Session : Vie avec un PM/DAI

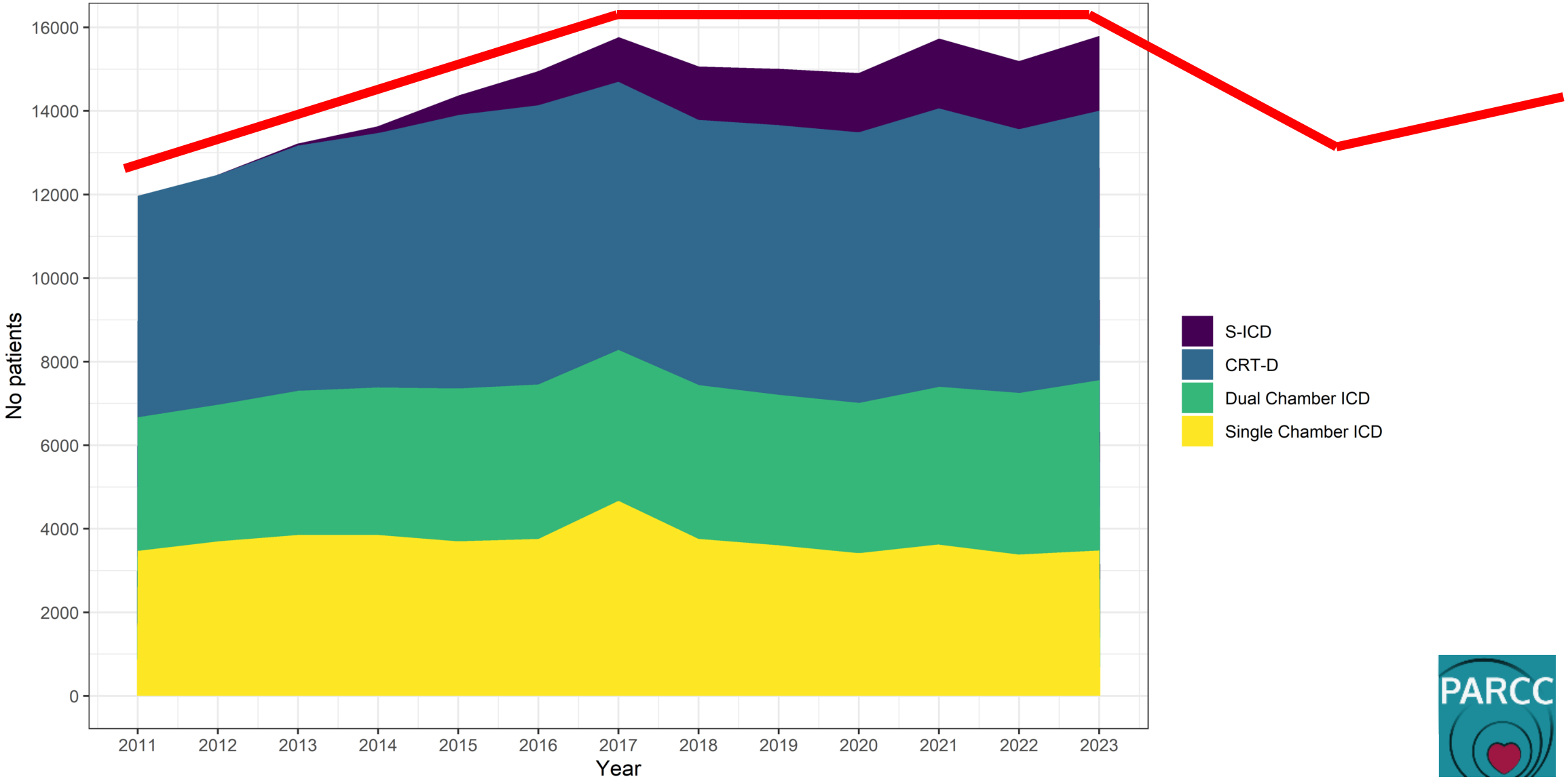
Retour sur 10 d'évolution du DAI et perspectives

Eloi Marijon
Hôpital Européen Georges Pompidou

ELECTRA, 05/12/2024, Marseille

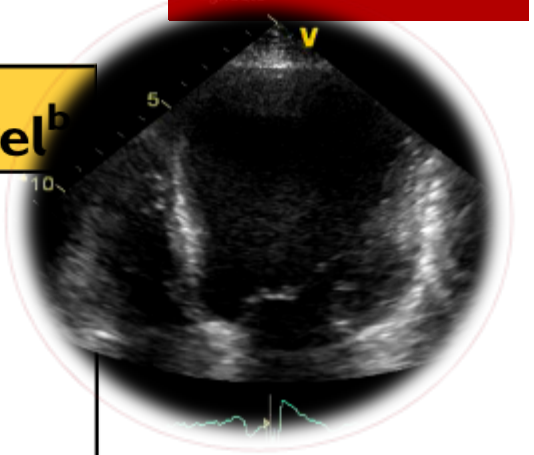
Temporal Trends in ICDs Implantations

2022-2023



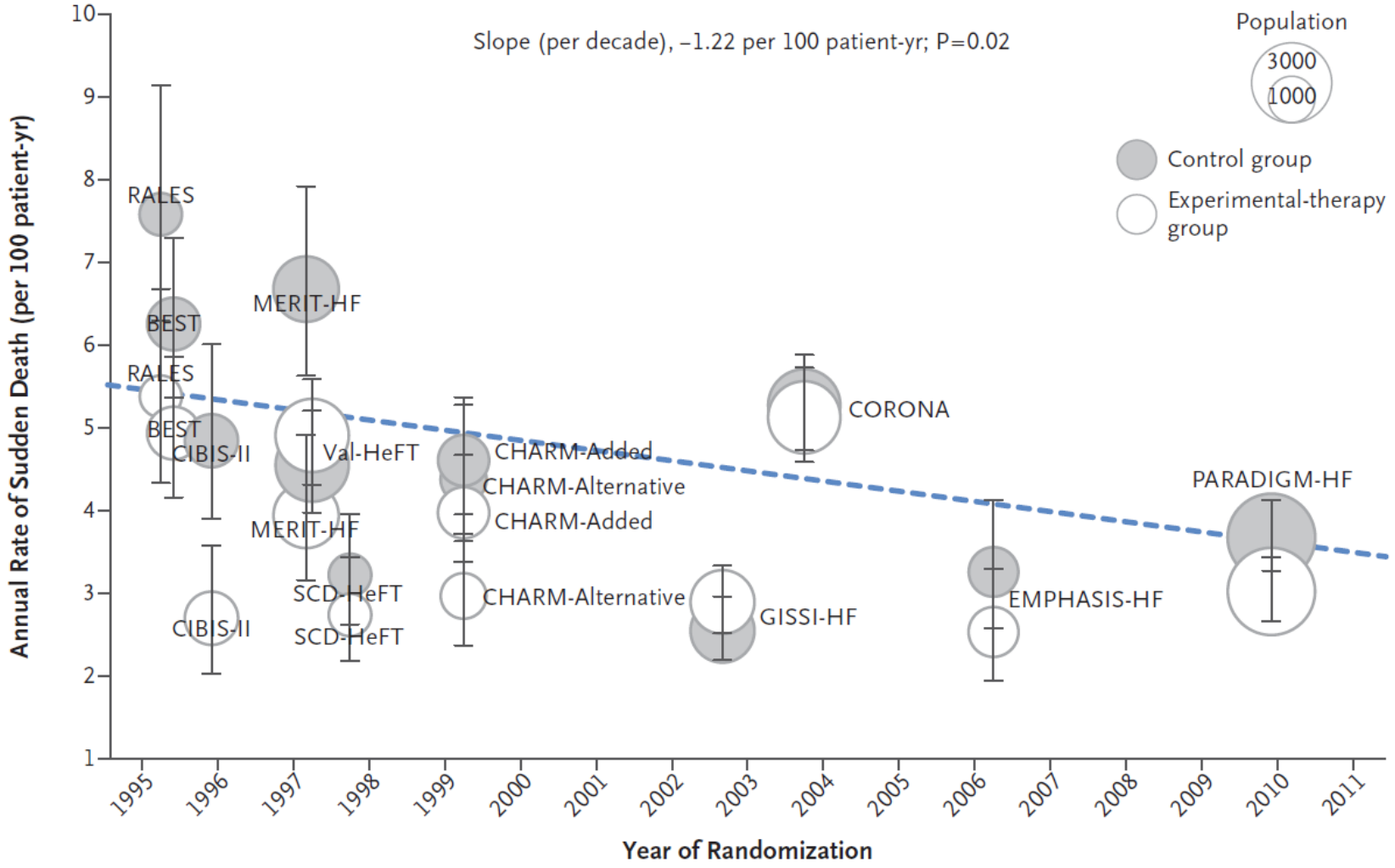
Indications

2015



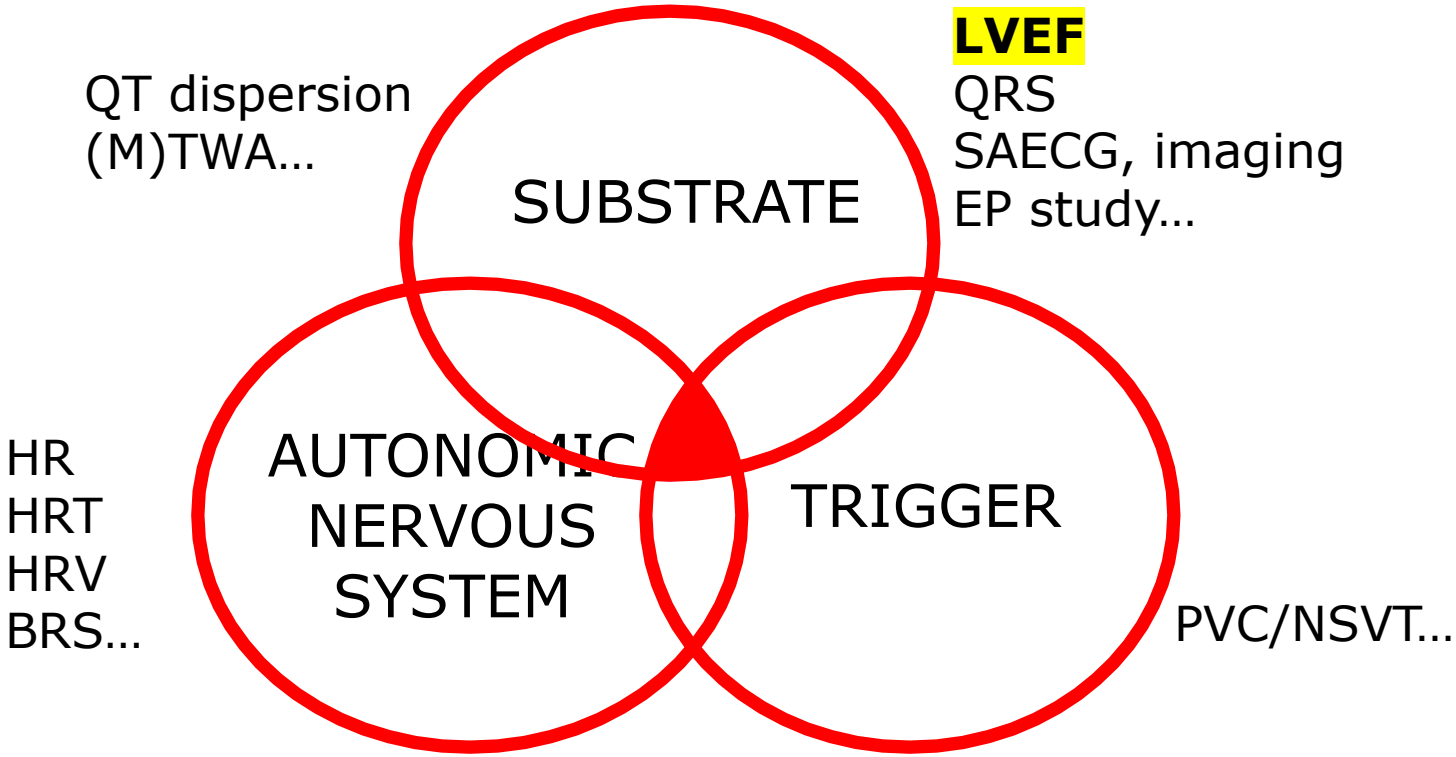
Recommendations	Class[a]	Level[b]
ICD therapy is recommended to reduce SCD in patients with symptomatic HF (NYHA class II–III) and LVEF ≤35% after ≥3 months of optimal medical therapy who are expected to survive for at least 1 year with good functional status:		
– Ischaemic aetiology (at least 6 weeks after myocardial infarction).	I	A
– Non-ischaemic aetiology.	I	B

