HeartRhythm

The Official Journal of the Heart Rhythm Society, The Cardiac Electrophysiology Society, and The Pediatric & Congenital Electrophysiology Society

Heart Rhythm Society SM

Check for updates

Predictive value of the PRAETORIAN score for defibrillation test success in patients with subcutaneous ICD: A subanalysis of the PRAETORIAN-DFT trial

Reinoud E. Knops, MD, PhD,[1] Mikhael F. El-Chami, MD, FHRS,[2] Christelle Marquie, MD,[3] Peter Nordbeck, MD,[4] Anne-Floor B.E. Quast, MD, PhD,[1] Roland R. Tilz, MD, PhD, FHRS,[5] Tom F. Brouwer, MD, PhD,[1] Pier D. Lambiase, BCH, BM, MBChB, PhD, FHRS,[6] Christopher J. Cassidy, MD,[7] Lucas V.A. Boersma, MD, PhD,[1,8] Martin C. Burke, DO,[9] Shari Pepplinkhuizen, MD,[1] Jolien A. de Veld, MD,[1] Anouk de Weger, MSc,[1] Frank A.L.E. Bracke, MD, PhD,[10] Harish Manyam, MD,[11] Vincent Probst, MD, PhD,[12] Timothy R. Betts, MD,[13] Nick R. Bijsterveld, MD, PhD,[1,14] Pascal Defaye, MD,[15] Thomas Demming, MD,[16] Jan Elders, MPA,[17] Duncan C. Field, MD,[18] Abdul Ghani, MD, PhD,[19] Gregory Golovchiner, MD,[20] Jonas S.S.G. de Jong, MD, PhD,[21] Nigel Lewis, MD, PhD,[22] Eloi Marijon, MD, PhD,[23] Claire A. Martin, MD, PhD,[24] Marc A. Miller, MD,[25] Naushad A. Shaik, MBBS, MD, FHRS, CCDS,[26] Willeke van der Stuijt, MD, PhD,[1] Jürgen Kuschyk, MD,[27,28] Louise R.A. Olde Nordkamp, MD, PhD,[1] Anita Arya, MD,[29] Alida E. Borger van der Burg, MD, PhD,[30] Serge Boveda, MD, PhD,[31] Dirk J. van Doorn, MD, PhD,[32] Michael Glikson, MD,[33] Lukas Kaiser, MD,[34] Alexander H. Maass, MD, PhD,[35] Léon J.P.M. van Woerkens, MD, PhD,[36] Amir Zaidi, MD,[37] Arthur A.M. Wilde, MD, PhD,[1] Lonneke Smeding, PhD[1]

ABSTRACT

BACKGROUND The PRAETORIAN score estimates the risk of failure of subcutaneous implantable cardioverter-defibrillator (S-ICD) therapy by using generator and lead positioning on bidirectional chest radiographs. The PRospective randomized compArative trial of subcutanEous implanTable cardiOverter-defibrillatoR ImplANtation with and without DeFibrillation

From the [1]Amsterdam UMC location University of Amsterdam, Heart Center, Department of Cardiology, Amsterdam Cardiovascular Sciences Heart Failure & Arrhythmias, Amsterdam, The Netherlands, [2]Division of Cardiology Section of Electrophysiology, Emory University, Atlanta, Georgia, [3]CHU de Lille, Department of Cardiology, Lille, France, [4]Department of Internal Medicine I, University and University Hospital Würzburg, Würzburg, Germany, [5]Department of Rhythmology, University Heart Center Lübeck, University Hospital Schleswig-Holstein, Lübeck, Germany, [6]Office of the Director of Clinical Electrophysiology Research and Lead for Inherited Arrhythmia Specialist Services, University College London and Barts Heart Centre, London, United Kingdom, [7]Lancashire Cardiac Centre, Blackpool Teaching Hospitals NHS Trust, Blackpool, United Kingdom, [8]Department of Cardiology, St. Antonius Hospital, Nieuwegein, The Netherlands, [9]CorVita Science Foundation, Chicago, Illinois, [10]Department of Electrophysiology, Catharina Hospital Eindhoven, Eindhoven, The Netherlands, [11]Department of Cardiology Erlanger Health System, University of Tennessee, Chattanooga, Tennessee, [12]Service de Cardiologie, L'institut du thorax, CHU Nantes, Nantes, France, [13]Oxford Biomedical Research Centre, Oxford University Hospitals NHS Trust, Oxford, United Kingdom, [14]Department of Cardiology, Flevoziekenhuis, Almere, The Netherlands, [15]Service de Cardiologie, Centre hospitalier universitaire, Grenoble, France, [16]Department of Internal Medicine III, Cardiology, Angiology, and Critical Care, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany, [17]Department of Cardiology, Canisius Wilhelminahospital, Nijmegen, The Netherlands, [18]Cardiology, Essex Cardiothoracic Centre, Mid and South Essex NHS Foundation Trust, Basildon, United Kingdom, [19]Department of Cardiology, Isala Heart Centre, Zwolle, The Netherlands, [20]Department of Cardiology, Rabin Medical Center, Petah Tikva, Israel, [21]Department of Cardiology, OLVG, Amsterdam, The Netherlands, [22]Department of Cardiology, Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, United Kingdom, [23]Division of Cardiology, European Georges Pompidou Hospital, Paris, France, [24]Department of Cardiology, Royal Papworth Hospital, Cambridge, United Kingdom, [25]Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, New York, New York, [26]Department of Cardiac Electrophysiology, Advent Health Orlando, Orlando, Florida, [27]First Department of Medicine, University Medical Center Mannheim, Mannheim, Germany, [28]First Department of Medicine–Cardiology, University Medical Center Mannheim, and the German Center for Cardiovascular Research Partner Site Heidelberg–Mannheim, Mannheim, Germany, [29]New Cross Hospital, Heart and Lung Centre, Division of Electrophysiology and Devices, Royal Wolverhampton NHS Trust, Wolverhampton, United Kingdom, [30]Department of Cardiology, Medisch Centrum Leeuwarden, Leeuwarden, The Netherlands, [31]Heart Rhythm Department, Clinique Pasteur, Toulouse, France, [32]Department of Cardiology, Spaarne Gasthuis, Hoofddorp, The Netherlands, [33]Jesselson Integrated Heart Center, Shaare Zedek Medical Center, Jerusalem, Israel, [34]Department of Cardiology and Critical Care Medicine, Asklepios Klinik St. Georg, Hamburg, Germany, [35]Department of Cardiology, University Medical Center Groningen, Groningen, The Netherlands, [36]Albert Schweitzer Ziekenhuis, Dordrecht, The Netherlands, and [37]Manchester Heart Centre, Central Manchester University Hospitals NHS Foundation Trust, Manchester Academic Health Sciences Centre, Manchester, United Kingdom.

