Inappropriate shock with subcutaneous ICD versus transvenous ICD

An individual participant data meta-analysis

William F. McIntyre MD PhD

For the PRAETORIAN and ATLAS Investigators

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PRAETORIAN

Amsterdam UMC

ATLAS S-ICD

Avoid Transvenous Leads in Appropriate Subjects S-ICD

Population Health Research Institute

HEALTH THROUGH KNOWLEDGE

ESC Congress 2025 Madrid

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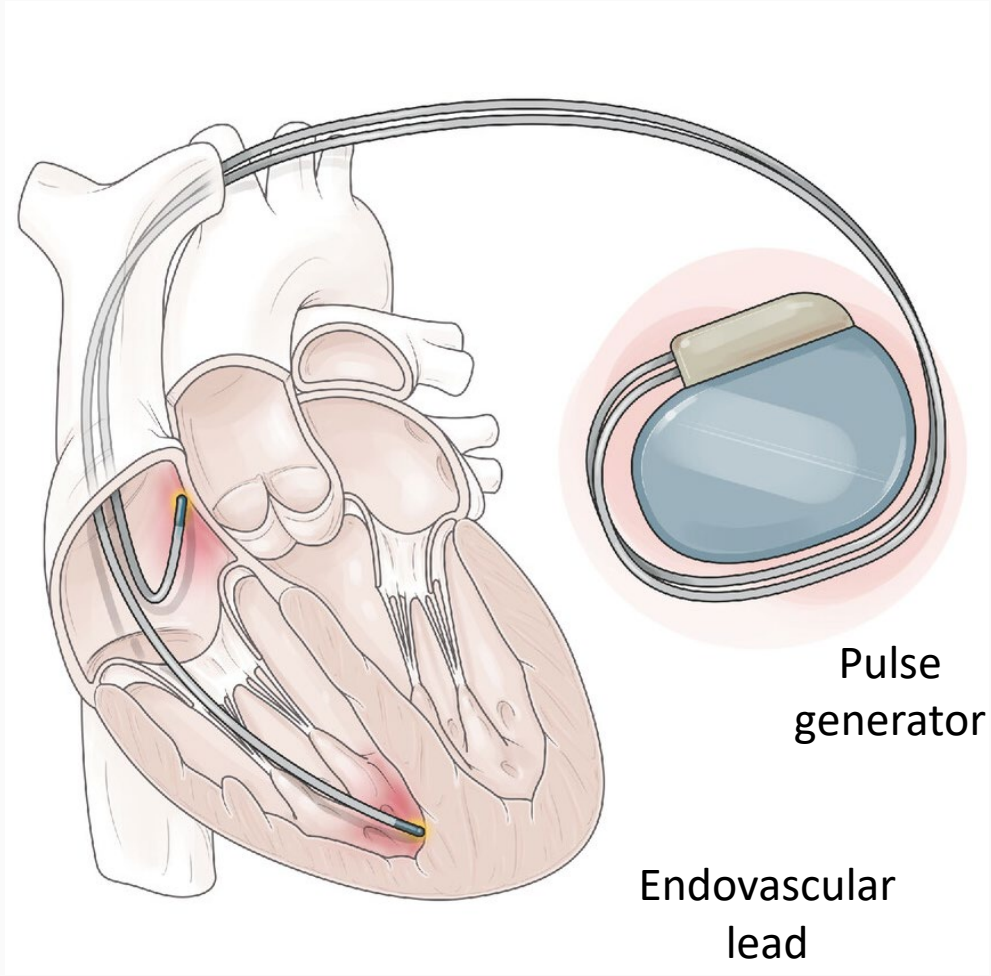
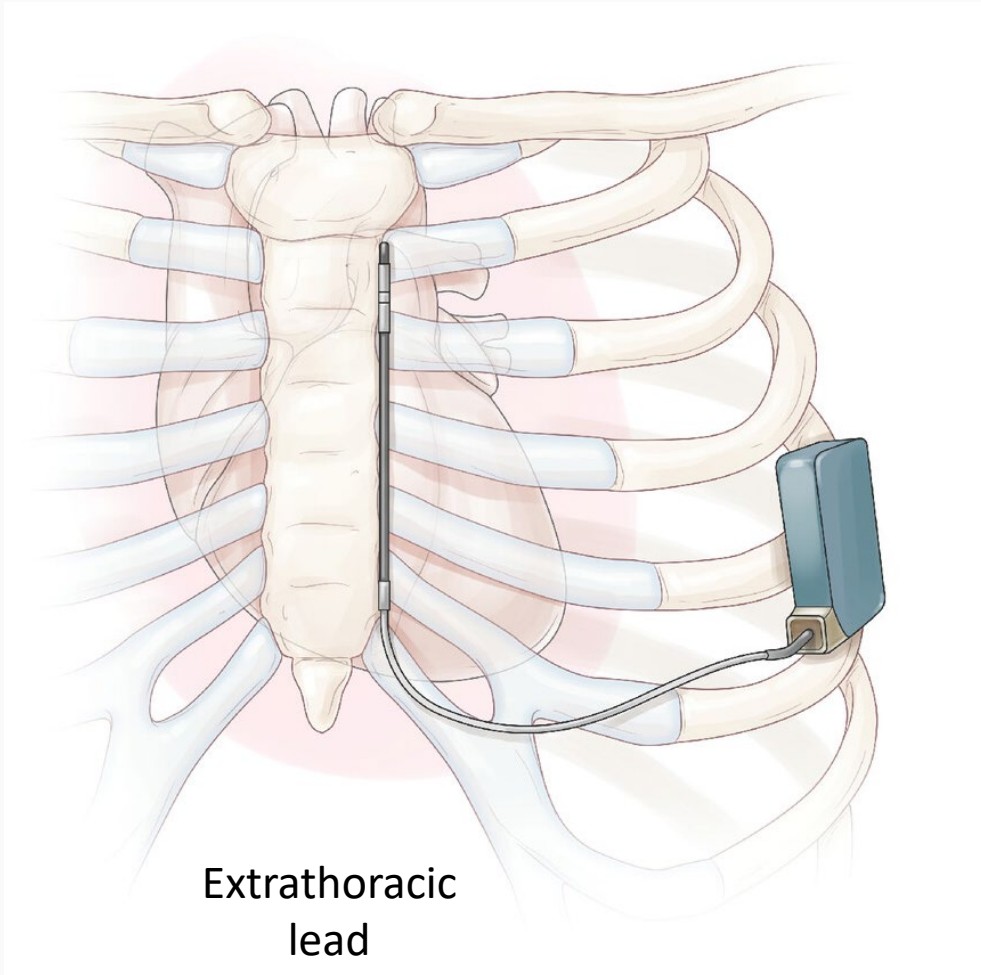
Background