Declining Risk of SCD in our Patients Optimally Treated
⇔ *Declining Relative Benefit of ICD*



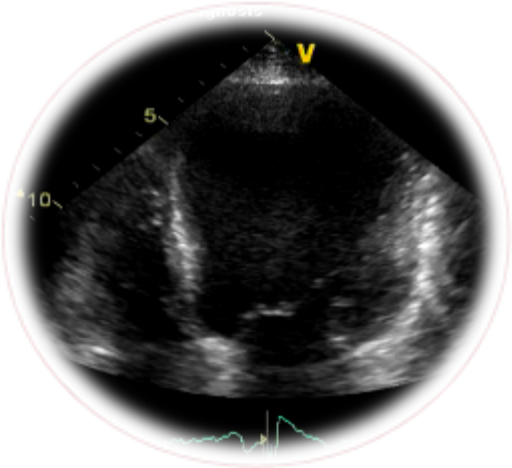
Li Shen et al. N Engl J Med 2017

Risk Stratification Approach
(1985-2015)



Buxton JACC 2005, Kadish NEJM 2004, Camm Circulation 2004, Bigger NEJM 1997, Galinier EHJ 1996, Buxton Circulation 2002, Kadish NEJM 2004, Bardy NEJM 2005

MADIT Story

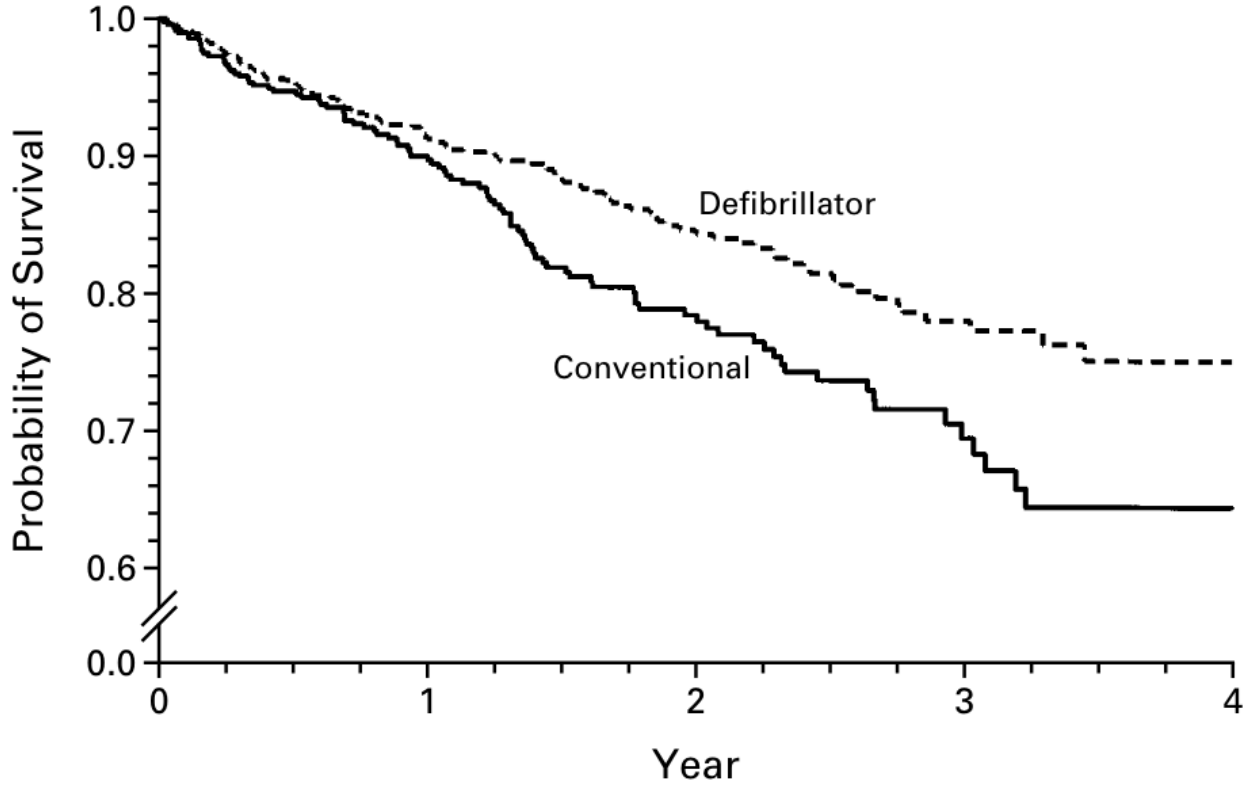


VOLUME 346

PROPHYLACT
WITH MYOCAR

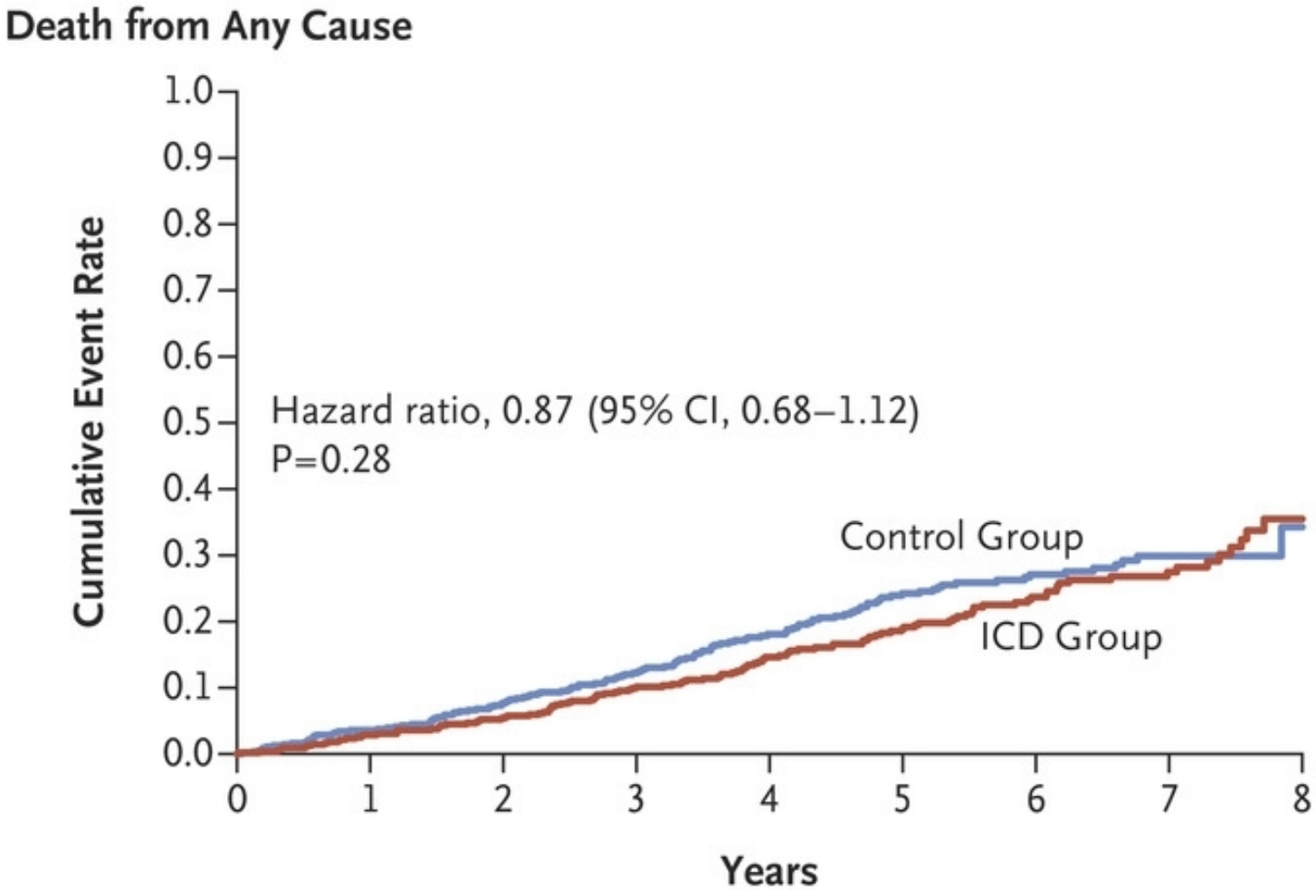
ARTHUR J. MOSS, M.
DAVID J. WILBER, M

FOR THE MU



No. at Risk					
Defibrillator	742	503 (0.91)	274 (0.84)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

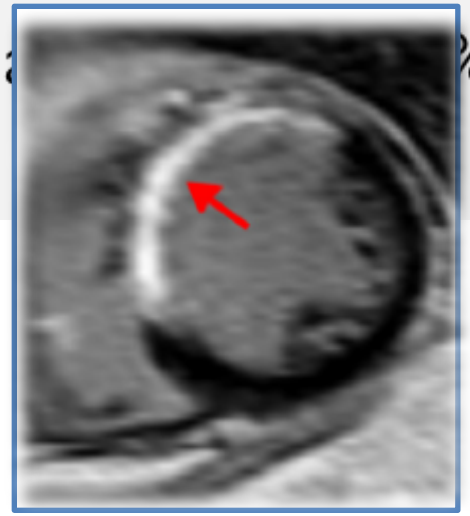
(Anticipated) Findings from DANISH trial in 2017



Køber L et al. NEJM 2017

2022

ICD therapy is recommended in patients with CAD, symptomatic heart failure (NYHA class II–III), and LVEF ≤35% despite ≥3 months of OMT.[354,356]	I	A
ICD implantation should be considered in patients with DCM/HNDCM, symptomatic heart failure (NYHA class II–III) [illegible]% after ≥3 months of OMT.	I	IIa



We commonly use absolute risk to determine candidacy for therapy in CVD.

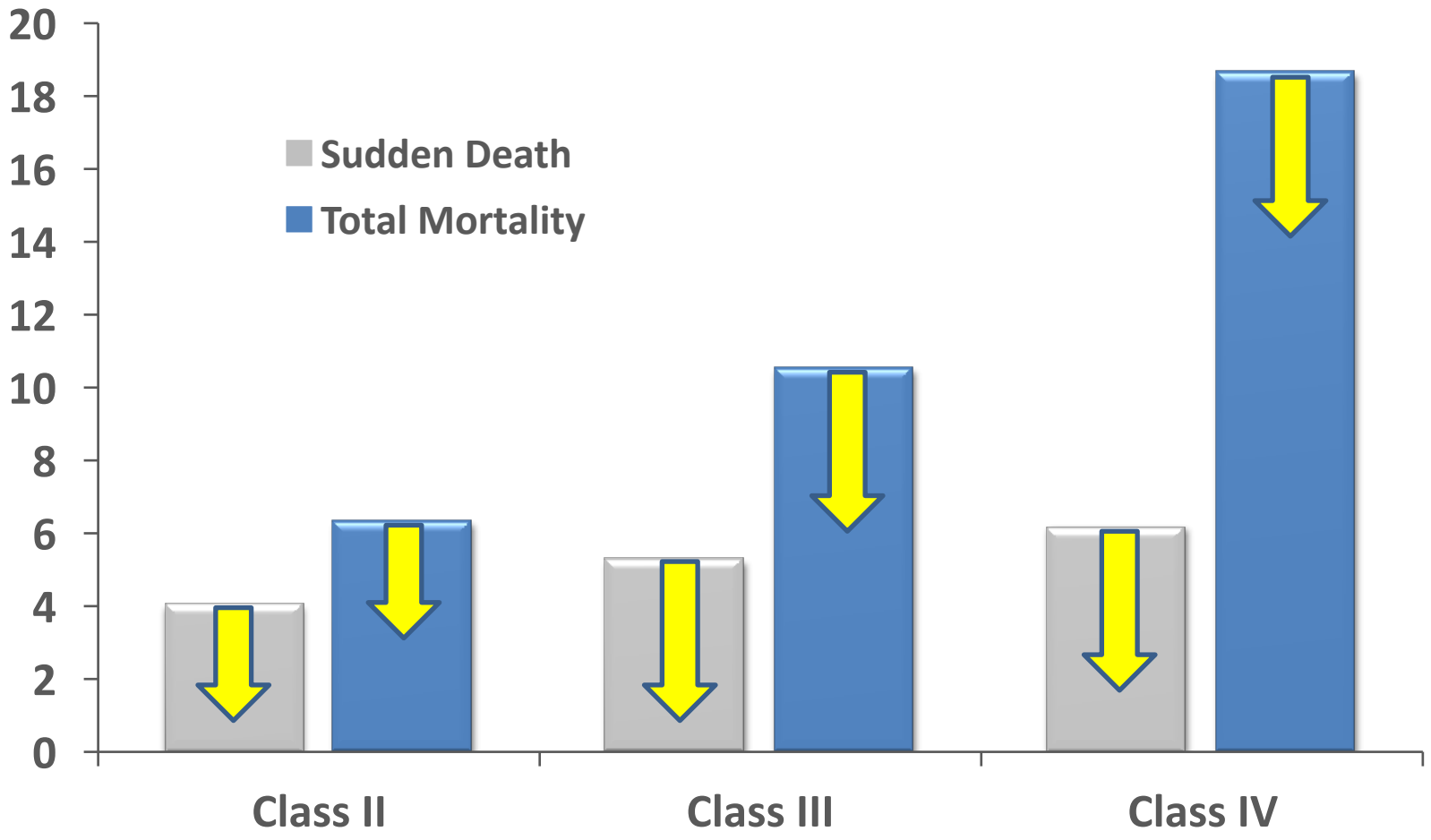
(Eg. in patients with AF, annualized stroke estimates guide decision making for anticoagulation…)

