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Table S1. Patient characteristics of the total population

|  |  |  |
| --- | --- | --- |
|  | **Subcutaneous ICD**  **(N = 426)** | **Transvenous ICD**  **(N = 423)** |
| Median age (IQR) - yr | 63 (54-69) | 64 (56-70) |
| Female ― no. (%) | 89 (20.9) | 78 (18.4) |
| Diagnosis ― no. (%) |  |  |
| Ischemic cardiomyopathy | 289 (67.8) | 298 (70.4) |
| Non-ischemic cardiomyopathy | 99 (23.2) | 98 (23.2) |
| Inherited cardiac disease | 20 (4.7) | 18 (4.3) |
| Hypertrophic cardiomyopathy | 15 (3.5) | 7 (1.7) |
| Idiopathic ventricular fibrillation | 11 (2.6) | 5 (1.2) |
| Congenital heart disease | 3 (0.7) | 3 (0.7) |
| Other | 4 (0.9)\* | 1 (0.2)\* |
| Secondary prevention ― no. (%) | 80 (18.8) | 84 (19.9) |
| Median ejection fraction (IQR) - % | 30 (25-35) | 30 (25-35 |
| NYHA class ― no. (%) |  |  |
| I | 144/423 (34.0) | 134/421 (31.8) |
| II | 205/423 (48.5) | 223/421 (53.0) |
| III/IV | 74/423 (17.5) | 64/421 (15.2) |
| Median Body-mass index (IQR) | 27.0 (24.5-30.5) | 27.9 (25.2-31.7) |
| History of atrial fibrillation― no. (%) | 115/426 (27.0) | 93/420 (22.1) |
| History of diabetes – no. (%) | 112/426 (26.3) | 126/421 (29.9) |

ICD implantable cardioverter-defibrillator, IQR interquartile range, NYHA New York Heart Association.

\* The patients in this category had ventricular fibrillation due to coronary spasm (one patient in the subcutaneous ICD group and one in the transvenous ICD group), coronary dissection (one in the subcutaneous ICD group), ischemic stroke (one in the subcutaneous ICD group), and myocarditis (one in the subcutaneous ICD group).

Table S2. Procedural characteristics

|  |  |  |
| --- | --- | --- |
| Characteristics | **S-ICD** | **TV-ICD** |
| No. of implantations of study device by implanter |  |  |
| 0-30 | 141 | 23 |
| 30-70 | 110 | 37 |
| > 70 | 175 | 363 |
| Median implantation duration (IQR) - min | 55 (43-74) | 50 (37-68) |
| Median fluoroscopy duration (IQR) – sec | 0 (0-12) | 144 (68-252) |
| Two-incision technique – no. (%) | 299 (70.2) | 5 (1.2) |
| Prophylactic antibiotics – no. (%) | 415 (97.4) | 408 (96.5) |
| General anesthesia – no. (%) | 208 (48.8) | 13 (3.1) |
| DFT testing performed – no (%) | 385 (90.4) | 195 (46.1) |
| Dual chamber ICD | 1 | 48 |
| Biventricular | 1 | 3 |

DFT defibrillation threshold testing, ICD implantable cardioverter-defibrillator, IQR interquartile range, S-ICD subcutaneous ICD, TV-ICD transvenous ICD

Table S3. Patients with multiple device-related complications

|  |  |  |  |
| --- | --- | --- | --- |
|  | **1st complication** | **2nd complication** | **3rd complication** |
| S-ICD |  |  |  |
| 1 | Sensing issue | Lead replacement\* |  |
| 2 | ICD related bleeding | Pacing indication |  |
| 3 | Lead repositioning | ICD-related infection |  |
| 4 | ICD related infection | Pain or discomfort\* | Sensing issue\* |
| TV-ICD |  |  |  |
| 1 | Pneumothorax | Lead repositioning |  |
| 2 | Pneumothorax | Lead replacement |  |
| 3 | Implant failure | Pacing indication† |  |
| 4 | Lead replacement | Pain or discomfort‡ |  |
| 5 | Perforation | Lead replacement |  |

ICD implantable cardioverter-defibrillator, S-ICD subcutaneous ICD, TV-ICD transvenous ICD

\* Crossover after first device-related complication, patients with a TV-ICD.

† Crossover after first device-related complication, patient with an S-ICD.

‡ Device-related complication after replacement of pulse generator.

