HKCC ASC 2020

S-ICD: Can it be the first choice in prevention of sudden cardiac arrest?

Dr. Jo Jo Hai

Clinical Assistant Professor
Department of Medicine
The University of Hong Kong
Queen Mary Hospital
Hong Kong

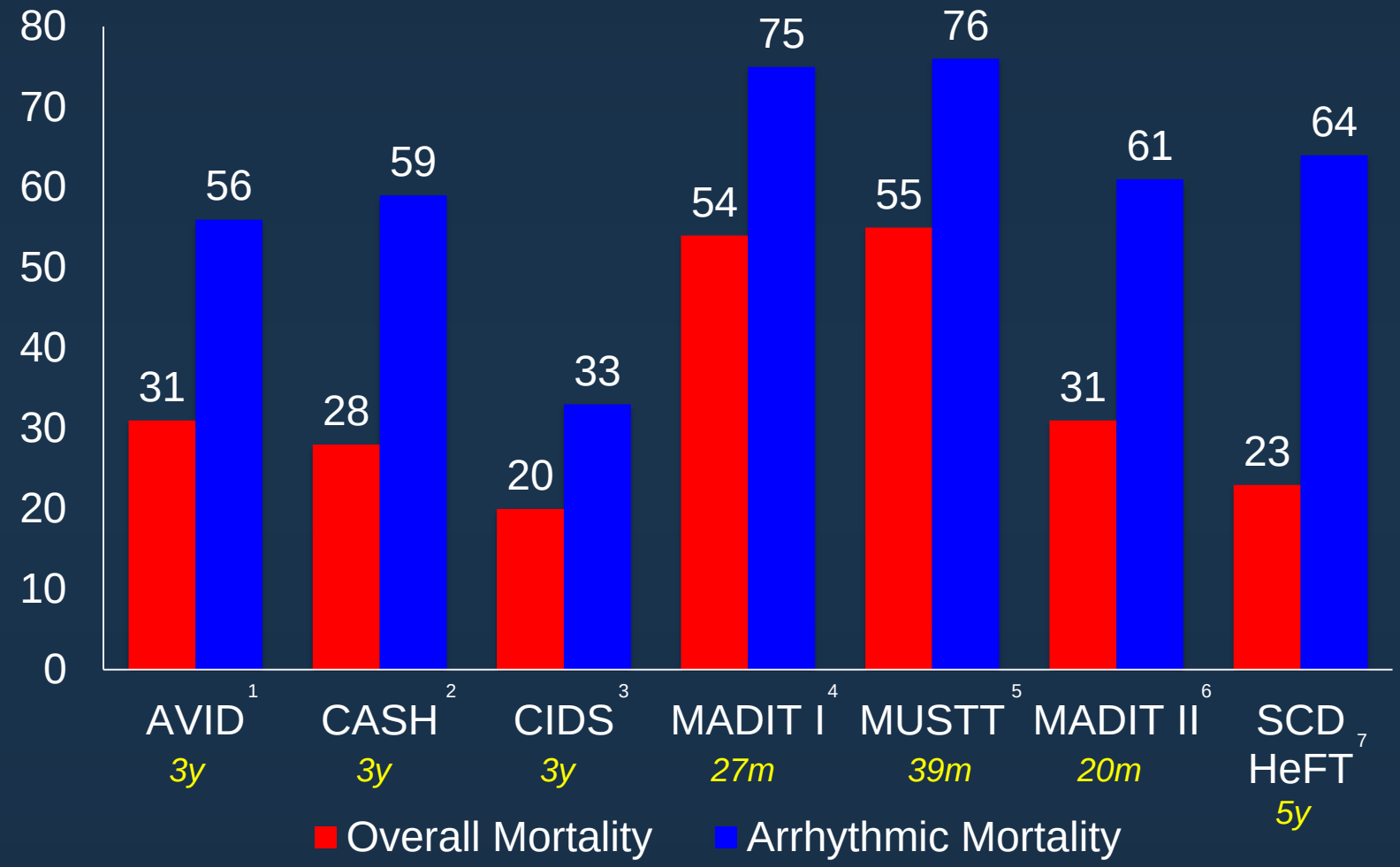
Disclosure

- None.

Agenda

- Current transvenous ICD system pitfall
- S-ICD therapy & update
- 2020 latest S-ICD PRAETORIAN & UNTOUCHED Trials results
- S-ICD current guideline

ICD Reduces Overall and Arrhythmic Mortality



Source: 1. AVID Investigators. NEJM 1997. 2. Kuck K et al. Circ 2000. 3. Connolly S et al. Circ. 2000. 4. Moss AJ et al. NEJM 1996. 5. Buxton AE et al. NEJM 1999. 6. Moss AJ et al. NEJM 2002. 7. Bardy GH et al. NEJM 2005.

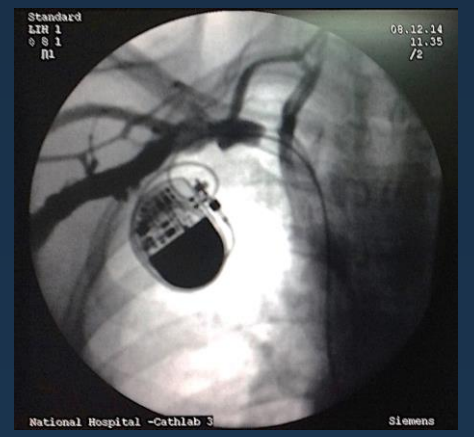
TV-ICD COMPLICATIONS

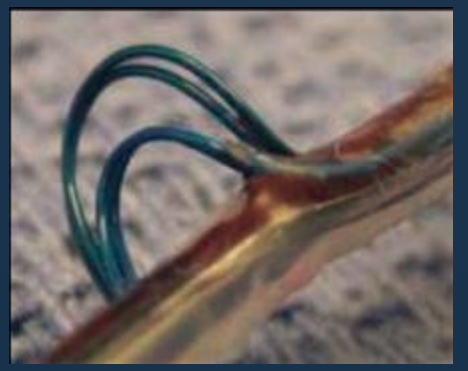
Risk of complication* at 6 years:[1-3]

15.5%

Most complications are a result of: [4,5]

Lead-related complications



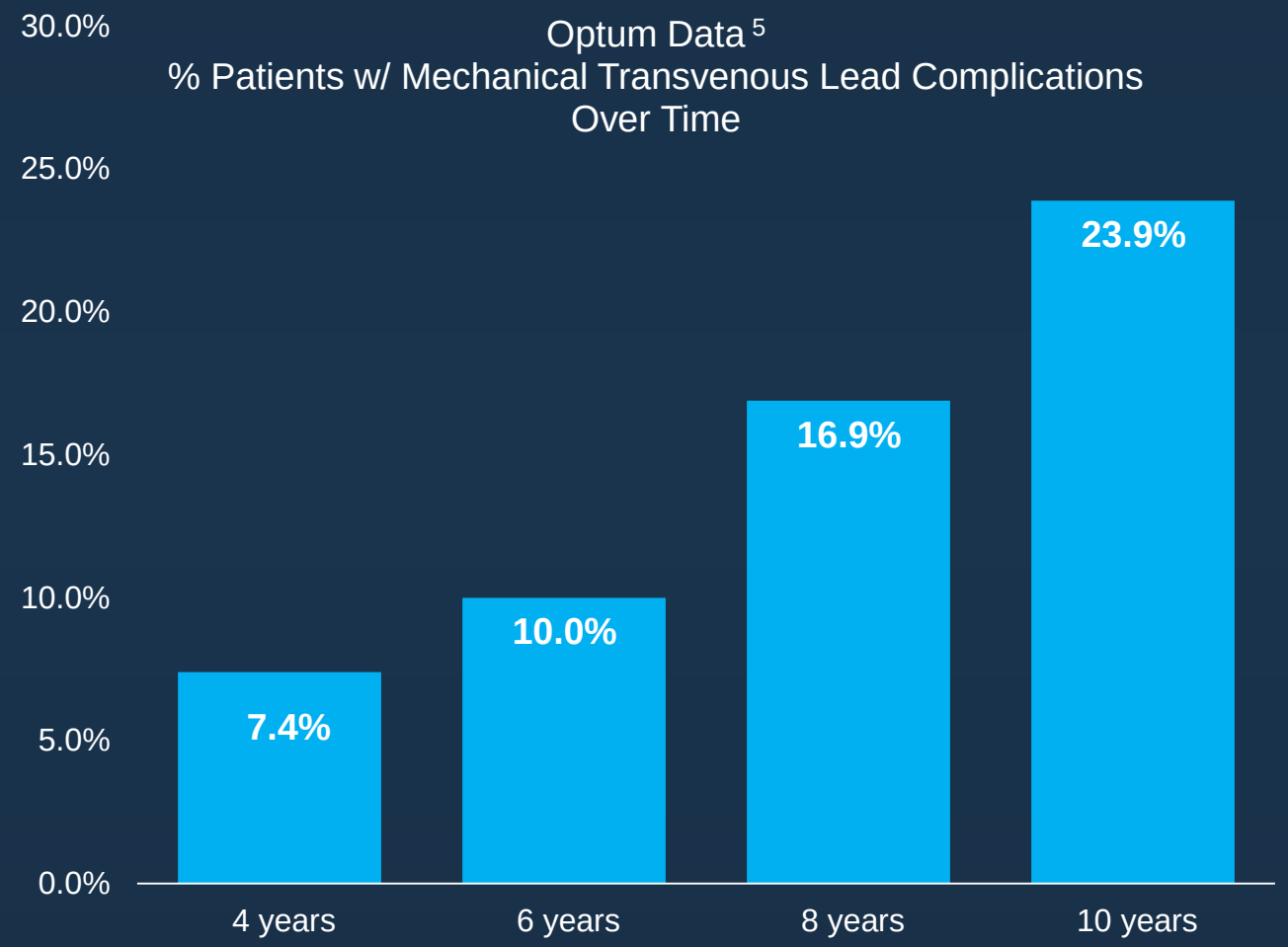


1. L.R.A. Olde Nordkamp et al. Heart Rhythm 2015.
2. Ranasinghe, I. et al. AHA 2014 Abstract 20158.
3. Ascoeta, M. S. et al. Heart Rhythm, 2016; 13:1045–1051.
4. Kirkfeldt, R.E. et al. European Heart Journal (2014) 35, 1186–1194.
5. Olde-Nordkamp, L.R.A. et al. Heart Rhythm 2015.

TV-ICD LEAD FAILURE

Multiple Studies showed that, UP TO 70% of all complications in young TV-ICD recipients were LEAD RELATED [1,2]

Lead failures are significant even for non-recalled leads [3,4]



1. Olde-Nordkamp, L.R.A. et al. Heart Rhythm 2015.
2. Honarbakhsh S, Providencia R, Srinivasan N, Ahsan S, Lowe M, Rowland E, et al. Int J Cardiol 2017; 228:280-5.
3. Koneru JN. HRS 2017; Chicago.
4. Borleffs, C.J.W. et al. Circ Arrhythmia Electrophysiol. 2009; 2:411-416.
5. Koneru JN, Jones PW, Hammill EF, et al. J Am Heart Assoc. 2018;7(10).