The goal must be the identification of patients the most likely to benefit from ICD therapy (who are not sytematically those at higher risk of SCD)

Competing risk situation…

Competing Risk Situation

Absolute and Proportional Risks



MERIT-HF Lancet 1998

Competing Risk Situation (Applied to CAD)
Illustration Using MADIT-II

Journal of the American College of Cardiology
© 2008 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 51, No. 3, 2008
ISSN 0735-1097/08/$34.00
doi:10.1016/j.jacc.2007.08.058

Risk Stratification for Primary Implantation of a Cardioverter-Defibrillator in Patients With Ischemic Left Ventricular Dysfunction

Ilan Goldenberg, MD,* Anant K. Vyas, MD, MPH,† W. Jackson Hall, PHD,‡ Arthur J. Moss, MD,* Hongyue Wang, PHD,‡ Hua He, MA,‡ Wojciech Zareba, MD, PHD,* Scott McNitt, MS,* Mark L. Andrews, BBA,* for the MADIT-II Investigators

Rochester and Buffalo, New York

Goldenberg et al. JACC 2008

Competing Risk Situation (Applied to CAD)
Illustration Using MADIT-II

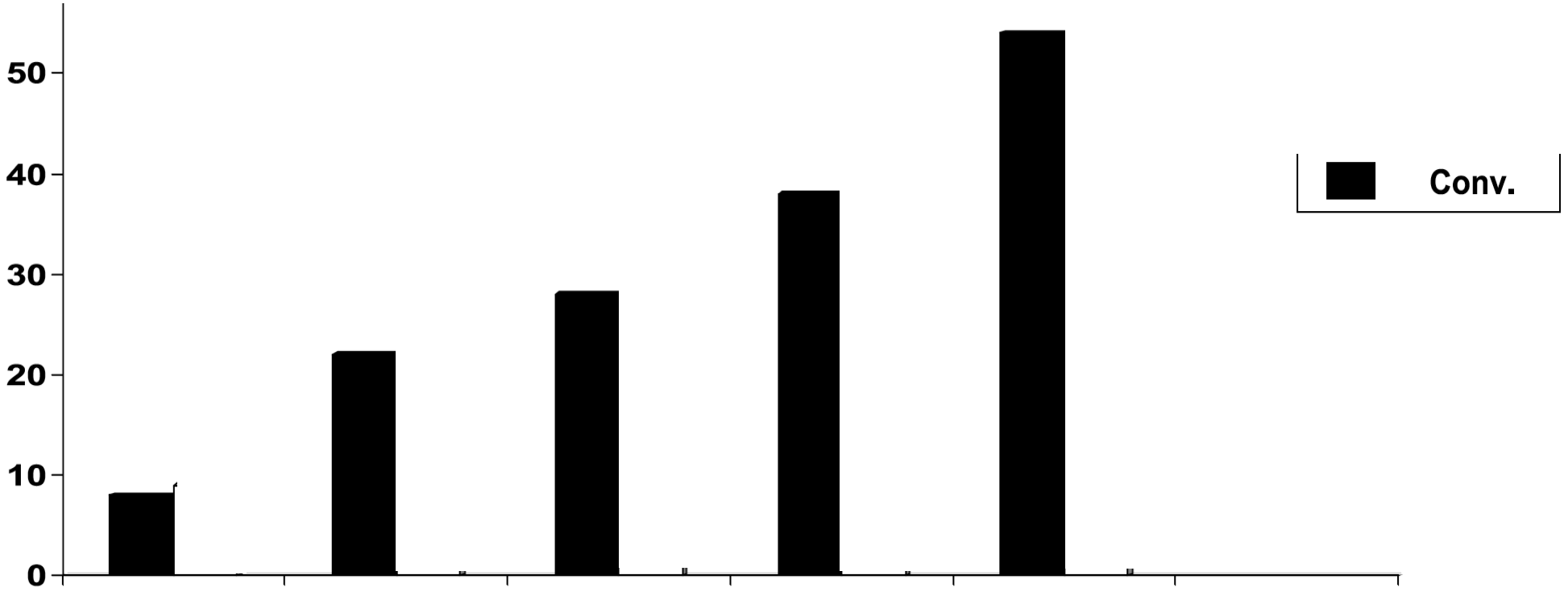
1,232 patients with documented previous MI and EF 30% were randomized to receive a prophylactic ICD or conventional medical therapy in a 3:2 ratio and were followed over a mean 2-yr period

Mortality Score

Risk Factor	HR	95% Confidence Interval	p Value
NYHA functional class >II	1.87	1.23–2.86	0.004
Atrial fibrillation‡	1.87	1.05–3.22	0.034
QRS >120 ms	1.65	1.08–2.51	0.020
Age >70 yrs	1.57	1.02–2.41	0.042
BUN >26 mg/dl (and <50 mg/dl)	1.56	1.00–2.42	0.048

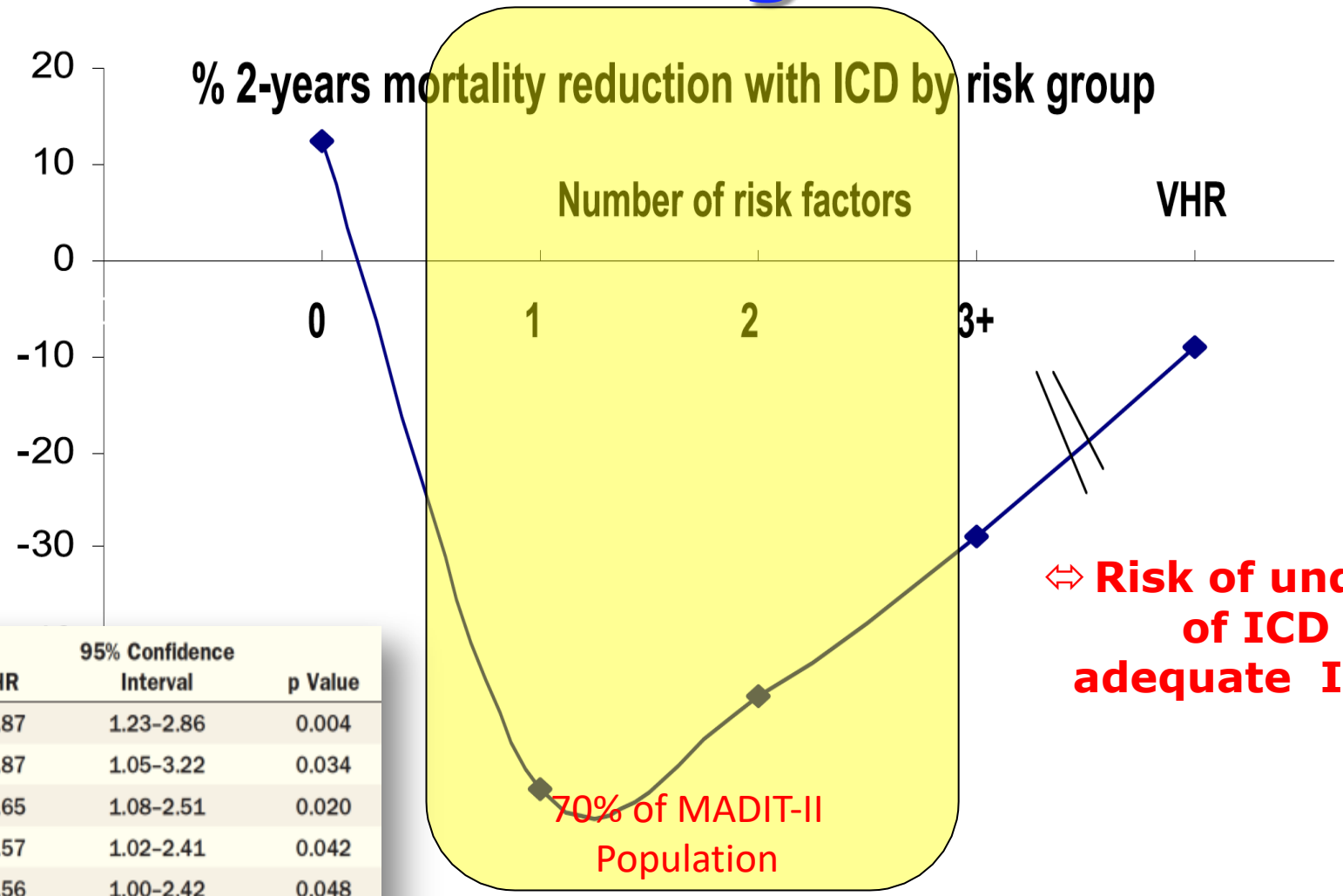
Goldenberg et al. JACC 2008

Competing Risk Situation (Applied to CAD)
Illustration Using MADIT-II



Goldenberg et al. JACC 2008

Competing Risk Situation (Applied to CAD)
Illustration Using MADIT-II



Risk Factor	HR	95% Confidence Interval	p Value
NYHA functional class >II	1.87	1.23–2.86	0.004
Atrial fibrillation‡	1.87	1.05–3.22	0.034
QRS >120 ms	1.65	1.08–2.51	0.020
Age >70 yrs	1.57	1.02–2.41	0.042
BUN >26 mg/dl (and <50 mg/dl)	1.56	1.00–2.42	0.048

⇔ **Risk of underestimation of ICD benefit in adequate ICD candidates**

Goldenberg et al. JACC 2008

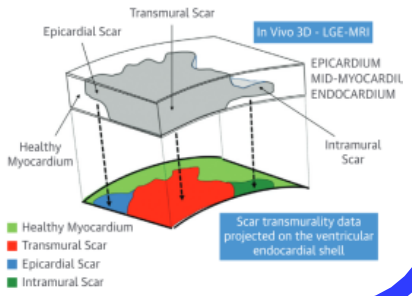
Challenging!!

DILEMMA Study

Randomisation
≥70 ans
Prévention primaire

SMART-DEF TRIAL

CHRU NANCY



PROFID

THE PROFID TRIAL

PREVENTION OF SUDDEN CARDIAC DEATH AFTER MYOCARDIAL INFARCTION BY DEFIBRILLATOR IMPLANTATION

This project has received funding from the European Union´s Horizon 2020 research and innovation programme under grant agreement No. 847999.

