17th WORLD CONGRESS of ARRHYTHMIAS

2–4 November, 2023 İstanbul/TURKEY

Elite World Convention Center

Transvenous ICD no Pacing Indication

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Fundación Jesús Serra Catalana Occidente

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cnic Centro Nacional de Investigaciones Cardiovasculares Carlos III — Desde la investigación a la salud

LIBIN CARDIOVASCULAR INSTITUTE

CAM Conflicts Of Interest

- Abbott, Adium, BSCI, Bayer, Baylis, Biotronik, BMS, Daiichi Sankyo, Kardium, Pfizer, Servier, Technopharma, Medtronic, Novartis

- CIHR, CaNet, Colciencias, Gates Foundation, NIH, NCE, TDR-WHO

- ACTIVE-A-W-I, ASSERT, AVERROES, AWARE I-II, ADVICE, BRUISE-CONTROL, CABANA, CAPCOST, CREDIT, COAST-AF, CRYO-LATS, CRYSTAL-AF, CTOPP, DISCERN-AF, EARLY- AF, ELIMINATE-AF, ICD-TEACH, ISSUE-3, LILAC, OPTIC, PADIT, PALLAS, PAPS, PARACHUTE-HF, POST 1-7, PROGRESSIVE-AF, PULSE-AF, SPAIN, SPRITELY, RAAFT-2, RAFT, RAFT-AF, RECIRCUIT, RELY,

First-generation S-ICD SQ-RX 1010 (Cameron Health)		Second-generation S-ICD EMBLEM (Boston Scientific)
15.7 mm	Thickness	12.7 mm
69.9 cc	Volume	59.5 cc
145 gram	Weight	130 gram
5.1 years	Longevity	7.3 years
Not available	Remote monitoring	LATTITUDE

Permanent Transvenous Lead System for an Implantable Pacemaker Cardioverter-Defibrillator
Non-thoracotomy Approach to Implantation

TABLE 2. Patient Characteristics

Patient	Age (years)	Sex	Diagnosis and associated conditions	LVEF (%)	Arrhythmia
1	77	M	IHD, MI, AVR	20	VT
2	55	F	IHD, MI, Crohn's	30	VF
3	75	M	IHD, MI, COPD	35	VF
4	65	M	IHD, MI, diabetes	40	VT
5	50	M	IHD, MI, CABG	20	VT
6	68	M	IHD, MI	30	VT
7	62	M	IHD, MI	25	VF
8	63	M	IHD	63	VT
9	39	M	Cardiac lipoma	35	VT
10	54	F	MVR	42	VT
11	55	M	IHD, MI, CABG	37	VT/VF
12	64	M	IHD, MI	22	VT
13	61	F	MVR	52	VF
14	52	M	IHD, MI, CABG	16	VT

Yee R et al. Circulation 1992;85:196-204.

Table 1. Randomized Clinical Trials of ICDs

Trial	Inclusion Criteria and Sample Size	Primary End Point	Main Finding
AVID[21]	Near-fatal VF; sustained VT with syncope; or sustained VT with an LVEF ≤0.40, and symptoms suggesting severe hemodynamic compromise as a result of the arrhythmia	Overall mortality	Reductions in mortality (with 95% confidence limits) with the ICD were 39±20%, 27±21%, and 31±21% at 1, 2, and 3 y, respectively (P<0.02)
Meta-analysis[23]	Near-fatal VF; sustained VT with syncope; or sustained VT with an LVEF ≤0.40, and symptoms suggesting severe hemodynamic compromise due to the arrhythmia (n=1866)	Overall mortality	There was a 28% reduction in the relative risk of mortality with the ICD that was attributable almost entirely to a 50% reduction in arrhythmic death, P<0.001
MADIT-I[20]	NYHA I, II, or III, prior MI, LVEF ≤35%, NSVT,* nonsuppressible ventricular arrhythmia on EPS (n=196)	Overall mortality	ICD resulted in a 56% relative risk reduction in mortality, P=0.009
MUSTT[22]	Coronary artery disease, LVEF ≤40%, NSVT, inducible sustained VT on EPS (n=704)	Cardiac arrest or death from arrhythmia	ICD resulted in a 76% relative risk reduction in the primary end point, P<0.001
MADIT-II[24]	History of MI, LVEF ≤30% (n=1232)	Overall mortality	ICD resulted in a 31% relative risk reduction in mortality, P=0.016
DEFINITE[25]	Nonischemic cardiomyopathy, LVEF ≤35%, PVCs, or NSVT (n=458)	Overall mortality	ICD resulted in a 35% relative risk reduction in mortality, P=0.08
SCD-HeFT[26]	NYHA II and III, LVEF ≤35% (n=2521)	Overall mortality	ICD resulted in a 23% relative risk reduction in mortality, P=0.007

Circulation. 2016;134:1390–1404.

Need for pacing in patients who qualify for an implantable cardioverter-defibrillator: Clinical implications for the subcutaneous ICD

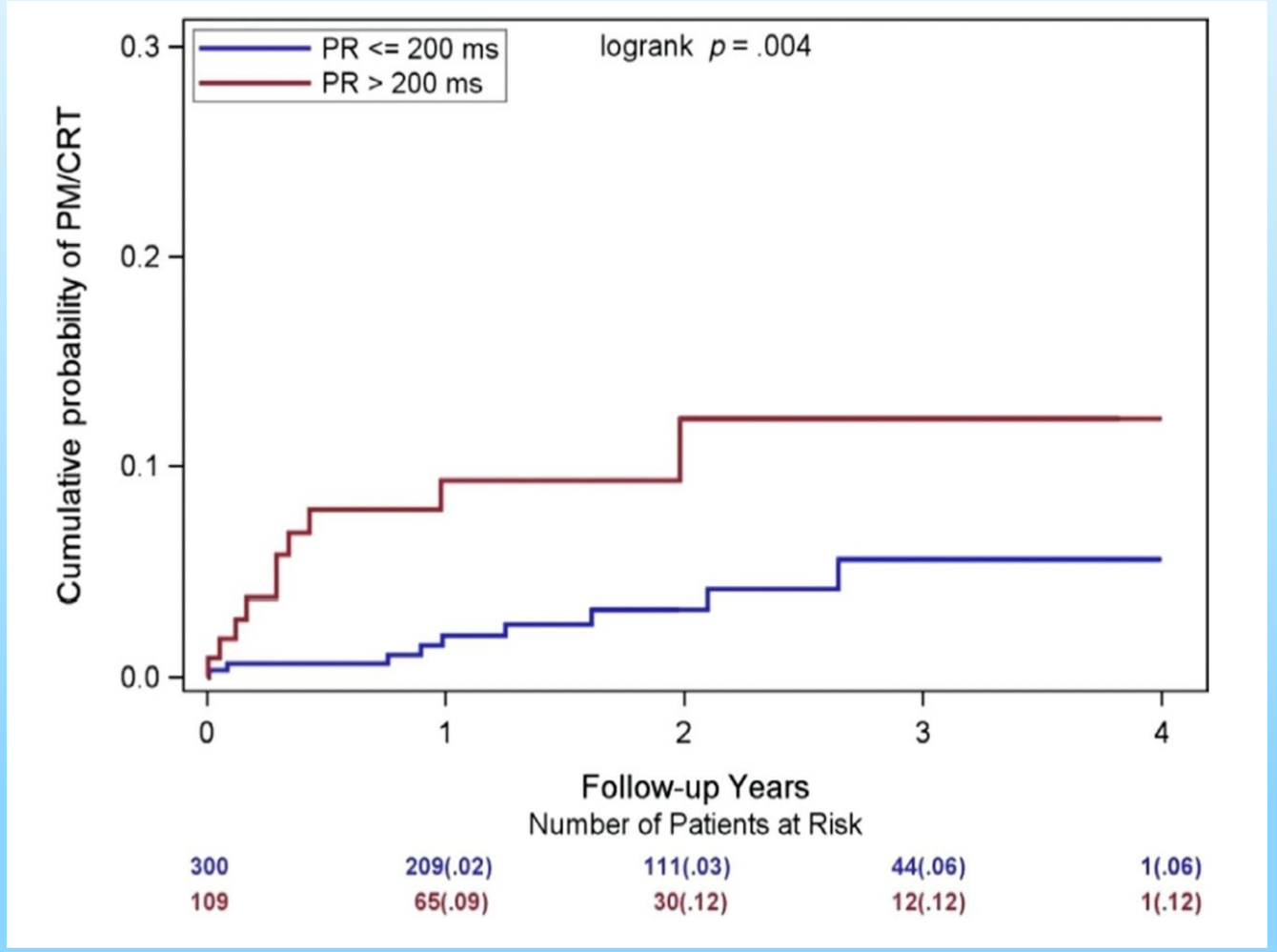
TABLE 2 Predictors of pacemaker/ CRT implantation