PATIENT OUTCOMES FOLLOWING CIED INFECTION

Europace (2014) 16, 1490–1495
doi:10.1093/europace/euu147

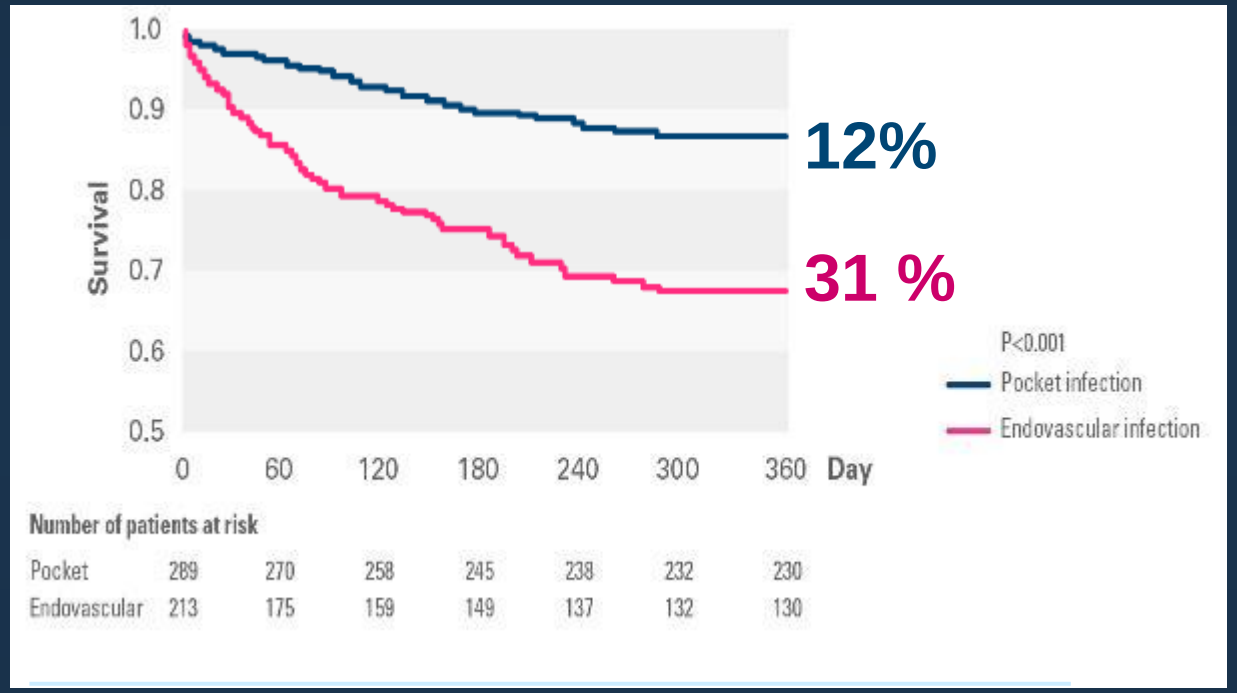
CLINICAL RESEARCH
Leads and lead extraction

Risk factors for 1-year mortality among patients with cardiac implantable electronic device infection undergoing transvenous lead extraction: the impact of the infection type and the presence of vegetation on survival

Khaldoun G. Tarakji*, Oussama M. Wazni, Serge Harb, Amy Hsu, Walid Saliba and Bruce L. Wilkoff

Section of Cardiac Pacing and Electrophysiology, Robert and Suzanne Tomsich Department of Cardiovascular Medicine, Heart and Vascular Institute, Cleveland Clinic, 9500 Euclid Avenue/J2-2, Cleveland, OH, Canada 44195

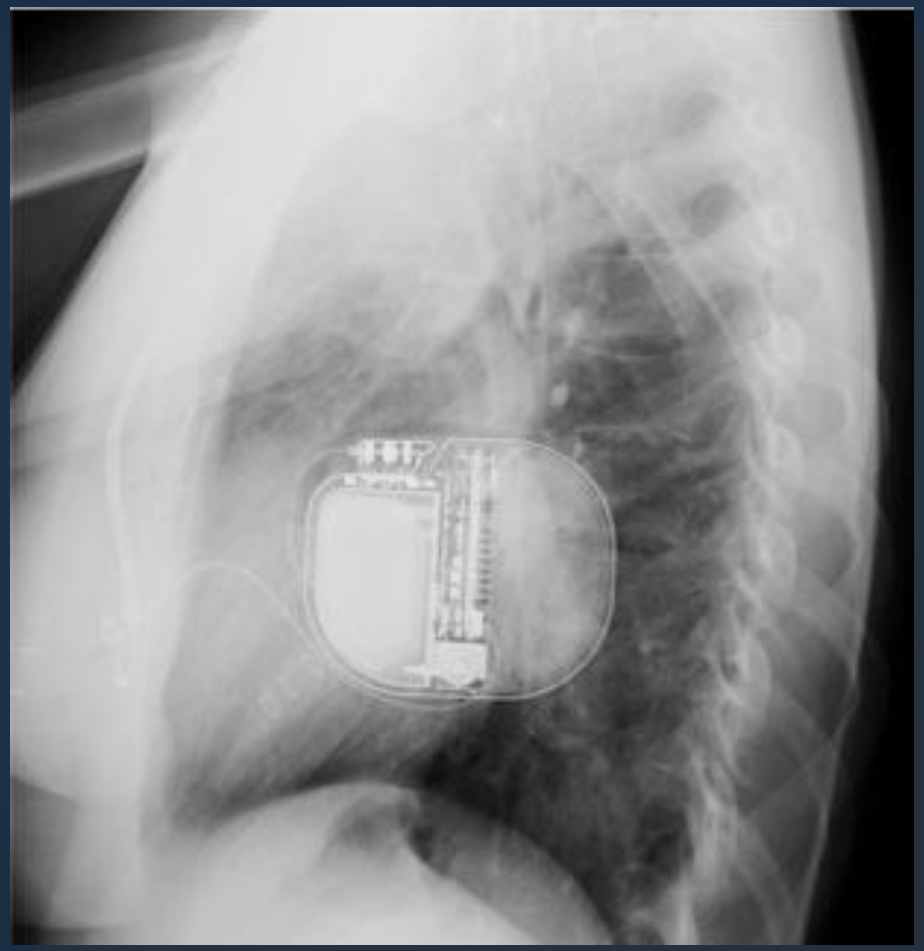
Received 2 April 2014; accepted after revision 9 May 2014; online publish-ahead-of-print 2 August 2014



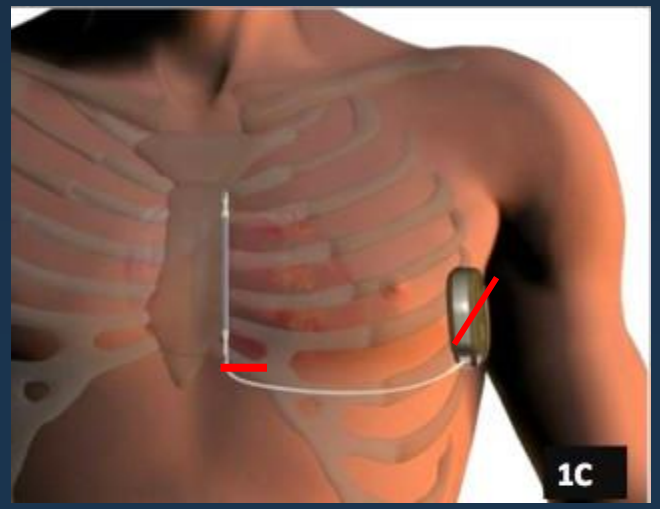
In this study from the Cleveland Clinic, ***lead-related infections*** were associated with ***3x higher risk of death at 1 year*** when compared to a pocket infection, ~31% at 1 year following lead extraction

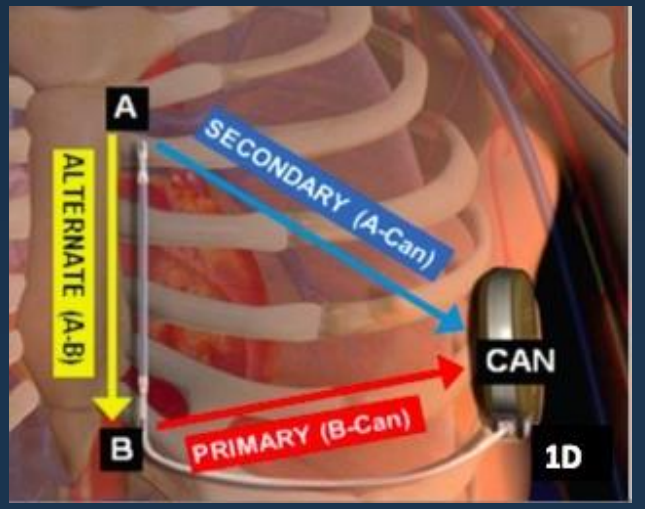
Source: Tarakji, K.G. et al. Arrhythmia & Electrophysiology Review, 2016; 5(1).

A totally subcutaneous ICD

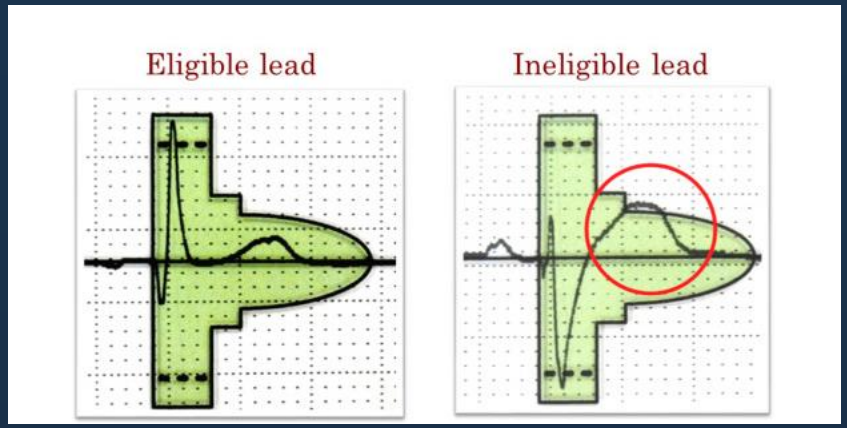


SICD: Simplify ICD System





- ✓ 80 Joules
- ✓ 1 / 2 zones
- ✓ 3 sensing / shock vectors
- ✓ Post-shock pacing for 30sec
- ✓ Episode storage



Source: Bardy GH et al. NEJM 2010.

Proven Effective Defibrillation without Transvenous Lead Complications

98.2%

defibrillation efficacy with S-ICD (As per the IDE/EFFORTLESS Pooled Analysis) [1]

99.7%

lead survival with S-ICD at 5 years.[2]

98%

freedom from complications with S-ICD at 1 year follow-up.[3]

1. Burke, M. et al. JACC 2015; 65: 16.
2. Boston Scientific CRM Product Performance Report published February 13th, 2017.
3. Boersma, L. et al. JACC, 2017; 70,7.

