

tween different emergency medical services (EMS), medical examiners, and 48 hospitals. The underlying cause was adjudicated by a dedicated working group (including one cardiologist and one intensivist), according to pre-specified definitions, after thoroughly reviewing all EMS and hospital records.

Results: Among 18,662 out-of-hospital cardiac arrests, 14,593 patients died before hospital admission, and 1,041 others did not fulfill the SCA definition. Considering the 3,028 SCA admitted alive (mean age 59.3 ± 15.7 years, 72.9% male), the cause remained uncertain in 1,040 (34.3%), and was due to an extra cardiac aetiology in 431 patients (14.2%). Overall, 1,557 (51.4%) patients had an established cardiac cause, with coronary artery disease (1,235; 79.3%) being the most frequent; among those, acute coronary syndromes (912; 73.8%) predominated. Non-ischemic cardiomyopathies represented the second principal cause of SCA with 155 cases (10.0%), including 99 (63.9%) dilated and 30 (19.4%) hypertrophic cardiomyopathies, 15 (9.7%) myocarditis and 6 (3.9%) arrhythmogenic right ventricular cardiomyopathies. Non-structural heart diseases were finally identified in a minority of patients (70; 4.5%), including 9 (12.9%) Brugada, 5 (7.1%) early repolarization, 4 (5.7%) long QT, 2 (2.9%) accessory pathways, 1 (1.4%) catecholaminergic polymorphic ventricular tachycardia, and 49 (70.0%) patients labelled as idiopathic ventricular fibrillation. Overall, 596 patients (38.3%) had known heart disease identified prior to SCA event.

Conclusions: We provide a comprehensive picture of underlying aetiologies of SCA in the community demonstrating the predominance of coronary artery disease. It follows that in order to make any tangible impact on SCA prevention, focused research to better understand how acute ischemia may trigger ventricular fibrillation as well as improve screening measures to identify at risk individuals is required.

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Device orientation of a leadless pacemaker and subcutaneous implantable cardioverter-defibrillator in canine and human subjects and the effect on device-device communication

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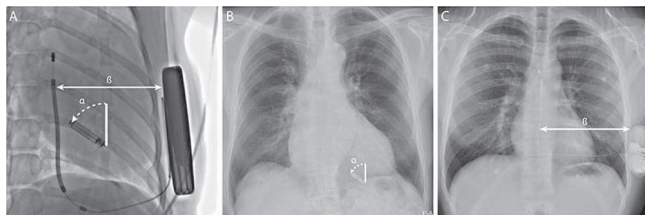
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Background: The development of communicating modular cardiac rhythm management systems relies on safe and effective device-device communication. Unidirectional device-device communication between a prototype subcutaneous implantable cardioverter-defibrillator (S-ICD) and a prototype leadless pacemaker (LP), using conducted communication, employs body tissue as a conductor. Communication success may be affected by the LP orientation and the distance between S-ICD coil and shock generator, which forms the communication vector. In theory, the optimal LP orientation is perpendicular to the S-ICD coil (90°) and parallel to the communication vector. The distance between the S-ICD coil and shock generator is one of the factors that determine the electrical field gradient of the communication vector.

Purpose: To describe device orientation of the LP and S-ICD in canine and human subjects and to describe the effect of device orientation on device-device communication.

Methods: All canine subjects with Anterior-Posterior (AP) fluoroscopy images at implant were included in this analysis. Communication threshold measurements were obtained at implant. For comparison, a retrospective analysis of human S-ICD and LP patients with a Posterior-Anterior (PA) chest X-ray from a single implanting center was performed. The angle of the long axis of the LP towards the vertical axis of 0° (α), and the distance between the S-ICD coil and shock generator (β) were measured as shown in the figure. The actual distances were calculated using the length of the LP and the S-ICD as reference values.

Results: Twenty-three canine subjects were analyzed. Mean angle of the LP was 28° ($\pm 10^\circ$) and mean distance of the S-ICD coil to shock generator was 9.92 cm (± 2.29 cm). All canine subjects had successful device-device communication. The median communicating threshold was 2.5V (interquartile range 2.0–3.0). In the human retrospective analysis, a total of 72 leadless pacemaker patients and 100 S-ICD patients were included. The mean angle of the LP was 57° ($\pm 14^\circ$) and the mean distance between the S-ICD coil and shock generator was 13.45 cm (± 1.63 cm).



