Epidemiological Risk Study in Tens of Thousands of Heart Failure Patients Using the Wearable Cardioverter Defibrillator (WCD)

RWD63

"How can we measure SCD risk when 50% of deaths go unwitnessed?"

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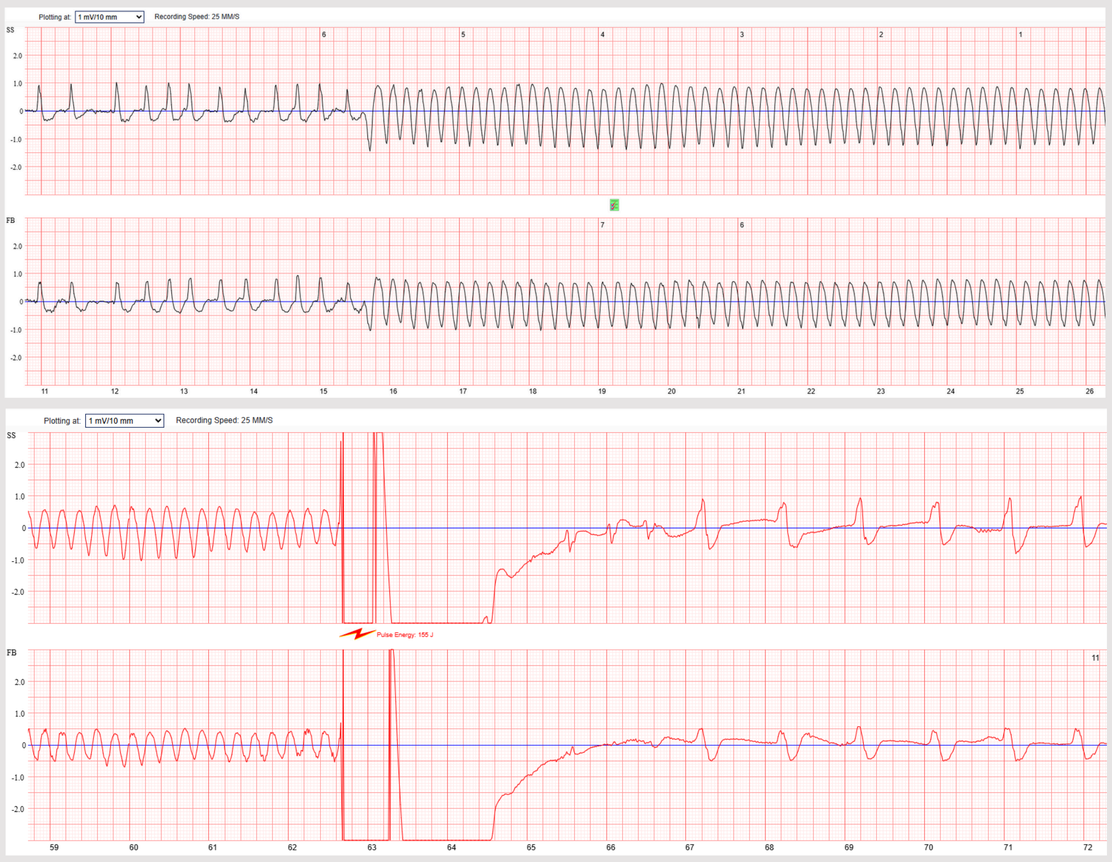
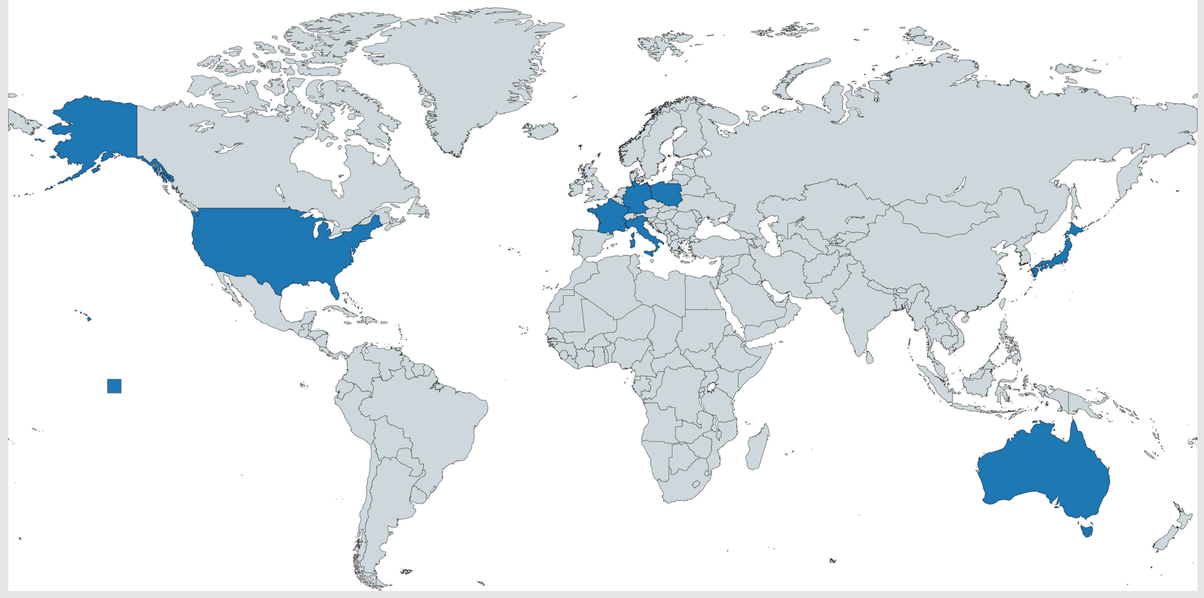
Background