Post-MI patients
LVEF ≤ 35%

Check of inclusion / exclusion criteria

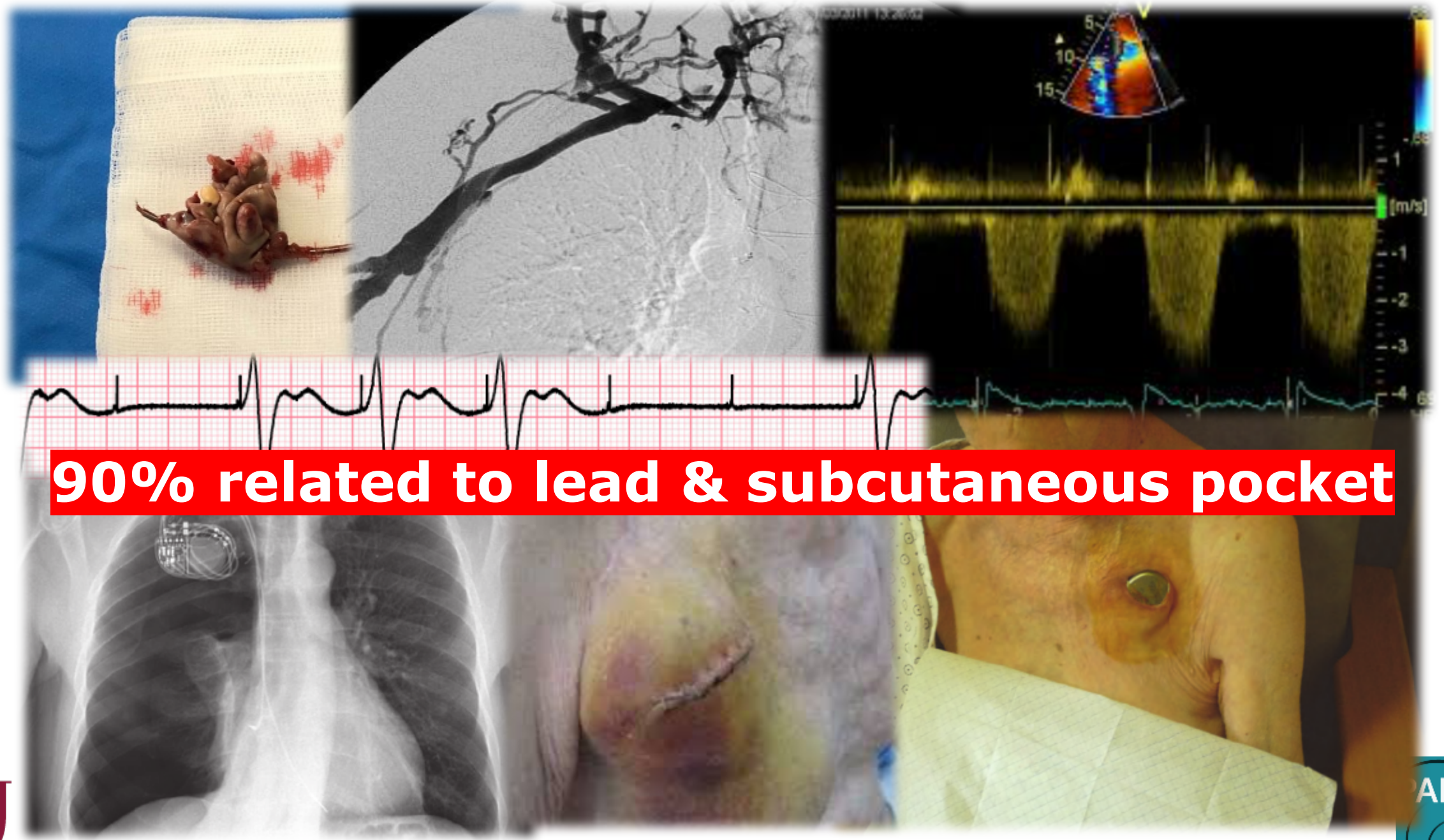
Randomisation

No ICD implantation

ICD implantation

Follow-up for primary endpoint
"all-cause death"

PARCC


90% related to lead & subcutaneous pocket

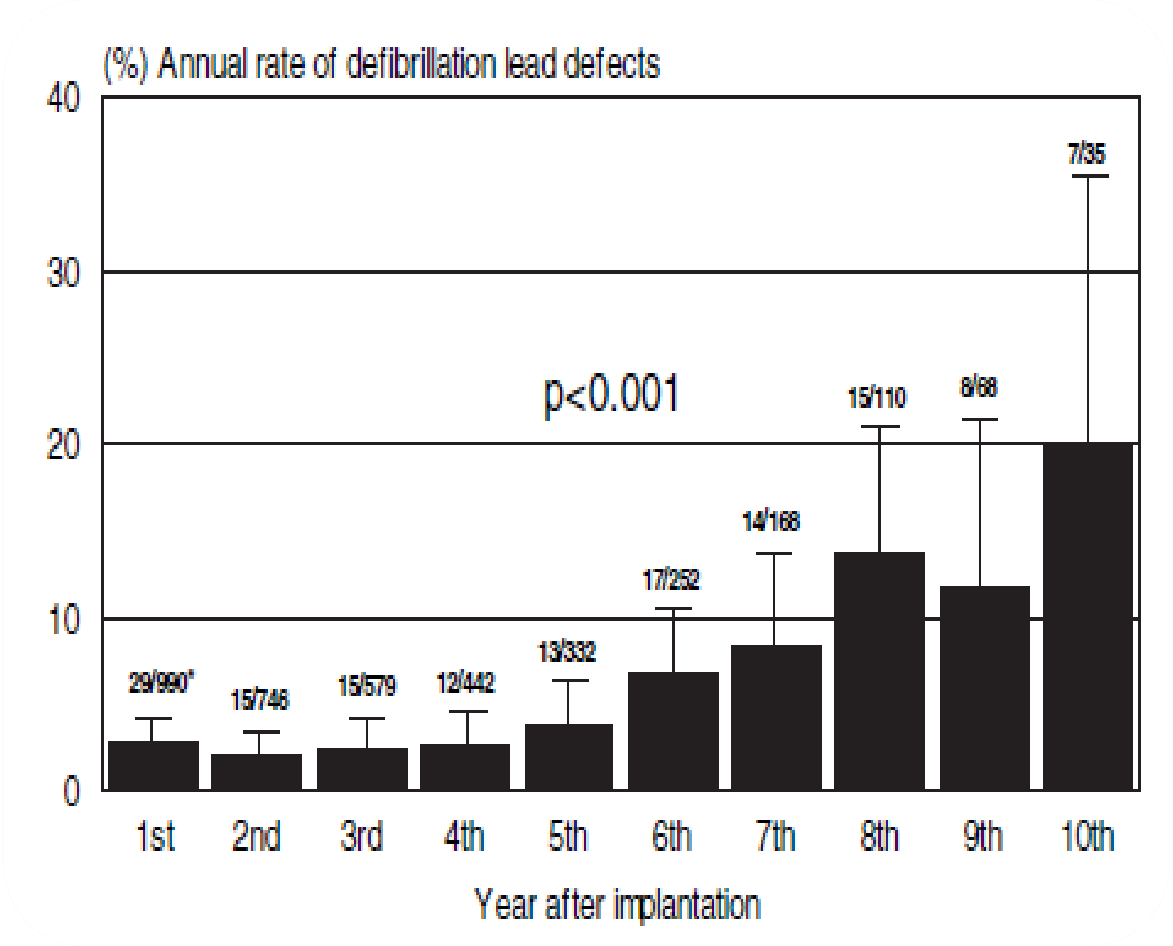
90% related to lead & subcutaneous pocket

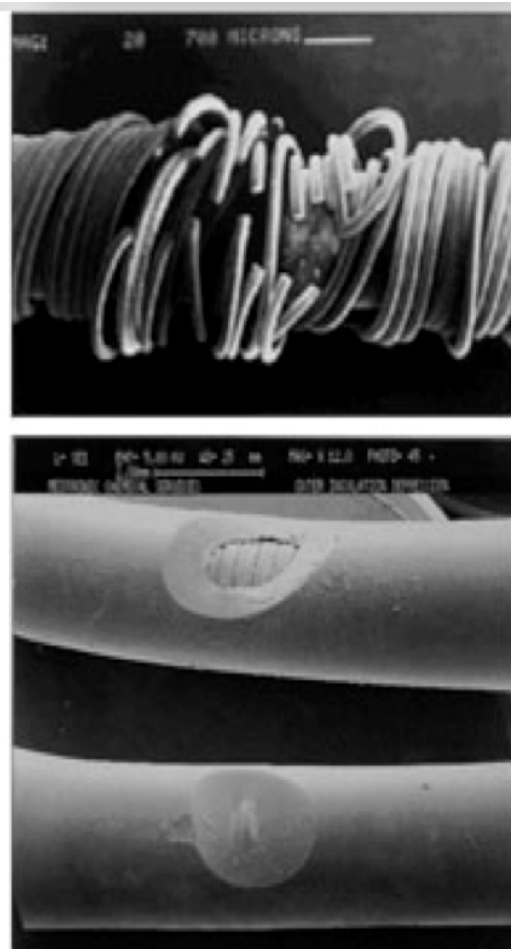
Solutions for Defibrillation?

- ❑ No lead
- ❑ No subcutaneous pocket
- ❑ Extravascular lead
- ❑ Take your time!

Lead – Achilles Tendon

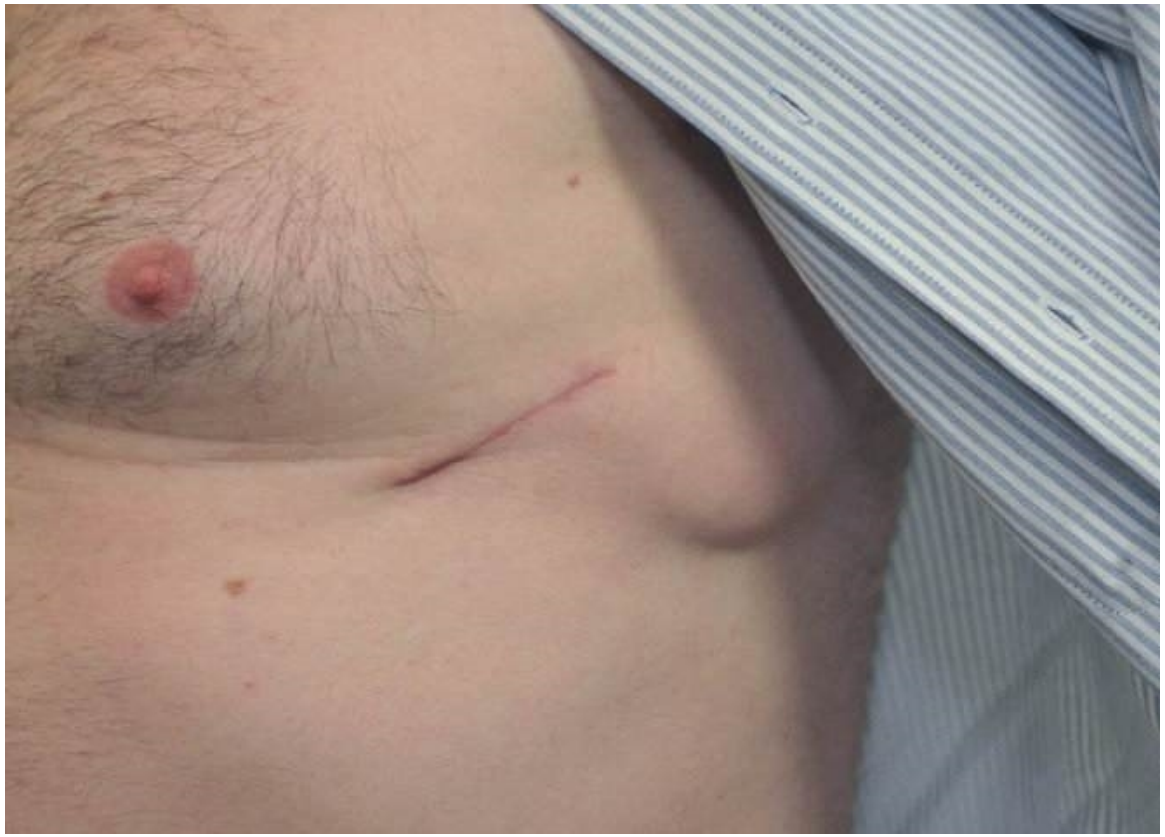
20% annual rate of failure for >10 yo ICD leads…