Table S4. Patients characteristics of patients with and without device-related complications in the S-ICD and TV-ID group

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Subcutaneous ICD (N=426)** | | | **Transvenous ICD (N=423)** | | |
|  | **With device-related complications** | **Without device-related complications** | **P-value** | **With device-related complications** | **Without device-related complications** | **P-value** |
| **(N=31)** | **(N=395)** | **(N=44)** | **(N=379)** |
| Median age (IQR) - yr | 65 (58-69) | 63 (54-70) | 0.37 | 62 (56-70) | 64 (56-70) | 0.63 |
| Female ― no. (%) | 6 (19.4) | 83 (21.0) | 1.00 | 11 (25.0) | 67 (17.7) | 0.33 |
| Diagnosis ― no. (%) |  |  | 0.84 |  |  | 0.56 |
| Ischemic cardiomyopathy | 22 (71) | 267 (67.6) |  | 35 (79.5) | 263 (69.4) |  |
| Non-ischemic cardiomyopathy | 7 (22.6) | 92 (23.3) |  | 7 (15.9) | 91 (24.0) |  |
| Inherited cardiac disease | 2 (6.5) | 18 (4.6) |  | 1 (2.3) | 17 (4.5) |  |
| Hypertrophic cardiomyopathy\* | 2 (6.5) | 13 (3.3) |  | 1 (2.3) | 6 (1.6) |  |
| Idiopathic ventricular fibrillation | 0 | 11 (2.8) |  | 1 (2.3) | 4 (1.1) |  |
| Congenital heart disease | 0 | 3 (0.8) |  | 0 | 3 (0.8) |  |
| Other† | 0 | 4 (1.0) |  | 0 | 1 (0.3) |  |
| Secondary prevention ― no. (%) | 3 (9.7) | 77 (19.5) | 0.27 | 4 (9.1) | 80 (21.1) | 0.09 |
| Median ejection fraction (IQR) - % | 28 (23-32)\* | 30 (25-35) | 0.31 | 29 (20-30) | 30 (25-35) | 0.11 |
| NYHA class ― no./total no. (%) |  |  | 0.55 |  |  | 0.66 |
| I | 14/31 (45.2) | 130/392 (33.2) |  | 12/44 (27.3) | 122/377 (32.4) |  |
| II | 12/31 (38.7) | 193/392 (49.2) |  | 27/44 (61.4) | 196/377 (52.0) |  |
| III/IV | 5/31 (16.1) | 69/392 (17.6) |  | 5/44 (11.4) | 59/377 (15.6) |  |
| Median body-mass index (IQR) | 27.4 (25.0-31.0) | 27.0 (24.5-30.3) | 0.25 | 27.1 (23.9-30.8) | 28.0 (25.3-31.7) | 0.25 |
| History of atrial fibrillation― no./total no. (%) | 13/31 (41.9) | 102/395 (25.8) | 0.08 | 3/44 (6.8) | 90/376 (23.9) | 0.03 |
| History of diabetes – no./total no. (%) | 11/31 (35.5) | 101/395 (25.6) | 0.32 | 15/44 (34.1) | 111/377 (29.4) | 0.73 |

ICD implantable cardioverter-defibrillator, IQR interquartile range, NYHA New York Heart Association.

\* Of which one hypertrophic cardiomyopathy patients also has Brugada

† The patients in this category had ventricular fibrillation due to coronary spasm (one patient in the subcutaneous ICD group and one in the transvenous ICD group), coronary dissection (one in the subcutaneous ICD group), ischemic stroke (one in the subcutaneous ICD group), and myocarditis (one in the subcutaneous ICD group).

Table S5. Univariable and Multivariable predictors of device-related complications