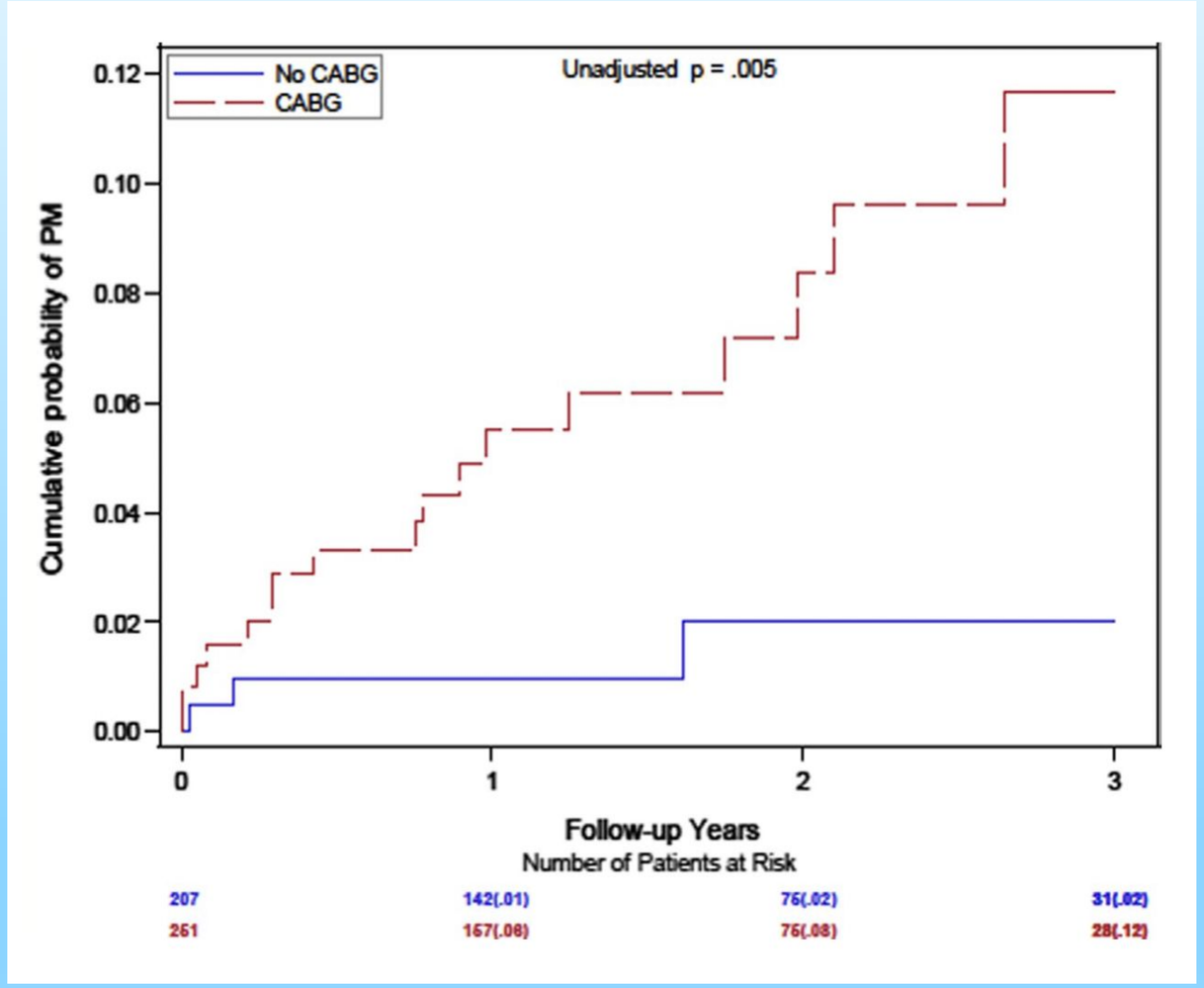
Pacemaker/CRT implantation during the follow-up			
Parameter	**Hazard ratio**	**95% CI**	***p*-Value**
Baseline PR > 200 ms	3.07	1.24 – 7.57	.02
CABG before enrollment	6.88	1.58 – 29.84	.01

458 299(.03) 150(.05) 59(.07) 3(.07)

Kutyifa V, et al. Ann Noninvasive Electrocardiol. 2020;25:e12744. doi.org/10.1111/anec.12744

Need for pacing in patients who qualify for an implantable cardioverter-defibrillator: Clinical implications for the subcutaneous ICD