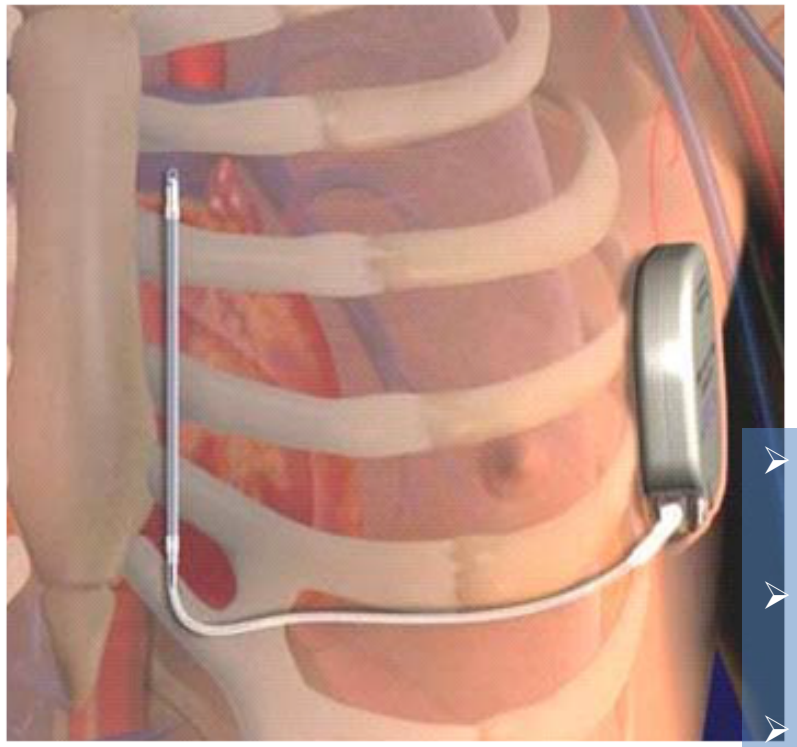




Kleemann, Circulation 2007

ICD – Sub-Cutaneous Approach





Boston Scientific
Advancing science for life™

- *Fully sub-cutaneous system*
- *"External" detection and cardioversion*
- *Biphasic shock (80J)*
- *Post-shock pacing capabilities*

Sub-Cutaneous Implantable Cardioverter Defibrillators (S-ICD)

PARCC

Cameron Health

1ère implantation chronique

Boston

1ère implantation France

Guidelines ESC CMH

Guidelines ESC

Guidelines AHA

130000 S-ICD monde
11700 France
fin 2023

2001 2008 2010 2012 2013 2014 2015 2017 2019

Etude princeps NEJM Bardy

Cohorte hollandaise (118)

IDE

Effortless (472)

Pool data analysis (882)

Effortless 3 ans (985)

Registre américain (1637)

Praetorian

2014

3000 S-ICD monde
54 France

2019

54000 S-ICD monde
5000 France

Sélection des Patients_V2

ABSTRACT

BACKGROUND Electrocardiographic screening before subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation is unsuccessful in around 10% of cases. A personalized screening method, by slightly moving the electrodes, to obtain a better R/T ratio has been described to overcome traditional screening failure.

OBJECTIVE The objectives of the SIS study were to assess to what extent a personalized screening method improves eligibility for S-ICD implantation and to evaluate the inappropriate shock rate after such screening success.

METHODS All consecutive patients eligible for an S-ICD implantation were prospectively recruited across 20 French centers between December 2019 and January 2022. In case of traditional screening failure, patients received a second personalized screening. If at least 1 vector was positive, the personalized screening was considered successful, and the patient was eligible for implantation.

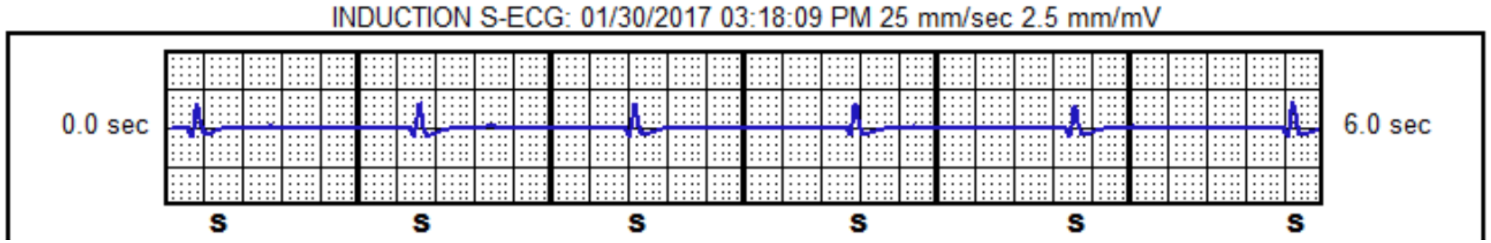
RESULTS The study included 474 patients (mean age, 50.4 ± 14.1 years; 77.4% men). Traditional screening was successful in 456 (96.2%) cases. This figure rose to 98.3% (n = 466; *P* = .002) when personalized screening was performed. All patients implanted after successful personalized screening had correct signal detection on initial device interrogation. Nevertheless, after 1-year follow-up, 3 of the 7 patients (43%) implanted with personalized screening experienced inappropriate shock vs 18 of the 427 patients (4.2%) with traditional screening and S-ICD implantation (*P* = .003).

CONCLUSION Traditional S-ICD screening was successful in our study in a high proportion of patients. Considering the small improvement in success of screening and a higher rate of inappropriate shock, a strategy of personalized screening cannot be routinely recommended.

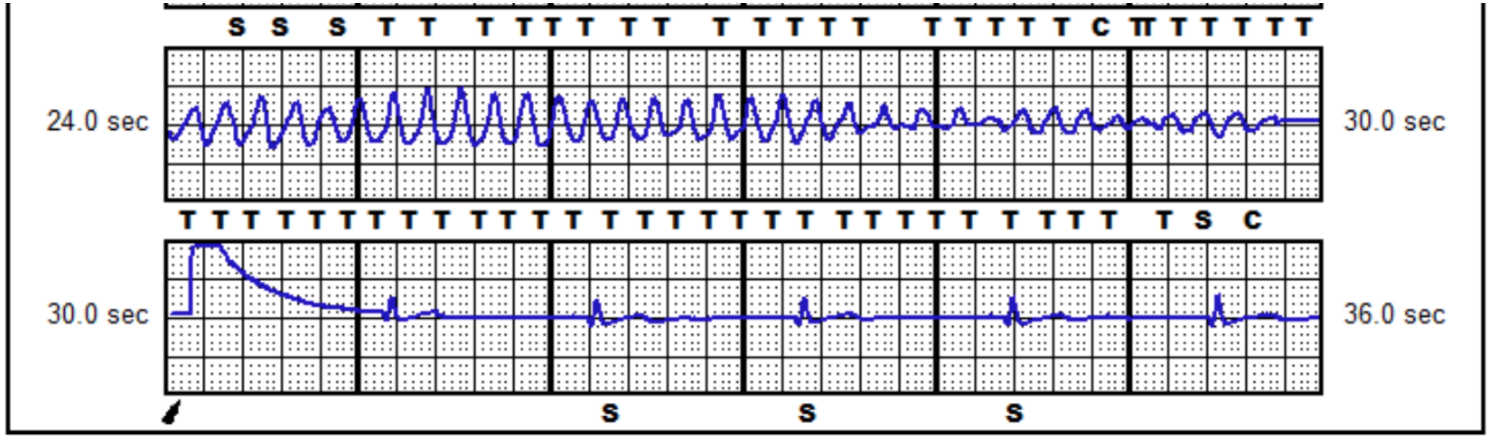
Serge Boveda, MD, PhD, Eloi Marijon, MD, PhD, on behalf of the SIS Study Investigators

SIS Study. Heart Rythm 2024

Implantation



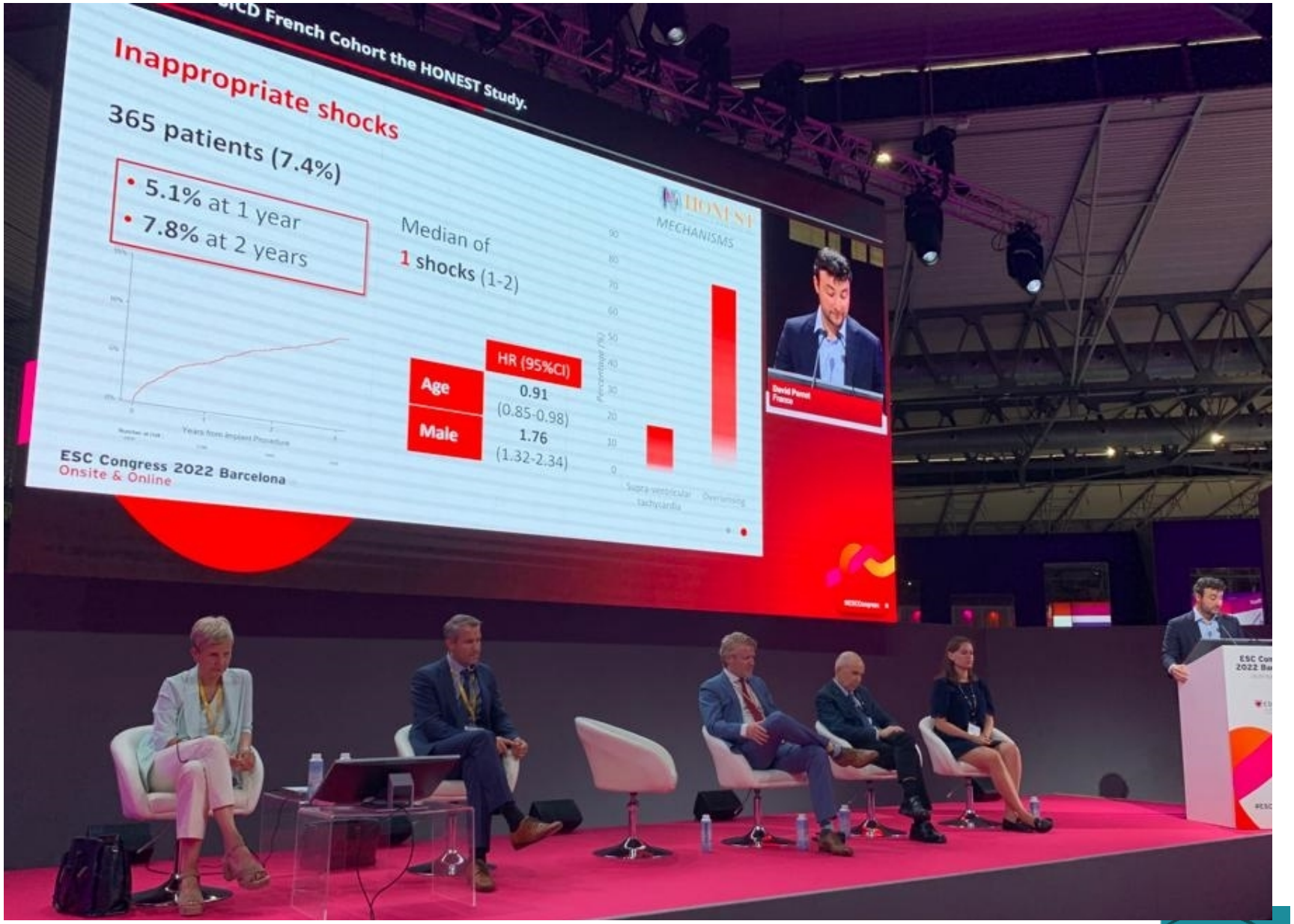
A prospective randomised comparative trial of subcutaneous implantable cardioverter-defibrillator implantation with and without defibrillation testing



