Low rates of inappropriate shocks in contemporary real-world implantable cardioverter defibrillator patients: the CARAT observational study.

RESULTS FROM THE CARAT STUDY*

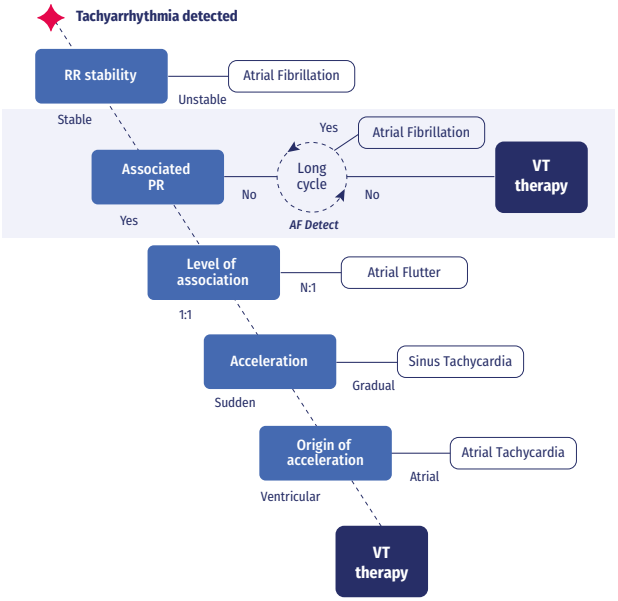
Background & objective

→ Among other complications of ICD therapy, inappropriate shocks negatively impact patients quality of life and may be associated with myocardial injury.

ICD implantation remains the mainstay of sudden cardiac death (SCD) prevention in high-risk patients.

Methods

› **The CARAT** (Clinical and Device Functional Assessment of Real World ICD Patients) trial is a **prospective, multi-center, international, observational, post-market** study of all approved and commercialized CE and/or FDA ICD devices (VR/DR/CRT-D) from MicroPort CRM™.



Results

› From July 1st, 2015, to October 31st, 2017, a total of **2032 patients**, either as a de novo implantation (n=1463, 72.1%) or replacement (n=565, 27.9%), were enrolled.

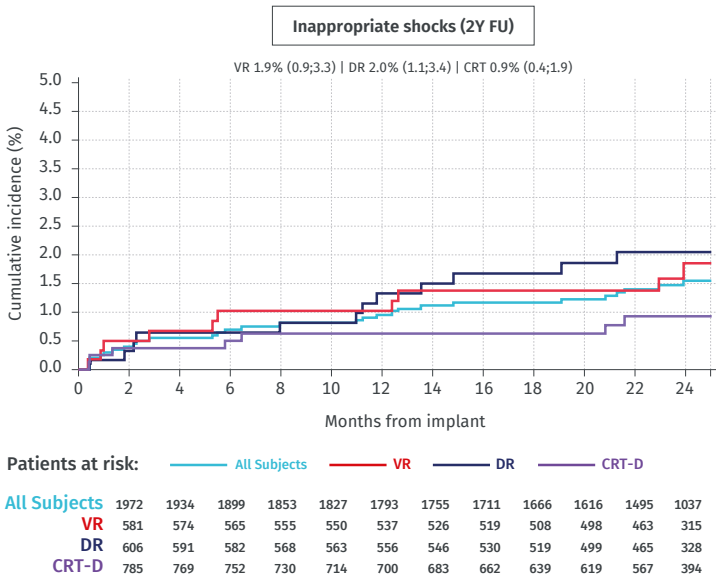
› **Detection programming was very similar across CRT-D, dual chamber, and single chamber ICD models.**

› There were only few and **non-meaningful differences in** tachyarrhythmia detection **programming** across countries, or between primary or secondary prevention of SCD.
A "shock box" programming was programmed in only 37 study participants (1.8%).

Within 2 years, 13.4% (n=250) and 3.8% (n=69) of patients received appropriate and inappropriate ICD therapies, respectively. Appropriate and inappropriate ICD shocks occurred in 5.0% (n=95) and 1.6% (n=29) of patients, respectively.

Discussion

CARAT study reports a remarkably low rate of inappropriate shocks in real-world contemporary ICD therapy (1.6% within 2 years).



› **CARAT confirms results** of previous studies such as OPTION or ISIS-ICD in terms of arrhythmia discrimination **in dual-chamber devices.**

› **The rate of inappropriate shocks in the VR patients** in the present study (1.9% at 2 years) **also compares favorably** with:
- the annual rate reported in a **systematic review:** 6.4% (Auricchio 2017);
- the **PainFREE SST** substudy: 3.7% at 2 years for VR patients;
- the **UMBRELLA** registry: 5% at 2 years;
- the **EU-CERT:** 7% at 2.7 years;
- the **PRAETORIAN** trial: 9.7% for S-ICD and 7.3% for transvenous ICD (mean follow-up 49.1 months);
- the **PIVOTAL** trial: 9.7% of patient implanted with a substernal ICD (mean follow-up 10.6 months).

› **Discrimination performance was obtained without compromise on the time to therapy delivery.**

› Detection zones and therapy programming were globally well aligned with consensus, allowing to fully benefit from ICD tachyarrhythmia detection and therapy capabilities.

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*DICHTL W. ET AL. - EUROPACE (2023) 25, 1–3 HTTPS://DOI.ORG/10.1093/EUROPACE/EUAD186.