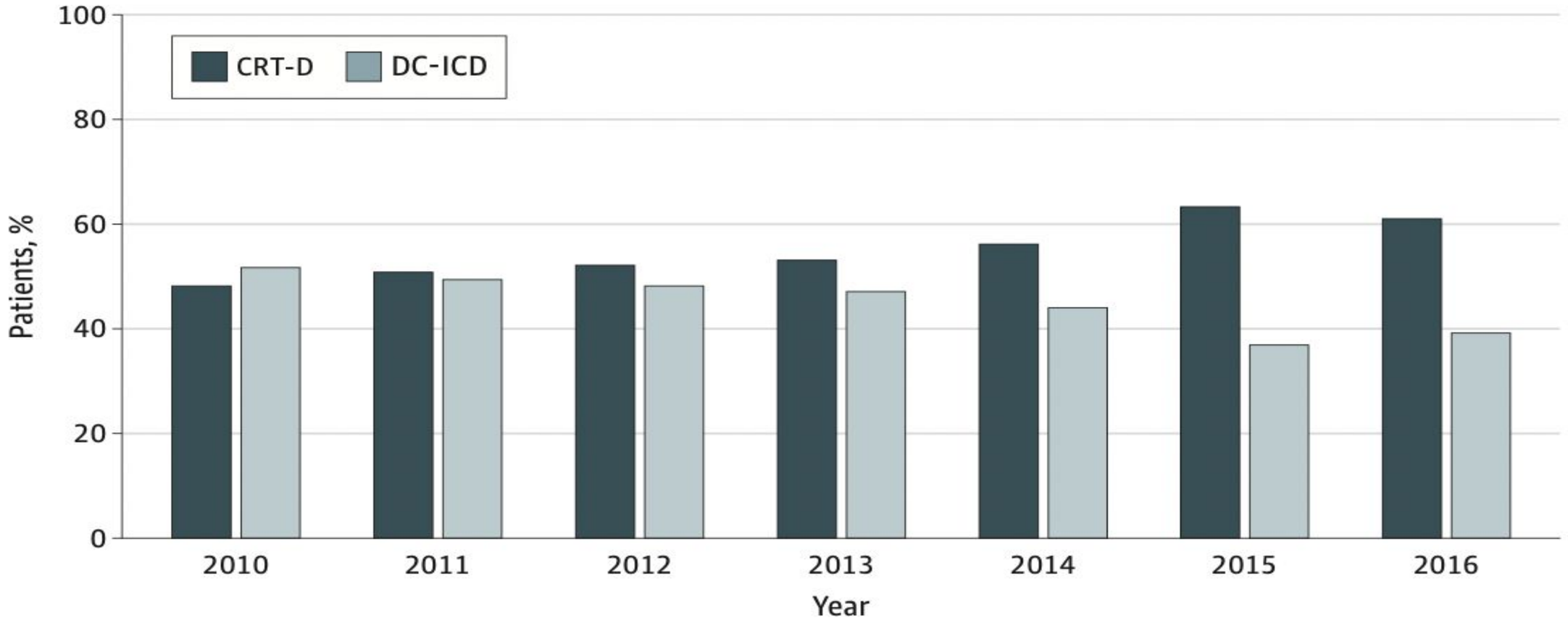




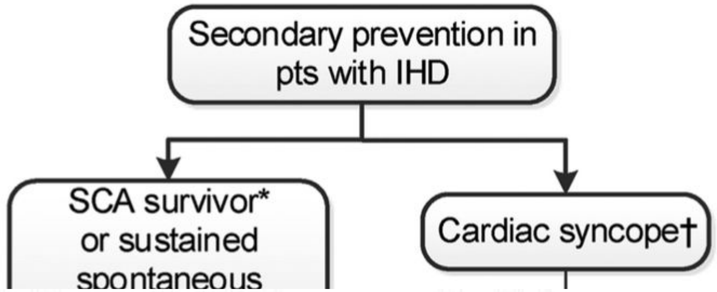
Kutyifa V, et al. Ann Noninvasive Electrocardiol. 2020;25:e12744. doi.org/10.1111/anec.12744

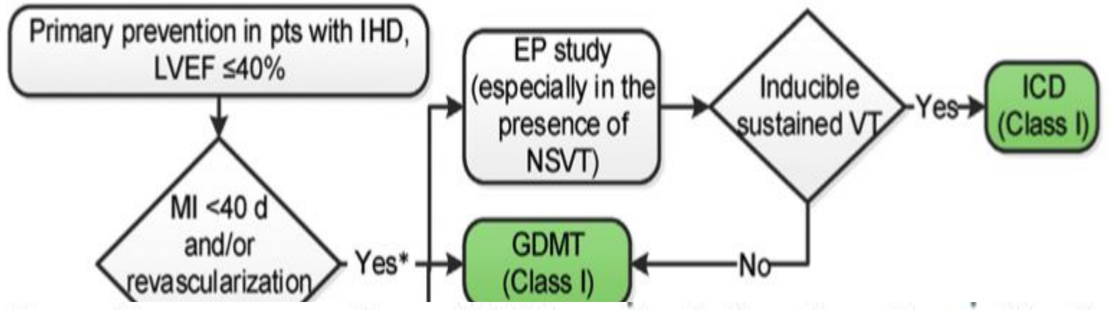
Use and Outcomes of Dual Chamber or Cardiac Resynchronization Therapy Defibrillators Among Older Patients Requiring Ventricular Pacing in the National Cardiovascular Data Registry Implantable Cardioverter Defibrillator Registry

Figure 3. Temporal Trends of Cardiac Resynchronization Therapy Defibrillator (CRT-D) or Dual Chamber Implantable Cardioverter Defibrillator (DC-ICD)



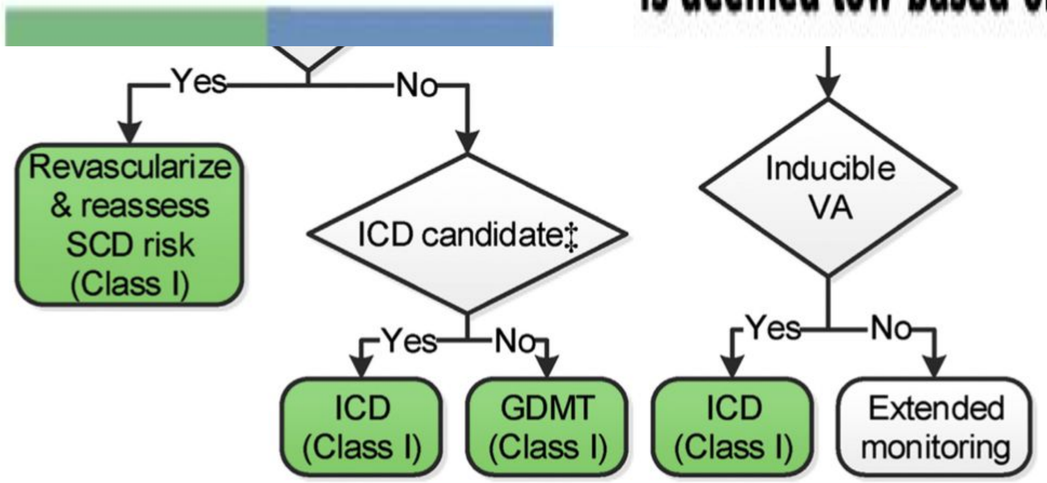
Borne RT, et al. JAMA Network Open. 2021;4(1):e2035470. doi:10.1001/jamanetworkopen.2020.35470