Transvenous ICD (TV-ICD)

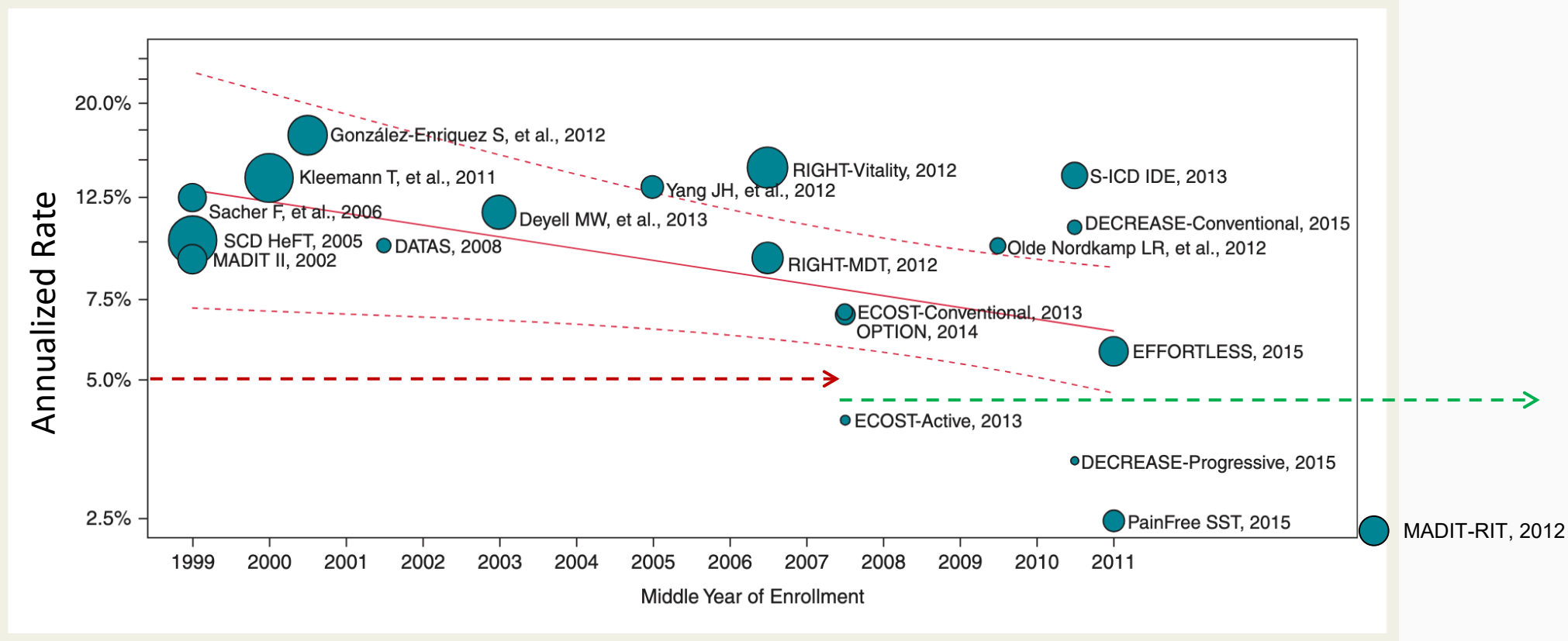


Subcutaneous ICD (S-ICD)



Al-Khatib SM. N Engl J Med. 2024.

Inappropriate shock in published ICD trials



Mechanisms:

- cardiac oversensing
- electromagnetic interference
- atrial arrhythmias

Negative consequences:

- painful
- impaired quality of life
- pro-arrhythmia
- accelerated battery depletion
- association with mortality

Auricchio et al. Europace. 2017.

The PRAETORIAN and ATLAS randomized trials

Both trials randomized patients with a standard indication for an ICD
without an indication for pacing
to a subcutaneous or transvenous ICD.

PRAETORIAN (2020)[1]
Primary endpoint: Composite of device-related complications and inappropriate shocks
Hazard ratio: 0.99, 95% CI 0.71 to 1.39; P = 0.01 for *non-inferiority*

ATLAS (2022)[2]
Primary endpoint: Perioperative major lead-related complication
Absolute reduction 4.4%; 95% CI 1.9 to 6.9; P = 0.001 for *superiority*

Neither trial was powered to assess shock outcomes, including inappropriate shock

(1) Knops RE. N Engl J Med. 2020. (2) Healey JS. Ann Intern Med. 2022.

PRAETORIAN/ATLAS
Individual Participant Data Meta-Analysis

Aims

1. To compare the rates of first inappropriate shock between subcutaneous and transvenous ICDs

2. To describe the mechanism of first inappropriate shocks

3. To compare the rates of first inappropriate ICD therapy (i.e., anti-tachycardia pacing or shock) between subcutaneous and transvenous ICDs

Methods

We created a central database harmonizing individual participant-level data of the PRAETORIAN and ATLAS trials

Primary endpoint: Time to first inappropriate shock

Shock in the absence of ventricular tachycardia or ventricular fibrillation.