3rd Generation EMBLEM S-ICD

ImageReady™ technology

Full Body, 1.5T
MRI-conditional System

Ergonomic Shape

Improves the implant experience and patient comfort

Boston Scientific Battery Technology

Decreases the need for change-out procedures

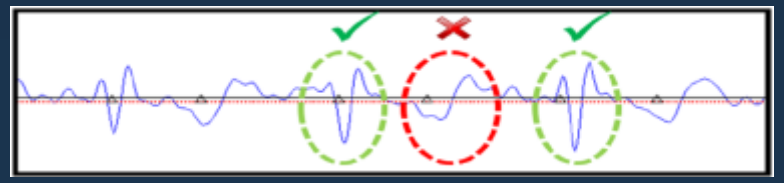
LATITUDE™ System

Designed to provide remote patient follow-up

Algorithms to Reduce Inappropriate Shocks (VT zone only)

SMR8 Alternating Morphology Algorithm

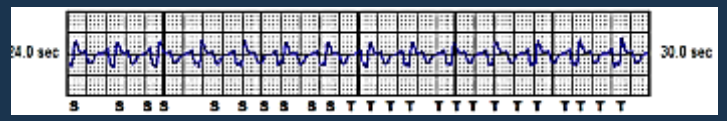
- Disregard beats in between two similar beats when <50% match to either of them



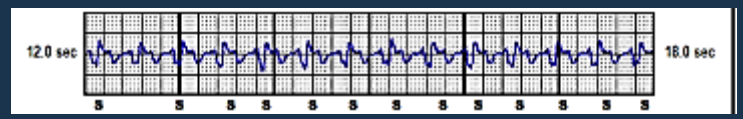
SMART Pass™

- an additional High Pass filter
- reduces the amplitude of lower frequency (slower moving) signals such as T-waves

SMART Pass OFF



SMART Pass ON

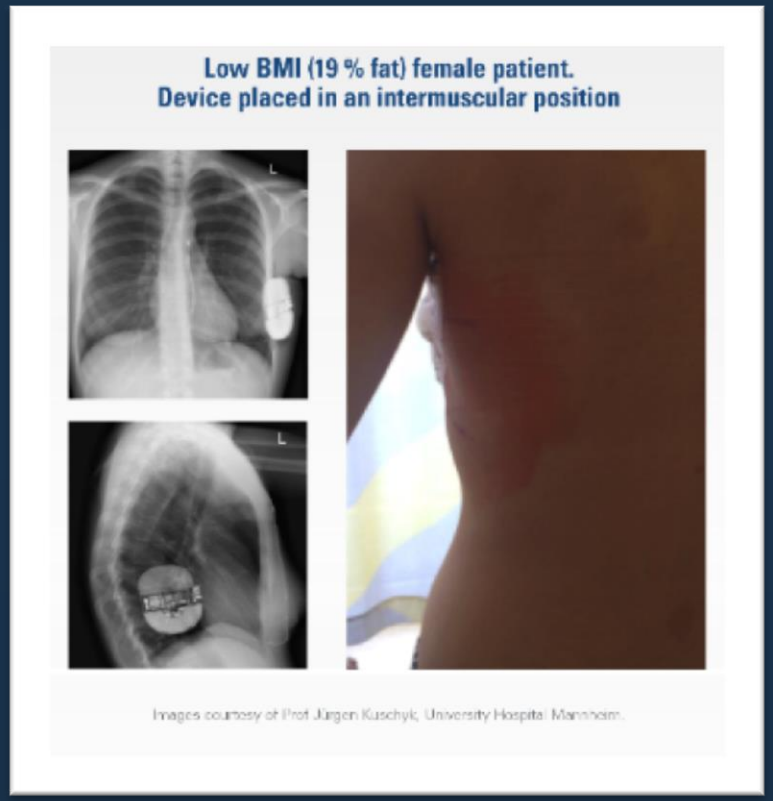


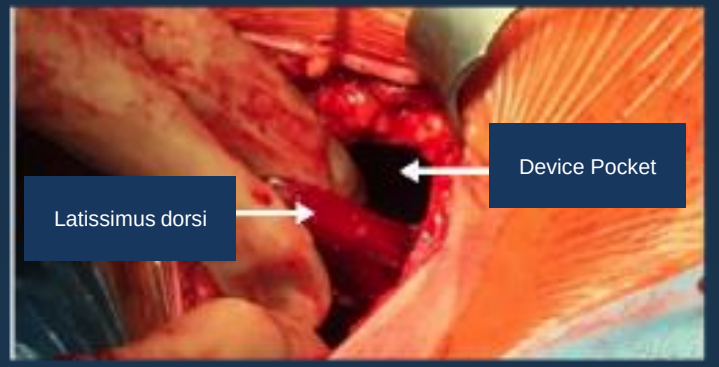
	Reduction in TWOS % vs. Gen 1 S-ICD
SMR8	39.8 %[1]
SMR8 +SMART Pass™	82 %[2]

Further Study showed SMART Pass™ can reduce inappropriate shock by **68%**[2] when turn On.

1. Brisben A. et al. J Cardiovasc Electrophysiol. 2015;26(4):417-423.
2. Theuns D. et al. Heart Rhythm. 2018;15(10):1515-1522.

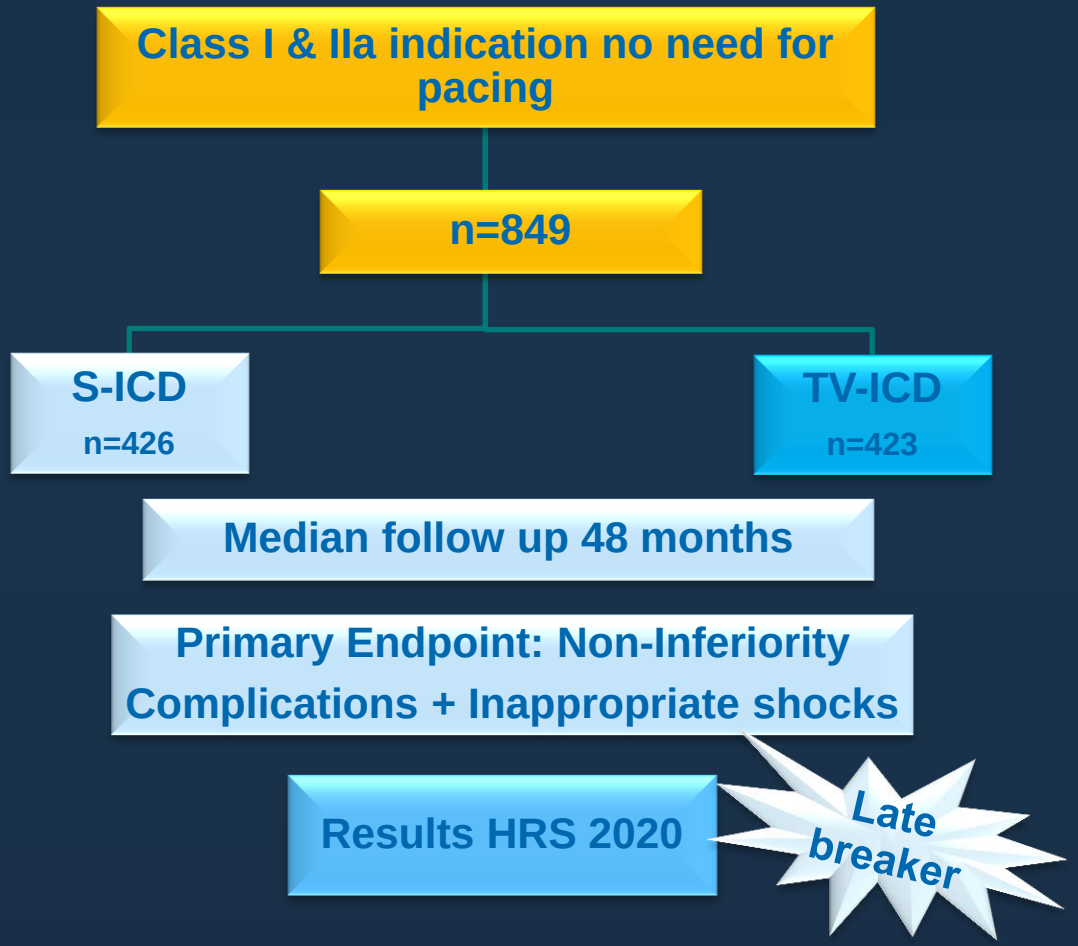
Recent Advancement of S-ICD Implant





2 Incision & Inter-muscular Technique

THE PRAETORIAN TRIAL (2011-2016)



Prospective
Randomized Head-Head

- ✓"Typical" sicker & older ICD population
- ✓ Composite endpoint (Complications + Inappropriate shocks)
- ✓ Standardized programming
- ✓ Secondary endpoints:
  - Device related complications
  - Lead-related complications
  - Inappropriate shocks
  - Cause of inappropriate shocks
  - Mortality (all-cause, arrhythmic, cardiac)

Source: Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.

S-ICD had comparable performance to TV-ICD yet avoided serious complications

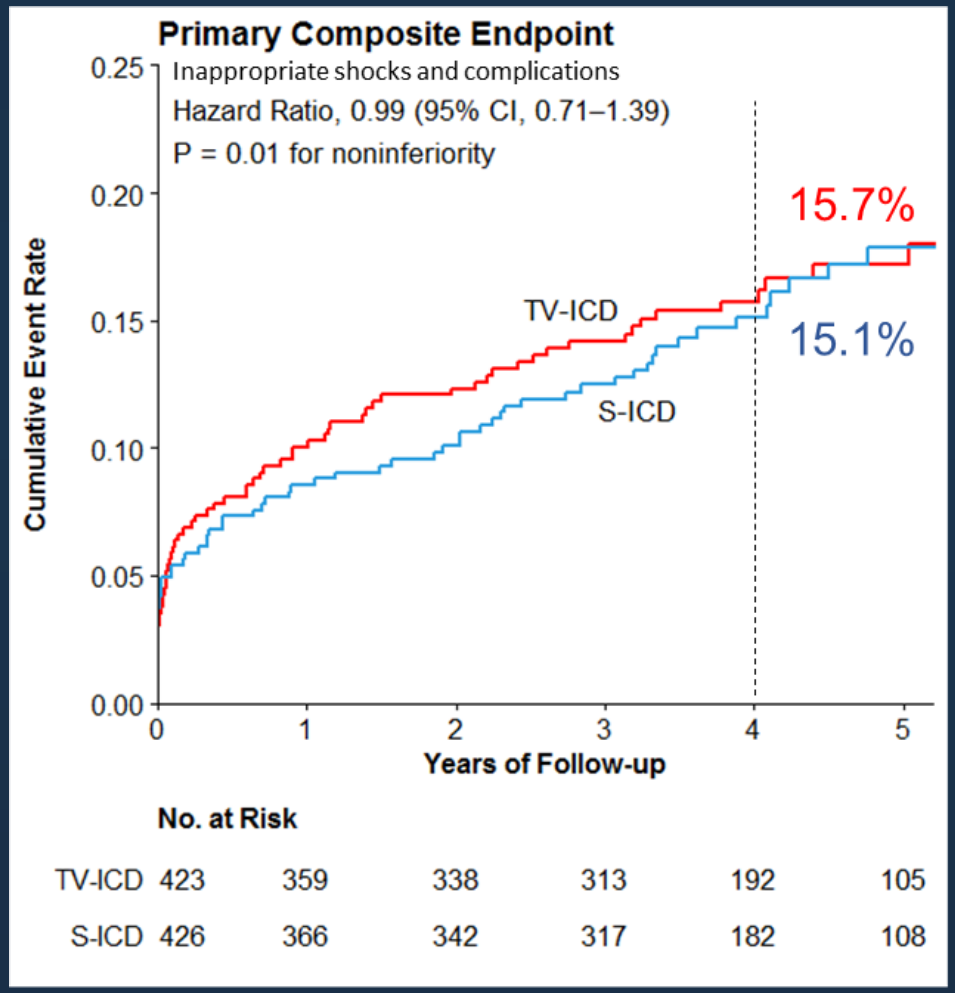
Primary Outcome: Non-inferiority Demonstrated

