14			
Other	2.4	0.6, 9.8	.21			
Left bundle branch block	0.92	0.3,2,5	.84			
Right bundle branch block	0.79	0.2, 2,2	.66			
AV block	1.4	0.5, 3.9	.51			
QRS width (ms)	0.99	0.98, 1.01	.56			
Shock impedance (Ω)	0.98	0.97, 0.99	**<.001**			
Shock energy (J)						
65	1.22	0.4, 3.2	.68			
75	0.82	0.2, 3.2	.77			
80	0.96	0.2, 3.9	.95			
Sensing vector						
Primary	1.8	1.18, 2.74	.36			
Secondary	0.73	0.47, 1.12	.151			
Alternative	0.48	0.22, 0.97	.05			
Defibrillation polarity						
Standard	0.022	0.005, 0.062	**<.001**	**0.022**	**0.007, 0.077**	**<.001**
Reversed	45.59	13.8, 150.1	**<.001**			

Bold values are statistically significant ($P = <.05$).
Bold CI and OR means they are significantly predictive.
CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

presence of HCM was an independent predictor of DFT failure by the S-ICD.

Many predictors for defibrillation success have been proposed, including BMI, S-ICD lead and generator placement, and shock impedance.[5,9] Regarding the predictive value of BMI, studies have shown inconsistent results. Hoster et al[5] reported no change in DFT success depending on BMI in an S-ICD cohort, whereas Quast et al[9] stressed the significance of BMI and therefore included it in the PRAETORIAN score. In this context, our analysis supports the results of Hoster et al,[5] revealing BMI to not be predictive of DFT failure. Many hypotheses on the discrepancy of studies have been proposed, with the most prominent explanation being nonoptimal placement of ICD device/leads with subsequent improvements in implantation technique rather than solely the BMI of the patient.[5] In this regard, large prospective multicenter studies are lacking.

Our analysis demonstrated a trend toward more successful DFT after 2015. Thus, the learning curve of the implanting physicians may play an important role. This is in line with previous findings by Knops et al[8] showing a correlation between the implanting physician's learning curve and operational success. In addition, the apparent drop in incidences of unsuccessful DFT likely is related to the intermuscular implantation technique, which was introduced after 2016 and used for all patients thereafter.[20] An improved implantation technique with more accurate placement of the subcutaneous lead and the device as the key factor in improved DFT effectiveness is evidenced by a significantly improved PRAETORIAN score.[12] The improvement in optimal device placement is supported by results from several trials,[12,21] which could indicate that in patients with optimal device placement the defibrillation threshold is far below 65 J and therefore recommend use of <30 J for DFT testing in these patients.[12,21] Van der Stuijt et al[21] even proposed smaller S-ICD devices with lower maximal energy .

The PRAETORIAN score[9] was demonstrated to be a valid predictive tool to assess the risk for DFT failure in our patient cohort, with an overall low rate of conversion failure in concordance with other studies.[1,9,22] Still, prospective clinical trials are needed to validate the score and increase its clinical usefulness. The ongoing PRAETORIAN-DFT trial hopefully will deliver certainty in this regard.[13]

Data on the effectiveness of the S-ICD in patients with HCM is inconsistent, with some studies reporting reduced defibrillation success in patients with HCM,[23] which is in line with our analysis. In addition, electrocardiographic abnormalities in HCM may predispose to T-wave oversensing and

inappropriate shocks,[24] which is in line with studies demonstrating increased risk of inappropriate shocks by the S-ICD due to T-wave oversensing in HCM.[25–27]

However, other studies have confirmed no association between HCM and acute DFT failure as well as similar S-ICD defibrillation success rates comparable to those of transvenous ICDs in HCM patients.[28,29] Lambiase et al[24] investigated this hypothesis by testing S-ICD performance with regard to DFT testing, arrhythmias, and complications indicating the safety and effectiveness of the S-ICD in patients with HCM who were enrolled in the IDE (S-ICD System IDE Clinical Investigation)[30] and EFFORTLESS (Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the S-ICD)[31] trials.

Study limitations

The analysis is limited to its retrospective nature. Data were gathered from 1 large tertiary center, which limits data generalizability. Data from S-ICD implantations before and after publication of the PRAETORIAN score were included, so a potential bias cannot be excluded. Chest radiographs were collected as standard clinical practice and were not adjudicated or performed in a standardized manner to achieve optimal interpretability of the PRAETORIAN score. To address this limitation, radiograph adjudication was performed by 2 experienced cardiologists. Unfortunately, as intraoperative radiographs are not transferred to the clinical data management software, comparing device and electrode positioning before and after repositioning due to intraoperative DFT failure cannot be analyzed. Only postoperative radiographs on the day of the procedure and the day after were available for analysis and used for this study.

Conclusion

Overall, the PRAETORIAN score was found to be a valid predictive tool to assess DFT success in patients with an S-ICD system. The learning curve of implanting physicians resulting in optimized positioning of the S-ICD as well as use of the second-generation device may have played a role in DFT success. HCM proved to be a negative predictor for S-ICD DFT efficacy. However, contrary to previous expectations, BMI was not predictive in our patient cohort.

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