https://doi.org/10.1016/j.hrthm.2024.02.005

Testing (PRAETORIAN-DFT) investigates whether PRAETORIAN score calculation is noninferior to defibrillation testing (DFT) with regard to first shock efficacy in spontaneous events.

OBJECTIVE This prespecified subanalysis assessed the predictive value of the PRAETORIAN score for defibrillation success in induced ventricular arrhythmias.

METHODS This multicenter investigator-initiated trial randomized 965 patients between DFT and PRAETORIAN score calculation after de novo S-ICD implantation. *Successful DFT* was defined as conversion of induced ventricular arrhythmia in <5 seconds from shock delivery within 2 attempts. Bidirectional chest radiographs were obtained after implantation. The predictive value of the PRAETORIAN score for DFT success was calculated for patients in the DFT arm.

RESULTS In total, 482 patients were randomized to undergo DFT. Of these patients, 457 (95%) underwent DFT according to protocol, of whom 445 (97%) had successful DFT and 12 (3%) had failed DFT. A PRAETORIAN score of ≥90 had a positive predictive value of 25% for failed DFT, and a PRAETORIAN score of <90 had a negative predictive value of 99% for successful DFT. A PRAETORIAN score of ≥90 was the strongest independent predictor for failed DFT (odds ratio 33.77; confidence interval 6.13–279.95; $P < .001$).

CONCLUSION A PRAETORIAN score of <90 serves as a reliable indicator for DFT success in patients with S-ICD, and a PRAETORIAN score of ≥90 is a strong predictor for DFT failure.

KEYWORDS Transvenous ICD; Subcutaneous ICD; PRAETORIAN score; Defibrillation testing; Ventricular arrhythmia

(Heart Rhythm 2024;21:836–844)

Introduction

The subcutaneous implantable cardioverter-defibrillator (S-ICD) is a safe and effective therapy for the termination of potential life-threatening ventricular arrhythmias.[1] Currently, a defibrillation test (DFT) is performed after S-ICD implantation to test the effective termination of induced ventricular arrhythmia as a result of correct device positioning and ventricular arrhythmia sensing. However, DFT carries a risk of complications, including stroke, prolonged resuscitation, and, in rare cases, death.[2,3] Moreover, DFT requires deep sedation or general anesthesia, which creates logistical challenges and may increase procedure time.[4] Omitting DFT after ICD implantation would eliminate the risk of these complications and reduce the logistical burdens.

In patients undergoing transvenous ICD (TV-ICD) implantation, the SIMPLE and NORDIC studies have shown no greater shock efficacy or survival when a DFT is performed.[5,6] As a result, DFT is no longer routinely performed after TV-ICD implantation. In contrast to the TV-ICD, the S-ICD is a completely extrathoracic device, implanted with the generator on the left side of the thoracic wall and the lead on the sternum.[7] The results from the aforementioned trials can therefore not be extrapolated to patients with S-ICD. Correct implant positioning is crucial to guarantee successful shock efficacy.[8] To predict defibrillation success in S-ICD recipients, the PRAETORIAN score was developed.[9] The score was generated on the basis of the results of a computer modeling study.[8] Thereafter, it was retrospectively validated in an external cohort, showing a negative predictive value of 99.6% and a positive predictive value of 51.2%, with a sensitivity and specificity of both 95%.[9]

Currently, it is unclear whether the PRAETORIAN score is a good predictor for shock efficacy in spontaneous events. The PRospective randomized compArative trial of subcutanEous implanTable cardiOverter-defibrillatoR ImplANtation with and without DeFibrillation Testing (PRAETORIAN-DFT) investigates whether S-ICD implantation without DFT but with PRAETORIAN score calculation is noninferior to implantation with DFT with regard to first shock efficacy in spontaneous events.[10] However, pending the long-term outcomes of this trial, prospective validation of the PRAETORIAN score is essential to enhance its use within current clinical practice. This prespecified subanalysis of the PRAETORIAN-DFT trial assesses the predictive value of the PRAETORIAN score for defibrillation success in induced ventricular arrhythmias.

Abbreviations

DFT: defibrillation test

IQR: interquartile range

PRAETORIAN-DFT: PRospective randomized compArative trial of subcutanEous implanTable cardiOverter-defibrillatoR ImplANtation with and without DeFibrillation Testing

S-ICD: subcutaneous implantable cardioverter-defibrillator

TV-ICD: transvenous implantable cardioverter-defibrillator

Methods

Trial design of the PRAETORIAN-DFT trial

The PRAETORIAN-DFT trial is an investigator-initiated, international, multicenter trial. In this trial, 965 patients with S-ICD were randomized in a 1:1 ratio to either undergo DFT or not undergo DFT. In the no DFT arm, the PRAETORIAN score was calculated on the basis of the standard bidirectional chest radiographs obtained after implantation to evaluate correct implant positioning and therefore predict defibrillation success.[10] Patients 18 years or older who underwent de novo S-ICD implantation were included. Main exclusion criteria were contraindications for DFT, such as intracardiac thrombus, atrial fibrillation without appropriate anticoagulation, or other contraindications for DFT per physician discretion. Ideally, DFT should be performed immediately after implantation. However, exceptions were allowed for

temporary DFT-related issues, such as hemodynamic instability, or logistical challenges, permitting the DFT to be performed within 6 weeks of implantation. A *successful DFT* was defined as successful conversion of induced ventricular arrhythmia in <5 seconds from shock delivery within 2 attempts. The first shock was delivered at 65 J in standard polarity. Only in case of failed conversion after the first attempt, a second induction and 65 J shock delivery in reversed polarity was performed. Further action on failed DFT was per physician discretion but included at least repositioning of the device and/or additional DFT. Bidirectional chest radiographs were obtained after implantation to calculate the PRAETORIAN sore. The PRAETORIAN-DFT study protocol was approved by the institutional medical ethical committees, and all patients provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki.