S-ICD had comparable performance to TV-ICD yet avoided serious complications including:

✓Infections that required lead extraction

✓Lead complications

Confirms S-ICD can be the preferred choice for most ICD indicated patients w/o need for pacing

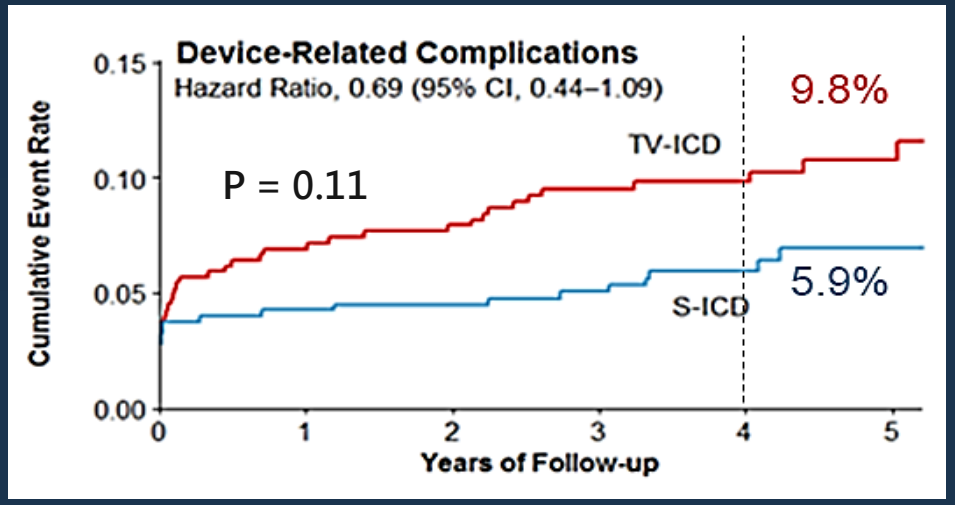


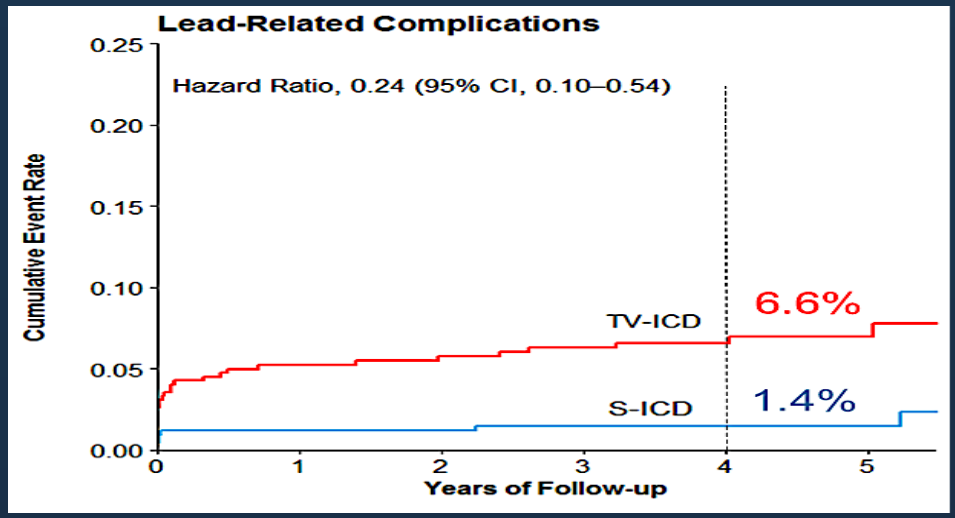
Source: Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.

PRAETORIAN: All Complications

PRAETORIAN XL Long Term Follow Up Study to be extended to 8 years

	S-ICD (n = 426)	TV-ICD (n = 423)
Device related complications	31 (5.9%)	44 (9.8%)
– Infection	4	8
– Bleeding	8	2
– Thrombotic event	1	2
– Pneumothorax	0	4
– Lead perforation	0	4
– Lead repositioning	2	7
– Other	19	20
• Lead replacement	3	9
• Device or sensing malfunction	8	6
• Pacing indication	5	1
• Implantation or DFT failure	3	3
• Pain or discomfort	2	3

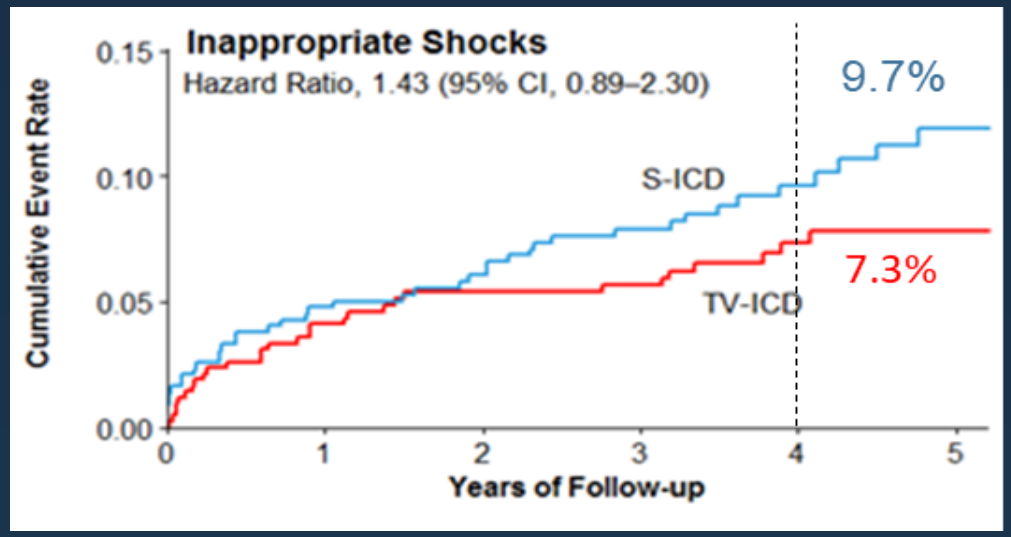




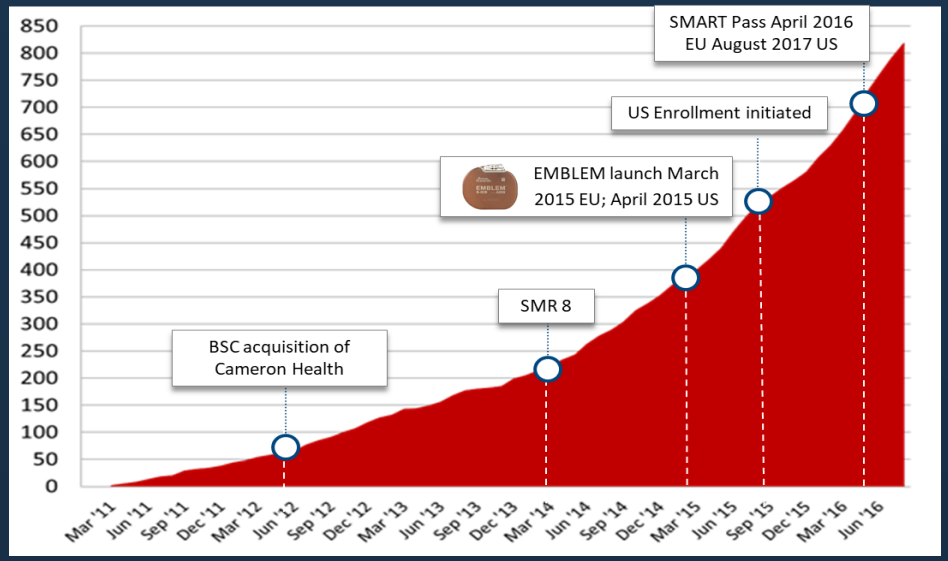
Source: Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.

PRAETORIAN: Inappropriate shocks [1]

- *Rate of Inappropriate shocks at 1 years was similar to rates seen in other TV-ICD studies.[2-4]*
- *Divergence of curves may be related to inclusion of old devices*
  - *Only in **70-75%** of S-ICD patients with SMR8 Alternating Morphology Algorithm.*
  - *Only in **22%** of S-ICD patients with SMART Pass™*



- Enrollment completed Oct 2016 -

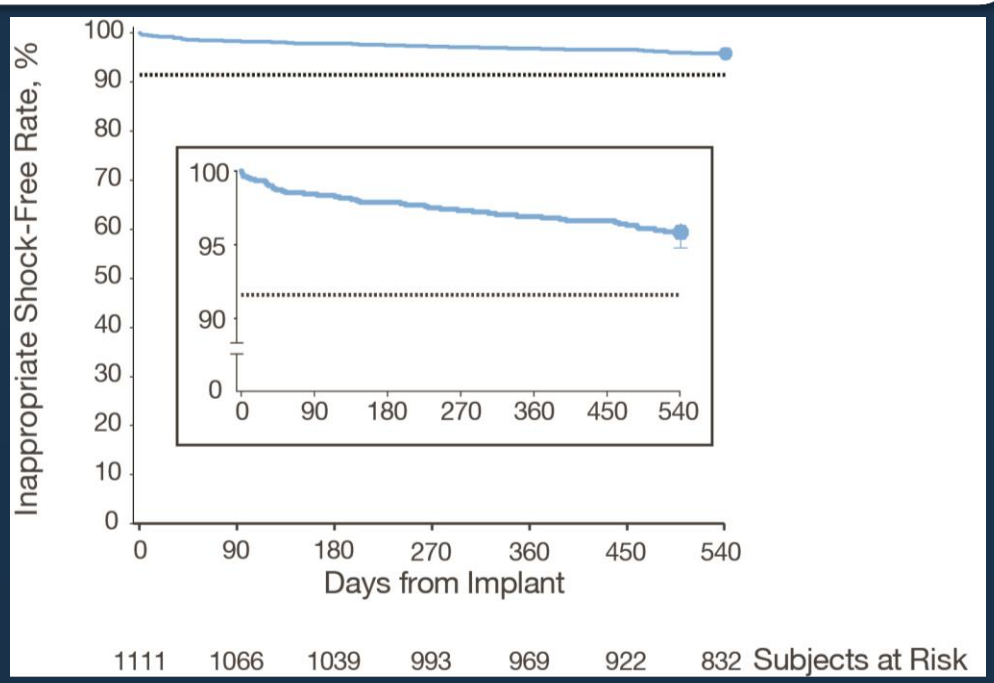


1. Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.
2. Gasparini M. et al. JACC: Clinical Electrophysiology. 2017;3:1275–82.
3. Kutyifa V. et al. Circ Arrhythm Electrophysiol. 2016;9(1):e001965.
4. Auricchio A. et al. Europace. 2017;19(12):1973-1980.
5. Brisben A. et al. J Cardiovasc Electrophysiol. 2015;26(4):417-423.
6. Theuns D. et al. Heart Rhythm. 2018;15(10):1515-1522.