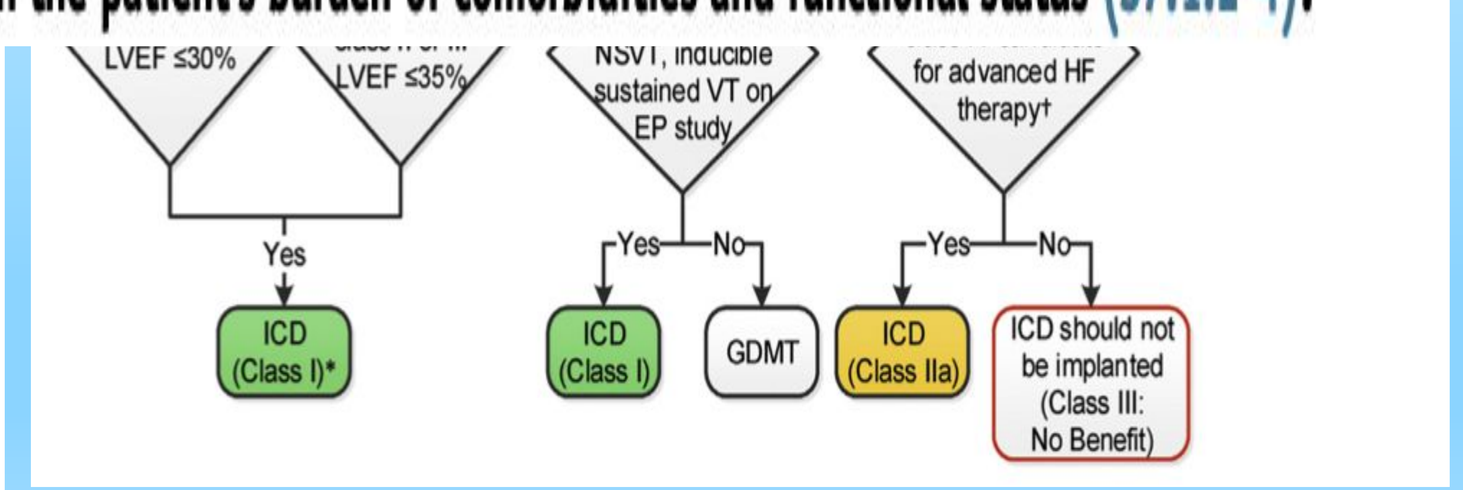




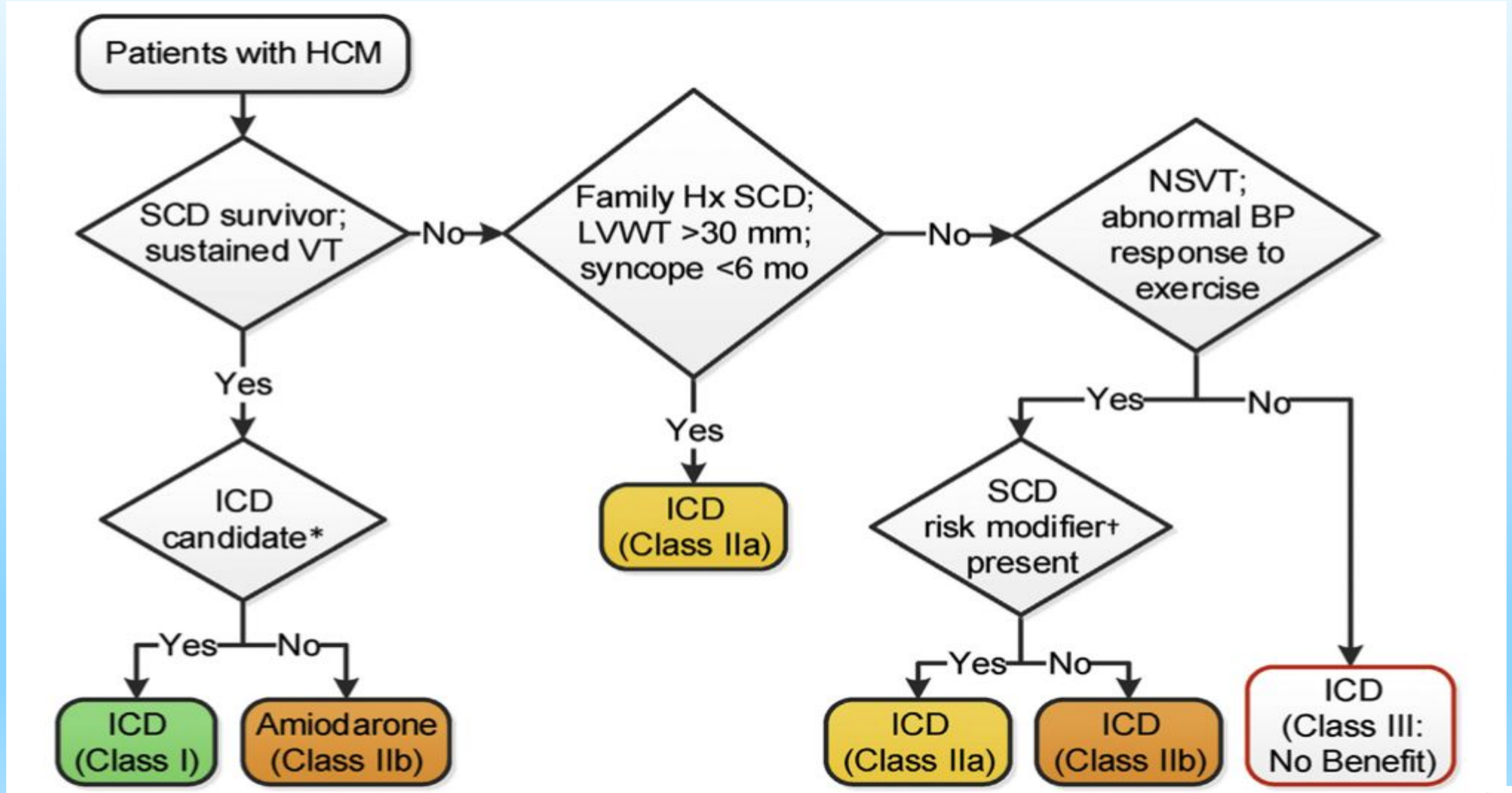
Value Statement: High Value (LOE: B-R)

3. A transvenous ICD provides high value in the primary prevention of SCD particularly when the patient's risk of death due to a VA is deemed high and the risk of nonarrhythmic death (either cardiac or noncardiac) is deemed low based on the patient's burden of comorbidities and functional status (S7.1.2-4).





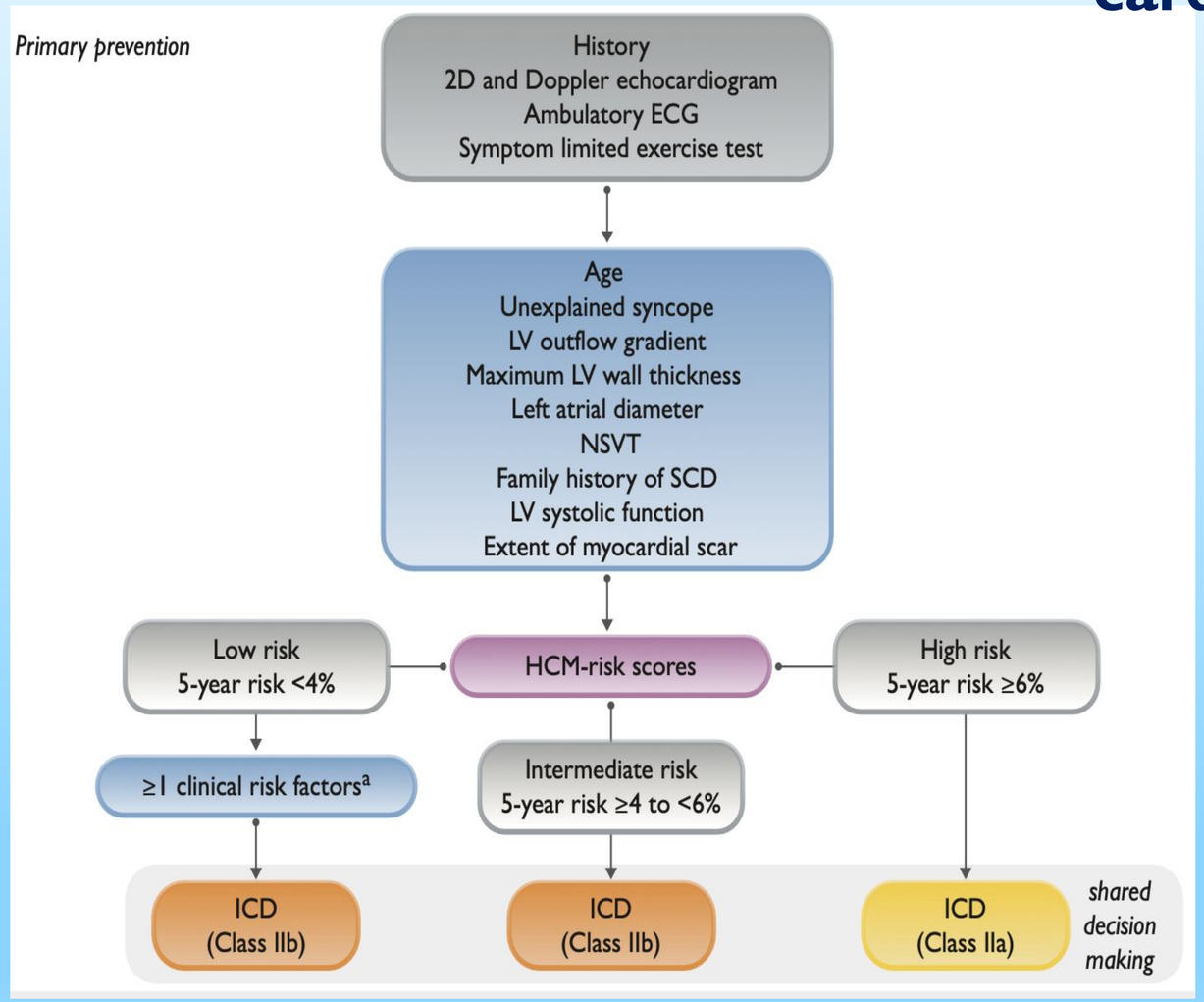
Al-Khatib et al. 2017 VA/SCD Guideline Heart Rhythm, Vol 15, No 10, October 2018