Chest radiograph requirements

Applying the PRAETORIAN score requires a standard chest radiograph of sufficient quality, which includes appropriate radiation dosage and clear visibility of at least the generator, lead, and sternum. In addition, in accordance with standard requirements for these radiographs, patient's positioning should involve minimal angulation, the arms elevated to ~90°, and sufficient inspiration. Lastly, the PRAETORIAN score can only be applied when the S-ICD generator and lead are implanted within the specific indicated anatomical areas (Figure 1). These anatomical areas are a lenient representation of the implantation requirements in the S-ICD manual.[11] The coil should not be positioned below the xiphoid process, above the manubriosternal junction, or more than a centimeter lateral from the sternal border. The cranial side of the generator has to project over the heart. If any of the above-mentioned criteria are not met, the score is not applicable.

PRAETORIAN score

An extensive description of the score has been published previously.[9] The PRAETORIAN score ranges from 30 to 900 and categorizes the risk of conversion failure into 3 categories: low risk (<90 points), intermediate risk (90–<150 points), and high risk (≥150 points). In short, the score involves 4 steps, with steps 1 and 2 determined from the lateral chest radiograph. In step 1, the amount of fat tissue between the coil and the sternum is determined, while step 2 assesses the position of the generator in relation to the midline of the left side of the thoracic wall. Step 3 is calculated using the posteroanterior chest radiograph and evaluates the amount of fat tissue between the nearest point of the generator and the thoracic wall. In the final step, step 4, 40 points are subtracted for patients with a body mass index of ≤25 kg/m^2 and a score of ≥90 points (Figure 2).

Data collection and definitions

This analysis included all patients randomized to the DFT arm. Data on DFT success and postimplant bidirectional chest radiographs were collected for all patients. The evaluation of the chest radiograph was conducted by a core laboratory that consisted of 3 physicians (R.E.K., N.R.B., and A.-F.B.E.Q.) who were trained for the calculation of the PRAETORIAN score and who were blinded to DFT results. First, the core laboratory members individually assessed the quality of the radiographs according to the criteria described above. If the criteria were met, the PRAETORIAN score was calculated. Agreement on score calculation was based on the majority opinion, and if necessary, consensus was reached by group discussion. In the no DFT arm of the study, patients with an intermediate or high PRAETORIAN score (≥90 points) are expected to have a considerable risk of conversion failure and performing an additional DFT is mandated by protocol. For this subanalysis, intermediate and high PRAETORIAN score categories were therefore combined. In cases where repositioning of the S-ICD occurred immediately after 1 or 2 failed DFT attempts with a 65 J shock, before a chest radiograph was obtained, a PRAETORIAN score of 150 points was allocated. In these cases, a high PRAETORIAN score before repositioning was most likely, as the lead and/or generator was repositioned because of a presumed incorrect implant position.

Statistical analysis

Descriptive statistics are presented as mean ± SD or median with interquartile range (IQR) for continuous variables and number and percentage for categorical variables. The positive and negative predictive values of the PRAETORIAN score were calculated by using 2 × 2 tables. A sensitivity analysis was performed excluding patients with immediate repositioning after DFT failure. Univariable and multivariable logistic regression analysis was performed to find predictors for DFT failure. We selected a height of 190 cm as the criterion for "tall height," aligning with the average height of the world's tallest population plus 1SD.[12] Similarly, a shock impedance of 100 Ω was chosen to indicate high shock impedance, as an impedance above 100 Ω is associated with a higher change of DFT failure.[9] Statistical analysis was performed using R software version 4.2.1 (RStudio PBC, Boston, MA).

Results

Patient and implant characteristics

In 27 centers across Europe, the United States, and Israel, a total of 965 patients were included in the study, of whom 482 were randomized to undergo a DFT. In this arm, the median age was 55 years (IQR 44–63 years) and the median body mass index was 27 kg/m^2 (IQR 24–31 kg/m^2). The majority had ischemic cardiomyopathy (222 patients; 46%), 175 patients (36%) had a secondary prevention indication, and 250 patients had an ejection fraction of ≤35% (52%) (Table 1). The mean procedure duration was 52 ± 22 minutes, and the 2-incision technique was used in 466 of 482 patients (97%). The generator was implanted intermuscularly in 367 patients (76%), subcutaneously in 79 patients (16%), and submuscularly in 36 patients (8%). Eighteen patients (4%) had the lead implanted on the right side of the sternum; all other patients had the lead implanted on the left side.

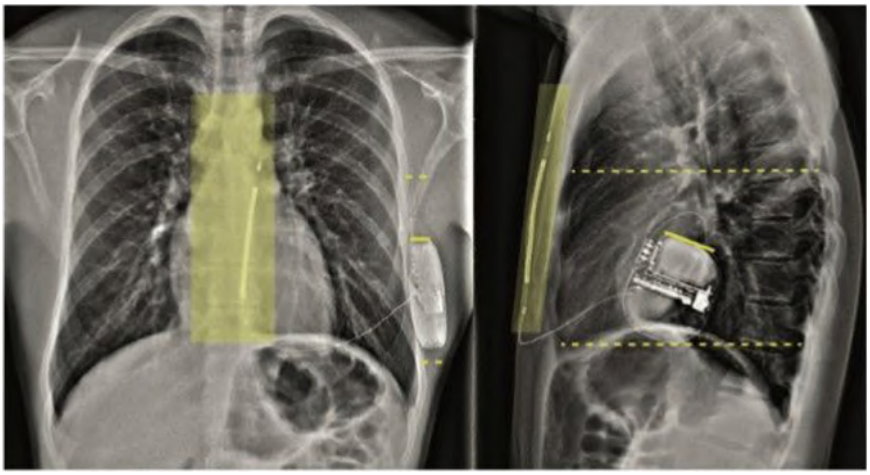

Figure 1
Anatomical criteria for the application of the PRAETORIAN score after subcutaneous implantable cardioverter-defibrillator implantation. Anatomical implant criteria: (1) The coil should not be positioned below the xiphoid process, above the manubriosternal junction, or more than a centimeter lateral from the sternal border (*yellow square*). (2) The cranial side of the generator has to project over the heart (*solid line* should be between the 2 *broken lines*).