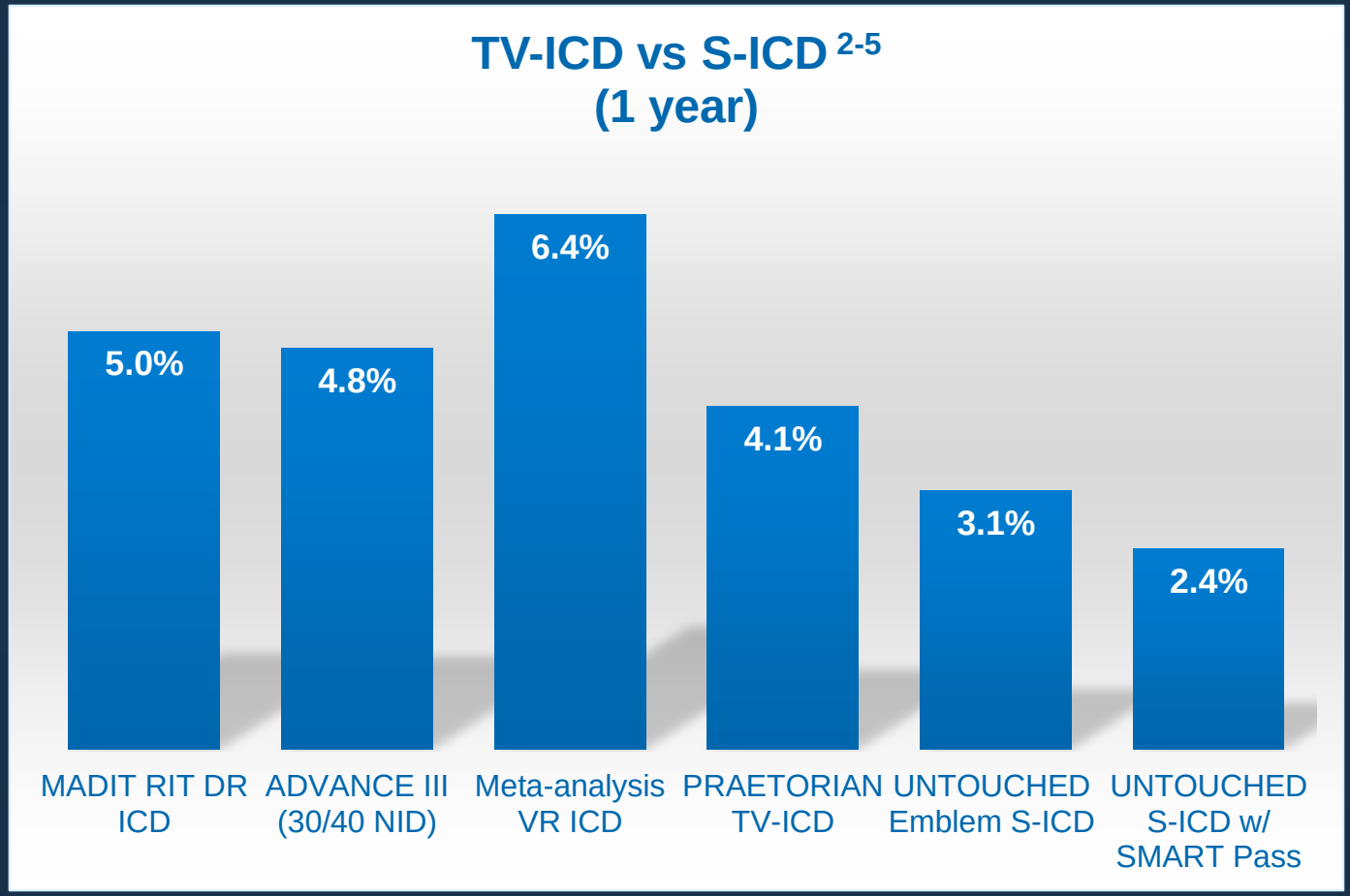
UNTOUCHED: Understanding Outcomes with the EMBLEM S-ICD in Primary Prevention Patients with LVEF ≤35 [1]

Low rate of inappropriate shocks in real-world patients

- ✓ **3.1% at 1 year** [1]
- ✓ **2.4% at 1 year in patients with SMART Pass™** [1]



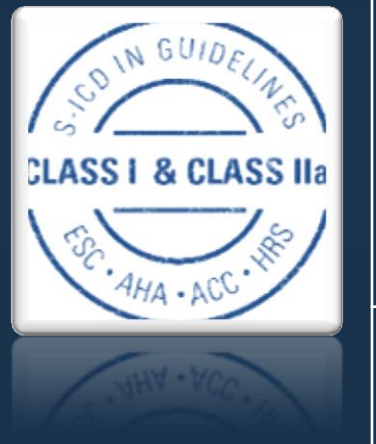
TV-ICD vs S-ICD [2-5] (1 year)



1. Gold M. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-02 2020.
2. Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.
3. Gasparini M, Lunati MG, Proclemer A, et al. JACC: Clinical Electrophysiology. 2017;3:1275–82.
4. Kutyifa V, Daubert JP, Schuger C, et al. Circ Arrhythm Electrophysiol. 2016;9(1):e001965.
5. Auricchio A, Hudnall JH, Schloss EJ, et al. Europace. 2017;19(12):1973-1980.

The in appropriate shock rate in UNTOUCHED was comparable to, or lower than, the rates observed in studies with TV-ICDs including the PRAETORIAN trial [2-4]

S-ICD: AHA/ ACC/ HRS/ ESC Guidelines



Guidance	2017 AHA/ACC/HRS Guidelines[1]	2015 ESC Guidelines[2]	For ICD patients…
Class I	✓		With inadequate vascular access or are at high risk of infection, including a prior device infection, ESRD, diabetes mellitus (up to 35% of the ICD population)[1]
Class IIa	✓	✓	Who meet indication for an ICD, wihtout the need for pacing (CRT, bradycardia, ATP)

1. Al-Khatib, SM, et al., Heart Rhythm, 2017.
2. Priori, SG. et al. Eur Heart J. 2015; Nov 1;36(41):2793-867.

PATIENT PRIORITISATION FOR THE S-ICD

Based on guidelines and clinical literature[1, 3, 4]

- **Bradycardia Pacing (~6% patients)** [3,4]
- **CRT-D Indication**
- **Need for ATP at implant (~7% patie**
- **S-ICD Screen Out (~4-10% patients)** [7-9]
- **High risk patients**
  Risk of lead complications
  s issues
  RS Class I) [1]
- **Future need for ATP (~1.8% patients)** [3, 5, 6]
- **Patients with no pacing indication**
  ass IIa) [1,2]
  ≥ 70 years

89%

of all ICD indicated patients were eligible to receive an **S-ICD**[10]

1. Al-Khatib, SM, et al., Heart Rhythm, 2017.
2. Priori, SG. et al. Eur Heart J. 2015; Nov 1;36(41):2793-867.
3. de Bie MK, et al. Heart 2013;99:1018–1023.
4. Botto GL, et al. Europace 2016; Epub 2016/12/25.
5. Boersma, L. et al. JACC, 2017; 70,7.
6. Boersma, L. ESC 2014.
7. Olde-Nordkamp, L.R.A. et al. Heart Rhythm 2015.
8. Groh CA, et al. Heart Rhythm. 2014 Aug;11(8):1361-6.
9. Ziacchi M, et al. Heart Lung Circ. 2016 May;25(5):476-83.
10. Botto GL, et al. Europace 2016; Epub 2016/12/25.

PATIENT PRIORITISATION FOR THE S-ICD

Based on guidelines and clinical literature

Optimal S-ICD candidate

STRONG INDICATION

- Young age*
- Previous infection
- Infection risk (mechanical valves, diabetes, renal dysfunction)
- Poor vascular access & Existing system
- Channelopathies (Long QT, Brugada)
- HOCM
- Primary prevention

Difficult venous access

Young patients facing a lifetime device therapy

Patients with particular risk of infection

RELATIVE CONTRAINDICATION

Need for ATP (difficult to define clinically)

CONTRAINDICATED

Pacing indication (bradycardia or CRT)

Failed screening (high inappropriate shock risk)

* <65 (10 – 15 years life expectancy) as defined by ESC guidelines for management of atrial fibrillation, 2011

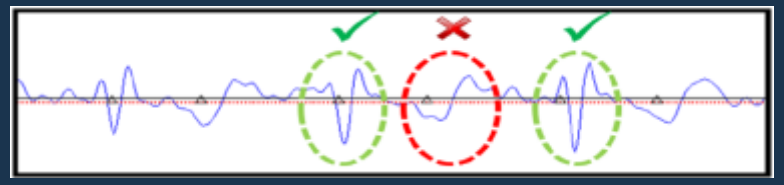
Source: McLeod CJ et al. Eur Heart J. 2017;38(4):247-257.