Secondary endpoint: Time to first inappropriate ICD therapy

Anti-tachycardia pacing or shock in the absence of ventricular tachycardia or ventricular fibrillation.

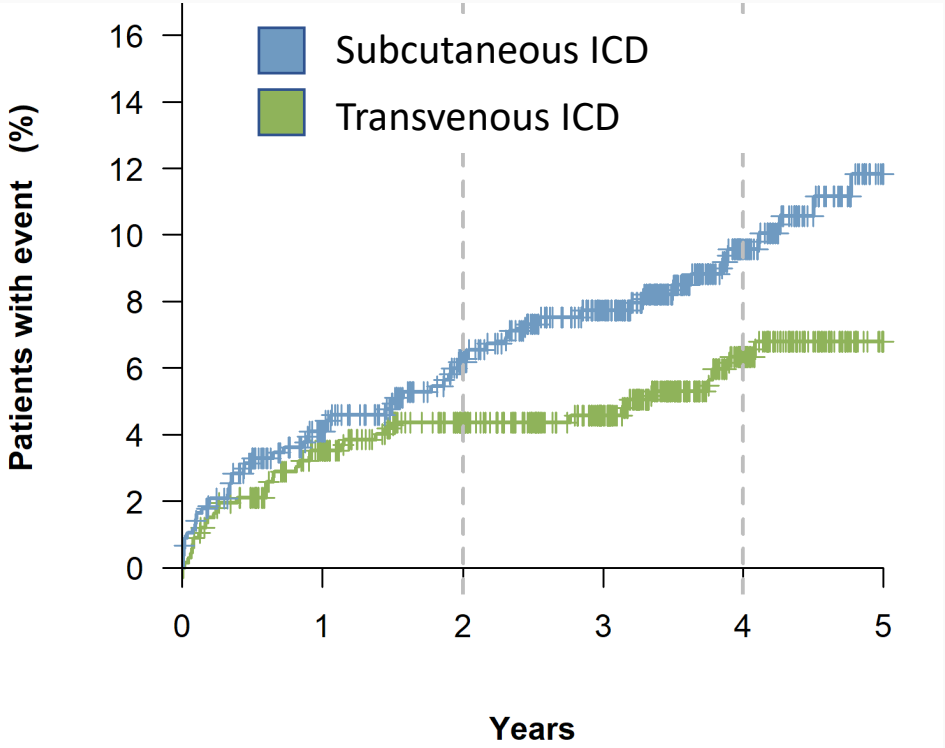
Adjudicated mechanism for inappropriate shock or inappropriate ICD therapy:

(1) cardiac oversensing, defined as P-wave or T-wave oversensing
(2) electromagnetic interference or myopotentials
(3) atrial arrhythmia, defined as atrial fibrillation or supraventricular tachycardia

Baseline characteristics

	Subcutaneous ICD n = 673	Transvenous ICD n = 669
Age (years), median (IQR)	57.8 (49.0-66.0)	59.0 (51.0-67.0)
Female sex	148 (22.0%)	145 (21.7%)
Body mass index (kg/m^2), median (IQR)	27.2 (24.5-31.1)	27.8 (25.0-31.7)
Primary prevention	521 (77.4%)	522 (78.0%)
Secondary prevention	152 (22.6%)	147 (22.0%)
Ischemic cardiomyopathy	375 (55.7%)	391 (58.5%)
Non-ischemic cardiomyopathy	153 (22.7%)	157 (23.5%)
Other	152 (22.6%)	132 (19.7%)
Left ventricular ejection fraction ≤35%	380 (68.3%)	389 (69.1%)
Beta blocker	550 (81.7%)	546 (81.6%)
Antiarrhythmic drugs	52 (7.7%)	40 (6.0%)
SQ-RX Model 1010 (first-generation)	183 (27.2%)	
A209 EMBLEM (second-generation)	208 (30.9%)	
A219 EMBLEM MRI (third-generation)	273 (40.6%)	
Crossed over to other ICD type	9 (1.4%)	11 (1.6%)