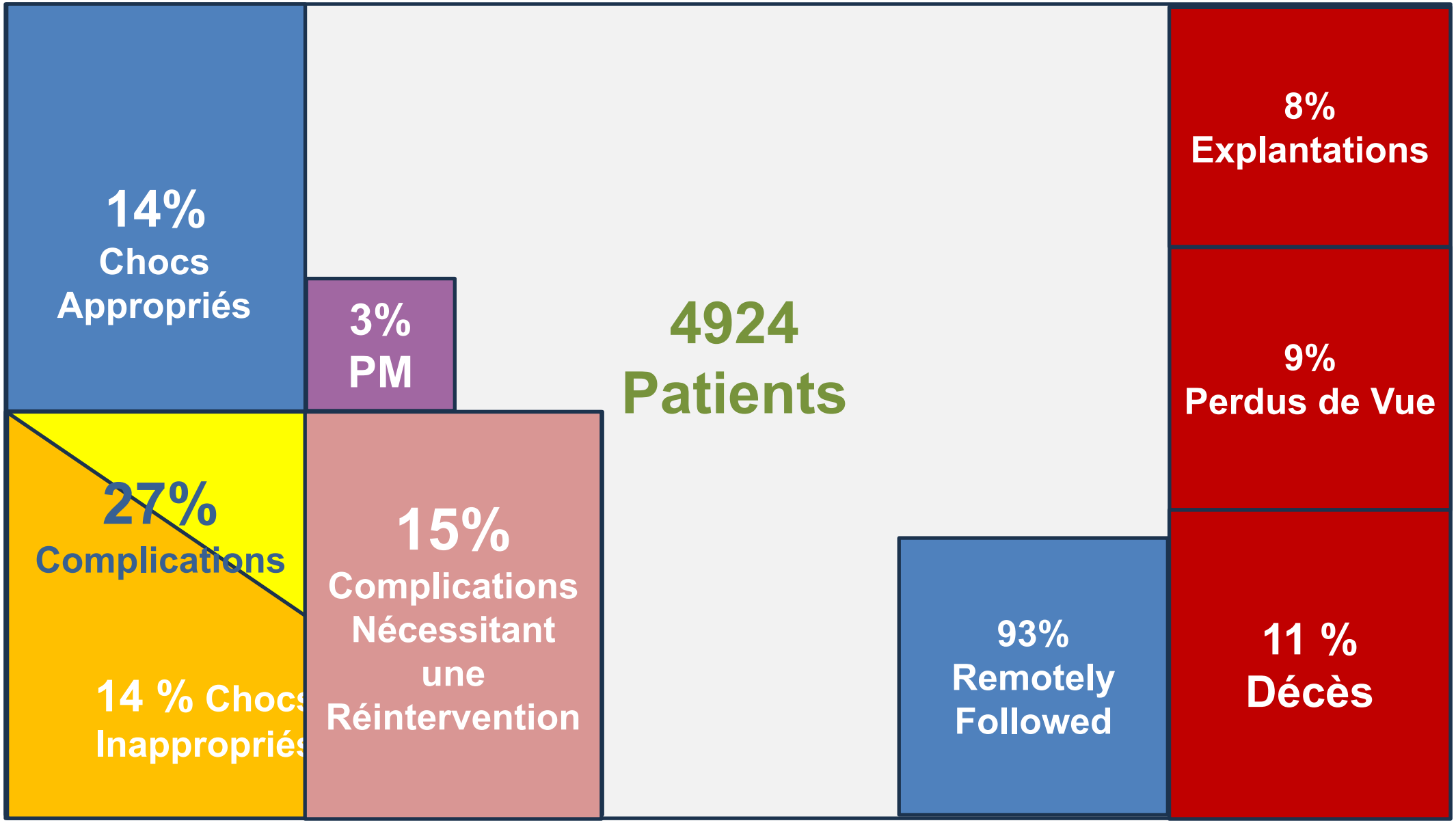
HONEST

coHOrte fraNçaise des dEfibrillateurs Sous-cuTanés

David Perrot, MD
LBT ESC 2022

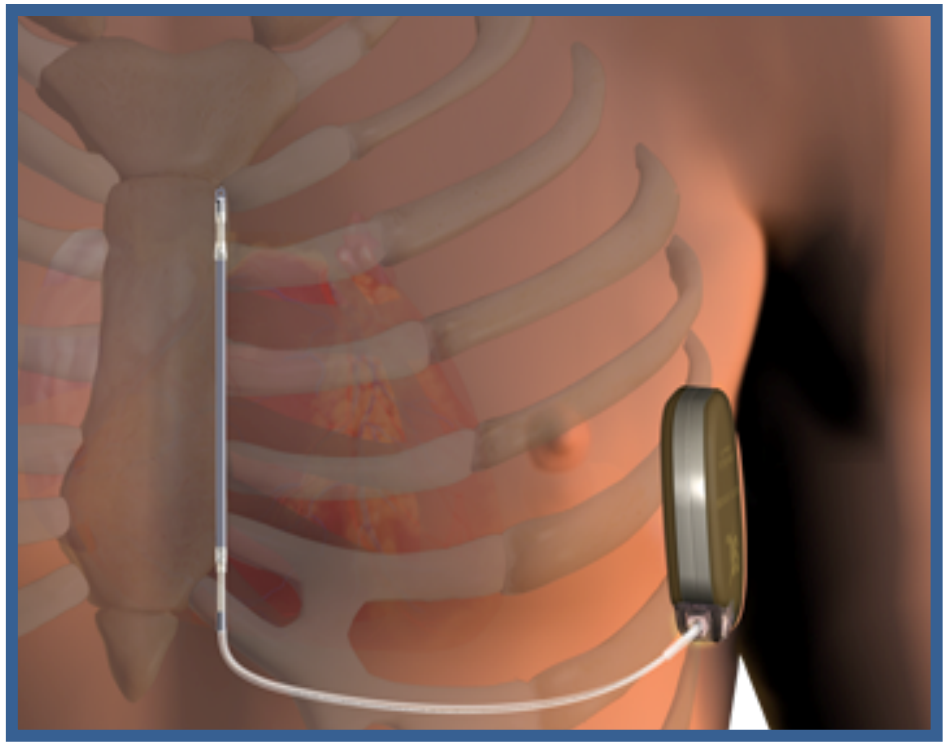


PARCC

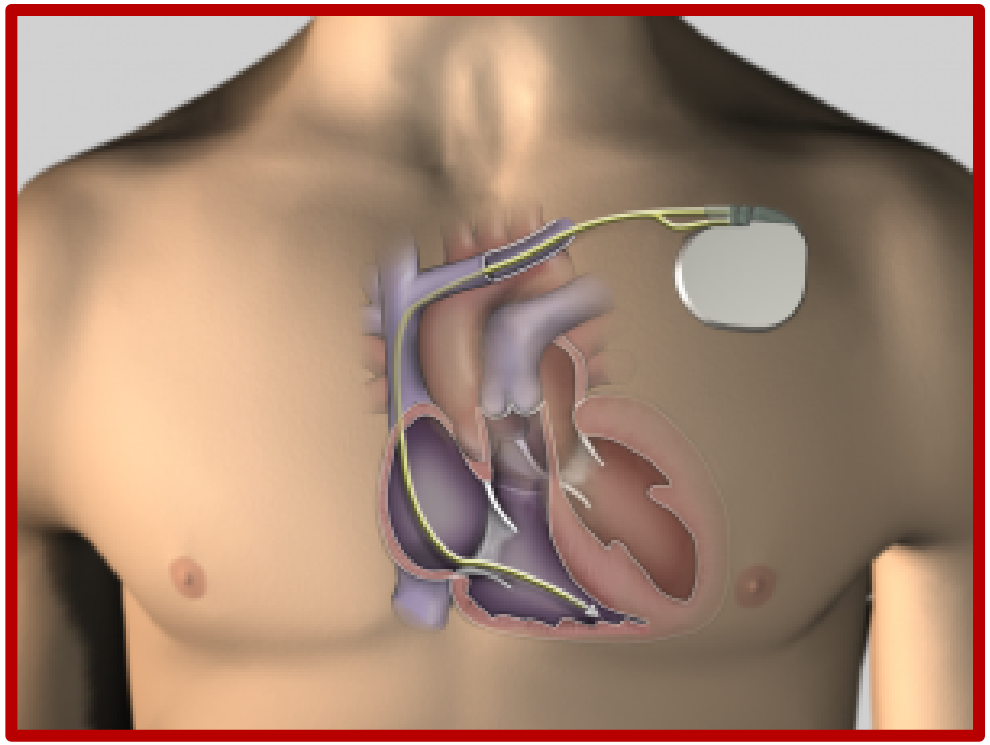


HONEST – 4-Yr Follow-Up Main Findings

S-ICD vs. TV-ICD



vs.



S-ICD

TV-ICD

PRAETORIAN Trial

Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy.

PRAETORIAN Trial

N Engl J Med 2020;383:526-36.