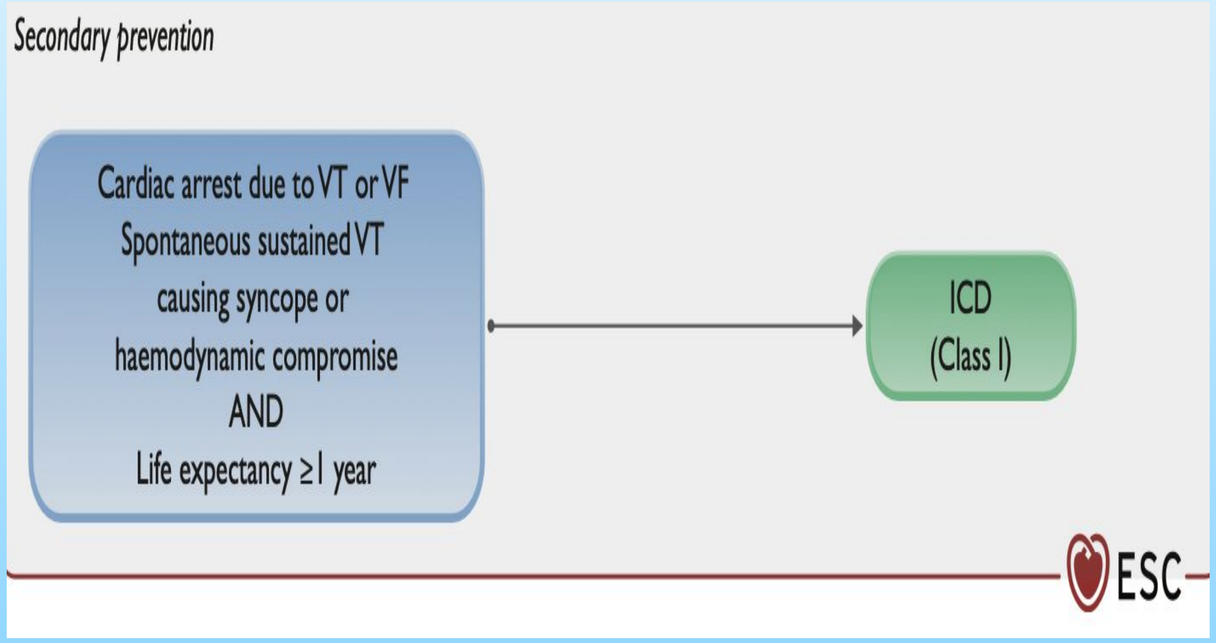


Al-Khatib et al. 2017 VA/SCD Guideline Heart Rhythm, Vol 15, No 10, October 2018

Implantable cardioverter defibrillator in patients with hypertrophic cardiomyopathy

ESC GUIDELINES





Arbelo E, et al. European Heart Journal (2023) **44**, 3503–3626.

ORIGINAL ARTICLE

Subcutaneous or Transvenous Defibrillator Therapy

R.E. Knops, L.R.A. Olde Nordkamp, P.-P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, H. Bonnemeier, E.R. Behr, T.F. Brouwer, S. Kääb, S. Mittal, A.-F.B.E. Quast, L. Smeding, W. van der Stuijt, A. de Weger, K.C. de Wilde, N.R. Bijsterveld, S. Richter, M.A. Brouwer, J.R. de Groot, K.M. Kooiman, P.D. Lambiase, P. Neuzil, K. Vernooy, M. Alings, T.R. Betts, F.A.L.E. Bracke, M.C. Burke, J.S.S.G. de Jong, D.J. Wright, J.G.P. Tijssen, and A.A.M. Wilde, for the PRAETORIAN Investigators*

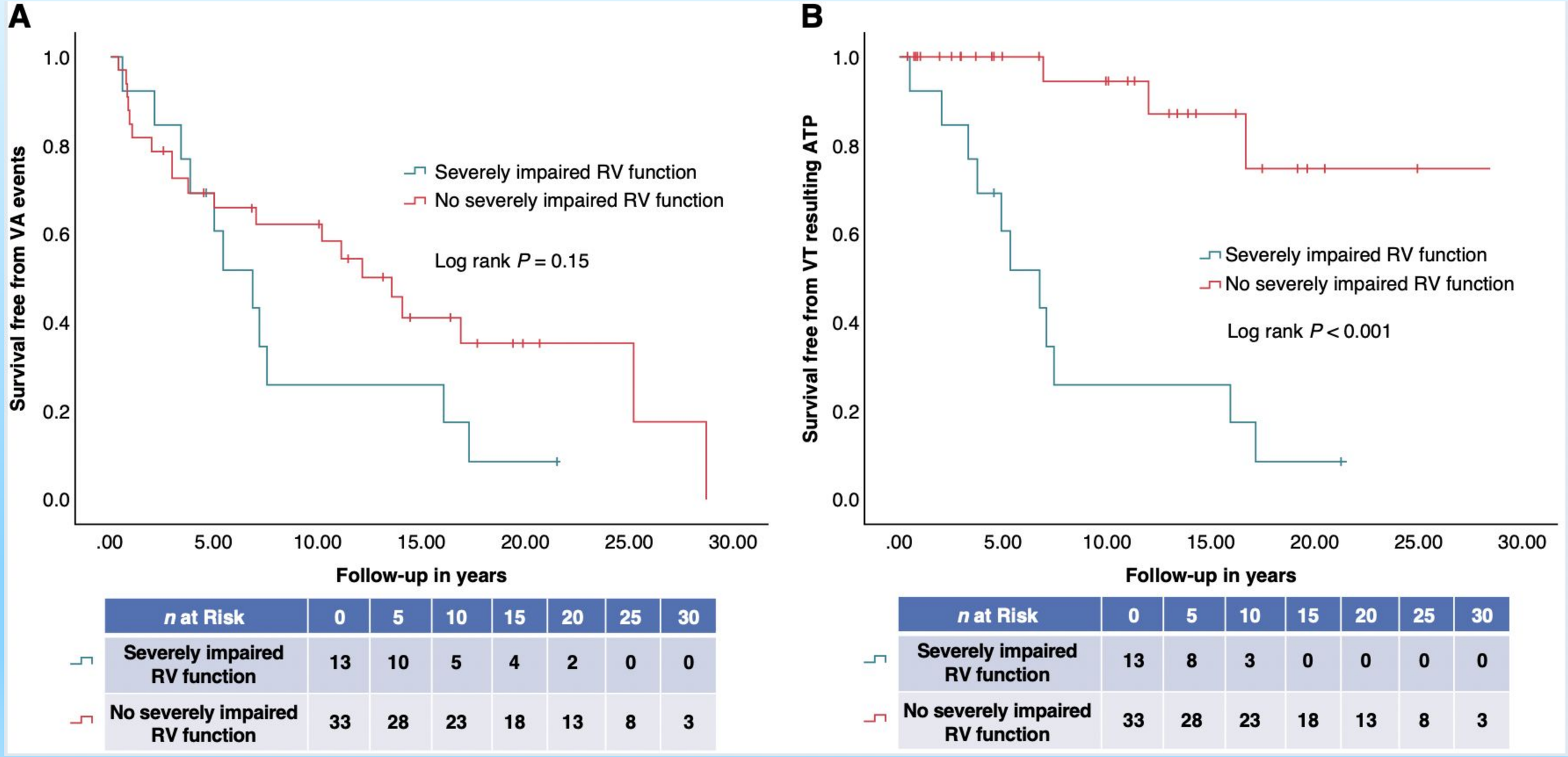
PRAETORIAN TRIAL

Table 3. Secondary End Points.*

End Point	Subcutaneous ICD (N=426)	Transvenous ICD (N=423)	Hazard Ratio (95% CI)
Death from any cause — no. (%)	83 (16.4)	68 (13.1)	1.23 (0.89–1.70)
Sudden cardiac death — no.†	18	18	
Death from other cardiovascular causes — no.	34	28	
Death from noncardiovascular causes — no.	31	22	
Appropriate shock therapy — no. (%)	83 (19.2)	57 (11.5)	1.52 (1.08–2.12)
Ventricular fibrillation — no.	32	22	
Ventricular tachycardia within therapy zone — no.	57	41	
Ventricular tachycardia below therapy zone — no.‡	11	0	
Antitachycardia pacing — no. (%)§			
Appropriate	6 (0.6)	54 (12.9)	
Inappropriate	1 (0.3)	30 (7.2)	
Major adverse cardiac event — no. (%)	64 (13.3)	80 (16.4)	0.80 (0.57–1.11)
Hospitalization for heart failure — no. (%)	79 (17.4)	74 (16.1)	1.08 (0.79–1.49)
Crossover to other study device — no. (%)	18 (4.3)	11 (2.7)	1.64 (0.77–3.47)
Before initial implantation — no.	4	6	
During implantation or follow-up — no.	14	5	
Upgrade to CRT-D — no. (%)	16 (3.5)	21 (4.2)	