haishjj@hku.hk

Dr. Jo Jo Hai

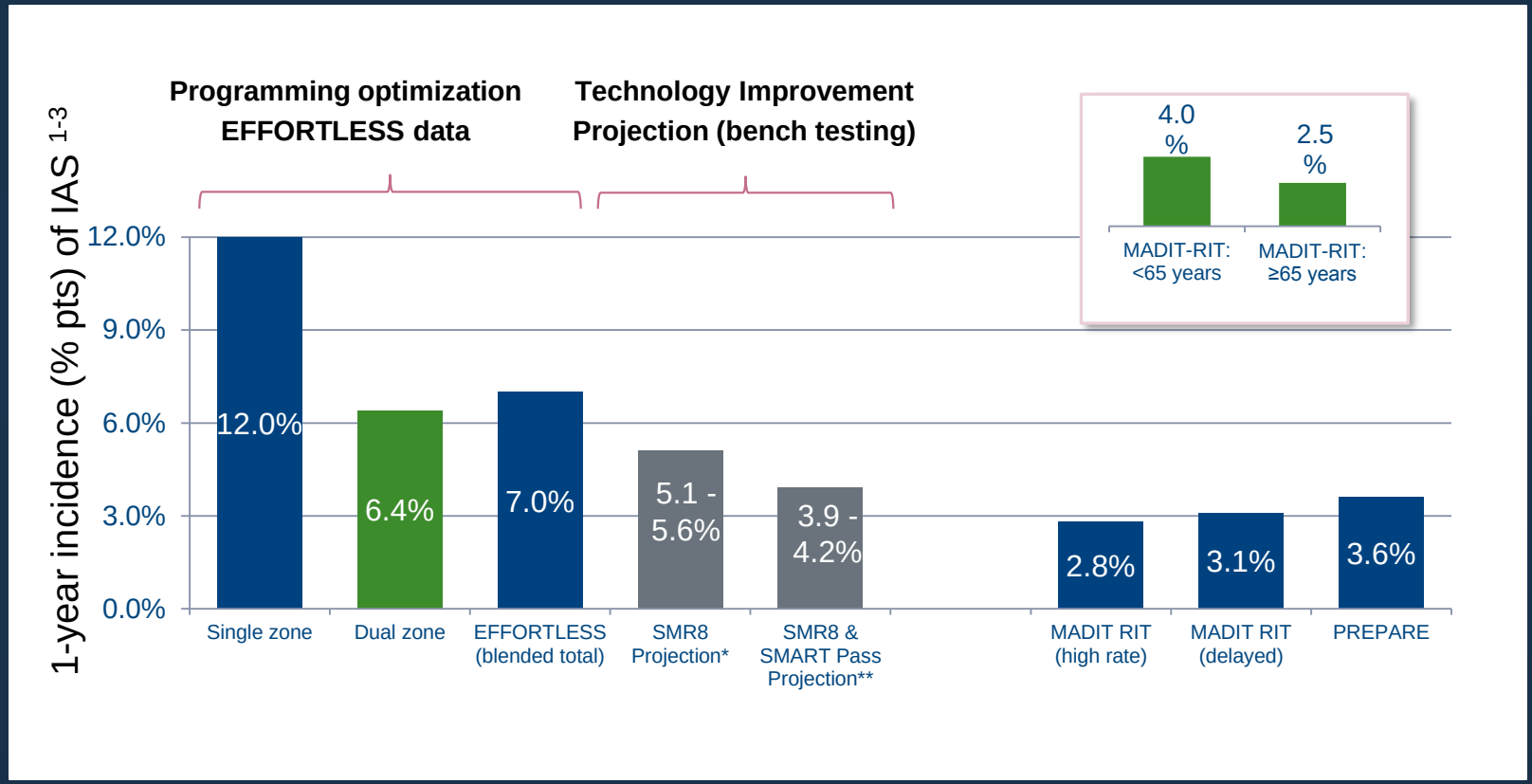
SMR8 Alternating Morphology Algorithm in reducing T-wave oversensing

Algorithm looks for two similar detections with a non-matching beat between them.



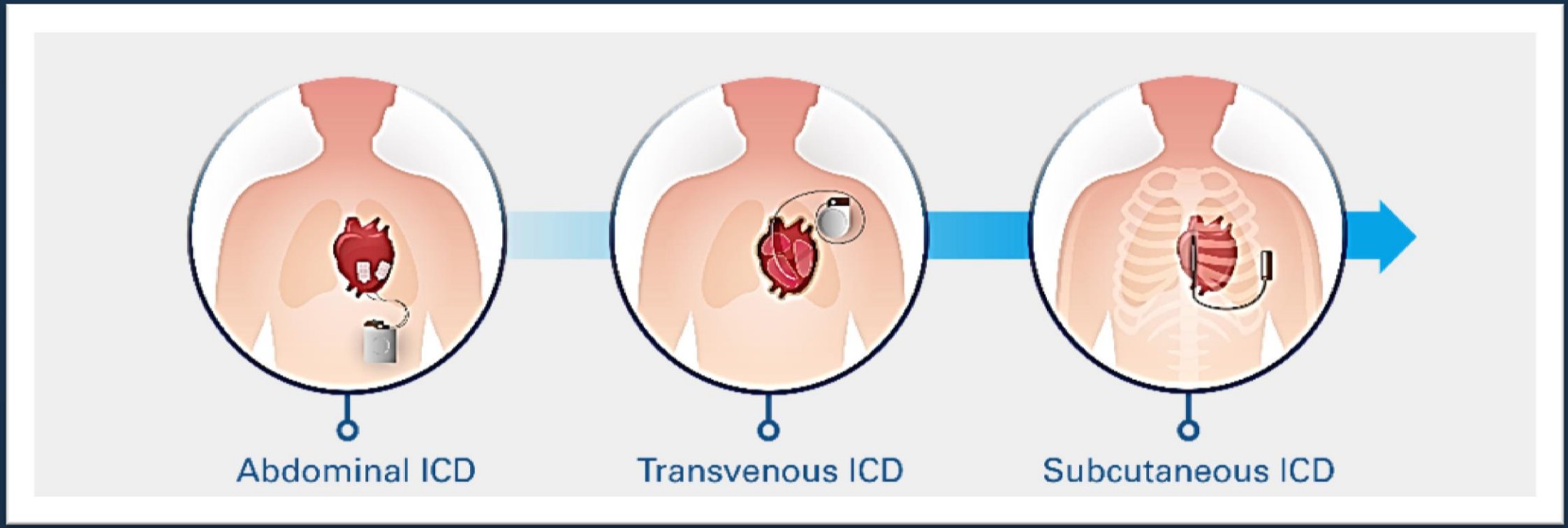
1. Look for 3 beats: 1 dissimilar beats between 2 similar beats
2. Middle beat: < 50% match to complexes on either side → discard the middle beat

Reduced T-wave oversensing by 39.8%.[1]



1. Brisben A. et al. J Cardiovasc Electrophysiol. 2015;26(4):417-423.
2. Boersma L. et al. J Am Coll Cardiol. 2017;70(7):830-841.
3. Schuger C. et al. Ann Noninvasive Electrocardiol. 2012;17(3):176-185.

S-ICD SYSTEM: A less invasive solution for patients at risk of sudden cardiac death



ICD INFECTIONS

ENDOVASCULAR INFECTIONS
(lead-related)

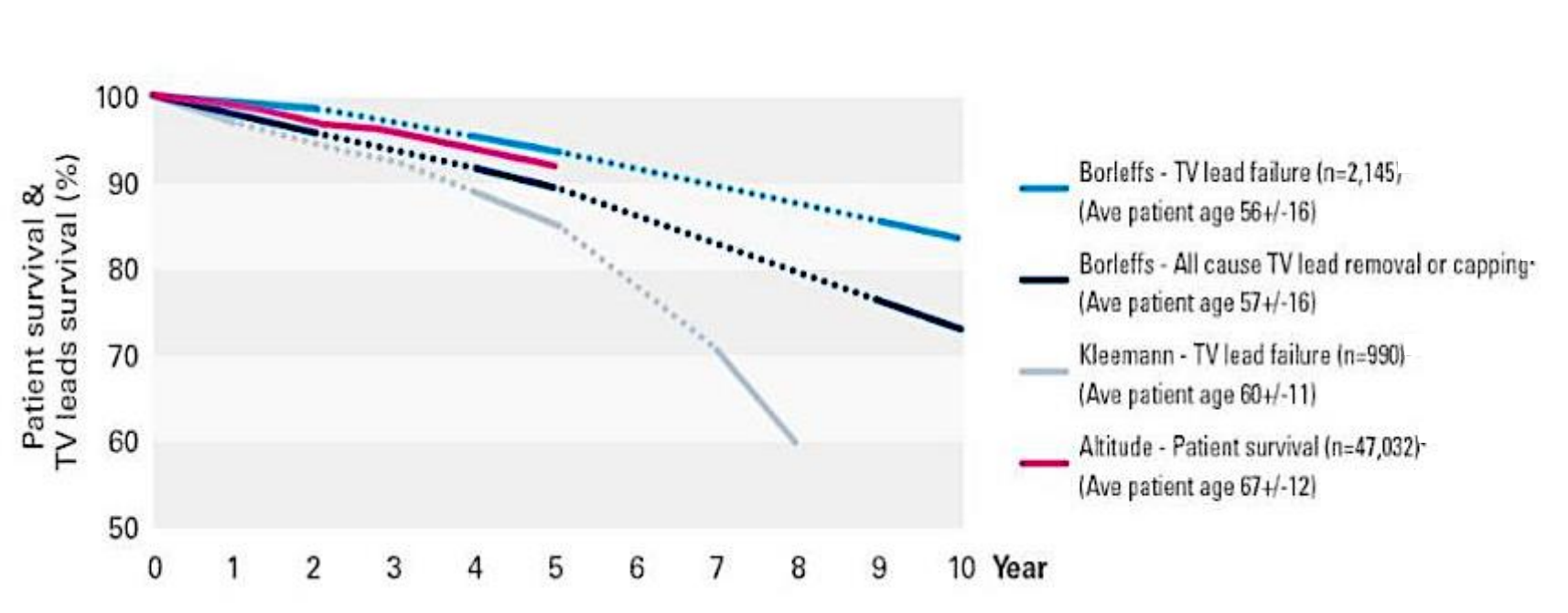
POCKET INFECTIONS
(device-related)

Infection can manifest at any time post-procedure, from early (up to 1 month post procedure) to late (>1 year)

Source: Lekkerkerker, J.C. et al. Heart; 2009; 95.

ICD LEAD FAILURE

Patient survival and TV lead survival



A majority of ICD patients may have a longer life-expectancy than their TV-ICD leads[1-3]

1. Borleffs, C.J.W. et al. Circ Arrhythmia Electrophysiol. 2009; 2:411-416
2. Kleeman, T. et al. Circulation 2007; 115:2474-2480.
3. Saxon, L.A. et al. Circulation. 2010; 122: 2359-2367.