Time to first inappropriate shock



No. at risk (No. of events)

S-ICD	673 (0)	584 (27)	508 (39)	427 (47)	211 (53)	117 (57)
TV-ICD	669 (0)	598 (23)	522 (28)	436 (29)	235 (35)	119 (36)

	Subcutaneous ICD N=673		Transvenous ICD N=669	
	n	(%/yr)	n	(%/yr)
Inappropriate shock	57	2.5	36	1.5

SMART Pass

A proprietary algorithm designed to reduce inappropriate shocks from cardiac oversensing (T-waves) in patients with a subcutaneous ICD

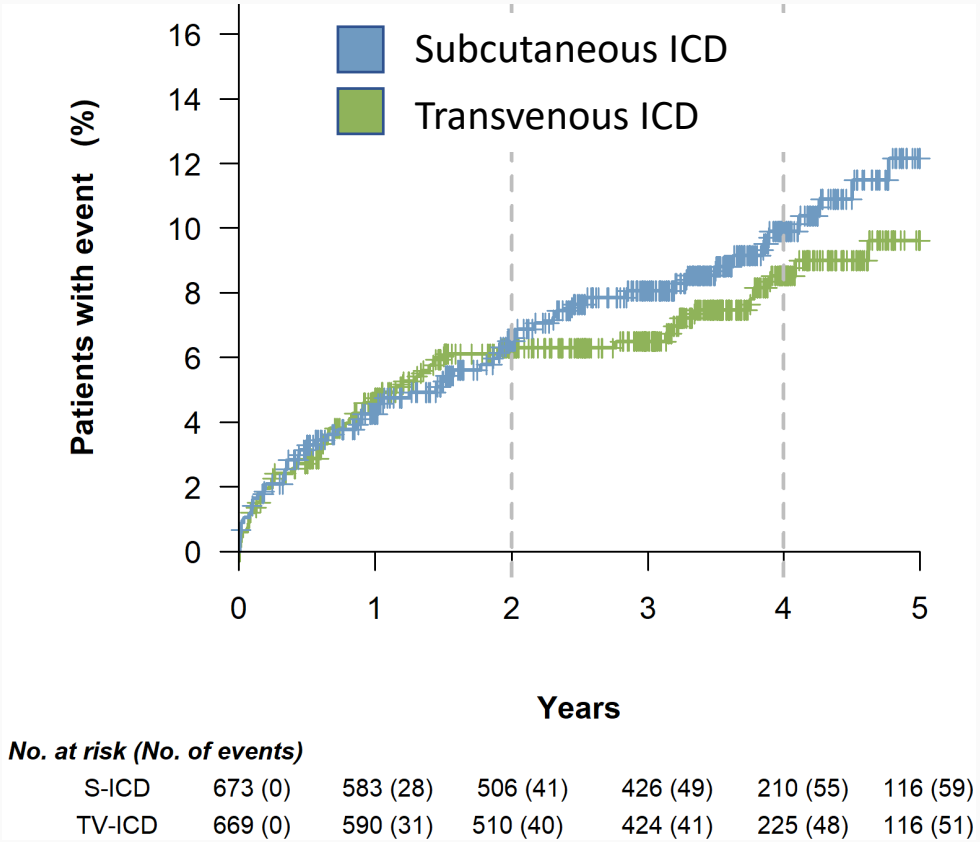
In patients randomized to receive a subcutaneous ICD:

- SMART Pass activated at baseline in 252 (37.4%)
- SMART Pass activated during follow-up in 267 (39.7%)
- SMART Pass never activated in 154 (22.9%)