Sudden Cardiac Arrest (SCA) and Sudden Cardiac Death (SCD) are leading causes of mortality worldwide. Measurement is challenging. This study investigates the incidence in high-risk, country-specific patient groups, often left without protection, monitored with a Wearable Cardioverter Defibrillator (WCD). The goal is to assess whether WCD recordings of appropriate treatments can help evaluate SCA/SCD risk in underdiagnosed patients during the acute phase of drug therapy optimization.



Objective

To measure incidence of SCA/SCD in high-risk HF patients during GDMT optimization, using WCD-recorded events across countries



Methods

Study type

Observational, non-interventional, multinational, multicentre, epidemiological

Objective

Evaluate SCA/SCD risk (cumulative incidence, incidence rate) in high-risk patients, country-specific

Procedure

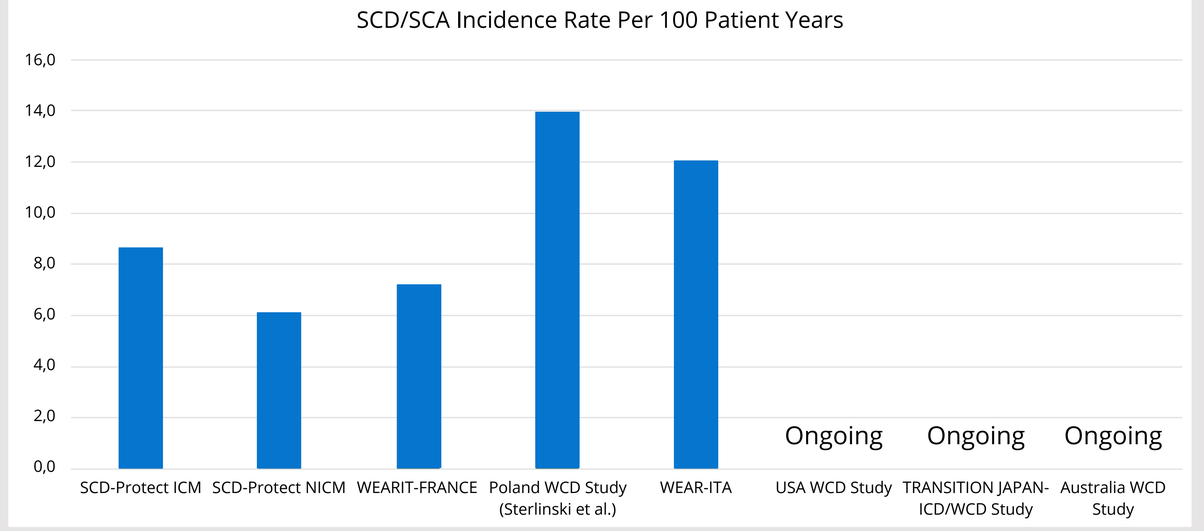
WCD prescribed by physician, patient wears device, ECG recording during wear; Prescription within routine clinical practice and GDMT

Statistics

Proposed true appropriate WCD treatment incidence: ≥1.2%; Detection expectation of 1.0% with p=0.05 (95% CI: 0.008–0.0123); Required sample size: 8,928 patients per HF aetiology

Results

- WCD ECG data integrated into national RWD databases
- Independent researcher validation
- Country-specific analyses



Discussion

- SCA from life-threatening arrhythmias (VT/VF), requires immediate defibrillation
- Incidence is difficult to assess, with approximately 50% of cases unwitnessed, limited reliability of classifications/autopsies
- WCDs and ICDs provide continuous monitoring, therapeutic intervention, and ECG documentation
- Most accurate tool to quantify SCD incidence in high-risk patients

Conclusions

- Full country-specific RWD dataset: insights into epidemiological SCA/SCD risk under modern GDMT
- Comprehensive database + ECG recordings: resource for future research
- Potential applications: AI-assisted tools to investigate the causes and disease burden of SCA/SCD