PREDICTORS OF CIED INFECTIONS

Predictors of device infection include[1]:

- Diabetes
- Heart failure
- Kidney disease
- Previous device infection

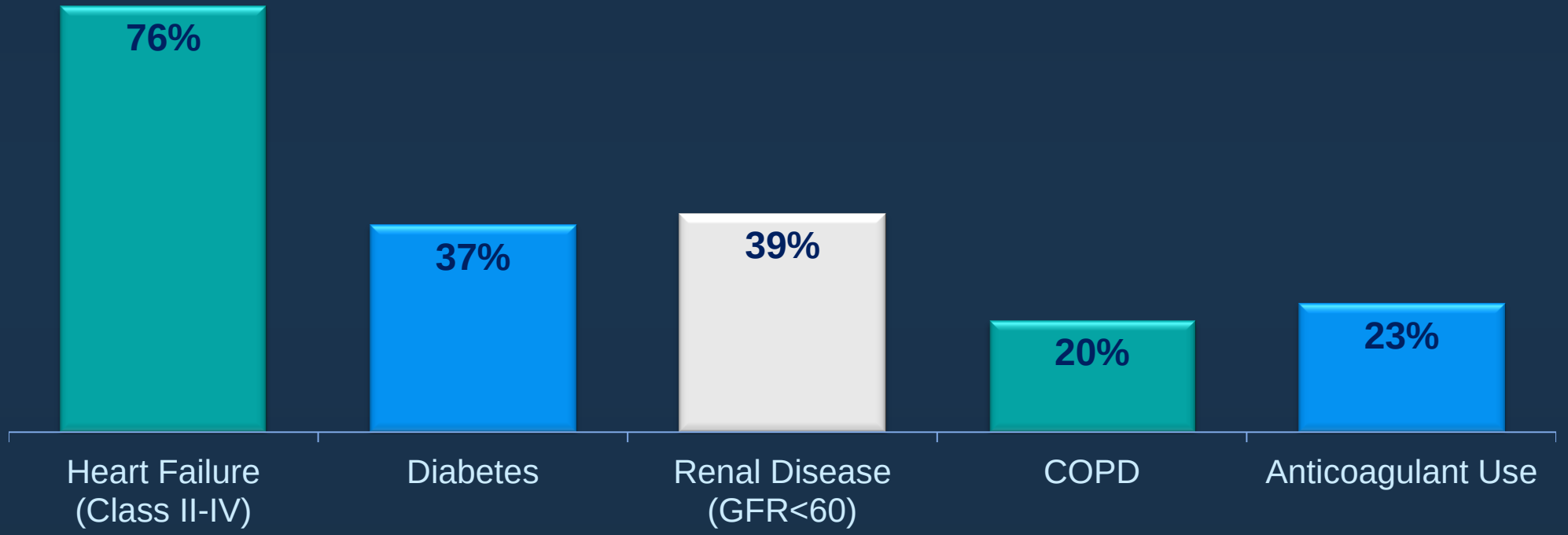
More than 70% if ICD indication patients over 60 yrs old have at least 1 predictors of device infection. [1, 2]

Cardiac device infection negatively impacts risk-benefit ratio, particularly in Primary Prevention patients.[3]

1. Polyzos, KA, et al. Europace, 2015. 17(5): p. 767-777.
2. Friedman, D.J., et al., JAMA Cardiol, 2016. 1(8): p. 900-911.
3. Lekkerkerker, J.C. et al. Heart; 2009; 95.

PREDICTORS OF CIED INFECTIONS

% of ICD Patients in the U.S. With Below Comorbidities [1]



Guidelines recommend S-ICD in patients at high risk for infection [2]

A high percentage ~40% of ICD indicated patients have ≥1 comorbidity associated with high infection risk

1. Friedman, DJ, Parzynski, CS, Varosy, PD, et al., JAMA Cardiol, 2016. 1(8): p. 900-911.
2. Al-Khatib, S. M., et al. Circulation 2018. 138(13): e272-e391.

PATIENT OUTCOMES FOLLOWING CIED INFECTION

In the ELECTRa registry, **1 in 6** patients died after systemic infection resulting in transvenous lead extraction [1]

Low incidence of mortality linked to procedure, but significant post-procedural mortality, with a strong correlation between mortality and lead extraction for infection [1]

Large vegetation on an extracted right ventricular ICD lead [2]

ESC European Society of Cardiology
European Heart Journal (2017) **38**, 2995–3005
doi:10.1093/eurheartj/ehx080
CLINICAL RESEARCH
Arrhythmia/electrophysiology

The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) Registry of Transvenous Lead Extraction Outcomes

Maria Grazia Bongiorni[1]*, Charles Kennergren[2], Christian Butter[3], Jean Claude Deharo[4], Andrzej Kutarski[5], Christopher A. Rinaldi[6], Simone L. Romano[1], Aldo P. Maggioni[7,8], Maryna Andarala[7], Angelo Auricchio[9], Karl-Heinz Kuck[10], and Carina Blomström-Lundqvist[11], on behalf of ELECTRa Investigators[†]

[1]Cardiology Department, University Hospital of Pisa, Via Paradisa 2, 56124, Pisa, Italy; [2]Department of Cardiothoracic Surgery, Sahlgrenska University Hospital, 413 45 Goteborg, Sweden; [3]Heart Center Brandenburg in Bernau , Department of Cardiology and Medical School Brandenburg, Ladeburger Str. 17m, 16321 Bernau b. Berlin, Germany; [4]Arrhythmias Unit, Department of Cardiology, La Timone University Hospital, CHU La Timone, 265 Rue Saint Pierre, 13005 Marseille, France; [5]Department of Cardiology, Medical University of Lublin, ul. Jaczewskiego 8, 20954 Lublin, Poland; [6]Cardiology Department, 6th Floor East Wing, Guy's & St Thomas' Hospitals, Westminster Bridge Rd, London, SE1 7EH, UK; [7]European Society of Cardiology, The European Heart House, Les Templiers, 2035 route des colles, CS 80179 Biot, 06903 Sophia Antipolis Cedex, France; [8]ANMCO Research Center, Via La Marmora 34, 50121 Firenze, Italy; [9]Division of Cardiology, Fondazione Cardiocentro Ticino, Via Tesserete 48, 6900 Lugano, Switzerland; [10]Department of Cardiology, Asklepios Klinik St. Georg, Lohmühlenstr. 5, 20099 Hamburg, Germany; and [11]Department of Cardiology, Institution of Medical Science, Uppsala University, S-75185 Uppsala, Sweden

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1. Bongiorni, M.G. et al. May 5th, 2016, HRS.
2. https://consultqd.clevelandclinic.org/2014/08/leading-from-experience-in-transvenous-lead-extraction/

In the EFFORTLESS registry

1000 PATIENTS OVER **3** YEARS,

Zer0 ENDOVASCULAR INFECTIONS[1]

Zer0 SYSTEMIC INFECTIONS[1]

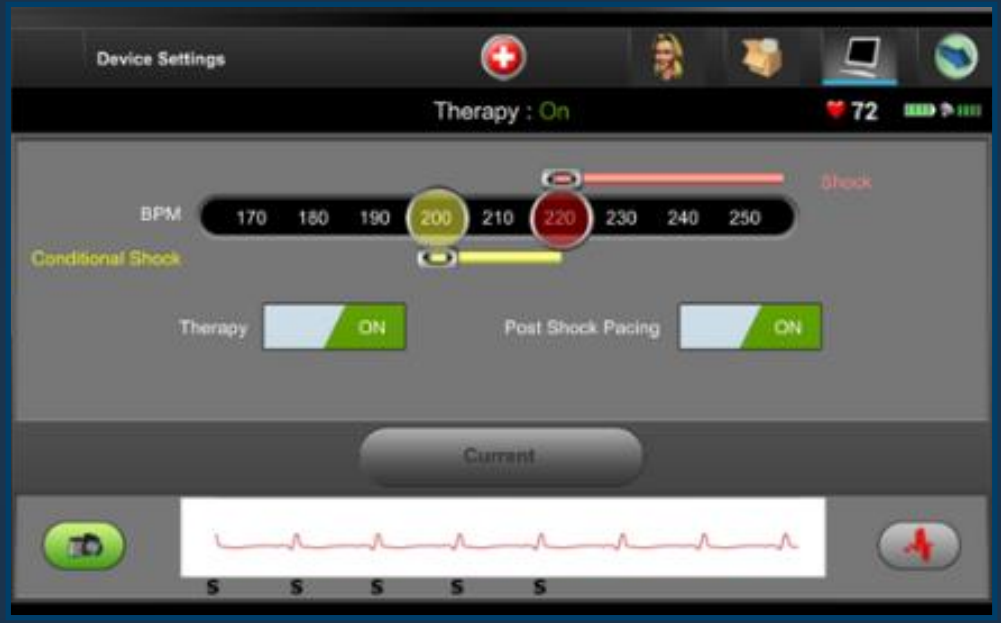
Zer0 ELECTRODE FAILURES[1]

Source: Boersma, L. et al. JACC, 2017; 70,7.

TWO ZONE PROGRAMMING

Considerations to reduce inappropriate shocks:

- The use of a Conditional Shock Zone (dual-zone programming) allows for SVT/AF discrimination with **SMART Pass™ and SMR8 Alternating Morphology Algorithm.**
- Dual-zone programming can significantly enhance SVT discrimination to determine appropriateness of therapy



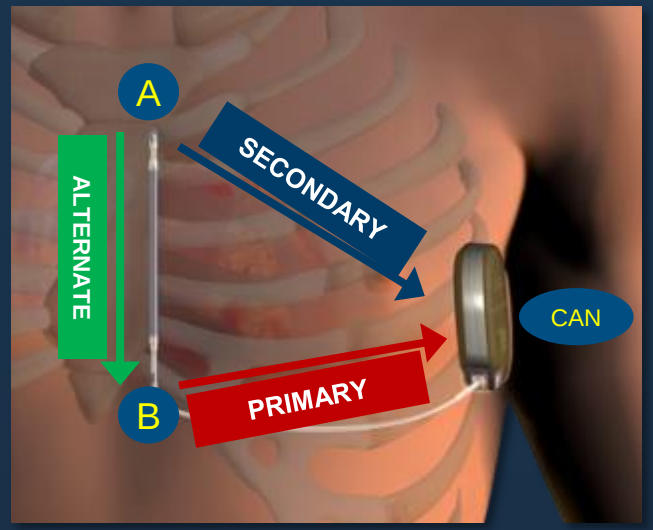
In the IDE study, patients with dual zone programming experienced significantly fewer inappropriate shocks due to SVT than those programmed with a single zone (2.7% vs. 10.2%; p-value=0.0085).

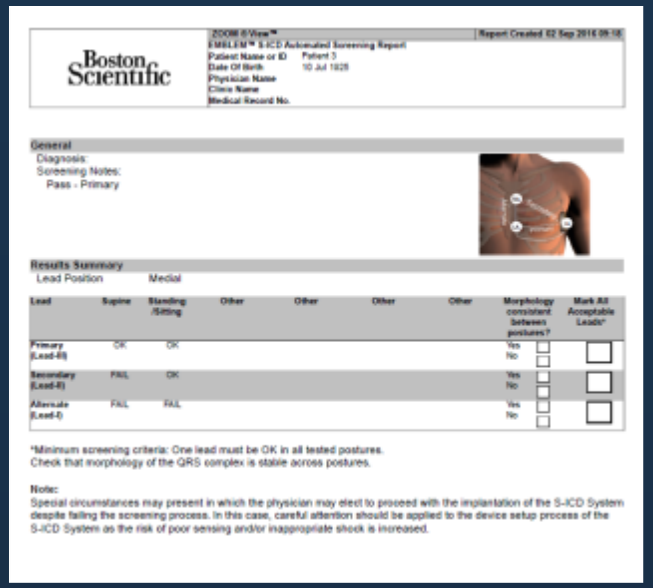
Source: Weiss R. et al. *Circulation*. 2013;128(9):944-953.