Defibrillation testing

In 16 patients, no DFT was performed, and in 12 of 16 patients, induction failed to provoke ventricular arrhythmias, 2 patients had ongoing spontaneous conversions, 1 patient underwent S-ICD removal owing to infection before DFT could be performed, and in 1 patient no DFT was performed per physician discretion (Figure 3). In 457 of 466 patients undergoing DFT, the DFT was performed according to protocol, of whom 445 had a successful DFT and 12 had a failed DFT. In 9 patients, after a first failed 65 J shock, no second DFT was performed, but a successful 80 J shock was accepted at physician discretion. Because of protocol violation, these patients were excluded for further analysis. In 5 patients, repositioning of the lead and/or generator was performed directly after failed DFT and no chest radiographs of the S-ICD position during this failed DFT were available. In these patients, a PRAETORIAN score of 150 was applied.

Chest radiograph selection

Radiographs of 27% of patients (122 of 457) were not eligible for calculation of the PRAETORIAN score. This included 120 chest radiographs of patients with a successful DFT and 2 of patients with a failed DFT (Figure 3). In 79 of 122 ineligible radiographs, the anatomical implant position was outside the indicated anatomical areas (Online Supplemental Figure 1). Furthermore, 61 patients assumed an incorrect position on the chest radiograph or visibility of elements was insufficient for the calculation of the PRAETORIAN score. Among these

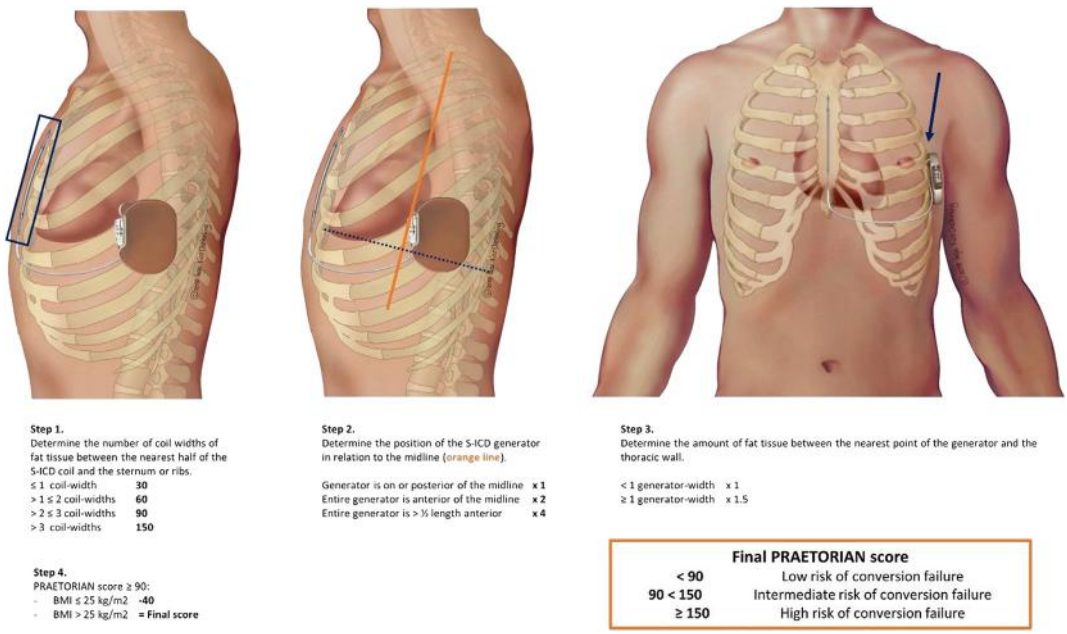

Figure 2
PRAETORIAN score. BMI = body mass index; S-ICD = subcutaneous implantable cardioverter-defibrillator.

Table 1 Patient characteristics (N = 482)

Characteristic	Value
Age (y)	55 (44–63)
Female sex	117/482 (24.3)
Height (cm)	176 ± 9.6
Secondary prevention	175/482 (36.3)
History of OHCA	176/482 (36.5)
Ejection fraction >35%	231/481 (48.0)
Diagnosis	
Ischemic cardiomyopathy	222/482 (46.1)
Nonischemic cardiomyopathy	162/482 (33.6)
Hypertrophic cardiomyopathy	51/482 (10.6)
Dilated cardiomyopathy	74/482 (15.4)
ARVC	7/482 (1.5)
Toxic cardiomyopathy	2/482 (0.4)
Other	28/482 (5.8)
Genetic arrhythmia syndrome	47/482 (9.8)
Idiopathic ventricular fibrillation	45/482 (9.3)
Congenital heart disease	6/482 (1.2)
Body mass index	27 (24–31)
History of atrial fibrillation	72/482 (14.9)
CIED in situ during implantation	
Transvenous ICD	13/482 (2.7)
Connected ICD lead in situ	9/482 (1.9)
Abandoned ICD lead in situ	6/482 (1.2)
Transvenous pacemaker	1/482 (0.2)
Implantable loop recorder	7/482 (1.5)
Use of medication at baseline	
β-Blocker	382/482 (79.3)
ACE inhibitor	225/482 (46.7)
Diuretic	244/482 (50.6)
Antiarrhythmic	51/482 (10.6)
Antiplatelet	235/482 (48.8)
Anticoagulant	128/482 (26.6)

Values are presented as mean ± SD, median (interquartile range), or n/total n (%).
ACE = angiotensin-converting enzyme; ARVC = arrhythmogenic right ventricular cardiomyopathy; CIED = cardiovascular implanted electronic device; DFT = defibrillation test; ICD = implantable cardioverter-defibrillator; OHCA = out-of-hospital cardiac arrest.

patients, 24 were excluded because of both anatomical implant position and incorrect positioning of the patient or insufficient visibility of elements. The other excluded chest radiographs were due to poor quality (n = 6) (Table 2). Finally, the PRAETORIAN score was calculated for a total of 335 patients, of whom 325 had a successful DFT and 10 patients had a failed DFT.

