

INAPPROPRIATE SHOCK REDUCTION WITH PARAD+™ RHYTHM DISCRIMINATION

Results from the Inappropriate Shock Reduction Study

Ruiz-Granell, R. et al. *Heart Rhythm*. 2019;16:1429-35.

BACKGROUND & OBJECTIVE

Although ICD shocks are lifesaving, inappropriate and unnecessary shocks remain a significant clinical issue with considerable consequences for patients and the healthcare system.¹⁻⁵

The PARAD+ arrhythmia discrimination algorithm has been previously shown to consistently reduce the rate of inappropriate shock (IS).⁶

The purpose of the Inappropriate Shock Reduction Study was to further assess the benefit of PARAD+ for the reduction of IS in a large population implanted for both primary and secondary prevention.⁵

METHOD⁵

Study design

> This study is an **interventional**, single-arm investigation of patients implanted with a dual or triple chamber implantable cardioverter defibrillator (DR-ICD or CRT-D) featuring the PARAD+ algorithm.

> A total of **1013 patients** were included in the trial at **112 sites in 7 countries worldwide**. Patients were followed for **2 years** after implant.

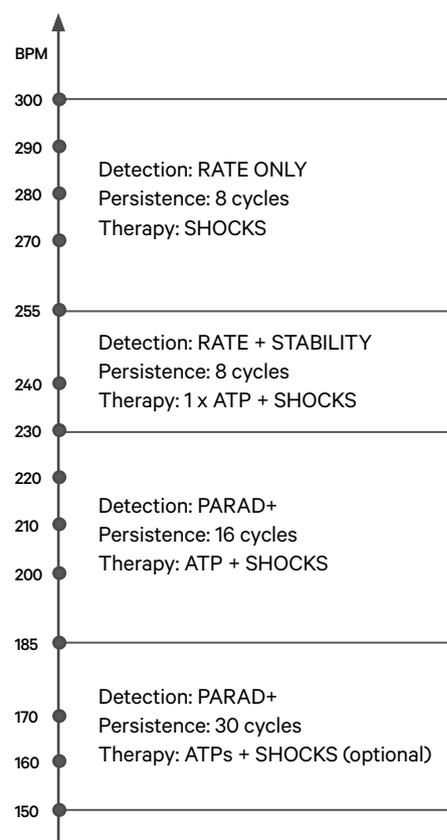
Endpoints

> The primary endpoint was the **proportion of patients free from IS at 24 months** compared to a predefined rate of 92.5%^{1,7}.

> A supplementary analysis of **annual incidence rates of patients with ≥ 1 IS** was also conducted.

METHOD⁵

Device programming



RESULTS⁵

The PARAD+ algorithm was enabled in implanted devices in **993 subjects** who were thus considered for the primary analysis.

> Over a median follow-up of 552 days, 64 patients (6,4%) received at least one shock. Fourteen patients received at least 1 IS.

> Therefore, **the percentage of patients free from IS at 24 months was 98,1%**. **The primary objective was met.**

> **Annual incidence rate of patients with inappropriate shock was as low as 1.0 patient per 100 person-year.**

DISCUSSION⁵

Device programming adjustment was reported to reduce IS in the MADIT-RIT, ADVANCE III, and PROVIDE studies.⁸⁻¹⁰

> IS can be further reduced by combining device programming adjustment with enhanced algorithm discrimination, as reported in the PainFREE SST observational study, which leads to an IS rate in patients of 1.5% at 1 year.¹¹

> The use of high cut-off rates and/or long detection time in these studies meant, however, that the sensitivity of VF detection was compromised.⁸⁻¹¹

> With PARAD+ it was not; the sensitivities of slow VT detection and VT/VF detection are 94% and 99.3%, respectively.⁶

— RESULTS OF CLINICAL TRIALS ON IS —

STUDY	MADIT-RIT (2012) ^{8,10}		ADVANCE III (2013) ¹⁰		PROVIDE (2013) ^{9,10}		PAINFREE SST (2015) ¹¹	INAPPROPRIATE SHOCK REDUCTION TRIAL (2017) ⁵
DEVICES	ICD & CRT-D		ICD & CRT-D		ICD & CRT-D		ICD & CRT-D	ICD & CRT-D
INDICATION	Primary		Primary & secondary		Primary		Primary & secondary	Primary & secondary
ARM	Conventional	TX reduction	Conventional	TX reduction	Conventional	TX reduction	Conventional	Conventional
STRATEGY FOR SHOCK REDUCTION								
Device programming		✓		✓		✓	✓	
Discrimination algorithm	✓		✓		✓		✓	✓
RATE OF INAPPROPRIATE SHOCKS								
Percent of patients	6% at 1.4 y	3% at 1.4 y	—	—	10.9% at 515 d	5.3% at 545 d	1.5% - 2.5% at 1 y* 2.8% - 3.7% at 2 y*	1.9% at 2 y
Patients per 100 person-year	15	4 to 7	10	4	10	8	—	1.0 - 2.1