Knops RE, et al. N Engl J Med 2020;383:526-36.DOI:

Right ventricular function is a predictor for sustained ventricular tachycardia requiring anti-tachycardic pacing in arrhythmogenic ventricular cardiomyopathy: insight into transvenous vs. subcutaneous implantable cardioverter defibrillator insertion

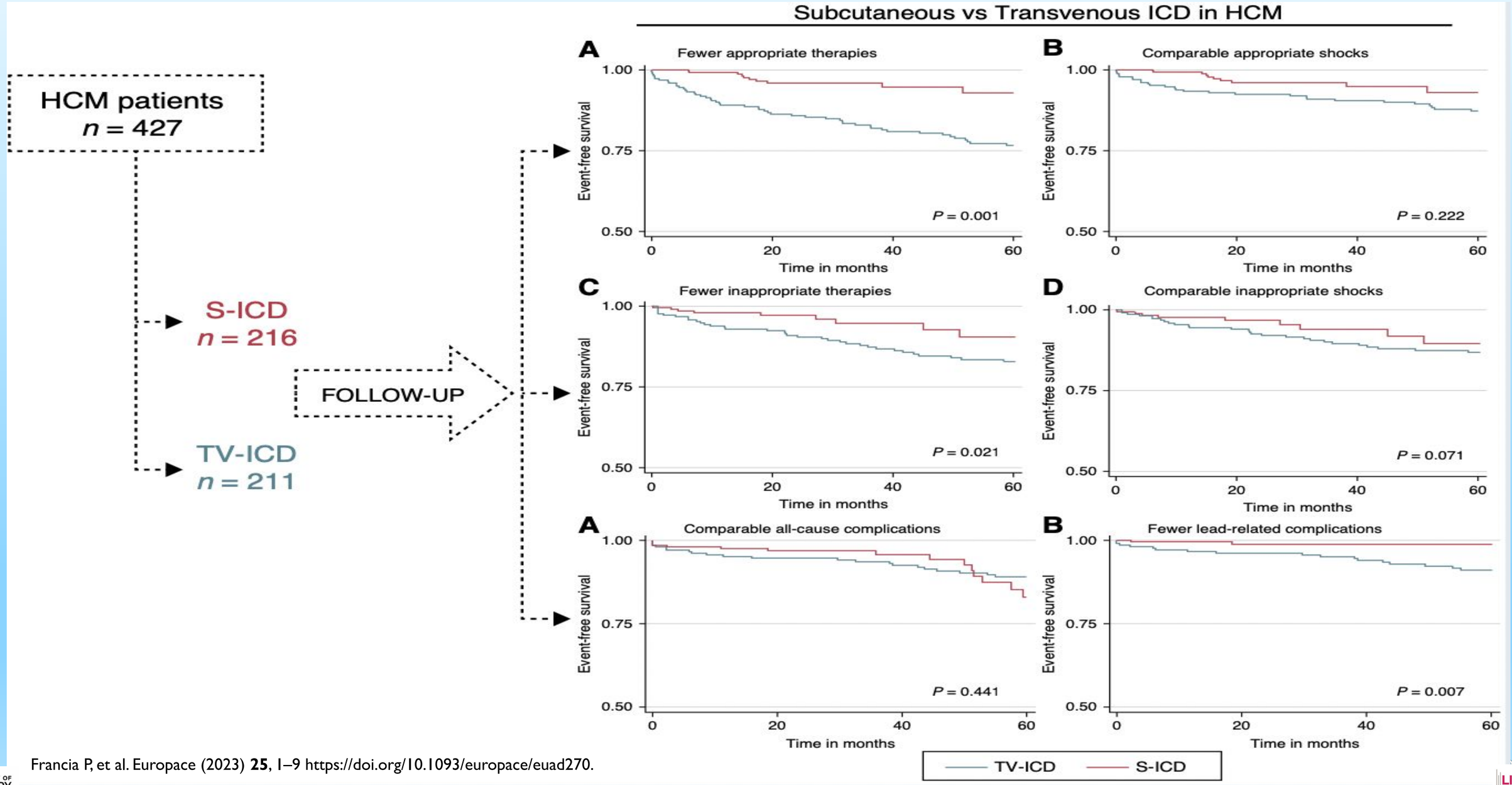


n at Risk	0	5	10	15	20	25	30
Severely impaired RV function	13	10	5	4	2	0	0
No severely impaired RV function	33	28	23	18	13	8	3

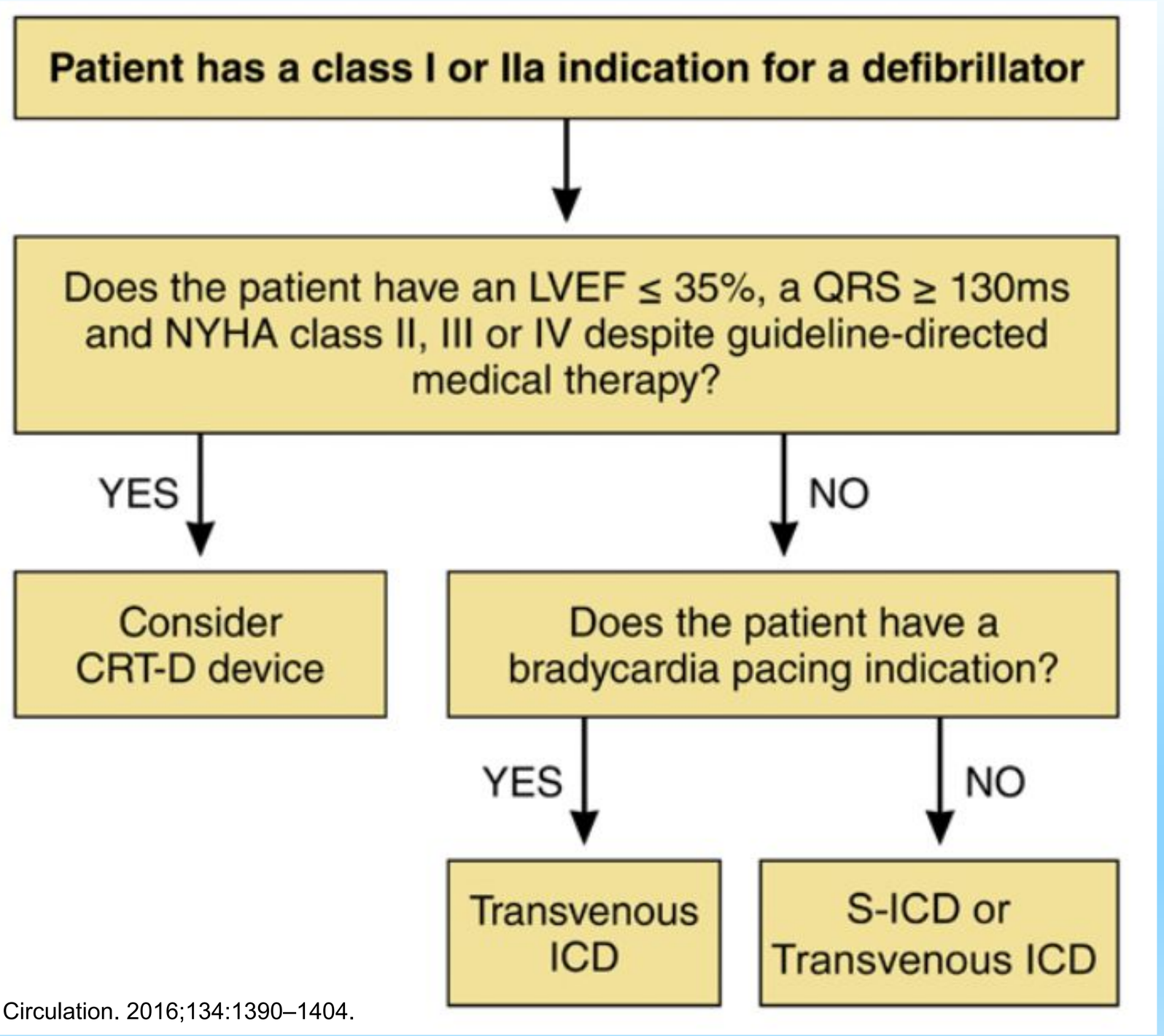
n at Risk	0	5	10	15	20	25	30
Severely impaired RV function	13	8	3	0	0	0	0
No severely impaired RV function	33	28	23	18	13	8	3

Europace (2023) **25**, 1–9 https://doi.org/10.1093/europace/euad073.