PRAETORIAN score and DFT success

In total, 307 patients had a PRAETORIAN score of <90, of whom 3 had a failed DFT. Twenty-eight patients had a PRAETORIAN score of ≥90, of whom 7 had a failed DFT. This resulted in a positive predictive value of 25% and a negative predictive value of 99% (Table 3).

Of the 307 patients with a PRAETORIAN score of <90, 246 had a score of 30. DFT was successful in 245 patients with a PRAETORIAN score of 30 and failed in 1 patient. Of the 3 patients with a PRAETORIAN score of <90 who had a failed DFT, 2 had a height of >190 cm. The third patient was treated with amiodarone (Online Supplemental Table 1). All these 3 patients successfully converted with an 80 J shock. This DFT result was accepted at physician discretion. The 65 J shock efficacy in patients with a PRAETORIAN score of <90 during DFT was 96.7% after the first shock, 99% after the second shock, and 100% after also including successful 80 J shocks when given. Of the 28 patients with a PRAETORIAN score of ≥90, 12 had a score of ≥150, of whom 5 had a failed DFT (Table 4; Online Supplemental Figure 2). A sensitivity analysis excluding patients with repositioning of the device immediately after failed DFT can be found in Online Supplemental Table 2. Interventions after DFT failure are provided in Online Supplemental Table 3. The median impedance of the first unsuccessful shock in patients who experienced a failed DFT was significantly higher than the impedance of the first shock in patients with a successful DFT (86.5; IQR 66.3–103.3 and 68.0; IQR 57.0–78.8, respectively; $P = .014$).

Predictors for DFT failure

Independent predictors for DFT failure were a height of ≥190 cm ($P = .004$) and an impedance of ≥100 Ω ($P = .01$) (Online Supplemental Tables 4 and 5). A PRAETORIAN score of ≥90 was a strong dependent predictor for failed DFT, and when included in the multivariable analysis, a PRAETORIAN score of ≥90 was the strongest independent predictor (odds ratio 33.77; confidence interval 6.13–279.95; $P < .001$) (Online Supplementary Table 6).

Discussion

This study showed that patients with a PRAETORIAN score of <90 have a 99% chance of DFT success whereas patients with a PRAETORIAN score of ≥90 have a 25% risk of DFT failure. A height of ≥190 cm and an impedance at the first DFT of ≥100 Ω were independent predictors for DFT failure. A PRAETORIAN score of ≥90 was the strongest predictor for failed DFT.

Negative predictive value of the PRAETORIAN score

The present study confirms the previously reported high negative predictive values of the PRAETORIAN score (100% and 99.6%), supporting the conclusion that a PRAETORIAN score of <90 serves as a reliable predictor for successful DFT.[9] However, it is important to acknowledge that DFT failure can still occur owing to factors unrelated to implant position, such as left ventricular hypertrophy or dilatation, body size, and medication such as amiodarone, or clinical circumstances such as hyperkalemia that increase the defibrillation threshold.[13–16] In this study, 2 of 3 patients with a failed DFT and a PRAETORIAN score of <90 had a height of >190 cm. Both also experienced an external rescue shock failure. A third patient with a failed DFT and a PRAETORIAN score of <90 was treated with amiodarone. As in these 3 patients DFT with 80 J was successful, we postulate that the DFT threshold is situated between 65 J and 80 J. Importantly, all patients with a PRAETORIAN score of <90 had successful conversion by the S-ICD.

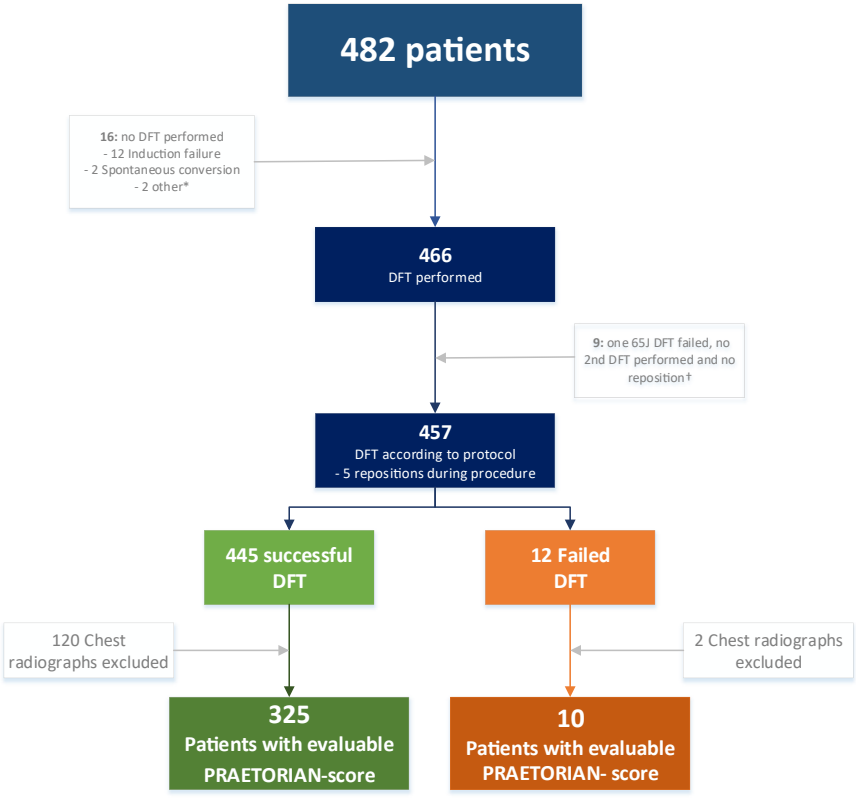

Figure 3
Flowchart of the exclusion of patients in the DFT arm. *One physician discretion and 1 extraction due to infection before DFT could be performed. †In 7 patients, an 80 J shock was successful and no second 65 J shock was performed; 1 patient experienced spontaneous conversion during second DFT; 1 patient had a first failed 65 J shock after which resuscitation was necessary, and for that reason, no second DFT was performed. DFT = defibrillation test.