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Univariable Analysis |  |  |  |  |  |  |  |
| S-ICD | | | | TV-ICD | | | |
| Variable | HR | CI | P-value | Variable | HR | CI | P-value |
| Age, per year increase | 1.02 | 0.99-1.06 | 0.21 | Age, per year increase | 1.00 | 0.97-1.03 | 0.93 |
| Female | 0.83 | 0.34-2.05 | 0.69 | Female | 1.51 | 0.76-2.99 | 0.24 |
| **History of AF** | **2.42** | **1.17-5.00** | **0.02\*** | **History of AF** | **0.25** | **0.08-0.82** | **0.02\*** |
| Secondary prevention | 0.40 | 0.12-1.30 | 0.13 | Secondary prevention | 0.38 | 0.14-1.08 | 0.07. |
| BMI, per 1 kg/m2 increase | 1.05 | 0.99-1.11 | 0.08 | BMI, per 1 kg/m2 increase | 0.96 | 0.90-1.03 | 0.24 |
| History of CABG | 1.17 | 0.51-2.72 | 0.71 | History of CABG | 0.88 | 0.41-1.90 | 0.75 |
| History of diabetes | 1.82 | 0.87-3.81 | 0.11 | History of diabetes | 1.25 | 0.67-2.33 | 0.48 |
| Hypertension | 1.62 | 0.78-3.34 | 0.20 | Hypertension | 0.92 | 0.51-1.67 | 0.79 |
| ICMP | 1.21 | 0.56-2.63 | 0.63 | ICMP | 1.67 | 0.80-3.48 | 0.17 |
| Multivariable Analysis † |  |  |  |  |  |  |  |
| Variable | HR | CI | P-value | Variable | HR | CI | P-value |
| Age, per year increase | 1.01 | 0.97-1.05 | 0.69 | Age, per year increase | 1.00 | 0.97-1.04 | 0.99 |
| Female |  |  |  | Female | 1.69 | 0.83-3.47 | 0.15 |
| History of AF | 2.02 | 0.93-4.38 | 0.07 . | **History of AF** | **0.29** | **0.09-0.96** | **0.04\*** |
| Secondary prevention | 0.46 | 0.14-1.52 | 0.20 | **Secondary prevention** | **0.35** | **0.12-0.97** | **0.04\*** |
| BMI, per 1 kg/m2 increase | 1.04 | 0.98-1.10 | 0.25 | BMI, per 1 kg/m2 increase | 0.96 | 0.90-1.03 | 0.27 |
| History of diabetes | 1.25 | 0.57-2.75 | 0.57 | History of diabetes |  |  |  |
| Hypertension | 1.16 | 0.53-2.56 | 0.71 | Hypertension |  |  |  |
| ICMP |  |  |  | ICMP | 1.92 | 0.86-4.28 | 0.11 |

† Predictors were included in the multivariable analysis when a p-value < 0.25 was observed in the univariable analysis. The models included age irrespective of the p-value.

Table S6. Predictors of Device Related Complications that required invasive intervention

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |
| Univariable Analysis |  |  |  |  |  |  |  |
| S-ICD | | | | TV-ICD | | | |
| Variable | HR | CI | P-value | Variable | HR | CI | P-value |
| Age, per year increase | 1.01 | 0.98-1.05 | 0.47 | Age, per year increase | 1.01 | 0.98-1.05 | 0.42 |
| Female | 0.97 | 0.36-2.63 | 0.95 | Female | 1.39 | 0.66-2.94 | 0.39 |
| History of AF | 2.14 | 0.91-5.00 | 0.08. | **History of AF** | **0.19** | **0.05-0.79** | **0.02\*** |
| Secondary prevention | 0.35 | 0.08-1.50 | 0.16 | Secondary prevention | 0.46 | 0.16-1.29 | 0.14 |
| **BMI, per 1 kg/m2 increase** | **1.08** | **1.03-1.14** | **0.004\*** | BMI, per 1 kg/m2 increase | 0.98 | 0.91-1.04 | 0.48 |
| History of CABG | 1.13 | 0.41-3.04 | 0.81 | History of CABG | 0.90 | 0.40-2.05 | 0.81 |
| History of diabetes | 1.77 | 0.75-4.19 | 0.20 | History of diabetes | 1.11 | 0.56-2.20 | 0.77 |
| Hypertension | 1.10 | 0.48-2.51 | 0.82 | Hypertension | 1.07 | 0.56-2.05 | 0.83 |
| ICMP | 1.13 | 0.46-2.75 | 0.79 | ICMP | 1.62 | 0.74-3.53 | 0.23 |
|  |  |  |  |  |  |  |  |
| Multivariable Analysis † |  |  |  |  |  |  |  |
| Variable | HR | CI | P-value | Variable | HR | CI | P-value |
| Age, per year increase | 1.00 | 0.96-1.05 | 0.87 | Age, per year increase | 1.02 | 0.99-1.06 | 0.24 |
| History of AF | 1.84 | 0.75-4.51 | 0.19 | **History of AF** | **0.18** | **0.04-0.75** | **0.02\*** |
| Secondary prevention | 0.41 | 0.10-1.78 | 0.23 | Secondary prevention | 0.42 | 0.15-1.19 | 0.10 |
| **BMI, per 1 kg/m2 increase** | **1.07** | **1.01-1.14** | **0.02\*** | BMI, per 1 kg/m2 increase |  |  |  |
| History of diabetes | 1.16 | 0.46-2.89 | 0.75 | History of diabetes |  |  |  |
| ICMP |  |  |  | ICMP | 1.36 | 0.60-3.06 | 0.46 |