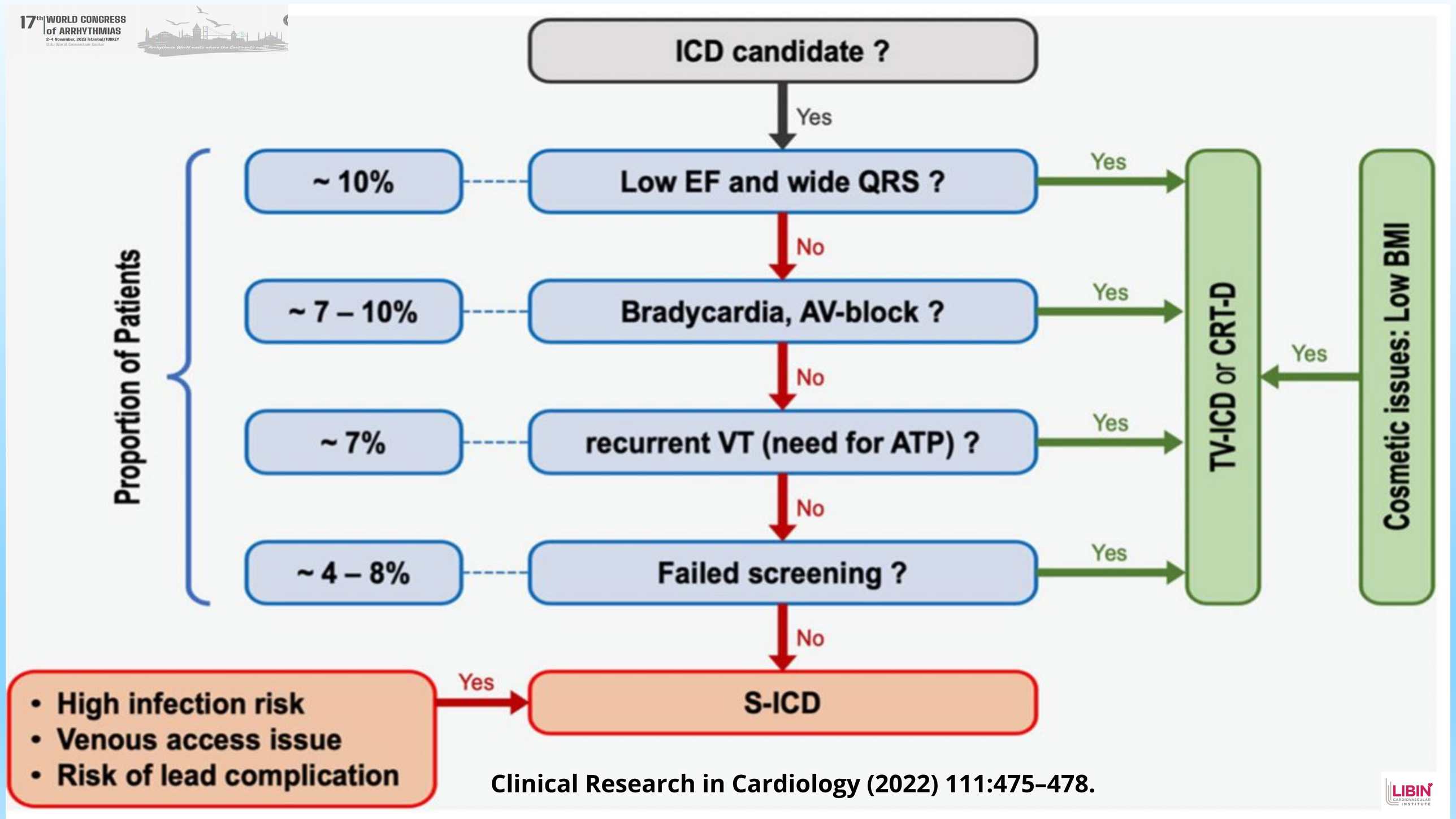
Clinical course of hypertrophic cardiomyopathy patients implanted with a transvenous or subcutaneous defibrillator



Francia P, et al. Europace (2023) **25**, 1–9 https://doi.org/10.1093/europace/euad270.



Circulation. 2016;134:1390–1404.



Clinical Research in Cardiology (2022) 111:475–478.

Perioperative Safety and Early Patient and Device Outcomes Among Subcutaneous Versus Transvenous Implantable Cardioverter Defibrillator Implantations ATLAS Trial

Table 1. Baseline Clinical Characteristics of Enrolled Patients With a Prevention Indication for an ICD

Characteristics	Randomly Assigned (*n* = 503)	S-ICD (*n* = 251)	TV-ICD (*n* = 252)
Mean age (SD), *y*	49 (11.5)	48 (11.9)	50 (11.1)
Secondary prevention indication	137 (27.2)	72 (28.7)	65 (25.8)
Previous sustained ventricular tachycardia, *n (%)*	46 (9.1)	23 (9.2)	23 (9.1)
Previous cardiac arrest, *n (%)*	113 (22.5)	59 (23.5)	54 (21.4)
Male, *n (%)*	373 (74.2)	191 (76.1)	182 (72.2)
Coronary artery disease, *n (%)*	183 (36.4)	87 (34.7)	96 (38.1)
Dilated cardiomyopathy, *n (%)*	116 (23.1)	56 (22.3)	60 (23.82)
Hypertrophic cardiomyopathy, *n (%)*	93 (18.5)	45 (17.9)	48 (19.0)
Idiopathic ventricular fibrillation, *n (%)*	84 (16.7)	47 (18.7)	37 (14.7)
Right ventricular cardiomyopathy, *n (%)*	21 (4.2)	11 (4.4)	10 (4.0)
Brugada syndrome, *n (%)*	12 (2.4)	5 (2.0)	7 (2.8)
Long QT syndrome, *n (%)*	7 (1.4)	4 (1.6)	3 (1.2)
Catecholaminergic polymorphic, *n (%)*	2 (0.4)	1 (0.4)	1 (0.4)
Congenital heart disease, *n (%)*	1 (0.2)	0 (0)	1 (0.4)
Valvular heart disease, *n (%)*	5 (1.0)	4 (1.6)	1 (0.4)
Hypertension, *n (%)*	176 (35.0)	88 (35.1)	88 (34.9)
Diabetes, *n (%)*	98 (19.5)	49 (19.5)	49 (19.4)
Heart failure, *n (%)*	243 (48.3)	126 (50.2)	117 (46.4)
Previous stroke, *n (%)*	18 (3.6)	9 (3.6)	9 (3.6)
Impaired renal function, *n (%)*	8 (1.6)	2 (0.8)	6 (2.4)
β-blocker (other than sotalol), *n (%)*	395 (78.5)	197 (78.5)	198 (78.6)
Sotalol, *n (%)*	5 (1.0)	3 (1.2)	2 (0.8)
Amiodarone, *n (%)*	25 (5.0)	13 (5.2)	12 (4.8)
Other antiarrhythmic therapy, *n (%)*	16 (3.2)	8 (3.2)	8 (3.2)