Positive predictive value of the PRAETORIAN score

The positive predictive value of a PRAETORIAN score of ≥90 in this study was 25%. This is lower than shown in the retrospective analysis of Quast et al,[9] which showed a positive predictive value of 50% for the failed DFT. This retrospective validation was performed in the cohort of the S-ICD Investigational Device Exemption Clinical Study, which included the first S-ICD implants of many implanters.[17] Since this trial, there have been substantial improvements in implant techniques and experience leading to better implants, which is seen in an increased percentage of implants with a PRAETORIAN score of <90 from 87% in the retrospective validation to 92% in the present analysis. A positive predictive value is lower in samples in which the event prevalence is low.[18] As a failed DFT occurred in only 10 of 335 patients (3%) in our population, a high positive predictive value is hard to obtain. Nevertheless, the results of the present prospective analysis confirm the substantial chance of unsuccessful defibrillation with a PRAETORIAN score of >90.

Exclusion of chest radiographs

A high percentage of radiographs was not eligible for the calculation of the PRAETORIAN score in this study. Because of the nature of a multicenter trial, fluctuations in the quality of and protocols used for chest radiographs were inevitable. In the study arm investigated in this analysis, images obtained as part of standard care were collected, but physicians were not obliged to check the radiographs and calculate the PRAETORIAN score. Immediate evaluation of the radiographs after implantation allows for a repeat radiograph in case of insufficient quality, which could have reduced the number of excluded radiographs. However, the majority of the radiographs was excluded because of implantation outside the indicated anatomical areas. This underlines that S-ICD implantation is not a trivial procedure and the use of fluoroscopy and/or marking with anatomical landmarks can be helpful to determine correct position.

Other predictors for DFT failure

Height (>190 cm) was identified as an independent predictor for DFT failure. Previous studies with TV-ICDs have also associated height with higher defibrillation thresholds.[13,19] In addition, in tall patients with S-ICD, the lead may be implanted too cranial, thereby not projecting over the heart while still being below the manubriosternal junction. In this position, the current of the S-ICD shock may not defibrillate the ventricles, resulting in failed conversion. In tall patients, the use of fluoroscopy during implantation to determine the relative position to the heart may be preferred over the use of anatomical landmarks.

Another independent predictor for DFT failure was shock impedance. A high impedance may be the result of fat tissue

Table 2 Exclusion of chest radiographs (n = 122*)

Reason for exclusion	Value
Anatomical implant position outside the indicated areas	79†
Coil under the xiphoid process	5
Coil above the manubriosternal junction	5
Coil >1 cm lateral of the sternum border‡	69
Coil left	63
Coil right	6
Generator outside the anatomical areas	8
Insufficient quality of the chest radiograph	6
Incorrect patient position and/or visibility of components	61§
Can poorly visible	4
Lead poorly visible	11
Sternum poorly visible	28
Oblique position	30
Arms not elevated‖	19
Incomplete inspiration	1

*A total of 24 patients had a combination of implantation outside the indicated anatomical areas and an incorrect position and/or no visibility of a component necessary to apply the PRAETORIAN score.
†Three patients had the coil above the manubriosternal junction and >1 cm lateral to the sternum. One patient had the coil under the xiphoid process and >1 cm lateral to the sternum. A total of 4 patients had a combination of the lead and generator outside the indicated anatomical areas.
‡The coil had to be outside the indicated anatomical areas for at least 50% to be excluded.
§A total of 22 patients had ≥1 reason to exclude the chest radiograph because of incorrect position and/or visibility of components. An overview of these patients and the reasons for exclusion can be found in Online Supplemental Table 7.
‖In case of an elevation of the arms <90°, but with sufficient visibility of the sternum and lead and without anterior shifting of the generator, the radiograph was accepted.

between the generator and the thoracic wall or between the lead and the sternum, which also leads to a higher PRAETORIAN score.[8,20] The S-ICD is currently able to measure a low voltage impedance value, without giving a shock, eliminating the risks and logistics associated with this procedure.[21] However, caution is warranted when using impedance as a predictor for defibrillation failure. Even though our study and earlier studies have shown a significantly higher impedance in patients with an unsuccessful DFT, determining an impedance value that almost always leads to DFT failure remains challenging.[19,22,23] Moreover, it is possible to have failed conversion regardless of low impedance, because of the anterior positioning of the S-ICD, which can lead to shunting of energy across the thoracic wall. Potentially, combining the PRAETORIAN score with the low voltage impedance could be helpful to predict defibrillation success even more accurately.

Table 3 PPV and NPV of the PRAETORIAN score

PRAETORIAN score	Total patients	Successful DFT	Failed DFT	
<90	307	304	3	NPV: 99% (95% CI 97%–100%)
≥90	28	21	7	PPV: 25% (95% CI 11%–45%)
		325	10	

CI = confidence interval; DFT = defibrillation test; NPV = negative predictive value; PPV = positive predictive value.

Table 4 PRAETORIAN scores adjudicated by the core laboratory

PRAETORIAN Score	Successful DFT	Failed DFT
30	245	1
45	8	1
50	5	1
60	46	–
90	12	1
110	1	–
120	–	1
140	1	–
150	4	5
225	2	–
300	1	–
TOTAL	*325*	*10*

DFT = defibrillation test.