SMART Pass (modeled as a time-dependent co-variate) was not associated with a reduction in:

- first inappropriate shock for any reason: hazard ratio 1.15, 95% CI 0.61-2.16
- first inappropriate shock due to cardiac oversensing: hazard ratio 0.80, 95% CI 0.32-1.97

Time to first inappropriate ICD therapy (anti-tachycardia pacing or shock)



	Subcutaneous ICD N=673		Transvenous ICD N=669	
	n	%/yr	n	%/yr
Inappropriate ICD therapy	59	2.6	51	2.2

Conclusions

From our individual participant data meta-analysis of PRAETORIAN and ATLAS:

1. The rates of first inappropriate shock were *historically* low
with both subcutaneous and transvenous ICDs (2.5% vs. 1.5% per year).

2. Patients with a subcutaneous ICD had a higher rate of first inappropriate shock
than those with a transvenous ICD.

3. A subcutaneous ICD was more likely to cause a first inappropriate shock
due to cardiac oversensing and electromagnetic interference.

4. A transvenous ICD was more likely to cause a first inappropriate shock
due to atrial arrhythmia.

Simultaneous publication

Alexander P. Benz, Louise R.A. Olde Nordkamp, William F. McIntyre, et al. Inappropriate shock with a subcutaneous or transvenous implantable cardioverter-defibrillator: an individual participant data meta-analysis of the randomized PRAETORIAN and ATLAS trials. J Am Coll Cardiol. 2025.

Now available:

https://www.jacc.org/

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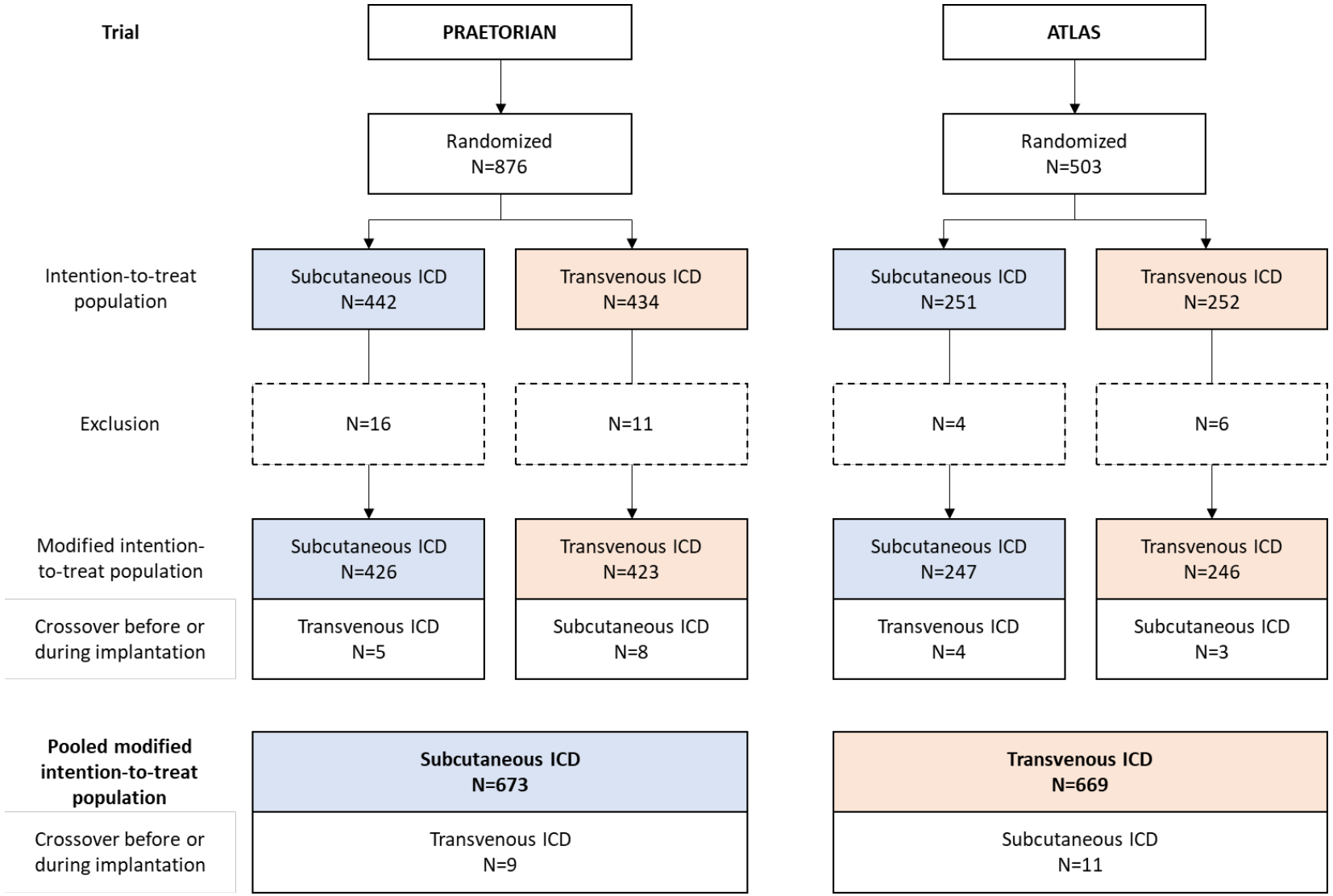
Supplemental Material