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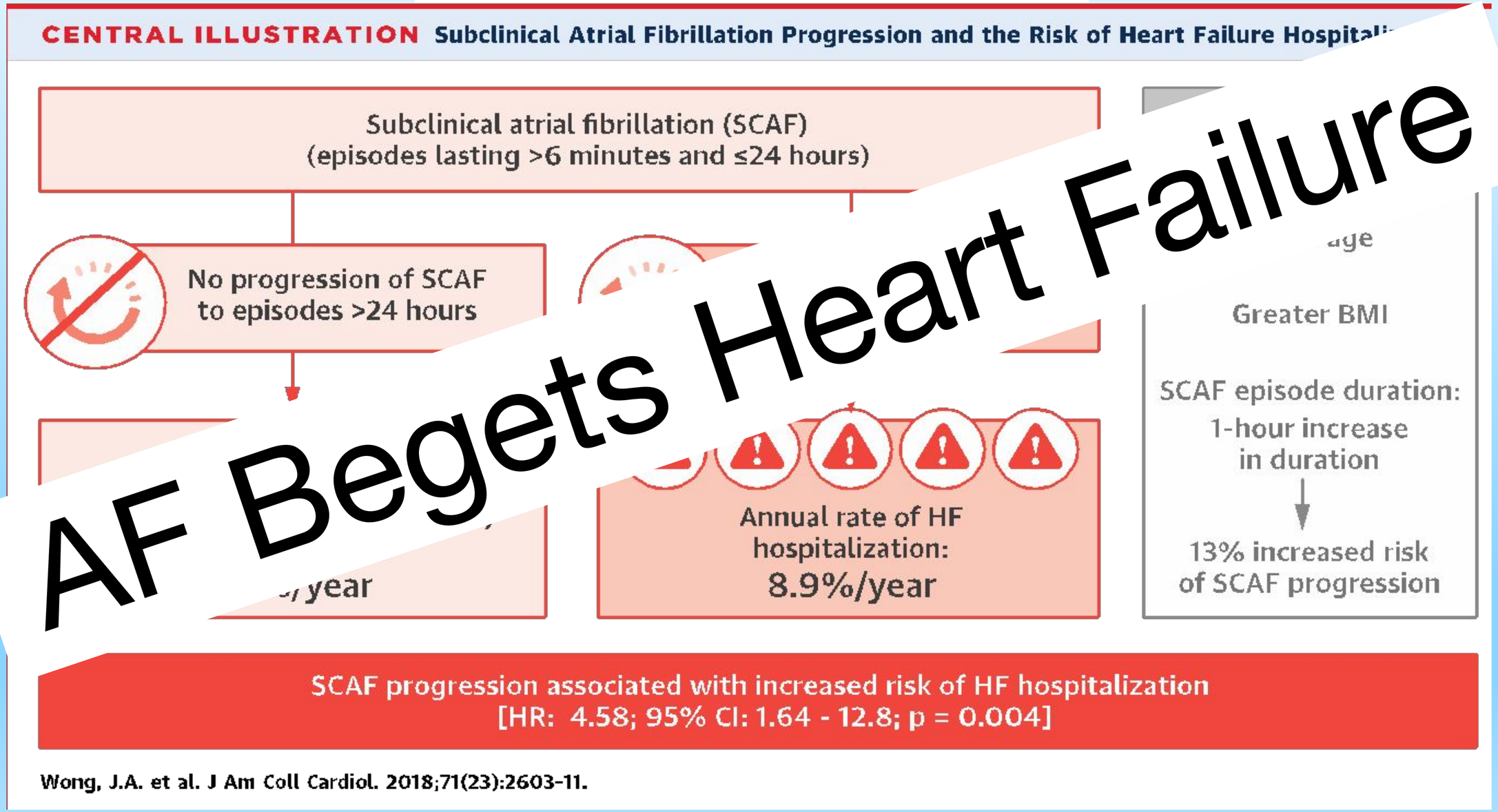
Healey JS et al. Ann Intern Med. 2022;175:1658-1665.
doi:10.7326/M22-1566

Progression of Device-Detected Subclinical Atrial Fibrillation and the Risk of Heart Failure



AF Begets Heart Failure

Wong, J.A. et al. J Am Coll Cardiol. 2018;71(23):2603-11.

Temporal Association of Atrial Fibrillation With Cardiac Implanted Electronic Device Detected Heart Failure Status

CENTRAL ILLUSTRATION Temporal Association of Atrial Fibrillation and Heart Failure

MultiSENSE Study (N = 900)
New or existing CRT-D, NYHA functional class II/II/IV

Clinical and Device Sensor Predictors:
Older age, male, NT-pro-BNP, heart sounds

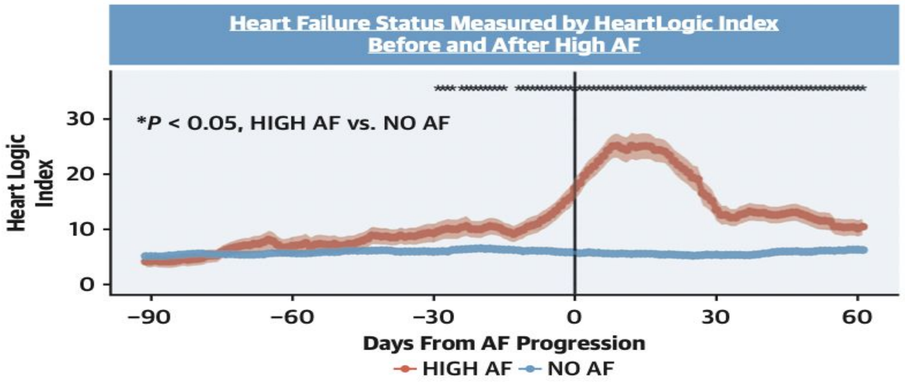
Highest daily AF burden	No AF <6 min 72.5%	MID AF 6 min - 24 h 16.2%	HIGH AF >24 h 11.3%
180 days post AF*	9% HF Event	14% HF Event	22% HF Event

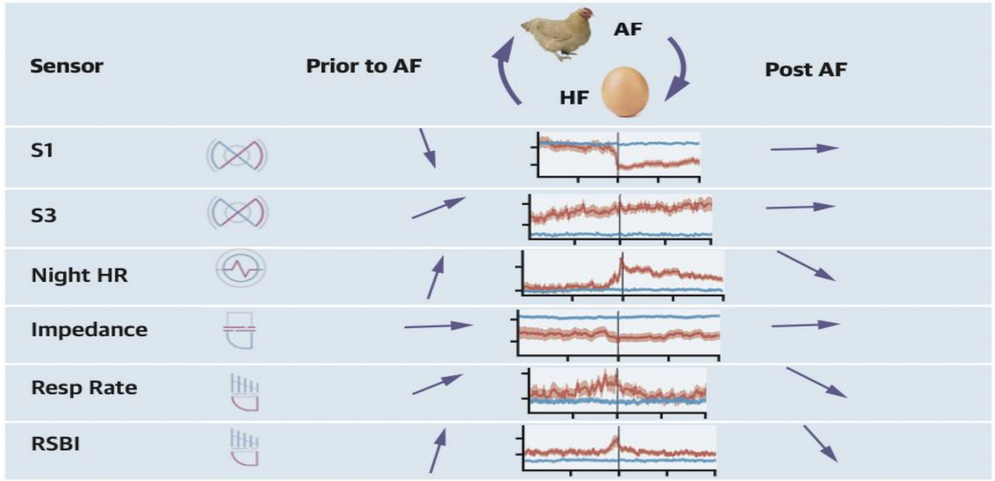
* Or randomly selected day, if no AF occurred during follow-up

High AF burden was associated with twice the risk of having an HF event
(HR: 1.96; 95% CI: 1.03-3.74; *P* = 0.041)

Capucci, A. et al. J Am Coll Cardiol EP. 2022;8(2):182-193.

CENTRAL ILLUSTRATION Continued





Device measured sensors changed in the direction of worsening HF prior to AF onset

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- The transvenous ICD has been in clinical use for > 3 decades, and robust data from high-quality RCTs support its use in various patient populations including survivors of cardiac arrest, patients with VT and structural heart disease, and patients with significant LV dysfunction.

Al-Khatib et al. Heart Rhythm, Vol 15, No 10, October 2018