Clinical implications

Several studies have investigated the S-ICD defibrillation threshold and showed that either with or without modification of the lead of the S-ICD, the defibrillation threshold is <65 J in a large proportion of patients with S-ICD.[24–26] These results demonstrate that in most cases, the S-ICD has a surplus in energy. Therefore, the likelihood of defibrillation failure with an 80 J shock, which is the default shock output of the S-ICD, is very low. Omitting DFT in patients, who are at increased risk of complications from DFT, therefore probably comes with little risk of conversion failure. In these patients, the PRAETORIAN score could also be used to ascertain correct device positioning. In current clinical practice, DFT should not be performed in patients with known intracardiac thrombus. Besides this, performing a DFT is discouraged in patients with atrial fibrillation or flutter without adequate systemic anticoagulation, patients with hemodynamic instability, patients with very poor ejection fraction, or in case of other morbidities associated with poor outcomes.[27] In these cases, the PRAETORIAN score can already be used to determine the correct positioning of the S-ICD. Furthermore, we encourage physicians to use the PRAETORIAN score to improve their implant technique and optimize implant positioning of the S-ICD. The upcoming follow-up of the PRAETORIAN-DFT trial will determine whether it is safe to omit DFT concerning spontaneous events after S-ICD implantation in the near future.

Limitations

This study is limited by the fact that 122 radiographs were unevaluable because of several shortcomings. Of these, 43 radiographs were excluded as a result of insufficient quality or incorrect positioning of the patient. Evaluation of the

radiograph directly after implantation would have reduced this amount. Nevertheless, 79 radiographs were excluded because of implantation of the S-ICD outside the indicated anatomical areas. Informing physicians about the importance of implantation within these anatomical areas is crucial if the PRAETORIAN score is to be implemented in standard care. The PRAETORIAN-DFT trial is designed to compare the PRAETORIAN score with DFT. If the results of the PRAETORIAN-DFT trial show that PRAETORIAN score calculation is noninferior to DFT, these results cannot be extrapolated for implantation outside the indicated anatomical areas.

For this study, DFTs were not always performed per protocol, which resulted in the exclusion of patients in whom no second DFT was performed after failure of the first. Furthermore, a positive predictive value was hard to discriminate as the incidence of DFT failure was low. Moreover, 5 patients were repositioned immediately after failed DFT and consequently allocated a score of 150. Since chest radiographs were not available, this exact score could not be confirmed. However for most of these patients at least one of the steps of the PRAETORIAN score was verified with fluoroscopy to be high, leading to a decision to reposition. The decision to include these patients in the analysis could be questioned. In our opinion, these patients were most likely to have a high PRAETORIAN score. Furthermore, any score $\geq$90 would have resulted in a similar positive predictive value.

Conclusion

Our findings demonstrate that a PRAETORIAN score of <90 serves as a reliable indicator for DFT success in patients with S-ICD and a PRAETORIAN score of $\geq$90 is a strong predictor for DFT failure. The results of the ongoing PRAETORIAN-DFT trial will provide further insights into the predictive value for spontaneous events and the feasibility of safely omitting DFT. Meanwhile, we recommend to continue performing a DFT following all S-ICD implants until the results of the trial are available and to use the PRAETORIAN score when DFT is contraindicated.

Acknowledgments

We thank the patients who participated in this trial, the members of the clinical event committee for adjudicating all events, the members of the data and safety monitoring board, the physicians, and the research coordinators for contributions to the conduct of this trial.

Appendix

Supplementary Data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2024.02.005.

Funding Sources: The PRospective randomized compArative trial of subcutanEous implanTable cardiOverter-defibrillatoR ImplANtation with and without DeFibrillation Testing was funded by Boston Scientific, which had no role in the design of the trial, analysis of the data, or the drafting and submission of the manuscript (grant number ISRCAR00081).

Disclosures: Dr Knops reports consultancy fees and research grants from Abbott, Boston Scientific, Medtronic, and Cardiac and has stock options from AtaCor Medical Inc. Dr El-Chami reports consultancy fees from Medtronic and Boston Scientific. Dr Marquie reports consultancy fees from Boston Scientific.Dr Tilz reports consultancy fees from Boston Scientific, Biotronik, Biosense Webster, and Abbott Medical; speaker's honoraria from Boston Scientific, Biotronik, Biosense Webster, Abbott Medical, and LifeTech; and research grants from Abbott, Biosense Webster, and LifeTech. Dr Lambiase reports research contracts with Boston Scientific and is a member of the advisory board of Boston Scientific. Dr Manyam reports consultancy fees from Janssen and Abbott. Dr Betts received honoraria for speaking and proctoring from Boston Scientific. Dr Bijsterveld presented at a conference of Abbott and gave a presentation sponsored by AstraZeneca. Dr Field reports being a speaker and proctor for Boston Scientific. Dr Golovchiner reports being a proctor for Boston Scientific. Dr de Jong reports consultancy fees from Medtronic. Dr Lewis reported to receive travel grants and honoraria from Abbott, Boston Scientific, and Medtronic. Dr Martin reported to receive research grants, honoraria, and speaker's fees from Boston Scientific and honoraria and speaker's fees from Medtronic and Biosense Webster. Dr Miller reported to receive consultancy fees from Boston Scientific. Dr Shaik reported to receive consultancy fees from Boston Scientific, Medtronic, and Biotronik. Dr Kuschyk reported to receive consultancy fees and honoraria from Boston Scientific, consultancy fees from Impulse Dynamics, and honoraria fees from Medtronic. Dr Boveda reported to receive consultancy fees from Medtronic, Boston Scientific, MicroPort, and Zoll. Dr Kaiser is a proctor for Boston Scientific. Dr Maass reported to receive consultancy fees from Boston Scientific and Medtronic, with all fees going to the department of Cardiology of the University Medical Center Groningen. Dr Wilde is a consultant for ARMGO and Thyrvv Therapeutics. The rest of the authors report no conflicts of interest.