The NEW ENGLAND JOURNAL of MEDICINE

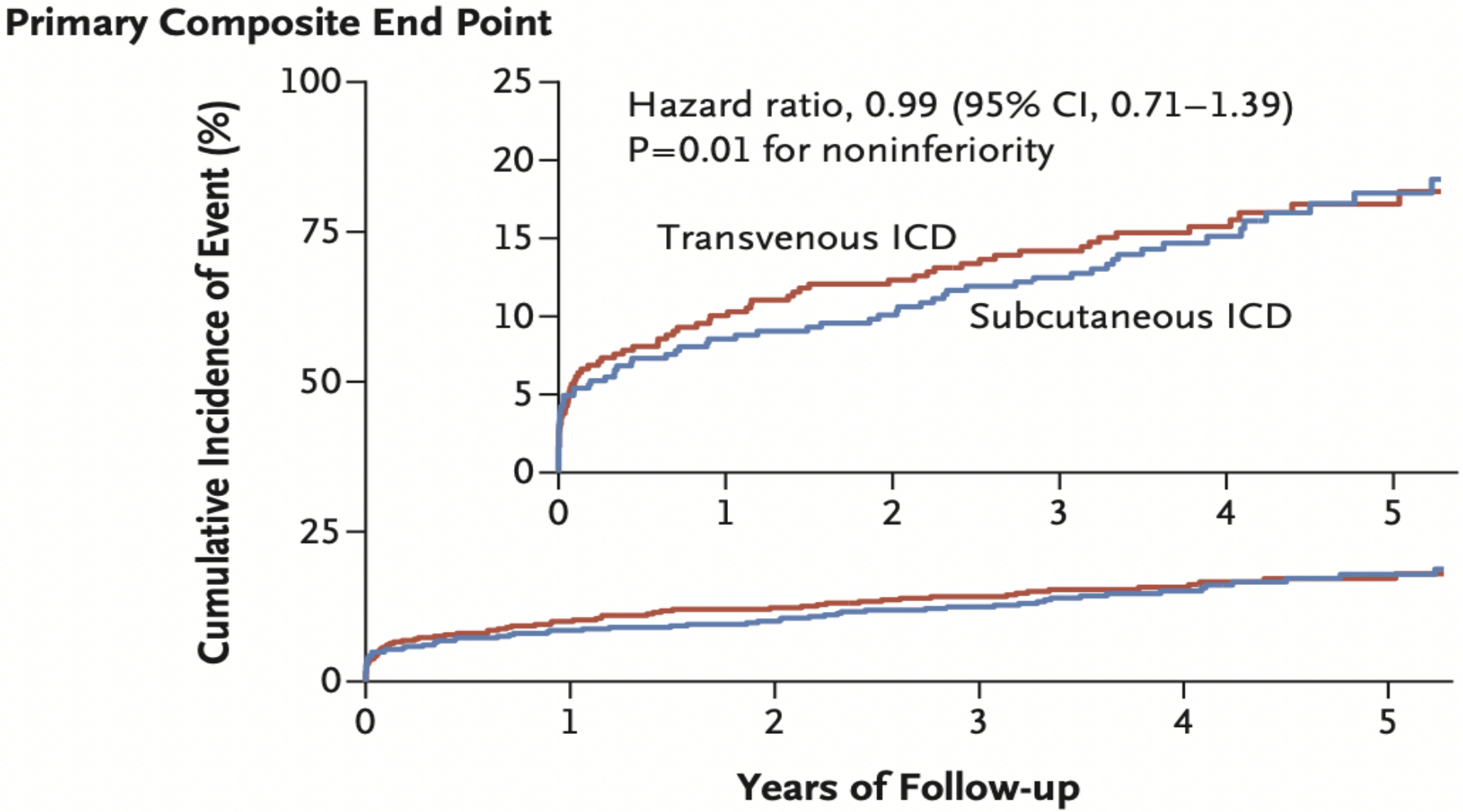
ORIGINAL ARTICLE

CONCLUSIONS

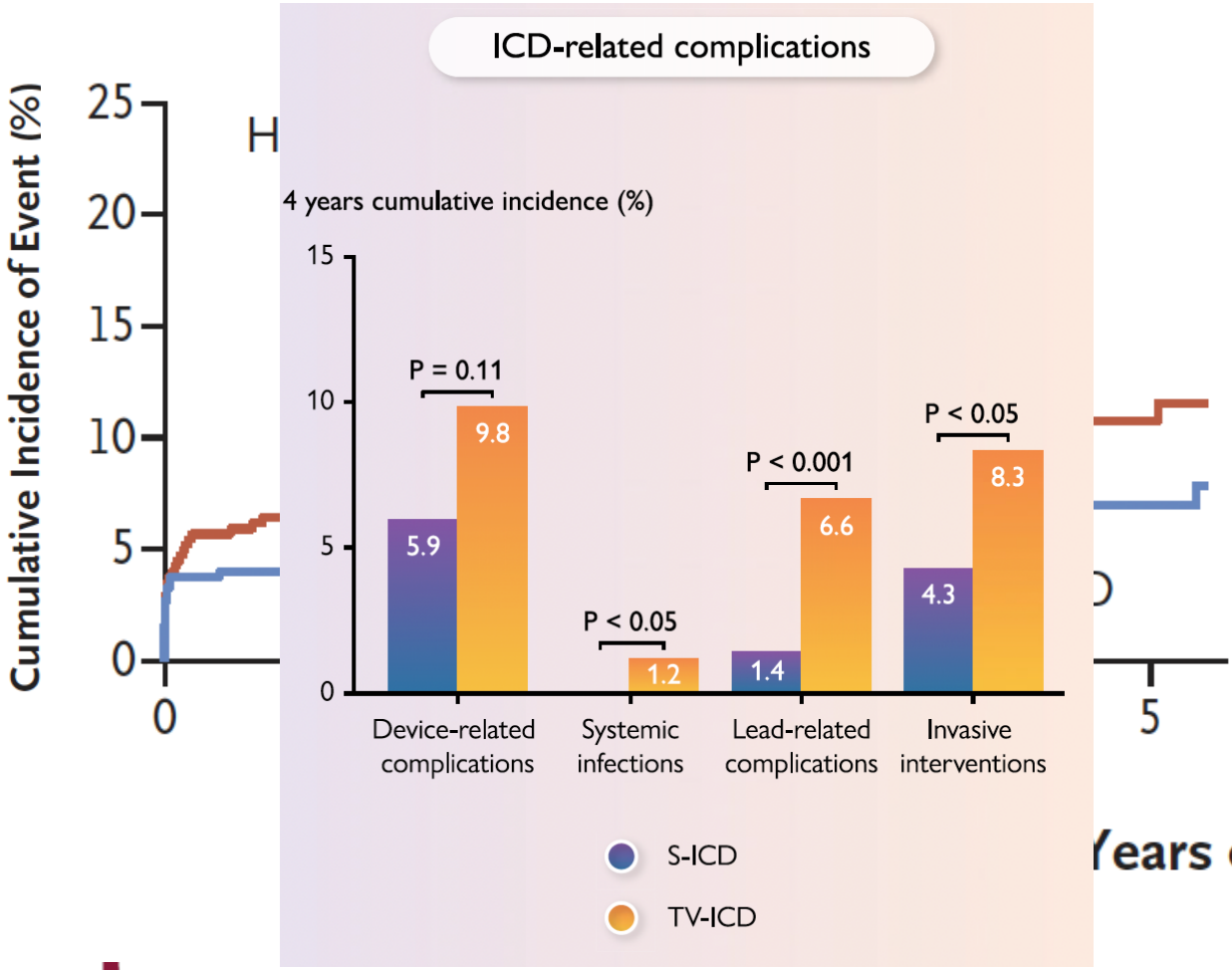
In patients with an indication for an ICD but no indication for pacing, the subcutaneous ICD was noninferior to the transvenous ICD with respect to device-related complications and inappropriate shocks. (Funded by Boston Scientific; PRAETORIAN ClinicalTrials.gov number, NCT01296022.)

S. Mittal, A.P.J.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*

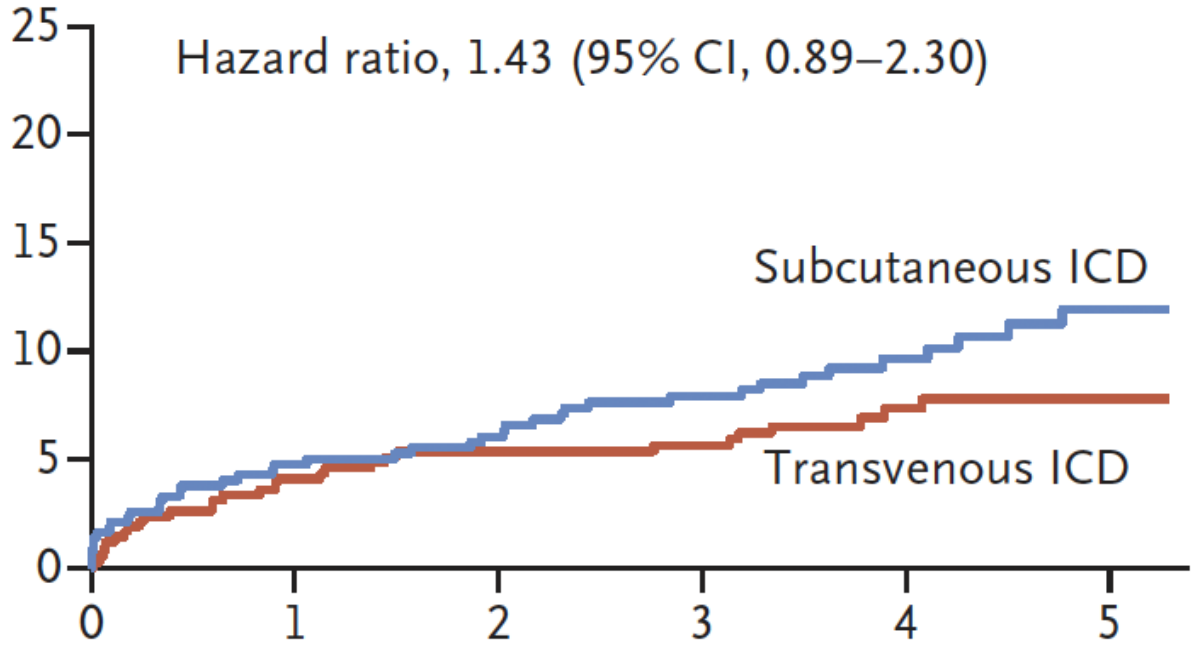
PRAETORIAN Trial



Device-Related Complications

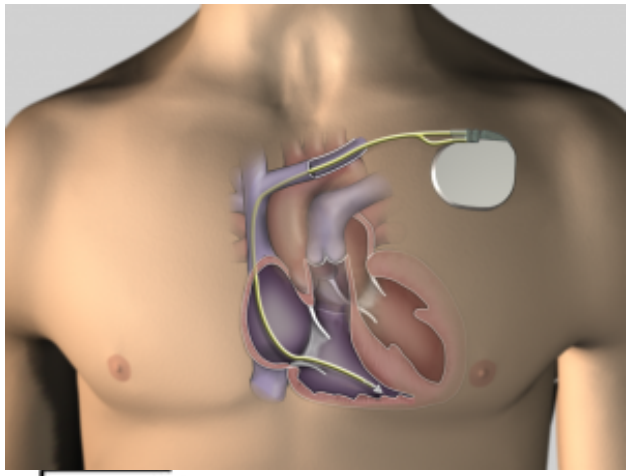


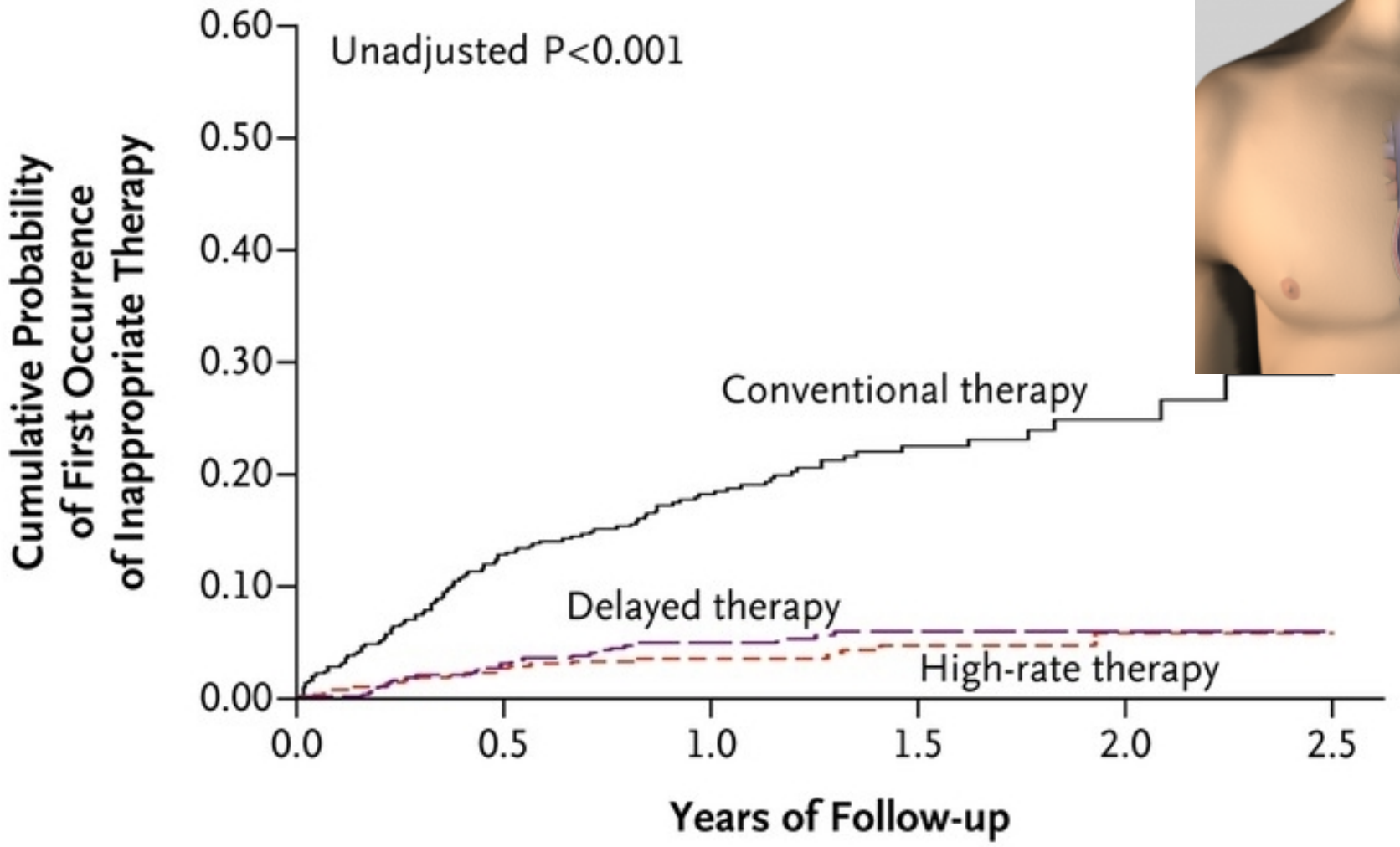
Inappropriate Shocks



Knops RE et al. N Engl J Med 2020
Knops RE et al. Eur Heart J 2022

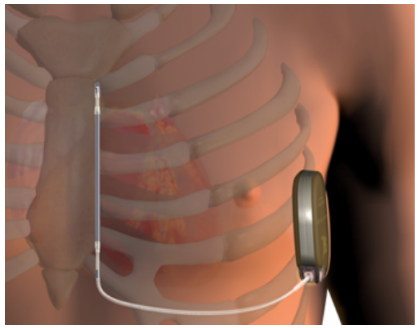
Lower Incidence of TV-ICD Inappropriate Shocks