Device orientation measurements.

Conclusion: Despite the less favorable LP orientation towards the communication vector, all communication attempts were successful in the canine subjects. In the human subjects we observed a greater and in theory more favorable LP angle towards the communication vector. The effect of the difference in distance between the S-ICD coil and shock generator in the human subjects on the device-

device communication has yet to be determined. This data suggests suitability of human anatomy for conductive device-device communication.

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Cardioverter-defibrillator does not improve survival among patients with dilative cardiomyopathy and reduced LV ejection fraction: Data from real-world registry EVITA-HF - The answer to DANISH

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Introduction: The DANISH-Trial raised doubts about the effectiveness of primary prevention of sudden cardiac death by ICD-implantation among patients with non-ischemic heart failure. We sought to analyse data from the EVITA-HF Registry to give an answer from real world registry data to the DANISH Trial.

Methods: 2289 patients were identified from the EVITA-HF Registry with chronic heart failure (CHF) and reduced left ventricular ejection fraction of $\leq 35\%$. The patients were divided into two groups: Patients with implanted cardioverter-defibrillator (ICD-group; mean age 66 ± 12 years, 77% male) and without ICD (no-ICD group; mean age 67 ± 14 years, 74% male). The subgroups were compared with regard to survival and predictive parameters affecting survival.

Results: 377 patients in the ICD-group and 1912 patients in the non-ICD groups showed no major differences between the primary cause of CHF, co-morbidities and heart failure medication.

After 1-year-follow-up patients with ischemic heart disease showed a significant improved survival in the ICD-group compared to non-ICD group (89.4% vs. 77.9%, OR 0.42 [0.26–0.67]; Table 1). Patients with dilative cardiomyopathy did not show a difference with regard to survival between the ICD and the non-ICD group (91.9% vs. 91.7%, OR 0.97 [0.49–1.93]; Table 2).

Conclusion: Real-world registry data reflect and support the evidence of the DANISH trial that patients with dilative cardiomyopathy and $EF \leq 35\%$ do not benefit from primary prevention of sudden cardiac death by an ICD whereas patients with ischemic cardiomyopathy do.

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Inappropriate shock reduction with PARAD+ rhythm arrhythmia discrimination. Results from the ISIS-ICD study

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Background: Inappropriate and unnecessary shock delivery from an ICD remains a significant clinical issue with considerable consequences for patients (pts) and the health care system. Recent studies have reported that modern programming strategies led to reduction of inappropriate shock (IS) rate ranging from 1.5% to 5% at 1 year. The PARAD+ arrhythmia discrimination algorithm - by processing the markers of endocardial atrial and ventricular electrograms among episodes falling into the VT zone/s - has been previously shown to consistently reduce the rate of IS. The purpose of the ISIS-ICD study was to further assess the benefit of PARAD+ on the reduction of IS in a general population implanted for primary and secondary prevention.

Methods: ISIS-ICD is an interventional, international, multi-centre, single arm investigation on pts implanted with a dual or triple chamber ICD featuring the PARAD+ algorithm. Pts were followed for 2 years after implant. IS, defined as shocks delivered for any reason but VT or VF, were adjudicated by an independent Clinical Event Committee (CEC). The primary endpoint was the percentage of pts free from IS at 1 year, as compared to a predefined rate of 92.5% (mean outcome in peer-reviewed published comparable literature) using a binomial exact test, one-sided alpha of 0.025, and 80% power.

Results: 1013 pts have been enrolled from 112 international active sites among 7 countries (80.7% male, 67.1 ± 11.4 years, 68%/30%/2% primary/secondary/other indication) and followed over a median [Q1; Q3] follow up of 552.0 days [354.0; 725.0]. Out of the 993 pts programmed with PARAD+ and thus considered for the primary endpoint analysis, 14 subjects had at least one IS, corresponding to 98.6% of pts free from IS (95% CI: 97.7% to 99.2%, p value < .001).

Conclusion: In the ISIS-ICD study, 98.6% of pts programmed with the PARAD+