† Predictors were included in the multivariable analysis when a p-value < 0.25 was observed in the univariable analysis. The models included age irrespective of the p-value.

Table S7. Total and reason for crossover as an intervention in the S-ICD and TV-ICD

|  |  |  |
| --- | --- | --- |
|  | **S-ICD (N=31)** | **TV-ICD (N=44)** |
| Patients with crossovers | 11\* | 5\* |
| Total crossovers | 11 | 6 |
| Reason for crossover |  |  |
| Pacing indication | 5 | 1§ |
| TV-ICD | 2 | - |
| CRT-D | 1 | - |
| Single-chamber pacemaker | 2† | - |
| Device infection | 3 | 3‡ |
| Sensing issues | 2 | 0 |
| Implantation failure | 0 | 2 |
| DFT failure | 1 | 0 |

CRT-D cardiac resynchronization therapy, DFT defibrillation threshold testing, S-ICD subcutaneous ICD, TV-ICD transvenous ICD

\* 2/11 patients in the S-ICD and 1/5 patients in the TV-ICD experienced a second device-related complication after their crossover.

† 1 patient received concomitant pacemaker therapy in addition to S-ICD therapy.

‡ One infection was systemic.

§ Patient with second crossover, first crossover from TV-ICD to S-ICD due to implantation failure.

Table S8. Type of total lead-related complications

|  |  |  |
| --- | --- | --- |
|  | **S-ICD** | **TV-ICD** |
| Lead dislocation | 3\* | 6 |
| Lead dysfunction | 0 | 9 |
| Inappropriate therapy | 1 | 0 |
| Lead infections | 1 | 5 |
| Lead perforations/tamponade | 0 | 5 |
| Thrombotic events | 0 | 2 |
| Pneumothorax | 0 | 4 |
| Implantation failure | 0 | 1 |
| DFT failure | 1 | 0 |
| Sensing issues | 1\* | 0 |
| Total | 7 | 32 |

S-ICD subcutaneous ICD, TV-ICD transvenous ICD

\* 1 patient with a crossover to TV-ICD before device-related complication.

Table S9. Three months and one year timing of device-related complications after implantation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 3 months | > 3 months | 1 year | > 1 year |
| S-ICD | 18 (50.0) | 18 (50.0) | 22 (61.1) | 14 (38.9) |
| Infection | 1 | 3 | 3 | 1 |
| Bleeding | 7 | 1 | 7 | 1 |
| Thrombotic event | 1 | 0 | 1 | 0 |
| Lead repositioning | 2 | 0 | 2 | 0 |
| Other lead or device complication | 7 | 14 | 9 | 12 |
| Lead replacement | 2 | 1 | 2 | 1 |
| Device malfunction | 1 | 3 | 1 | 3 |
| Sensing issues | 1 | 3 | 1 | 3 |
| Defibrillation test failure | 3 | 0 | 3 | 0 |
| Pain or discomfort | 0 | 2 | 2 | 0 |
| Pacing indication | 0 | 5 | 0 | 5 |
| TV-ICD | 25 (51.0) | 24 (49.0) | 31 (63.3) | 18 (36.7) |
| Infection | 2 | 6 | 3 | 5 |
| Bleeding | 2 | 0 | 2 | 0 |
| Thrombotic event | 1 | 1 | 2 | 0 |
| Perforation | 2 | 0 | 2 | 0 |
| Lead repositioning | 7 | 0 | 7 | 0 |
| Pneumothorax | 4 | 0 | 4 | 0 |
| Tamponade | 2 | 0 | 2 | 0 |
| Other lead or device complication | 5 | 17 | 9 | 13 |
| Lead replacement | 2 | 7 | 4 | 5 |
| Device malfunction | 0 | 6 | 0 | 6 |
| Implantation failure | 3 | 0 | 3 | 0 |
| Pain or discomfort | 0 | 3 | 2 | 1 |
| Pacing indication | 0 | 1 | 0 | 1 |