Derivation of study population



Subgroup analyses

Subgroup	Subcutaneous ICD (N=673)		Transvenous ICD (N=669)		Hazard ratio (95% CI)	p_{int}
	n/N (%)	Event rate	n/N (%)	Event rate		
Age (tertiles)[a]						
Lowest	14/248 (5.6)	1.8	9/209 (4.3)	1.4	1.31 (0.57-3.04)	0.23
Mid	17/211 (8.1)	2.3	14/227 (6.2)	1.9	1.23 (0.60-2.50)	
Highest	26/214 (12.1)	3.5	13/233 (5.6)	1.4	2.33 (1.20-4.54)	
Sex						
Female	7/148 (4.7)	1.3	4/145 (2.8)	0.8	1.66 (0.48-5.67)	0.98
Male	50/525 (9.5)	2.8	32/524 (6.1)	1.7	1.62 (1.04-2.52)	
Left ventricular ejection fraction[b]						
≤35%	33/380 (8.7)	2.4	23/389 (5.9)	1.5	1.52 (0.90-2.60)	0.41
>35%	19/176 (10.8)	3.1	8/174 (4.6)	1.3	2.31 (1.01-5.29)	
Baseline use of a betablocker and/or antiarrhythmic drug						
No	9/111 (8.1)	2.8	5/107 (4.7)	1.3	1.90 (0.63-5.66)	0.70
Yes	48/562 (8.5)	2.5	31/562 (5.5)	1.6	1.56 (0.99-2.45)	

The median age was 45 years in the lowest tertile, 58 years in the mid tertile and 70 years in the highest tertile.

[b] Calculations are based on available data (left ventricular ejection fraction was missing for 223 patients).

A proprietary algorithm designed to reduce inappropriate shocks from cardiac oversensing.
became available for patients who received a second-generation (A209 EMBLEM) or third-generation (A219 EMBLEM MRI) subcutaneous ICD model. This algorithm uses a high-pass filter at 8-9 Hz to attenuate low-frequency signals (e.g., T-wave), thereby enhancing the QRS-to-T-wave ratio and improving sensing accuracy.

proprietary algorithm

Of 57 patients in the subcutaneous ICD group who had a first inappropriate shock, 30 (52.6%) had their event before or in the absence of a first activation of the SMART Pass algorithm.