Address reprint requests and correspondence: Dr Reinoud E. Knops, Amsterdam UMC location University of Amsterdam, Heart Center, Department of Cardiology, Amsterdam Cardiovascular Sciences Heart Failure & Arrhythmias, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands. E-mail address: r.e.knops@amsterdamumc.nl

References

1. Knops RE, Olde Nordkamp LRA, Delnoy PHM, et al. Subcutaneous or transvenous defibrillator therapy. N Engl J Med 2020;383:526–536.
2. Birnie D, Tung S, Simpson C, et al. Complications associated with defibrillation threshold testing: the Canadian experience. Heart Rhythm 2008;5:387–390.
3. Alter P, Waldhans S, Plachta E, Moosdorf R, Grimm W. Complications of implantable cardioverter defibrillator therapy in 440 consecutive patients. Pacing Clin Electrophysiol 2005;28:926–932.
4. Romero J, Bello J, Díaz JC, et al. Tumescent local anesthesia versus general anesthesia for subcutaneous implantable cardioverter-defibrillator implantation. Heart Rhythm 2021;18:1326–1335.
5. Healey JS, Hohnloser SH, Glikson M, et al. Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). Lancet 2015;385:785–791.

6. Bänsch D, Bonnemeier H, Brandt J, et al. Intra-operative defibrillation testing and clinical shock efficacy in patients with implantable cardioverter-defibrillators: the NORDIC ICD randomized clinical trial. Eur Heart J 2015;36:2500–2507.
7. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010;363:36–44.
8. Heist EK, Belalcazar A, Stahl W, Brouwer TF, Knops RE. Determinants of subcutaneous implantable cardioverter-defibrillator efficacy: a computer modeling study. JACC Clin Electrophysiol 2017;3:405–414.
9. Quast ABE, Baalman SWE, Brouwer TF, et al. A novel tool to evaluate the implant position and predict defibrillation success of the subcutaneous implantable cardioverter-defibrillator: the PRAETORIAN score. Heart Rhythm 2019;16:403–410.
10. Quast ABE, Baalman SWE, Betts TR, et al. Rationale and design of the PRAETORIAN-DFT trial: a prospective randomized CompArative trial of SubcutanEous ImplanTable CardiOverter-DefibrillatoR ImplANtation with and without DeFibrillation testing. Am Heart J 2019;214:167–174.
11. User's manual EMBLEMTM S-ICD, EMBLEMTM MRI S-ICD. Boston Scientific Web site, https://www.bostonscientific.com/content/dam/bostonscientific/Rhythm%20Management/portfolio-group/EMBLEM_S-ICD/Download_Center/359481-001%20EMBLEM%20S-ICD%20PTM_English.pdf. Accessed December 1, 2023.
12. Schönbeck Y, Talma H, van Dommelen P, et al. The world's tallest nation has stopped growing taller: the height of Dutch children from 1955 to 2009. Pediatr Res 2013;73:371–377.
13. Khalighi K, Daly B, Leino EV, et al. Clinical predictors of transvenous defibrillation energy requirements. Am J Cardiol 1997;79:150–153.
14. Shih MJ, Kakodkar SA, Kaid Y, et al. Reassessing risk factors for high defibrillation threshold: the EF-SAGA risk score and implications for device testing. Pacing Clin Electrophysiol 2016;39:483–489.
15. Nagai T, Kurita T, Satomi K, et al. QRS prolongation is associated with high defibrillation thresholds during cardioverter-defibrillator implantations in patients with hypertrophic cardiomyopathy. Circ J 2009;73:1028–1032.
16. Quin EM, Cuoco FA, Forcina MS, et al. Defibrillation thresholds in hypertrophic cardiomyopathy. J Cardiovasc Electrophysiol 2011;22:569–572.
17. S-ICD® System IDE Clinical Study. ClinicalTrials.gov Web site, https://clinicaltrials.gov/study/NCT01064076. Accessed December 1, 2023.
18. Zimmerman M. Positive predictive value: a clinician's guide to avoid misinterpreting the results of screening tests. J Clin Psychiatry 2022;83:22com14513.
19. Lubiński A, Lewicka-Nowak E, Zienciuk A, et al. Clinical predictors of defibrillation threshold in patients with implantable cardioverter-defibrillators. Kardiol Pol 2005;62:317–328. discussion 29–31.
20. Amin AK, Gold MR, Burke MC, et al. Factors associated with high-voltage impedance and subcutaneous implantable defibrillator ventricular fibrillation conversion success. Circ Arrhythm Electrophysiol 2019;12:e006665.
21. Stelzer M, Speakman B, Stahl WK, et al. B-PO05-047 Evaluation of mechanical placement, impedance, and low voltage measurement corollary study (EMILY Study) for the S-ICD. Heart Rhythm 2021;18:S390.
22. Rudic B, Tülümen E, Fastenrath F, Akin I, Borggrefe M, Kuschyk J. Defibrillation failure in patients undergoing replacement of subcutaneous defibrillator pulse generator. Heart Rhythm 2020;17:455–459.
23. de Veld JA, Pepplinkhuizen S, van der Stuijt W, et al. Successful defibrillation testing in patients undergoing elective subcutaneous implantable cardioverter-defibrillator generator replacement. Europace 2023;25:euad184.
24. Heist EK, Knops RE, Yap SC, et al. Reduction in defibrillation threshold by modifications to the subcutaneous implantable-cardioverter defibrillator coil. Heart Rhythm 2023;20:783–785.
25. Quast A, Baalman SWE, Van der Stuijt W, Wilde AAM, Knops RE. Minimal defibrillation thresholds and the correlation with implant position in subcutaneous implantable-defibrillator patients. J Cardiovasc Electrophysiol 2019;30:2441–2447.
26. van der Stuijt W, Pepplinkhuizen S, de Veld JA, et al. Defibrillation threshold in elective subcutaneous implantable defibrillator generator replacements: time to reduce the size of the pulse generator? Int J Cardiol 2024;398:131639.
27. Wilkoff BL, Fauchier L, Stiles MK, et al. 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. Heart Rhythm 2016;13:e50–e86.