Table S10. Trial Organisation

## PRAETORIAN Investigators Steering Committee

Reinoud E Knops*, Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands*

Arthur AM Wilde, *Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands; ‘Member of the European Reference Network for rare, low prevalence and complex diseases of the heart: ERN GUARD-Heart’; http://guardheart.ern-net.eu.*

Louise RA Olde Nordkamp, *Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands*

Jan GP Tijssen, *Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands*

Peter Paul HM Delnoy, *Department of Cardiology, Isala Heart Centre, Zwolle, The Netherlands*

Lucas VA Boersma, *Department of Cardiology, St Antonius Hospital, Nieuwegein, The Netherlands; Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular SciencesHeart failure & arrhythmias, Amsterdam, the Netherlands*

Stefan Kääb, *Department of Medicine I, Klinikum Grosshadern, University of Munich (LMU), Munich, Germany; German Centre for Cardiovascular Research (DZHK); Partner Site: Munich Heart Alliance, Munich, Germany*

Suneet Mittal, *Valley Health System, Ridgewood, NJ, United States*

Elijah R Behr, *Cardiology Clinical Academic Group, St. George's, University of London and St. George's University Hospitals NHS Foundation Trust London, United Kingdom; ‘Member of the European Reference Network for rare, low prevalence and complex diseases of the heart: ERN GUARD-Heart’; http://guardheart.ern-net.eu.*

Helen H Petersen, *Department of Cardiology, The Heart Centre, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark*

## PRAETORIAN Investigators Sponsor study staff

Reinoud E Knops, Louise RA Olde Nordkamp, Arthur AM Wilde, Jan GP Tijssen, Kirsten M Kooiman, Lonneke Smeding, Tom F Brouwer, Anne Floor BE Quast, Willeke van der Stuijt, Shari Pepplinkhuizen, Jolien A de Veld, Anouk de Weger, Linde V Vertelman, Ingeborg K Go

*Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands*

## List of PRAETORIAN participating centers and principal PRAETORIAN investigators

|  |  |
| --- | --- |
| **Center** | **Principal Investigator** |
| Amsterdam UMC location University of Amsterdam, Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular SciencesHeart failure & arrhythmias, Amsterdam, the Netherlands | Reinoud E Knops  Louise RA Olde Nordkamp |
| Department of Cardiology, Isala Heart Centre, Zwolle, The Netherlands | Peter Paul HM Delnoy |
| Department of Cardiology, Flevoziekenhuis, Almere, The Netherlands  Department of Cardiology, Tergooi Ziekenhuis, Blaricum, The Netherlands | Nick R Bijsterveld  Ward P.J. Jansen |
| University Medical Centre Mannheim, I. Medical Department, Mannheim, Germany | Jürgen Kuschyk |
| Department of Electrophysiology, Heart Center at University of Leipzig, Leipzig, Germany | Sergio Richter |
| Klinik für Innere Medizin III, Schwerpunkt Kardiologie und Angiologie, Universitätsklinikum Schleswig-Holstein, Campus Kiel, Kiel, Germany | Hendrik Bonnemeier |
| Department of Cardiology, St Antonius Hospital, Nieuwegein, The Netherlands | Lucas VA Boersma |
| Department of Cardiology, Cardiovascular Research Institute Maastricht (CARIM), Maastricht University Medical Center, Maastricht, the Netherlands | Kevin Vernooy |
| Cardiology, Radboudumc, Nijmegen, The Netherlands | Marc A Brouwer |
| Division of Cardiology Section of Electrophysiology, Emory University, Atlanta, GA, United States | Mikhael F El-Chami |
| Department of Electrophysiology, Catharina Hospital, Eindhoven, The Netherlands | Frank ALE Bracke |
| Amphia Ziekenhuis and Werkgroep Cardiologische Centra Nederland, the Netherlands | Marco Alings |
| Oxford Biomedical Research Centre, Oxford University Hospitals NHS Trust, Oxford, United Kingdom | Timothy R Betts |
| Department of Cardiology, OLVG, Oosterpark 9, AC Amsterdam, The Netherlands | Jonas SSG de Jong |
| Liverpool Heart and Chest Hospital, Liverpool, United Kingdom | David J Wright |
| Heart Surgery, Heart Center Dresden, Carl Gustav Carus Medical Faculty, Dresden University of Technology, Dresden, Germany | Michael Knaut |
| Department of Cardiology, Homolka Hospital, Prague, Czech Republic | Petr Neuzil |
| Department of Cardiology, The Heart Centre, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark | Berit T Philbert |
| University and University Hospital Würzburg, Würzburg, Germany | Peter Nordbeck |
| Medical Spectrum Twente, Enschede, the Netherlands | Jurren van Opstal |
| Imperial College Healthcare NHS Trust, London, United Kingdom | Zachary I Whinnett |
| UCL & Barts Heart Centre, London, United Kingdom | Pier D Lambiase |
| Department of Cardiology, and Amsterdam Cardiovascular Sciences (ACS), Amsterdam University Medical Centers, Vrije Universiteit, Amsterdam, the Netherlands | Cor P Allaart |
| Division of Cardiology, Northwestern Memorial Hospital, Northwestern University, Chicago, IL, United States | Alexandru B Chicos |
| Icahn School of Medicine at Mount Sinai, Mount Sinaï Hospital, New York, NY, United States | Marc A Miller |
| Center for Arrhythmia Care, Heart and Vascular Institute, University of Chicago Pritzker School of Medicine, Chicago, IL, United States | Gaurav A Upadhyay |
| Department of Medicine I, Klinikum Grosshadern, University of Munich (LMU), Munich, Germany; German Centre for Cardiovascular Research (DZHK); Partner Site: Munich Heart Alliance, Munich, Germany | Stefan Kääb |
| Department of Internal Medicine I, Jena University Hospital, Jena, Germany | Ralf Surber |
| Medisch Centrum Leeuwarden, Leeuwarden, the Netherlands | Alida E Borger van der Burg |
| Valley Health System, Ridgewood, NJ, United States | Suneet Mittal |
| Cardiac Electrophysiology Division, Department of Medicine, Englewood Hospital and Medical Center, Englewood, NJ, United States | Dmitry Nemirovsky |
| Department of Medicine - Cardiology, Columbia University Irving Medical Center, New York, NY, United States | Jose M Dizon |
| Cardiology Clinical Academic Group, St. George's, University of London and St. George's University Hospitals NHS Foundation Trust London, United Kingdom | Elijah R Behr |
| Department of Internal Medicine, Section of Cardiovascular Medicine, Yale University School of Medicine, New Haven, CT, United States | Jude F Clancy |
| North-West Hospital Group, Alkmaar, The Netherlands | Tjeerd Germans |
| Division of Cardiovascular Medicine, College of Medicine, The Ohio State University, Columbus, OH, United States | Raul Weiss |
| Division of Cardiology, Department of Medicine, New York Presbyterian Hospital, Cornell University Medical College, New York, NY, United States | Jim W Cheung |
| Cardiology Department, Queen Elizabeth Hospital, Mindelsohn Way, Birmingham B15 2TH, United Kingdom | Francisco Leyva |
| Corvita Science Foundation, Chicago, IL, United States | Martin C Burke |
| Department of Cardiology, Erasmus Medical Center, Rotterdam, The Netherlands | Dominic AMJ Theuns |

## Data and Safety Monitoring Board

Joris R de Groot, *Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands*

Bruce L Wilkoff, *Cleveland Clinic, Cleveland OH, USA*

Antoine HG Driessen, *Amsterdam UMC location University of Amsterdam,* *Heart Center, Department of Cardiology, Amsterdam, The Netherlands; Amsterdam Cardiovascular Sciences Heart failure & arrhythmias, Amsterdam, the Netherlands*

Johannes Sperzel, *Department of Cardiology, Hospital Kerckhoff Klinik GmbH, Bad Nauheim, Germany*

## Clinical Events Committee

Regitze Videbaek, *Department of Cardiology, Rigshospitalet, Copenhagen University Hospital, Blegdamsvej 9, 2100 Copenhagen, Denmark*

Alexander H Maass, *Department of Cardiology, University Medical Centre Groningen, University of Groningen, Groningen, the Netherlands*

Pascal HFM van Dessel, *Department of Cardiology, Thorax Centre Twente, Medisch Spectrum Twente, Enschede, The Netherlands*