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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

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