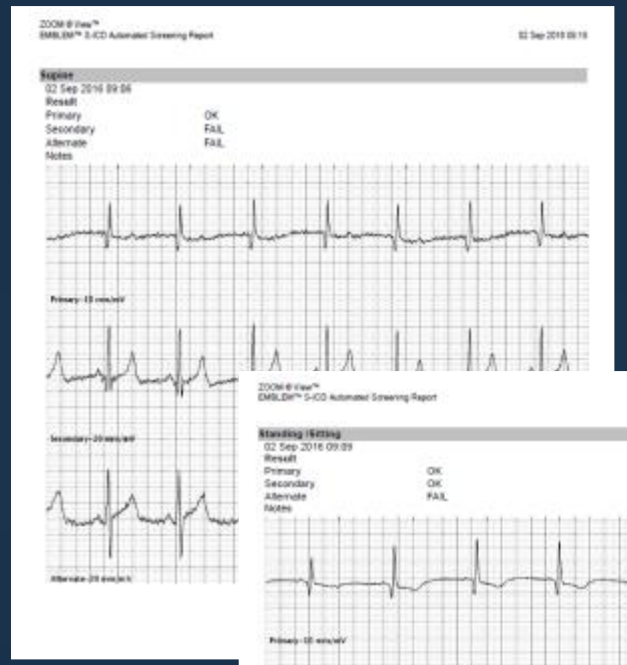
S-ICD SCREENING

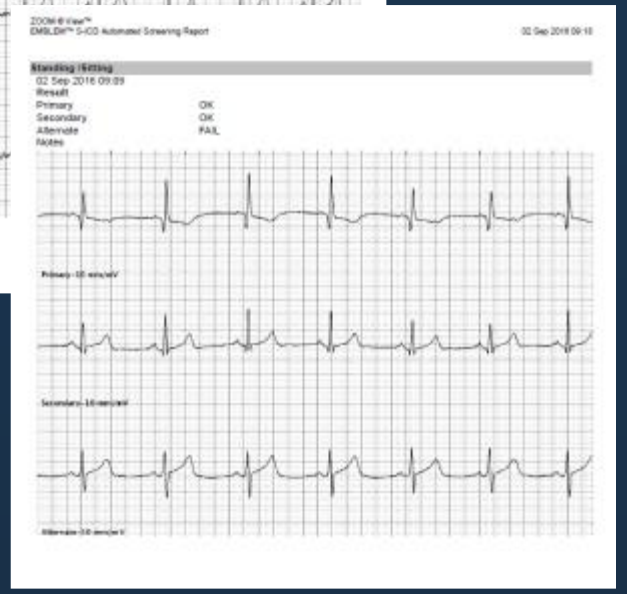
S-ICD screening was implemented to determine whether patients have a suitable signal for device sensing at implant.

Maximising system sensitivity and specificity for rhythm identification and therapy and to minimise the risk of cardiac oversensing.





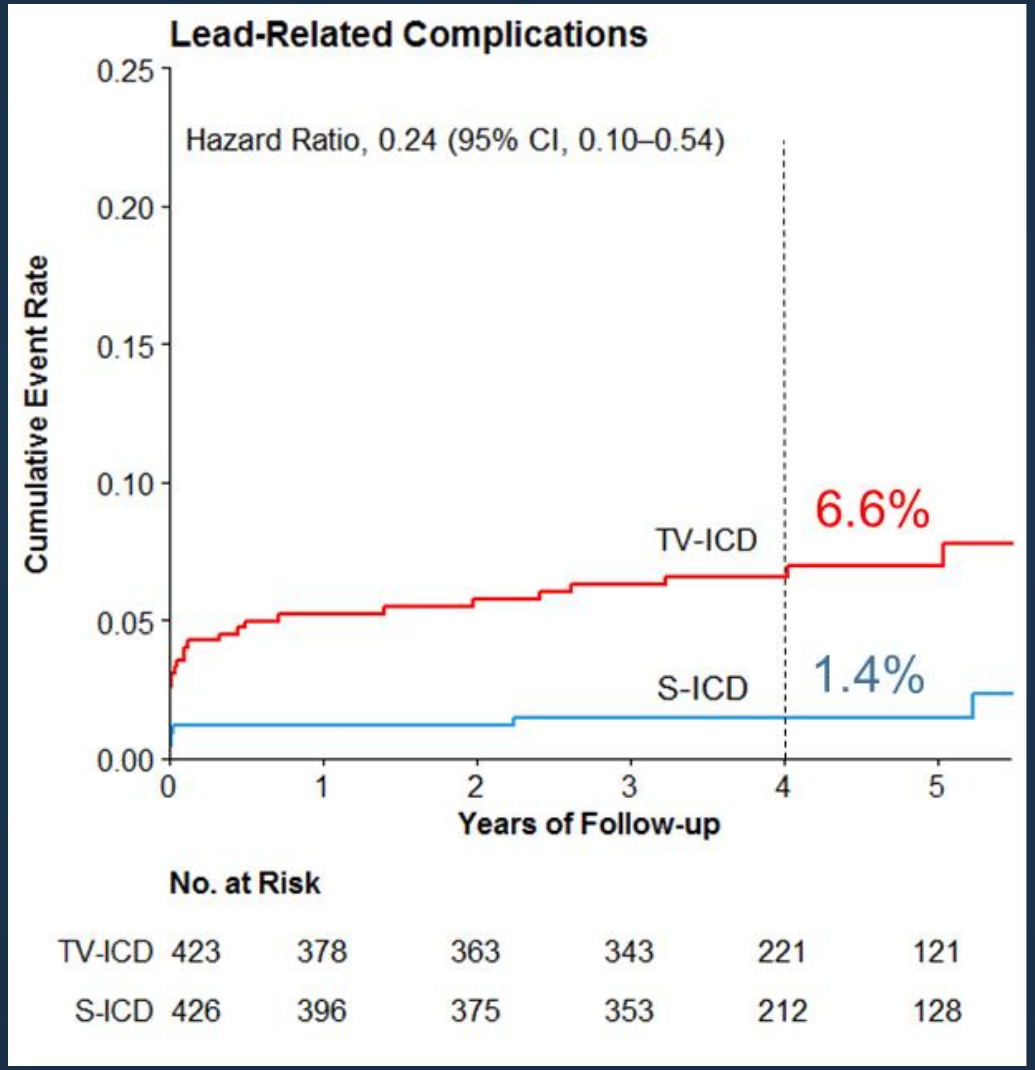




PRAETORIAN: Lead-related Complications[1]

Significantly fewer lead-related complications
- ✓ **6.6% (n=24) in the TV-ICD arm vs**
- ✓ **1.4% (n=5) in the S-ICD arm (P =0.001)**

- *More than **4 times** as many patients experienced a lead complication in the TV-ICD arm.*
- *Eliminating device leads within the vasculature is particularly important for many ICD-indicated patients with comorbidities, such as diabetes, and renal disease who often are at an increased risk of infection and vascular access issues.[2]*



1. Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.
2. Polyzos K. et al., Europace. 2015;17(5):767-777.

2 Incision & Inter-muscular Technique

Source: https://www.youtube.com/watch?v=EYiTtT0Q6hU

PRAETORIAN: Infections requiring extraction[1]

Higher infection rate requiring extraction for patients with a TV-ICD

- ✓ 8 pts (1.9%) with a TV-ICD
- ✓ 4 pt (0.9%) with an S-ICD

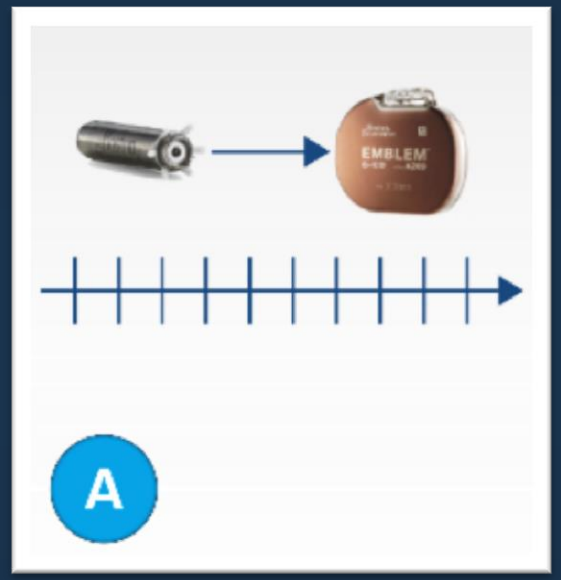
	S-ICD (n = 426)	TV-ICD (n = 423)
Primary composite endpoint	68 (15.1%)	68 (15.7%)
Device related complications	31 (5.9%)	44 (9.8%)
– Infection	4	8
– Bleeding	8	2
• Pacing indication	5	1

1.9% TV-ICD Infection requiring **Extraction**

1.9% S-ICD Bleeding

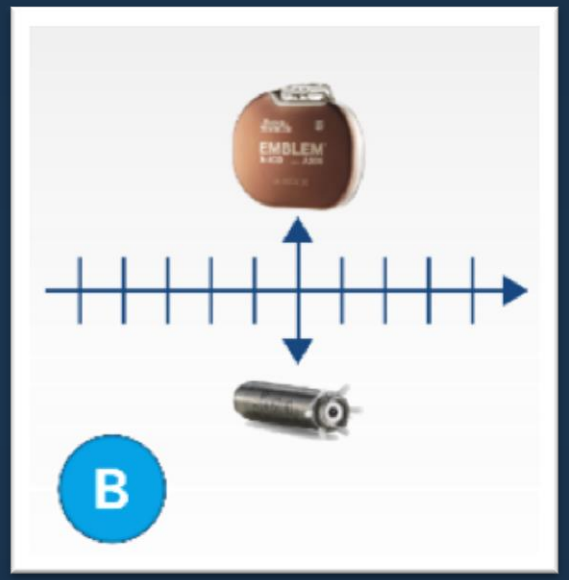
Source: Knops R. et al., Heart Rhythm Society Late Breaking Clinical Trials LBCT-01 2020.

Future of S-ICD: modular CRM system



- **LP implanted first**
- **S-ICD implanted later**

Potential application for patient with pacing need, but no ICD indication at implant.



- **LP and S-ICD implanted together**

Potential application for patient with pacing and ICD indication at implant.

- **S-ICD implanted first**
- **LP implanted later**

Potential application for patient with ICD indication at implant, who later develops a need for pacing.

Source: https://investors.bostonscientific.com/~/media/Files/B/Boston-Scientific-IR/documents/events/boston-scientific-investor-update-at-hrs.pdf

S-ICD: AHA/ACC/ HRS Guidelines

Class I Recommendation

✓

11.1. Subcutaneous Implantable Cardioverter-Defibrillator

Recommendations for Subcutaneous Implantable Cardioverter-Defibrillator
References that support the recommendations are summarized in Online Data Supplement 55.

COR	LOE	Recommendations
I	B-NR	1. In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended (1-5).
IIa	B-NR	2. In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated (1-4).
III: Harm	B-NR	3. In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted (1-4, 6-8).

*"The risk of infection appears to be **lower with S-ICD** than with transvenous ICDs. Therefore, S-ICD may be preferred in patients who are at high risk of infection, such as those with a prior device infection, ESRD, **diabetes mellitus**, or who are chronically immunosuppressed."*

S-ICD: Can it be the first choice in prevention of sudden cardiac arrest?

According to the Italian subcutaneous implantable cardioverter-defibrillator survey:

"S-ICD, WHY NOT?"

89%

of all ICD indicated patients were eligible to receive an **S-ICD**[44]

Source: Botto GL, et al. Europace 2016; Epub 2016/12/25.