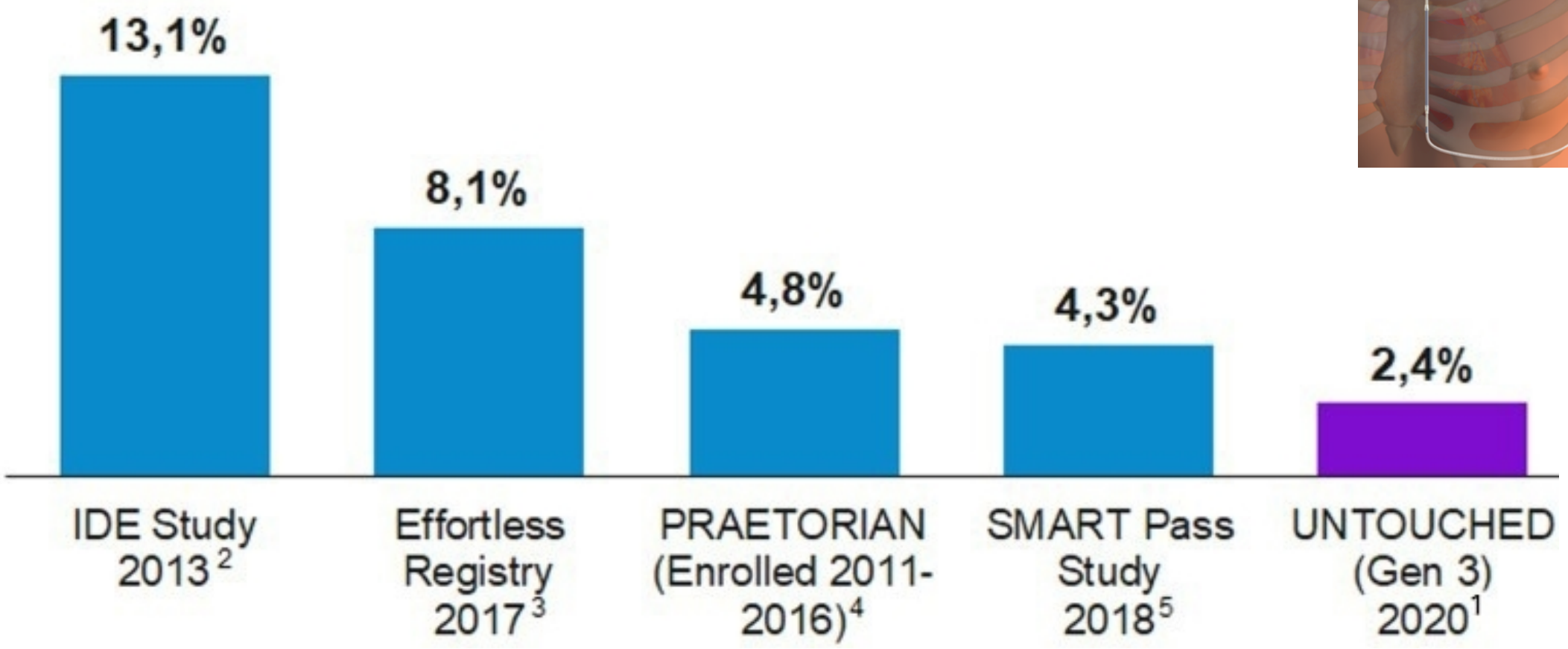




Moss AJ et al. NEJM 2012

Lower Incidence of ICD Inappropriate Shocks





ESC European Society of Cardiology **2022**

Recommendations	Class[a]	Level[b]
Subcutaneous defibrillator should be considered as an alternative to transvenous defibrillator in patients with an indication for an ICD when pacing therapy for bradycardia, cardiac resynchronization, or ATP is not needed.[366]	**IIa**	**B**

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Modular Communicative Leadless Pacing–Defibrillator System

R.E. Knops, M.S. Lloyd, P.R. Roberts, D.J. Wright, L.V.A. Boersma, R. Doshi, P.A. Friedman, P. Neuzil, C. Blomström-Lundqvist, M.G. Bongiorni, M.C. Burke, D. Gras, S.P. Kutalek, A.K. Amin, E.Y. Fu, L.M. Epstein, J.M. Tolosana, T.D. Callahan, J.D. Aasbo, R. Augostini, H. Manyam, D.G. Nair, B. Mondésert, W.W. Su, C. Pepper, M.A. Miller, J. Grammes, K. Saleh, C. Marquie, F.M. Merchant, Y.-M. Cha, C. Cunnington, D.S. Frankel, J. West, E. Matznick, B. Swackhamer, A.J. Brisben, J. Weinstock, K.M. Stein, V.Y. Reddy, and L. Mont, for the MODULAR ATP Investigators*

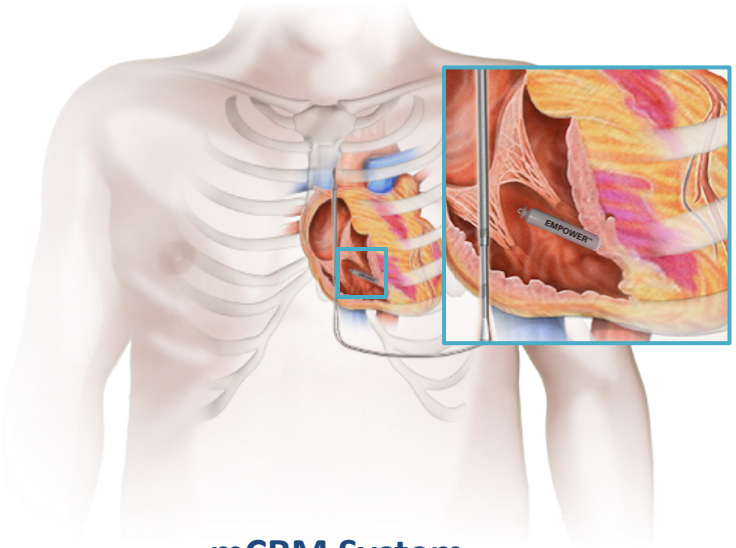
PARCC

Knops et al N Engl J Med 2024

mCRM™ System* overview

+

=



EMBLEM™ S-ICD

- All patients with an existing S-ICD† can be upgraded to have the mCRM system upon FDA approval of the EMPOWER™ Leadless Pacemaker* (LP).

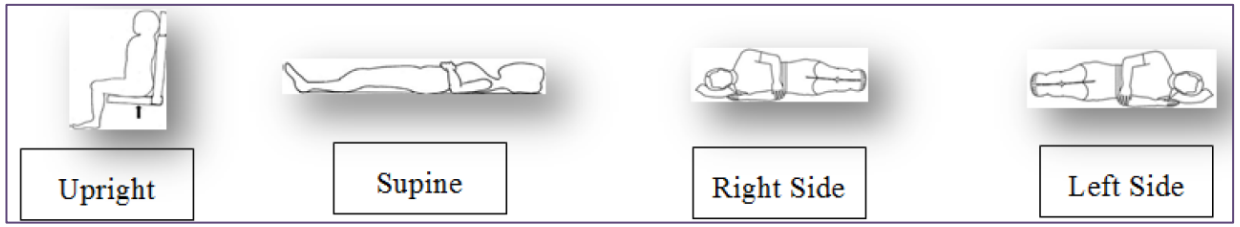
EMPOWER™ Leadless Pacemaker (LP)

- Delivers ATP after receiving a request from the S-ICD.
- Standalone VVIR pacemaker.

mCRM System

- EMBLEM S-ICD
- EMPOWER LP

6-month endpoints *(293 Pts)*

Endpoint	Performance Goal
Major EMPOWER™ System and procedure-related complication-free rate	>86%[a]
Communication success rate between the S-ICD and EMPOWER LP Communication testing required in 4 body posters 	>88%[b]
% of patients with adequate pacing capture threshold (PCT) ≤2 V @ 0.4 ms	>80%[c]

Extravascular ICD Pivotal Study

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator

P. Friedman, F. Murgatroyd, L.V.A. Boersma, J. Manlucu, D. O'Donnell, B.P. Knight, N. Clémenty, C. Leclercq, A. Amin, B.P. Merkely, U.M. Birgersdotter-Green, J.Y.S. Chan, M. Biffi, R.E. Knops, G. Engel, I. Muñoz Carvajal, L.M. Epstein, V. Sagi, J.B. Johansen, M. Sterliński, C. Steinwender, T. Hounshell, R. Abben, A.E. Thompson, C. Wiggenhorn, S. Willey, and I. Crozier, for the Extravascular ICD Pivotal Study Investigators*

- **10% inappropriate shocks at M10**
- **P wave oversensing+++**
- **70% efficient ATP**

Friedman P et al. N Engl J Med 2022

Take the Time!!

L RESEARCH

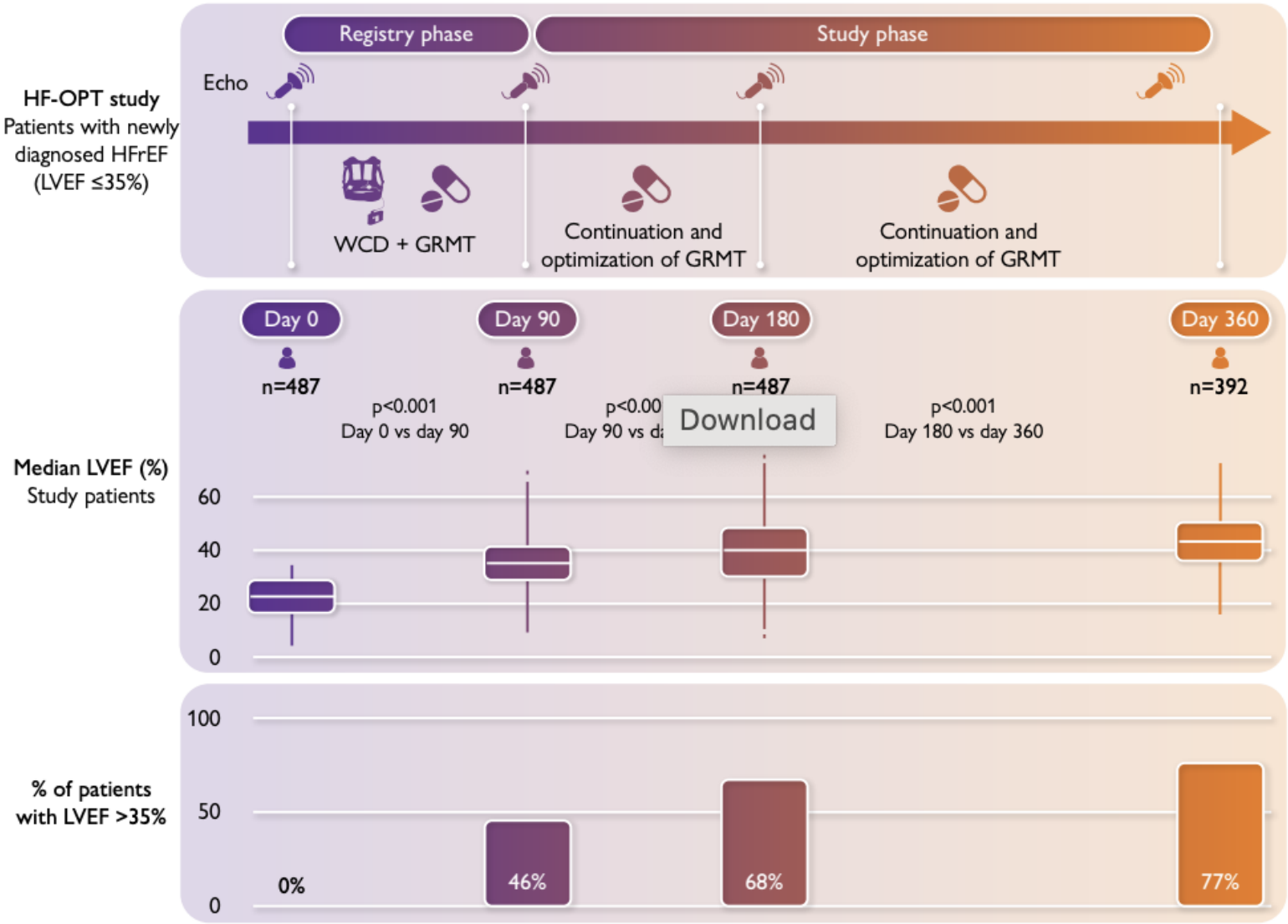
l cardiomyopathies

Th
ve
th

ure:

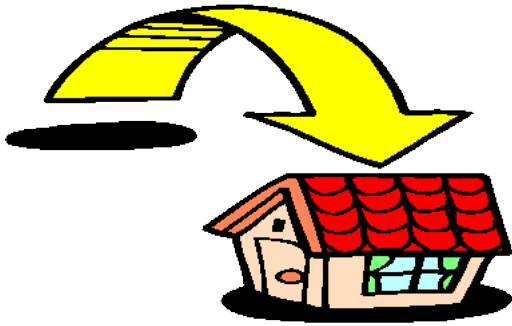
Chri
Siva
Chri
and
Inve

ley[7],
chez[10],
)PT)



Take-Home Messages

"Nouvelles" Stratégies de Défibrillation



- Reconsideration – Towards better selection of patients to benefit from ICD therapy
  - Consider competing risk situation…
  - Give time to non-antiarhythmics to act!!
  - Investigate new groups of pts who could actually benefit from ICD
- Towards better technology to protect our patients…

Inserm

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

HEGP
HÔPITAL EUROPÉEN GEORGES POMPIDOU

CEMS-PARIS
Centre d'Expertise Mort Subite

PARCC