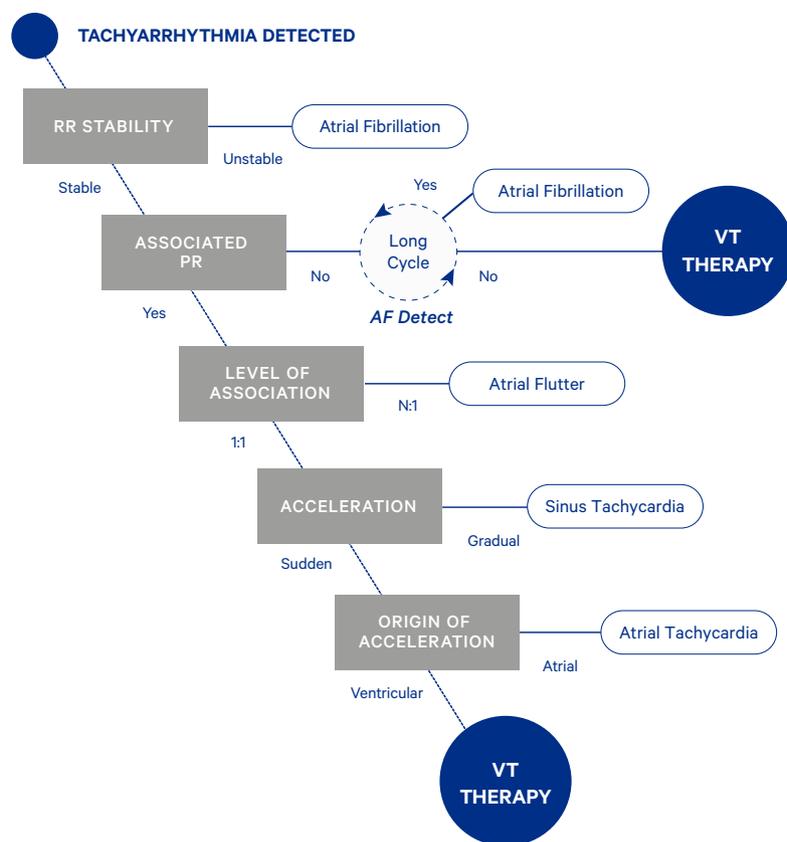
CRT-D = cardiac resynchronization therapy-defibrillator; TX = therapy.

*Lower percentage in range for dual-/triple-chamber implantable cardioverter-defibrillators (ICDs), higher percentage for single-chamber ICDs.

Inappropriate Shock Reduction with PARAD+™ Rhythm Discrimination

PARAD+ algorithm

DISCRIMINATION OF VENTRICULAR TACHYCARDIA
FROM SUPRAVENTRICULAR TACHYCARDIA



CONCLUSION⁵

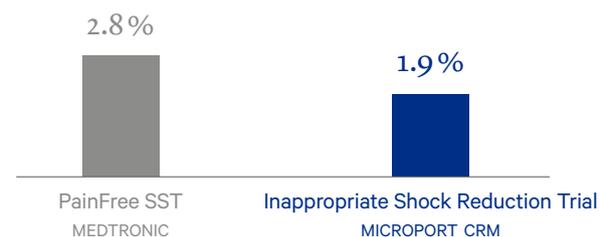
In the Inappropriate Shock Reduction Study, the use of an enhanced discrimination strategy (PARAD+) alone in a wide spectrum of frequencies without the programming of a high cut-off rate and/or extended persistence, allowed the rate of IS to be reduced to as low as 1.0 patient per 100 person-year in a general population implanted for primary or secondary prevention, which is, to our knowledge, **the lowest rate of IS reported in the literature so far.**

References

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MICROPORT CRM

- ✓ **Rate of IS at 2 years with PARAD+ alone is lower than in PainFree SST study, where device therapy adjustment and an enhanced algorithm were combined.**^{5,11}
- ✓ **Annual incidence rate of IS with PARAD+ is 1.0 patient per 100 person year, the lowest rate ever reported in the literature.**⁵



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